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COMMITTEE NAME Food Protection Manager Certification Committee (FPMCC)

DATE OF FINAL REPORT: *12/5/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☒ ***Executive Board***

REPORT SUBMITTED BY: **Susan Quam and Justin Daniel**

COMMITTEE CHARGE(S):

Issue # 2020-II-001

1. To carry out charges assigned via the Conference Issue process and from the Conference Executive Board relating to food protection manager certification and to adopt sound, uniform accreditation standards and procedures that are accepted by the Conference while ensuring that the conference Standards for Accreditation for Food Protection Manager Certification programs and the accreditation process are administered in a fair and responsible manner

Issue # 2020-II-004

1. Review the impact and feasibility of changing the frequency of required certification examination to a time period not to exceed four years from date of issuance, aligning knowledge demonstration by examination with the routine four-year update and publication of the FDA Retail Food Code.

COMMITTEE WORK PLAN AND TIMELINE: The committee met virtually every other month to complete its charges.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   All meetings were scheduled from 2:00-4:00 p.m. Eastern time..

   December 1, 2021
   February 2, 2022
   April 6, 2022
   June 1, 2022
   August 3, 2022
   October 5, 2022

   Final reports and issues were reviewed via email

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. **2020-II-001**
      As part of the committee's normal review process, a Standards workgroup reviewed changes to the Standard and the proposed changes are submitted as a separate issue. The recommended changes are to either clarify a standard for the purpose of accreditation review or to fix grammar, punctuation, and formatting issues.

      The Bylaws workgroup reviewed the committee's bylaws (which are separate from the Conference's bylaws) and the proposed changes are submitted as a separate issue. The major update to the bylaws clarifies the maximum number of voting Certification providers on the committee to 5 total voting members, with those 5 members having one whole vote. Under the committee's current bylaws, if there is more than 5 accredited certification providers, the votes would be fractioned and the 5 votes would be spread out to the 6 or more providers. Fractionizing the votes is not practical. Under the change, all providers would be able to participate in the committee, but only the 5 appointed as voting members will have a vote.

   b. **2020-II-004**
      The committee discussed each of the II-004 impacts/feasibility issues at its April 6 and June 1 meetings. After vetting all of the issues identified, the committee unanimously voted to keep the maximum time frame for Certified Food Protection Manager certifications to five years. The committee felt the proposed change to four years would not improve food safety and would impact both regulatory and industry stakeholders in a negative way. Documents used in deliberation can be found in the 2021-22 FPMCC Minutes attachment.

3. ***Charges INCOMPLETE and to be continued to next biennium: none***

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.
2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name: Food Protection Manager Certification Committee (FPMCC)***
List of content documents submitted with this Issue:
Committee Member Roster:
☒ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***
"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

i. ***2023 CFP FPMCC Bylaws with Proposed Changes***

ii. ***2023 CFP Standard for Accreditation of FPM Certification Programs with Proposed Changes***

b. **List of supporting attachments:** ☐ ***Not applicable***

(1) 2021-22 FPMCC Minutes

1. ***Committee Issue #2***: Proposed Changes to the FPMCC Committee Bylaws
2. ***Committee Issue #3***: Proposed Changes to the Conference for Food Protection Standard for Accreditation of Food Protection Manager Certification Programs
3. ***Committee Issue #4:*** FPMCC Response to 2020-II-004

Committee Name: FOOD PROTECTION MANAGER CERTIFICATION revised 12.31.2022

Last Name	First Name	Position	Vote / Non-vote	Constituency	Employer	City	State	Telephone	Email	Notes
Quam	Susan	Chair	Non Voting	Industry - Support At Large	Wisconsin Restaurant Association	Madison	WI	608-216-2875	squam@wirestaurant.org	
Daniel	Justin	Vice Chair	Voting	Regulator - Local	Lincoln-Lancaster County Health Department	Lincoln	NE	402-441-8033	jdaniel@lincoln.ne.gov	
Sweet	Bridget	Member	Voting	Academia	Johnson & Wales University	Providence	RI	774-434-5146	bridget.sweet@jwu.edu	
Reich	Allen	Member	Voting	Academia	Northern Arizona University	Flagstaff	AZ	928-853-6340	allen.reich@nau.edu	
Wilson	David	Member	Voting	Consumer	After School Matters	LaGrange	IL	708-582-0022	d.wilson180@my.chicago.chefs.edu	
Dolhanyk	Anne	Member	Voting	Consumer	STOP Foodborne Illness	West Linn	OR	360-601-4264	adolhanyk@gmail.com	
Luebkemann	Geoffrey	Member	Voting	Industry - Food Service	Florida Restaurant & Lodging Association	Tallahassee	FL	850-224-2250	gluebkemann@frla.org	
Halbrook	Courtney	Member	Voting	Industry - Food Service	Topgolf	Dallas	TX	704-236-0890	courtney.halbrook@topgolf.com	
Wynne	Rebecca	Member	Voting	Industry - Food Service	Darden	Denver	CO	303-895-4042	rwynne@darden.com	
Dwyer	Tara	Member	Voting	Industry - Retail Food	Dave's Marketplace	East Greenwich	RI	401-4748905	tarad@davesmarketplace.com	
Allen	Consuelo	Member	Voting	Industry - Retail Food	Whole Foods Market	Austin	TX	512-426-8709	consuelo.allen@wholefoods.com	
vacant				Industry - Retail Food						Jeff Hawley retired from Harris Teeter December 1. Approved as CFP rep to ACAC by EB. See non-voting list
Koester	Laura	Member	Voting	Industry - Retail Food At Large	Harmons	Salt Lake City	UT	801-957-8472	laurakoester@harmonsgrocery.com	
Ciarimboli	Ellen	Member	Voting	Industry - Retail Food At Large	Hy-Vee, Inc.	West Des Moines	IA	515-453-2789	eciarimboli@hy-vee.com	
Corchado Torres	Liz	Member	Voting	Industry - Support Certification Org	National Registry of Food Safety Professionals	Orlando	FL	407.999.8126	lcorchado@nrfsp.com	
Piche	Kate	Member	Voting	Industry - Support Certification Org	National Restaurant Association / ServSafe	Chicago	IL	312-261-5348	kpiche@restaurant.org	
Smith	Melissa	Member	Voting	Industry - Support Certification Org	StateFoodSafety	Orem	UT	503-729-5667	melissa.smith@statefoodsafety.com	
Eastwood	Nick	Member	Voting	Industry - Support Certification Org	Always Food Safe	St. Paul	MN	612.203.4872	nick.eastwood@alwaysfoodsafe.com	
Anderson	Tom	Member	Voting	Industry - Support Certification Org	360 Training	Austin	TX	512-212-7343	tom.anderson@360training.com	

Derr	Samuel	Member	Voting	Industry - Support Training	Elite Food Safety Training	Naperville	IL	630-776-3430	sderr@elitefoodsafety.com	
Paster Cammarata	Tara	Member	Voting	Industry - Support Training	Paster Training, Inc.	Gilbertsville	PA	610-970-1776	tara.paster@pastertraining.com	
Roughan	George	Member	Voting	Industry - Support Training	TAP Series	Westlake Village	CA	818-889-8799 x 101	gr@tapseries.com	
Straughn	Ki	Member	Voting	Regulator - Local	Public Health Seattle & King County	Bellevue	WA	206-263-8088	kstraughn@kingcounty.gov	
Wiedmeyer	Lindy	Member	Voting	Regulator - Local At Large	City of Racine Public Health Department	Racine	WI	262-636-9567	lindy.wiedmeyer@cityofracine.org	
Woods	Yolanda	Member	Voting	Regulator - Local At Large	Shelby County Government	Memphis	TN	901-222-9190	yolanda.woods@shelbycountytn.gov	
Burns Savage	Nikki	Member	Voting	Regulator - Local At Large	Southern Nevada Health Districtg	Las Vegas	NV	702-686-7691	ntburns@cox.net	
Jackson	Jeff	Member	Voting	Regulator - State	Arkansas Department of Health	Little Rock	AR	870-847-7619	jeff.jackson@arkansas.gov	
Huffman	Troy	Member	Voting	Regulator - State (Federal replacement)	Colorado Department of Public Health & Environment	Denver	CO	303-692-3664	troy.huffman@state.co.us	
Smith	Colleen	Member	Voting	Regulator - State (Federal replacement)	NH DHHS	Concord	NH	603-271-4858	colleen.smith@dhhs.nh.gov	
Unkart	Sharon	Alternate	Non-Voting	Regulator - State	NEHA	Denver	CO	720-802-2142	sdunkart@neha.org	Moved to voting position from the alternate list. Replacing Sean Dunleavy
Non-voting										
Morris	Sheri	Member	Non-Voting	ACAC Representative	Pennsylvania Department of Agriculture	Harrisburg	PA	717-787-5289	shmorris@pa.gov	
Hawley	Jeff	Member	Non-Voting	ACAC Representative	Retired - Retail Industry	Matthews	NC	704-844-3098	jehawley718@gmail.com	
Krishna	Vijay	Consultant	Non-Voting	ANAB Representative	ANAB	Washington	DC	202-331-3614	vkrishna@ansi.org	
Wittry	Beth	Consultant	Non-Voting	Federal Govt	CDC	Atlanta	GA	770-488-7333	Xks5@cdc.gov	
Williams	Laurie	Consultant	Non-Voting	Federal Govt	FDA	College Park	MD	240-402-2938	laurie.williams@fda.hhs.gov	
Duggins	Quwanza	Consultant - alternate	Non-Voting	Federal Govt	FDA	Oklahoma City	OK	240-535-5969	quwanza.duggins@fda.hhs.gov	
Baker	Michael	Alternate	Non-Voting	Industry - Support Certification Org	National Registry of Food Safety Professionals	Chicago	IL	312-651-5783	mbaker@restaurant.org	
Conley	Mark	Alternate	Non-Voting	Industry - Support Certification Org	National Restaurant Association / ServSafe	Chicago	IL	312.583.9853	MConley@restaurant.org	

Johnson	Lars	Alternate	Non-Voting	Industry - Support Training	LAJ Consulting/ FoodSafetyGuy	San Jose	CA	507-990-5129	fsg@foodsafetyguy.com	
Morrison	Laura	Alternate	Non-Voting	Industry - Support	Ohio Restaurant Association	Columbus	OH	614-246-0205	lmorrison@ohiorestaurant.org	
Gillam	Tim	Alternate	Non-Voting	Industry - Food Service	Subway Restaurants	Milford	CT	570-688-3310	gillam_t@subway.com	
Rivas	April	Alternate	Non-Voting	Industry - Support Training	ATC Food Safety	Pfafftown	NC	707-363-6032	april.rivas@atrainingcompany.com	
Pollock	Evelin	Alternate	Non-Voting	Regulator - Local	Harris County Public Health	Houston	TX	713-248-5691	evelin.pollock@phs.hctx.net	

Food Protection Manager Certification Committee Bylaws

Preamble

The Food Protection Manager Certification Committee, hereinafter referred to as the Committee, of the Conference for Food Protection, hereinafter referred to as the Conference, exists to carry out charges assigned via the Conference Issue process and from the Conference Executive Board, hereinafter referred to as the Board, relating to food protection manager certification and operates within the objectives stated in the Constitution and Bylaws of the Conference.

Article I. Name.

The Name of the Committee is Food Protection Manager Certification Committee.

Article II. Objectives.

Section 1. Systematically identify and address issues concerning Food Protection Manager Certification Programs.

Section 2. Adopt sound, uniform accreditation standards and procedures that are accepted by the Conference.

Section 3. Promote uniformity among all jurisdictions that subscribe to the principles of the Conference by obtaining their recognition and adoption of the Conference Standards for Accreditation of Food Protection Manager Certification Programs.

Section 4. Promote strategies to enhance equivalence among food protection manager certificates issued by certifying organizations.

Section 5. Establish and refine policies and standards to which certifying organizations shall conform.

Article III. Organization and Operation.

Section 1. The Committee is a standing committee within the Conference.

Section 2. The Committee shall consider all Issues charged to the Committee and shall work to develop consensus. The Board may submit charges to the Committee at any time. The Committee is to deliberate the charges expeditiously, or within the time frame determined by the Board or the Committee Chair.

Section 3. The Committee shall use the protocol established in these Bylaws to address its charges.

Section 4. All Committee recommendations shall be submitted as Issues to the Conference for deliberation. The Committee shall follow the protocol for Issue submission as established by the Conference.

Section 5. All Issues, intellectual properties, and/or inventions created by the Committee and approved by the Assembly of Delegates become the property of the Conference.

Article IV. Quorum

A quorum to conduct Committee meetings and conference calls shall be the presence or participation of one more than half of the filled Committee positions**.** A Committee quorum shall be considered a sufficient number for voting on issues under deliberation. The decisions resulting from a quorum vote shall be deemed representative of the Committee.

Article V. Composition of Organizational Components and Eligibility Requirements for Serving in Official Capacities.

Section 1. The Committee shall be chaired by a Chair and Vice-Chair. Prior to each biennial Conference meeting, the incoming Chair and Vice-Chair shall be selected by the outgoing committee. The Chair, Vice-Chair and committee members shall be approved by the Board.

The Chair and Vice-Chair shall not be selected from the same constituency affiliation.

Section 2. The Committee Chair and Vice-Chair shall serve until the conclusion of the next biennial Conference meeting.

Section 3. The Committee Chair and Vice-Chair may serve consecutive terms with approval of the Board.

Article VI. Committee Structure and Representation.

Section 1. To be eligible to serve on the Committee as a voting member or non-voting alternate, individuals must commit in writing to active participation and be approved by the Conference Chair and the Board.

Section 2. The Committee Chair and Vice-Chair will select committee members and alternates from the list of volunteers from the most recent biennial meeting or recruit volunteers as appropriate to balance the committee as delineated in these Bylaws. In the event of a Committee vacancy with no designated alternate in that constituency, the Chair will first recruit from the remaining list of volunteers provided during the initial Committee selection process.

Section 3. The composition of voting members of the Committee is a balanced representation of industry, regulatory, academia, certification organizations, training providers, and consumers. The Committee membership representation shall consist of a maximum of thirty (30) full votes from the following constituencies:

Subsection 1. Nine (9) representatives from regulatory agencies with food safety responsibilities:

a. Two (2) Three (3) from State regulatory agencies;

b. Two (2) Three (3)from local regulatory agencies;

c. Two (2) from federal government agencies; and

d. Three (3) "At Large" appointments; (At large selections may include federal government agencies, state regulatory agencies and local regulatory agencies with food safety responsibilities.)

Subsection 2. Nine (9) industry representatives:

a. Three (3) from the foodservice (restaurant) industry;

b. Three (3) from the retail food store industry; and

c. Three (3) "At Large" appointments. (*At large selections may include professional or trade organizations that directly represent the restaurant, retail food, institutional foodservice, and food vending segments of the industry, and whose mission incorporates a public health protection component.)

Subsection 3. Five (5) total votes for certification organizations that are accredited by the Conference's accreditation process. Although there is no limit to the number of accredited certification organizations, this constituency shall have a maximum of five (5) votes.

Subsection 4. Three (3) Food Protection Manager training providers;

Subsection 5. Two (2) representatives from academia; and

Subsection 6. Two (2) consumer/independent representatives/public members.

Section 4. Committee members will serve a two (2) year term, concurrent with the cycle of the biennial Conference meeting. Committee members are eligible to serve for consecutive terms contingent upon an assessment by the Committee Chair and Vice-Chair to ensure a balance between members who have previously served on the Committee and new members.

Section 5. Up to two (2) non-voting alternates will be included on the Committee roster each for industry, regulatory, academia, training providers, and consumers to best represent the category of each constituency. Each certification organization participating on the Committee may designate one (1) alternate from their own organization. In the event a Committee member resigns or is no longer able to serve the remainder of their term, the Chair shall select an alternate from the affected constituency to fill the open seat.

Section 6. The incoming Chair of the Committee shall make every effort to retain at least 50% of the Committee membership for a continuing term. This retention is recommended due to the complexity of issues, the need to retain continuity of Committee functions, and the short time frame between biennial Conference meetings.

Section 7. In the event a Committee member changes constituency during their term, the Chair may consider them for any open seat on the Committee which needs representation from their constituency or consider any open alternate position. If the Chair determines that there are no appropriate openings available, the Committee member will be asked to resign from the committee.

Article VII. Committee Organization, Operation, and Meetings

Section 1. The Committee shall receive its direction from the Board. The Board shall assign the Committee its charges as approved during the biennial Conference meeting. The Board may assign additional charges to the Committee to ensure that the Conference Standards for Accreditation of Food Protection Manager Certification Programs and accreditation process are administered in a fair and responsible manner.

Section 2. The Committee shall meet in-person at least annually and at the biennial Conference meeting. All Committee meetings are open to anyone to attend. In addition to meetings, the Committee shall schedule conference calls, as deemed appropriate, for addressing issues under deliberation. In the event that sensitive, financial or proprietary information is under consideration by the Committee, the Chair shall have the option to conduct an executive session until the confidential portion of the proceedings has been concluded.

Section 3. In addition to the charges received from the Board, Committee members may submit Issues and alternative recommendations to the Committee for discussion. Issues and recommendations introduced by Committee members shall be submitted using the Conference format.

Section 4. Presentations for in-person Committee meetings shall be submitted to the Committee Chair and Vice-Chair for review at least 2-weeks prior to meeting dates.

Section 5. Voting.

Subsection 1. A consensus building decision process will be used. When Committee members are asked to vote, each member will be able to express one of three positions.

- A thumb up indicates agreement with the issue on the floor
- A thumb sideways means the position on the floor is not the member's optimal solution, but they can accept the position
- A thumb down indicates that a member does not agree with the issue on the floor and would like an alternative recommendation considered.

The Committee Chair shall provide an opportunity for the dissenting member(s) to express the alternative position(s). After discussion of these alternative positions, the Chair will call for a final vote from the Committee.

Subsection 2. Except for certification organizations, all voting Committee members and alternates designated for that meeting shall have one (1) vote.

Subsection 3. All certification organizations accredited by the Conference's accreditation process participating on the Committee shall not to exceed a total of five (5) votes.

- If more than five (5) certification organizations volunteer to participate on the Committee, the five (5) votes allocated to certification organizations shall be fractionalized (evenly divided).
- The voting fraction shall be determined when the final committee membership is approved by the Board and shall remain in effect until the next biennial Conference meeting.
- Each certification organization shall be allowed no more than one (1) vote or one (1) voting fraction at any meeting.

Subsection 4 3. The Vice-Chair may voice positions on issues and may vote on all matters before the Committee.

Subsection 5 4. The Chair is a non-voting member of the Committee; however, in the event of a tie, the Chair may vote as the tie-breaker.

Section 6. Committee funding. The Board may allocate funds to the Committee for its charges. These funds may be used to contract the services of outside experts to assist the Committee, attend meetings with potential accreditation entities, and other miscellaneous expenses that the Committee must incur, e.g., use of meeting rooms. Funding shall not be allocated to cover an individual Committee member's travel or per diem expenses to attend meetings. Committee funding may be used only as directed by the Board.

Article VIII. Duties of the Committee Chair

Section 1. The Chair and Vice Chair, with the approval of the Board shall select Committee members in accordance with these Bylaws.

Section 2. The Chair, with concurrence of two-thirds (2/3) of the voting members of the Committee may appoint non-voting Ex-Officio consultants and advisors to the Committee in accordance with these Bylaws.

Section 3. The Chair shall preside at all meetings of the Committee, except as provided in these Bylaws.

Section 4. The Chair shall coordinate the arrangement of meetings and conference calls and ensure that meeting dates and locations are posted in advance on the Conference web site.

Section 5. The Chair shall be responsible for distributing to Committee members and other meeting participants an agenda for the meeting or conference call. This agenda may be distributed by email, fax, mail, or other suitable means.

Section 6. The Chair may assign a Committee member, using a rotation basis or other appropriate means among all Committee members, to take minutes during designated meetings and conference calls.

Section 7. The Chair shall be responsible for distributing minutes of all Committee meetings or conference calls in a timely manner, usually within three weeks of the event.

Section 8. The Chair may designate ad hoc workgroups to conduct research, study proposals, and develop procedures or recommendations related to complex issues and/or charges to address the charges of the Board and complete the duties of the Committee.

Article IX. Duties of the Committee Vice-Chair

Section 1. In the event the Chair is unable to perform the duties of the Chair, the Vice-Chair shall act as Chair.

Section 2. When acting as Chair, the Vice-Chair shall perform all the necessary duties for the Committee as outlined in these Bylaws.

Section 3. The Vice-Chair shall perform all duties assigned by the Chair.

Article X. Duties of Committee Members/Alternates

Section 1. Committee members shall have the responsibility to notify the Committee Chair of their inability to attend a meeting or participate on a conference call at least

fifteen (15) days prior to the scheduled meeting or conference call. For any committee member that is unable to attend a scheduled meeting or conference call, an alternate will be assigned. Selection of the designated alternate will be agreed upon by the Committee Chair and the absent member and chosen to best represent the constituency of the absent member. This designated alternate may vote on issues before the committee only during the specified meeting or conference call.

Section 2. Committee members and alternates shall have the responsibility to review for comment standards, reports, recommendations, issues or other Committee documents distributed within the time frames designated by the Committee.

Section 3. Committee members and alternates shall have the responsibility to complete work assignments within time frames designated by the Committee.

Section 4. Committee members and alternates shall have the responsibility to notify the Committee Chair or the Chair's designee of their inability to complete a work assignment.

Section 5. Committee members that do not participate for three (3) consecutive meetings and/or conference calls shall have their continued participation as Committee member assessed by the Committee Chair and evaluated by the Committee. The Committee member may be subject to being removed from their membership position. Removal of a Committee member for failure to perform duties as specified in these Bylaws, shall require the concurrence of two-thirds (2/3) of the voting members of the Committee.

Article XI. Committee Advisors, Subject Matter Experts, Paid Consultants and Conference Appointments

Section 1. Federal participants (FDA/USDA/CDC) may appoint an advisor and an alternate to serve as non-voting ex-officio members of the Committee. The alternate may act in the advisor's place if the advisor is unable to attend.

Section 2. The Conference Chair, at the request of the Committee Chair, with approval of the Executive Board, may appoint a psychometrician advisor to serve as a non-voting ex officio member of the Committee.

Section 3. The Chair and Vice-Chair may invite, with approval from the Committee, subject matter experts, external to the Committee, to participate in meetings and conference calls, or to work with an ad hoc workgroup, if it is determined that such individuals would provide additional information, insight, clarification, guidance or other assistance to the Committee, for a specified purpose. These subject matter experts will be non-voting guests in meetings and conference calls.

Section 4. The Committee may contract the services of a paid consultant for issues beyond the scope of the Committee's expertise, if deemed necessary or if charged by the Board. Contractual obligations for paid consultant services shall have the concurrence of two-thirds (2/3) of the voting members of the Committee and be approved by the Board.

Section 5. Conference appointments to the ANSI-CFP Accreditation Committee (ACAC) shall serve as non-voting ex-officio members of the Committee.

Article XII. Workgroups

Section 1. Workgroups shall report to the Committee Chair and Vice-Chair as determined by the Committee Chair.

Section 2. Each workgroup shall select a group leader who is responsible to report group activities to the Committee Chair and Vice-Chair.

Section 3. Workgroups shall provide written reports and recommendations to the full Committee for deliberation.

Article XIII. Committee Reports

Section 1. The Committee Chair shall be responsible for preparing written or oral reports to the Board detailing the activities and expenditures of the Committee. Written reports of the Committee's activities shall be submitted as required by the Conference procedures.

Section 2. The Committee Chair shall coordinate the development of a final report of the Committee activities to Council II with recommended actions. The final report shall be done as part of an Issue submission and shall comply with all Conference procedures.

Section 3. The Committee Chair, Vice-Chair, or designee as specified in writing to the Council II Chair, shall be in attendance when Council II meets during the Conference meeting to present and discuss the Committee's report and any Issues submitted by the Committee.

Article XIV. Amendments

The Food Protection Manager Certification Committee Bylaws may be altered, amended, or repealed by two-thirds (2/3) vote of the Committee and final concurrence from the Board, and then submitted as an Issue during the next biennial meeting.

Conference for Food Protection

Standards for Accreditation of Food Protection Manager Certification Programs

Preamble

The Conference for Food Protection, hereinafter referred to as the CFP, is an independent voluntary organization that has identified the essential components of a nationally recognized Food Protection Manager *Certification* Program and established a mechanism to determine if *certification organizations* meet this Standard. The CFP Standard for *Accreditation* of Food Protection Manager *Certification* Programs is intended for all *legal entities* that provide *certification* for this profession. The Standard has been developed after years of CFP's research into, and discussion about, Food Protection Manager *Certification* Programs.

All *certification organizations* attesting to the *competency* of Food Protection Managers, including *regulatory authorities* that administer and/or deliver *certification* programs, have a responsibility to the individuals desiring *certification*, to the employers of those individuals, and to the public. *Certification organizations* have as a primary purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and Standard established through the CFP. *Certification organizations* issue *certificates* to individuals who meet the required level of *competency*.

The professionals involved in the credentialing process for *Certified Food Protection Managers* shall recognize that the justification for regulating entrance to the occupation of *Certified Food Protection Manager* is to:

- protect and promote food safety for the welfare of the public;
- ensure that the responsibility and liability for overseeing the protection of safety and welfare of the public lies with those governmental jurisdictions at the Federal, state and local levels having the power to set forth laws regulating entrance to and performance in this occupation;
- ensure that the rights of the public at large and of those members of the public who wish to enter this occupation shall be balanced in terms of fairness and due process in the form of a credentialing process for admitting qualified persons to perform in that occupation; and
  ~~Delete space~~
  ensure the highest possible degree of validity in the Certified Food Protection Manager credentialing process by carefully determining the competencies necessary to prevent foodborne illness, implementing standardized testing processes, and

promoting the appropriate interpretation and use of test results ~~ensure that the *validity* of the credentialling process for *Certified Food Protection Manager* is dependent on unbiased application of all aspects of that process, requiring careful determination of the competencies necessary to prevent foodborne illness, unbiased education and training for acquisition of those competencies, and fair assessment practices to ensure that individuals have achieved master of the competencie~~

Therefore, professionals involved in the credentialing process for *Certified Food Protection Manager* accept responsibilities based on these considerations.

The CFP Standard is based on nationally recognized principles used by a variety of organizations providing *certification* programs for diverse professions and occupations.*Accreditation*, through the process recognized by CFP, indicates that the *certification organization* has been evaluated by a third-party *accrediting organization* and found to meet or exceed all of the CFP's established Standard.

To earn *accreditation*, the *certification organization* shall meet the following CFP Standard and provide evidence of compliance through the documentation requested in the application. In addition, the *certification organization* shall agree to abide by *certification* policies and procedures, which are specified by the CFP Food Protection Manager *Certification* Committee, hereinafter referred to as the FPMC Committee, approved by the CFP, and implemented by the *accrediting organization*.

The *accrediting organization* shall verify and monitor continuing compliance with the CFP Standard through the entire *accreditation* period. The CFP FPMC Committee will work directly with the *accreditation organization* to enhance and maintain *certification* policies and procedures that meet the specific needs of Food Protection Managers while ensuring a valid, reliable and *legally defensible* evaluation of *certification* programs.

The American National Standards Institute (ANSI) was selected as the *accrediting organization* for the CFP Standard for *Accreditation* of Food Protection Manager *Certification* Programs and assumed its duties in January 2003. The CFP FPMC Committee continues to work within the Conference structure to monitor the criteria and selection process for the organization serving as the accrediting body for Food Protection Manager *Certification* Programs.

The CFP strongly encourages regulatory authorities and other entities evaluating credentials for Food Protection Managers to recognize and endorse this Standard and the *accreditation* process. The CFP Standard for *Accreditation* of Food Protection Manager *Certification* Programs provides the framework for universal acceptance of individuals who have obtained their credentials from an *accredited certification program*. In the U.S Food and Drug Administration's Food Code, hereinafter referred to as the FDA Food Code, Section 2-102.20 recognizes Food Protection Manager *certificate*s issued by an*accredited certification program* as one means of meeting the FDA Food Code's "Demonstrationof Knowledge" requirement in Section 2-102.1 and as satisfying the requirement of section
2-102.12 for the Person in Charge to be a Ce~~e~~rtified Ff~~f~~ood P~~p~~rotection M~~m~~anager.

Please note that words that appear in italics are defined terms.

Modifications and Improvements

The FPMC Committee followed the Conference directive to use the 1996 conference working document, Standard for Training, Testing and *Certification* of Food Protection Managers, in the development of accreditation standards. Extensive revision of this document was presented to CFP's 2012 Biennial Meeting of the Conference~~s~~ for Food Protection under the title, Standard for *Accreditation* of Food Protection Manager *Certification* Programs.

The charge to the FPMC Committee from the 2010 Biennial Meeting of the Conference for Food Protection resulted in revisions to the Standard to enhance the integrity of the entire examination process, which included identification and analysis of root causes of security violations and implementation of solutions.

The revision and reformatting of the document were made after a comprehensive FPMC Committee review of each section. This revision of the Standard for *Accreditation* of Food Protection Manager *Certification* Programs:

1. adds and improves definitions that are more precise and more consistent with terminology and definitions used in the *psychometric* community and by *accreditation* organizations;
2. reorganizes the Standard to eliminate duplication and align with purpose;
3. modifies or creates the Standard to better address professional credibility and training of *test administrators/proctors*; handling of examination packages; shipping irregularities; location(site) irregularities; and breach of the *certification organization's test administrators/proctor's* protocols and requirements;
4. uses "*test administrator/proctor*" in the Standard to indicate duties for both "*test administrator*" and "*proctor;*" and
5. adds a standard for management systems.

Annexes

Annex A is the result of the deliberation and recommendations from the FPMCC from the 2016 Biennial Meeting of the Conference for Food Protection, and represents the process and requirements for CFP to recognize a certification body that is accredited by ANSI under the ISO/IEC 17024 STANDARD.

Annex B is not part of the Standard, but provides information to guide those responsible for implementing or reviewing Food Protection Manager *Certification* Programs. This annex provides guidelines for specific responsibilitiesthat affect the effective implementation of the Conference Standard for *Accreditation* of Food Protection Manager *Certification* Programs.

Annex B provides guidance to regulatory authorities that incorporate Food Protection Manager *Certification* as part of their requirements to obtain or retain a permit to operate. The CFP Standard for *Accreditation* of Food Protection Manager *Certification* Programs is designed to be a voluntary unifying mechanism for the universal acceptanceof F~~f~~ood P~~p~~rotection M~~m~~anagers who obtain their *certificate*s from an *accredited certification program*.

Over the past twenty-five years, many regulatory authorities have developed their own Food Protection Manager *Certification* Programs. This has resulted in a variety of standards for *certification* programs. The CFP Standard for universal acceptance of *Certified Food Protection Manager*s provide regulatory authorities consistent and *legally defensible* criteria for evaluating *certification* programs. In addition, they eliminate duplication of testing and additional cost forthe industry.

Regulatory authorities that may not be in a position to eliminate their existing programs are encouraged to recognize F~~f~~ood P~~p~~rotection M~~m~~anagers certified in accordance with this Standard as fulfilling their program requirements. Annex B provides additional guidance, developed through the CFP, for the implementation of these regulatory *certification* programs.

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SECTION 1.0 - DEFINITIONS

1.0 Definitions.

1.1 **Accreditation** means that an *accrediting organization* has reviewed a Food Protection Manager *Certification* Program and has verified that it meets Standards set by the CFP as set forth in this document.

1.2 **Accrediting organization** means an independent organization that determines whether a Food Protection Manager *Certification* Program meets the Standards set by the CFP.

1.3 **Accredited certification program** means a Food Protection Manager *Certification* Program that has been evaluated and listed by an *accrediting organization* as being in conformity with the CFP Standard for such programs asset forth in this document. This does not refer to training functions or educational programs.

1.4 **Algorithm** means a set of procedures or rules pertaining to the selection of questions on an examination.

1.5 **Certificate** means documentation issued by a *certification organization*, verifying that an individual has complied with the requirements of an *accredited certification program*.

1.6 **Certification** means the process wherein a *certificate* is issued.

1.7 **Certification organization** means an organization that provides a *certification* program and issues the *certificate*.

1.8 **Certified Food Protection Manager** means a person who has successfully passed an *accredited food safety certification examination* demonstrating that he/she has the *knowledge, skills and abilities (KSA's)* required to protect the public from foodborne illness.

1.9 **Competency** means a defined combination of *knowledge, skills and abilities (KSA's)* required in the satisfactory performance of a job.

1.10 **Competency examination** means an instrument that assesses whether an individual has attained at least the minimum level of *competency* necessary to perform effectively and safely in a particular occupation or job.

1.11 **Computer-adaptive testing (CAT)** means a method of *computer-based testing* that uses *algorithm*s to select *items* at various difficulty levels to determine an *examinee's* proficiency.

1.12 **Computer-based testing (CBT)** means an examination administered on a computer.

1.13 **Continued proficiency** means a *certification organization's* process or program designed to assess continued *competence* of *Certified FoodProtection Managers*.

1.14 **Demographic data**, in this context, means the geographic distribution, education, credentials, stakeholder representation, and other relevant characteristics of the referenced group.

1.15 **Entry level performance** means carrying out job duties and tasks effectively at a level that does not pose a threat to public safety but not necessarily beyond that level.

1.16 **Equivalency** (in "equivalent examinations") means that two or more versions of a test measure the same constructs in the same ways and are built to the same content and statistical specifications .

1.17 **Examination adaptation** means a process by which an examination is transformedfrom a source language and/or culture into a target language and/or culture.

1.18 **Examination blueprint** means the plan that specifies how many questions fromevery job/task analysis content area must be included on each test form.

1.19 **Examination developers** means the individuals involved in the process of creatingthe Food Safety *Certification* Examination**.**

1.20 **Examination forms** means equivalent, alternate, and differing sets of *items,* compiled according to the same *examination blueprint* and conforming to the same *examination specifications*.

1.21 **Examination Materials** means all materials necessary for creating, disseminating, retrieving, administering, and grading examination items and forms.

1.22 **Examination specifications** means the description of the specific content areas of an examination, stipulating the number or proportion of *item*s for each measured *competency,* the total number of scored and unscored items, the amount of time allotted to complete the exam, and requirements for receiving a passing score.

1.23 **Examination version** means an examination in which the exact set of *item*s in an *examination form* is presented in another order, language, manner, or medium.

1.24 **Examinee** means a person who takes an examination.

1.25 **Exposure plan** means the policies and procedures in place to ensure that examination *item*s and forms are not made available to such a degree that their discrimination value is diminished.

1.26 **Food establishment** means an operation that stores, prepares,packages, serves, vends, or otherwise provides food for human consumption as defined inthe FDA Food Code 2017.

1.27 **Food safety certification examination** means an examination in food safety approved in accordance with the provisions of this program.

1.28 **Instructor** means an individual who teaches a course that includes *competencies* in prevention of foodborne illness. May also be called "educator" or "trainer."

1.29 **Item** means an examination question.

1.30 **Item bank** means all ~~of~~ the *item*s that have been developed for the several forms ofan examination. It includes all the *item*s available to create *examination forms*.

1.31 **Item sequence** means the presentation order of examination *item*s in an examination.

1.32 **Job Task Analysis** means the description of functions or tasks required for an individual to perform to entry-level standards in a specific job or occupation, including information about the attributes required for that performance. It defines the performance dimension of a job and includes *knowledge, skills and abilities (KSA's)* necessary to carryout the tasks.

A. **Tasks** are the individual functions, whether mental or physical, necessary to carry out an aspect of a specific job.

B. **Knowledge, skills, and abilities (KSAs)** include the information and other attributes that the worker shall possess in order to perform effectively and safely. They include information and understanding as well as learned behaviors and natural attributes.

1.33 **Legal entity** means an organization structured in a manner that allows it to function legally and be recognized as a responsible party within the legal system.

1.34 **Legally defensible** means the ability to withstand a legal challenge to the appropriateness of the examination for the purpose for which it is used.

1.35 **Linear Examination Form** means a fixed examination form, in any deliveryformat, where the form does not change or adapt based on the examinee's responses.

1.36 **Overexposure** refers to an *item* that has been selected or viewed to such a degree that its discrimination value is diminished.

1.37 **Exam Candidate** means an individual who may be reasonably expected to take a *food safety certification* examination.

1.38 **Proctor** means a person under the supervision of a *test administrator*, who assists by assuring that all aspects of an examination administration are being carried out with precision, with full attention to security and to the fair treatment of *examinees*.

1. 39 **Psychometric** means scientific measurement or quantification of human qualities, traits, or behaviors.

1.40 **Psychometrician** means a professional with specific education and training in development and analysis of examinations and other assessment techniques and in statistical methods.

1.41 **Regulatory authority** means a government agency that has been duly formed underthe laws of that jurisdiction to administer and enforce the law.

1.42 **Reliability** means the degree to which test scores for a group of test takers are consistent over repeated applications of a measurement procedure and, hence, are inferred to be dependable and consistent for an individual test taker.

1.43 Remote proctoring means supervision of an examinee during testing by a proctor who is in a different location. Examinee behavior is monitored by a human proctor using online monitoring software and artificial intelligence software.

1.443 **Retail food industry** means those sectors of commerce that operate *food establishments*.

1.454 **Test administrator** means the individual at the test site who has the ultimate responsibility for conducting a *food safety certification examination*. The *test administrator* can also be a *proctor*.

1.465 **Validity** means the degree to which accumulated evidence and theory support a specific interpretation of test scores for a given use of a test

SECTION 2.0 – PURPOSE OF CERTIFICATION ORGANIZATIONS

2.0 Purpose of *Certification Organizations.*

2.1 The *certification organization* shall have as a purpose the evaluation of those individuals who wish to secure or maintain Food Protection Manager *Certification* in accordance with the criteria and Standards established through the CFP, and the issuance of *certificates* to individuals who meet the required level of *competency*.

2.2 A *certification organization* responsible for attesting to the *competency* of Food Protection Managers has a responsibility to the individuals desiring *certification*, to the employers of those individuals, and to the public.

2.3 A *certification organization* for Food Protection Manager *Certification* Programs shall not be the *accrediting organization* nor shall the *certification organization* have any conflict of interest with said *accrediting organization.*

SECTION 3.0 – STRUCTURE AND RESOURCES OF CERTIFICATION ORGANIZATIONS

3.0 Structure and Resources of *Certification Organizations.*

3.1 **Structure of *certification organizations*.** The *certification organization* shall be incorporated as a *legal entity* (applies to the parent organization if the *certification organization* is a subsidiary of another organization).

3.2 A *certification organization* shall conform to all CFP Standards for *accreditation* and demonstrate that the relationship between the *certification organization* and any related association, organization or agency ensures the independence of the *certification* program and its related functions.

3.3 If a certification organization provides both education and certification, the certification organization shall at a minimum, demonstrate that the education part of the organization has no undue influence on the certification process. Additionally, the Certification Organization shall demonstrate that the certification process is not financially dependent on the associated education part of the organization.

3.4 **Resources of *Certification Organizations*.** A *certification organization* shall demonstrate.

A. the availability of financial resources to effectively and thoroughly conduct regular and ongoing *certification* program activities.

B. that its employees and any contracted professionals possess the skills and knowledge necessary to conduct the *certification* program activities.

C. that the roles and responsibilities of *certification personnel* are adequately defined.

SECTION 4.0 – FOOD SAFETY CERTIFICATION EXAMINATION DEVELOPMENT

4.0 ***Food Safety Certification Examination*** **Development.**

4.1 *Food safety certification examinations* administered by *accredited certification organizations* shall comply fully with all criteria set by the CFP and shall meet explicit and implicit Standards to protect the public from foodborne illness. The *accredited certification organization* shall provide a *food safety certification examination* that:

A. conforms to all CFP Standards for *Accreditation* of Food Protection Manager *Certification* Programs;

B. has been developed from secure *item bank* that is of the size and compositionto assemble tests that will support the intended use and interpretation of test scores, as well as the legal defensibility of test scores and for paper- or computer-based *linear examination forms*, the number of active items inany given content domain must be a minimum of three (3) times the number of items specified in the *examination blueprint*. For computer adaptive examination programs (*Computer Adaptive Testing*), the number of active items for each content domain mustbe a minimum of six (6) times the number of items specified in the *examination blueprint*.

Type of Form Assembly	**Scaling Factor of Bank vs. Blueprint**
Linear Examination Forms (paper or computer-based)	Minimum of 3 times the number listed in the blueprint
Computer Adaptive Testing	Minimum of 6 times the number listed in the blueprint

C. *Certification organizations* must have a policy that supports the monitoring and controlling of item exposure rates, use of an appropriate and defensible number of concurrent, equivalent *linear examination forms* (for print-based or computer-based), or an item bank of sufficient size and composition to support *computer adaptive testing*.

4.2 The certification organization must demonstrate to the accreditation agency the appropriateness of the policies, procedures, processes, and decisions regarding the following :

a. examination development, maintenance, and delivery;
b. certification decisions;
c. *examination materials* and data storage;
d. reporting;
e. resolution of complaints and appeals;
f. impartiality; and
g. examination security.

4.3 The *certification organization* shall provide complete information about the *food safety certification examination*, including information related to procedures and personnel involved in all aspects of the examination development and analysis. Actual or potential conflicts of interest that might influence judgment or performance of *Examination Developers* shall be disclosed. The information required for *accreditation* will include but is not necessarily limited to:

A. complete description of the scope and usage of the examination;
B. *job task analysis* list, with *knowledge, skills, and abilities(KSAs);*
C. *examination specifications*;
D. evidence that the number of active items in the *item bank* is (1) aligned with the weight specified in the *examination blueprint*, (2) appropriate for the format of the examination, with special consideration for *computer-adaptive testing*, and (3) meets the requirements of the item exposure plan;
E. statistical performance of each *item* in the bank;
F. number of *examination forms* and evidence of their *equivalence* to each other;
G. description of method used to set passing score;
H. copies of all logs, diaries, and personnel lists and descriptions kept as required in the development process;
I. appropriate summary statistics for each *examination ~~form~~*, regardless of assembly or delivery method; and
J. names, credentials, and *demographic* information for all persons involved in the *job task analysis*, *item* writing and review, and setting the passing score.

4.4 ***Job Task Analysis.*** A food safety certification examination shallbe based on a valid job task analysis. The job task analysis shall be developed by qualified individuals, including retail food industry and public health stakeholders and subject matter experts.

4.5 The job task analysis shall provide a complete description of the knowledge, skills, and abilities (KSAs) required to function competently in the occupation of Certified Food Protection Manager, with emphasis on those tasks most directly related to the Certified Food Protection Manager's role in the prevention of foodborne illness and controlling foodborne pathogens.

4.6 The *examination blueprint* shall be derived from a valid study of the *job task analysis. Examination specifications* deriving from the *exam blueprint* shall be publicly available.

4.7 The credential awarded upon passing a food safety certification examination is designed to be recognized nationwide and throughout the *retail food industry*. As such, the certification organization shall regularly evaluate practices in the *retail food industry* to ensure the job task analysis on which its examination is based remains appropriate and relevant. The maximum length of use for any *job task analysis* is five years fromthe date of validation.

4.8 ***Psychometric*** **Standards**. *Food safety certification examination* development, including setting the passing score, shall ~~be~~ follow the most recent edition of Standards for Educational and Psychological Testing, developed jointly by the American Psychological Association, American Educational Research Association and National Council for Measurement in Education, and on all appropriate Federal requirements (for example, Americans with Disabilities Act). *Food safety certification examinations* shall be revised as needed to comply with changes in the Standards for Educational and Psychological Testing or in any of the Federal requirements.

4.9 The *food safety certification examination* development procedures shall ensure that the *competencies* assessed in the *accredited certification program* are those required for *competent entry level performance* in the role of *Certified Food Protection Manager*, as defined by law and industry standards, and that they focus on factors related to the prevention of foodborne illness in the *retail food industry*.

4.10 The*certification organization* shall ensure relative equivalence and reliability across its various *examination forms* and administration methodologies (e.g., paper-pencil, CBT).

4.11 The *food safety certification examination* shall be developed to be as free from bias as possible. Certification organizations shall provide evidence that all examinations are evaluatedfor sensitivity and appropriateness with respect to a diverse population of examinees. .

4.12 When any *food safety certification examination* is translatedor adapted into another language, the *certification organization* shall demonstrate comparability between the source examination and the translated or adapted examination. The *certification organization* is responsible for defending its translation/*adaptation* processes to the accrediting organization. To avoid potential problems in translation of industry-specific terminology, the *certification organization* shall work in consultation with a food safety subject matter expert (SME) who is fluent in both the original language and the target language and who does not pose a conflict of interest or examination security risk.

4.13 *Examination Developers* shall maintain a log and diary of the procedures and a list ofthe qualifications, identities, and *demographic data* of the persons who participated in *item* development, examination development, translations, setting the passing score, and the statistical analyses of the examination *item*s and of the full examination. Those materials shall be provided to the *accrediting organization* on demand.

4.14 **Examination Development Security**. The certification organization will demonstrate that procedures are developed and implemented to ensure that individual items, item banks, food safety certification examinations presented in all media, test answer sheets and examinee scores are and remain secure. The *certification organization* is required to demonstrate how its examination security plan covers each step in the examination development, administration,scoring, and maintenance.

All examinations shall be delivered and administered in a format that ensures the security of the examination ~~(i.e., in a secured environment with a *test administrator/proctor*)~~. Un-proctored examinations are not acceptable regardless of the mode of administration.

4.15 Periodic Review. At least annually, each *certification organization* shall report tothe accrediting organization, providing a review of its *food safety certification examination(s)*.The report will include at minimum the following summary information for all examinations(for each examination used) administered during the preceding 12 months, as well as other information that may be reasonably requested by the *accrediting organization*.

A. number of *food safety certification examinations* administered;
B. mean, corresponding standard deviation, and range of candidate scores;
C. ~~A~~ measure of form-level reliability;
D. ~~A~~ measure of decision consistency;
E. p~~P~~assing rates (both number and percentage of examinees that passed the examinationin the given 12-month period); and
F. s~~S~~ummary statistics for all items used during the preceding 12-month period, which may be presented using classical test theory, item response theory, or similar models.
G. For the purposes of clarity and identifying data trends, annual summary information may need to be presented in concise reports, such as semi-annual or quarterly, to the *accrediting organization.*

4.16 Requirements for Examination Standardization. *Certification organizations* shall specify conditions and procedures for administering all *food safety certification examinations* in a standardized manner to provide examinees with a fair andequitable opportunity to demonstrate competency.

SECTION 5 – FOOD SAFETY CERTIFICATION EXAMINATION ADMINISTRATION

5.0 ***Food Safety Certification Examination*** **Administration.** All sections of the~~se~~ Standard~~s~~ apply to *Computer Based Testing (CBT)* Administration except Section<u>s</u> 5.1, and 5.4B. All sections of these Standards apply to *remote proctoring* except Sections 5.4B, 5.11B, 5.13 C & D.

5.1 **Security for *Examination Materials.***

A. Policies and procedures shall be developed and documented by the *certification organization* to ensure the security of *examination materials*. At a minimum, security provisions shall address:
   1) t~~T~~he type of test materials (i.e<u>.,</u> electronic or paper);
   2) t~~T~~he locations of the test materials (i.e., transportation, electronic delivery, disposal,storage, examination center (when applicable));
   3) t~~T~~he steps in the examination process (e.g.<u>,</u> development, administration, results reporting);
   4) t~~T~~he threats arising from repeated use of examination materials<u>.</u>

B. Packaging by c*ertification organization.*
   1) Each individual examination booklet shall be securely sealed before packing.
   2) Secure tamper-resistant shipping material, such as Tyvek envelopes or similar materials that are designed to reveal any tampering or violation of the package's security, is required for all shipment of materials in all phases.
   3) Packaging must include a packing list that contains:
      a. *examination form* language(s) or version(s) enclosed; and
      b. quantity of examinations enclosed.

C. Shipping to the *test administrator/proctor* from the c*ertification organization.*
   1) Shipping shall be done by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.
   2) A signature is required upon delivery.
   3) Only an individual authorized by the *test administrator/proctor* may sign for the package.

D. Storage by *test administrator/proctor.*
   The package(s) of examination booklets shall be secured at all times immediately upon delivery. Under no circumstances may examination booklets, *examinee* used answer sheets, or other examination materials be kept where other employees or the public ~~has~~ <u>have</u> access.

E. Shipping to the *certification organization* from the *test administrator/proctor*<u>.</u>
   1) After examination administration, examination booklets and answer sheets shall remain in secure storage until returned to c*ertification organization.*
   2) The following shall be in tamper-resistant shipping material:

a. all used and unused examination booklets for each examination administration;
b. *examinees'* used answer sheets; and
c. all required c*ertification organization* forms.

3) Shipping shall be done within two business days following the examination date by certifiable, traceable means, with tracking numbers so that the location can be determined at any given time.

F. Handling unused examination booklets that have been held for up to ninety days. The *test administrator/proctor* will:
1) ensure that all examination booklets are accounted for;
2) package examination booklets securely as described above; and
3) ship to the certification organization securely packaged and according to these *Standards* and the *Certification Organization*'s instructions.

5.2 Test Site Requirements.

Sites chosen for administering *food safety certification examination*s shall conform to all legal requirements for safety, health, and accessibility for all *examinees*.

A. ~~Additionally, the~~ Aaccommodations, lighting, space, comfort, and workspace for takingthe examination shall reasonably allow *examinees* to perform at their highest level of ability.

B. Requirements at each test site include, but are not limited to:
1) reasonable accommodation requests, in accordance with the requirements of the Americans with Disabilities Act, shall be fulfilled for *examinees*;
2) conformity to all fire safety and occupancy requirements of the jurisdiction in which they are located;
3) sufficient spacing between each *examinee* in the area in which the actual examination is conducted, or other appropriate and effective methods, to preclude any *examinee* from viewing another *examinee's* examination;
4) acoustics allowing each *examinee* to hear instructions clearly, using an electronic audio system if necessary;
5) lighting at each *examinee's* workspace adequate for reading;
6) ventilation and temperature appropriate for generally recognized health and comfort of *examinees*;
7) use of private room(s) where only examination personnel and *examinees* are allowed access during the examination administration; and
8) no further admittance into the test site once examination administration has begun.

5.3 Test Site Language Translation.

A *certification organization* shall have a published, written policy regarding test site language translation of *food safety certification examinations*. If a *certification organization* allows test site language translation of a *food safety certification examination* when an *examination version* is not available in the *examinees'* requested language, the *certification organization* shall have a published, formal application process available to all *potential examinees*. Procedures shall include but not be limited to:

A. An application process for *potential examinees* that includes an evaluation and documentation component to determine the eligibility of the *potential examinee* for test site language translation.,

B. An application process for translators that includes clear and precise qualifications that shall include but not be limited to the following:
   1) being fluent in both languages;
   2) have a recognized skill in language translation;
   3) trained in the principles of objective examination administration;
   4) have no personal relationship with the *examinee* (may not be another *examinee*, may not be a relative or friend of the *examinee* and may not be a co-worker, employer, or an employee of the *examinee*);
   5) not having any vested interest in Food Protection Manager *certification* or conflict of interest;
   6) provide references or other proof attesting to the translator's competencies and professional acumen; and
   7) agree in writing to maintain the security of the examination.

C. A proctored environment where the translator and *examinee* are not a distraction to other *examinees*, and

D. A proctored environment where the translator is not active as the *test administrator*/*proctor*.

5.4 Scoring.

A. Only the *certification organization* may score the examination by nationally accepted scoring methods ~~approvedby the *accrediting organization*~~. No official scoring is to be done at the test site for paper-pencil based examinations.

B. *Food safety certification examination* scores for paper-pencil based examinations will not be released as ~~being~~ official untilverified and approved by the c*ertification organization*.

C. *Examinee* scores will be confidential, available only to the *examinee,* the Certification Organization, the Accrediting Organization, and to persons or organizations approved in writing by the *examinee*.

D. Score reports will be available to *examinees* in a time frame specified in the application, which will not exceed fifteen business days following the administration of the *food safety certification examination*. If there is a delay due to problems in verification or authentication of scores, *examinees and the test administrator/proctor* will be so informed and an approximate date for release of the scores will be announced.

5.5 *Test Administrator/Proctor(s)* Role. *Test administrators/proctors* shall have successfully completed the *certification organization's* specific training in examination administration and security procedures. They shall provide written assurance of maintaining confidentiality of examination contents, of adhering to the *certification organization's*

standards and ethics of secure examination administration, and of agreeing to abide by the *certification organization's* policies, procedures, and rules.

5.6 ***Test Administrator/Proctor*** **Roles and Requirements.** To serve as a *test administrator/proctor* for an accredited *certification organization* the qualified individual shall complete the *certification organization's*:

A. signed Application;

B. Nnon-Disclosure Agreement (NDA);

C. training program for *test administrators/proctors;* and

D. Ceonflict of Interest Disclosure Agreement (can be a part of the NDA).

5.7 ***Test Administrator/Proctor*** **Renewal.** *Test administrators/proctors* shall renew the training program for *test administrators/proctors* and Non-Disclosure Agreement with the *certification organization* a minimum of every three (3) years.

5.8 ***Instructor*** **as** ***Test Administrator/Proctor*****.**
When a person acts as *an instructor* and a *test administrator/proctor*, thatperson relinquishes the role of *instructor* when acting in the role of *test administrator/proctor.*

5.9 ***Test Administrator/Proctor*** **Responsibilities.**
Test Administrators/proctors shall utilize documented procedures provided by the certification body to ensure a consistent examination administration. These include, but are not limited to:

A. Schedule examinations. *Food safety certification examination*s shall be scheduled far enough in advance to allow for timely shipment of supplies or pre-registration for computer-based examinations.

B. The *certification organization's* criteria for conditions for administering examinations shall be followed. Conditions can include, but are not limited to: lighting, temperature, separation of candidates, noise, candidate verification and safety, *test administrator/proctor* conduct and *examination materials* security throughout examination process, etc.

C. Report possible security breaches and examination administration irregularities in compliance with the *certification organization's* policies.

5.10 The number of approved *proctors* assigned to a *test administrator* shall be sufficient to allow each *examinee* to be observed and supervised to ensure conformance to security requirements. The *certification organization* shall develop and justify to the *accrediting organization,* through documented policies, the ratio of test administrator/proctor to

examinees.

5.11 Examination Security.

A. All aspects of *food safety certification examination* administration are to be conducted in a manner that maximizes the security of the examinations, in keeping with the public protection mandate of the CFP. This shall be accomplished in a manner that ensures fairness to all *examinees*.

B. For test site/testing center administered examinations, a~~A~~ll *examinees* shall begin taking the examination at the same time. No *examinee* shall be admitted into the test site/testing center once examination administration has begun.

C. Where reasonable accommodation~~s is~~ are provided for *ex~~x~~aminees* under provisions of the Americans with Disabilities Act, care shall be takento ensure that security of the examination is maintained. Individuals assisting in providing accommodation (Assistants) shall disclose in writing any actual or potentialconflict of interest prior to assisting in any exam administration. The *certification organization* shall address any identified conflicts of interest and maintain a signed nondisclosure agreement with Assistants.

5.12 The *certification organization* shall provide procedures to be followed in any instance where the security of a *food safety certification examination* is, or is suspected to be, breached.

A. Included shall be, at a minimum, specific procedures for handling and for reporting to the *certification organization*, any suspected or alleged:
   1) cheating incidents;
   2) lost or stolen examination materials~~;~~
   3) intentional or unintentional divulging of examination *item*s by *examinees* or examination administration personnel; or
   4) any other incidents perceived to have damaged the security of the examination or any of its individual *item*s.

B. Corrective actions to guard against future security breaches shall be established and implemented.

C. Documentation of corrective actions and their effectiveness shall be made available to the *accrediting organization*.

5.13 *Item* and Examination Exposure.

The *certification organization* shall have an *exposure plan* that:

A. controls for *item* and examination exposure;

B. accounts for the number of times an *examination item*, *examination form,* and

examination version is administered;

C. ensures that no *examination form* is retained by any *examination administration* personnel for more than ninety days;

D. at all times accounts for all copies of all used and unused examination booklets; and

E. systematically and actively demonstrates that every used answer sheet, examination booklet, and any other examination materials and answer keys are accounted for to prevent, reduce, or eliminate examination exposure.

5.14 ***Certification Organization's*** **Responsibility to** ***Test Administrators/Proctors.***

A. The *certification organizations* shall specify the responsibilities of *test administrator/proctor*, set minimum criteria for approval of *test administrators*/ *proctors*, and provide a training program to enable *potential examinees* to meet the approval criteria. Responsibilities, duties, qualifications and training of *test administrators*/*proctors* shall be directed toward assuring standardized, secure examination administration and fair and equitable treatment of *examinees*.

B. The *certification organization* shall define and provide descriptions for the roles of *test administrators/proctors* clearly indicating theresponsibilities for these roles. The *certification organization* shall demonstrate how itensures *administrators/proctors* understand and practice the procedures identified for their roles.

C. *Test administrator/proctor* training programs shall include:
   1) specific learning objectives for all activities of *test administrator/proctor*; and
   2) an assessment component that shall be passed before an *applicant* for *test administrator/proctor* will be approved.

5.15 ***Certification Organization*** **Test Administrator/Proctor Agreements.** The *certification organization* shall enter into a formal agreement with the *test administrator/proctor*. The formal agreement shall at a minimum address:

A. provisions that relate to code of conduct;

B. conflicts of interest; and

C. consequences for breach of the agreement.

5.16 The *certification organization* shall assess and monitor the performance of *test administrators/proctors* in accordance with all documented procedures and agreements.

5.17 The *certification organization* is not permitted to hire, contract with, or use the services of any person or organization that claims directly or indirectly to guarantee passing any certification examination. *Instructors* making such a claim, whether independently or as an employee of another organization making the claim, are not eligible to serve as *test administrators/proctors* for any *certification organization.*

5.18 Policies and procedures for taking corrective action(s) when any *test administrator* or *proctor* fails to meet job responsibilities shall be implemented and documented. *Test administrators/proctors* that have been dismissed by the *certification organization* for infraction of policies or rules, incompetence, ethical breaches, or compromise of examination security will be reported to the *accrediting organization*.

5.19 Examination Administration Manual.
The *certification organization* shall provide each *test administrator/proctor* with a manual detailing the requirements for all aspects of the *food safety certification examination* administration process. The Examination Administration Manual shall include a standardized script for the paper examination *test administrator/proctor* to read to *examinees* before the examination commences. For computer-based tests (CBT), standardized instructions shall be available for *examinees* to read.

5.20 Examination Scripts. Separate scripts/instructions may be created for different delivery channels or *certification organizations*. *Certification organizations* may customize elements of the scripts to fit their particular processes, but each script shall contain the following:

A. Introduction to the Examination Process
   1) composition of the examination (number of questions, multiple choice, etc.);
   2) time available to complete the examination;
   3) role of the *test administrator/proctor*;
   4) process for restroom breaks; and
   5) process for responding to *examinee* comments and questions.

B. Copyright and Legal Responsibilities
   1) ~~(spacing)~~description of what constitutes cheating on the examination;
   2) penalties for cheating; and
   3) penalties for copyright violations.

C. Examination Process
   1) maintaining test site security;
   2) description of examination components unique to the *certification organization* (examination booklet, answer sheet completion, computer process in testing centers, etc.);
   3) instructions for proper completion of personal information on answer sheets/online registration and examination booklets;
   4) instructions on properly recording answers on answer sheets or online; and
   5) instructions on post-examination administration process.

SECTION 6.0 – COMPUTER-BASED TESTING (CBT)

6.0 **Computer-Based Test Development and Administration** All sections of the~~se~~ Standards apply to *Computer Based Testing* (CBT) Administration except Section 5.1.

6.1 **Computer-Based Test Development.** *Examination specifications* for *computer-based testing* shall describe the method for development, including the *algorithm*s used for test *item* selection, the *item* response theory model employed (if any), and examination *equivalency* issues.

6.2 *Item*s shall be evaluated for suitability for computer delivery, be reviewed in the delivery medium, and be reviewed in the presentation delivery medium. Assumptions shall not be made that *item*s written for delivery via a paper/pencil medium are suitable for computer delivery nor should it be assumed that computer test *item*s are suitable for paper/pencil delivery.

6.3 When *examination forms* are computer-generated, whether in *Computer-Adaptive Testing* (CAT) or in a simple linear *algorithm*, the *algorithm* for *item* selection and the number of *item*s in the *item bank* from which the examination is generated shall ensure that the *item*s are protected from *overexposure*. *Item* usage statistics shall be provided for all available *item*s in the pool.

6.4 ***Computer-Based Testing*** **Administration.** ~~Where examination environments differ (for example, touch screen versus mouse) evidence shall be provided to demonstrate equivalence of the *examinee*s' scores.~~The Computer-Based Test designer shall be accountable to assure that the visual representation of the exam questions, the answers, and the directions is clear and generally easy to interpret, allowing the examinee optimal chance to accurately select their desired response to the exam questions.

6.5 Tutorials and/or practice tests shall be created to provide the *examinees* adequate opportunity to demonstrate familiarity and comfort with the computer test environment.

6.6 If the time available for computer delivery of an examination is limited, comparability of scoring outcomes with non-timed delivery of the exam shall be demonstrated. Data shall be gathered and continually analyzed to determine if scoring methods are comparable.

6.7 Evidence of security in the *computer-based testing* environment shall be provided. Factors affecting test security include, but are not limited to, *examinee* workspace, access to personal materials, level of *examinee* monitoring, and *test encryption and decoding*.

6.8 Documentation of precautions to protect *examination forms* and the *item bank* from unauthorized access shall be provided. (Spacing issue with 6.9)

6.9 Policies and procedures regarding the recording and retention of the *item sequence* and *item* responses for each *examinee* shall be developed and followed. Computer examinations using a unique sequence of *item*s for each *examinee* shall record the information necessary to recreate the sequence of *item*s and *examinee* responses on the

computer examination.

6.10 Systems and procedures shall be in place to address technical or operational problems in examination administration. For example, the examination delivery system shall have the capability to recover *examinee* data at the appropriate point in the testing session prior to test disruption. Policies regarding recovery for emergency situations (such as retesting) shall be developed.

6.11 **Due Process.** *Examinees* shall be provided with any information relevant to *computer-based testing* that may affect their performance or score. Examples of such information might include but not be limited to: time available to respond to *item*s; ability to change responses; and instructions relating to specific types of *item*s.

SECTION 7.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO *POTENTIAL EXAMINEES, EXAMINEES* AND THE PUBLIC

7.0 A *certification organization's* Responsibilities to *Examinees* and the Public.

7.1 Responsibilities to *Potential Examinees* and/or *Examinees* for *Certification*. A *certification organization* shall develop and implement policies, which address the following:

A. an overview to *exam candidates* of the process by which one obtains *certification*;

B. ~~a~~ notice to *exam candidates* of non-discrimination.

C. protocols for the periodic review of examination policies and procedures to ensure fairness;

D. procedures for uniform~~ly~~ and prompt reporting of *food safety certification examination* results to *examinees*;

E. procedures for providing *examinees* failing the *food safety certification examination* with information on general areas of deficiency;

F. protocols that assure the confidentiality of each *examinee's food safety certification examination* results; and

G. appeals procedures– for– *exam*– *candidates* regarding any part of the *accredited certification program*.

7.2 Qualifications for Initial *Certification*. To become a *Certified Food Protection Manager* an individual shall pass a *food safety certification examination* from an *accredited certification program* recognized by the CFP. The *certificate* shall be valid for no more than five years.

~~(space)~~

7.3 *Individual Certification* C*ertificates:*

A. Each *certification organization* will maintain a secure system with appropriate backup or redundancy to verify validity of individual *certification certificates*.

B. *Certificates* shall include, at a minimum:
   1) issue date/date examination was taken;
   2) length of time of *certification* validity;
   3) name and *certification* mark of *certification organization;*
   4) *accrediting organization* mark;
   5) name of certified individual;
   6) unique *certificate* number;

7) name of *certification*;
8) contact information for the *certification organization*; and
9) examination form identifier.

C. Replacement or duplicate *certificates* issued through an *accredited certification organization* shall carry the same issue date, or date of examination, as the original *certificate*, and will be documented by the *certification organization*.

7.4 **Discipline of *Certificate* Holders and *Examinees*.** A *certification organization* shall have formal *certification* policies and operating procedures including the sanction or revocation of the *certificate*. These procedures shall incorporate due process.

7.5 ***Continued Proficiency*.** An *accredited certification program* shall include a process or program for assessing continued competence that includes an examination component at an interval of no more than five years. The outcome of the process or program shall demonstrate that the person has maintained the minimum competencies as determined by the job task analysis.

7.6 **Responsibilities to the Public and to Employers of Certified Personnel.** ~~-~~ A *certification organization* shall maintain a registry of ~~individuals~~ certified individuals. Any title, credential, or certificate awarded by the certification organization shall be relevant to the retail food industry and role of Food Protection Manager and not designed to mislead or intentionally confuse *examinees* and other stakeholders.

7.7 **Complaints and Appeals.** Each *certification organization* shall have a published procedure addressing complaints and appeals. Such procedures shall include a stated timeframe for response from the *certification organization*. (spacing issue)

7.8 **Misrepresentation.** Only *certification organizations* that conform to all requirements of the Standard and are *accredited* by the agent selected by the CFP as the *accrediting organization* for such programs are allowed to refer to themselves as being *accredited*. Those programs may not make any other reference to the CFP in their publications or promotional materials in any medium.

SECTION 8.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO THE ACCREDITING ORGANIZATION

8.0 *Certification Organization* Responsibilities to the *Accrediting Organization*.

8.1 Application for *Accreditation*. *A certification organization* seeking *accreditation* for development and/or administration of a *certification* program shall provide at least the following information, as well as other information that might be requested by the *accrediting organization:*

A. the name and complete ownership structure of the *legal entity*;~~.~~

B. the address, telephone/fax number(s) and other contact information of the *certification organization's* headquarters;~~.~~

C. the name, position, address, and telephone/fax/e-mail information of the contact personfor projects related to the CFP Standards for *Accreditation* of Food Protection Manager*Certification* Programs;~~.~~

D. such fiscal information as may be needed to establish evidence of ability to carry out obligations under the~~se~~ Standard~~s~~.

8.2 Summary Information. A *certification organization* shall:

A. provide evidence that the mechanism used to evaluate individual competence is objective, fair, and based on the knowledge and skills needed to function as a *Certified Food Protection Manager* to the extent possible;

~~B.~~ provide evidence that the evaluation mechanism, ~~is based on standards which establish *reliability* and *validity* for each form of the *food safety certification examination*~~ measures to the extent possible:

1. Reliability
2. Intended interpretation
3. Use of test scores

C. provide evidence that the pass/fail levels are established in a manner that is generally accepted in the *psychometric* community ;

D. have a formal policy of periodic review of evaluation mechanisms and shall provide evidence that the policy is implemented to ensure relevance of the mechanism to knowledge and skills needed by a *Certified Food Protection Manager*;

E. provide evidence that appropriate measures are taken to protect the security of all *food safety certification examination*s;

F. publish a comprehensive summary or outline of the information, knowledge, or functions covered by the *food safety certification examination*;

G. make available general descriptive materials on the procedures used in examination construction and validation and the procedures of administration and reporting of results; and

H. compile at least annually a summary of *certification* activities, including numberof *examinees*, number tested, number passing, number failing, and number certified.

8.3 Responsibilities to the *Accrediting Organization*. The *certification organization* shall:

A. make available upon request to the *accrediting organization* copies of all publications related to the *certification* program;~~,~~

B. notify the *accrediting organization* of any proposed changes in structure or activities of the *certification organization*;~~,~~

C. advise the *accrediting organization* of substantive change in *food safety certification examination* administration;~~,~~

D. advise the *accrediting organization* of any major changes in testing techniques or in the scope or objectives of the *food safety certification examination*;~~,~~

E. annually complete and submit to the *accrediting organization* information requested on the current status of the Food Protection Manager *Certification* Program and the *certification organization*;~~,~~

F. submit to the *accrediting organization* the report requirements information specified for the Food Protection Manager *Certification* Program;~~,~~ and

G. be re-accredited by the *accrediting organization* at least every five years.

SECTION 9.0 – MANAGEMENT SYSTEMS

9.0 Management Systems.

9.1. Each c*ertification* o*rganization* shall have a formal management system in place to facilitate continuous quality improvement and produce preventive and corrective actions. The management system shall contain the following three components.

A. Document control to include:
   1) lists of all documents pertaining to the *certification organization*;
   2) dates for documents approved for implementation by the *certification organization*;
   3) the person(s) within the *certification organization* responsible for the documents; and
   4) listing of individuals who have access to the documents.

B. Internal audits to include:
   1) identification of critical activities;
   2) data collection process and evaluation schedule;
   3) audit methodology and evaluation process;
   4) the person(s) authorized to perform audits; and
   5) report audit findings and identify corrective action required.

C. ~~A~~ Management Review that includes:
   1) a documented annual review of internal audit results;
   2) a management group that conducts the review;
   3) a review of the audit results to determine corrective actions needed;
   4) a review of the audit results to determine preventive actions needed; and
   5) the effectiveness of corrective and preventive actions taken.

ANNEX A

Conference for Food Protection

Conference for Food Protection Requirements for Certification Organizations to Provide Food Protection Manager Certifications using the ISO/IEC 17024 Personnel Certification Standard

The requirements described in this document shall be applied in conjunction with the ISO/IEC 17024 standard(International Organization for Standardization/ International Electrotechnical Commission). All clauses of ISO/IEC 17024 standard continue to apply. This document provides supporting criteria to that standard for certification bodies that want to be recognized by the CFP.

SECTION 1.0 – CONFERENCE FOR FOOD PROTECTION ACCEPTANCE OF ISO/IEC 17024 ACCREDITED PROGRAMS

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document(including any amendments) applies. A) ISO/IEC 17024 Standard, B) FDA Food Code.

A1.0 Conference for Food Protection acceptance of *ISO/IEC 17024* accredited Food Protection Manager Certification programs.

A1.1 Wherein, the Conference for Food Protection ("CFP") maintains the *Standards for Accreditation of Food Protection Manager Certification Programs* ("CFP Standard");

A1.2 And, the CFP recognizes *ISO/IEC 17024, Conformity assessment – General requirements for bodies operating certification of persons* ("ISO/IEC 17024 Standard") as an alternative personnelcertification standard to the CFP Standard;

A1.3 And, that the recognition of ISO/IEC 17024 Standard does not impact the CFP Standard;

A1.4 And, that the CFP recognizes that certification organizations accredited under either the CFP Standard or ISO/IEC 17024 Standard may offer Food Protection Manager Certifications;

A1.5 So long as organizations seeking accreditation to provide Food Protection Manager Certifications using the ISO/IEC 17024 Standard abide by the requirements listed herein.

SECTION 2.0 – DEFINITIONS

A2.0 Definitions

A2.1 For definitions, please refer to *FDA Food Code, section 1-201.10*.

SECTION 3.0 – SCHEME

A3.0 Scheme

A3.1 **Purpose**. The Purpose of the ISO 17024 Standard, as it relates to the CFP Food Protection Manager Certification is to ensure that:

> "…the competencies assessed in the accredited certification program are those required for competent entry level performance in the role of Certified Food Protection Manager, as defined by (United States) law and industry standards, and that they focus on factors related to the prevention of foodborne illness in the retail food industry," (CFP Standard Section 4.10).

A3.2 A food protection manager as addressed in *FDA Food Code, section 2-102.12* and *FDA Food Code, section 2-102.20*.

A3.3 A Certified Food Protection Manager may work in a "food establishment" as defined in *FDA Food Code, section 1-201.10*.

A3.4 **Scope.** The Food Protection Manager Certification is based on the *FDA Food Code*. Certification organizations must update their programs to the latest *FDA Food Code* version within five (5) years of its release.

A3.5 **Geographic Limitations.**

- **A.** The scope of this personnel certification is based on the United States FDA Food Code; therefore, it is inherently for individuals working in the United States or those who utilize itsFDA Food Code;
- **B.** So long as an applicant outside of the United States is certified through an accredited program adhering to the requirements set forth in this document, the CFP recognizes that certification as a Food Protection Manager Certification.

A3.6 **Job Task Analysis.** Certification organizations must complete a job task analysis using the requirements defined in CFP Standard, section 4.4-4.76.

SECTION 4.0 – PRE-REQUISITES

A4.0 Pre-requisites

A4.1 There are no training or other pre-requisites for Food Protection Manager Certification candidates.

SECTION 5.0 – TRANSLATOR/TRANSLATION REQUIREMENTS

A5.0 Translator/Translation Requirements

A5.1 **Application Process.** In the event a personnel certificate candidate requires an onsite translator, the application process for translators must include clear and precise qualifications for those translators.

A5.2 **Test Site Language Translation.** Certification organizations must follow the requirements set forth in CFP STANDARD, section 5.3.

SECTION 6.0 – REPRESENTATION

A6.0 Representation

A6.1 **Certificates.** All certificates delivered upon the successful passing of a certification exam accredited under the ISO 17024 Standard must include the Conference for Food Protection logo and the ANSI accreditation mark.

SECTION 7.0 – DOCUMENT REFERENCES

A7.0 The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

A. FDA Food Code.

B. CFP Standard

C. ISO 17024.

ANNEX B

Guidelines for Regulatory Authorities Implementing Food Protection Manager Certification Programs

B1. Each permitted *food establishment* should have a minimum of one designated *Certified Food Protection Manager* who is accountable for food safety.

Documentation of *certification* of *Certified Food Protection Manager*(s) should be maintained at each *food establishment* and shall be made available for inspection by the *regulatory authority* at all times.

B2. A *Certified Food Protection Manager* is responsible for:

1) identifying hazards in the day-to-day operation of a *food establishment*;

2) developing or implementing specific policies, procedures or standards aimed at preventing foodborne illness;

3). coordinating training, supervising or directing food preparation activities and taking corrective action as needed to protect the health of the consumer; and

4) conducting in-house self-inspection of daily operations on a periodic basis to see that policies and procedures concerning food safety are being followed.

B3. **Qualifications for *Certification*.** To become a *Certified Food Protection Manager*, an individual shall pass a *food safety certification examination* from an accredited *certification organization* recognized by the CFP. The CFP recognizes the importance and need for the provision of food safety training for all food employees and managers. The CFP recommends the content of food protection manager training be consistent with paragraph 2-102.11 (C) of the most recent FDA Food Code. The CFP promotes the information contained in the FDA Food Code as well as content outlines based on job tasks analyses, provided on the CFP website, which may be of value in developing or evaluating training.

B4. Regulatory authorities should work with the *certification organization* on a mutually agreeable format, medium and time frame for the submission of score reports pertaining to the administration of *food safety certification examinations*.

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | December 1, 2021 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Chapman, Ciarimboli, Corchado Torres, ~~Derr~~, ~~Dolhanyk~~, ~~Dunleavy~~, Dwyer, Eastwood, Halbrook, Hawley, Huffman, Jackson, Koester, Luebkemann, Paster Cammarata, Piche, Reich, Roughan, Smith, Straughn, Sweet, Wiedmeyer, Wilson, Woods, Wynne [25 voting members present]

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, Duggins, Gillam, Johnson, Krishna, ~~Morrison~~, ~~Pollock~~, Rivas, Unkart, Williams, Wittry

Interested Parties & Guests:

Agenda Items

1. Welcome & Introduction of Committee Members
2. CFP Anti-trust Statement
3. Committee orientation - powerpoint deck
4. Committee administration and constituencies
   a. Standing committee, reports to Executive Board
   b. Purpose of Committee
   c. 6 constituencies: academic, certification, consumer/Independent, industry (food service, retail), regulatory (local, state, federal), training providers
   d. Roles of Chair (non-voting), Vice-chair (voting), 30 voting members, alternates
   e. Advisors/consultants, non-voting: ACAC, ANSI, FDA/USDA, psychometrician
   f. Meeting procedures
   g. Voting procedures
5. Election of New Committee Chair
6. Committee Bylaws
7. Food Protection Manager Certification Standards
8. Charges from CFP
9. Formation of Workgroups (Standards, Bylaws)
10. Meeting Schedule: Next Meeting – 2/2/22, 2-4:00 pm (eastern)

Minutes

Items 1-4: Acting Chair Jeff Hawley convened the meeting in "virtual" format at 2 PM eastern, and explained he would be Acting Chair as a result of Sharon Wood's retirment, only until elections occur later in the meeting. The anti-trust statement was read, attendance was recorded, and a quorum established. Chair Hawley then presented committee orientation and administration information.

Allen Reich inquired as to whether members would receive any background information on committee issue II-004 "Limit CPFM accredited exam certificate validity to four years," submitted by Lars Johnson. Chair Hawley advised that at the appropriate time the submitter would be recognized to explain the issue.

Item 5: Chair Hawley called for Chair and Vice Chair nominations. Luebkemann and Huffman nominated Susan Quam for Chair, and Justin Daniel for Vice Chair for the remainder of the 2021-23 biennium. No additional nominations were advanced.

Motion
Luebkemann moved and Huffman seconded that: Susan Quam be elected Chair and Justin Daniel be elected Vice Chair for the remainder of the biennium. Motion carried with unanimous consent.

Susan Quam assumed the Chair and presided over the remainder of the meeting.

Item 6-9:
Chair Quam summarized the work the committee would undertake, and called for establishment of and volunteers for two workgroups to perform routinely-charged maintentance: FPMCC Bylaws - Jeff Hawley, Chair; and Food Protection Manager Certification Standards ("Standards") - Kate Piche, Chair.

Item 10:
Chair Quam reminded members FPMCC meetings are currently set to recur every other month on the first Wednesday, with the following 2022 dates scheduled: Feb. 2, Apr. 4, Jun. 1, Aug. 3, Oct. 5, Dec. 7.

Next meeting will convene virtually on Feb. 2, 2022, 2-4 PM eastern.

Motion
Corchado Torres moved and Dwyer seconded adjournment. Motion carried with unanimous consent.

Meeting adjourned at 3:37 PM eastern.

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | February 2, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Chapman, Ciarimboli, Corchado Torres, ~~Derr~~, ~~Dolhanyk~~, ~~Dunleavy~~, Dwyer, Eastwood, Halbrook, Hawley, Huffman, ~~Jackson~~, Koester, Luebkemann, Paster Cammarata, Piche, Reich, Roughan, Smith, Straughn, Sweet, Wiedmeyer, Wilson, Woods, Wynne [25 voting members present]

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, Duggins, Gillam, Johnson, Krishna, ~~Morrison~~, Pollock, Rivas, Unkart, Williams, ~~Wittry~~

Interested Parties & Guests:

Agenda Items

1. Welcome & Introduction of Committee Members, Attendance
2. CFP Anti-trust Statement
3. Formation of Workgroups - Standards, Bylaws
4. Overview of discussion format: speaker recognition, voting
5. Issue 2020 II-004
   a. Issue Background – Lars Johnson, issue submitter
   b. Identify impacts and feasibility questions
      - to facilitate future discussion, the committee will develop a "10,000-foot level" list of impacts and feasibility to be further discussed at the April meeting
      - committee leadership will organize the list for deeper discussion beginning in April
6. Meeting Schedule: next meeting April 6, 2022, 2-4 PM eastern

   FPMCC meetings recur every even month on the first Wednesday, 2-4 PM eastern
   Meeting Zoom link: https://us02web.zoom.us/j/87071250980
   Meeting ID: 870 7125 0980
   One tap mobile: +13126266799,,87071250980# US (Chicago)
   +16468769923,,87071250980# US (New York)

Quam Notes for Discussion of Issue II-004 4-Year Exam Validity / Areas of impact and feasibility

- Time lapse between CFP/FDA/Code publication
  - Test provider impact – what is the date of implementation
- Will the change reduce the number of risk factor violations – is there studies behind it
- Providers are already able to have shorter time period, with five as the max
- Is it legally justifiable
- Impact on update timelines and justification for changes and taking different methodologies into consideration
- Impact on the CFP Standard
- What is the frequency of the JTA? Some may already be less than 5 years
- Does existing work done by providers already capture and address the issue
- Financial impact – shorter timeline increases frequency
- E.g. Rhode Island operated on 3 year basis – do they have data on impact of more frequency - change in seat time requirements. Utah has 3 year frequency as well
- Need for research to justify change
- How does this impact time lines outlined in state statute and local ordinance

- Timing of exam vs timing of FC release
- Practical day to day knowledge vs no hands on experience
- Is this aligning with FC or is this justifiable as a way to improve food safety
- How many jurisdictions have times other than 5 years
- 2017 FC update to have CFPM on duty at all times, already impacts industry, will this requirement make it greater
- Different ways to "recertify" other than by exam. Is there a bigger issue to address relating to best ways to recertify
- Pandemic related delays to recertification
- Why was 5 years chosen in the first place
- Financial impact on industry

Minutes

Items 1-2: Chair Susan Quam convened the meeting in "virtual" format at 2 PM eastern, the anti-trust statement was referenced, attendance was recorded, and a quorum established.

Items 3: Chair Quam then called for volunteers for the Standards and Bylaws workgroups and the following groups were formed:

Standards, Chair Kate Piche - Allen Reich, April Rivas, Lars Johnson, Laura Koester, Laurie Williams, Lindy Wiedmeyer, Liz Corchado Torres, Nikki Burns Savage, Sean Dunleavey, Sharon Unkart, Tara Dwyer, Yolanda Woods

Bylaws, Chair Jeff Hawley - Bryan Chapman, Evelin Pollock, Justin Daniels, Laurie Williams, Nick Eastwood, Tara Paster Cammarata, Troy Huffman

Item 4: Chair Quam explained how discussion and voting would proceed in context of the virtual meeting format.

Item 5: Chair Quam introduced charged issue 2020 II-004, "Limit CPFM accredited exam certificate validity to four years," and Lars Johnson, the issue submitter. Mr. Johnson was recognized and stated objectives of the issue include: alignment of the CFPM certificate with the Food Code publication cycle; reduce the number of people that could miss a Food Code update without need to be recertified; improve manager knowledge at "little to no cost" to certificate holders.

Chair Quam then called for committee input on impacts and feasibility, with these responses:

- Williams asked if Johnson considered two-year supplemental Food Code updates, which can be significant
- Johnson stated a change to 4-year certification would capture all changes in a cycle
- Anderson asked if Johnson considered increased costs to exam providers; Johnson stated he did not
- Corchado Torres asked what the required response time is for FDA to act on CFP Biennial Meeting recommendations; Williams responded CFP has 45 days to transmit recommendations after the Biennial meeting, then FDA has 60 days to respond
- Corchado Torres asked about implementation time for certifying organizations to incorporate FDA's changes to Food Code; Huffman stated the issue proposed has no effect on exam content updates
- Huffman asked if there is any available science on the impact to food safety risk in changing from a 5-year to a 4-year credential expiration; Johnson stated there to be a dearth of data in this regard
- Chapman stated the certifying organizations must justify to ANSI the credential expiration; 5 years is a current maximum, but less is optional
- Krishna states this change will impact certifying organizations legal defensibility, and could have JTA implications, i.e., whether the exam is demonstrating job competence; he further stated that JTAs would need to align with changed expiration dates which has a cost, and there could be impacts to the Standards and exam validity

- Roughan stated the assumption this change would come at “little to no cost” is not accurate
- Dwyer stated that Rhode Island had experience with shorter expirations and associated instruction time required of exam candidates, but no associated data with regard to food borne illness risk reduction had been gathered
- Koester stated Utah requires training and examination every three years
- Reich stated the proposed change in credential expiration should be based on research rather than anecdote, and how to implement alignment of credential expiration with Food Code updates is unclear
- Anderson stated this matter is not as simple as “4 is better than 5,” and that considering the proposal should include a demonstration of efficacy versus simple alignment
- Burns Savage stated that Southern Nevada Health District uses a 5-year expiration
- Piche stated that the National Restaurant Association tracks jurisdictions that depart from 5-year expirations and can make that information available to the committee
- Johnson stated that in addition to some regulatory jurisdiction varying from 5-year expirations, some private sector organizations do also
- Chapman stated increased adoption of the 2017 Food Code and its increased CFPM “onsite” requirement has already disproportionately increased costs for small / independent operators
- Ciarimboli stated Hy-Vee has adopted a three-year expiration due to a Minnesota state requirement
- Rivas asked what the basis for the 5-year standard is; discussion ensued that FDA and or John Marcello may have information in this regard
- General discussion ensued that this change may more appropriately within the purview of regulatory jurisdictions, and nothing prohibits them from adopting shorter expirations

Chair Quam asked for the members to email her their comments on impact, feasibility, cost, stakeholder impacts by sector (certifying organizations, trainers, food operators, or others).

The meeting was adjourned at 3:22 PM by unanimous acclimation.

###

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | April 6, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, Allen, Anderson, Burns Savage, Chapman, Ciarimboli, Corchado Torres, Derr, ~~Dolhanyk~~, ~~Dunleavy~~, Dwyer, ~~Eastwood~~, Halbrook, Hawley, Huffman, Jackson, Koester, Luebkemann, Paster Cammarata, Piche, Reich, ~~Roughan~~, ~~Smith~~, Straughn, ~~Sweet~~, Wiedmeyer, ~~Wilson~~, Woods, Wynne [21 voting members present]

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, Duggins, ~~Gillam~~, Johnson, ~~Krishna~~, ~~Morrison~~, Pollock, Rivas, ~~Unkart~~, Williams, Wittry

Interested Parties & Guests:

Agenda Items

1. Welcome & Roll Call
2. CFP Anti-trust Statement
3. Workgroup reports
   a. Standards
   b. Bylaws
4. Overview of discussion format
   a. Speaker recognition – raise hand virtually
   b. Voting – roll call vote
5. Issue 2020 II-004
   a. Discussion begins on each issue raised by the committee at the last meeting
   b. Handout: *0322 FPMCC 4 Year Impact List Word Doc*
   c. Handout: *State Food Protection Manager Recertification certification timeframe PDF*
   d. Discussion will resume at June meeting for issues not covered in this meeting
6. Meeting Schedule: Next Meeting – 06.01.22, 2-4:00 pm EDT

   FPMCC meetings recur every even month on the first Wednesday, 2-4 PM eastern
   Meeting Zoom link: https://us02web.zoom.us/j/87071250980
   Meeting ID: 870 7125 0980
   One tap mobile: +13126266799,,87071250980# US (Chicago)
   +16468769923,,87071250980# US (New York)

   FPMCC April 6, 2022 Meeting Packet (Attachments inserted at end of Minutes):

Attachment 1	FPMCC Roster
Attachment 2	Agenda and Issue 2020 II-004 discussion topics
Attachment 3	Issue 2020 II-004 additional discussion topics
Attachment 4	Recertification frequencies by jurisdiction (source: National Restaurant Assoc.)
Attachment 5	John Marcello, FDA - historical narrative re Five-year certification term
Attachment 6	Laurie Williams, FDA - historical narrative re Food Code publication frequency
Attachment 7	Glenda Lewis, FDA - historical narrative re Food Code publication terminology
Attachment 8	FPMCC Progress Report April 2022

Handout: *0322 FPMCC 4 Year Impact List Word Doc*
Issue II-004 4-Year Exam Validity - Areas of impact and feasibility
For committee discussion April 6, 2022 (Agenda Item 5.b.)

I. Financial Impact - Industry/Providers/Regulatory Agencies

1. At what frequencies are the providers updating their JTAs?
    a. Some may already be updating at less than five years, by addressing the Food Code changes, whenever they are released
    b. If so, do these JTA updates already capture and address the concern of keeping up with Food Code changes?
    c. Does the time lapse between CFP Issue approval/FDA acceptance/Food Code publication impact the JTA process?
2. Shorter certification validity increases frequency
    a. Providers must process and issue certificates more frequently
        - How does this impact providers financially?
    b. Will industry ultimately pay more as employees recertify more frequently?
        - How many industry employees need to be recertified after five years now?
        - Does industry turnover impact this?
    c. The 2017 Food Code update requires CFPM on duty at all times, already impacts industry, will this requirement make it greater?
3. Impact on the CFP Standard
    a. Will this financially impact the CFP?

II. Statutory Implications

1. Is changing the exam validity legally justifiable?
    a. Can a candidate or regulatory authority challenge the change?
    b. Is this justifiable as a way to improve food safety?
2. How does this impact time lines outlined in state statute and local ordinance? *(Please refer to the accompanying State Food Protection Manager Recertification certification timeframe PDF)*
    a. If a statute or ordinance specifies five years, how many jurisdictions are willing to change their laws to four years?
    b. If a jurisdiction does not change, what takes precedence? Law or the certification expiration?
3. Why was five years chosen in the first place? *(Chair Quam is communicating with John Marcello to discuss history and will hopefully have information by meeting time)*

III. Other Issues

1. Some states allow different ways to “recertify” other than by exam. Is there a bigger issue to address relating to best ways to recertify?
2. Will the change reduce the number of risk factor violations – are there studies behind it?
3. Should the committee ask for research to justify change?

Minutes

Items 1-2: Chair Susan Quam convened the meeting in "virtual" format at 2:04 PM eastern, the anti-trust statement was referenced, attendance was recorded, and a quorum established.

Item 3: Chair Quam called for reports from the workgroups. Standards has not met yet, Piche has not received the roster. Bylaws Chair Hawley reported and recommended the following:

Recommendation 1 - this recommendation is made in recognition of difficulty filling regulator seats.

Revisions to Article VI, Section3, Subsection 1.
Subsection 1. Nine (9) representatives from regulatory agencies with food safety responsibilities:
a. ~~Two (2)~~ Three (3) from State regulatory agencies;
b. ~~Two (2)~~ Three (3) from local regulatory agencies; and
~~c. Two (2) from federal government agencies; and~~
c. Three (3) "At Large" appointments. (*At large selections may include federal government agencies, state regulatory agencies and local regulatory agencies with food safety responsibilities.)

Williams stated this recommendation may need edits due to some federal agencies being implicated in, but having no formal retail food safety role or involvement.

Motion
Huffman moved and Jackson seconded that: Recommendation 1 be accepted as submitted, with Jeff Hawley authorized to make necessary clerical edits reflecting federal agency retail food responsibility. Motion carried without objection.

Recommendation 2
Delete Article VII, Section 5, Subsection 3.

Subsection 3. All certification organizations accredited by the Conference's accreditation process participating on the Committee shall not to exceed a total of five (5) votes.
• If more than five (5) certification organizations volunteer to participate on the Committee, the five (5) votes allocated to certification organizations shall be fractionalized (evenly divided).
• The voting fraction shall be determined when the final committee membership is approved by the Board and shall remain in effect until the next biennial Conference meeting.
• Each certification organization shall be allowed no more than one (1) vote or one (1) voting fraction at any meeting.

Fractionalized approach is difficult to manage and not practical. Bylaws workgroup recommends deletion of Article VII, Section 5, Subsection 3. If there are more than five certification organizations who want to participate on the committee the additional ones would be At-large committee members. As a reminder, At-large committee members can participate fully in all committee meetings, except they would not have voting privileges.

Additional information on committee membership:
Article VI, Section 3, Subsection 3 says "Five (5) total votes for certification organizations that are accredited by the Conference's accreditation process. Although there is no limit to the number of accredited certification organizations, this constituency shall have a maximum of five (5) votes."

Halbrook asked how voting would be allocated if more than five certifying bodies were to participate; the Chair replied that recommendations would be made to the Executive Board by the Chair and Vice Chair for final action by the Executive Board. Certifying organization members Anderson and Chapman indicated no objection to this.

Motion
Huffman moved and Jackson seconded that: Recommendation 2 be accepted as submitted, with Jeff Hawley authorized to make necessary clerical edits reflecting federal agency retail food responsibility. Motion carried without objection.

Items 4-5: discussion of Issue II-004 4-Year Exam Validity - Areas of impact and feasibility

I. Financial Impact: Industry/Providers/Regulatory Agencies

1. a. Discussion: At what frequencies are the providers updating their JTAs?
Corchado-Torres - update JTA every five years, change if/when significant Food Code changes occur.
Chapman - Major changes every five years unless Food Code changes warrant otherwise.
Piche - JTA five years unless Food Code changes warrant otherwise.
Anderson - Same for us.
Sharon Unkart – Exams updated as soon as Food Code changes are published.

2.a. Discussion: Shorter certification validity increases frequency
Anderson - Updating exam content and JTAs are separate from certification validity. Beneficial for providers, but increased cost to industry. The question should be "does greater frequency support better food safety?" Unkart and Chapman expressed agreement.
Unkart – Exam content is updated as soon as the food code is published.
Corchado-Torres – Is the expectation that when the Food Code changes, the testing agencies update content? It takes time to update content for testing, so there is still a lag after Food Code updates.
Johnson – The point is not to accelerate testing, but keep pace with the Food Code regular flow.

The question of whether training should be required of exam candidates, and the committee was reminded this is beyond the scope of the standards and the committee's current charges.

2.b. Discussion: Will industry ultimately pay more as employees recertify more frequently?
Halbrook - costs could be significant to businesses footing the bill, with employees numbering in the hundreds of thousands. Increased frequency increases costs, with no known increase in food safety.
Paster Cammarata – It depends on what each state is doing; could be difficult to small businesses. More care should be on retention of the information.

3. General discussion concluded that if the frequency standard is reduced to four years, no financial impact is expected to CFP.

Chair Quam called for any additional questions from the committee, none were heard.

II. Statutory Implications

1. Discussion: Is changing the exam validity legally justifiable?
Quam - Any change must be legally defensible.
Johnson - Some jurisdictions currently have less than five years.

2. Discussion: How does this impact time lines outlined in state statute and local ordinance? *(see PDF: State Food Protection Manager Recertification certification timeframe)*
Luebkemann – Laws, whether local, state, or federal override the Standards.
Johnson – Minnesota requires three years and renewal with CEU's, managed by the state.

Huffman – State statute may not recognize shorter certification expirations in the Standards, creating inconsistency and conflicting guidance. A minority of states have less than five year frequencies.
Pollock – Texas does not require renewal, just a current FPM.

The was much general discussion with concern expressed for creating conflict or inconsistency with existing laws. Huffman stated that a law or ordinance could create a shorter frequency without impacting the Standards, but not vice versa.

3. Discussion: Why was five years chosen in the first place?
Meeting Packet Attachments 5, 6, and 7 provide related background:

Attachment 5	John Marcello, FDA - historical narrative re Five-year certification term
Attachment 6	Laurie Williams, FDA - historical narrative re Food Code publication frequency
Attachment 7	Glenda Lewis, FDA - historical narrative re Food Code publication terminology

III. Other Issues

1. Discussion: Some states allow different ways to "recertify" other than by exam. Is there a bigger issue to address relating to best ways to recertify?
Luebkemann – This is tangential to the substance of the charge, and is a government prerogative.
Hawley – Recertification is not addressed in the Standards, and may vary by locality and action of the authority having jurisdiction.

2. Discussion: Will the change reduce the number of risk factor violations – are there studies behind it?
General committee discussion concluded awareness of no studies available regarding exam frequency requirements and an associated impact to food borne illness risk factors.

3. Discussion: Should the committee ask for research to justify change?
General committee discussion concluded that a change in frequency should be based on or informed by an associated impact to risk factors. The question was raised as to whether the FDA Risk Factor Studies may have relevant information, with Williams responding they do not. The question was raised regarding effect on jurisdictions that currently have a five-year certification codified into law or rule, with the response being that a law or rule overrides the Standards. Dwyer stated research should be part of the decision making process.

The question was raised as to the sense of the committee on this issue, and if a straw poll may be in order; discussion ensued indicating that members may need more time to consider the question, and additional discussion is scheduled for the June 1, 2022 FPMCC meeting.

Item 6:
Chair Quam reminded members FPMCC meetings are currently set to recur every other month on the first Wednesday, with the following 2022 dates scheduled: June 1, Aug. 3, Oct. 5, Dec. 7.

Next meeting will convene virtually on June 1, 2022, 2-4 PM eastern.

Motion
Luebkemann moved and Corchado Torres seconded adjournment. Motion carried without objection.

Meeting adjourned at 3:35 PM eastern.

###

ATTACHMENT 1

Committee Name: FOOD PROTECTION MANAGER CERTIFICATION revised 12.09.2021

Last Name	First Name	Position	Vote / Non-vote	Constituency	Employer	City	State	Telephone	Email	Notes
Quam	Susan	Chair	Non Voting	Industry - Support At Large	Wisconsin Restaurant Association	Madison	WI	608-216-2875	squam@wirestaurant.org	
Daniel	Justin	Vice Chair	Voting	Regulator - Local	Lincoln-Lancaster County Health Department	Lincoln	NE	402-441-8033	jdaniel@lincoln.ne.gov	
Sweet	Bridget	Member	Voting	Academia	Johnson & Wales University	Providence	RI	774-434-5146	bridget.sweet@jwu.edu	
Reich	Allen	Member	Voting	Academia	Northern Arizona University	Flagstaff	AZ	928-853-6340	allen.reich@nau.edu	
Wilson	David	Member	Voting	Consumer	After School Matters	LaGrange	IL	708-582-0022	d.wilson180@my.chicago.chefs.edu	
Dolhanyk	Anne	Member	Voting	Consumer	STOP Foodborne Illness	West Linn	OR	360-601-4264	adolhanyk@gmail.com	
Luebkemann	Geoffrey	Member	Voting	Industry - Food Service	Florida Restaurant & Lodging Association	Tallahassee	FL	850-224-2250	gluebkemann@frla.org	
Halbrook	Courtney	Member	Voting	Industry - Food Service	Topgolf	Dallas	TX	704-236-0890	courtney.halbrook@topgolf.com	
Wynne	Rebecca	Member	Voting	Industry - Food Service	Darden	Denver	CO	303-895-4042	rwynne@darden.com	
Dwyer	Tara	Member	Voting	Industry - Retail Food	Dave's Marketplace	East Greenwich	RI	401-4748905	tarad@davesmarketplace.com	
Allen	Consuelo	Member	Voting	Industry - Retail Food	Whole Foods Market	Austin	TX	512-426-8709	consuelo.allen@wholefoods.com	
Hawley	Jeff	Member	Voting	Industry - Retail Food	Harris Teeter	Matthews	NC	704-844-3098	jhawley@harristeeter.com	
Koester	Laura	Member	Voting	Industry - Retail Food At Large	Harmons	Salt Lake City	UT	801-957-8472	laurakoester@harmonsgrocery.com	
Ciarimboli	Ellen	Member	Voting	Industry - Retail Food At Large	Hy-Vee, Inc.	West Des Moines	IA	515-453-2789	eciarimboli@hy-vee.com	
Corchado Torres	Liz	Member	Voting	Industry - Support Certification Org	National Registry of Food Safety Professionals	Orlando	FL	407.999.8126	lcorchado@nrfsp.com	
Piche	Kate	Member	Voting	Industry - Support Certification Org	National Restaurant Association / ServSafe	Chicago	IL	312-261-5348	kpiche@restaurant.org	
Chapman	Bryan	Member	Voting	Industry - Support Certification Org	StateFoodSafety	Orem	UT	801-494-1879	bchapman@statefoodsafety.com	
Eastwood	Nick	Member	Voting	Industry - Support Certification Org	Always Food Safe	St. Paul	MN	612.203.4872	nick.eastwood@alwaysfoodsafe.com	
Anderson	Tom	Member	Voting	Industry - Support Certification Org	360 Training	Austin	TX	512-212-7343	tom.anderson@360training.com	
Derr	Samuel	Member	Voting	Industry - Support Training	Elite Food Safety Training	Naperville	IL	630-776-3430	sderr@elitefoodsafety.com	

Paster Cammarata	Tara	Member	Voting	Industry - Support Training	Paster Training, Inc.	Gilbertsville	PA	610-970-1776	tara.paster@pastertraining.com
Roughan	George	Member	Voting	Industry - Support Training	TAP Series	Westlake Village	CA	818-889-8799 x 101	gr@tapseries.com
Straughn	Ki	Member	Voting	Regulator - Local	Public Health Seattle & King County	Bellevue	WA	206-263-8088	kstraughn@kingcounty.gov
Wiedmeyer	Lindy	Member	Voting	Regulator - Local At Large	City of West Allis Health Department	West Allis	WI	414-302-8654	lwiedmeyer@westalliswi.gov
Woods	Yolanda	Member	Voting	Regulator - Local At Large	Shelby County Government	Memphis	TN	901-222-9190	yolanda.woods@shelbycountytn.gov
Burns Savage	Nikki	Member	Voting	Regulator - Local At Large	Southern Nevada Health Districtg	Las Vegas	NV	702-686-7691	ntburns@cox.net
Jackson	Jeff	Member	Voting	Regulator - State	Arkansas Department of Health	Little Rock	AR	870-847-7619	jeff.jackson@arkansas.gov
Huffman	Troy	Member	Voting	Regulator - State (Federal replacement)	Colorado Department of Public Health & Environment	Denver	CO	303-692-3664	troy.huffman@state.co.us
Smith	Colleen	Member	Voting	Regulator - State (Federal replacement)	NH DHHS	Concord	NH	603-271-4858	colleen.smith@dhhs.nh.gov
Dunleavy	Sean	Member	Voting	Regulator - State	Michigan Department of Agriculture and Rural Development	Lansing	MI	517-243-8895	dunleavys@michigan.gov
Non-voting									
Morrison	Sheri	Member	Non-Voting	ACAC Representative	Pennsylvania Department of Agriculture	Harrisburg	PA	717-787-5289	shmorris@pa.gov
Albrecht	Julie	Member	Non-Voting	ACAC Representative	Dept. of Nutrition and Health Sciences, University of Nebraska - Lincoln	Lincoln	NE	402-464-2702	jalbrecht1@unl.edu
Krishna	Vijay	Consultant	Non-Voting	ANAB Representative	ANAB	Washington	DC	202-331-3614	vkrishna@ansi.org
Wittry	Beth	Consultant	Non-Voting	Federal Govt	CDC	Atlanta	GA	770-488-7333	Xks5@cdc.gov
Williams	Laurie	Consultant	Non-Voting	Federal Govt	FDA	College Park	MD	240-402-2938	laurie.williams@fda.hhs.gov
Duggins	Quwanza	Consultant - alternate	Non-Voting	Federal Govt	FDA	Oklahoma City	OK	240-535-5969	quwanza.duggins@fda.hhs.gov
Baker	Michael	Alternate	Non-Voting	Industry - Support Certification Org	National Registry of Food Safety Professionals	Chicago	IL	312-651-5783	mbaker@restaurant.org
Conley	Mark	Alternate	Non-Voting	Industry - Support Certification Org	National Restaurant Association / ServSafe	Chicago	IL	312.583.9853	MConley@restaurant.org
Johnson	Lars	Alternate	Non-Voting	Industry - Support Training	LAJ Consulting/ FoodSafetyGuy	San Jose	CA	507-990-5129	fsg@foodsafetyguy.com
Morrison	Laura	Alternate	Non-Voting	Industry - Support	Ohio Restaurant Association	Columbus	OH	614-246-0205	lmorrison@ohiorestaurant.org

Gillam	Tim	Alternate	Non-Voting	Industry - Food Service	Subway Restaurants	Milford	CT	570-688-3310	gillam_t@subway.com
Rivas	April	Alternate	Non-Voting	Industry - Support Training	ATC Food Safety	Pfafftown	NC	707-363-6032	april.rivas@atrainingcompany.com
Pollock	Evelin	Alternate	Non-Voting	Regulator - Local	Harris County Public Health	Houston	TX	713-248-5691	evelin.pollock@phs.hctx.net
Unkart	Sharon	Alternate	Non-Voting	Regulator - State	NEHA	Denver	CO	720-802-2142	sdunkart@neha.org

ATTACHMENT 2

Food Protection Manager Certification Committee (FPMCC)
April 4, 2:00-4:00 pm EDT

- Welcome & Roll Call

- CFP Anti-trust Statement

- Workgroup reports
  - Standards
  - Bylaws

- Overview of discussion format
  - Speaker recognition – raise hand virtually
  - Voting – roll call vote

- Issue 2020 II-004
  - Discussion begins on each issue raised by the committee at the last meeting
  - Handout: *0322 FPMCC 4 Year Impact List Word Doc*
  - Handout: *State Food Protection Manager Recertification certification timeframe PDF*
  - Discussion will resume at June meeting for issues not covered in this meeting

- Meeting Schedule: Next Meeting – 06.01.22, 2-4:00 pm EDT

Issue II-004 4-Year Exam Validity
Areas of impact and feasibility

- Time lapse between CFP/FDA/Code publication
  - Test provider impact – what is the date of implementation
- Will the change reduce the number of risk factor violations – is there studies behind it

ATTACHMENT 2

- Providers are already able to have shorter time period, with five as the max
- Is it legally justifiable
- Impact on update timelines and justification for changes and taking different methodologies into consideration
- Impact on the CFP Standard
- What is the frequency of the JTA? Some may already be less than 5 years
- Does existing work done by providers already capture and address the issue
- Financial impact – shorter timeline increases frequency
- E.g. Rhode Island operated on 3 year basis – do they have data on impact of more frequency - change in seat time requirements. Utah has 3 year frequency as well
- Need for research to justify change
- How does this impact time lines outlined in state statute and local ordinance
- Timing of exam vs timing of FC release
- Practical day to day knowledge vs no hands on experience
- Is this aligning with FC or is this justifiable as a way to improve food safety
- How many jurisdictions have times other than 5 years
- 2017 FC update to have CFPM on duty at all times, already impacts industry, will this requirement make it greater
- Different ways to “recertify” other than by exam. Is there a bigger issue to address relating to best ways to recertify
- Pandemic related delays to recertification
- Why was 5 years chosen in the first place
- Financial impact on industry

ATTACHMENT 3

Issue II-004 4-Year Exam Validity
Areas of impact and feasibility
For committee discussion April 6, 2022

I. Financial Impact - Industry/Providers/Regulatory Agencies

1. At what frequencies are the providers updating their JTAs?
   a. Some may already be updating at less than 5 years, by addressing the Food Code changes, whenever they are released
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3. Should the committee ask for research to justify change?

ATTACHMENT 4

Food Protection Manager Certification Recertification*

State	Certs valid	Certification Required?	State	Certs valid	Certification Required?	State	Certs valid	Certification Required?
DC	3 years	Yes	IA	5 years	Yes	NJ	5 years	Yes
MN	3 years	Yes	ID	5 years	Yes	NM	5 years	Yes
MT	3 years	Yes	IL	5 years	Yes	NV	5 years	Yes
RI	3 years	Yes	IN	5 years	Yes	NY	5 years	Yes
UT	3 years	Yes	KS	5 years	Demonstration of Knowledge	OK	5 years	City/County Requirements
SD	4 years	Yes	KY	5 years	Yes	OR	5 years	Demonstration of Knowledge
AK	5 years	Yes	LA	5 years	Yes	PA	5 years	Yes
AL	5 years	Yes	MA	5 years	Yes	SC	5 years	Yes
AR	5 years	Yes	MD	5 years	City/County Requirements	TN	5 years	Demonstration of Knowledge
AZ	5 years	City/County Requirements	ME	5 years	Yes	TX	5 years	Yes
CA	5 years	Yes	MI	5 years	Yes	VA	5 years	Yes
CO	5 years	Yes, except Denver	MO	5 years	City/County Requirements	WI	5 years	Yes
CT	5 years	Yes	MS	5 years	Yes	WV	5 years	Yes
DE	5 years	Yes	NC	5 years	Yes	WY	5 years	City/County Requirements
FL	5 years	Yes	ND	5 years	City/County Requirements	VT	5 years	Demonstration of Knowledge
GA	5 years	Yes	NE	5 years	City/County Requirements	WA	5 years	Yes- Effective 3/1/23
HI	5 years	Demonstration of Knowledge	NH	5 years	Yes	OH	No expiration	Yes

* ordered by shortest to longest recertification timeframes and at the state level

ATTACHMENT 5

From: Marcello, John <John.Marcello@fda.hhs.gov> **Marcello email response re 5-year certification term**
Sent: Friday, March 25, 2022 3:21 PM **2022-03-25**
To: Susan Quam <SQuam@wirestaurant.org>
Cc: 'jdaniel@lincoln.ne.gov' <jdaniel@lincoln.ne.gov>; Geoff Luebkemann <gluebkemann@FRLA.org>; Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>; Williams, Laurie (CFSAN) <Laurie.Williams@fda.hhs.gov>; Cartagena, Mary <Mary.Cartagena@fda.hhs.gov>; Pierce, Andre <Andre.Pierce@fda.hhs.gov>; O'Malley, Elizabeth <Elizabeth.OMalley@fda.hhs.gov>; Smith, Chris <Chris.Smith@fda.hhs.gov>; Destromp, Kimberly <Kimberly.Destromp@fda.hhs.gov>; Duggins, Quwanza <Quwanza.Duggins@fda.hhs.gov>; DelMundo, Katherine <Katherine.DelMundo@fda.hhs.gov>
Subject: Marcello response re 5-year certification term

Susan:

Good to hear from you!! Hope all is well!! Your request implies that I can provide some historical background on this subject which means I'm old.

I do have some insights to provide. It is helpful to start with the genesis of best practices for developing and delivering Food Protection Manager Certification. In the late 1970s – early 1980's the National Institute for the Food Service Industry (NIFI) developed the first manager certification coursebook titled – *Applied Foodservice Sanitation*. One of the primary resources used to develop the content of this coursebook is the *1976 Food Service Sanitation Manual including A Model Food Service Sanitation Ordinance, 1976 Recommendations of the Food and Drug Administration.*

This certification textbook becomes the early foundation upon which both industry and regulatory agencies begin to build Food Protection Manager certification programs. At this time, there is not a single recognized standard for developing and providing food protection manager certification programs. The Education Foundation of the National Restaurant Association (NRA) obtains the NIFI rights to the *Applied Food Sanitation Textbook* and begins to develop its Food Protection Manager certification program which ultimately evolves into the ServSafe program. The NRA develops "best practices" for their program – one of them being that their certification be valid for no more than three years. Keep in mind that this time frame was based on a considered "best practice" and not based on any recognized standard. A significant number of other certification providers, including regulatory agencies, adopt the same recertification time frame but other chose different time frames (four years; five years, etc.). This was just one of many examples of differences in certification providers requirements. This fragmentation created an environment that presented disincentives to certification due to lack of recognition and reciprocity of certificates accepted within the regulatory community which in turn resulted in duplicative cost and staff resources for the industry trying to meet the varied certification requirements of regulatory jurisdictions.

From 1994 through 2002, the CFP's Food Protection Manager Certification Committee did extensive work to develop a national standard. This resulted in what today is known as the *CFP Standards for Accreditation of Food Protection Manager Certification Programs*. During this same period, FDA issues the 1993 FDA Food Code (the first edition in the current format) and commits to a process to update the Code every four years. During this same period, The FDA *Food Code* begins to incorporate provisions related to Food Protection Manager Certification.

NOTE: Laurie Williams had previously submitted an e-mail on the background history related to the naming and cycle of Food Code publications. Glenda Lewis has also provided some additional information on this process. Both of these resources are included as attachments to my response

It is at this point in time that the CFP Committee recognizes the needs to address the issue you raised below regarding time frame for certification length. There are some important points to keep in mind as part of this discussion, including how CFP defines a certification program.

Section 1.0 of the Accreditation Standards defines what an accredited certification program is:

- **1.3 Accredited certification program** means a Food Protection Manager Certification Program that has been evaluated and listed by an accrediting organization as being in conformity with the CFP Standards for such program as set forth in this document. This does not refer to training functions or educational programs.

The current FDA Food Code definition of 'accredited certification program' is consistent with CFP. One of the primary responsibilities of a Food Protection Manager certification provider is the development of an examination that conforms with sound psychometric standards and is valid, reliable, and legally defensible. At its core, the certification examination must be based on a job task analysis,

- **4.4 Job Task Analysis** – A food safety certification examination shall be based on a valid job task analysis. The job task analysis shall be developed by qualified individuals, including retail food industry and public health stakeholders and subject matter experts.

The connection of the Job Task Analysis (JTA) to the current version of the Food Code is implied in Section 4.5 of the Standards. Keep in mind that the Food Code is only one of several technical resources that can be used to base the JTA.

- **4.5** The job task analysis shall provide a complete description of the knowledge, skills, and abilities (KSAs) required to function completely in the occupation of CFPM with the emphasis on those tasks most directly related to the CFPM's role in prevention of foodborne illness and controlling foodborne pathogens.

I've underlined the second half of this provision because of the importance of the Food Code as a source for the JTA.

Now here is where the rationale for the 5-year certification period originates. It is based on the CFP Standard's requirement for the JTA to be updated every five years per Section 4.7:

- **4.7** The credential awarded upon passing a food safety certification examination is designed to be recognized nationwide and throughout the retail food industry. As such, the certification organization shall regularly evaluate practices in the retail food industry to ensure the job task analysis on which the examination is based remains appropriate and relevant. **The maximum length of use for any job task analysis is five years from the date of its validation.**

So the 5 year certification period referenced in Section 7.2 of the CFP Standards is set to align with when the certification provider is required to update their job task analysis.

- **7.2 Qualifications for Initial Certification** – To become a Certified Food Protection Manager an individual shall pass a food safety examination from an accredited certification program by the Conference for Food Protection. **The certification shall be valid for no more than 5 years.**

The FDA Food Code does not specify any specific time frame for certification length. Rather **Section 2-102.20 Food Protection Manager Certification. Paragraph (B)** refers back to the CFP Standards:

> (B) A FOOD ESTABLISHMENT that has a PERSON IN CHARGE that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs is deemed to comply with Section 2-202.12.

Section 2-102.12 Certified Food Protection Manager:

> (A) The PERSON IN CHARGE shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM

With all of this, there still may be some discussion within the CFP Committee relative to reducing the validation period to 4 years to align with the planned updated versions of the Food Code. It is important to keep in mind that FDA works very closely with CFP to identify and assess areas in the Food Code that may need to be updated. The normal frequency for publication of the full edition of the Food Code is a 4-year period, with Supplements issued in the interim 2-years. In addition, some SLTT stakeholders have expressed a desire for the period between release of full editions to be lengthen due to their challenges with following the dedicated process for Food Code Adoption in their states.

Even more importantly, for the CFP CFPM Committees I had the honor to Co-Chair, the members recognized that the certification providers could not turn on a dime as soon as the new Food Code was published and produce an updated examination(s). They first needed to conduct the JTA and validate the results. This would then have to be followed with an examination development process that included item writing, fairness reviews, passing score reviews, etc. This is a process in its own right that needs time and resources to be conducted correctly and in accordance with sound psychometric standards.

In summary, it has been 20 years since I have been directly engaged with the CFP CFPM Committee but I would think any recommendation to change the certification length in the Standards needs to take into consideration:

- What problem is the change in length of certification time frame seeking to address? How will such a change impact the regulatory community, industry, and certification providers? There is always a cost-benefit assessment that needs to be weighed.
- The current process certification organizations have in place for updating their job task analysis every 5 years. The 5-year time frame was based on nationally recognized psychometric practices for maintaining up-to-date assessments of professional practices. Is this still the standard within the psychometric community? ANSI may be able to provide some perspective.
- What has been the certification organizations experience with the scope of changes that may occur during the 5-year period of their JTAs that may result in changes to the technical content in their certification examination focus on the KSAs for food protection managers?
- What economic impact would any change in length have on a certification organizations efforts to update their JTAs and examinations?
- In turn, what might the impact of changing the certification have on industry's access to updating examinations? Would their be any increased in costs for the retail food and foodservice industries.

I hope this helps! Please let me know if you have any questions or need additional information.

John

John A. Marcello
Senior Advisor to the OSCP Director

ORA/OHAFO/Office of State Cooperative Programs (OSCP)
U.S. Food and Drug Administration
Tel: 480-829-7396 ext. 2035 Cell: 602-402-9227
John.marcello@fda.hhs.gov

From: Susan Quam <SQuam@wirestaurant.org>
Sent: Wednesday, March 23, 2022 9:52 AM
To: Marcello, John <John.Marcello@fda.hhs.gov>
Cc: 'jdaniel@lincoln.ne.gov' <jdaniel@lincoln.ne.gov>; Geoff Luebkemann <gluebkemann@FRLA.org>
Subject: [EXTERNAL] CFPM

Good morning John,

I am hoping you can reach back in to your memory and give me some insight on how the FPMCC reached consensus on a 5-year certification length. I was participating in committee meetings when the Standard was first developed, but I cannot remember any discussion regarding the certification timing.

As you know, the FPMCC is looking at the impact of moving to a 4-year certification. Knowing the history of why it is five years now will be helpful.

WRA has your back.
Susan Quam, CAE, IOM
Executive Vice President
Wisconsin Restaurant Association
direct: 608.216.2875 • mobile: 608.217.4513
squam@wirestaurant.org
wirestaurant.org

From: Williams, Laurie (CFSAN)
To: Susan Quam; jdaniel@lincoln.ne.gov
Cc: Duggins, Quwanza; DelMundo, Katherine; Cartagena, Mary
Subject: FPMCC - Food Code
Date: Friday, February 4, 2022 8:51:00 AM
Attachments: image003.png

ATTACHMENT 6

Greetings Susan and Justin,

I sent an email to John Marcello asking if he would be so kind as to provide input to the historical background for the 5-year examination renewal for the food protection manager certification. He would be happy to help! He asks that Susan contact him and fill him in on what is needed. His contact information is: John.marcello@fda.hhs.gov

In addition, I did a little research on the change in publication intervals of the Food Code from 2 years to 4 years with the Supplement and I am sharing language to that effect:

Issue 00-I-065 Periodicity of the FDA Food Code

The Conference recommends that an ad hoc committee be established under Council 1 to develop a Conference paper to explore the impact of changing the periodicity of the Food Code, with equal representation of stakeholders, prior to the next Conference. The Committee shall report back to Council 1 at the 2002 Conference.

Issue 2002-II-022 Periodicity of the Food Code was accepted as amended. The recommended solution: That new editions of the Food Code be published every four (4) years instead of two (2) years except that issues of public health significance should be acted upon immediately. Council Recommendation: Accept as amended. Assembly Action: Affirm.

The very first Supplement was FDA 2001 Food Code Supplement which published August 29, 2003. This Supplement was introduced with the following language:

“The Food and Drug Administration (FDA) is pleased to issue this Supplement to the 2001 Food Code (hereafter referred to as Supplement). This Supplement updates the 2001 Food Code to address several recommendations made by the 2002 Conference for Food Protection (CFP) with which the FDA, Centers for Disease Control and Prevention (CDC), and United States Department of Agriculture (USDA) concur. The changes contained in this Supplement reflect the current science and emerging food safety issues, and imminent health hazards related to food safety.

From 1993 through 2001, the complete Food Code has been issued every two years. With the support of the Conference for Food Protection, FDA has decided to move to a four-year interval between complete Food Code revisions. The next complete revision of the Food Code will be published in 2005. Until that time, this Supplement allows several changes upon which there is substantial concurrence among the Federal Agencies and the other stakeholders to be incorporated into the Food Code. The Supplement ensures that the most current food safety provisions are available to agencies planning to initiate rule-making activities prior to 2005.

This Supplement provides other users of the Food Code, such as educators, trainers, and the food service, retail food, and vending industries, with up-to-date information of how to best mitigate risk factors that contribute to foodborne illness.”

FDA 2001 Food Code Supplement

The Food Code Supplement is intended to keep the Food Code up to date and provides the most current food safety provisions to agencies planning to initiate rule-making activities before the next edition of the Food Code. As evidenced in the present FDA Food Code starting on page iv, the Food Code is updated every 2 years with the Supplement included.

If you have any questions or require additional information please do not hesitate to contact me.

ATTACHMENT 7

From: Marcello, John
To: Marcello, John
Subject: FW: Review requested - Response to a question received from the CFP Certification of Food Protection Managers Committee
Date: Friday, March 25, 2022 7:34:14 AM

From: Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>
Sent: Thursday, March 24, 2022 11:17 PM
To: Marcello, John <John.Marcello@fda.hhs.gov>; Williams, Laurie (CFSAN) <Laurie.Williams@fda.hhs.gov>; Cartagena, Mary <Mary.Cartagena@fda.hhs.gov>; Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>
Cc: Farmer, Laurie <Laurie.Farmer@fda.hhs.gov>; Pierce, Andre <Andre.Pierce@fda.hhs.gov>; O'Malley, Elizabeth <Elizabeth.OMalley@fda.hhs.gov>; Destromp, Kimberly <Kimberly.Destromp@fda.hhs.gov>; Smith, Chris <Chris.Smith@fda.hhs.gov>; Duggins, Quwanza <Quwanza.Duggins@fda.hhs.gov>; DelMundo, Katherine <Katherine.DelMundo@fda.hhs.gov>; Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>
Subject: RE: Review requested - Response to a question received from the CFP Certification of Food Protection Managers Committee

John,

Thanks for sharing and the opportunity to review. You did an excellent job laying out the history. In the email that Laurie sent to the CFP Committee referring the question to you, she provides a nice summation of the CFP history for the change in the publication cycle of the Food Code. I add to that here with some additional notes on the naming and cycle of Food Code publication. You may want to include this aspect in your response when describing the Food Code history.

The language used in 2003 for naming the Supplement, 'FDA 2001 Food Code – Supplement' has evolved to be, 'Supplement to the 2001 Food Code'. This has carried through to each Supplement that has been released since 2003 and they are named as, 'Supplement to the [date year] Food Code.

We now also refer to the 4 year version as a 'full edition' Food Code whereas in 2001 we called it 'complete Food Code'. In later years questions arose around the 'complete Food Code description' and we landed on 'full edition' to characterize/make a separation from the Supplement and the full edition.

Below is the description of the Food Code cycle, excerpted from the Food Code Adoption Annual Report 2020.

Between 1993 and 2001, the FDA Food Code was issued every two years. The 2005 Food Code was the first full edition published on the new four-year interval. During the interim period between full editions, FDA may publish one Food Code Supplement that updates, modifies, or clarifies certain provisions. As of December 31, 2020, the 2017 Food Code (https://www.fda.gov/media/110822/download) is the most recent full edition published by FDA, and it was followed by the Supplement to the 2017 Food Code (https://www.fda.gov/media/133749/download), which was published in 2019. . . This Report may use two terms to describe the FDA Food Code – 'version' and 'edition'. The term 'version' is associated with the year of publication/ release and the term 'edition' is associated with the number of times the Code has been published in its current format. So, the 1993 version is the 1st edition, the 1995 version is the 2nd edition, the 1997 version is the 3rd edition, the 1999 version is the 4th edition, the 2001 version is the 5th edition, the 2005 version is the 6th edition, the 2009 version is the 7th edition, the 2013 version is the 8th edition and the 2017 version is the 9th edition.

ATTACHMENT 8

Conference for Food Protection – Committee Progress Report

Committee Progress Reports are considered DRAFT until accepted by the Executive Board
Approved 7/13/21

The Conference Chair, Executive Director, Council Chair, or Issue Chair may return committee reports, Issues, or attached documents requesting edits to improve understanding, or to include missing information.

Committee-submitted documents may impact the image, credibility, and integrity of the Conference as an organization. With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, documents) become the property of the Conference.

COMMITTEE NAME:

DATE OF REPORT: ☐ ***Initial fall progress report*** X ***Spring progress report*** ☐ ***Second fall progress report***
Date submitted: *04.01.2022* **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** X ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Susan Quam and Justin Daniel**

COMMITTEE CHARGE(S):

Issue # **2020 II-001**

1. Food Protection Manager Certification Committee (FPMCC) is to carry out charges assigned via the Conference Issue process and from the Conference Executive Board relating to food protection manager certification and to adopt sound, uniform accreditation standards and procedures that are accepted by the Conference while ensuring that the conference Standards for Accreditation for Food Protection Manager Certification programs and the accreditation process are administered in a fair and responsible manner.
2.

Issue # **2020 II-004**

1. The Food Protection Manager Certification Committee is to review the impact and feasibility of changing the frequency of required certification examination to a time period not to exceed four years from date of issuance, aligning knowledge demonstration by examination with the routine four-year update and publication of the FDA Retail Food Code.
2.

COMMITTEE WORK PLAN AND TIMELINE: It is anticipated that this Committee will meet regularly via virtual platform and, if possible, in-person.

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:***
   The following are our scheduled virtual meeting dates. All meetings are from 2:00-4:00 p.m. Eastern time. All meetings have been virtual so far. We are still considering a face to face meeting in late summer/early fall
   December 1, 2021
   February 2, 2022
   April 6, 2022
   June 1, 2022
   August 3, 2022
   October 5, 2022
   December 7, 2022

2. ***Overview of committee activities:***
   The committee held its first meeting on December 1. Interim chair Hawley led the committee through an orientation session and reviewed the committee's charges. The committee elected Susan Quam and Justin Daniel as chair and vice chair respectively. Jeff Hawley was appointed chair of the Committee Bylaws workgroup and Kate Piche was appointed chair of the Standard workgroup. Volunteers for both groups were also recruited.

   At the February 2 meeting, the committee reviewed Issue II-004 and identified potential impacts and feasibility issues related to changing the validity of certification from 5 years to 4 years.

   The committee will begin discussing each of the impacts/feasibility issues at its April 6 meeting. We anticipate it will take at least two meetings to fully vet all points, and possibly discover any that were missed in the initial discussion.

3. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. No charges completed at this time

b.

4. ***Status of charges still <u>PENDING</u> and activities yet to be completed:***

   a. **2020 II-001 Both the Bylaws and Standard workgroups have just begun their work reviewing their respective committee documents**

   b. **2020 II-004 As reported above, the committee will begin discussion on the 4-year vs 5-year certification at its April meeting**

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

X Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.

□ Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.

ATTACHMENTS:

1. ***Content Documents:***

   a. ***Committee Member Roster:*** ☐ ***See changes noted above under "requested action"*** *"Committee Members Template" (Excel) available at: www.foodprotect.org/work/report.*

   X ***No changes to previously approved roster*** *Committee roster to be submitted as a PDF attachment to this report.*

   b. ***Committee Generated Content Documents (OPTIONAL):*** X ***No draft content documents submitted at this time***

2. ***Supporting Attachments (OPTIONAL):*** ☐ ***Not applicable***

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FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | June 1, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Ciarimboli, ~~Corchado Torres~~, ~~Derr~~, ~~Dolhanyk~~, Dwyer, Eastwood, Halbrook, Hawley, Huffman, Jackson, Koester, ~~Luebkemann~~, Paster Cammarata, ~~Piche~~, ~~Reich~~, ~~Roughan~~, Smith, Straughn, ~~Sweet~~, Wiedmeyer, ~~Wilson~~, Woods, Wynne [17 of 27 voting members present]

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, Duggins, ~~Gillam~~, ~~Johnson~~, Krishna, ~~Morrison~~, ~~Pollock~~, Rivas, ~~Unkart~~, Williams, Wittry

Interested Parties & Guests:

Agenda Items

1. Welcome & Roll Call
2. CFP Anti-trust Statement
3. Approval of Minutes
4. Workgroup reports
   a. Standards
   b. Bylaws (if needed)
   c. ANAB Contract
5. Overview of discussion format
   a. Speaker recognition – raise hand virtually
   b. Voting – roll call vote
6. Issue 2020 II-004
   a. Straw Poll
      I. What is the will of the committee?
      II. Motion needed to determine direction of the committee's response
   b. Discussion/vote
   c. Formation of work group to craft final response
7. Meeting Schedule: Next Meeting – 08.03.22, 2-4:00 pm EDT

Minutes

Items 1-2: Welcome & Roll Call – Chair Quam called the meeting to order at 2:03 PM eastern on a virtual meeting platform; roll was called and quarum established. Members Bryan Chapman and Sean Dunleavey are no longer voting members due to changes in their constituency status. The anititrust statement was referenced.

Item 3: Jeff Hawley moved approval of the minutes, Jeff Jackson seconded, motion passed unanimously.

Item 4: Workgroup reports

a. Standards – Burns Savage reported the group met, member feedback was solicited, and is being reviewed.
b. Bylaws – work is completed.

c. ANAB Contract - Hawley led a workgroup to review the ANAB contract, which was 20 years old, and needing updating. Input from ACAC is pending. An updated contract has been approved bu the CFP Executive Board and sent to ANAB. Vijay Krishna requested the revised contract, and gave an update on ANAB accreditation process.

Item 5: An overview of committee discussion and voting in the virtual environment was presented to inform the members and faciltate effective discussion in this format.

Item 6: Action to date on Issue 2020 II-004 was reviewed by Chair Quam and asked for the will of the Committee. Hawley recommended no change to the current five-year certification term, as the Committee has been presented no compelling basis for the change. Anderson, Eastwood, and Wynne concurred. Krishna offered information on the process to accredit certification organizations, including that JTAs supporting the exam validity must be periodically updated at a frequency that would keep exams aligned with changes to the Food Code.

A straw poll was called for to gauge the sense of the Committee. Hawley moved and Halbrook seconded that the Committee formulate a response statement that the Committee does not support the proposed change to a four-year certification term; motion passed unanimously with 17 yeas, 0 nays, 0 abstentions.

Discussion ensued and it was determined a workgroup would form to draft the response.

Item 7: Meeting Schedule – the next meeting is scheduled for August 3, 2022, from 2-4 PM east. Members were reminded to save the dates for the 2023 Biennial Meeing in Houston, and to stay alert for Council formation notices in May or June, and Council applications in July.

The meeting adjourned at 2:46 PM eastern by unaimous acclimation.

###

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | August 3, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Ciarimboli, Corchado Torres, ~~Derr~~, ~~Dolhanyk~~, Dwyer, Eastwood, Halbrook, Hawley, ~~Huffman~~, ~~Jackson~~, ~~Koester~~, Luebkemann, Paster Cammarata, Piche, Reich, ~~Roughan~~, Smith C., Smith M., Straughn, ~~Sweet~~, Wiedmeyer, ~~Wilson~~, Woods, ~~Wynne~~ [18 of 28 voting members present].

Non-voting: Morris, ~~Albrecht~~, Baker, Conley, ~~Duggins~~, ~~Gillam~~, Johnson, Krishna, ~~Morrison~~, Pollock, ~~Rivas~~, Unkart, Williams, Wittry.

Interested Parties & Guests: Tiffany Vowell.

Agenda Items

1. Welcome & Roll Call
2. CFP Anti-trust Statement
3. Approval of Minutes
4. Workgroup reports
   a. Standards
   b. Issue II-004 Response
5. Issue development
   a. Committee Report
   b. Changes to the Standard
   c. Changes to Committee Bylaws
   d. Issue II-004
6. Discussion format
   a. Speaker recognition – raise hand virtually
   b. Voting – roll call vote
7. Next Meeting – 10-05-2022, 2-4:00 pm EDT

Minutes

Items 1-2: Welcome & Roll Call – Chair Quam called the meeting to order at 2:00 PM eastern on a virtual meeting platform; roll was called, and a quorum established. Melissa Smith has been added to the FPMCC voting roster representing State Food Safety and succeeding Bryan Chapman. The antitrust statement was referenced, and made available in the “chat” feature.

Item 3: Minutes will be reviewed and approved at a later date.

Item 4: Workgroup reports

a. Standards – Piche advised the Committee that the workgroup has met, is developing changes, and will present them at the October FPMCC meeting.
b. Issue II-004 Response – a workgroup was formed and drafted a response to this issue (inserted below); Chair Quam presented the draft response, minor edits were suggested by the committee members, and a final draft completed and approved by the committee.

Item 5: Issue development – Chair Quam reported the following items will be developed / finalized for review by the FPMCC then submitted to the CFP Executive Board:

a. Committee Report
b. Changes to the Standard
c. Changes to Committee Bylaws
d. Issue II-004 response

Item 6: An overview of committee discussion and voting in the virtual environment was presented to inform the members and facilitate effective discussion in this format.

Item 7: Meeting Schedule – the next meeting is scheduled for

The meeting adjourned at 2:41 PM eastern by unanimous consent.

Draft FPMCC Response to 2020 II-004
Issue 2020 II-004

The Food Protection Manager Certification Committee is to review the impact and feasibility of changing the frequency of required certification examination to a time period not to exceed four years from date of issuance, aligning knowledge demonstration by examination with the routine four-year update and publication of the FDA Retail Food Code.

Public Health Significance

The FPMCC committee thoroughly reviewed the impact and feasibility of reducing the maximum to four years and concluded that no change to the current maximum of five years for certification validity is warranted. The committee met four times to discuss the pros and cons of reducing the period to four years and found the negative impact a change would have on the industry, and jurisdictions where CFPMs are mandated, to be significant. These negative impacts included:

1. Staff shortages within the Food Industry coupled with the increased expense associated with maintaining certification for retail food facilities may place an undue burden on foodservice owners/operators.

2. Insufficient evidence exists that more frequent Food Manager Certification renewals would lead to fewer food borne illness outbreaks or improved public health outcomes.

3. Given the delay in FDA Model Food Code adoption by State/Territorial/Local jurisdictions as well as the time necessary to modify course materials and examinations, increasing the recertification timeframe to four years may be an impossible task.

Recommended Solution: The Conference recommends…
No change to the frequency of required certification examination from the current maximum of five years.

###

FOOD PROTECTION CERTIFICATION COMMITTEE
Minutes of the Meeting | October 5, 2022 | 2-4 PM eastern

Attendance ~~strikethrough~~ indicates absence

Chairs/Voting: Chair Quam, Vice Chair Daniel, ~~Allen~~, Anderson, Burns Savage, Ciarimboli, Corchado Torres, ~~Derr~~, ~~Dolhanyk~~, ~~Dwyer~~, Eastwood, Halbrook, Hawley, Huffman, Jackson, Koester, ~~Luebkemann~~, Paster Cammarata, Piche, ~~Reich~~, Roughan, Smith C., Smith M., ~~Straughn~~, ~~Sweet~~, Wiedmeyer, ~~Wilson~~, Woods, Wynne [20 of 28 voting members present]

Non-voting: ~~Morris~~, ~~Albrecht~~, Baker, Conley, Duggins, ~~Gillam~~, ~~Johnson~~, Krishna, Morrison, Pollock, ~~Rivas~~, Unkart, Williams, Wittry

Interested Parties & Guests:

Agenda Items

1. Welcome & Roll Call
2. CFP Anti-trust Statement
3. Standard workgroup report – review Standards updates proposed by the workgroup
4. CFP ACAC Representative
5. Issue development
   a. Committee Report
   b. Changes to the Standard
   c. Changes to Committee Bylaws
   d. Issue II-004
6. Discussion format
   a. Speaker recognition – raise hand virtually
   b. Voting – roll call vote
7. Next Meeting – 12-07-2022, 2:00-4:00 pm EDT

Minutes

Items 1-2: Welcome & Roll Call – Chair Quam called the meeting to order at 2:05 PM eastern on a virtual meeting platform; roll was called, and a quorum established. The antitrust statement was referenced in the "chat" feature. An overview of committee discussion and voting in the virtual environment was presented to inform the members and facilitate effective discussion in this format (**Item 6**).

Item 3: Standard Workgroup report – workgroup Chair Piche thanked the members of the group and referenced the proposed changes (see separate attachment) that were emailed to the FPMCC in September for review. Piche presented the changes as a whole, and hearing no comments offered when called for, Hawley moved and Paster Cammarata seconded acceptance of all changes; motion approved by unanimous consent using "hands raised" and audio in the virtual platform.

In other Standards business, Vijay Krishna requested some clarifications on behalf of ANAB (inserted below).

Item 4: CFP ACAC Representative – Chair Quam advised that the current CFP ACAC members Julie Albrecht and Sherri Morris. Albrecht is retiring and seeks to be replaced. Krishna offered comments on the role of ACAC representative, the time commitment, meeting cadence, and typical agenda items such as matters of non-compliance or non-conformities to the Standard, and that the nominee must avoid

conflicts of interest with the certifying bodies. Chair Quam advised that Jeff Hawley has volunteered to take on this role; Hawley referenced his over 20-year involvement on the FPMCC committee, work with the Standard, expressed willingness to serve as CFP ACAC representative, and as he is retiring from his constituency he would welcome the opportunity to remain involved with the FPMCC.

Halbrook moved, Roughan seconded Hawley's nomination as CFP ACAC representative; role call vote resulted in 18 yeas and 1 abstention (Hawley) for unanimous approval

Item 5: Issue development – Chair Quam advised these four issues will be presented at the 2023 Biennial Meeting, and committee will be provided review drafts for review prior to submission:

a. Committee Report
b. Changes to the Standard
c. Changes to Committee Bylaws
d. Issue II-004

Unagendaed New Business Item 1:
The FPMCC was advised that during its October 4, 2022 meeting the CFP Executive Board discussed Prometric's voluntary withdrawal from ANAB accreditation, that Prometric ceased CFPM exam administration at the end of August 2022, and that communication from CFP may be appropriate in this regard. The Executive Board requested FPMCC input on this, including addressing validity of Prometric certificates issued prior to termination of their ANAB accreditation.

Discussion ensued, and it was suggested that information for the public would be helpful, including linking to Prometric's voluntary withdrawal notice posted on the ANAB website and that certain Prometric certifications remain valid. Chair Quam will appoint a workgroup draft to an explanation of this matter for posting on the CFP website, and report back to the Executive Board; George Roughan volunteered for the workgroup.

Unagendaed New Business Item 2:
Chair Quam reported that the final updated ANAB contract was presented to the Executive Board during its October 4, 2022 meeting and approved. Chair Quam thanked Jeff Hawley for successfully leading the contract update workgroup. The Executive Board also approved the FPMCC Fall Progress Report, roster changes, and vote regarding Issue II-004.

Item 7: Meeting Schedule – the next meeting is scheduled for

The meeting adjourned at 2:48 PM eastern by unanimous consent.

###

Conference for Food Protection Standard for Accreditation of Food Protection Manager Certification Programs (2021): ANAB Feedback/Requests for Clarification

Conference for Food Protection Manager Certification Committee responses in red text.

Clause	ANAB Feedback/Request for Clarification
1.20	The 2021 revision removed the requirement of "at least 25% alternate questions" between examination forms. Why was this removed? Is there no longer a maximum overlap requirement? What is considered acceptable overlap? Please revise for clarity. This is a definition, not a standard and previously it was indicated we should not be too prescriptive and to allow this type of specificity to be provided in a guidance document that ANAB would create to accompany the Standard.
1.25 and 1.36	Does just checking for discrimination suffice as checking for exposure/cheating? Are there additional checks that should be required? Please revise for clarity. This is a definition, not a standard and previously it was indicated we should not be too prescriptive and to allow this type of specificity to be provided in a guidance document that ANAB would create to accompany the Standard.
1.30, 4.1 B., 4.3 D.	We understand "available items" and "active items" to mean items that have been pretested and are usable (i.e., they have acceptable stats). However, certification organizations may understand "available" and "active" to mean items that have been written but not necessarily pretested/have acceptable stats. Please revise for clarity. We will revise in the next certification committee cycle
1.8, 1.9, 1.32, 1.32 B., 4.3 B., 4.5	Are knowledge, skills, and abilities required (all 3)? Or are just knowledge areas acceptable? Please clarify and revise as needed. We will revise in the next certification committee cycle
1.34	We understand "legally defensible" to include being "psychometrically sound" (valid and reliable). Please revise for clarity. We will revise in the next certification committee cycle
5.4 A.	ANAB as the accreditation organization does not approve scoring methods. We suggest revising "by methods approved by the accrediting organization" to "by nationally accepted scoring methods." This will be completed this committee period.
5.4 A. and B.	We understand the requirements that "no official scoring is to be done at the test site" and "scores will not be released as being official until verified and approved" to apply to paper/pencil tests. Computer-based testing (at a test site or via remote proctoring) that uses an algorithm to score the exam is acceptable. Please revise for clarity. This will be completed this committee period.
5.11 B.	We interpret this requirement to apply only to test sites/test centers (not remote proctoring). Please revise for clarity. This will be completed this committee period.
5.13 C. and D.	We interpret these requirements to apply only to test sites/test centers (not remote proctoring). Please revise for clarity. This will be completed this committee period.
Overall	Replace references to ANSI with references to ANAB throughout. We will revise in the next certification committee cycle
Overall	Please fix spacing issues and other typos throughout. This will be completed this committee period.

Template approved: 7/13/2021

Standing Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME *Constitution Bylaw & Procedures Committee*

DATE OF FINAL REPORT: *11/18/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Davene Sarrocco-Smith and Sean Dunleavy**

COMMITTEE CHARGE(S):

1. ***Issue # 2020 II-006***
   - **a.** These governing documents be reviewed on a recurrent basis every biennium, prioritized in this manner: 1. Constitution 2. Biennial Meeting/CFP Procedures document 3. Position descriptions 4. Policy documents
2. Since Issue ***# 2020 II-006*** mandated reoccurring review this language needs to be incorporated into the Constitution.

3. ***Issue #2020 II-010***

a. Representation from the Constitution and ByLaws Committee on the Local Regulatory Representation Committee.

4.Item 1.8.3 from April 2022 Executive Board meeting

a. Constitution, Bylaws, and Procedures (CB&P) Committee to update the "CFP Biennial Meeting/Conference Procedures" document with the policy change regarding membership effective dates and submit the revised document for Board review and approval.

b. CB&P Committee to draft an Issue for the 2023 Biennial Meeting to amend the governing documents to reflect the membership effective date change.

5. Item 1.8.3 from April 2022 Executive Board meeting

a. Constitution and Bylaws/Procedures Chair to work with the Executive Assistant to ensure concerns addressed on pages 3-4 in the Executive Assistant's report are merged with activities related to document review and retention. (record retention)

b.CB&P Committee to start review of Policy documents prior to Position Descriptions so that

they can provide assistance and direction to the Ad Hoc Committee that will be created April
2023.

c. At the April 2023 Board Meeting, an ad hoc committee is to be created for the 2023-2025 biennium to address concerns regarding document retention.

6. Provide clarifying Constitutional language for Article XV Section 1, Subsection 2 regarding Committees and Federal partners.

Committee Work Plan and Timeline:

1. Harmonize the Biennial Meeting CFP Procedures document with the 2021 delegate approved Constitution and ByLaws.
2. Evaluate current policies (2) regarding record retention. Develop CFP document spreadsheet and evaluate those documents pursuant to record retention and provide recommendations.
3. Vice Chair participation on the Local Regulatory Representation Committee.

Committee Activities: Dates of committee meetings or conference calls: 2/1,2/15, 3/1, 3/15, 3/29, 4/5, 4/19, 5/3, 5/17, 6/7, 6/21, 7/5, 7/19, 8/2, 8/16, 8/30, 9/20, 10/18, and 11/1/22. Committee votes occurred via email.

1. ***Overview of committee activities:***
   - **1.a.** Started by wordsmithing the CFP Biennial Meeting and Procedures document. Reached a point and found the organization within the document to be jumbled; the Procedures document did not flow with the proceedings of the Biennial Meeting. CB & P Committee took a step back and reorganized existing contents of document. Started wordsmithing again and adding clarity to content. The CB & P Committee formatted and reorganized the CFP Biennial Meeting/Conference Procedures document as well as harmonized with the current version of the CFP Constitution and Bylaws. The completed draft is a step-by-step process of the CFP's Biennial Meeting and Conference Procedures that a new member could use and understand what and how things take place. Our objective was to provide clarity while being explanatory in this functional procedural document.

   - **1.b.** Looked at 2 current policies regarding record retention. Developed CFP document spreadsheet using Executive Assistants Board report list. Created standard 8 questions for evaluation of each document on the spreadsheet. Created policy for policies and policy template. Collected recommendations throughout the process to aid in developing final recommendations.

   - **1.c.** Chair and Vice Chair conferred on item 1.8.3 regarding registration policy change provided to Conference Chair & Vice Chair June 3, 2022.

   - **1.d.** Vice Chair attended 5-6-22, 6-3-22, 7-15-22, 8-5-22 Local Regulatory Representation Committee meetings.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

A.a. Constitutional language for Article XVI Section 3 Subsection 1, regarding CB & P duties, added and approved by Executive Board on May 17, 2022.

A.b. Draft version of CFP Biennial Meeting/Conference Procedures document completed and unanimously approved by committee and approved by Executive Board on October 5, 2022, and became effective then.

A.c. Item 1.8.3 registration Constitutional language change for Article III Section 4, regarding registration and membership, approved by Executive Board on November 18, 2022.

A.d. Vice Chair participated on Local Regulatory Representation Committee.

A.e. Constitutional language for Article XV Section 1, Subsection 2, regarding Committees and Federal partners, approved by Executive Board on November 11, 2022.

3. ***Charges INCOMPLETE and to be continued:***

3.a. Report with final recommendations to the Executive Board regarding Record Retention to be provided at Spring 2023 Board meeting.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☐ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☒ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1. *After the Assembly approves Constitutional changes, those changes be automatically sent to the Constitution and ByLaws Committee. The CB & P will review the CFP Constitution and ByLaws and CFP Biennial Meeting/Conference Procedures document and update all sections that would apply to the changes the Assembly of Delegates approved. Reasoning: to attempt to keep the two governing documents updated and consistent with each other.*

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. *Issue #1: Report – Committee Name:* List of content documents submitted with this Issue: *Committee Member Roster:*

☐ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) *Other content documents: CFP Biennial Meeting/Conference Procedures document*

b. List of supporting attachments: ☐ ***Not applicable***

(b.i.1)

1. ***Committee Issue #2***: CB & P duties; Constitution Article XVI
2. ***Committee Issue #3***: Federal partners and Committee membership; Constitution Article XV

3. ***Committee Issue#4***: Membership; Constitution Article III

Committee Nam	Constitution, Bylaws and Procedures							
Last Name	**First Name**	**Position (Chair/Member)**	**Constituency**	**Employer**	**City**	**State**	**Telephone**	**Email**
Sarrocco-Smith	Davene	Chair	Emeritus		Dallas	GA	440-476-2429	davenesarrocco@yahoo.com
Dunleavy	Sean	Vice Chair	Emeritus		Howell	MI	517-861-7991	sdunleavy67@gmail.com
Bacon	Brenda	voting	Emeritus 7-22					baconbc@outlook.com
Sanchez	Angela	voting	Industry Retail Food	Amazon	Nashville	TN		ajaynethomas@yahoo.com zanglas@amazon.
Woodbury	Thomas	Voting	Industry Support	ComplianceMate	Holladay	UT	801-330-9511	thomas.g.woodbury@gmail.com
Sparks	Christopher	voting	Local Regulatory	Houston Health Dept.	Houston	TX		christopher.sparks@houstontx.gov
Burns-Savage	Nikki	voting	Local Regulatory	Southern Nevada Health District	Las Vegas	NV		ntburns@cox.net
Cartagena	Mary	FDA Consultant	Federal Regulatory				240-402-2937	**Mary.Cartagena@fda.hhs.gov**
Lewis	Glenda	FDA Alternate	Federal Regulatory				240-402-2150	**Glenda.Lewis@fda.hhs.gov**
Hazard	Tennetta	USDA Consultant	Federal Regulatory					Tennetta.hazard@usda.gov

Constitution & Bylaws	governing
Biennial Meeting/Conference Procedures	governing
Position Descriptions	
EXECUTIVE Administration Positions	
Board Member	governing
Director	governing
Executive Treasurer	governing
Executive Assistant	governing
LEADERSHIP Positions	
Conference Chair	governing
Conference Vice Chair	governing
Immediate Past Chair	governing
COUNCIL Positions	
Council Chair	governing
Vice Chair	governing
Council Member	governing
Council Scribe	governing
Council Runner	governing
Parliamentarian	governing
App Liaison	governing
STANDING Committee Positions	
Audit Committee Chair	governing
Constitution & Bylaws Committee Chair	governing
Finance Committee Committee Chair	governing
Food Protection Manager Certification Committee Chair	governing
Issue Committee Committee Chair	governing
Nominating Committee Chair	governing
Program Committee Chair	governing
Program Standards Committee Chair	governing
Publications Committee Chair	governing
Resolutions Committee Chair	governing
Strategic Planning Committee Chair	governing
Committee Chair Handbook	governing
Policies	
Antitrust Policy	governing
Archiving CFP Documents	governing
Audit Policy	governing
Commercialism & Comity Policy	governing
Crumbine Award Policy	governing

Late Issue Submission Policy	governing
Open Meeting Policy	governing
Record Retention Policy	governing
Travel Subsidy Policy	governing
Conference Spokesperson Policy	governing
Invoice Approval Policy	governing
Privacy Policy	governing

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COMMITTEE NAME Program Standards Committee (PSC)

DATE OF FINAL REPORT: *11/18/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ☐ ***Council III*** ☒ ***Executive Board***

REPORT SUBMITTED BY: Angie Wheeler, Chair; Kenesha Williamson, Co-Vice Chair; DeBrena Hilton, Co-Vice Chair

COMMITTEE CHARGE(S):

Issue # __2020 II-017_____

1. Identify inconsistencies in language between all Standards in the Retail Program Standards
2. Continue review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities
3. Maintain the "Crosswalk – Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training

Issue # __2020 II-023_____

1. The Program Standards committee and FDA staff continue to explore the feasibility of incorporation of plan review functions into the standards either as a stand-alone standard or inserted into the existing standards in the Voluntary National Retail Food Regulatory Program Standards
2. Acknowledgement of the Preliminary Plan Review Proposal document to be utilized as a starting point for the Program Standards Committee work on this issue

Issue # __2020 II-033_____

1. Conduct a thorough review of Standard 5 "Foodborne Illness and Food Defense Preparedness and Response of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).
2. The review should include comparing the Standard to other similar FDA standards in food.
3. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program.
4. Review Standard 5 "Data Review and Analysis" from a sampling of jurisdictions to determine if certain data analysis requirements typically have no or such limited data to make the information not valuable.
5. Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS), Environmental Assessment Training Series (EATS), and Council to Improve Foodborne Outbreak Response (CIFOR) to consider inclusion of specific components.
6. Propose amendments to Standard 5 of the VNRFRPS.
7. Report back committee findings and recommendations to the next Biennial Meeting.

Subcommittee #5 Retail Program Standards Symposium

This subcommittee worked to develop the agenda and identify speakers for a 2 ½ day virtual meeting in 2022 focused on sharing information about the Retail Program Standards. The co-chairs of the subcommittee, as well as other Program Standards Committee members, worked with NEHA on the symposium. The dates of the symposium were June 7-9, 2022.

COMMITTEE WORK PLAN AND TIMELINE: The assigned charges were divided into 5 subcommittees. Each subcommittee set their workplan and timeline with a goal for all subcommittees to complete their work by 10/31/22 and then draft issues for pre-submittal.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

a. PSC leadership met on November 3, 2021.

b. Full PSC meeting was held on November 16, 2021. Members interest in a specific subcommittee

was gathered. Subcommittee co-chairs were assigned in December 2021.

c. PSC leadership met on January 6, 2022, to discuss the subcommittee assignments.

d. Subcommittee 2 co-chairs met on January 6, 2022, to discuss the charges, develop a base plan for meeting charges, meeting dates, meeting platforms and set agenda for the first meeting.

e. Subcommittee 1 met on January 13, 2022, February 17, 2022, March 15, 2022, April 19, 2022, May 31, 2022, June 28, 2022, August 24, 2022, and September 8, 2022.

f. Subcommittee 2 met on January 18, 2022, February 15, 2022, March 15, 2022, April 19, 2022, and July 19, 2022.

g. PSC leadership met with FDA to discuss the Standard 6 worksheet as well as other changes to the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) on January 24, 2022.

h. Subcommittee 3 met on January 25, 2022, February 8, 2022, February 28, 2022, April 11, 2022, April 25, 2022, September 8, 2022 and October 25, 2022. Additional meetings have been also held with the FDA, PSC Chair and subcommittee co-chairs during the preparation of the Issue documents to ensure that FDA is aware of what is being submitted.

i. Subcommittee 4 met on February 23, 2022, March 21, 2022, April 18, 2022, May 25, 2022, June 22, 2022, July 27, 2022, August 31, 2022, September 23, 2022 and October 20, 2022.

j. Subcommittee 5 met bi-weekly beginning on February 4, 2022, through June 6, 2022.

k. Full PSC met on March 1, 2022, and August 18, 2022. A full committee meeting is also planned for December 2022 to review the Issues submitted.

l. Subcommittee 5 co-chairs, NEHA and the PSC Chair and Co-Vice Chairs met with FDA representatives on March 24, 2022 to discuss the needs for the Retail Program Symposium in June 2022.

m. Subcommittee 5 chair met with FDA consultants on March 30, 2022 to further discuss support needs for the Retail Program Symposium.

n. The PSC leadership, along with subcommittee 1 co-chairs, met with representatives from FDA on June 23, 2022 to discuss re-standardization requirements for those that don't standardize others.

o. The subcommittee co-chairs, along with the PSC leadership met on May 3, 2022, and August 18, 2022.

p. Subcommittee 1 leadership, subcommittee members, the PSC Chair and FDA met on August 23, 2022 to discuss Issue 2020 II-31. It was determined that this subcommittee would look further at this issue as part of their charges even though it was not assigned to the PSC for action.

q. The PSC chair attended a meeting of the Clearinghouse Workgroup on September 8, 2022 to get instructions for pilot testing a new Retail Program Standards reference system database that's being developed for the interpretations.

r. The PSC chair provided feedback on two items sent to the Clearinghouse Workgroup for an interpretation on 10/5/22.

s. The chair, co-vice chair and some of the PSC members attended a meeting with FDA on 11/10/22 to be briefed on VNRFRPS related activities that the FDA is considering. Issue documents from the PSC related to what was discussed during the meeting was also shared with FDA.

2. ***Overview of committee activities:***

a. The Chair and Co Vice-Chairs developed the committee roster from those who expressed interest in participating on the PSC. There has been turnover of members, including the local representative serving as the Co-Vice Chair. Additional members were solicited and added to the roster. Five subcommittees were formed to work on the charges. Microsoft Teams folders were created for each of the subcommittees. All the subcommittees have been routinely meeting to work on their assigned charges.

b. Issue 2020 II-17 Charges 1 and 2 (subcommittee #1) reviewed the committee charges,

determined the timeline for addressing charges and decided to use Microsoft Teams for document sharing. A preliminary discussion of the VNRFRPS and review of poll responses regarding initial feedback on any known gaps within the VNRFRPS was conducted. Charge 2 was addressed during the February 3, 2022 call, and a list of training, evaluation and/or certification courses available to food safety inspection officers was reviewed based on the draft created during the last biennium. Starting February 17, 2022, the committee started work on edits to the list of training, evaluation and/or certification courses. The addition and removal of entries to the list of courses was completed through screen sharing. Committee members provided feedback on their review assignments. Changes to member assignments were made based on the feedback and overall experience with the VNRFRPS.

At the request of our FDA consultants, a special meeting was held on March 15, 2022 for Standard 6 to discuss the Standardized Key Crosswalk to the 2017 FDA Food Code and the Compliance and Enforcement worksheet. For this discussion, we hosted issue submitter Dan Joseph from State of Colorado. The conference call on April 19, 2022 was another special session which focused on Standard 8. Issue submitter Jo Ann Monroy presented at the meeting to review their staffing model pilot study on Standard 8 – Program Resources. On May 31, 2022 the committee began discussing the updates from the workgroups to review their assigned Standards. As each workgroup presented, the group screenshared the notes and discussions within the CFP Microsoft Teams folder. On June 28, 2022, the workgroups screenshared notes within the CFP Microsoft Teams folders and discussed possible Issues to be drafted for Standard 2 and 3 in the coming months.

c. Issue 2020 II-17 Charge 3 and Issue 2020 II-33 Charge 5 (subcommittee #2): During each meeting, members were assigned sections of the Crosswalk-Requirements for Foodborne Illness Training Programs to evaluate and report updates and changes at the next meeting. Subcommittee members has reviewed NEARS, EATS and CIFOR to consider including additional components in VNRFRPS Standard 5. The subcommittee review has been finalized with no major changes or revisions noted. They do recommend adding a reference/resource information regarding the Crosswalk document to VNRFRPS Standards 2 and 5 to bring more awareness to the document as a resource. They will also be recommending cleanup of the documents on the CFP website so only the current version of the Crosswalk is available to reduce confusion.

d. Issue # 2020 II-023 (subcommittee #3) Issue documents have been drafted to incorporate plan review within Standard 3 as a new element seven as well as adding the new element to the self-assessment/verification audit form. Another Issue document has been drafted as well as to re-create the Plan Review Committee to update the CFP Plan Review Guidance document to include requirements in the current food code as well as incorporating food safety management system elements within the plan review document.

e. Issue 2020 II-33 Charges 1-4 & 6-7 (subcommittee #4) reviewed the charges, compared the VNRFRPS Standard 5 with the Manufactured Food Regulatory Program Standard 5 to determine if they can be aligned to achieve the desired outcomes. The committee solicited input from enrolled jurisdictions about concerns with VNRFRPS Standard 5 and possible guidance on solutions. They looked at whether the VNRFRPS need to be more flexible to achieve the intent of Standard 5. The committee determined that, at this time, Standard 5 was aligned with achieving the best approach to respond to foodborne illness outbreaks but a Road Map to assist jurisdictions on how to meet the standard would be a resource to include in the Standard. The Road Map would provide steps to set up relationships with other agencies involved with outbreak response and tools to collect and track data. They also determined that they would like to continue to work on charges 3, 4 & 5 from the Issue in the next biennium and an Issue has been drafted for this.

f. Subcommittee 5 co-chairs attended multiple meetings weekly and bi-weekly with stakeholders to develop the agenda, speakers, symposium layout, registration, and website development for a Retail Program Standards Symposium (RPSS). An initial Save the Date was developed, as well as a website. A timeline was developed as well as identification of the responsible individual(s) for each task. The registration announcement was drafted and registration for the symposium opened on March 24, 2022. An agenda grid was developed, and speakers and moderators were contacted. The final agenda and speaker information was completed on March 30, 2022. The RPSS was held June 7-9, 2022. Planning for the next RPSS in 2024 is underway.

3. ***Charges <u>COMPLETED</u> and the rationale for each specific recommendation:***
   a. Issue #2020 II-017 charges have been completed and Issue documents have been drafted recommending revisions to the VNRFRPS.
   b. Issue #2020 II-023 charges have been completed and Issue documents have been drafted to incorporate plan review within Standard 3 as well as to re-create the Plan Review Committee to update the CFP Plan Review document to the current food code as well as incorporating food safety management system elements within the plan review document.
   c. The Retail Program Standards Symposium (RPSS) was held in June 7-9, 2022. 958 individuals registered (not including speakers) for the RPSS, while 755 individuals attended the symposium. A complete breakdown of attendance is provided in the RPSS Post Event Data document. Planning for the next RPSS in 2024 has begun.
   d. Issue 2020 II-33 charges were completed but subcommittee members felt that charges 3, 4 & 5 could be explored further in the next biennium, so a continuation issue was drafted. The subcommittee also feels that a roadmap to assist jurisdictions on how to meet the standard would be a good resource to include in VNRFRPS Standard 5. An issue to continue work on developing the roadmap has been drafted.
4. ***Charges <u>INCOMPLETE</u> and to be continued to next biennium:***
   a. Issue 2020 II-33 charges 3, 4 & 5.
   b. Standing committee charges to review and update the VNRFRPS as well as the ongoing review and updating of the Crosswalk – Requirement for Foodborne Illness Training Programs Based on Standard 5

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1) ***Issue #1: Report – Program Standards Committee (PSC):*** **List of content documents submitted with this Issue:** ***Committee Member Roster: Program Standards Committee Roster***

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***

Other content documents:

(1) PSC6 Draft Program Standard 2 – NCS Added
(2) PSC7 Program Standards 2022 Standard 3 Requirements
(3) PSC7 Program Standards 2022 Standard 3 Self-Assessment and VA form edits
(4) PSC9 Program Standards 2022 Standard 5 Edits
(5) PSC9 Program Standards 2022 Definitions Edits
(6) PSC10 Draft Standard 6 Establishment File Worksheet Food Code Form 3A Based
(7) PSC11 Draft Standard 6 Standardized Key Crosswalk to the 2017 FDA Food Code
(8) PSC13 Draft Program Standard 2 Additional Exam Based on NCS
(9) PSC15 Proposed Revised Program Standards 3 SA VA Form to Include Plan Review
(10) PSC15 Proposed Revised Program Standard 3 Requirement to Include Plan Review
(11) PSC16 Standard 5 Roadmap Draft 10 22
(12) PSC16 Standard 5 Data Collection Template
(13) PSC17 Program Standards 2022 Standard 2 with Crosswalk added
(14) PSC17 Program Standards 2022 Standard 5 with Crosswalk added

2) **List of supporting attachments:** ☐ ***Not applicable***

a. PSC Subcommittee 1 Final Report
b. PSC Subcommittee 2 Final Report
c. PSC Subcommittee 3 Final Report
d. PSC Subcommittee 4 Final Report
e. PSC Subcommittee 1 Final Report Charge 2 supporting attachment
f. RPSS Post Event Data_Part1
g. RPSS Post Event Data_Part2
h. RPSS Post Event Data_Part3
i. RPSS Post Event Data_Part4
j. PSC2 2022 Program Standards Standard 1 Regulatory Foundation
k. PSC2 CFP Issue 2020 II-031
l. PSC3 & PSC5 2022 Program Standard 2 Appendix B-1
m. PSC4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff
n. PSC5 Course Descriptions and Objectives - FDA38 FDA39
o. PSC5 AFDO – Risk-Based Inspection Methods in Retail FD218
p. PSC6 & PSC13 National Curriculum Standard
q. PSC7 2022 Program Standards 3 Inspection Program Based on HACCP Principles
r. PSC7 RPS 2022 Standard 3 Self-Assessment and Verification Audit form
s. PSC8 RPS Standard 2 Trained Staff Instructions and Worksheet for a VA
t. PSC8 RPS Standard 6 Compliance Enforcement Inst and Worksheet for a VA
u. PSC9 & PSC17 Standard 5 FBI and Food Defense Preparedness and Response
v. PSC9 2022 Program Standards Definitions
w. PSC12 2022 Program Standards 8 Program Support and Resources
x. PSC12 Issue 2020 II-017 Packet
y. PSC4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff
z. PSC13 IFSS Framework Basic Advanced Feb 2021 first tab
aa. PSC13 IFSS Framework Basic Advanced Feb 2021 Color Chart
bb. PSC13 IFSS Framework Basic Advanced Feb 2021 Descriptors tab
cc. PSC14 & PSC15 Plan Review for Food Establishments Guide 2016
dd. PSC15 Annex 3 Ch. 8 Comp and Enf Const Insp and Approval 8-201.12 & 8-203.10
ee. PSC18 www.foodprotect.org – Crosswalk Screenshot
ff. PSC19 Issue 2020 II-033

2) ***Committee Issue #2***: PSC2 Assign 2020 II-031 to Program Standards Committee
3) ***Committee Issue #3***: PSC3 Tracking Versions Standard 2 Appendix B-1
4) ***Committee Issue #4***: PSC4 Re-standardization Frequency for staff not standardizing others
5) ***Committee Issue #5***: PSC5 Add FD218 to Standard 2 Post Curriculum
6) ***Committee Issue #6***: PSC6 Reference National Curriculum Standard in VNRFRPS Standard 2
7) ***Committee Issue #7***: PSC7 Std 3 Requirements and Self-Assessment & Verification Audit Form Edits
8) ***Committee Issue #8***: PSC8 Create Standard 4 Verification Audit Instructions
9) ***Committee Issue #9***: PSC9 Edits to Standard 5 and Definitions
10) ***Committee Issue #10***: PSC10 Standard 6 Establishment File Worksheet Form 3A
11) ***Committee Issue #11***: PSC11 Standard 6 Crosswalk Update
12) ***Committee Issue #12***: PSC12 Defining Standard 8 Verification Audit Parameters
13) ***Committee Issue #13***: PSC13 Add NCS Exam Option to Standard 2
14) ***Committee Issue #14***: PSC14 Recreate Plan Review Committee
15) ***Committee Issue #15***: PSC15 Incorporation of Plan Review into VNRFRPS Standard 2
16) ***Committee Issue #16***: PSC16 Development of a Roadmap for the requirements in VNRFRPS Standard 5
17) ***Committee Issue #17:*** PSC17 Referencing Crosswalk – Requirements for Foodborne Illness Training Program

18) ***Committee Issue #18:*** PSC18 Requirements for Foodborne Illness Training Program Crosswalk Content User Accessibility

19) ***Committee Issue #19:*** PSC19 Continuation of Issue 2020 II-033 Charges 3 4 & 5

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STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. These knowledge, skills, and abilities (i.e. competencies) are outlined in the FDA National Curriculum Standard (NCS). The NCS identifies the competencies needed by FSIOs for successful job performance. The NCS has been developed through Cooperative Agreements with FDA, by subject matter experts representing local, state, and federal jurisdictions. Several courses have been developed based on the competencies in the NCS, specifically the "GenEds". The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

Note: *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*

- *Logs/records that are completed based on sign-in sheets; or*
- *Information validated from the certificate at the time-of-issuance; or*
- *A college transcript with a passing grade or other indication of successful completion of the course; or*
- *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
- *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

Note: *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*

- *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
- *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

Note: *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*

- *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
- *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

STANDARD 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

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STANDARD 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines, and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for:
    a) The identification of risk factors and interventions.
    b) Documentation of the compliance status of each risk factor and intervention (i.e., a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
    c) Documentation of all compliance and enforcement activities and
    d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
4. Develops and implements a program policy ***that requires:
    a) On-site corrective actions* as appropriate to the type of violation.
    b) Discussion of long-term control** of risk factor options, and
    c) Follow-up activities.
5. Establishes and implements written policies addressing code variance requests related to risk factors and interventions.
6. Establishes written policies regarding the ~~verification and~~ validation <u>and verification</u> of HACCP plans when a plan is required by the code.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:

1. Inspection form that requires the selection of IN, OUT, NO, or NA,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,

3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

*Note: **On-site** corrective action as appropriate to the violation would include such things as:

a. Destruction of foods that have experienced extreme temperature abuse,
b. Embargo or destruction of foods from unapproved sources,
c. Accelerated cooling of foods when cooling time limits can still be met,
d. Reheating when small deviations from hot holding have occurred,
e. Continued cooking when proper cooking temperatures have not been met.
f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

***Note: Consideration of the elements outlined in Standard 4 will ensure a strong foundation for a quality and uniform inspection program.

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Program Self-Assessment & Verification Audit Form

The *Standard 3: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 3. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 3 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a self-assessment of Standard 3 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self-Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 3 criteria listed on this form are available for review.

The *Standard 3: Program Self-Assessment and Verification Audit Form* is the only form a jurisdiction needs to use to record the results of their self-assessment. Standard 3 requires inspection policies to be established, written, and implemented. A policy without documentation of implementation does not meet the Standard 3 criteria.

The *Standard 3: Program Self-Assessment and Verification Audit Form* divides the Standard 3 criteria into six steps:

1. Inspection Form Design
    a. The jurisdiction's inspection form identifies foodborne illness risk factors and *Food Code interventions*.
    b. The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.
    c. The jurisdiction's inspection form documents compliance and enforcement activities.
2. Risk Assessment Categories
    a. A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.
3. Inspection Frequency
    a. The jurisdiction's inspection frequency is based on assigned risk categories.
4. Corrective Action Policy
    a. The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.
    b. The jurisdiction has a written and implemented policy that requires discussion for long- term control of foodborne illness risk factors.
    c. The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.
5. Variance Request Policy
    a. The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.

6. ~~Verification and~~ Validation and Verification of HACCP Plan Policy
    a. The jurisdiction has a written and implemented policy for the ~~verification and~~ validation and verification of HACCP plans, when a HACCP plan is required by the *Food Code*.

The self-assessor must review each Standard 3 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 3: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 3 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction*'s Self-Assessment" column of the* Standard 3: Program Self-Assessment and Verification Audit Form. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 3: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 3: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 3 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria.

Documenting the Findings from the Verification Audit
The jurisdiction requesting the verification audit must provide their completed *Standard 3: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 3: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The jurisdiction must meet all six program performance criteria outlined in Standard 3.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any

Standard 3 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria if the auditor does not confirm the self-assessment findings.

Standard 3: Inspection Program based on HACCP Principles
Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:	
Self-Assessor's Title:	
Jurisdiction Name:	
Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Standard 3 Self-Assessment was Completed:	
Self-Assessment indicates that the Jurisdiction MEETS the Standard 3 criteria (indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct. **Signature of the Self-Assessor:**	

VERIFICATION AUDIT SUMMARY

Printed Name of the Person who conducted the Verification Audit:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Verification Audit of Standard 3 was Completed:	
Verification Audit indicates that the Jurisdiction MEETS the Standard 3 criteria (indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standard 3 is true and correct. **Signature of the Verification Auditor:**	

Standard 3: Inspection Program based on HACCP Principles
Program Self-Assessment and Verification Audit Form

Jurisdiction Name: _____

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Inspection Form Design	a) The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions						
1. Inspection Form Design	b) The jurisdiction's inspection form documents actual observations using the convention (IN, OUT, NO, and NA).						
1. Inspection Form Design	c) The jurisdiction's inspection form documents compliance and enforcement activities.						
2. Risk Assignment Categories	a) A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.						
3. Inspection Frequency	a) The jurisdiction's inspection frequency is based on the assigned risk categories.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
4. Written and Implemented Corrective Action Policy	a) The jurisdiction has a written and implemented policy that requires on-site corrective actions for foodborne illness risk factors observed to be out of compliance.						
4. Written and Implemented Corrective Action Policy	b) The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.						
4.Written and Implemented Corrective Action Policy	c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.						
5. Variance Requests	a) The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and Food Code interventions.						
6. ~~Verification and~~ Validation and Verification of HACCP Plans	a) The jurisdiction has a written and implemented policy for the ~~verification and~~ validation and verification of HACCP plans, when a HACCP plan is required by the Code.						

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

Voluntary National Retail Food Regulatory Program Standards

DEFINITIONS

The following definitions apply in the interpretation and application of these Standards.

1) **Active Managerial Control** – The purposeful incorporation of specific actions or procedures by industry management into the operation of a business to attain control over foodborne illness risk factors.
2) **Auditor** – Any authorized city, county, district, state, federal, tribal, or other third-party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit, which confirms the accuracy of the self-assessment.
3) **Baseline Survey** – See Risk Factor Study.
4) **Candidate** - A regulatory officer whose duties include the inspection of retail food establishments.
5) **Compliance and Enforcement** – Compliance includes all voluntary or involuntary conformity with provisions set forth by the regulatory authority to safeguard public health and ensure that food is safe. Enforcement includes any legal and/or administrative procedures taken by the regulatory authority to gain compliance.
6) **Confirmed Foodborne Disease Outbreak** – means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiologic analysis implicates the food as the source of the illness or epidemiological analysis alone implicates the food as the source of the illness.
7) **Direct Regulatory Authority (DRA) –** The organizational level of government that is immediately responsible for the management of the retail program. This may be at the city, county, district, state, federal, territorial, or tribal level.
8) **Enforcement Actions –** Actions taken by the regulatory authority such as, but not limited to, warning letters, revocation or suspension of permit, court actions, monetary fines, hold orders, destruction of food, etc., to correct a violation found during an inspection.
9) **Follow-up Inspection –** An inspection conducted after the initial routine inspection to confirm the correction of a violation(s).
10) **Food Code Interventions** – the preventive measures to protect consumer health stated below:
    1. management's demonstration of knowledge;
    2. employee health controls;
    3. controlling hands as a vehicle of contamination;
    4. time / temperature parameters for controlling pathogens; and
    5. consumer advisory.
11) **Food-Related Injury** – Means an injury from ingesting food containing a physical hazard such as bone, glass, or wood.
12) **Foodborne Disease Outbreak** – The occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. Foodborne Disease Outbreaks include both Suspect Foodborne Outbreaks and Confirmed Foodborne Disease Outbreaks.
13) **Good Retail Practices (GRP's)** – Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the *FDA Food Code* interventions or risk factors.
14) **Hazard** – A biological, chemical, or physical property that may cause food to be unsafe for human consumption.

15) **National Registry of Retail Food Protection Programs (National Registry) – A** listing of retail food safety programs that have voluntarily enrolled as participants in the *Voluntary National Retail Food Regulatory Program Standards*.
16) **Person in charge (PIC)** – The individual present at a food establishment who is responsible for the operation at the time of inspection.
17) **Program Element –** One of the program areas for which a National Standard has been established such as regulations, training, inspection system, quality assurance, foodborne illness investigation, compliance and enforcement, industry and consumer relations, and program resources.
18) **Program Manager** – The individual responsible for the oversight and management of a retail food regulatory program.
19) **Quality Records –** Documentation of specific elements of program compliance with the National Standards as specified in each Standard.
20) **Risk Control Plan (RCP)** – a concisely written management plan developed by the retail or food service operator with input from the health inspector that describes a management system for controlling specific out-of-control risk factors.
21) **Risk Factors** – the improper employee behaviors or improper practices or procedures in retail food and food service establishments stated below which are most frequently identified by epidemiological investigation as contributing to foodborne illness or injury:
    1. improper holding temperature;
    2. inadequate cooking;
    3. contaminated equipment;
    4. food from unsafe source; and
    5. poor personal hygiene.
22) **Risk Factor Study** (formerly Baseline Survey) – A study on the occurrence of foodborne illness risk factors within institutional, foodservice, restaurants, and retail food facility types under a jurisdiction's regulatory authority. Criteria for a Risk Factor Study are detailed in Standard 9, including at a minimum:
    1. Data Collection, analysis, and a written report;
    2. A collection instrument with data items pertaining to the five foodborne illness risk factors;
    3. A collection instrument that uses the convention of IN, OUT, NA and NO to document observations;
    4. All facility types identified by FDA's national study that are under the jurisdiction's regulatory authority; and
    5. Studies subsequent to the initial study repeated at 5-year intervals.
23) **Routine Inspection – A** full review and evaluation of a food establishment's operations and facilities to assess its compliance with Food Safety Law, at a planned frequency determined by the regulatory authority. This does not include re-inspections and other follow-up or special investigations.
24) **Self-Assessment** – An internal review by program management to determine whether the existing retail food safety program meets the *Voluntary National Retail Food Regulatory Program Standards*.
25) **Self-Assessment Update** – Comparison of one or more program elements against the *Voluntary National Retail Food Regulatory Program Standards* between the required 60-month periodic self-assessment.

26) **Standardization Inspection** – An inspection used to demonstrate a candidate's knowledge, communication skills, and ability to identify violations of all regulatory requirements and to develop a risk control plan for identified, uncontrolled risk factors.
27) **Suspect Foodborne Outbreak** – Means an incident in which two or more persons experience a similar illness after ingestion of a common food or eating at a common food establishment/gathering that did not meet the definition of a Confirmed Foodborne Disease Outbreak.
28) **Trainer** – An individual who has successfully completed the following training elements as outlined in Steps 1 – 3, Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.
    1. Satisfactory completion of the prerequisite curriculum;
    2. Completion of a field training process similar to that contained in Appendix B-2; and
    3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum.
29) **Training Standard** – An individual who has successfully completed the following training elements AND standardization elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees. The training and standardization elements include:
    1. Satisfactory completion of the prerequisite curriculum;
    2. Completion of a field training process similar to that contained in Appendix B-2;
    3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum;
    4. Successful completion of a standardization process based on a minimum of eight inspections that includes development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP plan, similar to the FDA standardization procedures;
    5. Completion of a minimum of 20 contact hours of continuing education in food safety every 36 months after the initial training is completed as outlined in Standard 2; and
    6. Standardization maintained every three (3) years as outlined in Standard 2.
30) **Verification Audit** – A systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment.

STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury, and outbreaks.

Requirement Summary

The program has an established system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. Investigative Procedures

a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and FOOD-RELATED INJURY. The procedures clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, FOOD-RELATED INJURY or contamination of food.

c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.

d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, FOOD-RELATED INJURY or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.

e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.

f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.

g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, FOOD- RELATED INJURY, or outbreak investigations.

h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.

i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

a. Possible contributing factors to the food-related illness, FOOD-RELATED INJURY or intentional food contamination are identified in each on-site investigation report.

b. The program shares final reports of investigations with the state epidemiologist and reports of CONFIRMED FOODBORNE DISEASE OUTBREAKS with CDC.

3. Laboratory Support Documentation

a. The program has a letter of understanding, written procedures, contract, or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.

b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak, or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.

b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.

c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and FOOD-RELATED INJURY investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or FOOD-RELATED INJURY. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.

b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:

1) FOODBORNE DISEASE OUTBREAKS, SUSPECT FOODBORNE OUTBREAKS and CONFIRMED FOODBORNE DISEASE OUTBREAKS in a single establishment;
2) FOODBORNE DISEASE OUTBREAKS, SUSPECT FOODBORNE OUTBREAKS and CONFIRMED FOODBORNE DISEASE OUTBREAKS in the same establishment type;
3) FOODBORNE DISEASE OUTBREAKS, SUSPECT FOODBORNE OUTBREAKS and CONFIRMED FOODBORNE DISEASE OUTBREAKS implicating the same food;
4) FOODBORNE DISEASE OUTBREAKS, SUSPECT FOODBORNE OUTBREAKS and CONFIRMED FOODBORNE DISEASE OUTBREAKS associated with similar food preparation processes;
5) Number of CONFIRMED FOODBORNE DISEASE OUTBREAKS;
6) Number of FOODBORNE DISEASE OUTBREAKS and SUSPECT FOODBORNE DISEASE OUTBREAKS;
7) Contributing factors most often identified;
8) Number of complaints involving real and alleged threats of intentional food contamination; and
9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

c. In the event that there have been no food-related illness or FOOD-RELATED INJURY outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual CONFIRMED FOODBORNE DISEASE OUTBREAK and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no FOODBORNE DISEASE OUTBREAK investigations occur.

Note: *Regulatory Programs are encouraged to also participate in the CDC National Environmental Assessment Reporting System (NEARS). NEARS is designed to provide a more*

comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NEARS: http://www.cdc.gov/nceh/ehs/nears/index.htm)

Outcome

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and FOOD-RELATED INJURY complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, FOOD-RELATED INJURY, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts, or MOUs with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

STANDARD 6: COMPLIANCE AND ENFORCEMENT
ESTABLISHMENT FILE WORKSHEET
Based on FDA Food Code Form 3A

File Number: _____ Establishment Name: _____ Permit Number: _____ Inspection Date (Start Point): _____

Risk Factor and Public Health Interventions

	Supervision	Employee Health	Good Hygienic Practices	Preventing Contamination by Hands	Approved Source	Protection from Contamination	Time/Temperature Control for Safety	Consumer Advisory	HSP Populations	Food Color Additives and Toxic Substances	Conformance with Approved Procedures
Reference to local inspection items	1, 2	3, 4, 5	6, 7	8, 9, 10	11, 12, 13, 14	15, 16, 17	18, 19, 20, 21, 22, 23, 24	25	26	27, 28	29
Start Point Inspection Violations											
Was on-site corrective action taken?											
Was follow-up corrective action taken?											
Was enforcement action taken?											

Note: Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed

Was the Written Procedure Followed? _____ YES _____ NO

Jurisdiction's definitions of acronyms and notations used to reflect follow-up action

Acronym /Notation	Definitions	Acronym /Notation	Definitions	Acronym/Notation	Definitions

File Meets the Standard 6 Criteria: _____ YES _____ NO

Standardized Key Crosswalk to the 2017 FDA Food Code

This crosswalk is intended to assist jurisdictions in making comparisons with their code against the 2017 FDA Food Code. The Form 3-A Food Inspection Report Item numbers are based on the model FDA inspection form found in Annex 7 of the 2017 FDA Food Code. Completion of the crosswalk is intended to assist jurisdictions completing Standard 6 documentation which identifies major risk factors and public health interventions on the jurisdiction's inspection report form. Annex 5 contains additional information regarding the content of Form 3-A.

FBI Risk Factors and Interventions	Food Establishment Inspection Report (Form 3-A) Item Number	Applicable 2017 FDA Food Code References
Supervision		
PIC	1	2-101.11; 2-102.11(A), (B), (C)(1), (4)-(16); 2-103.11 (A), (P)
CFPM	2	2-102.12(A)
Employee Health		
Management	3	2-102.11(C)(2), (3), (17); 2-103.11(O); 2-201.11(A), (B), (C), (E)
Restriction and Exclusion	4	2-201.11(D), (F); 2-201.12; 2-201.13
Vomit and Diarrheal events	5	2-501.11
Good Hygienic Practices		
Eating, Tasting and Drinking	6	2-401.11; 2-301.12
Discharge from eyes, nose, and mouth	7	2-401.12
Preventing Contamination by Hands		
Hands Clean and Properly Washed	8	2-301.11; 2-301.12; 2-301.14; 2-301.15; 2-301.16
No Bare Hand Contact with RTE Foods	9	3-301.11; 3-801.11(D)
Adequate handwashing sinks	10	5-202.12; 5-203.11; 5-204.11; 5-205.11; 6-301.11; 6-301.12; 6-301.13; 6-301.14
Approved Source		
Food obtained from approved source	11	3-201.11-17; 3-202.13-14; 3-202.110; 5-101.13
Food Received at proper temperature	12	3-202.11
Food in good condition, safe and unadulterated	13	3-101.11; 3-202.15
Required records available, shellstock tags, parasite destruction	14	3-202.18; 3-203.12; 3-402.11; 3-402.12
Protection from Contamination		
Food Separated and Protected	15	3-302.11; 3-304.11; 3-304.15(A); 3-306.13(A)
Food Contact surfaces; cleaned and sanitized	16	4-501.111-115; 4-601.11(A); 4-602.11-12; 4-702.11; 4-703.11

FBI Risk Factors and Interventions	Food Establishment Inspection Report (Form 3-A) Item Number	Applicable 2017 FDA Food Code References
Proper disposition or returned, previously served, reconditioned and unsafe food	17	3-306.14; 3-701.11
Time/Temperature Control for Safety		
Cooking	18	3-401.11; 3-401.12; 3-401.14
Reheating	19	3-403.11
Cooling	20	3-501.14
Hot Holding	21	3-501.16(A)(1)
Cold Holding	22	3-501.16(A)(2), (B)
Date marking	23	3-501.17; 3-501.18
Time as Public Health Control	24	3-501.19
Consumer Advisory		
Consumer Advisory provided for raw/undercooked foods	25	3-603.11
HSP Populations		
Pasteurized foods used; prohibited foods not offered	26	3-801.11(A), (B), (C), (E), (G)
Food Color Additives and Toxic Substances		
Food Additives approved and properly used	27	3-202.12; 3-302.14
Toxic substances identified, stored, and used	28	7-101.11; 7-102.11; 7-201.11; 7-202.11; 7-202.12; 7-203.11; 7-204.12; 7-204.13; 7-204.14; 7-205.11; 7-206.11; 7-206.12; 7-206.13; 7-207.11; 7-207.12; 7-208.11; 7-209.11; 7-301.11
Conformance with Approved Procedures		
Compliance with variance/specialized process/HACCP	29	3-404.11; 3-502.11; 3-502.12; 4-204.110(B); 8-103.12; 8-201.13; 8-201.14

*Item numbers listed in this column refer to the item numbers within FDA's Food Establishment Inspection Report (Form 3-A, found in Annex 7).

STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the ~~four~~ five written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the ~~four~~ five written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

5. A food protection certification examination based on the National Curriculum Standard that is developed using methods that are psychometrically valid and reliable.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

Note: *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*

- *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
- *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

Note: *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*

- *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
- *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

PSC15 Proposed Revised Standard 3 Requirement to Include Plan Review

STANDARD 3

INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for:
   a) The identification of risk factors and interventions.
   b) Documentation of the compliance status of each risk factor and intervention (i.e. a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
   c) Documentation of all compliance and enforcement activities and
   d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk
4. Develops and implements a program policy ***that requires:
   a) On-site corrective actions* as appropriate to the type of violation.
   b) Discussion of long-term control** of risk factor options, and
   c) Follow-up activities.
5. Establishes and implements written policies addressing code variance requests related to risk factors and interventions.
6. Establishes written policies regarding the verification and validation of HACCP plans when a plan is required by the code.
7. <u>Develops and implements a program policy to require the REGULATORY AUTHORITY to have a review and approval process for the construction plans*****, equipment specifications, and other information submitted by the PERMIT applicant or PERMIT HOLDER for the FOOD ESTABLISHMENT that is consistent with the requirements of the FDA Food Code. The policy should include a requirement that the REGULATORY AUTORITY discusses the establishments food safety management system**** as part of the plan review process. Contents of the PERMIT applicant's or PERMIT HOLDER's submission must include at least the following information:
   a) Intended menu
   b) Anticipated volume of FOOD to be stored, prepared, and sold or served
   c) Proposed layout, mechanical schematics, construction</u>

d) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications
e) Standard operating procedures and HACCP plan if applicable, and
f) Other information that may be required by the REGULATORY AUTHORITY for the proper review of the proposed construction, conversion or modification, and procedures for operating a FOOD ESTABLISHMENT and
g) Documentation of all plan reviews conducted (approval, conditional, denial) or if the regulatory program does not conduct plan review or shares responsibility for the plan review with other entities or agencies, there are agreements in place and the process is documented.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:
1. Inspection form that requires the selection of IN, OUT, NO, or NA,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category
3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections,
7. Documentation of the review and approval process for submission of a food safety management system plan, construction plans, equipment specifications, and other information that is consistent with the requirements of the FDA Food Code or if the plan review is conducted externally, documentation of the process (policy, contract, MOU). The review and approval should include at minimum:
a) Food safety management system plan discussion
b) Intended menu
c) Anticipated volume of FOOD to be stored, prepared, and sold or served
d) Proposed layout, mechanical schematics, construction
e) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications
f) Standard operating procedures and HACCP plan if applicable, and
g) Documentation of all plan reviews conducted (approval, conditional, denial)

*Note: On-site corrective action as appropriate to the violation would include such things as:
a. Destruction of foods that have experienced extreme temperature abuse,
b. Embargo or destruction of foods from unapproved sources,
c. Accelerated cooling of foods when cooling time limits can still be met,
d. Reheating when small deviations from hot holding have occurred,
e. Continued cooking when proper cooking temperatures have not been met.

PSC15 Proposed Revised Standard 3 Requirement to Include Plan Review

f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

***Note: Consideration of the elements outlined in Standard 4 will ensure a strong foundation for a quality and uniform inspection program.

*****Note 1: Through their committee process, the Conference for Food Protection has developed Plan Review for Food Establishment guidance on the CFP web site: www.foodprotect.org located under the icon titled, "Conference Developed Guides and Documents" and can be downloaded at http://www.foodprotect.org/guides-documents/plan-review-for-food-establishments-2016/.

**** Note 2: Food Safety Management System
refers to a specific set of actions (e.g., procedures, training, and monitoring) to help achieve active managerial control.

- **Procedures:** A defined set of actions adopted by food service management for accomplishing a task in a way that minimizes food safety risks. Procedures may be oral or written and include who, what, where, when, and how a task should be performed. The goal is to move toward complete, consistent, and primarily written procedures and may include topics such as when to wash your hands, how to set up a 3-compartment sink, how food temperatures are achieved and maintained/monitoring food temperatures.
- **Training:** The process of management's informing employees of the food safety procedures within the food service establishment and teaching employees how to carry them out. Information may be presented in formats such as a set of instructions/illustrations, recipe cards with process instructions, wall charts, wallet cards, or live demonstration. The goal is to provide and document training for all food safety tasks in a format and frequency adequate to ensure employees have the knowledge to carry out the procedures consistently and effectively.
- **Monitoring:** Routine observations and measurements conducted to determine if food safety procedures are being followed. Monitoring systems should include who, what, where, when, and how monitoring is to be performed and may be conducted visually or documented in writing. The goal is to move toward a well-documented system that can be verified and may include use of automated systems, digital thermometers, logs, charts, checklists, and other job aids and tools.

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

Program Self-Assessment & Verification Audit Form

The *Standard 3: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 3. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 3 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self Assessment

Jurisdictions conducting a self-assessment of Standard 3 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 3 criteria listed on this form are available for review.

The *Standard 3: Program Self-Assessment and Verification Audit Form* is the only form a jurisdiction needs to use to record the results of their self-assessment. Standard 3 requires inspection policies to be established, written, and implemented. A policy without documentation of implementation does not meet the Standard 3 criteria.

The *Standard 3: Program Self-Assessment and Verification Audit Form* divides the Standard 3 criteria into seven steps:

1. Inspection Form Design
    a. The jurisdiction's inspection form identifies foodborne illness risk factors and *Food Code interventions*.
    b. The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.
    c. The jurisdiction's inspection form documents compliance and enforcement activities.
2. Risk Assessment Categories
    a. A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.
3. Inspection Frequency
    a. The jurisdiction's inspection frequency is based on assigned risk categories.

4. Corrective Action Policy
    a. The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.
    b. The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.
    c. The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.

5. Variance Request Policy
    a. The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.
6. Verification and Validation of HACCP Plan Policy
    a. The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the *Food Code*.
7. Plan Review
    a. The jurisdiction develops and implements a program policy to require the submission and review of food establishment construction plans, and equipment specifications that is consistent with the FDA Food Code, or the program maintains a written agreement with another entity that is responsible for the plan review process. The policy should include a requirement that the REGULATORY AUTHORTY discusses the establishments food safety management system as part of the plan review process.

        Specifically, plan review criteria for self-assessment and verification language:
        a) The jurisdiction develops and implements a program policy to require the discussion of the establishment food safety management system plan.
        b) The jurisdiction develops and implements a program policy to require the submission, review and approval of establishment construction plans consistent with the FDA Food Code.
        c) The jurisdiction develops and implements a program policy to require the submission, review and approval of equipment specifications consistent with the FDA Food Code.
        d) Or, the program maintains a written agreement with another entity that is responsible for the plan review process.

The self-assessor must review each Standard 3 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 3: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 3 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdict*ion's Self-Assessment" column of the* Standard 3: Program Self-Assessment and Verification Audit Form. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 3: Program Self-Assessment and*

Verification Form to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 3: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 3 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 3: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 3: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings. The

jurisdiction must meet all six program performance criteria outlined in Standard 3.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the verification audit. In particular, any Standard 3 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria if the auditor does not confirm the self-assessment findings.

Standard 3: Inspection Program Based On HACCP Principles
Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:		
Self-Assessor's Title:		
Jurisdiction Name:		
Jurisdiction Address:		
Phone:	**FAX:**	**E-Mail:**
Date the Standard 3 Self-Assessment was Completed:		
Self-Assessment indicates that the Jurisdiction MEETS the Standard 3 criteria: YES ☐ NO ☐		
I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct.		
Signature of the Self-Assessor:		

VERIFICATION AUDIT SUMMARY

Printed Name of the Person who conducted the Verification Audit:		
Verification Auditor's Title:		
Auditor's Jurisdiction Name:		
Auditor's Jurisdiction Address:		
Phone:	**FAX:**	**E-Mail:**
Date the Verification Audit of Standard 3 was Completed:		
Verification Audit indicates that the Jurisdiction MEETS the Standard 3 criteria: YES ☐ NO ☐		
I affirm that the information represented in the Verification Audit of Standard 3 is true and correct.		
Signature of the Verification Auditor:		

Standard 3: Inspection Program Based On HACCP Principles
Program Self-Assessment and Verification Audit Form

Jurisdiction Name:

Criteria	Jurisdiction's Self-Assessment			Auditor's Verification		
	YES	NO	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
1. Inspection Form Design						
a) The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions.	☐	☐		☐	☐	
b) The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.	☐	☐		☐	☐	
c) The jurisdiction's inspection form documents compliance and enforcement activities.	☐	☐		☐	☐	
2. Risk Assessment Categories						
a) A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.	☐	☐		☐	☐	
3. Inspection Frequency						
a) The jurisdiction's inspection frequency is based on the assigned risk categories.	☐	☐		☐	☐	
4. Written and Implemented Corrective Action Policy						
a) The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.	☐	☐		☐	☐	
b) The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.	☐	☐		☐	☐	

Criteria	Jurisdiction's Self-Assessment			Auditor's Verification		
	YES	NO	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.	☐	☐		☐	☐	
5. Variance Requests						
a) The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.	☐	☐		☐	☐	
6. Verification and Validation of HACCP Plans						
a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.	☐	☐		☐	☐	
7. Plan Review						
a) The jurisdiction develops and implements a program policy to require a food safety management system plan discussion as part of the plan review process. b) The jurisdiction develops and implements a program policy to require the submission, review, and approval of establishment construction plans consistent with the FDA Food Code. c) The jurisdiction develops and implements a program policy to require the submission, review, and approval of equipment specifications consistent with the FDA Food Code d) Or, the program maintains a written agreement with another entity that is responsible for the plan review process.	☐	☐		☐	☐	

Standard 3: Inspection Program Based On HACCP Principles
Program Self-Assessment and Verification Audit Form

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

PSC16 Standard 5 Data Collection Template

Note: This document is a PDF document of a Excel spreadsheet with tabs for Instructions, Data_Entry, Summary and Lookup.

Instructions:

This workbook is designed to help a food regulatory program maintain the data needed for compliance with FDA Voluntary National Retail Food Regulatory Program Standards #5.	
For each outbreak complete a new row on the Data_Entry tab - Row 2 contains an example	
OutbreakID	Enter the local health department identifier for the outbreak - this could also be the NEARS or NORS outbreak reporting ID - If multiple facilities are implicated use the same outbreakID for all implicated facilities
Facility	Enter the name of the facility that was implicated, you can have multiple facilities per outbreak (e.g., a contaminated ingredient was distributed to multiple restaurants)
LicenseID	Enter the license/permit id for the implicated restaurant
Establishment Type	Enter the establishment type
Single Location	Indicate if a single location was implicated
Outbreak Status	For the outbreak identify if the agent was confirmed, suspected, unknown, or if the outbreak is still ongoing.
Date Notified	Enter the date that the food program was made aware of the potential outbreak
Date of First Contact	Enter the date that the food program first made contact with the implicated establishment

Date Completed	Enter the date that the food program completed their investigation
Implicated Food	Enter the name of the implicated food (please use the same spelling for the same food))
Food Process	Indicate the basic food preparation process for the implicated food (No cook - food is not cooked, Cook-Serve - Food is cooked and then served, Complex - Food is cooked then cooled and reheated)
Contributing Factors Identified	Enter the contributing factors (what went wrong) for the implicated food - this only needs to be entered for one establishment per outbreak. If you choose Other - include the specifics in the Notes column
Agent	Select the implicated agent
Agent Other	If you select Other for Agent then enter the name here
Intentional Contamination	Indicate if intentional contamination was suspected for this outbreak
NOTES	Record any notes about the outbreak that will be helpful for understanding what occurred
On the Summary tab, you can change the year to get a summary for the year.	

Data_Entry

OutbreakID	Facility	LicenseID	Establishment Type	Single Location	Outbreak Status	Date Notified	Date of First Contact	Date Completed	Implicated Food	Food Process
2022-02	John's Doe	ABC123	Restaurant	YES	Confirmed	1/23/1976	1/24/1976	1/31/1976	Venison	Complex

Contributing Factors Identified	Agent	Agent Other	Intentional Contamination	NOTES
C1, C2	Other	Brucella	No	

Summary

XYZ County Health Department - Summary of Foodborne Illness Outbreaks									
Number of foodborne outbreaks			**Number of outbreaks by establishment type**						
Single Facility				Confirmed	Suspected	Ongoing	Unknown	Multifacility	
Confirmed	0		Restaurant	0	0	0	0	0	
Suspected	0								
Ongoing	0								
Unknown	0								

	TOTAL	**0**							
	MultiFacility								
	Confirmed	0							
	Suspected	0							
	Ongoing	0							
	Unknown	0							
	TOTAL	**0**							
TOTAL OUTBREAKS									
	Confirmed	0							
	Suspected	0							
	Ongoing	0							

	Unknown	0							
	TOTAL	**0**							
Intentional Food Contamination									
	0								

Number of outbreaks by food type						**Number of outbreaks by food process**				
	Confirmed	Suspected	Ongoing	Unknown			Confirmed	Suspected	Ongoing	Unknown
Venison	0	0	0	0		No Cook	0	0	0	0
						Cook-Serve	0	0	0	0
						Complex	0	0	0	0

Frequency of Contributing Factors			**Frequency of Agent**	
		# times marked		# times identified
C1	Toxin or chemical agent naturally part of the tissue	0	Norovirus	0

C2	Poisonous substance or infectious agent intentionally added to food cause illness (does not include injury)	0	Hepatitis A virus	0
C3	Poisonous substance accidentally/inadvertently added to food	0	Salmonella	0
			Campylobacter	0
C4	Ingredient's toxic in large amounts accidentally added to food	0	Clostridium	0
C5	Container or equipment used to hold or convey food was made with toxic substances	0	STEC O157	0
C6	Food contaminated by animal or environmental source at point of final preparation/sale	0	Other STEC	0
C7	Food contaminated by animal or environmental source before arriving at point of final preparation (pre- or post-harvest)	0	Listeria	0
C8	Cross-contamination of foods, excluding infectious food workers/handlers	0	Shigella	0
C9	Contamination from infectious food worker/handler through bare hand contact with food	0	Yersinia	0
			Other	0
C10	Contamination from infectious food worker/handler through glove-hand contact with food	0	Unknown	0
C11	Contamination from infectious food worker/handler through unknown type of hand contact with food or indirect contact with food	0		
C12	Contamination from infectious non-food worker/handler through direct or indirect contact with food	0		

C13	Other sources of contamination (specify)	0		
P1	Allowing foods to remain out of temperature control for a prolonged period during preparation	0		
P2	Allowing foods to remain out of temperature control for a prolonged period during food service or display	0		
P3	Inadequate cold holding temperature due to malfunctioning refrigeration equipment	0		
P4	Inadequate cold holding temperature due to an improper practice	0		
P5	Inadequate hot holding temperature due to malfunctioning equipment	0		
P6	Inadequate hot holding temperature due to an improper practice	0		
P7	Improper cooling of food	0		
P8	Extended refrigeration of food for an unsafe amount of time, relative to the food product and pathogen	0		
P9	Inadequate reduced oxygen packaging (ROP) of food	0		
P10	Inadequate non-temperature dependent processes (e.g., acidification, water activity, fermentation) applied to a food to prevent pathogens from multiplying	0		
P11	Other situations that promoted or allowed microbial growth or toxic production (specify)	0		
S1	Inadequate time and temperature control during initial cooking/thermal processing of food	0		
S2	Inadequate time and temperature control during reheating of food	0		

S3	Inadequate time and temperature control during freezing of food designed for pathogen destruction	0		
S4	Inadequate non-temperature dependent processes (e.g., acidification, water activity, fermentation) applied to a food to prevent pathogens from surviving	0		
S5	No attempt was made to inactivate the contaminant through initial cooking/thermal processing, freezing, or chemical processes	0		
S6	Other process failures that permit pathogen survival (specify)	0		

Lookup

YES	Suspected	No Cook	C1	Norovirus
NO	Confirmed	Cook-Serve	C2	Hepatitis A virus
	Ongoing	Complex	C3	Salmonella
	Unknown		C4	Campylobacter
			C5	Clostridium
			C6	STEC O157
			C7	Other STEC
			C8	Listeria
			C9	Shigella
			C10	Yersinia
			C11	Other
			C12	Unknown
			C13	
			P1	

			P2	
			P3	
			P4	
			P5	
			P6	
			P7	
			P8	
			P9	
			P10	
			P11	
			S1	
			S2	
			S3	
			S4	
			S5	
			S6	

A sample roadmap for Retail Food Program Standard 5 Foodborne Illness and Food Defense Preparedness and Response

Establishing an FBI program from Start to Finish

The intent of this document is to assist with the development of a Foodborne Illness and Food Defense Program. Often time when a jurisdiction starts to develop their FBI/FD Program in conformance with Standard 5, the task can seem complicated and at times overwhelming. This document is intended to be used as a job aide to assist with the crafting and implementation of your own FBI/FD program by walking through the minimum requirements step by step. Some smaller jurisdictions may find that answering the step-by-step questions may provide sufficient details for development of their FBI/FD Program. Whereas, some larger jurisdictions may need expand beyond the minimum requirements to meet their needs for a functional FBI/FD Program. Each jurisdiction has unique challenges and opportunities that cannot be entirely addressed by a single document. Therefore, this document is not intended to be a blueprint or blank template to the development of your program but to assist with your FBI/FD Program development.

To conform to the requirements of Standard 5, your FBI/FD Program needs to contain 7 elements, which include the following:

1. Investigative Procedures
2. Reporting Procedures
3. Laboratory Support Documentations
4. Trace-Back Procedures
5. Recall Procedures
6. Media Management
7. Data Review and Analysis

These 7 elements can be completed in any sequence, and often times you may find some elements more challenging than others. It is recommended that the easier or most straightforward elements be addressed first. The more challenging elements usually take longer and may seem insurmountable to some jurisdictions trying to meet Standard 5, particularly smaller jurisdictions. Also, you may find that by addressing the easier elements, you will find answering the more complicated questions less challenging, since there are frequent overlapping components. It is important to remember any progress in developing an FBI/FD Program improves the security and safety of the people that we serve, as well as highlights gaps in our programs that can be addressed.

One of the essential lessons of this job aide is to understand that the role or roles that your jurisdiction plays in Foodborne Illness and Food Defense is part of a broader network of Programs and jurisdictions. In fact one of the easiest steps that a jurisdiction can start with is the development of a contact list of mission critical personnel in the event of a Foodborne Illness or Food Defense event.

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The trip begins:

1. **Investigative Procedures**
   a. **The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and food-related injury that clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies.**

   (The procedures may be contained in a single source document or in multiple documents.)

It is critical that prior to an FBI/FD event that the role and roles that a jurisdiction may play in an event be determined and procedures developed. So, it is important to understand what role or roles your program may play. There are simple questions that can assist with this determination. These include the following:

- Who will receive the complaint(s)?
- Who conducts the illness interviews?
- Who will conduct the field inspections/ investigations?
- Who will liaise with federal agencies?
- Who will collect samples? Environmental, clinical, etc.
- Who will analyze collected samples?
- Who will coordinate the activities?
- Who will handle follow-up activities if needed?
- Who will write the final report?
- Who will determine when an FBI event has stopped?

is only investigations, decide how these inspections will be covered in general and by

Answering these questions can assist a jurisdiction to start understanding your role in investigating FBI/FD events. Some jurisdictions/ EHS units play a reduced role in these events, and others play a significant role or multiple roles in these events. Understand the scope of your activities and responsibilities in FBI/ FD events will help determine what procedures are needed to be developed and standardized. If a role(s) is outside your scope, then determine whose role is it. For example, if your role is limited to field inspections/ investigations, then you may not need to develop procedures for conducting illness interviews.

a. Next identify essential roles that are played in an FBI event.
b. Next if you do not perform all of the above roles, began to find out who does perform the role. Gather their contact information.
c. If no one is conducting an essential role, then this is a gap that should be worked on to be filled. Remember you do not necessarily need to fill the gap yourself, but recognizing a gap is a very good thing!
d. By now, you have a better understanding of your role(s) in an FBI event. Now start putting pen to paper and building your system. Remember that being general is ok. The key is developing a program that covers all of your responsibilities. If your role is

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only investigations, decide how these inspections will be covered in general and by which staff but not specifically who.

e. Next decide how information will be shared. Teleconferences, individual phone calls, emails, etc.
f. Next decide who will lead the information sharing. Having a coordinator or a point person can make the process go smoother.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illnesses, food-related injuries, or contamination of food.

1. Knowing who to contact in an emergency is one of the first steps in navigating an emergency.
2. Maintain a list of State, local, Federal contacts. (can include law enforcement contacts needed in step h) Remember that list from above in section c?
    i. Note: in general, a contact list has already been established by someone else in your State. Your do not need to reinvent the wheel.
        1. Do you have a State Rapid Response Team (RRT)?
        2. Does your State have a Manufactured Food Regulatory Program Standards (MFRPS) program?
        3. State Public Health often maintains lists of emergency contacts.
        4. Are you a small jurisdiction or program? Reach out to other jurisdictions in your State?

c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program / department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.

How complex or formal you wish to establish roles is up to you.

i. If you feel a formal MOU with everyone's roles, is your process, then feel free to go that route.
ii. If you prefer a less formal approach, then as long as each role is identified, particularly your specific role(s), you have met the expectation.

Remember all the hard work in section 1a? Now it we pay off again. Summarize the roles of each group in the essential roles list, particularly your group's role. Be specific when it comes to your role(s). Now you can take the contact information from section b and publish this summary.

Provide examples/templates

d. The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, food-related injury, or unintentional

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food contamination. The final disposition for each complaint is recorded in the database or log and is filed in, or linked to, the establishment record for retrieval purposes.

This could be the Template that Adam Kramer developed.
Washtenaw County Template

e. **Program procedures describe the disposition, action, or follow-up and reporting required for each type of complaint or referral report.** What does this mean? Have a plan/procedure for each type of complaint you get. Lindy can ask Julie. Clinical, outbreak, suspect. Step by step instructions on what you would do based on the complaint type

f. **Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.**

This is where many smaller jurisdictions cannot meet the Standard.
Need to flesh out to provide some flexibility. What is the minimum to meet this. Depends on what the complaint reveals. (single complaint with only symptoms vs. confirmed lab illness, large numbers of ill. Define "initiate". Have at a minimum the "follow-up" step. Could be a simple as referring to the food person (text/email/phone call). Need to do some sort of follow-up. Need to figure out how to meet it. On call person without compensation may be a big challenge.

g. **The program has established procedures and guidance for collecting information on the suspect foods' preparation, storage or handling during on-site illness, food-injury, or outbreak investigations.**

The environmental investigation could involve another agency separate from the local jurisdiction. This should be included in the roles defined above.

This is a written procedure that could include a data collection form to document the collected information.
- Preparation
- Storage/handling

Develop flowchart for a small jurisdiction

h. **Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.**

Need to determine position within law enforcement to contact and include in the procedures. Written into the procedures include contact information for local/state/federal law enforcement agencies. Can be included in B-b.
Provide a template

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i. **Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.**

Contact FDA Customer Complaint Line
USDA
State Departments of Agriculture/Health

2. Reporting Procedures

a**. Possible contributing factors to the food-related illness, food-related injury or intentional food contamination are identified in each on-site investigation report.**

CDC 5213 NORs report (all states are participating in NOR's)
https://www.cdc.gov/nors/downloads/form-52-13.pdf

Investigation Collection form to have section to record this information.

Usually determine this after the investigation, during briefing meetings/teleconferences

Provide an example and a link to the CDC CF's
https://www.cdc.gov/nceh/ehs/nears/what-are-contributing-factors.htm

b**. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks with CDC.**

Write this in your procedures. If above process is followed, State Epi and CDC will more than likely already be involved.

3. Laboratory Support Documentation

a. **The program has a letter of understanding, written procedures contract or MOU acknowledging that a laboratory is willing and able to provide analytical support to the jurisdiction's food program. The document describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.**

Smaller jurisdictions may not have the role to sample.

Labs that meet certain certifications then they will be capable of these tests.

Determine the capacity of your local or state labs. If they cannot provide the testing include the closest FDA lab. (Could provide a list/link of the FDA labs)

b. **The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental**

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laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

This can be included contact list in Part 1

4. **Trace-Back Procedures**

a. **Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.**

a. Is there anything already written for this?

5. **Recalls**
   a. **Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.**

Is there anything already written for this?

b. **When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed**

c. **Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.**

Is there existing documents for this

6. **Media Management**
   a. **The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak for food safety emergency. The policy/procedure should address the coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.**

7. **Data Review and Analysis**

a. **At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food related injury. These periodic reviews of foodborne illness may suggest a need for further investigation and may suggest steps for illness prevention.**

NOTE: This data collection tool could be stated as a Pre-Requisite at the beginning of the Standard. Everything is built on having this data.

The data has been collected so an annual review of the data that is documented will suffice.

Example of how to do data review may be found in your existing inspection/complaint database (Excel data collection tool as an example)

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b. **The review is conducted with prevention in mind and focuses on, but is not limited to the Food Borne Disease Outbreaks, Suspect Foodborne Outbreaks and Confirmed Foodborne Disease Outbreaks in the following:**
   - **Single establishment**
   - **Same establishment type**
   - **Implicating the same food**
   - **Associated with similar food preparation processes**

   Also determine:
   - **Number of confirmed foodborne disease outbreaks**
   - **Number of foodborne disease outbreaks (this seems the same as above??)**
   - **Number of suspect foodborne disease outbreaks**
   - **Contributing factors most often identified**
   - **Number of complaints involving real and alleged threats of international food contamination.**
   - **Number of complaints involving the same agent**
   - **Number of complaints involving unusual agents when identified.**

   This section can seem overwhelming especially for jurisdictions that rarely have outbreaks, suspected outbreaks or confirmed outbreaks and all the other things mentioned above. As long as you have a data collection tool with these fields to show that if it ever happens you would have the data to review.

Many jurisdictions will not have enough complaints to collect this data. Data collection tool will need to have these fields in the event the data is there.

c. **In the event that there have been no food-related illness or food-related injury outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne illness disease outbreak and include on-site inspection, sample collection and analysis. A mock investigation must be completed once per year when no foodborne disease outbreak investigation occur.** (this last sentence is redundant to me)

   Is the on-site piece required? The on-site requirement seems onerous

Outcome

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and food-related injury* complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, food-related injury*, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts or MOU's with the supporting laboratories.

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5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

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STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine ten activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
   - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
   - Satellite Broadcasts.
6. Foodborne illness training referenced in the Crosswalk Requirements for Foodborne Illness Training Programs - Standard 5.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury, and outbreaks.

Requirement Summary

The program has an established system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. Investigative Procedures

a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food-related injury*. The procedures clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.

c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.

d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.

e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.

f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.

g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.

h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.

i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.

b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks* with CDC.

3. Laboratory Support Documentation

a. The program has a letter of understanding, written procedures, contract, or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.

b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak, or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.

b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.

c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.

b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:

1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment;
2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type;
3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food;
4) Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food preparation processes;
5) Number of confirmed foodborne disease outbreaks*;
6) Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*;
7) Contributing factors most often identified;
8) Number of complaints involving real and alleged threats of intentional food contamination; and
9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak* investigations occur.

Note: *Regulatory Programs are encouraged to refer to the Crosswalk - Requirements for Foodborne Illness Training Programs located on the CFP website at www.foodprotect.org under the Conference-Developed Guides and Documents tab and to also participate in the CDC National*

Environmental Assessment Reporting System (NEARS). The Crosswalk is a table that identifies training resources that correlate to the requirements listed in Standard 5. NEARS is designed to provide a more comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NEARS: http://www.cdc.gov/nceh/ehs/nears/index.htm)

Outcome

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and food-related injury* complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, food-related injury*, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts, or MOUs with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

*[*Note: See the Standards Definitions for the meaning of these defined terms.]*

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COMMITTEE NAME: Program Standards (PSC), Subcommittee 1

DATE OF REPORT: ☐ ***Initial fall progress report*** ☐***Spring progress report*** ☒ ***Second fall progress report***
Date submitted: 10/31/2022 **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: *Kenesha Williamson and Michael Touhey*

COMMITTEE CHARGE(S):

***Issue* # 2020 -II-017 Charges 1 & 2**

1. Identify inconsistencies in language between all Standards in the Retail Program Standards.
2. Continue review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities.

COMMITTEE WORK PLAN AND TIMELINE:

An introductory meeting in January 2022 followed by bi-weekly meetings January - February 2022 then monthly meetings through September 2022. Workgroup documents will be shared via CFP Microsoft Teams and attached to calendar invitations. Microsoft Teams will be used for presenting workgroup material and reviewing documents, during monthly meetings. The committee's members will be assigned individual Standards to evaluate for discussion within the group. Polls will be forwarded via email, as needed, to voting members to finalize recommendations. Periodic reports will be prepared and submitted in March 2022, July 2022, and October 2022, in accordance with the CFP master calendar.

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:*** January 13, 2022, February 3, 2022, February 17, 2022, March 15, 2022, April 19, 2022, May 31, 2022, June 28, 2022, August 24, 2022, September 8, 2022.

2. ***Overview of committee activities:***

    a. The conference call on January 13, 2022 was used to review the committee charges, determine the timeline for addressing the charges, and it was decided that Microsoft Teams will be used for document sharing. There was preliminary discussion of the Standards and review of poll responses regarding initial feedback on any known gaps within the Standards. The conference call on February 3 addressed charge 2, and a list of training, evaluation and/or certification courses available to food safety inspection officers was reviewed based on the draft created during the last biennium. The conference call on February 17, 2022 addressed charges 1 and 2, and the committee started work on edits to the list of training, evaluation and/or certification courses. The addition and removal of entries to list of courses were completed through screen sharing during the meeting. Committee members provided feedback on their review assignments. Changes to the assignments were made from the feedback and overall experience with the Standards.

    b. At the request of our FDA consultants, a special meeting was held on March 15, 2022 for Standard 6 to discuss the Standardized Key Crosswalk to the 2017 FDA Food Code and the Compliance and Enforcement worksheet. For this discussion, we hosted issue submitter Dan Joseph from State of Colorado. The conference call on April 19, 2022 was another special session which focused on Standard 8. Issue submitter Jo Ann Monroy presented at the meeting to review their staffing model pilot study on Standard 8 – Program Resources. On May 31, 2022 we began discussing the updates from the workgroups to review their assigned Standards. As each workgroup presented, the group screenshared the notes and discussions within the CFP Microsoft Teams folder. On June 28, 2022, the workgroups screenshared notes within the CFP Microsoft Teams folders and discussed possible Issues to be drafted for Standard 2 and 3 in the coming months.

    c. The full committee met on August 18, 2022 to discuss updates from each subcommittee. During the full committee meeting, subcommittee 5 gave us feedback on a Standard 1 Issue from the previous biennium, 2020 II-031. Regarding that Issue, consensus was reached on drafting a new Issue that would assign 2020 II-031 to Program Standards Committee. Program Standards can then continue working on the Issue given that it was originally submitted by AFDO and needs further review within the committee process. During the conference call on August 24, 2022 with the subcommittee, we discussed updates from the workgroups on reviewing Standards 1 through 9 to address Charge 1. The group also discussed the list of training, evaluation, and certification resources for Charge 2. Discussion continued on the proposed CFP Issues and selecting Issue submitters and presenters. We reached consensus on all of the proposed Issues after voting not to proceed with recommending Appendix B-1

be removed from Standard 2. During our final meeting on September 8th, we identified three Standards which still needed to be reviewed for issue recommendations, Standards 1, 7, and 9. To complete charge 1, we reviewed created a table of proposed Issues and discussed public health significance for Issues drafted thus far. The group decided to continue communications via email or phone going forward to finalize their Issues. Individual workgroups would meet again as needed to assist completion of their Issues.

3. ***Charges COMPLETED and the rationale for each specific recommendation:***
    a. Charge 1: We identified gaps and inconsistencies in language between all the Standards in the Retail Program Standards.
        i. Reassign Issue 2020 II-031 to the PSC Committee (see attachment 2.j). Missing Priority and Priority Foundation items will lead to a significant increase of out-of-control foodborne illness risk factors in those jurisdictions that do not fully meet all the provisions in the FDA Food Code.
        ii. Tracking versions of Standard 2 Appendix B-1: Adding a version number and/or revision date to Appendix B-1, will clarify which required courses should appear in FSIO training records. Attachment 2.k shows that Appendix B-1 does not include a version number or revision date.
        iii. Changing Re-Standardization Frequency: Changing the frequency of re-standardization from three years to five years for inspection staff who do not standardize others and maintaining that standardization officers continue to be re-standardized every three years. Agencies are struggling with resources and need to focus on standardizing newer staff instead of the more experienced staff. Staff turnover also has a major impact on meeting Standard 2. For standardization officers, the existing re-standardization frequency of every three years should be maintained.
        iv. Add FD218 to Standard 2 "post" curriculum. Inspectors need proper training to conduct risk-based inspections. Risk-based inspection methodology is not currently included in the key learning objectives of the general education courses in Standard 2. Risk-Based Inspection Methods, FD218, is being considered as an advanced course. But it is foundational (see attachment 2.l). Attachment 2.m shows the key learning objectives for FDA 38 and 39 Basics of Inspection.
        v. Adding language to Program Standard 2 that references the FDA's National Curriculum Standard (NCS) as a blueprint for Food Safety Inspection Officer (FSIO) training. The National Curriculum Standard (NCS) as part of the Integrated Food Safety System (IFSS) identifies the competencies (knowledge, skills, and abilities) needed by regulatory food protection professionals to successfully perform their job functions, whether they are inspecting retail food, manufactured food, animal food, or unprocessed food facilities. See attachment 2.o. The NCS also provides behavioral anchors (performance indicators) that serve to clarify the competencies and can be used for assessment purposes. Attachment 1.b.i shows drafted language about the current NCS within Standard 2.
        vi. Correcting the order of the terms "Validation" and "Verification" in the Standard 3 – Self Assessment and Verification Audit form. The HACCP concepts of "Validation" and "Verification" can be confusing concepts. In addition, the reuse of the terms for a regulatory approval of a submitted HACCP plan adds additional confusion. In both cases, the term "Validation" comes before "Verification". By reversing the terminology (Verification and Validation) in the Standard 3 documents, unnecessary additional confusion can be caused.
        vii. Create Standard 4 Uniform Inspection Program verification audit instructions. Verification auditors do not have standardized instructions on how to conduct a verification audit on Standard 4 which may result in audits not being assessed equally. There is no guidance on:
            - How many retail food inspection staff may fall short of having three field reviews during the five-year self-assessment period and the jurisdiction still meet the Standard (90% of staff for field standardization in Standard 2).
            - How many employee quality assurance records to review.
            - When additional employee quality assurance records may need to be reviewed.
            - The rate of agreement between the verification auditor and the self-assessment to meet the Standard.
        viii. Edits to the primary Standard 5 document and the standards definitions document to correct errors and achieve consistency with the other Standards. Attachments 1.b.ii and 1.b.iii demonstrate suggested changes to Standard 5 and Program Standards Definitions. The following summarizes the proposed edits:
            1. Add the word "foodborne" in the Standard 5 Data Review and Analysis section. The term was unintentionally omitted.
            2. Remove the footnote from Standard 5 page 5-5 and all corresponding asterisks.
            3. Reformat all defined terms in Standard 5 to small caps as shown in Standard 9.
            4. Expand the definition of "Foodborne Disease Outbreak" to establish that both suspect and confirmed outbreaks fit under this term, on page iv of the Program Standards Definitions document.
            5. Expand the definition of "Suspect Foodborne Outbreak", on page vi of the Program Standards Definitions document, to differentiate it from "Foodborne Disease Outbreak" and to establish that it is a foodborne illness outbreak that is not confirmed.
        ix. Establishment file worksheet based on FDA Food Code Form 3-A: Standard 6 requires that the program must demonstrate credible follow-up for each violation noted during an inspection, with particular emphasis being placed on risk factors that most often contribute to foodborne illness and public health interventions intended to prevent foodborne illness. Standard 6 includes a Compliance and Enforcement Establishment File Worksheet based on the risk factors and interventions. Many jurisdictions use regulations based on the FDA Model Food Code and an inspection

report based on the model FDA inspection form found in Annex 7 of the FDA Food Code (Food Inspection Report Form 3-A). Items 1 – 29 on inspection report Form 3-A are based on the risk factors and interventions. An additional Compliance and Enforcement Establishment File Worksheet based on Form 3-A would help jurisdictions more easily assess the required provisions of Standard 6. Attachment 1.b.iv demonstrates suggested changes for an additional Compliance and Enforcement Establishment File Worksheet.

x. Update Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code with the attached version and replacing "Quick Reference Applicable Food Code Risk Factor Provisions" with "Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code". Attachment 1.b.v demonstrates suggested changes to the Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code. This document having a file name and website link title which differ from the document's title is confusing. The crosswalk lists risk factors and public health interventions as identified on the model FDA inspection form found in Annex 7 of the 2017 FDA Food Code (Food Inspection Report Form 3-A) with corresponding Food Code references. It serves as a resource for jurisdictions conducting a self-assessment of Standard 6 in making comparisons with their code against the 2017 FDA Food Code. The current version of this document has some errors including:
    - The formatting references for PIC,
    - The references for adequate handwashing sinks, and
    - A typo in Consumer Advisory provided for raw/undercooked foods.

xi. Define Standard 8 Verification Audit parameters. Updated language in Standard 8 for "Section 1: Staffing Levels" was much needed. There are now three choices/options within the Standard for ways to ensure that there is adequate staff to ensure inspectional and surveillance system needs are met to reduce risk factors. Two of the choices have clearly defined metrics and parameters around conformance or non-conformance. The third option is vague.

b. Charge 2: We continued review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities. See Attachment 2.n.

4. ***Status of charges still PENDING and activities yet to be completed:***

N/A

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.***
☐ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

ATTACHMENTS:

1. ***Content Documents:***
    a. ***Committee Member Roster:*** ☐ ***See changes noted above under "requested action"*** ☒ ***No changes to previously approved roster***
    "Committee Members Template" (Excel) available at: www.foodprotect.org/work/ Committee roster to be submitted as a PDF attachment to this report.
    b. ***Committee Generated Content Documents (OPTIONAL):*** ☐ ***No draft content documents submitted at this time***
        i. Issue 5 Attachment Draft Program Standard 2 - NCS Added
        ii. Issue 8 Attachment Program Standards 2022 Standard 5 Edits
        iii. Issue 8 Attachment Program Standards 2022 Definitions Edits
        iv. Issue 9 Attachment Draft Standard 6 Establishment File Worksheet - Food Code Form 3A Based
        v. Issue 10 Attachment Draft Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code
2. ***Supporting Attachments (OPTIONAL):*** ☐ ***Not applicable***
    a. Meeting #1 Minutes 01/13/2022
    b. Meeting #2 Minutes 02/03/2022
    c. Meeting #3 Minutes 02/17/2022
    d. Meeting #4 Minutes 03/15/2022
    e. Meeting #5 Minutes 04/19/2022
    f. Meeting #6 Minutes 05/31/2022
    g. Meeting #7 Minutes 06/28/2022
    h. Meeting #8 Minutes 08/24/2022
    i. Meeting #9 Minutes 09/08/2022
    j. Issue 1 Attachment CFP Issue 2020 II-031

k. Issue 2 Attachment 2022 Program Standard 2 Appendix B-1
l. Issue 4 Attachment AFDO - Risk-Based Inspection Methods in Retail FD218
m. Issue 4 Attachment Course Descriptions and Objectives - FDA 38 and 39
n. Charge 2 Training Evaluation and Certification Initiatives
o. Issue 5 Attachment IFSS Framework Basic Advanced Feb 2021

Template approved: 7/13/2021

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COMMITTEE NAME ***Program Standards (PSC), Subcommittee 2***

DATE OF FINAL REPORT: *10/29/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: DeBrena Hilton and Jennifer Hutson, Co-chairs

COMMITTEE CHARGE(S):

Issue # Issue # 2020 II-017

3. Maintain the "Crosswalk – Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training.

Issue # Issue # 2020 II-033

5. Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS), Environmental Assessment Training Series (EATS), and Council to Improve Foodborne Outbreak Response (CIFOR) to consider inclusion of specific components.

COMMITTEE WORK PLAN AND TIMELINE: Committee members initially began reviewing documents outlined in Issues #2020 II-017 and #2020 II-033 by splitting out sections amongst our workgroup. We initially planned to meet monthly to report any updates that were needed to the documents selected. During our second meeting, we decided to review of certain documents individually and then report back in July with any needed updates.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   Sub-committee 2 met via conference call on April 19, 2022; July 19, 2022.

   The subcommittee found that there weren't any changes needed to be made to the Crosswalk or NEARS, EATS, and CIFOR that would necessitate changes at this time. Forwarded the following recommendations to PSC Subcommittee 4:

   - *Recommend that the Crosswalk be referenced as a resource document in VNRFRPS - Standard 2 & Standard to bring more awareness to the document.*
   - *Committee recommended that the reiterations of the Crosswalk posted on CFP website be updated so that only the most current version be posted to alleviate any confusion.*
   - *Recommend that NEHA IFITT-RR (directed to food industry), Epi-Ready course, and all other documents/resources be easier to find for review.*

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a.

3. ***Charges INCOMPLETE and to be continued to next biennium:***
   a. Issue 2020 II-033 Charge 5 has been submitted for continuation in the next biennium.
   b. Committee recommendation is that charges be continued to next biennium.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.
2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name:*** **List of content documents submitted with this Issue:** ***Committee Member Roster:***

☐ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

b. List of supporting attachments: ☐ ***Not applicable***

(1)

a. ***Committee Issue #2***:

b. ***Committee Issue #3***:

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COMMITTEE NAME PSC Subcommittee 3 Final Report

DATE OF FINAL REPORT: *11/1/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Catherine Feeney and Amanda Anderson (Co-chairs)**

COMMITTEE CHARGE(S):

Issue # *2020 II-023*

1. *The Program Standards committee and FDA staff continue to explore the feasibility of incorporation of plan review functions into the standards either as a stand-alone standard or inserted into the existing standards in the Voluntary National Retail Food Regulatory Program Standards.*
2. *Acknowledgement of the Preliminary Plan Review Proposal document to be utilized as a starting point for the 2020-2022 Program Standards Committee work on this issue.*

COMMITTEE WORK PLAN AND TIMELINE:

COMMITTEE ACTIVITIES: **Dates of committee meetings or conference calls:**

1. ***Overview of committee activities:***

   1/25, 2/8, 2/28, 3/21, 4/11, 4/25, 10/25

   Reviewed previous committee's work. Utilized Preliminary Plan Review Proposal as a starting point to the discussion.

   Discussed options for adding Plan Review as a separate standard or incorporating it into one or more existing Standards.

   Unanimously agreed to include plan review into Standard 3- Inspection Program based on HACCP Principles.

   Worked on wording for the Standard Requirement, Documentation, and accompanying Self-Assessment and Verification Audit.

   Discussed options for agencies that do not do plan review independently or at all so that Standard 3 could still be met.

   Deliberated expanding the scope of plan review to include food safety plans as well as construction, equipment, and HACCP plans.

   Met with Food Safety Management Committee to align Plan Review subcommittee's work.

   Plan Review subcommittee met to decide on incorporating the FSMS terminology and concept into the plan review element being proposed for Standard 3.

   Two issues that been drafted:

   1- a. Request that Plan Review Committee be reformed to work on updating the CFP 2016 Plan Review for Food Establishments document, b. Align work with the Food Safety Management System Committee

   2- a. Add plan review to Standard 3. Revise the SA/VA to reflect the addition.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   - **a.** *Acknowledged Preliminary Plan Review Proposal document to be utilized as a starting point. This approach was taken to leverage work of previous plan review committee.*
   - **b.** *Recommendation to include Plan Review as an element of Standard 3. Language was added to the Standard and also the Self-Assessment and Verification Audit to reflect the addition for Council II's consideration. Plan review is a critical step in ensuring that an establishment is set up to ensure safe food. Submission, review, and approval of a food safety*

management system, construction plan, equipment specifications and location are key to a food businesses success in operating a safe food establishment.

c.

3. ***Charges INCOMPLETE and to be continued to next biennium:***

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.

2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name:*** **List of content documents submitted with this Issue:** ***Committee Member Roster:***

☐ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

b. **List of supporting attachments:** ☐ ***Not applicable***

(1)

Committee Issue #2*:*

Request that Plan Review Committee be reformed to work on updating the CFP 2016 Plan Review for Food Establishments document, Align work with the Food Safety Management System Committee

Committee Issue #3:

Recommend including Plan Review as an element of Standard 3. Language was added to the Standard and also the Self-Assessment and Verification Audit to reflect the addition for Council II's consideration. Plan review is a critical step in ensuring that an establishment is set up to ensure safe food. Submission, review, and approval of a food safety management system, construction plan, equipment specifications and location are key to a food businesses success in operating a safe food establishment.

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COMMITTEE NAME PSC Subcommittee 4 Final Report

DATE OF FINAL REPORT: *11/1/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Elizabeth A Nutt Co-Chair, Jeff Lindholm, Co-Chair**

COMMITTEE CHARGE(S):

Issue # 2020-II-033

1. Conduct a thorough review of Standard 5 "Foodborne Illness and Food Defense Preparedness and Response of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);
2. The review should include comparing the Standard to other similar FDA standards in food;
3. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program;
4. Review Standard 5 "Data Review and Analysis" from a sampling of jurisdictions to determine if certain data analysis requirements typically have no or such limited data to make the information not valuable;
5. ~~Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS), Environmental Assessment Training Series (EATS), and Council to Improve Foodborne Outbreak Response (CIFOR) to consider inclusion of specific components.~~ This Charge was reassigned to Subcommittee #2.
6. Propose amendments to Standard 5 of the VNRFRPS;
7. Report back committee findings and recommendations to the next Biennial Meeting.

COMMITTEE WORK PLAN AND TIMELINE:

Reviewing Charges
Comparing VNRFRPS (Retail Standards) and MFRPS (Manufacturing Standards) to determine if they can be aligned and achieve desired outcomes
Soliciting input from enrolled jurisdictions about concerns with Program Standard 5 and possible guidance on solutions.

COMMITTEE ACTIVITIES: **Dates of committee meetings or conference calls:**

1. ***Overview of committee activities:***
   Determined that Standard 5 was aligned with achieving the best approach to response to foodborne illness outbreaks but a Road Map to assist jurisdictions on how to meet the standard would be a resource to be available as an addendum. Road Map would provide steps to develop written procedures, MOU's, set up relationships with other agencies involved with outbreak response and tools to collect and track data.
2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. Charge 1- Review of Standard 5 done by committee; no action
   b. Charge 2-Compared Retail food Standard 5 to Manufactured Foods Standards; no action.
   c. Charges 3 & 4- After reviewing these charges the committee determined that the creation of a Road Map would be the approach to assist jurisdictions in assessing the Standard.
3. ***Charges INCOMPLETE and to be continued to next biennium:***
   a. The subcommittee was unable to complete the road map and recommends continuation of Issue 2020 II-023. Specifically, the committee identified that a roadmap outlining the requirements of Standard 5 would be beneficial to assist enrolled jurisdictions in conducting self-assessments. Templates and examples of required documentation would accompany the roadmap. A first draft of the roadmap has been drafted but was not able to be finalized during this biennium.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☐ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☒ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name:*** **List of content documents submitted with this Issue:** ***Subcommittee Member Roster:***

☐ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

Copy of Subcommittee 4 rost

(1) ***Other content documents: Subcommittee Minutes***

Copy Minutes 2.23.22.pdf

Minutes 4.18.22 (002).docx

Minutes 5.25.22.docx

Minutes 6.22.22.docx

Minutes 7-27-22.docx

Minutes 8_31_22.docx

Minutes 9_23_2022.docx

Minutes 10_20_22.docx

b. **List of supporting attachments:** ☐ ***Not applicable***

(1) **Draft Road Map:**

STD 5 RoadMap DRAFT 10_2022.docx

(2) **Draft Data Collection Template:**

Data Collection Template.xlsx

Issue 2020-II-017

Charge 2: Initiatives (existing, new, or under development) involving the training, evaluation and/or certification available to Food Safety Inspection Officers (FSIO):

Training – Existing

ORAU Pre

- Public Health Principles FDA 36
- Overview of Microbiology MIC01
- Food Microbiological Control 2A: Gram-Negative Rods MIC02
- Food Microbiological Control 2A: Gram-Positive Rods and Cocci MIC03
- Food Microbiological Control 2A: Foodborne Viruses MIC04
- Food Microbiological Control 4: Foodborne Parasites MIC05
- Food Microbiological Control: Mid-Series Exam MIC16
- Food Microbiological Control 5: Controlling Growth Factors MIC06
- Food Microbiological Control 6: Control by Refrigeration and Freezing MIC07
- Food Microbiological Control 7A: Control by Thermal Processing MIC08
- Food Microbiological Control 7B: Control by Pasteurization MIC09
- Food Microbiological Control 10: Aseptic Sampling MIC13
- Food Microbiological Control 10: Cleaning and Sanitizing MIC15
- Basic Food Law for State Regulators FDA35
- Basics of Inspections: Beginning an Inspection FDA38
- Basics of Inspections: Issues and Observations FDA39
- An Introduction to Food Security Awareness FD251 **(https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness)** NOTE: Required Exam is available via **www.compliancewire.com**
- Communication Skills for Regulators

ORAU Post

- An Introduction to Food Security Awareness MIC10
- Food Microbiological Control 8: Technology-based Food Processes MIC11
- Food Microbiological Control 9: Natural Toxins MIC12
- Basics of HACCP: Overview of HACCP FDA16
- Basics of HACCP: Prerequisite Programs and Preliminary Steps FDA17
- Basics of HACCP: Prerequisite Programs and Preliminary Steps FDA18
- Foodborne Illness Investigations 1: Collecting Surveillance Data FI01
- Foodborne Illness Investigations 2: Beginning an Investigation FI02
- Foodborne Illness Investigations 3: Expanding the Investigation FI03
- Foodborne Illness Investigations 4: Conducting a Food Hazard Review FI04
- Foodborne Illness Investigations 5: Epidemiological Statistics FI05
- Foodborne Illness Investigations 6: Final Report FI06

- Food Allergens (CC8029W) Course must be accessed through FDA Pathlore at**:** **(https://orauportal.fda.gov/stc/ora/psciis.dll?linkid=436613&mainmenu=ORA&top_frame=1)**

FEMA courses can be accessed at: **http://training.fema.gov/IS/NIMS.asp**

- Introduction to Incident Command System IS-100.C
- ICS for Single Resources and Initial Action Incidents IS-200.C
- NIMS an Introduction IS-700.B

FDA ComplianceWire

- Food Code Chapter 7: Poisonous and Toxic Materials FD112 Food Code (FDAFC01)
- Food Code Chapter 1: Purpose and Definitions FD112 Food Code (FDAFC02)
- Food Code Chapter 3: Part I FD112 Food Code (FDAFC03)
- Food Code Chapter 5: Water, Plumbing, and Waste FD112 Food Code (FDAFC04)
- Food Code Chapter 3: Part II FD112 Food Code (FDAFC05)
- Food Code Chapter 3: Part III FD112 Food Code (FDAFC06)
- Food Code Chapter 2: Supervision FD112 Food Code (FDAFC07)
- Food Code Chapter 4: Part I FD112 Food Code (FDAFC08)
- Food Code Chapter 6 FD112 Food Code (FDAFC09)
- Food Code Chapter 4: Part II FD112 Food Code (FDAFC10)
- Food Code Chapter 8: Enforcement and Annex 1 FD112 Food Code (FDAFC11)
- HACCP (CC8033W)
- Employee Hygiene: Food Service (FOOD1)
- HACCP (FOOD5)
- Preventing Microbial Cross-Contamination (FOOD3)

IFPTI Courses on ComplianceWire

- Regulatory Program Foundations (CC8021W)
- Allergens (CC8029W)
- Biological Hazards (CC8028W)
- Biosecurity (CC8023W)
- Communication Skills (CC8030W) Course must be accessed through FDA Pathlore at**:** **(https:// orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&mainmenu=ORA&top_frame=1)**
- Data & Information Systems (CC8017W)
- Emergency Response
- Environmental Hazards (CC8027W)
- HACCP (CC8033W)
- Imports (CC8034W)
- Integrated Food Safety System (CC8018W)
- Inspections, Compliance, & Enforcement (CC8019W)
- Investigation Principles (CC8020W)

- Jurisdiction (CC8037W)
- Labeling (CC8038W)
- Laws, Regulations, Policies, & Procedures (CC8039W)
- Personal Safety (CC8031W)
- Pest Control
- Plumbing
- Preventive Controls (CC8040W)
- Professionalism (CC8025W)
- Public Health Principles (CC8026W)
- Recalls (CC8041W)
- Sampling (CC8035W)
- Sanitation Practices (CC8032W)
- Traceability (CC8042W)
- Transportation (CC8036)

FDA Pathlore

- Fermentation at Retail (FD8009W)
- Curing, Smoking, Drying of Meat, Poultry and Fish and the Processing of Fermented Sausages (FD8005W)
- Reduced Oxygen Packaging at Retail (FD8004W)
- Juicing at Retail (FD8008W)
- Shellfish Tanks at Retail (FD8007W)
- Custom Processing of Meats at Retail (FD8006W)
- HACCP (CC8033W)
- Plumbing Controls for Commercial Food Establishments (CC8001W)
- Pest Control in Food Establishments (FD180W100)

Instructor Led Courses

- FD112 – Food Code
- FD218 - Risk-Based Inspection Methods in Retail
- FD204 - Temporary Food Establishments
- FD207 – Plan Review for Food Establishments
- FD312 - Special Processes at Retail
- FD215 - Managing Retail Food Safety
- ER310 - Food Safety Issues in the Event of Disasters
- EPI-Ready in person training through (NEHA/Centers of Excellence)
- AFDO – Environmental Sampling in Retail Food Facilities

In-house training provided by State/Local Health Departments:

- Report writing
- State-specific
- Software
- Compliance and enforcement

- Risk-based inspection methods
- HACCP (application)
- Plumbing/backflow
- Consistency training (marking under same number)
- Meat/poultry inspection
- Scenario/mock inspection/role playing
- Ethnic Food Book
- Temporary Food Establishment training
- Mobile Vending training
- NAU Back Country Excursions
- Food Service During Disasters

Training Resources

- AFDO Ethnic Food CD/App
- AFDO Salvage Food
- AFDO Dented Cans
- AFDO Incubator (Community/Shared) Kitchens
- AFDO Cottage Food
- Centers of Excellence (COE) food safety tools
- CDC EATS 101
- CDC EATS 102

Evaluation

- CFP Training manual forms for new hires
- Standard 4 - 20 Quality Elements
- Standardization

Certification

- NEHA Registered Environmental Health Specialist/Registered Sanitarian (REHS/RS)
- NEHA Certified Professional - Food Safety (CPFS)
- NEHA Certified in Comprehensive Food Safety (CCFS) Credential
- NEHA Certified Foodborne Outbreak Investigator (CFOI)
- HACCP Alliance – Certified HACCP Manager
- NSF – Certified HACCP Manager
- ASQ (American Society for Quality) Root Cause Analysis Training
- 40 Hour HAZWOPER
- ANSI Food Safety Manager

Post Event Data

Retail Program Standards Symposium

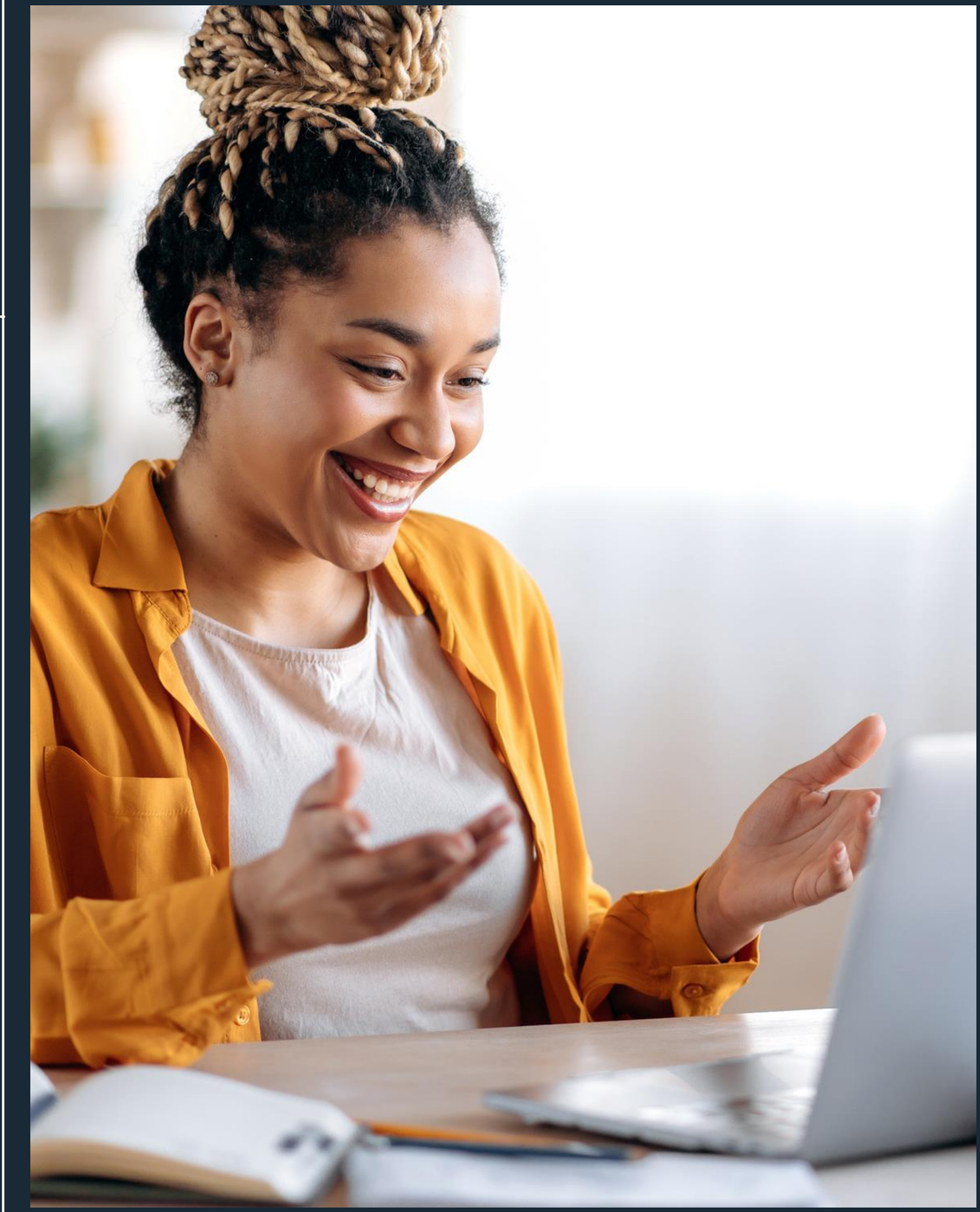
Presented by the NEHA-FDA RFFM Grant Program
in collaboration with the Conference for Food Protection

Contents

- Introduction
- Total Registrations
- Total Attendees
- Attendees by Session & Exhibit Hall Sessions
- RFFM Attendees
- Attendees by Agency
- Attendees by State
- Key Findings

Introduction

The following data was compiled from the 2022 Retail Program Standards Symposium (RPSS). This data includes total registrations for the RPSS and total attendees. Further detail is provided for attendees by session, to breakdown of attendees by agency classification, by region, and then by localities.



Registrations

958

Total RPSS Registrations

Includes all Registered Individuals
Does not include Speakers, Panelists, Moderators, or Staff

Attendees

755

Total RPSS Attendees

Includes all registered individuals that attended all or part of the RPSS
Does not include Speakers, Panelists, Moderators, or Staff

78.8% of Registrants

Day 1 Sessions

Session	Attendees
Welcome, Keynote Address & General Session	653
Track 1 Session: Roadmap for Success; Why Enroll in RPS?	227
Track 2 Session: Technology to Assist with Maintenance of RPS Records/ Supporting Docs	221
Track 3 Session: Sustaining RPS Activities/Having a Succession Plan	134
Day 1 Wrap Up Session	318

Day 2 Sessions

Session	Attendees
Welcome & General Session	586
Track 1 Session: What is Initial Self-Assessment; SA/VA Gap Analysis Tool; Continuous Strategic Improvement Plan (CSIP)	300
Track 2 Session: Self-Assessment & Verification Audit Resources; How to Find an Auditor	149
Track 3 Session: Mentorship Program	105
Day 2 Wrap Up Session	277

Day 3 Sessions

Session	Attendees
Welcome & General Session	524
Track 1 Session: Mentorship Programs (NACCHO)	127
Track 2 Session: What Does a Retail Program Standards Coordinator Do?	214
Track 3 Session: Retail Program Standards Networks/Champions	132
Day 3 Closing Session	264

Exhibit Hall Sessions

Session	Day 1	Day 2	Day 3
Retail Program Standard 1	117	45	27
Retail Program Standard 2	87	65	41
Retail Program Standard 3	37	52	30
Retail Program Standard 4	41	50	50
Retail Program Standard 5	44	59	49

*Exhibit Hall Session numbers are reflective of session page visits

Exhibit Hall Sessions

Session	Day 1	Day 2	Day 3
Retail Program Standard 6	21	46	36
Retail Program Standard 7	23	34	46
Retail Program Standard 8	13	25	27
Retail Program Standard 9	30	41	30

*Exhibit Hall Session numbers are reflective of session page visits

Exhibit Hall Sessions

Session	Day 1	Day 2	Day 3
Administrative Procedures	22	22	10
Comprehensive Strategic Improvement Plan (CSIP)	43	39	31
Mentorship	14	9	14
National Environmental Public Health Internship Program (NEPHIP)	12	4	7

*Exhibit Hall Session numbers are reflective of session page visits

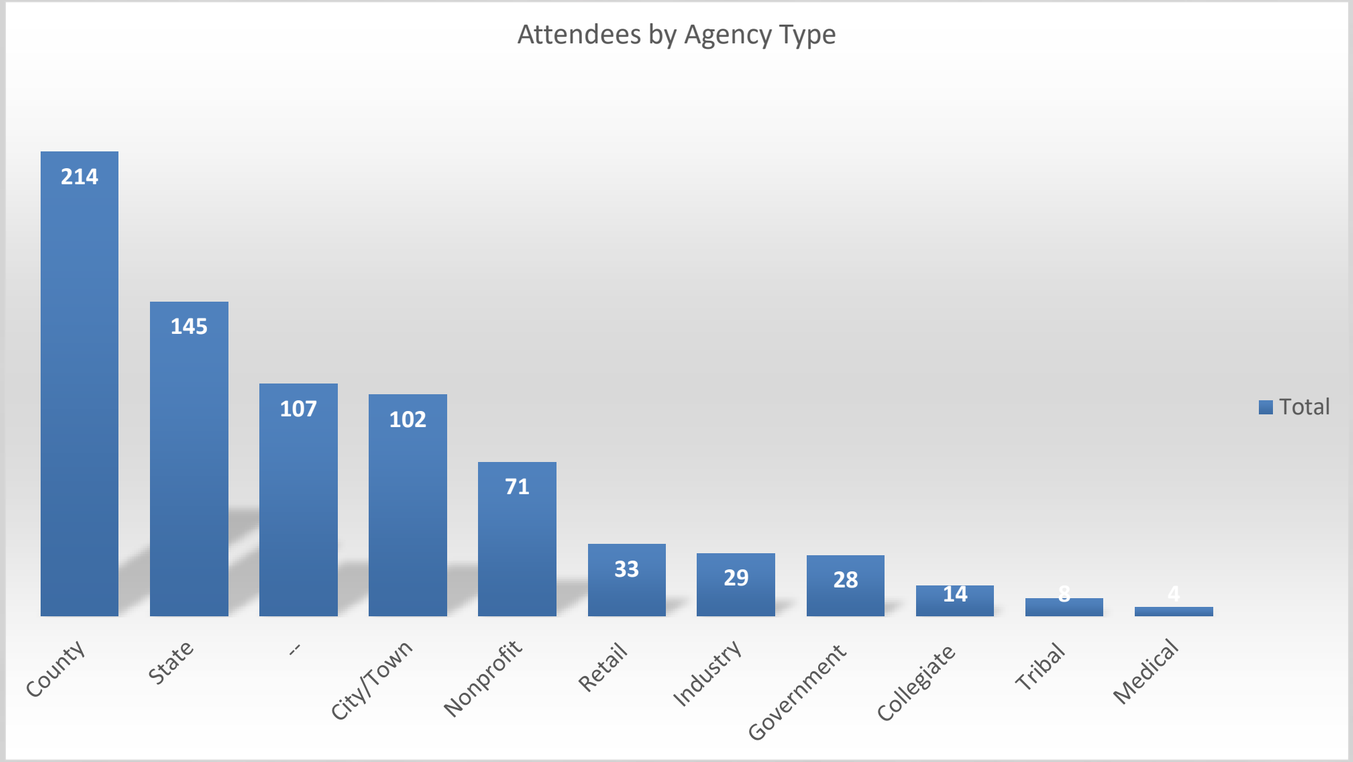
RFFM Attendees

Attendees	Registered & Attended RPSS
RFFM Subawardees	96
Registered in RFFM Portal (not Awarded)	17
TOTAL	113

Attendees by Agency

Includes Attendees counts by their respective agency type

Attendees from County agencies far exceeded the other categories, followed by State and City/Town agencies.

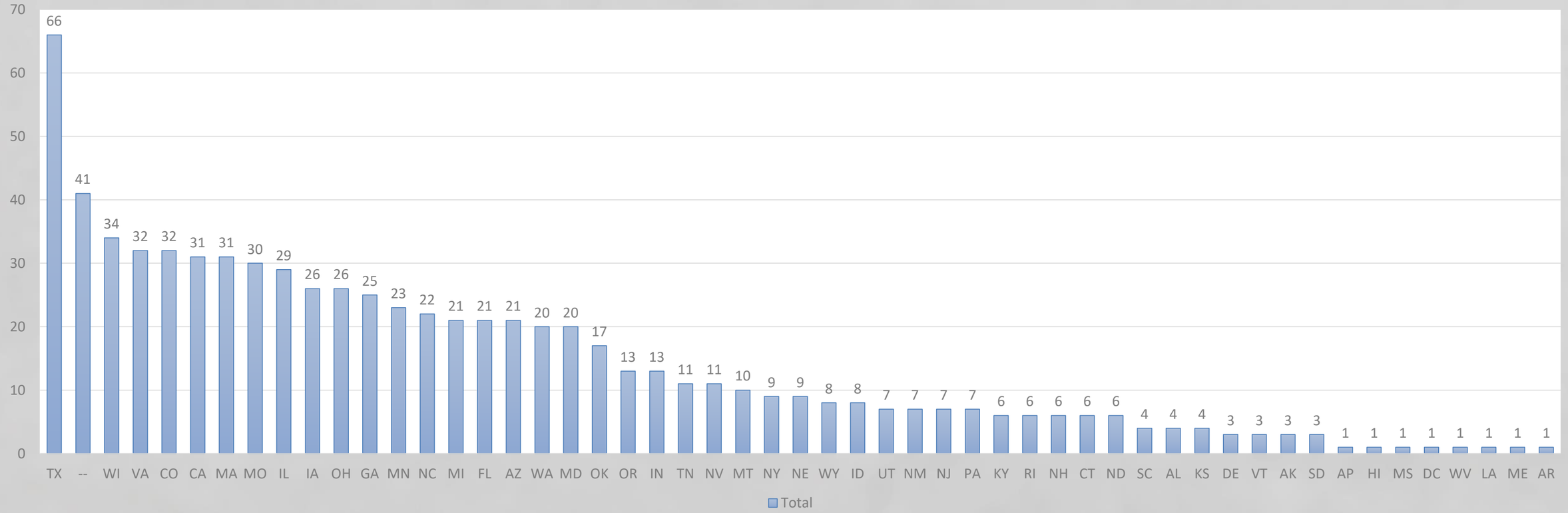


Attendees by State

Distribution of Attendees by State

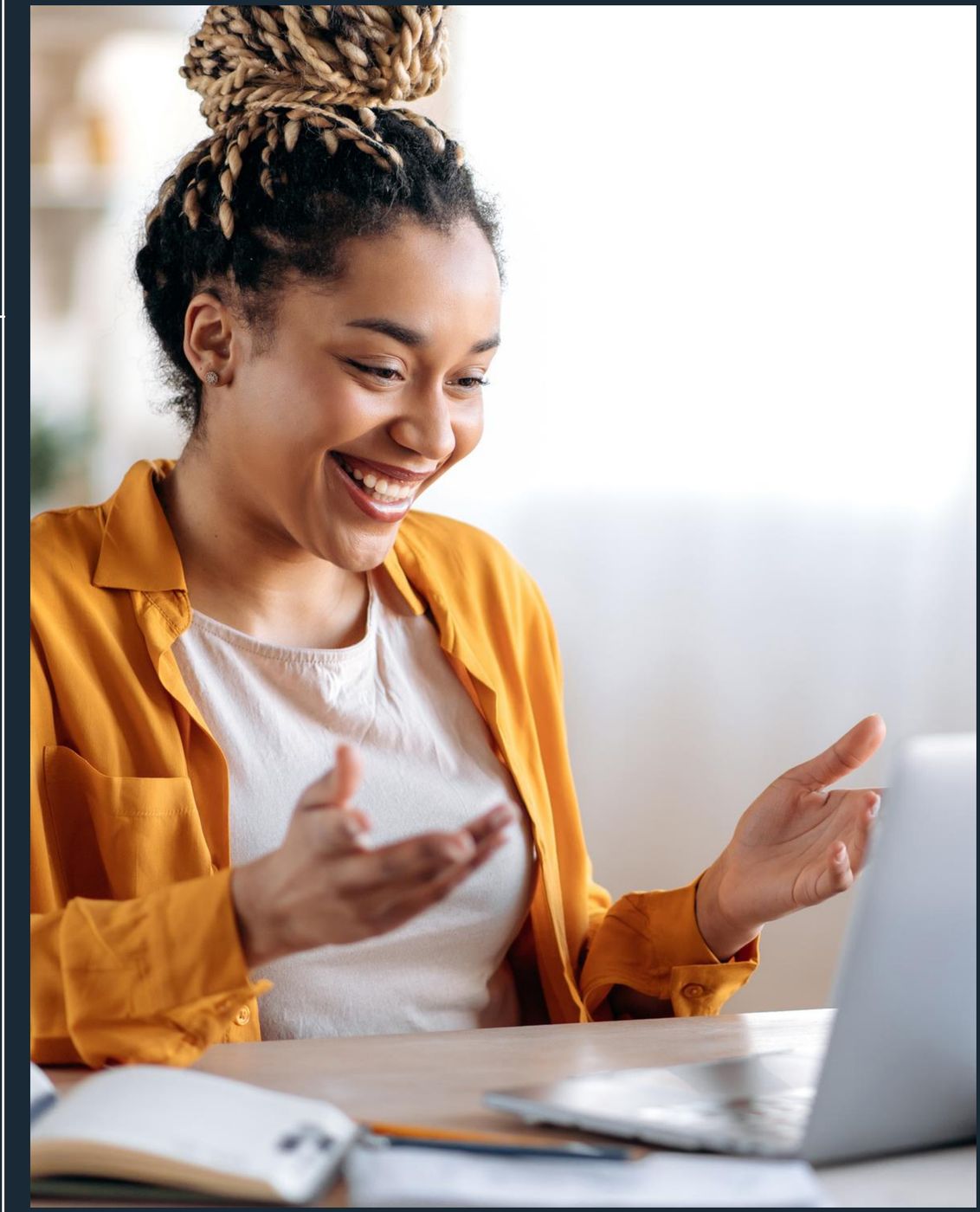
Includes all registered individuals that attended all or part of the RPSS

Most attendees came from the Texas, followed by Wisconsin, Virginia, and Colorado



Key Findings

The following data was compiled from the survey responses collected thus far. A Comprehensive Evaluation Report will be Distributed Separately.



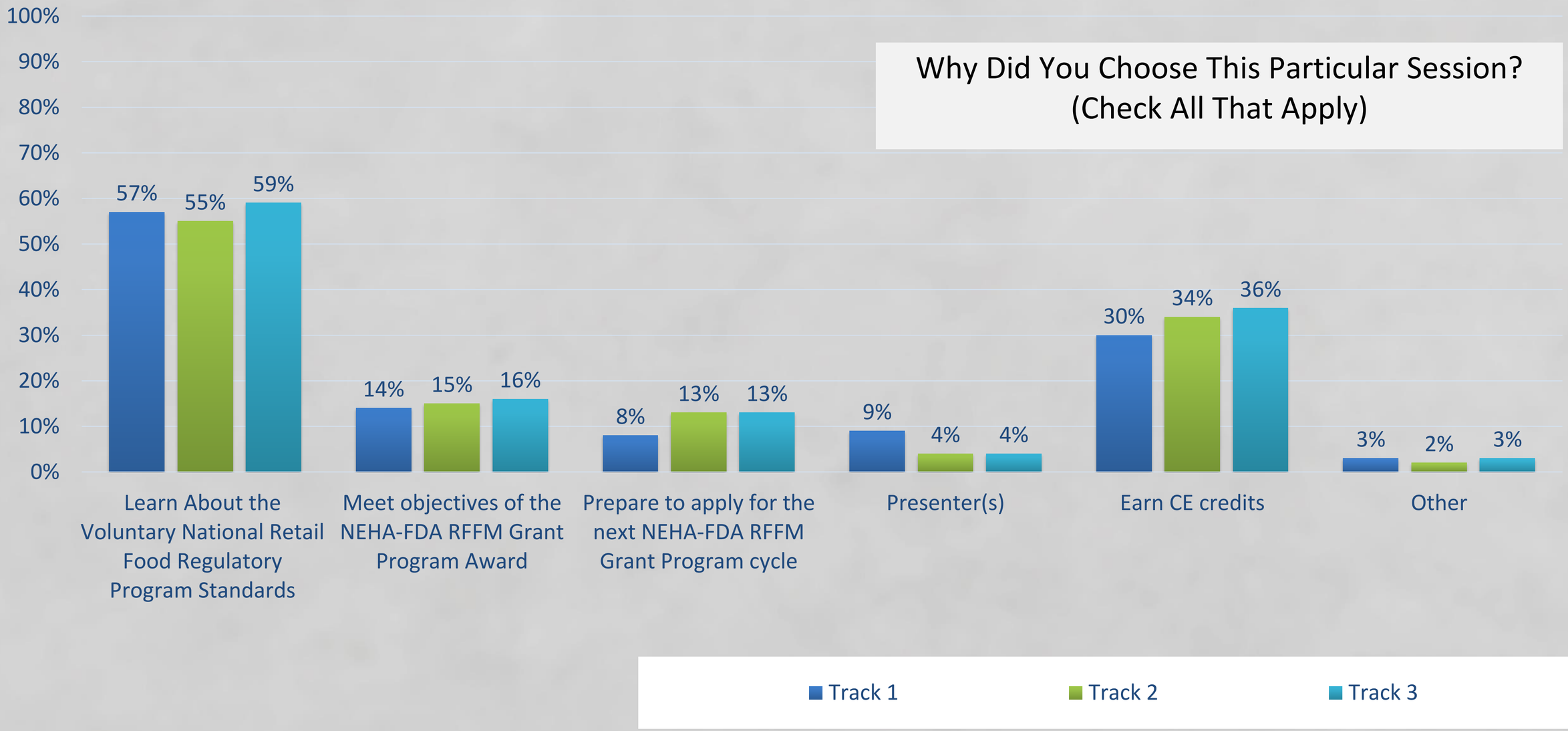
Response Rates

Sessions	June 7	June 8	June 9
Track 1 Survey	144 of 227 (63%)	147 of 300 (49%)	64 of 127 (50%)
Track 2 Survey	104 of 221 (47%)	81 of 149 (54%)	89 of 214 (42%)
Track 3 Survey	101 of 134 (75%)	59 of 105 (56%)	70 of 132 (53%)

Final Exit Questionnaire

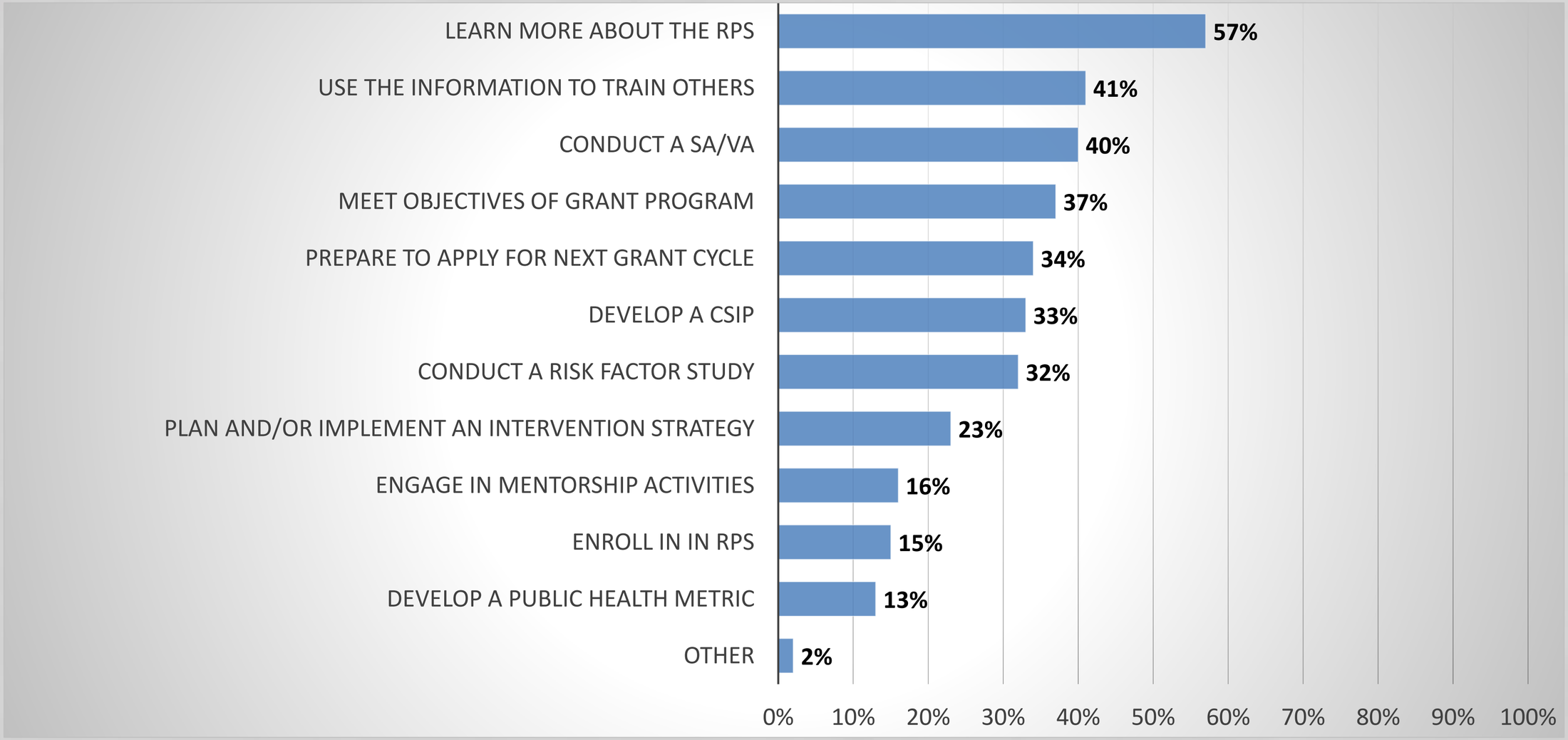
n=262 responses of 755 attendees
(35% response rate)

Reasons for Choosing Sessions- Tracks 1-3



Intention to Apply Information

How do you and/or your organization plan to apply some or all of the information learned from the RPSS? (Check All That Apply)

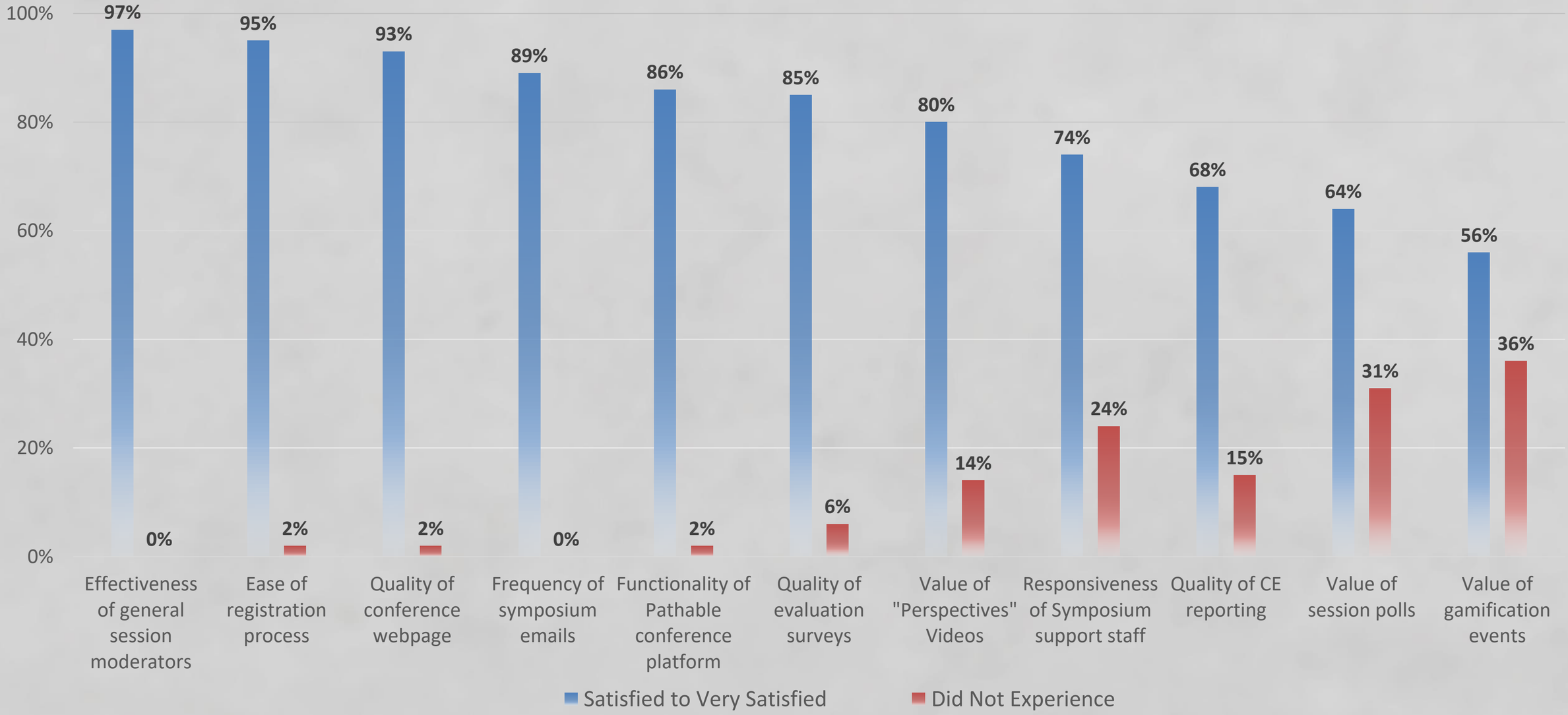


Note: From Final Exit Questionnaire

Satisfaction with Conference Features

Rate Your Satisfaction with the Following Conference Features

("Satisfied to Very Satisfied" Shown Below)



Note: From Final Exit Questionnaire

Conclusion

STANDARD 1 REGULATORY FOUNDATION

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STANDARD 1 REGULATORY FOUNDATION

This standard applies to the regulatory foundation used by a retail food program. Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment.

Requirement Summary

The regulatory foundation includes provisions for:

1. The public health interventions contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code;*
2. Control measures for the risk factors known to contribute to foodborne illness;
3. Good Retail Practices (GRP's) at least as stringent as the *Food Code* edition as specified in 1 above; and
4. Compliance and enforcement at least as stringent as the selected provisions from *Food Code* and Annex 1 of the *Food Code* edition as specified in 1 above.

Description of Requirement

A. *Food Code* Interventions and Risk Factor Control Measures

The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*. Jurisdictions that meet Standard 1 but who may become noncompliant due to the release of a new edition of the *Food Code* are considered to continue meeting the Standard for a period of two years from the release date of the new *Food Code* edition in order to complete the process of updating its regulations.

To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part I*, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations." For initial listing, the regulatory foundation must contain at least 9 of the 11 interventions and risk factor controls. In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.

B. Good Retail Practices

The regulations contain provisions that address Good Retail Practices that are at least as stringent as those described in the edition of the *Food Code* as specified in A. To meet this element of the Standard, regulations must have a corresponding requirement for 95 percent of the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part II*, from #12 "Personnel" through #37 "Variance for Smoking."

C. Compliance and Enforcement

The regulations contain provisions that address Compliance and Enforcement requirements that are at least as stringent as those contained in the edition of the *Food Code* as specified in A. To meet this element of the Standard, regulations must have a corresponding requirement for each of the *Food Code* sections as listed in the *Standard 1: Self-Assessment Worksheet for Part III*, items 1 through 12; except item 12 pertaining to "Legal Remedies," where only one of the sections pertaining to criminal, injunctive, or civil penalties is required.

Outcome

The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

Documentation

The quality records needed for this standard include:

1. The statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that govern the operation of a retail food establishment; and
2. The completed *Standard 1: Program Self-Assessment and Verification Audit Form*.
3. The completed *Standard 1: Self-Assessment Worksheet* for:
   - Part I – *Food Code* Intervention and Risk Factor Controls
   - Part II – Good Retail Practices
   - Part III – Compliance and Enforcement

Conference for Food Protection
2020 Issue Form

Issue: 2020 II-031

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Standard 1 Update to Require 80% of Certain Provisions

Issue you would like the Conference to consider:

Many times policy makers such as state legislatures and others outside the retail food program make decisions that impact the ability of the retail food program to meet all of the interventions and risk factors. This proposes changing the evaluation component to eighty percent adopting a percentage standard similar to the Good Retail Practices and not requiring a full-adoption of all invention and risk factors after the second self-assessment. For example, a legislature may choose to not ban barehand contact of ready-to-eat foods and all regulatory programs with the state automatically do not meet one of the of the 11 areas and after the second self-assessment would no-longer meet the Standard 1, because of an action completed un-related to the conduct of the regulatory program.

Public Health Significance:

This Standard currently is evaluating not only the regulatory program, but also decisions policy makers are making outside the regulatory programs control. The revisions allows programs to conform to the Standard if 80% of currently 9 to 11 of the Foodborne illness risk factors and public health interventions are adopted. While we absolutely support full adoption of the Code, the Standards already allow for this lower number for the first two self-assessments and the amendment seeks to eliminate the subsequent requirement for 100% adoption.

Recommended Solution: The Conference recommends...:

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard 1 - Regulatory Foundation be amended as follows:

Many times policy makers such as state legislatures and others outside the retail food program make decisions that impact the ability of the retail food program to meet all of the interventions and risk factors. This proposes changing the evaluation component to eighty percent adopting a percentage standard similar to the Good Retail Practices and not requiring a full-adoption of all invention and risk factors after the second self-assessment. For example, a legislature may choose to not ban barehand contact of ready-to-eat foods and all regulatory programs with the state automatically do not meet one of the of the 11 areas and after the second self-assessment would no-longer meet the Standard 1, because of an action completed un-related to the conduct of the regulatory program.

1. Amend Standard 1, Description of Requirement, lettered paragraph "A" as follows (language to be deleted is in strikethrough format; language to be added is underlined):

A. *Food Code* Interventions and Risk Factor Control Measures
The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*. Jurisdictions that meet Standard 1 but who may become noncompliant due to the release of a new edition of the *Food Code* are considered to continue meeting the Standard for a period of two years from the release date of the new *Food Code* edition in order to complete the process of updating its regulations.

To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part I*, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations." ~~For initial listing, the~~ The regulatory foundation must ~~contain~~ include at least 80% ~~9 of the 11~~ interventions and risk factor controls. ~~In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.~~

1. Amend Standard 1 Instructions and Worksheet for Conducting a Self-Assessment as follows., Step 3, as follows (language to be deleted is in strikethrough format; language to be added is underlined):

STEP 3 - Document the Self-Assessment Results for Part I

A summary table is provided in Part I of the *Standard 1: Self-Assessment Worksheet* to document the results of the self-assessment for each of the 11 public health intervention and risk factor control measures. For80 each public health intervention and risk factor control measure, the self-assessor must record the findings from the self-assessment. If each *Food Code* section listed under an Intervention/ Risk Factor has a check in the "Full Intent is Met" column, the Standard criteria is met. Place an "X" in the Self-Assessment Results "YES" column.

If any of the *Food Code* sections are missing, or the jurisdiction's regulatory requirements only partially meet the intent of the language, place an "X" in the Self-Assessment Results "NO"
column for that intervention/risk factor control measure.

At the bottom of Part I of the *Standard 1: Self-Assessment Worksheet*, the self-assessor must record the jurisdiction's name and the number of interventions/risk factors that are

met. ~~For initial participation and listing purposes, the~~ The jurisdiction's self-assessment must indicate conformance with at least ~~9 of the 11~~ 80% of the intervention/risk factor categories. ~~By the third verification audit, the jurisdiction must meet 11 of the 11 intervention/risk factor control categories in order to meet the Standard 1 criteria.~~

Examples of documents that may be reviewed:
ØThe jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments

ØVersion of the *Food Code* that was used for the self-assessment

ØCompleted *Standard 1: Self-Assessment Worksheet,* Part I - *Food Code* Interventions and Risk Factor Controls

ØIf applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

1. Amend Standard 1 Instructions and Worksheet for Conducting a Verification Audit as follows Step 4, as follows (language to be deleted is in strikethrough format; language to be added is underlined):

STEP 4 - Document the Verification Audit Results for Part I

Part I of the *Standard 1: Self-Assessment Worksheet*, included at the end of these instructions, contains 11 public health interventions and risk factor controls:

1. Demonstration of Knowledge
2. Employee Health
3. Consumer Advisory
4. Approved Source
5. Time/Temperature
6. Protection from Contamination
7. Control of Hands as a Vehicle of Contamination
8. Good Hygienic Practices
9. Chemical
10. Conformance with Approved Procedures
11. Highly Susceptible Population

To meet any one of the 11 public health intervention and risk factor controls identified under the self-assessment process, the self-assessment must indicate that the jurisdiction's regulatory requirements address all *Food Code* sections listed for that area. ~~For initial listing, the~~ The jurisdiction's regulatory foundation must ~~contain~~ include at least ~~9 of the 11~~ 80% of public health interventions and risk factor controls. ~~In order to fully meet the requirement of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third verification audit cycle.~~

If four or more of the 15 selected code sections reviewed during the audit process do not meet the stringency of language criteria, the Standard 1, Part I element fails to meet the criteria, and no further sampling is necessary. If one, two or three of the 15 selected code sections do not meet the stringency of the language criteria but the jurisdiction continues to meet the required number of interventions and risk factor controls to meet the Standard, then randomly select an additional 15 *Food Code* sections. No more than three total disagreements are acceptable in the thirty (30) Code sections drawn for comparison in

order for the audit to confirm the Part I element of Standard 1 as met. In addition, at least 9 out of the 11 (80%) interventions and risk factor controls must still be met at the end of the first audit after the disagreements are taken into account~~, and the jurisdiction must meet 11 out of the 11 interventions and risk factor controls by the third regular audit in order to meet the Standard 1 criteria~~.

Examples of documents that may be reviewed:

ØThe jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments

ØVersion of the *FDA Food Code* that was used for the self-assessment Ø? Completed *Standard 1: Self-Assessment Worksheet*, Part I - *Food Code* Interventions and Risk Factor Controls
ØIf applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

d) Amend any forms and instructions as needed to conform with the above changes.

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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Standard 2: Trained Regulatory Staff
APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

NOTE about course information: The courses listed below are updated and moved across different learning management systems over time. The latest information will be posted on the FDA Program Standards Landing Page at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019

For state, local, tribal, & territorial (SLTT) regulators to register on-line for free access to web courses, go to: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

Pre-requisite ("Pre") Curriculum Courses

(To be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

PUBLIC HEALTH PRINCIPLES

Courses	Course Number
1-Public Health Principles	FDA36 (90)

MICROBIOLOGY

Courses	Course Number
1-Overview of Microbiology	MIC01 (60)
2A-Gram Negative Rods	MIC02 (60)
2B-Gram-Positive Rods & Cocci	MIC03 (90)
3- Foodborne Viruses	MIC04 (60)
4- Foodborne Parasites	MIC05 (90)
Mid-Series Exam	MIC16 (30)
5- Controlling Growth Factors	MIC06 (90)
6-Control by Refrigeration & Freezing	MIC07 (60)
7A-Control by Thermal Processing	MIC08 (90)
7B- Control by Pasteurization	MIC09 (90)
10- Aseptic Sampling	MIC13 (90)
12-Cleaning & Sanitizing	MIC15 (90)

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Courses	Course Number
1. Basic Food Law for State Regulators	FDA35 (60)
2. Basics of Inspection: Beginning an Inspection	FDA38 (90)
3. Basics of Inspection: Issues & Observations	FDA39 (90)
4. An Introduction to Food Security Awareness	FD251 (60) A PDF/READABLE VERSION at (https://www.fda.gov/training-and- continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness) Note: Required exam is available via www.compliancewire.com.

5. FDA Food Code: Specific SLTT laws and regulations to be addressed by each jurisdiction.	**Note:** Some jurisdictions may require the FDA Food Code Course in addition to SLTT food code training.

COMMUNICATION SKILLS

Courses	Course Number
1. Communication Skills	CC8030W **NOTE**: Course must be accessed through FDA Pathlore at: (https:// orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&mainmenu=ORA &top_frame=1)

Curriculum ("Post") Courses

(To be completed any time prior to Food Code Standardization AND within 24 months of hire or assignment to the regulatory retail food program)

MICROBIOLOGY

Courses	Course Number
7C-Control by Retorting	MIC10 (90)
8-Technology-Based Food Processes	MIC11 (120)
9-Natural Toxins	MIC12 (90)

HACCP

Courses	Course Number
1. Overview of HACCP	FDA16 (60)
2. Prerequisite Programs & Preliminary Steps	FDA17 (60)
3. The Principles	FDA18 (60)

ALLERGEN MANAGEMENT

Courses	Course Number
1. Allergens	CC8029W on PATHLORE https://orauportal.fda.gov/stc/ora/psciis.dll?linkid=436613&mainmenu=ORA&top_frame=1

EPIDEMIOLOGY

Courses	Course Number
1. Collecting Surveillance Data	FI01 (90)
2. Beginning the Investigation	FI02 (90)
3. Expanding the Investigation	FI03 (90)
4. Conducting a Food Hazard Review	FI04 (90)
5. Epidemiological Statistics	FI05 (90)
6. Final Report	FI06 (30)

EMERGENCY MANAGEMENT – FEMA

Incident Command System and National Incident Management System: Course available from FEMA web link http://training.fema.gov/IS/NIMS.asp

Courses	Course Number
1. Introduction to Incident Command System	IS-100.C, Introduction to the Incident Command System, (180) ICS-100 for FDA
2. Basic Incident Command System for Initial Response	IS-200.C, Basic Incident Command System for Initial Response (180)
3. An Introduction to NIMS	IS 700.B, An Introduction to NIMS, (180) ICS-700

( ) Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

Estimated total hours for "Pre" courses are 42 hours.

Estimated total hours for "Post" courses are 26 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 68 hours

STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

- Identify the activities that occur during an inspection
- Identify the types of evidence that may be collected during an inspection
- Recognize the importance of taking good notes during an inspection
- Identify the remedies that are available if the establishment repeatedly fails to comply with the law
- Identify the behaviors that you should demonstrate when testifying in court
- Identify the role of hearsay in a trial

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FDA38 – Basics of Inspection: Beginning an Inspection
After completing this course, you will be able to identify how to prepare for an inspection. You will also recognize how to properly deal with management and recognize initial observations you should make at the start of an inspection. In addition, you will identify the purpose of a Hazard Analysis Critical Control Point (HACCP) plan. You will also recognize what to look for when searching for potential food contaminants, and you will identify examples of chemical and physical hazards. Finally, you will recognize the purpose of corrective actions.
Length: 90 mins
CEUs: 0.2
Available at http://www.eduneering.com/Partners/fdaora (http://www.eduneering.com/Partners/fdaora) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Objectives:

- Recognize what to look for when reviewing the history of the facility to be inspected.
- Identify recommended equipment and supplies needed during an inspection.
- Recognize the proper attire for an inspection.
- Recognize how to best deal with management when beginning an inspection.
- Identify initial observations during an inspection.
- Identify the definition of HACCP.
- Recognize observations for food flow cycles.
- Recognize observations for time/temperature controls.
- Recognize how to identify if a food is potentially hazardous.
- Recognize where and what to look for when searching for product cross-contamination.
- Identify the definition of a chemical hazard.

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- Recognize examples of chemical hazards.
- Identify the definition of a physical hazard.
- Recognize examples of physical hazards.
- Recognize why corrective actions are needed.
- Recognize the importance of a recall/traceback program.

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FDA39 – Basics of Inspections: Issues and Observations
After completing this course, you will be able to identify the unsatisfactory practices that lead to contaminated food, including: processing equipment issues; employee practices; food storage/display issues; contamination; and water supply and plumbing concerns. You will also be able to recognize proper sampling procedures. In addition, you will be able to identify what to include in an inspection report and how to conduct a closing conference at the conclusion of an inspection.
Length: 90 mins
CEUs: 0.2
Available at http://www.eduneering.com/Partners/fdaora (http://www.eduneering.com/Partners/fdaora) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Objectives:

- Recognize poor hygienic practices.
- Recognize what constitutes bare-hand contact with ready-to-eat foods.
- Recognize proper handwashing procedures.
- Recognize the potential contamination that may come from ill employees.
- Recognize the importance of food safety training programs.
- Recognize cleaning and sanitation issues to look for while inspecting processing equipment.
- Recognize how to identify equipment condition issues.
- Recognize what constitutes improper use of equipment.
- Recognize the need for equipment to perform as desired.
- Recognize approved source requirements.
- Recognize typical observations of conditions that may indicate a problem with foods offered for sale.
- Recognize proper label compliance procedures.

Top ()

- Recognize examples of poor practices that result in cross-contamination.
- Recognize proper storage and disposal of objectionable products.
- Recognize conditions that indicate the presence of pests.
- Recognize how to determine if a water source is approved.
- Recognize proper water temperatures for various activities that use water.
- Recognize proper plumbing systems for food facilities.
- Recognize proper warewashing procedures.
- Recognize the purpose of a sample.
- Identify the steps in sampling and the properties of each step.
- Recognize information that should be included in the inspection report.
- Identify the purpose of evidence documentation in the inspection report.
- Recognize the usefulness of photographs in the inspection report.
- Recognize how to handle corrections to the inspection report.
- Identify supporting documents that should be reviewed.
- Recognize the critical elements of the closing conference.
- Identify the individual(s) that should be present during the closing conference.
- Recognize how to handle disputes.

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FDA16 – Basics of HACCP: Overview of HACCP
Hazard Analysis and Critical Control Point (HACCP) is a food safety management system designed for use in all segments of the food industry. This course provides an introduction to HACCP and is the first in the three-part Basics of HACCP series. Basics of HACCP is intended for individuals involved with the control of food safety at any point in the food industry. There are no prerequisites.
Length: 60 mins
CEUs: 0.1
Available at http://www.eduneering.com/Partners/fdaora (http://www.eduneering.com/Partners/fdaora) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Objectives:

- Recall characteristics of HACCP and CCP.
- Recall characteristics of a HACCP plan and a HACCP system.

Top ()

- Recall key developments involved in the origin of HACCP.
- Identify factors that make HACCP important to the U.S. and global food supply.
- Identify the benefits gained from using HACCP.
- Recall specific U.S. and foreign government organizations that utilize HACCP.

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FDA17– Basics of HACCP: Prerequisite Programs and Preliminary Steps
After completing this course, you will be able to recognize important prerequisite programs for a HACCP system, including basic sanitation, good facility design, and proper personal hygiene practices, and recognize how these prerequisite programs help make a HACCP system successful. You will also be able to identify the five preliminary steps to developing a HACCP plan and recognize how those steps benefit HACCP plan development. Finally, you will recognize other practices that must be in place before you implement a HACCP plan.
Length: 60 mins
CEUs: 0.1
Available at http://www.eduneering.com/Partners/fdaora (http://www.eduneering.com/Partners/fdaora) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Objectives:

- Recall specific prerequisite programs.
- Identify characteristics of prerequisite programs.
- Recognize the benefits of prerequisite programs.
- Recognize how prerequisite programs provide a foundation for a successful HACCP system.
- Recognize the five preliminary steps to developing a HACCP plan.
- Identify appropriate members of the HACCP team.
- Recognize the benefit of assembling a HACCP team.
- Recognize how to describe the food and its distribution.
- Recognize the benefit of describing the food and its distribution.
- Recognize how to describe the intended use and consumers of the product.
- Recognize the benefit of describing the intended use and consumers of the product.
- Recognize how to develop a flow diagram describing the process under consideration.
- Recognize the benefit of developing and verifying the flow diagram.

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Risk-Based Inspection Methods in Retail (FD218)

Upcoming Courses

Registration Process

Questions about FD218

This workshop builds upon concepts learned in FD215 Managing Retail Food Safety and is designed to further enhance the knowledge, skills, and abilities of food safety inspection officers in conducting risk-based inspections.

Topics include:

- Key terms, applicable laws/policies, and necessary equipment
- Food microbiology
- Three common food preparation processes and their associated hazards and control measures
- Communication techniques related to risk-based inspections including establishing rapport, active listening, asking strategic questions, and oral versus print culture communication styles
- Strategies used to focus the inspection, set priorities, and determine inspection flow
- Differences between assessing code compliance and active managerial control (AMC) of foodborne illness risk factors during inspections and the reasons why assessing AMC is essential to public health
- Techniques for determining code compliance and AMC of foodborne illness risk factors
- Determining the most appropriate immediate corrective actions for out-of-control foodborne illness risk factors
- Determining the most appropriate long-term intervention strategies for out-of-control risk factors

AFDO is a regulatory organization that connects food and medical-products safety stakeholders and impacts the regulatory environment by shaping sound, science-based rules, law, regulations, and sharing best practices that protect public health. Or simply put: connect, share, impact, and protect.

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Contact

National Curriculum Standard

Through a Cooperative Agreement* with the US Food and Drug Administration (FDA), IFPTI is leading the development and build-out of the National Curriculum Standard (NCS). The NCS is a key element of the ***Integrated Food Safety System*** (IFSS), a seamless partnership and collaboration among human and animal food regulatory jurisdictions: Federal, State, Local, Tribal, and Territorial.

The NCS represents a ***national competency standard*** for human and animal food regulatory professionals, across their entire careers. The NCS depicts the ***knowledge, skills, and abilities*** needed by these regulators in

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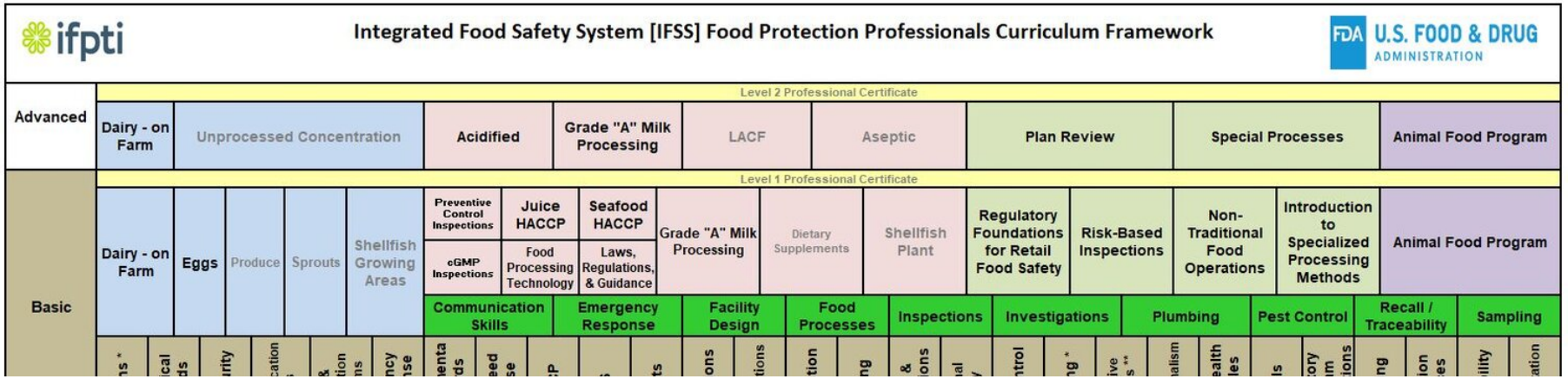
order to successfully perform their jobs, thereby assuring a ***competent regulatory workforce doing comparable work*** across all jurisdictions.

A key component of the NCS is the IFSS Curriculum Framework, shown below. The IFSS Framework is a color-coded schematic of the human and animal food regulatory profession, demonstrating the interrelationship between and among professional career levels, program areas, and content or topic areas. The Framework is a living, breathing document, and is consistently being revised and updated as buildout of the Framework continues.



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The NCS, along with the IFSS Framework, serve three primary purposes: 1. Creating “blueprints” for training development, 2. Acting as a cataloging system, and 3. Helping with assessment.

Blueprint for course development

One of the foundational processes used by training developers in the instructional systems design (ISD) field is the ADDIE model, which outlines the five steps for developing effective training. The chronological steps in the model are: Analysis, Design, Development, Implementation, and Evaluation.

When we build out a particular content or topic area within the IFSS Framework, we are essentially creating a “blueprint” for training

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Taken together, the competencies and behavioral anchors provide all the details concerning what should be covered in a training course.

ISD professionals, therefore, can use these content or topic area “blueprints” and, in close collaboration with appropriate subject matter experts, can create course learning objectives (which are often modified versions of the competencies), build course content, course activities, learner interactions, and knowledge checks, all of which are recommended components of any learning event.

Looking back at the ADDIE model, then, we can see that these “blueprints” represent the Analysis and Design phases of the process. The Analysis involves identifying what the regulator needs to know or be able to do, and the Design relates to arranging the competencies and behavioral anchors into a sequenced, organized blueprint that can be utilized during the next step of the ADDIE process, the Development phase.

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Cataloging system and gap analysis/inventory

The IFSS Framework is a carefully organized schematic, arranged by professional levels (Basic, Advanced, etc.), specific program areas or concentrations such as Retail Food, Manufactured Food, Unprocessed Food, and Animal Food, and focused content or topic areas tailored to each professional level.

As such, the Framework can serve as a unique, open-source system to be

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training developers to arrange existing materials into their appropriate slot, much like a book is placed on a particular shelf in a library.

This cataloging system can be used to organize any existing training courses, guidance documents, and reference materials. Additionally, the system can help identify gaps in existing training across the US, and can help identify learning events in need of development.

Assessment against competencies

The content area “blueprints” aid in the assessment process.
Remember, the blueprints comprise a set of:

1. competencies (knowledge, skills,

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regulatory professionals to successfully perform their job functions; and

2. behavioral anchors tailored to each competency, which are indicators that an individual can actually demonstrate the particular knowledge, skills, or ability.

Taken together, the competencies and behavioral anchors can be used by an *assessor* to help measures an individual's level of competency and help identify any competency gaps that can be addressed through training, mentoring, job shadowing, or field experience. For example, an individual can conduct a self-assessment to determine if he or she possesses competencies necessary at a particular career level, and can use the results of the self-assessment to determine their progress within a particular career path.

Additionally, a supervisor or manager can assess an entire staff against a set of competencies, to help determine if any new or refresher training is

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Basic Level Courses

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STANDARD 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

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STANDARD 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines, and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for:
    a) The identification of risk factors and interventions.
    b) Documentation of the compliance status of each risk factor and intervention (i.e., a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
    c) Documentation of all compliance and enforcement activities and
    d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
4. Develops and implements a program policy ***that requires:
    a) On-site corrective actions* as appropriate to the type of violation.
    b) Discussion of long-term control** of risk factor options, and
    c) Follow-up activities.
5. Establishes and implements written policies addressing code variance requests related to risk factors and interventions.
6. Establishes written policies regarding the verification and validation of HACCP plans when a plan is required by the code.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:

1. Inspection form that requires the selection of IN, OUT, NO, or NA,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,

3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

*Note: **On-site** corrective action as appropriate to the violation would include such things as:

a. Destruction of foods that have experienced extreme temperature abuse,
b. Embargo or destruction of foods from unapproved sources,
c. Accelerated cooling of foods when cooling time limits can still be met,
d. Reheating when small deviations from hot holding have occurred,
e. Continued cooking when proper cooking temperatures have not been met.
f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

***Note: Consideration of the elements outlined in Standard 4 will ensure a strong foundation for a quality and uniform inspection program.

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Program Self-Assessment & Verification Audit Form

The *Standard 3: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 3. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 3 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a self-assessment of Standard 3 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self-Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 3 criteria listed on this form are available for review.

The *Standard 3: Program Self-Assessment and Verification Audit Form* is the only form a jurisdiction needs to use to record the results of their self-assessment. Standard 3 requires inspection policies to be established, written, and implemented. A policy without documentation of implementation does not meet the Standard 3 criteria.

The *Standard 3: Program Self-Assessment and Verification Audit Form* divides the Standard 3 criteria into six steps:

1. Inspection Form Design
    a. The jurisdiction's inspection form identifies foodborne illness risk factors and *Food Code interventions*.
    b. The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.
    c. The jurisdiction's inspection form documents compliance and enforcement activities.
2. Risk Assessment Categories
    a. A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.
3. Inspection Frequency
    a. The jurisdiction's inspection frequency is based on assigned risk categories.
4. Corrective Action Policy
    a. The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.
    b. The jurisdiction has a written and implemented policy that requires discussion for long- term control of foodborne illness risk factors.
    c. The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.
5. Variance Request Policy
    a. The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.

6. Verification and Validation of HACCP Plan Policy
    a. The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the *Food Code*.

The self-assessor must review each Standard 3 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 3: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 3 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdict*ion's Self-Assessment" column of the* Standard 3: Program Self-Assessment and Verification Audit Form. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 3: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 3: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 3 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria.

Documenting the Findings from the Verification Audit
The jurisdiction requesting the verification audit must provide their completed *Standard 3: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 3: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The jurisdiction must meet all six program performance criteria outlined in Standard 3.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any

Standard 3 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 3: Program Self-Assessment and Verification Audit Form*. The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria if the auditor does not confirm the self-assessment findings.

Standard 3: Inspection Program based on HACCP Principles
Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:	
Self-Assessor's Title:	
Jurisdiction Name:	
Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Standard 3 Self-Assessment was Completed:	
Self-Assessment indicates that the Jurisdiction MEETS the Standard 3 criteria (indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct. **Signature of the Self-Assessor:**	

VERIFICATION AUDIT SUMMARY

Printed Name of the Person who conducted the Verification Audit:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Verification Audit of Standard 3 was Completed:	
Verification Audit indicates that the Jurisdiction MEETS the Standard 3 criteria (indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standard 3 is true and correct. **Signature of the Verification Auditor:**	

Standard 3: Inspection Program based on HACCP Principles
Program Self-Assessment and Verification Audit Form

Jurisdiction Name: _____

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Inspection Form Design	a) The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions						
1. Inspection Form Design	b) The jurisdiction's inspection form documents actual observations using the convention (IN, OUT, NO, and NA).						
1. Inspection Form Design	c) The jurisdiction's inspection form documents compliance and enforcement activities.						
2. Risk Assignment Categories	a) A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.						
3. Inspection Frequency	a) The jurisdiction's inspection frequency is based on the assigned risk categories.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
4. Written and Implemented Corrective Action Policy	a) The jurisdiction has a written and implemented policy that requires on-site corrective actions for foodborne illness risk factors observed to be out of compliance.						
4. Written and Implemented Corrective Action Policy	b) The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.						
4.Written and Implemented Corrective Action Policy	c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.						
5. Variance Requests	a) The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and Food Code interventions.						
6. Verification and Validation of HACCP Plans	a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.						

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

STANDARD 2-TRAINED REGULATORY STAFF

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

STEP 1 – Verify Employees Training Records

The jurisdiction should document and retain a training record for each employee. The training record must include the date of hire or assignment to the retail food program. The Standard 2 Self-Assessment Worksheet may be used by the jurisdiction as a training record. The worksheet is included at the end of these instructions. In lieu of the Standard 2 Self-Assessment Worksheet, other manual forms or automated records may be used by the jurisdiction to retain training records related to the self- assessment as long as the information required in the Standard 2 criteria is documented in some manner.

STEP 2 – Verify Jurisdiction's Worksheet Percentage Calculation

Review the jurisdiction's Standard 2 Self-Assessment Worksheet, or equivalent documentation, to determine if the results of the jurisdiction's self-assessment indicate that ninety percent (90%) of the retail food program staff successfully completed all the Standard 2 training and standardization elements within the required time frames. If audit calculations result in a percentage that is less than 90%, the auditor can conclude that the jurisdiction does not meet the Standard 2 criteria. If this conclusion is reached, the audit process for Standard 2 is completed. There is no need to randomly select and review individual employee training records.

STEP 3 – Determine the Number of Employee Training Records to Review

If the jurisdiction used the Standard 2: Self-Assessment Worksheet, the employees will be listed in numerical order. The verification auditor must use a random selection method to determine which employees' training records will be reviewed. Employees should be substituted during the random selection process if they meet one of the following criteria:

1. The employee has been employed or worked in the retail food program for less than 24 months; or
2. The employee is no longer assigned to the retail food program; or
3. The self-assessor indicated on the Self-Assessment Worksheet that the employee did not meet each Standard 2 element.

The number of training records that must be randomly selected is based on the number of employees conducting retail food establishment inspections. Use the chart below to determine the number of employee training records to review.

Number of Employees	Number of Files to Select
5 or less	All
20 or less	5
21 or more	25 percent

STEP 4 – Obtain Random Numbers

A list of random numbers can be obtained from the following web site: www.randomizer.org
Record the random numbers generated from the web site (or from an alternate random number selection process) on the Standard 2 Verification Audit Worksheet. The worksheet is included at the end of these instructions.

STEP 5 – Select Employee Training Records to Review

Using the jurisdiction's Standard 2 Self-Assessment Worksheet, or equivalent documentation, the verification auditor must identify the employee training records that correspond to the randomly selected numbers recorded on the Standard 2 Verification Audit Worksheet. Record the employee's name adjacent to the corresponding random number on the Standard 2 Verification Audit Worksheet.

Only those employees' training records that the jurisdiction reports as meeting all the Standard 2 training and standardization elements are to be reviewed. If an employee is randomly selected but the jurisdiction indicated that employee does not meet the Standard 2 criteria, the verification auditor should randomly select a substitute employee training record to review.

STEP 6 – Verify Documentation of the Completion of the Standard Training Criteria

The verification auditor must review the training file for each of the randomly selected employees to confirm completion of the following items:

- coursework related to the Standard 2 Pre-requisite ("Pre") curriculum;
- a minimum of 25 joint field training inspection, including documentation that confirms Food Safety Inspection Officers (FSIOs) are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments;
- a minimum of 25 independent inspections and ALL the Standard 2 ("Post") curriculum requirements;
- field standardization within 18 months of hire or re-standardization every three years after initial standardization, and
- 20 hours of food safety related continuing education every three years

NOTE: For new hires or employees newly assigned to the retail food protection program, the date recorded in the "Completion of Field Standardization" column must be within 18 months of the date recorded in the "Date of Hire or Assignment to the Retail Food Protection Program."

For experienced employees, however, the completion date for standardization may be in excess of 18 months of their date of hire. This is because the jurisdiction may not have been standardizing their retail food protection program staff prior to enrollment in the Program Standards. Keep in mind that the Standard 2 language was written to establish a training and standardization process for new employees. As long as the experienced FSIO has successfully completed standardization at the time of the self-assessment the Standard 2 criteria is met.

STEP 7 – Making a Determination Based on the Results of the Audit

For each employee training file reviewed, the verification auditor must mark the appropriate box on the Standard 2 Verification Audit Worksheet. The auditor must indicate "YES –Standard 2 criteria are met" or "NO" – Standard 2 criteria is not met." If the verification auditor determines an employee training record did not meet the Standard 2 criteria, an explanation must be provided noting any deficiencies. A jurisdiction meets the Standard 2 criteria if ninety percent (90%) of the retail food program inspection staff fulfilled all the training and standardization requirements within the specified time frames.

Standard 2: Trained Regulatory Staff
Verification Audit Worksheet

No.	Randomly Selected Number	Employee Name	Yes Standard 2 Criteria are Met	No Standard 2 Criteria are Not Met	If NO, auditor is to specify why criterion is not met
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

NOTE:

1. All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed.
2. Based on the documentation from this worksheet, record your determination for each of the items on the jurisdiction's *Standard 2: Program Self-Assessment and Verification Audit Form*.

ADDITIONAL STANDARD 2 VERIFICATION AUDIT WORKSHEET (if needed)

Standard 2: Trained Regulatory Staff
Verification Audit Worksheet

No.	Randomly Selected Number	Employee Name	Yes Standard 2 Criteria are Met	No Standard 2 Criteria are Not Met	If NO, auditor is to specify why criterion is not met
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

NOTE:

1. All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed.
2. Based on the documentation from this worksheet, record your determination for each of the items on the jurisdiction's *Standard 2: Program Self-Assessment and Verification Audit Form*.

STANDARD 6 – COMPLIANCE AND ENFORCEMENT

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

Using the Standard 6: Verification Audit Worksheet

The auditor should have the *Standard 6: Verification Audit Worksheets* available as a reference when reading through this guidance. The following worksheet is provided at the end of these instructions:

- *Standard 6: Verification Audit Worksheet*

The Standard 6: Verification Audit Worksheet is designed to provide a listing of the establishments randomly selected from the jurisdiction's inventory that were reviewed as part of the self-assessment process. This worksheet provides a summary as to whether or not the inspection file/records for each of the randomly selected establishments meet the Standard 6 criteria.

The Standard 6: Establishment File Worksheet provides a systematic way of collecting the compliance and enforcement history for each of the randomly selected establishments. Jurisdictions do not have to use this form. However, a jurisdiction must provide documentation of the review process. The documentation must indicate if appropriate compliance and enforcement actions were taken for out-of-control risk factors and *Food Code* interventions at each establishment randomly selected for the self-assessment.

STEP 1 – Verify the Elements in the Written Compliance & Enforcement Program

To meet the criteria of Standard 6, the jurisdiction must have written step-by-step procedures outlining its compliance and enforcement process. The verification auditor should review its compliance and enforcement policies and procedures to ensure that there is clear guidance for staff. The policies and procedures should provide steps and actions to be taken when various categories of violations occur. The policies and procedures should also provide a progression of steps to be taken when violations are not corrected within regulatory or administratively established time frames.

Standard 6 does not dictate a required compliance process. The jurisdiction is free to determine any actions to be taken for violations of its regulations and the progression of consequences for repeated violations. The time frames and triggers for additional actions are also left to the discretion of the jurisdiction.

In addition, to meet the requirements of Standard 6, the jurisdiction's inspection form must use the IN compliance, OUT of compliance, Not Applicable, and Not Observed conventions to record the compliance status of the foodborne illness risk factors and the public health interventions identified in the *Food Code*.

Jurisdictions that have not adopted all the recommended foodborne illness risk factors and *Food Code* interventions are not penalized under Standard 6 for these omissions.

STEP 2 – Verify the Effectiveness of the Compliance & Enforcement Program

Randomly selected establishment files must be reviewed to determine if documented violations were resolved satisfactorily. The results of the review will be used to assess the success of the compliance and enforcement program. This section of the self-assessment process has been broken down into the following four parts:

Part I Verify that the jurisdiction reviewed the appropriate number of files

Part II Randomly select establishment files from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*

Part III Verify Self-Assessment findings for each selected establishment file

Part IV Verify that 80% of selected establishment files adhere to the jurisdiction's written compliance and enforcement procedures

Part I - Verify that the jurisdiction reviewed the appropriate number of files

The number of establishment files a jurisdiction must review as part of the Standard 6 self-assessment process is based on the size of their establishment inventory. Jurisdictions with less than 800 total establishments must select at least 40 files for review. If a jurisdiction has less than 40 establishments in the inventory, then all files will be reviewed. Jurisdictions with 800 or more establishments must select a sample size equal to 5% of the total establishments up to a maximum of 70 files.

Establishment Inventory	Number of Files to Review for the Self-Assessment
Less than 800	40 establishment files
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)

Some of the randomly selected establishment files listed on the *Standard 6: Self-Assessment Summary Worksheet* may not qualify for the self-assessment process. Deletion of an establishment from the sample of files to be reviewed as part of the self-assessment process is limited to those establishments where:

1. The selected establishment has not been in business long enough to have at least three regularly scheduled routine inspections; or
2. A review of inspection reports in the selected establishment file reveals that there were no risk factor or *Food Code* intervention violations documented on the "start-point" inspection

The jurisdiction's self-assessment process must include a listing of the substitute establishment files that were reviewed as replacements for those that did not qualify. When an establishment does not qualify for the self-assessment process, the substitute establishment must not be recorded on the *Standard 6: Self-Assessment Summary Worksheet*, but instead on the *Standard 6: Self-Assessment Summary Worksheet Substitute Establishment Files Worksheet*. The auditor should verify this.

Part II - Randomly select establishment files from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*

Using a table of random numbers or a random number generator is the preferred method of sample selection. The random selection will be made from the establishment files listed on the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*. The number of establishment files that must be selected for review as part of the verification audit process is indicated in the chart below.

Establishment Inventory	Number of Files to Review for the Self-Assessment	Number of Files to Select for the Verification Audit
Less than 800	40 establishment files	5
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)	10

Using the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*, the verification auditor will identify the establishment files that correspond to the randomly selected number recorded on the *Standard 6: Verification Audit Worksheet*. The verification auditor must record the establishment name or identification number for each of the randomly selected numbers on the *Standard 6: Verification Audit Worksheet.*

The verification auditor must only review establishment files that the jurisdiction has indicated as meeting all the elements of their compliance and enforcement procedures. This will require the verification auditor to eliminate establishment files that are marked "NO" on the jurisdiction's Self-Assessment Summary Worksheet. (An "X" placed in the "NO" box indicates that the self-assessment review process determined that the inspection history documented in the establishment file did not meet, or only partially met, the Standard 6 criteria and all the elements in the jurisdiction's written compliance and enforcement procedures.)

In instances where the verification auditor has randomly selected an establishment file from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet* that did not qualify (D.N.Q.) for the self-assessment review process, the substitute establishment that the jurisdiction selected for that disqualified establishment should be used.

Note: There are two types of substitutes for the audit process, which are treated differently:

1. If the auditor selects an establishment that was previously failed by the self-assessor, then use the auditor-generated substitute list of random numbers to select a substitute establishment.
2. If the auditor selects an establishment that "did not qualify" for the original self-assessment, then use the substituted establishment that was already assigned in the original self- assessment review.

Part III - Verify Self-Assessment findings for each selected establishment file

Using the jurisdiction's written compliance and enforcement procedures, the verification auditor will review the Establishment File Worksheet for each of the establishments randomly selected for the verification audit.

The *Standard 6: Establishment File Worksheet* provides a systematic way of documenting the compliance and enforcement history for each of the randomly selected establishments. Jurisdictions do not have to use this form but must provide documentation of the review process conducted to determine whether the appropriate compliance and enforcement actions for out-of-control risk factors and *Food Code* interventions were taken for each selected establishment.

Review the inspection history in each selected file beginning with the identified "start-point" inspection and moving forward through two additional inspections. Verify that either on-site corrective action, follow-up corrective action or enforcement action occurred by the end of the third inspection for each out-of-compliance risk factor or intervention marked on the start point inspections. In addition, verify that the actions taken on each violation documented on the "start-point" inspection followed the jurisdiction's written compliance policy and procedures.

In order for an establishment file to meet the Standard 6 criteria, each column marked with a violation at the "start-point" inspection must have a subsequent indication that at least one type of follow-up action was taken, and the jurisdiction's written procedures must have been followed. A single violation on the "start-point" inspection without a final resolution, either correction or compliance/enforcement activity, will result in a determination that the establishment file does not meet the Standard 6 criteria. In any instances where the auditor disagrees with the jurisdiction's self-assessment of a file, the auditor must meet with the jurisdiction's program manager or representative to gain a full understanding of the rationale used for the self-assessment determination.

The verification auditor will record his or her findings for each of the establishment files reviewed on the *Standard 6: Verification Audit Worksheet*. If the verification audit of the establishment file review indicates that the full intent of the Standard 6 criteria is met, place an "X" in the "YES" box. If full intent of the Standard 6 criteria is not met, place an "X" in the "NO" box. If the verification auditor disagrees with the jurisdiction's self-assessment decision, an explanation must be provided in the last column of the *Standard 6: Verification Audit Worksheet*. Additional sheets can be used to document the need for expanded explanations.

Part IV - Verify that 80% of selected establishment files adhere to the jurisdiction's written compliance and enforcement procedures

The criteria for Standard 6 requires that 80 percent of the files with an identified violation of a foodborne illness risk factor or a *Food Code* intervention on the "start-point" inspection adhere to the jurisdiction's written compliance and enforcement procedures. Files that "did not qualify" (D.N.Q.) for the self-assessment review are not used in the calculation of the percentage.

Legitimate differences of opinion regarding stringency of language may occur during the verification audit process. An approximate ten percent (10%) discrepancy allowance is made to accommodate potential differences in interpretations.

Jurisdictions with less than 800 Establishments - If two or more of the five audited establishment files rated as passing by the jurisdiction are not verified by the auditor as having met the Standard 6 criteria, the Part III element fails to meet the criteria, and no further sampling is necessary. Even if no additional disagreements are found by sampling an additional set of randomly drawn establishment files, the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Determine the need for supplemental sampling. If only one establishment file from the initial sample is determined by auditor to have not met the Standard 6 criteria, then randomly select an additional 5 establishment files. Follow the same audit process used to review the first set of establishment files. The *Standard 6: Verification Audit Worksheet* for substitute establishment files, provided on a following page, can be used to record all the information related to the supplemental sampling of establishment files.

If no additional disagreements in the review of establishment files are noted, then the jurisdiction meets the Standard 6 criteria. If one or more additional establishment files fails the audit review, then the Standard 6 criteria are not met, since the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Jurisdictions with more than 800 Establishments - If three or more of the ten audited establishment files rated as passing by the jurisdiction are not verified by the auditor as having met the Standard 6 criteria, then the jurisdiction fails to meet Standard 6. Even if no additional disagreements are found by sampling an additional set of randomly drawn establishment files, the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Determine the need for supplemental sampling. If one or two establishment files from the initial sample are determined by auditor to have not met the Standard 6 criteria, then randomly select an additional 10 establishment files. Follow the same audit process used to review the first set of establishment files. The *Standard 6: Verification Audit Worksheet* for substitute establishment files, provided on a following page, can be used to record all the information related to the supplemental sampling of establishment files.

No more than a total of two of 20 establishment files drawn can be determined by the auditor as not meeting the Standard 6 criteria. If more than two establishment files fail the audit review, then the Standard 6 criteria are not met, since the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Standard 6: Compliance and Enforcement
Verification Audit Worksheet
Establishment Files

Jurisdiction Name: _____

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
1						
2						
3						
4						
5						
6						
7						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
18						
19						
20						

STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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STANDARD 5
FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury, and outbreaks.

Requirement Summary

The program has an established system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. Investigative Procedures

a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food-related injury*. The procedures clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.

c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.

d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.

e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.

f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.

g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.

h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.

i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.

b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks* with CDC.

3. Laboratory Support Documentation

a. The program has a letter of understanding, written procedures, contract, or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.

b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak, or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.

b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.

c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.

b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:

1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment;
2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type;
3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food;
4) Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food preparation processes;
5) Number of confirmed foodborne disease outbreaks*;
6) Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*;
7) Contributing factors most often identified;
8) Number of complaints involving real and alleged threats of intentional food contamination; and
9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak* investigations occur.

Note: *Regulatory Programs are encouraged to also participate in the CDC National Environmental Assessment Reporting System (NEARS). NEARS is designed to provide a more*

comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NEARS: http://www.cdc.gov/nceh/ehs/nears/index.htm)

Outcome

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and food-related injury* complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, food-related injury*, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts, or MOUs with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

*[*Note: See the Standards Definitions for the meaning of these defined terms.]*

Voluntary National Retail Food Regulatory Program Standards

DEFINITIONS

The following definitions apply in the interpretation and application of these Standards.

1) **Active Managerial Control** – The purposeful incorporation of specific actions or procedures by industry management into the operation of a business to attain control over foodborne illness risk factors.
2) **Auditor** – Any authorized city, county, district, state, federal, tribal, or other third-party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit, which confirms the accuracy of the self-assessment.
3) **Baseline Survey** – See Risk Factor Study.
4) **Candidate** - A regulatory officer whose duties include the inspection of retail food establishments.
5) **Compliance and Enforcement** – Compliance includes all voluntary or involuntary conformity with provisions set forth by the regulatory authority to safeguard public health and ensure that food is safe. Enforcement includes any legal and/or administrative procedures taken by the regulatory authority to gain compliance.
6) **Confirmed Foodborne Disease Outbreak** – means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiologic analysis implicates the food as the source of the illness or epidemiological analysis alone implicates the food as the source of the illness.
7) **Direct Regulatory Authority (DRA) –** The organizational level of government that is immediately responsible for the management of the retail program. This may be at the city, county, district, state, federal, territorial, or tribal level.
8) **Enforcement Actions –** Actions taken by the regulatory authority such as, but not limited to, warning letters, revocation or suspension of permit, court actions, monetary fines, hold orders, destruction of food, etc., to correct a violation found during an inspection.
9) **Follow-up Inspection –** An inspection conducted after the initial routine inspection to confirm the correction of a violation(s).
10) **Food Code Interventions** – the preventive measures to protect consumer health stated below:
    1. management's demonstration of knowledge;
    2. employee health controls;
    3. controlling hands as a vehicle of contamination;
    4. time / temperature parameters for controlling pathogens; and
    5. consumer advisory.
11) **Food-Related Injury** – Means an injury from ingesting food containing a physical hazard such as bone, glass, or wood.
12) **Foodborne Disease Outbreak** – The occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.
13) **Good Retail Practices (GRP's)** – Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the *FDA Food Code* interventions or risk factors.
14) **Hazard** – A biological, chemical, or physical property that may cause food to be unsafe for human consumption.

15) **National Registry of Retail Food Protection Programs (National Registry) – A** listing of retail food safety programs that have voluntarily enrolled as participants in the *Voluntary National Retail Food Regulatory Program Standards*.
16) **Person in charge (PIC)** – The individual present at a food establishment who is responsible for the operation at the time of inspection.
17) **Program Element –** One of the program areas for which a National Standard has been established such as regulations, training, inspection system, quality assurance, foodborne illness investigation, compliance and enforcement, industry and consumer relations, and program resources.
18) **Program Manager** – The individual responsible for the oversight and management of a retail food regulatory program.
19) **Quality Records –** Documentation of specific elements of program compliance with the National Standards as specified in each Standard.
20) **Risk Control Plan (RCP)** – a concisely written management plan developed by the retail or food service operator with input from the health inspector that describes a management system for controlling specific out-of-control risk factors.
21) **Risk Factors** – the improper employee behaviors or improper practices or procedures in retail food and food service establishments stated below which are most frequently identified by epidemiological investigation as contributing to foodborne illness or injury:
    1. improper holding temperature;
    2. inadequate cooking;
    3. contaminated equipment;
    4. food from unsafe source; and
    5. poor personal hygiene.
22) **Risk Factor Study** (formerly Baseline Survey) – A study on the occurrence of foodborne illness risk factors within institutional, foodservice, restaurants, and retail food facility types under a jurisdiction's regulatory authority. Criteria for a Risk Factor Study are detailed in Standard 9, including at a minimum:
    1. Data Collection, analysis, and a written report;
    2. A collection instrument with data items pertaining to the five foodborne illness risk factors;
    3. A collection instrument that uses the convention of IN, OUT, NA and NO to document observations;
    4. All facility types identified by FDA's national study that are under the jurisdiction's regulatory authority; and
    5. Studies subsequent to the initial study repeated at 5-year intervals.
23) **Routine Inspection – A** full review and evaluation of a food establishment's operations and facilities to assess its compliance with Food Safety Law, at a planned frequency determined by the regulatory authority. This does not include re-inspections and other follow-up or special investigations.
24) **Self-Assessment** – An internal review by program management to determine whether the existing retail food safety program meets the *Voluntary National Retail Food Regulatory Program Standards*.
25) **Self-Assessment Update** – Comparison of one or more program elements against the *Voluntary National Retail Food Regulatory Program Standards* between the required 60-month periodic self-assessment.

26) **Standardization Inspection** – An inspection used to demonstrate a candidate's knowledge, communication skills, and ability to identify violations of all regulatory requirements and to develop a risk control plan for identified, uncontrolled risk factors.
27) **Suspect Foodborne Outbreak** – Means an incident in which two or more persons experience a similar illness after ingestion of a common food or eating at a common food establishment/gathering.
28) **Trainer** – An individual who has successfully completed the following training elements as outlined in Steps 1 – 3, Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.
    1. Satisfactory completion of the prerequisite curriculum;
    2. Completion of a field training process similar to that contained in Appendix B-2; and
    3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum.
29) **Training Standard** – An individual who has successfully completed the following training elements AND standardization elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees. The training and standardization elements include:
    1. Satisfactory completion of the prerequisite curriculum;
    2. Completion of a field training process similar to that contained in Appendix B-2;
    3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum;
    4. Successful completion of a standardization process based on a minimum of eight inspections that includes development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP plan, similar to the FDA standardization procedures;
    5. Completion of a minimum of 20 contact hours of continuing education in food safety every 36 months after the initial training is completed as outlined in Standard 2; and
    6. Standardization maintained every three (3) years as outlined in Standard 2.
30) **Verification Audit** – A systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment.

STANDARD 8 PROGRAM SUPPORT AND RESOURCES

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STANDARD 8 PROGRAM SUPPORT AND RESOURCES

This standard applies to the program resources (budget, staff, equipment, etc.) necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness.

Requirement Summary

The program provides funding, staff, and equipment necessary to accomplish compliance with the Voluntary National Retail Food Regulatory Program Standards.

Description of Requirement

The program budget provides the necessary resources to develop and maintain a retail food safety program that meets the following criteria:

1. Staffing Level

Note: Jurisdictions can achieve conformance using one of two methods. Both methods can be accessed for downloading from the Conference for Food Protection (CFP) web site: www.foodprotect.org and located under the icon titled, "Conference Developed Guides and Documents."

Option 1: Standard 8 Staffing Level Assessment

A staffing level of one full-time equivalent (FTE) devoted to food for every 280 – 320 inspections performed. Inspections for purposes of this calculation include routine inspections, re- inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training.

A process should exist for the regulated food establishments to be grouped into at least three categories based on food safety risk (See Standard 3). The number of inspections assigned per FTE should be adjusted within the 280 – 320 range depending upon the composition of low- to high –risk establishments in the assigned inventory. When an FTE is divided between program areas, the total number of food inspections planned for that FTE should be adjusted to compensate for the additional training time required to maintain competency in multiple program areas. An adjustment of planned inspections per FTE should also occur when food establishments are geographically dispersed due to increased travel time. Through their committee process, the CFP has developed an assessment tool and instruction guide as resources that can be used by a jurisdiction to calculate the FTE to inspection ratio.

Option 2: Standard 8 Staffing Level Alternative Conformance Method

Jurisdictions may access an alternative model for achieving conformance with Standard 8 from the Conference for Food Protection (CFP) web site: www.foodprotect.org and located under the icon titled, "Conference Developed Guides and Documents."

2. Inspection Equipment

Inspection equipment of each inspector to include head covers, thermocouples, flashlights, sanitization test kits, heat sensitive tapes or maximum registering thermometers, necessary forms, and administrative materials. The following equipment must be available for use by inspectors when needed: computers, cameras, black lights, light meters, pH meters, foodborne illness investigation kits, sample collection kits, data loggers and cell phones.

3. Administrative Program Support

Equipment for administrative staff to include computers, software and/or items necessary to support the record keeping system utilized by the program. A system is in place to collect, analyze, retain, and report pertinent information.

4. Regulatory Foundation

Staff and resources to adopt a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry required in Standard No. 1.

5. Trained Regulatory Staff

Training and training documentation for all regulatory staff to meet the level specified in Standard No. 2.

6. Inspection Program Based on HACCP Principles

Staff to meet all of the requirements in Standard No. 3, inspection based on HACCP principles.

7. Uniform Inspection Program

Administrative and supervisory staff to administer and monitor a uniform inspection program based on HACCP principles that meet Standards No. 3 and 4.

8. Foodborne Illness & Food Defense Preparedness & Response

Staff and resources to maintain a foodborne illness investigation and response system that meets Standard No. 5.

9. Compliance & Enforcement

A program that demonstrates follow-though on all compliance and enforcement actions initiated according to the written step-by-step procedures required in Standard No. 6.

10. Industry & Community Relations

An industry and consumer relations program as specified in Standard No. 7.

11. Program Assessment

Sufficient staff and resources to conduct regular program self-assessment and risk factor surveys as specified in Standard No. 9.

12. Accredited Laboratory

Funds to provide access to accredited laboratory resources in support of the program as specified under these nine Standards.

The essential program elements required to demonstrate compliance with this standard are:

A. Full-time equivalent (FTE) personnel to inspections accomplished ratio as described in section 1.
B. Inspection equipment assigned or available as described in section 2.
C. Equipment and/or supplies required for administering the program as described in Section 3.
D. A full and accurate completion of the *Standard 8: Self-Assessment Worksheet* or equivalent whether or not those standards are met.

Outcome

The desired outcome of this standard is that resources are available to support a risk-based retail food safety program designed to reduce the risk factors known to contribute to foodborne illness.

Documentation

The quality records needed for this standard include:

1. Documentation of FTE to inspections ratio,
2. Inventory of assigned and available inspection equipment,
3. Documentation and demonstration of records system and adequacy of support,
4. The completed Standard 8 Self-Assessment Worksheet

*[*NOTE: An average workload figure of 150 establishments per FTE with two inspections per year was originally recommended in the 1976 Food Service Sanitation Manual, the standard originating from a book entitled, "Administration of Community Health Services." Annex 4 of the Code since 1993 has included a recommendation that 8 to 10 hours be allocated for each establishment per year to include all the activities reflected here in the definition of an inspection. The range of 280 – 320 broadly defined inspections per FTE is consistent with these previous recommendations. A measure of resources defined as inspections per FTE rather than establishments per FTE allows for the same unit of measure to be used for any jurisdiction regardless of the frequency of routine inspections conducted among the various priority categories.]*

Standard 8 Staffing Level

Purpose of Standard 8 staffing level section:

Standard 8 Section 1. Staffing Level requires a health department (HD) to demonstrate that they have the staff "necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors know to contribute to foodborne illness"

Current criteria to pass Standard 8:

A HD currently meets this standard if they demonstrate an inspection to FTE ratio range of 280-320 inspections per FTE. The Conference for Food Protection (CFP) developed an assessment tool and instruction guide that can be used by a HD if desired. If not the HD has to calculate their inspection to FTE ratio through their own method and see if it falls within the required range.

Problem with inspection to FTE ratio range:

It has been agreed by upon by subcommittee that this range is problematic as it's based on the idea that every inspection should take 4 hours. The subcommittee has also agreed that a range is problematic as it allows for an adequately staffed health department to fail the standard as they could fall below the range.

Recommendations:

We are recommending removing the range and allowing HDs to demonstrate to independent auditors that they are adequately staffed in a more appropriate way. The following are the 3 options we think are reasonable that a HD can use to demonstrate staffing levels.

1. A HD can use their own method they feel is appropriate for them to demonstrate adequate staffing levels

2. A HD can use the current assessment tool (with inspection to FTE section removed) developed by CFP to assess if they're adequately staffed

3. A health department can use the updated CFP assessment tool that calculates staffing levels by risk category
    a. Using the updated vs. current assessment tool may make it easier for a HD to prove to their auditor that they are adequately staffed because:
        i. It has a section that calculates how many FTEs a HD *should* have based on risk categories (current assessment does not do this)
        ii. It then automatically compares how many FTEs a health department *currently* has with how many they *should* have (the current assessment only calculates *current* FTE, so it may be challenging to convince an auditor that a current calculated FTE # demonstrates a HD to be adequately staffed)

Updated CFP Assessment Tool

The following is an example of how to use the updated assessment tool to calculate if a health department is adequately staffed.

Discussion on Table 1. The risk category column is broken into three categories, the minimum required by Standard 8. The number of establishments will be unique to each health department. The rows in the remaining columns show values that are based off of survey data of 100 local and state health departments throughout the country (see footnotes for more details). A HD should feel free to use these values or input ones that more appropriately fit their organization.

Table 1.

Risk Category	Number of Establishments	Inspection Frequency[1]	Average Inspection Time (does not include travel)[2]	Reinspection frequency[3]	FBI Inspection Frequency[4]	Other Frequency[5]
Low	1,000	1	45 minutes	15%	1%	10%
Medium	2,000	2	75 minutes	15%	1%	10%
High	1,000	3	120 minutes	15%	1%	10%

Step 1. Calculate available annual inspection time per full time equivalent (FTE) using assessment tool. 1200 hours a year will be used for this example.

Step 2. Calculate number of FTE currently available at health department. This # is calculated in the current and updated assessment tools.

Step 3. Calculate total number of hours required to inspect each risk category. Formula for calculating # of inspection hours per risk type below (low risk type used for example):

(1000 establishments x 1 inspection a year = 1000 inspections) + (1000 establishments x 15 % reinspections a year = 150 inspections) + (1000 establishments x 1% FBI inspections a year = 10 inspections) + (1000 inspections x 10% other inspections a year = 100 inspections) = 1260 inspections a year x 45 minutes an inspection = 945 hours a year

Medium risk = 4520 inspections a year x 75 minutes = 5650 hours

High Risk = 3260 inspections a year x 120 minutes =6520 hours

Total inspection time = 945 + 5650 + 6520 = 13,115 inspection hours a year

Step 4. Calculate number of FTE's required

13,115 total inspection time hours /1200 inspection hours available per FTE = 10.93 FTEs

Step 5. Calculate if health department is adequately staffed

If FTEs currently available >= 10.93 FTEs that a HD should have then that HD is adequately staffed

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[1] Median inspection frequencies of 100 health departments from 2017 survey
[2] Median inspection times of 100 health departments from 2017 survey
[3] Median reinspection frequency %s of 60 health departments form 2017 survey2
[4] Median food borne illness inspection frequency %s of 60 health departments from 2017 survey2
[5] Final % value still being calculated, 10% being used for this demonstration

Appendix 8.2 Calculation for determining a required number of inspectors

This appendix is an example of how to calculate the number of field staff required to conduct inspections[21] of food plants. The data in the following table will vary significantly based on local or regional conditions. The State program may use the risk categories and inspection frequencies found in the statement of work for the food contract as a basis for determining the required number of inspectors.

Risk category	Number in inventory	Inspection frequency	Average inspection time (includes travel) [22]	Reinspection frequency
High	1,000	12 months	7.2 hours	10%
Medium	2,000	18 months	5.7 hours	10%
Low	1,000	24 months	4.2 hours	10%

1. Calculate available annual inspection time per full time equivalent (FTE).

For example, the State agency determines that after allowances for annual leave, sick leave, holidays, training, administrative time, and other activities each State program FTE has 1200 hours available for conducting inspections.

2. Calculate the number of hours required to inspect establishments in each risk category.

Formula for high risk establishment inspection time:
1000 firms x 100% coverage = 1000 inspections + 10% reinspection = 1100 total inspections per year x 7.2 hours = 7920 hours

Formula for medium risk establishment inspection time:
2000 firms x 66.6% coverage = 1333 inspections + 10% reinspection = 1466 total inspections per year x 5.7 hours = 8356 hours

Formula for low risk establishment inspection time:
1000 firms x 50% coverage = 500 inspections + 10% reinspection = 550 inspection total inspections x 4.2 hours = 2320 hours

3. Calculate the number of FTE's required.

Formula:
7920 hours for high risk + 8356 hours for medium risk + 2320 hours for low risk = 18596 inspection hours required / 1200 inspection hours available per FTE = **15.5 FTEs**

[19] Includes routine surveillance, reinspections, complaint or outbreak investigations, compliance follow-up investigations, risk assessment reviews, process reviews, and other direct establishment contact time such as on-site training.

[20] Inspection times based on calculations presented in "DHHS Office of Inspector General's FDA Oversight of State Food Firm Inspections" dated June 2000.

PSC13 IFSS Framework Basic Advanced Feb 2021 Color Chart

#	Color	Shade Level	R	G	B	Hex	Used For	Example
1	Yellow	1	255	255	167	FFFFA7	Certificate Rows	
2	Yellow	2	255	255	71	FFFF47	Leadership Skills PL Span	
3	Orange	1	255	216	93	FFD85D	IFSS PL Span	
4	Orange	2	250	191	143	FABF8F	Leadership Level	
5	Orange	3	252	205	166	FCCDA6	Vessel Sanitation Placeholder	
6	Blue	1	218	238	243	DAEEF3	Instructor Skills PL Span	
7	Blue	2	197	217	241	C5D9F1	NMFS Placeholder, Unprocessed Foundations	
8	Blue	4	184	204	228	B8CCE4	Professionalism PL Span	
9	Green	1	213	255	215	D5FFD7	Communication Skills Spanning	
10	Green	2	171	255	175	ABFFAF	ITP Placeholder	
11	Green	3	216	228	188	D8E4BC	Retail Food Program	
12	Green	4	196	215	155	C4D79B	Emerging Issues PL Span	
13	Green	5	111	207	116	8ED992	Food Foundations	
14	Pink	1	242	220	219	F2DCDB	Manufactured Foundations	
15	Pink	2	233	194	193	E9C2C1	Meat & Poulty Placeholder	
16	Gray	1	213	213	213	D5D5D5	Technical Specialist Electives	
17	Gray	2	191	191	191	BFBFBF	Technical Specialist (Expert) Level	
18	White	1	255	255	255	FFFFFF	Advanced Level	
19	Purple	1	212	202	224	D4CAE0	Emergency Response Spanning	
20	Purple	2	200	187	224	C8BBE0	Import Foundations	
21	Brown	1	237	213	181	EDD5B5	DOD Placeholder	
22	Brown	2	196	189	151	C4BD97	Entry (Basic) Level	

IFSS Curriculum Framework

Intended Audience: U.S. government human and animal food protection employees who conduct regulatory activities.

Basic Level	Human and animal food protection professionals who are newly hired in a local, state or federal feed/food protection program. These individuals have developed their investigational and communications knowledge and skills through formal education, training courses, and on-the-job-training activities, often working with more experienced inspectors.
Allergens	An overview of food allergens, including labeling requirements, preventive controls, and societal impact
Biological Hazards	Introductory knowledge, skills, and abilities related to biological hazards, focusing on sources of contamination, growth factors, and control methods.
Biosecurity	Introductory knowledge, skills, and abilities related to controlling disease transmission between people, animals and plants.
Communication Skills	Skills required for an effective communicator in the regulatory field.
Data & Information Systems	Introductory knowledge, skills, and abilities related to systems used by regulatory agencies to store, process, and manage data and information.
Emergency Response	Foundational knowledge related to reacting to emergency public health situations.

Environmental Hazards	Introductory knowledge, skills, and abilities related to environmental hazards focusing on sources of contamination and associated control methods.
Food/Feed Defense	Introductory knowledge, skills, and abilities related to the reduction of intentional contamination of the feed or food supply.
HACCP	Introductory knowledge, skills, and abilities related to the hazard analysis and critical control points (HACCP) system.
IFSS	Introductory knowledge, skills, and abilities related to the regulation of feed and food products grown, produced, or manufactured outsie of or returned to the U.S.
Imports	Introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. feed and food supply.
Inspections, Compliance, and Enforcement	Introductory knowledge, skills, and abilities related to ensuring regulatory compliance through inspection and enforceent activities.
Investigations	Introductory knowledge, skills, and abilities related to conducting an investigation of a feed or food safety-related event.
Jurisdiction	Introductory knowledge, skills, and abilities related to various regulatory agencies and their authority over feed and food.
Labeling	Introductory knowledge, skills, and abilities related to labeling requirements, and the components of feed and food product labels.

Laws & Regulations	Inroductory knowledge, skills, and abilities related to the system of federal, state, and local laws that provide the authority to regulate feed and food, and associated policies and procedures.
Personal Safety	Introductory knowledge, skills, and abilities related to hazards encountered by regulators, and appropriate protective actions to mitigate hazards.
Pest control	The management of pests that can be perceived to be detrimental to the production of safe human food and food for animals.
Plumbing	Knowledge, skills, and abilities related to the deliver, distribution or storage of potable and non-potable water in a manufacturing food facility and retail food establishment.
Preventive Controls	Introductory knowledge, skills, and abilities related to measures implemented by feed and food manufacturing facilities to ensure feed and food safety.
Professionalism	Introductory knowledge, skills, and abilities related to ethics, integrity, and personal conduct during job-related activities.
Public Health Principles	Introductory knowledge, skills, and abilities related to how regulatory agencies promote health and prevent and control feed and food-related illness.
Recalls	Introductory knowledge, skills, and abilities related to the process of removing a product from commerce.
Regulatory Program Foundations	Introductory knowledge, skills, and abilities related to the elements of feed and food regulatory programs

Sampling	Introductory knowledge, skills, and abilities related to feed and food sample collection, and the role of the laboratory.
Sanitation Practices	Introductory knowledge, skills, and abilities related to cleaning, sanitizing, and disinfecting, and the importance of facility and euqipment sanitary design.
Traceability	Introductory knowledge, skills, and abilities related to tracking feed and food throughout the supply chain.
Transportation	Introductory knowledge, skills, and abilities realted to preventing contamination of feed and food during transport.
Dairy On-farm	Regulatory activities related to dairy on-farm operations.
Eggs	Regulator activities related to egg operations.
Produce	
Sprouts	
Shellfish Growing Areas	
Communication Skills	Knowledge, skill, and abilities to follow policies that guide communication practices across all commodities.
Emergency Response	Knowledge, skills, and abilities to prepare for, execute, and recover from events that affect public health.
Facility Design	Knowledge related to the design and construction of a faciity.
Food Processes	Knowledge of how food is porcessed.
Inspections, Compliance, and Enforcement	Knowledge, skills, and abilities to evaluate food safety.
Investigations	Knowledge, skills, and abilities to participate in an investigation.
Plumbing	Knowledge, skills, and abilities related to reviewing the water and wastewater systems.

Pest Control	Knowledge, skills and abilities realted to assessing pest management systems.
Recall/Traceability	Knowledge, skills, and abilities needed to trace product and remove products from commerce.
Sampling	Knowledge, skills, and abilities realted to sampling.
cGMP Inspections	Knowledge, skills, and abilities related to ensuring regulatory compliance through inspection.
Food Processing Technology	Knowledge, skills, and abilities related to the evaluation of food processes.
Laws, Regulations, and Guidance	Knowledge and application of regulations and guidance related to manufactured food.
Preventive Controls Inspections	Knowledge, skills, and abilities related to conducting a preventive controls inspection.
Juice HACCP	Control strategies and practices associated with juice products.
Seafood HACCP	Control strategies and practices associated with fish and fishery products.
Grade A Dairy Processing	Regulatory activities realted to milk plant operations.
Non-Grade A Dairy Processing	
Dietary Supplements	
Shellfish Plant	
Regulatory Foundations for Retail Food Safety	The public health rationale and science behind the guidance incorporated into the FDA Food Code that can be used by federal, state, local, tribal, and territorial agencies to regulate retail food operations.

Risk-based Inspections	An inspectional approach to assess the occurrence and daily control of foodborne illness risk factors. The methodology provides a structure for prioritizing time based on risk; evaluating code compliance and active managerial control; obtaining immediate, science-based corrective actions for out-of-control risk factors; and implementing intervention strategies for long-term compliance.
Non-traditional Food Operations	Food operations not fitting the model of a typical brick and mortar restaurant or supermarket.
Introduction to Specialized Food Processing Methods	Introduction to food processes at retail.
Animal Food & Ingredients	Product used in the production of animal food.
Animal Food Safety Plans and Preventive Controls	Regulatory requirements to mitigate hazards in animal food
Animal Nutrition	Basic knowledge of animal nutrition.
Animal Species and Classes	The different species, classes, and life stages of livestock, poultry, and pets.
BSE Inspections	Conducting Bovine Spongiform Encephalopathy inspections.
Current Good Manufacturing Practices	Regulatory requirements for producing safe feed.
Feed Mill Overview	Introductory knowledge related to feed mills.
Labeling	Required components of product labeling for animal food.
Laws and Regulations	Regulatory authority related to animal food.
Medicated Feed Overview	An introduction to feed that contains medication.
Sampling	Agency-approved procedures to collect, prepare, and transport animal food samples.

Advanced	Human and animal food protection professionals who are able to independently perform sanitary inspections at a variety of facilities in addition to performing more complex investigations than inspectors at the basic level. These professionals would normally comprise the bulk of the feed/food inspection workforce and perform most of the core feed/food protection activities for their program.
Communication Skills	Adapting content, style, tone, and medium of communication in order to convey feed/food safety-related information to a variety of stakeholders.
Emergency Response	Minimizing the impact of an adverse event related to feed/food safety, public health or animal health.
Enforcement	Regulatory actions taken to address non-compliance
Evidence	Legally defensible items and information used to support regulatory actions.
Food/Feed Defense	Assessing systems for the potential of intentional adulteration, determining if intentional adulteration has occurred and responding to intentional adulteration.
Imports	
IFSS	Advanced knowledge, skills, and abilities related to a collaborative and cooperative global feed/food safety network.
Inspections	Advanced knowledge, skills, and abilities to conduct integrated, multi-faceted inspections in a flexible manner.
Instructor Skills	

Investigative Techniques	Advanced knowledge, skills, and abilities related to conducting an investigation.
Leadership Skills	
Laboratories	Knowledge of the interface between laboratory and regulatory activities.
Outbreak Investigation	Using a systematic approach to identify the source of an outbreak and mitigate the impact on public health.
Product Disposition	Knowledge, skills, and abilities to address salvage, diversion, and disposal of feed/food.
Risk Analysis	Basic knowledge, skills, and abilities related to risk analysis in feed/food protection.
Sampling	Advanced knowledge, skills, and abilities related to feed/food sample collection.
Transportation	Advanced knowledge, skills, and abilities related to preventing contamination of feed and food during transport.
Dairy On-farm	Regulatory activities related to dairy-on farm operations.
Unprocessed Concentration	
Acidified	
LACF	
Aseptic	
Plan Review	A regulatory procedure intended to ensure that retail food facilities and proposed operational processes are properly designed and that sanitary practices are implemented in order to serve their intended purposes.
Special Processes	Knowledge, skills, and abilities related to the inspection of special food processes at retail as defined in the Food Code.
Animal Food & Ingredients	Products used in the production of animal feed, including complete feed, supplements, minerals, medication, and by-products.

Animal Food Safety Plans and Preventive Controls	Advanced resource for internal training and external education related to food safety plans and preventive controls.
Animal Nutrition	Advanced knowledge of animal nutrition, including complex rations, micro-ingredients, and uncommon feed ingredients.
Aseptic Sampling	Procedures to collect non-routine feed samples.
Complaints	Feed related issues reported by consumers and/or industry.
Compliance and Enforcement Actions	Activities to achieve compliance with relevant laws and regulations.
Labeling	
Medicated Feed Mill Overview	Inspections at FDA-licensed medicated feed manufacturing facilities.
Safety Issues	Hazards associated with production and distribution of feed.
Technical Specialist	Human and animal food protection professionals with knowledge in a specific technical area, and who may or may not have a great deal of field experience. These professionals are able to conduct complex, high risk inspections and investigations, coordinate or convene key stakeholders in process development/improvement activities and will be engaged in problem solving activities. These professionals are depended upon to provide assistance and advanced or specialized support to inspectors at the Basic and Advanced Levels.
Audit	
Communication Skills	
Critical Thinking	
Emergency Response	

Rood Defense Vulnerability Assessment	
IFSS	
Leadership Skills	
Legal Proceedings Preparation	
Management Skills	
Policy Development	
Professional Development Planning	
Program Evaluation	
Program Management	
Reference Materials	
Report Evaluation	
Risk Analysis	
Supervision Skills	
Researvh Design	
Statistical Analysis	
Dairy On-farm	
Unprocessed Concentration	
Manufactured Concentration	
FDA Retail Program Standards	
Special Processes	
Animal Food & Ingredients	Feed ingredient expertise to support agency personnel and industry.
Animal Food Safety Plans & Preventive Controls	Providing expertise to agency personnel and industry related to preventive controls.
Animal Nutrition	Animal nutrition expertise provided to agency personnel and industry.
Complex Feed Labeling	Expertise in all labeling issues to support agency personnel and industry.
Compliance & Enforcement Actions	Developing strategies to achieve compliance with relevant laws and regulatrions.
Investigation Management	Managing a multi-agency response during a large-scale feed incident.
Laboratory Services	Managing the coordination between laboratory services and feed regulatory programs.

Safety Issues	Expertise applied in response to complex food safety issues.
Leadership	Human and animal food protection professionals who design, improve, and prioritize program activities, and communicate these activities within the program and to external stakeholders. Human and animal food protection professionals at the Leadership Level are involved in strategic planning and policy making for their program, and often serve as mentors and role models for other feed/food protection professionals.
Advocacy	Providing information, conducting outreach and education, and justifying program resource needs to influence decisions within politiacl, economic, and social systems.
Communication Management	Crafting and controlling program messaging.
Communication Skills	
Compliance	Influencing industry to adhere to laws and regulations.
Emergency Response	
Human Resource Management	Overseeing the employee performance system to maximize efficiency based on program priorities, ensuring that the program meets its objectives, making decisions related to staffing, and addressing employee/employer concerns.
IFSS	Ensuring alignment with a shared feed and food safety vision.
Laws & Regulations	Managing the application and understanding the impact of legal authorities on program functions and activities.
Leadership Skills	

Legislative Affairs	Regulatory program interactions with the executive and lawmaking branches of government.
Mediation	Facilitating the process of finding solutions to disagreements, disputes, or conflicts.
Organizational Design	Creating and operationalizing organizational structures.
Program Resources	Planning and overseeing the personnel, physical, and financial assets necessary to carry out program activities.
Risk Management	Balancing program policies, strategies, and activities to address public health concerns.
Strategic Planning	The process of defining the mission, and assessing the current landscape, to determine the program's future direction.

Integrated Food Safety System [IFSS] Food Protection Professionals Curriculum Framework

ifpti

U.S. FOOD & DRUG ADMINISTRATION

Advanced

Level 2 Professional Certificate

Dairy - on Farm	Unprocessed Concentration	Acidified	Grade "A" Milk Processing	LACF	Aseptic	Plan Review	Special Processes	Animal Food Program

Basic

Level 1 Professional Certificate

Dairy - on Farm	Eggs	Produce	Sprouts	Shellfish Growing Areas	Preventive Control Inspections / cGMP Inspections	Juice HACCP / Food Processing Technology	Seafood HACCP / Laws, Regulations, & Guidance	Grade "A" Milk Processing	Dietary Supplements	Shellfish Plant	Regulatory Foundations for Retail Food Safety	Risk-Based Inspections	Non-Traditional Food Operations	Introduction to Specialized Processing Methods	Animal Food Program

Communication Skills	Emergency Response	Facility Design	Food Processes	Inspections	Investigations	Plumbing	Pest Control	Recall / Traceability	Sampling
Allergens *	Biological Hazards	Biosecurity	Communication Skills	Data & Information Systems	Emergency Response	Environmental Hazards	Food/Feed Defense	HACCP	IFSS	Imports	Inspections	Investigations	Jurisdiction	Labeling	Laws & Regulations	Personal Safety	Pest Control	Plumbing *	Preventive Controls **	Professionalism	Public Health Principles	Recalls	Regulatory Program Foundations	Sampling	Sanitation Practices	Traceability	Transportation

Food Establishment Plan Review Manual

2016 Version

As recommended by the Conference for Food Protection, Plan Review Committee

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PREFACE

The FOOD Establishment Plan Review Manual was developed to assist the REGULATORY AUTHORITY and architects, FOOD consultants and other interested professionals in the plan review process when proposing to build or remodel a FOOD ESTABLISHMENT. However, it does not establish regulatory requirements and the recommendations contained herein are not intended to supplant, or otherwise serve as, the rules and regulations applicable to FOOD ESTABLISHMENTs in a given Federal, State, local, or tribal jurisdiction.

- This Manual is intended as a training tool for individuals responsible for conducting plan reviews and can be used in Food and Drug Administration (FDA)-sponsored training courses on Plan Review.
- Is intended to be consistent with the recommendations of the FDA as contained in the FDA 2013 Food Code. The FDA Food Code contains requirements for safeguarding public health and ensuring FOOD is unadulterated and honestly presented when offered to the consumer. Terminology with respect to the word "shall" is based on the recommendations within the FDA Food Code.
- Was developed by the Conference for Food Protection's 2014-2016 Plan Review Committee to update the 2008 Plan Review for Food Establishments Document.

INTRODUCTION

The plan review process presents a unique opportunity to discuss and prepare a proper foundation that will enable a FOOD ESTABLISHMENT to be successful, remain in compliance over time, and protect public health. Quality plan review, process improvement and the dedication to providing excellent customer service are high priorities for this Manual. Plan review assists in providing greater uniformity, technical assistance, and is essential for customer success and avoiding future establishment problems. Poor design, repair, and maintenance will compromise the functionality of the PHYSICAL FACILITIES and its operations. Plan review is intended to ensure PHYSICAL FACILITIES and proposed operational processes are properly designed and sanitary practices implemented in order to serve their intended purposes.

The plan review process provides the REGULATORY AUTHORITY with the opportunity to complete an effective evaluation of a FOOD ESTABLISHMENT's ability to ensure the following:

- Minimum standards are met for the protection of environmental health and safety of the public.
- Prevention of environmental health related illness and promote public health.
- Minimum standards are met for the sanitary design, facility layout, operational and product flow, menus, construction, operation and maintenance of regulated establishments, PREMISES, and surroundings.
- Food Code violations are eliminated prior to construction or implementation.
- Conditions are corrected and prevented that may adversely affect persons utilizing regulated establishments.

- Technical assistance is provided to industry to establish organized and efficient operations.
- Meets consumer expectations for the safe operation of a permitted FOOD ESTABLISHMENT.

No establishment is to be constructed and no major alteration or addition is to be made until detailed plans and specifications for such construction, alteration or addition have been submitted to and APPROVED by the REGULATORY AUTHORITY.

The REGULATORY AUTHORITY may impose specific requirements and provisions in addition to the requirements contained in codes that are authorized by law that are necessary to protect against public health hazards or nuisances. The REGULATORY AUTHORITY shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale.

The function of plan review, construction inspections, pre-operational inspections, and the permit approval process is to provide a comprehensive overview of proposed operations with an emphasis on contents of plans, EQUIPMENT specifications, architectural design, and operational procedures. The end goal of the plan review process is to prevent foodborne illness resulting from poor sanitary facility design and/or floor plans, and, where applicable, when the process is based on menu, FOOD preparation, and FOOD product flow.

DEFINITIONS

The following definitions as used in this document are intended to assist in the understanding of this manual.

Definitions found within the FDA Food Code have been identified in CAPS within this document. A link to the FDA Food Code is included for your reference.
http://www.fda.gov/FOOD/GuidanceRegulation/RetailFOODProtection/FOODCode/ucm374275.htm

"Easily Disassembled Equipment" means EQUIPMENT that is accessible for cleaning and inspection by:

(1) Disassembling without the use of tools, or

(2) Disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

"Flashing" means an impervious sheet of material placed in construction to prevent water penetration or direct flow of water.

"Service Sink" means a curbed cleaning facility or janitorial sink used for the disposal of mop water and similar liquid wastes.

CONTENTS AND FORMAT OF PLANS AND SPECIFICATIONS

Proper plan review submittal with EQUIPMENT listed and located on floor plans as well as specifications for finish and plumbing schedules will highlight potential problems on paper while allowing for modifications to be made before costly purchases, installations, and construction are performed.

All facilities, systems, processes, and menus, when applicable, will be evaluated to determine minimum operational requirements. Refer to Appendix A for a copy of the Plan Review Application.

The following is a summary of what should be included in the plan submittal:

- Legible plans at minimum of 11 x 14 inches in size drawn to scale (scale - ¼ inch = 1 foot)
- Proposed menu, seating capacity, and projected daily meal volume for the FOOD ESTABLISHMENT.
- Provisions for adequate rapid cooling, including ice baths and refrigeration, and for hot and cold-holding of TIME/TEMPERATURE CONTROL for SAFETY (TCS) FOOD.
- Location of all FOOD EQUIPMENT. Each piece of EQUIPMENT must be clearly labeled, marked, or identified. Provide EQUIPMENT schedule that identifies the make and model numbers and listing of EQUIPMENT that is certified or classified for sanitation by an ANSI accredited certification program (when applicable). Elevation drawings may be requested by the REGULATORY AUTHORITY.
- Location of all required sinks: HANDWASHING SINKS, WAREWASHING sinks, Utility Sink and FOOD preparation sinks (if required).
- Auxiliary areas such as storage rooms, garbage rooms, toilets, basements and/or cellars used for storage or FOOD preparation.
- Entrances, exits, loading/unloading areas and delivery docks.
- Complete finish schedules for each room including floors, walls, ceilings and coved juncture bases.
- Plumbing schedule including location of floor drains, floor sinks, water supply lines, overhead waste-water lines, hot water generating EQUIPMENT with capacity and recovery rate, backflow prevention, and wastewater line connections.
- Location of lighting fixtures.
- Source of water and method of SEWAGE disposal.
- A color coded flow chart may be requested by the REGULATORY AUTHORITY demonstrating flow patterns for:
  - FOOD (receiving, storage, preparation, service);
  - UTENSILS (clean, soiled, cleaning, storage); and
  - REFUSE (service area, holding, storage, and disposal).
- Storage of Employee Personal Items.
- Ventilation.

MENU REVIEW AND FOOD FLOW

The menu review and the flow of FOOD through the FOOD ESTABLISHMENT are integral parts of the plan review process. The menu or a listing of all of the FOOD and beverage items to be offered at the FOOD ESTABLISHMENT must be submitted as part of the plan review application to the REGULATORY AUTHORITY.

As with the inspection process, the plan review process should focus on the FOOD and its flow through receipt, storage, preparation and service. The source and quantity of FOOD to be served should be reviewed along with the preparation and post-preparation operations. It is imperative to have knowledge of this information so that a proper assessment of the PHYSICAL FACILITIES can be made.

The food that flows through retail FOOD ESTABLISHMENT operations can be placed into the 3 following processes:

- **FOOD PROCESSES WITH NO COOK STEP**
  - **Receive – Store - Prepare – Hold – Serve**

  (Other processes may occur, but there is **NO cooking step**)
  - Examples: Salads, deli meats, cheeses, sashimi, raw oysters

- **FOOD PREPARATION FOR SAME DAY SERVICE**
  - **Receive – Store - Prepare - Cook – Hold – Serve**

  (Other processes may occur, including thawing)
  - Examples: Hamburgers, fried chicken, hot dogs

- **COMPLEX PROCESSES**
  - **Receive – Store - Prepare – Cook – Cool – Reheat – Hot Hold – Serve** (Other processes may occur, but the key is repeated trips through the temperature danger zone)
  - Examples: Refried beans, leftovers

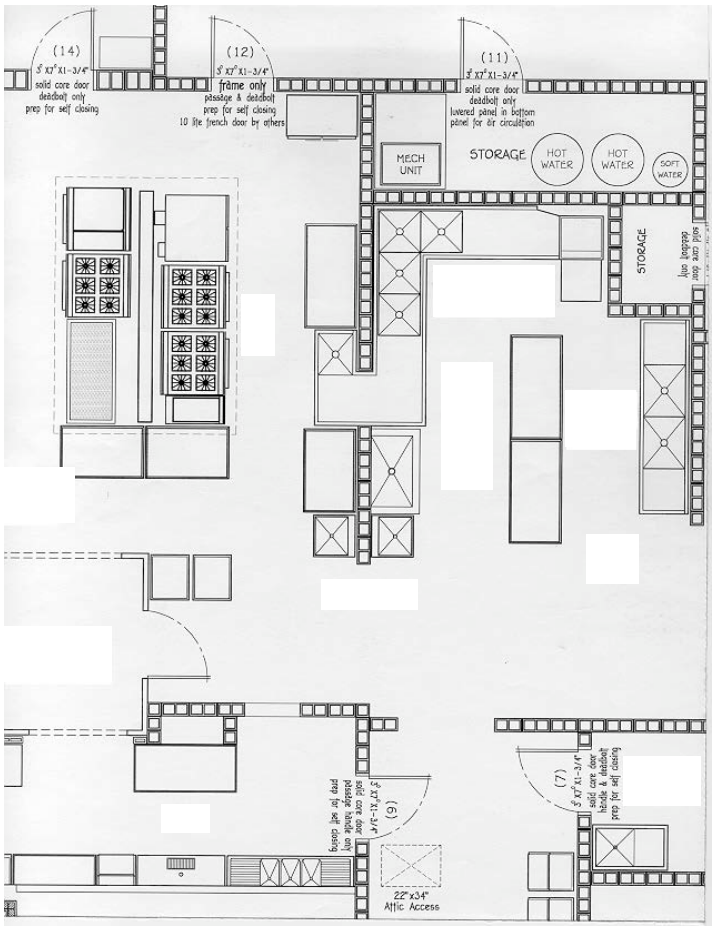
Knowledge of how the FOOD is intended to flow through the FOOD ESTABLISHMNET is very useful since the CRITICAL CONTROL POINTS for each process remain the same regardless of the individual menu ingredients.

Special attention should be given to the review of complex FOOD processes which involve:

- Multiple ingredients being assembled or mixed
- TIME/TEMPERATURE CONTROL FOR SAFETY(TCS) FOODs
- FOODs which will be prepared or held for several hours prior to service
- FOODs requiring cooling and reheating
- Multiple step processing (passing through the Time Temperature Danger Zone,

135˚F - 41˚F more than once)

The process approach can be described as dividing the many flows in a FOOD ESTABLISHMENT into broad categories, analyzing the risks, and placing manager controls on each grouping of FOOD processes. These groupings will also impact the facility design; FOOD flow; and the numbers, types, function and placement of EQUIPMENT.



The drawing above is an example of a fixture plan submitted for plan review. It is a handy tool when following the FOOD process as described by the FOOD ESTABLISHMENT operator or their representative.

Layout, flow and menu (including FOOD preparation processes) should be major considerations to help facilitate an operator's Active Managerial Control (AMC) of the risk factors for foodborne illness. Strategic layout and placing of facilities and EQUIPMENT will separate different FOOD preparation processes, a major step towards preventing contamination of FOOD that may result from poor personal hygiene, contaminated EQUIPMENT, and improper holding temperatures. Adequate and convenient storage will also enhance operations.

The menu for a FOOD ESTABLISHMENT dictates the space and EQUIPMENT requirements for the safe preparation and service of various FOOD items. The menu will determine if the proposed receiving and delivery areas, storage area, preparation and handling areas, and thawing, cooking and reheating areas are available and adequate to handle the types and volumes of FOODs being prepared and served.

When reviewing the menu, it is important to evaluate the flow patterns for the preparation of the FOOD to be sure that the lay-out of the facility provides an adequate separation of raw ingredients from READY-TO-EAT FOODs, and that the traffic patterns are not crossing paths with waste items and other sources of contamination. Cross contamination can be minimized when the flow of FOOD is considered during plan review.

With a proper understanding of the menu and flow, the plans for FOOD ESTABLISHMENTS can be reviewed to help assure that the FOOD items being considered can be protected during all aspects of the FOOD operation.

FOOD Process and Steps Required

	Receive	Store	Prepare	Cook	Cool	Reheat	Hold	Service
NO COOK	X	X	X				X	X
SAME DAY SERVICE	X	X	X	X			X	X
COMPLEX PROCESSES	X	X	X	X	X	X	X	X

Anticipated EQUIPMENT needs

Receive	Store	Prepare	Cook	Cool	Reheat	Hold	Serve
Thermometer	**Dry Storage**	**Preparation Tables**	**EQUIPMENT**	**Preparation Sink**	**Fryers**	**Refrigerators**	**Cold Holding Facilities**
	Refrigerated Storage	**Cutting Boards**	**Fryer**	**Ice Bath**	**Oven**	**Ice**	**UTENSILs**
	Frozen Storage	**UTENSILs**	**Oven**	**Blast Chiller**	**Grills**	**Cold Holding**	**Hot Holding Facilities**
	Thermometer	**Hand wash Sinks**	**Broiler**	**Shallow Plans**	**Burners**	**Hot Holding**	
		Preparation Sinks	**Grill**	**Refrigerators**	**Griddle**	**FOOD Warmers**	
		Refrigerators	**Cook Top**	**Chill Sticks**	**Other**	**Thermometer**	
			Griddle	**Thermometer**	**Hand wash Sink**	**Hand wash Sinks**	
			Other	**Hand wash Sink**			
			Thermometer	**Preparation Table**			
			Hand wash Sink	**Other**			

PREVENTIVE TOOLS FOR THE FOOD ESTABLISHMENT

Active Managerial Control (AMC)

To effectively reduce the occurrence of foodborne illness risk factors, operators of FOOD ESTABLISHMENTs must focus their efforts on achieving active managerial control. The term "active managerial control" is used to describe industry's responsibility for developing and implementing FOOD safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors.

Elements of an effective FOOD safety management system may include the following:

- Certified FOOD protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for performing critical operational steps in a FOOD preparation process, such as cooling.
- Recipe cards that contain the specific steps for preparing a FOOD item and the FOOD safety critical limits, such as final cooking temperatures, that need to be monitored and verified.
- Purchase specifications

HACCP

Hazard Analysis and Critical Control Points (HACCP) plays a vital role in proper FOOD ESTABLISHMENT design. However, the risk management tool is not considered a "stand-alone" FOOD safety system. Design and construction are essential pre-requisites and must be put in place prior to the implementation and operation of effective FOOD production practices. The purpose of quality plan review is to ensure that FOOD ESTABLISHMENTs are safe, sanitary, and efficient. Proper design, construction, and HACCP principles work to achieve these purposes and minimize the aforementioned hazards.

Effective HACCP principles are essential to a successful FOOD ESTABLISHMENT and begin with the design and layout of the facility, monitoring the FOOD flow throughout the establishment, from delivery, storage, preparation, cooking, service and consumption. A well-designed progressive FOOD flow system will minimize cross-contamination and maximize efficiency in an establishment.

Good manufacturing policies or practices, standard operating procedures (SOPs), and documentation are essential to an establishment's HACCP-based FOOD safety program and control over potential hazards. HACCP policies specifically address requirements set out in the FDA Food Code. Additional standards or good retail practices are required as foundation for FOOD safety and are detailed in the FDA Food Code. Examples include employee hygiene, employee restriction or exclusion, general sanitation, design, etc. HACCP/VARIANCE under the Plan Review & Construction Program is responsible for the review of HACCP procedures and VARIANCE applications in order for establishments to conduct specialized operations.

The FDA Food Code requires an APPROVED HACCP PLAN to be in place for some specialized processes not listed under §3-502.11. A formal HACCP PLAN review is required and needs to be APPROVED prior to conducting these operations. For information on creating a HACCP PLAN, contact the local regulatory plan reviewer or visit one of these informational hyperlinks: FDA Guidance to Implement HACCP Systems or USDAHACCPGuidelines.

FACILITIES TO MAINTAIN PRODUCT TEMPERATURE

Refrigerators and freezers are required to maintain TCS FOOD at or below 41°F and 0°F (frozen) respectively. It is recommended that refrigerators be maintained between 36°F and 38°F. All refrigeration units must have numerically scaled indicating thermometers accurate to ±3°F. Sufficient refrigeration and freezers shall be provided to support the intended menu. Consideration must be taken with the placement and installation of refrigeration units to allow for adequate ventilation. Air circulation within refrigeration and freezer units should not be obstructed and should allow for an even and consistent flow of cold air throughout the units

Refrigeration and freezer storage involves five major areas:

1. Storage for short-term holding of perishable and TCS FOOD.
2. Long-term storage.
3. Storage space for quick chilling of FOODs.
4. Space for assembling and processing of TCS FOOD.
5. Display storage for customer service.

If TCS foods are prepared a day or more in advance of service, a rapid cooling procedure capable of cooling TCS foods from 135°F to 41°F within 6 hours (135°F to 70°F within 2 hrs.) must be provided. The capacity of the rapid cooling facilities must be sufficient to accommodate the volume of food required to be cooled to 41°F within 6 hours. The location of the rapid cooling facilities (e.g., sinks for ice baths, freezer storage for ice wands, blast chillers) must be identified. Refrigerators and freezers at work stations for operations requiring preparation and handling of TCS foods should be considered. For example, it may be necessary to locate a freezer near the fryer where frozen products will be deep-fried. Refrigeration units, unless designed for such use, should not be located directly adjacent to cooking EQUIPMENT or other high heat producing EQUIPMENT which may adversely impact the cooling system's operation.

A. Refrigeration Storage Calculations

Calculating the amount of refrigeration and freezer space should be based on the menu and expected FOOD volume. The amount and location of refrigeration and freezer EQUIPMENT should complement the FOOD flow of the operation from receiving, storage and FOOD processing, to the point of service.

To plan refrigeration storage, the following items should be considered: menu, type of FOOD

operation, number of meals per day, number of deliveries per week, and adequate ventilation in the areas where the refrigeration systems will be located. When assessing the refrigeration needs, shelving space within the refrigeration and freezer units should be designed to prevent the cross-contamination of FOODs. Separating raw meats and poultry from ready-to-eat FOODs such as produce and prepared FOOD items. Thermometers must be conspicuously located in all units. Thermometer sensing elements should be located near the door

Formulas can be used to estimate refrigerated storage space. To calculate, you will need information on number of meals estimated to be served per day, days between deliveries and storage area availability. Links to example calculators can be found in Appendix C.

B. Walk-in Cooler/Freezer Units

Walk-in units should meet an ANSI accredited certification or equivalent, or deemed acceptable by the Regulatory Authority. A walk-in beverage or beer cooler is not recommended for FOOD storage. APPROVED flooring and integral cove bases need to be provided. Quarry tile, ceramic, and galvanized flooring are not recommended flooring materials for walk-in units. All gaps, cracks, penetrations, seams, and plug holes shall be SEALED SMOOTH and flush with the surface material.

Walk-in units should be installed when there is a need for long-term storage of perishable and TCS FOOD or when cooling space is needed for prepared and cooked FOODs. These coolers should be located near delivery or receiving areas. EASILY CLEANABLE curtain strips are recommended at walk-in doors. This not only helps in maintaining the temperature of the walk-in but also leads to an energy cost savings.

Exterior walk-in unit locations shall be properly designed for exterior installation and consideration given varied environmental concerns. Walk-in units should be designed with a roof, APPROVED overhead waterproof protection, and walkways shall be provided for the transportation of FOOD items. Walk-in units shall be APPROVED by the local building official and are evaluated and APPROVED on a case-by-case basis by the REGULATORY AUTHORITY.

If the walk-in floors will be water-flushed for cleaning or receive the discharge of liquid waste or excessive melt water, the floors should be sloped to drain. If the structure of the walk-in is integral with the building, properly installed floor drains may be installed inside the unit.

Each walk-in unit shall be equipped with lighting that provides 10 foot candles of light throughout the unit when it is full of product. Lights must be properly shielded or shatter resistant.

Condensate lines from walk-in units shall drain to APPROVED floor drains or alternative method APPROVED by the REGULATORY AUTHORITY. Without prior approval floor sinks or floor drain sinks shall not be installed in walk-in units. All walk-in units shall be properly

flashed off and SEALED to the ceiling and side walls. Walk-in units are not to be confused with refrigerated FOOD processing rooms. Refer to Item G-Refrigerated Processing Rooms.

C. Reach-in Refrigerators

These units are for short-term storage of perishable and TCS FOODs. These units should be considered to meet the daily storage demands of the kitchen operation. They are to be conveniently located at points of FOOD preparation and FOOD assembly. These units are not to be considered for the quick chilling of cooked and prepared FOODs.

D. Reach-in Freezers

Freezers are for long-term storage. They are not designed to be used as quick-chill units. These units should be located near delivery and DRY STORAGE AREAs.

E. Blast Chillers/Rapid Chill Units

These units are recommended for use when handling large volumes of FOOD that require quick chilling. A blast chiller is an efficient cooling mechanism for any amount of FOOD to be chilled, and where refrigeration cooling space is limited.

F. Refrigerated Worktables

These units are suggested when the menu includes assembling TCS FOODs. These units provide easy access of FOODs from the top of the unit. These units are not designed for long-term storage of FOOD or cooling.

G. Refrigerated Processing Rooms

These areas (e.g. meat cutting rooms) should be considered when there is extensive handling of cold TCS FOOD. APPROVED hand sinks should be located in these areas.

H. Display Storage Refrigerators

These units are designed to display TCS FOOD under refrigeration. Examples of these units are deli display, fresh fish, and meat and poultry cases.

I. Customer Service Display Units/ Cold Buffet Units

These units are designed for holding FOOD under refrigeration for customer access. They are designed for short-term display and are not designed for the cooling of FOOD. Beverage display coolers are not APPROVED for storing open TCS FOODs.

Cold buffets and salad bars are designed for short-term display. They should be mechanically refrigerated, and have APPROVED sneeze guards with side panel protection.

J. Ice Machines

If ice is to be used as a cooling medium for FOOD and beverage items the unit should be adequately designed and sized to meet all operational needs in an APPROVED location. Ice machines designed for outdoor dispensing will need National Automatic Merchandising Association (NAMA) certification

K. General Cooking and Hot Holding

Cooking and hot holding units are designed to heat FOOD to a required temperature within a required amount of time for FOOD safety. Cooking and reheating temperatures have been determined using scientific analysis. The time and temperature requirements are based on the pathogens that are likely to be present on the product. It is recommended that the units are commercial grade and meet NSF/ANSI standards. Consideration must be taken with the placement and installation of cooking/reheating/hot holding EQUIPMENT to ensure that proper ventilation and sanitation can occur. Construction of these units should be durable and EASILY CLEANABLE

NOTE: The commercial appliances described in this section are placed under a vent hood to evacuate grease, steam, and fumes, which could pose a potential fire or health risk. Refer to the topic on Ventilation of this Manual or your REGULATORY AUTHORITY for specific requirements.

Units used to heat FOOD are divided into two categories:

1. Cooking/Reheating
2. Hot Holding

All units in use must be able to meet the minimum required heated temperatures outlined in the FDA Food Code, Chapter 3-4 Destruction of Organisms of Public Health Concern. http://www.fda.gov/FOOD/GuidanceRegulation/RetailFOODProtection/FOODCode/default.htm

L. Stovetops and Grills

Gas, electric, or wood-burning stoves are used to cook and reheat product in pots or pans. A grill is similar to a stove with the ability to place the FOOD directly over the flame.

M. Ovens

Ovens are thermally insulated chambers used for cooking or reheating FOODs. They can be gas, electric, or wood-burning units.

N. Combination Oven/Steamer (Combi Oven)

A Combi oven/steamer is similar to a convection oven with the ability to produce dry heat, moist heat, or a combination of the two.

O. Rice Cooker/Warmer

The unit is an electric appliance that is capable of cooking rice and then hot holding the rice at 135°F or above. Scoops or ladles for serving may be stored in a running dipper well.

P. Kettle

Kettles are cooking pots used to boil large quantities of FOOD products. The units are generally clean-in-place and should have the necessary tools for sanitation. Adequate floor drains must be present for disposal of spent water.

Q. Rotisserie

Rotisseries are self-contained units that include a heat source and racks for skewers or spits. Beef, pork, or poultry is rotated over the fire to cook the FOOD to the required temperature.

R. Small Appliances

Small appliances (table top) include microwaves, Panini press, broilers, and toasters. These units are used to heat FOOD to the required cook or reheat temperature depending on the application.

S. Fryers

Fryers are cooking devices that use oil heated to a high temperature. The hot oil has a flash point that can result in a fire. Follow the manufacturer's instructions for operation, maintenance and cleaning to prevent a fire incident.

T. Hot Tables

Hot tables are gas or electrically heated units that are design to maintain temperature. They should never be used to cook or reheat TCS FOODs. The design should allow for disassembly and deep cleaning of interior surfaces. These units must be able to maintain a minimum temperature of 135°F.

U. Customer Service Display Units/Hot Buffet Units

These are gas or electrically heated units that are designed to maintain temperature. They should never be used to cook or reheat TCS FOODs. They should be constructed of durable and EASILY CLEANABLE materials. The design should allow for disassembly and deep cleaning of interior surfaces. The design should protect FOOD from contamination that could occur from the environment or customers by using sneeze shields or covers. The units must be able to maintain a minimum temperature of 135°F

EQUIPMENT AND INSTALLATION

All EQUIPMENT in a FOOD ESTABLISHMENT must comply with the design and construction standards contained in Chapter 4 of the FDA Food Code. FOOD EQUIPMENT that is certified or classified for sanitation by an ANSI accredited program is deemed to comply with Parts 4-1 and 4-2 of the FDA Food Code.

EQUIPMENT including ice makers and ice storage EQUIPMENT, shall not be located under exposed or unprotected sewer lines, open stairwells or other sources of contamination.

The following EQUIPMENT installation recommendations will help ensure proper spacing and sealing allowing for adequate and easy cleaning.

A. Floor-Mounted Equipment

EQUIPMENT should be mounted on APPROVED lockable casters, gliders or wheels to facilitate easy moving, cleaning, and flexibility of operation whenever possible. Moveable EQUIPMENT requiring utility services such as gas or electrical connections should be provided with easily accessible quick-disconnects or the utility service lines should be flexible and of sufficient length to permit moving the EQUIPMENT for cleaning. If a flexible utility line is used, a safety chain that is shorter than the utility line must be installed. Check with local fire safety and building codes to ensure that such installations are acceptable.

Floor-mounted EQUIPMENT that is not mounted on wheels or casters with the above utility connections should be:

1. Permanently SEALED to the floor around the entire perimeter of the EQUIPMENT. The sealing compound should be pliable and non-shrinking. It should retain its elasticity and provide a water- and vermin-tight joint; or
2. Installed on a solid, SMOOTH, non-absorbent masonry base. Masonry bases and curbs should have a minimum height of 2" and be coved at the junction of the platform and the floor with at least a 1/4" radius. The EQUIPMENT should overhang the base by at least 1" but not more than 4". Spaces between the masonry base and the EQUIPMENT must be SEALED as above; or
3. Elevated on legs to provide at least a 6" clearance between the floor and EQUIPMENT. The legs shall contain no hollow open ends.
4. For EQUIPMENT not readily moveable by one person, spacing between and behind EQUIPMENT must be sufficient to permit cleaning under and around the unit. EQUIPMENT shall be spaced to allow access for cleaning along the sides, behind and above. At least 6" of clear, unobstructed space under each piece of EQUIPMENT must be provided or EQUIPMENT must be SEALED to the floor.
5. If EQUIPMENT is against a wall and is not movable, the EQUIPMENT must be joined to and/or SEALED to the wall in a manner to prevent liquid waste, dust and debris from collecting between the wall and the EQUIPMENT.
6. When EQUIPMENT is joined together, or spreader plates are used between

EQUIPMENT, the resultant joint must be SEALED to prevent liquid waste, dust and debris from collecting between the EQUIPMENT.

Unobstructed and functional aisle and working spaces must be provided. A minimum width of 36" is required by fire and building codes.

All utility and service lines and openings through the floor and walls must be adequately SEALED. Penetrations through walls and floors must be minimized. Exposed vertical and horizontal pipes and lines must be kept to a minimum. The installation of exposed horizontal utility lines and pipes on the floor is prohibited. Any insulation materials used on utility pipes or lines in the FOOD preparation or dishwashing areas must be SMOOTH, non-absorbent, and easy to clean. Electrical units which are installed in areas subject to splash from necessary cleaning operations or FOOD preparation should be water-tight and washable.

B. Counter-Mounted Equipment

COUNTER-MOUNTED EQUIPMENT is defined as EQUIPMENT that is not portable and is designed to be mounted off the floor on a table, counter, or shelf. All COUNTER-MOUNTED EQUIPMENT shall be:

- SEALED to the table or counter; or
- Elevated on APPROVED legs to provide at least a 4" clearance between the table or counter and the EQUIPMENT to facilitate cleaning.

C. Other

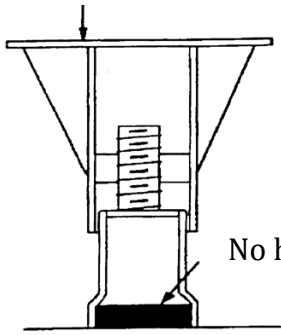
EQUIPMENT that is open underneath, such as drain boards, dish tables, and other tables that are not moveable should be spaced to allow for ease of cleaning or should be SEALED to the wall.

Non-FOOD contact surfaces of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning shall be constructed of corrosion-resistant, non-absorbent, and SMOOTH material.

Legs of all EQUIPMENT should not have hollow, open ends.

If running water dipper wells are installed, methods for filling and draining the units must be identified.

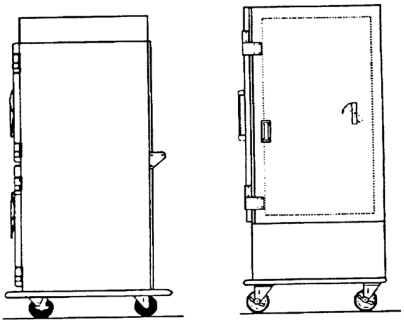
Equipment sealed to floor



No hollow open ends

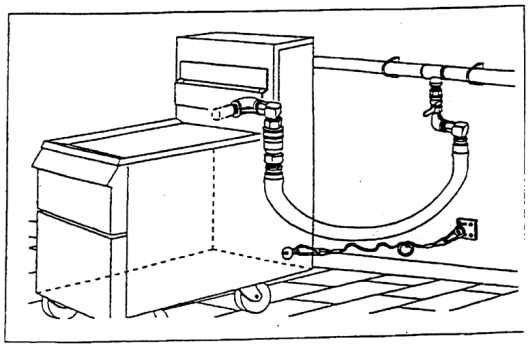
Elevate equipment for effective cleaning.

Sanitary Leg Example



Mobile Kitchen equipment mounted on Castor

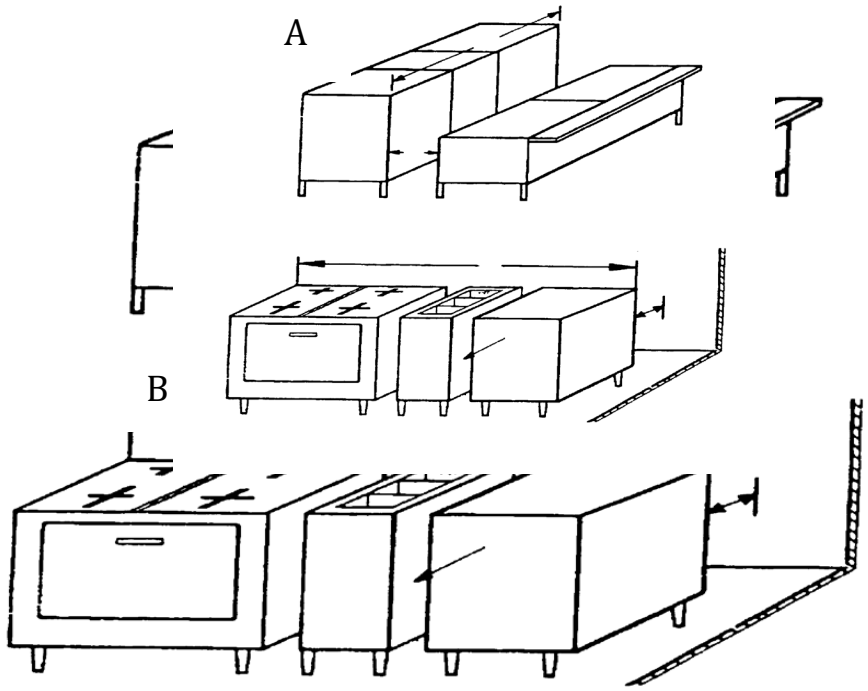
Holding Cabinet & a Reach-in Refrigerator



Refer to your Local Regulatory Authority for Gas Code Requirements

Flexible Gas Connection with Safety Chain

Equipment Spacing



Recommended EQUIPMENT spacing; provided access is available from both ends:

EQUIPMENT Length (A)	Space From Walls and Adjacent EQUIPMENT (B)
4' or less	6"
4' - 8'	12"
8' or more	18

WAREWASHING FACILITIES

The minimum requirement for WAREWASHING in a FOOD ESTABLISHMENT is a three-compartment sink. A mechanical WAREWASHING machine may be installed in addition to the three-compartment sink.

A. Manual Ware washing

For manual WAREWASHING, a stainless steel sink with no fewer than three compartments must be provided, with the exception that a two-compartment sink may be allowed by the REGULATORY AUTHORITY under certain conditions.

- The sink compartments shall be large enough to completely immerse the largest pot, pan or piece of EQUIPMENT to be used in the establishment that will not be cleaned in-place.
- Each compartment shall be supplied with adequate hot and cold potable running water, temperature of the wash solution shall be maintained at not less than 110°F, or the temperature specified on the cleaning agent manufacturer's label instructions.
- Drain boards, UTENSIL racks or tables large enough to accommodate clean and soiled UTENSILs shall be provided. The drain boards shall be self-draining.
- Adequate facilities for pre-flushing or pre-scrapping EQUIPMENT and UTENSILs must be provided.
- If hot water is used to sanitize EQUIPMENT and UTENSILs, the means for heating the water to 171°F in the 3rd compartment must be identified. The racks for the immersion of EQUIPMENT and UTENSIL must be specified.

B. Mechanical Ware washing

WAREWASHING machines shall be installed in accordance with the manufacturer's recommendations and applicable code requirements. If used, the hot water booster for WAREWASHING machines must be identified during plan review.

Adequate facilities shall be provided to air dry washed EQUIPMENT and UTENSILs. Drain boards, UTENSIL racks or tables must be large enough to allow proper and sufficient air drying of EQUIPMENT and UTENSILs.

Storage facilities shall be provided to store cleaned and sanitized UTENSILs and EQUIPMENT at least 6" above the floor; protected from splash, dust, overhead plumbing or other contamination. The plan must specify the location and facilities used for storing all UTENSILs and EQUIPMENT.

PLUMBING

A. Water Supply

The primary concerns relative to the water supply in a FOOD ESTABLISHMENT are:
1. Ensure the facility is supplied with a safe and adequate water supply, including adequate supply of hot water; and
2. Verify that the water can remain safe while it is in the facility.

Safe Source: Start at the water source. Determine if the water is potable or non-potable. The availability of an APPROVED public water supply must be verified. Any use of a non-public water source (well water) shall comply with local, state, and/or federal laws, and construction and testing standards.

Sufficient potable water: Potable water shall be provided from a source constructed and

operated according to law that meets the peak water demands of the FOOD ESTABLISHMENT.

B. Hot Water Supply:

The hot water supply shall be sufficient to satisfy peak hot water demands of the FOOD ESTABLISHMENT. Hot water for hand washing and most FOOD ESTABLISHMENT uses shall be at least 100°F. Hot water for mechanical WAREWASHING must be boosted up to 150°F-165°F for washing and 165°F-180°F for sanitizing or according to the manufacturer's data plate on the machine. The temperature of the wash solution for spray-type ware washers that use chemicals to sanitize may not be less than 120°F.
The temperature of the wash solution for manual WAREWASHING must be maintained to not be less than 110°F. The water temperature for manual hot water sanitization must be at least 171°F.

Tank less water heaters shall be installed and used in accordance with the manufacturer's recommendations.

For guidance on calculating Hot Water Requirements see Appendix C – Model Calculations

C. Sewage Disposal, Grease Interceptors/Traps

All SEWAGE including liquid waste shall be disposed into a public SEWAGE system or an individual SEWAGE disposal system constructed and operated according to law. Where individual SEWAGE disposal systems are utilized, the location shall be noted on the plans and certification of compliance with state and local regulations shall be provided.

A grease trap/interceptor is a chamber designed for wastewater to pass through and allow any grease to float to the top for retention as the remainder of the wastewater passes through. If used, a grease trap shall be located to be easily accessible for cleaning; FOOD solids entering the grease trap/interceptor should be minimized.

It is recommended that waste water from fixtures or drains which would allow fats, oils, and grease to be discharged be directed to a grease trap/interceptor. Local municipalities/jurisdictions will determine the number and size of grease traps, grease interceptors or catch basins. If installed, grease traps shall be properly spaced so they are easily accessible for servicing and cleaning. Refer to the local municipality/jurisdiction for the installation requirements.

D. Backflow Protection

Plumbing shall be sized and installed according to applicable codes. There shall be no cross connections between the potable water supply and any non-potable system or a system of unknown quality. Where non-potable water systems are permitted for purposes such as air conditioning and fire protection, the non-potable water must not contact directly or

indirectly: FOOD, potable water or EQUIPMENT that contacts FOOD or UTENSILs. The piping of any non-potable water system shall be durably identified so that it is readily distinguishable from piping that carries potable water.

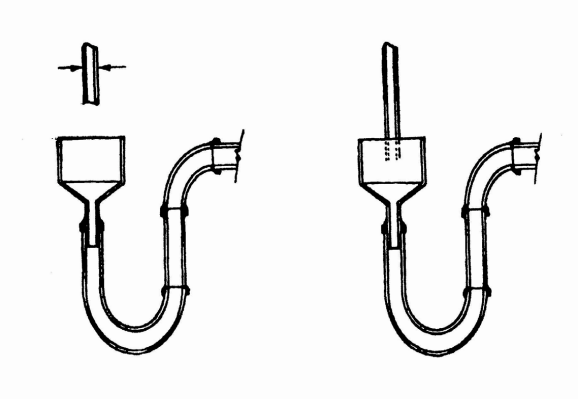
A connection to a sewer line may be direct or indirect. A direct connection may not exist between the sewerage system and any drains originating from EQUIPMENT in which FOOD, portable EQUIPMENT, or UTENSILs are placed, except if otherwise required by law. When a WAREWASHING machine is located within 5 feet of a trapped floor drain, the dishwasher waste outlet may be connected directly on the inlet side of a properly vented floor drain trap.

An **indirect connection** may be one of two types, air gap or air break:

1. For a potable water supply, an **air gap** means the unobstructed, vertical air space that separates a potable system from a non-potable system.

2. An **air break** is a waste line from a fixture that discharges used water or liquid waste to a drain where the waist line terminates below flood level.

AIR GAP AIR BREAK



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HYGIENE FACILITIES

A. Handwashing

Handwashing is a critical factor to prevent contamination of FOODs. Proper handwashing reduces the amount of pathogens that can be transmitted via cross contamination from raw

FOODs to READY-TO-EAT-FOODS. It is imperative to have adequate numbers and conveniently placed HANDWASHING SINKS to ensure employees are washing hands. It is important that handwashing be done only at properly equipped HANDWASHING SINKS to help ensure that employees effectively clean their hands and minimize contamination of FOOD and FOOD-CONTACT SURFACES.

A HANDWASHING SINK, hand drying device or disposable towels, hand cleanser and waste receptacle shall be located for convenient use by employees who work in FOOD preparation, FOOD dispensing, and WAREWASHING areas.

Nothing must block the approach to a HANDWASHING SINK.

HANDWASHING SINKS must also be located in or immediately adjacent to toilet rooms.

HANDWASHING SINKS shall be of sufficient number and conveniently located for use by all employees in FOOD preparation, FOOD dispensing, and WAREWASHING areas.

HANDWASHING SINKS shall be easily accessible and may not be used for purposes other than handwashing. Sinks used for FOOD preparation, washing EQUIPMENT or UTENSILs, or service (mop) sinks shall not be used for handwashing.

Each handwashing sink shall be provided with hot and cold water tempered by means of a mixing valve or a combination faucet to provide water at a temperature of at least 100˚F. If used, self-closing, slow-closing or metering faucets shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

Splash from use of a handwashing sink may not contaminate FOOD, FOOD-CONTACT SURFACES, clean EQUIPMENT or UTENSILs. A washable baffle or barrier may be needed if the handwashing sink is located next to a FOOD preparation area, UTENSIL or EQUIPMENT storage, or FOOD-CONTACT SURFACE and if the space between the handwashing sink and FOOD, FOOD preparation, FOOD-CONTACT SURFACES, and clean UTENSILs and EQUIPMENT does not provide adequate protection.

Similarly, the location of soap and paper towel dispensers at HANDWASHING SINKS must be reviewed during plan review so that their use does not contaminate FOOD, FOOD-CONTACT SURFACES, UTENSILs and EQUIPMENT. In addition, the distance that employees would have to reach the faucet handles, soap and paper towels must be reviewed during plan review to assure that they will have proper access to the HANDWASHING SINKS and will not have to reach across dirty surfaces while washing their hands.

B. Toilet Rooms

Properly functioning toilet facilities must be accessible to employees at all times.

If required by federal, state, local or tribal laws and regulations, toilet facilities must be made available to the customers. If the public toilet facilities are used by employees,

separate toilet facilities may not have to be installed for the employees. Toilet facilities must be made accessible in accordance with the Americans with Disabilities Act (ADA) of 1990.

The floors, walls, and ceiling in toilet rooms shall be SMOOTH and EASILY CLEANABLE. The walls around toilets, urinals, toilet paper dispensers, soap dispensers, and paper towel dispensers should be water resistant and durable for frequent cleaning.

The minimum requirements for toilet facilities shall include:

- **Toilet:** At least one toilet and not fewer than the number of toilets required by law shall be provided. If authorized by law, urinals may be substituted for additional toilets in men's toilet rooms.
- **HANDWASHING SINK:** Each HANDWASHING SINK shall be provided with hot and cold water tempered by means of a mixing valve or a combination faucet to provide water at a temperature of at least 100˚F. If used, self-closing, slow-closing or metering faucets shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet.
- **Handwashing cleanser:** Each HANDWASHING SINK or group of two adjacent HANDWASHING SINKS shall be provided with hand cleaning liquid, powder, foam or bar soap. A dispenser shall be provided for handwashing cleanser provided in liquid or powder form.
- **Hand drying facility:** Each HANDWASHING SINK or group of adjacent HANDWASHING SINKS shall be provided with individual, disposable towels; a continuous towel system that supplies the user with a clean towel; heated-air hand drying device; or hand drying device with air-knife, high velocity air at ambient temperatures.
- **Toilet paper:** A supply of toilet paper shall be provided in a dispenser at each toilet.
- **Waste receptacle:** If disposable towels are used, a waste receptacle shall be located at each sink or group of sinks. At least one covered waste receptacle shall be provided in toilet rooms used by females.
- **Ventilation:** Toilet rooms must be vented to the outside. Mechanical Ventilation shall be installed in toilet rooms according to law. If allowed by law, operable screened windows may be used in lieu of mechanical ventilation devices.
- **Toilet room doors:** Toilet room doors shall be tight-fitting and self-closing.
- **Lighting:** At least 215 lux (20 foot candles) shall be provided in toilet rooms.

STORAGE

A. Dry Storage-

The dry storage space needed depends on the menu, number of meals served between deliveries, frequency of deliveries, and the amount and type of SINGLE-SERVICE ARTICLES to be stored. The location of dry storage should be adjacent to the FOOD preparation area and convenient to receiving. Adequate ventilation should be provided. FOOD should not be

stored under exposed sewer lines. Similarly, a cabinet that is used for the storage of FOOD, shall not be located under exposed or unprotected sewer lines, open stairwells or other sources of contamination. Stationary shelving needs to have a minimum 6" floor clearance.

Shelving, dollies, racks, pallets and skids shall be corrosion-resistant, non- absorbent and SMOOTH. Pallets, racks and skids used for bulk cased or overwrapped items shall be designed to be moved by hand or by conveniently located hand trucks or forklifts. Shelving, dollies, racks, pallets and skids should be spaced away from walls to allow for cleaning and pest monitoring/inspection.

APPROVED FOOD containers with tight-fitting covers and dollies should be used for storing bulk FOODs such as flour, cornmeal, sugar, dried beans, rice and similar.

B. Dry Storage Calculations

Formulas can be used to estimate the amount of dry storage space that may be needed. To determine, you will need information on number of meals estimated to be served per day, days between deliveries and storage area availability. Links to example calculators can be found in Appendix C.

C. Poisonous or Toxic Materials Storage

Designate an area for POISONOUS OR TOXIC MATERIAL storage that is away from FOOD and clean UTENSILs. These include detergents, sanitizers, related cleaning or drying agents and caustics, acids, polishes and other chemicals. Install cabinets, cages, or physically separate shelves for storing chemicals.

D. Clean Equipment, Utensil and Linen Storage

Designate areas for clean cooking UTENSILs, cutting boards, glassware and dishware. Store them at least 6-inches off the floor in a clean, dry location where they will be protected from dust and splash.

LIGHTING

A. Intensity

The light intensity shall be at least 108 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry FOOD storage areas and rooms during periods of cleaning.

The light intensity shall be at least 215 lux (20 foot candles) at a surface FOOD is provided for consumer self-service such as buffets and salad bars or where fresh product or packaged FOODS are sold or offered for consumption; inside EQUIPMENT such as reach-in

and under-counter refrigerators; at a distance of 75 cm (30 inches) above the floor in areas used for handwashing, WAREWASHING, and UTENSIL storage, and in toilet rooms.

The light intensity shall be at least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILs or EQUIPMENT such as knives, slicers, grinders, or saws where employee safety is a factor.

B. Protective Light Shielding

Shielding such as plastic shields, plastic sleeves with end caps, shatterproof bulbs and/or other APPROVED devices shall be provided for all artificial lighting fixtures located in areas where there is exposed FOOD; clean EQUIPMENT, UTENSILs, and LINENS; or unwrapped single-service and single-use articles.

Heat lamps shall be protected against breakage by a shield surrounding and extending beyond the bulb, leaving only the face of the bulb exposed.

FINISHES

A. Floors

Example floor materials are as follows:

- Quarry tile, ceramic tile
- SEALED curbed concrete
- Seamless poured epoxy minimum 3/16-inch thick.
- Commercial-grade sheet vinyl **(no felt backing)**
- Commercial-grade vinyl composition tile (VCT)

Pre-approval from the REGULATORY AUTHORITY should be obtained prior to use of carpet and/or wood.

B. Walls

Example wall materials are as follows:

- Stainless steel
- Ceramic tile
- Aluminum
- Fiber-glassed reinforced panels (FRP)
- SEALED Concrete blocks or bricks
- Epoxy or glazed drywall

C. Ceilings

Example ceiling materials may include wall finish material listed above along with the following:

- EASILY CLEANABLE, non-absorbent ceiling tiles
- Painted drywall

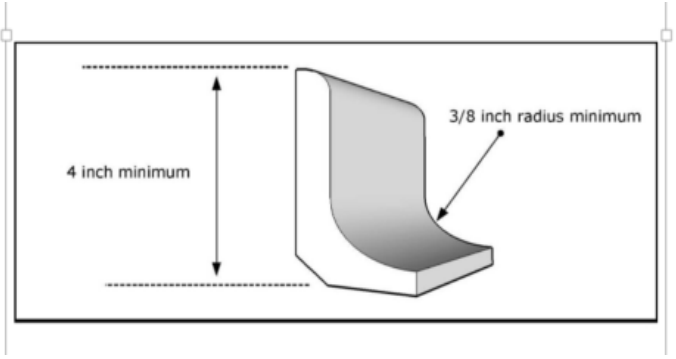
D. Coving

Coving is the floor material found at the base of walls (wall/floor junctures) and is required in most areas of the FOOD ESTABLISHMENT, such as:
FOOD preparation, storage, handling, and packaging areas

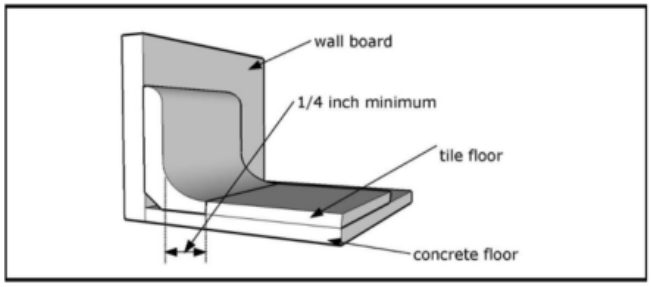
- UTENSIL washing and storage areas
- Interior waste disposal areas (garbage, REFUSE, grease)
- Restrooms
- Hand washing areas
- Janitorial facilities
- Walk-in refrigerator and freezer units (inside and outside)
- Bars (employee side)
- Customer self-serve areas where non-individually prepackaged FOODs or beverages are sold or dispensed (e.g., salad bars, buffets, bulk FOOD sales, beverage stations)
- Employee change and storage areas
- Wait stations

Coved flooring material should extend integrally up the walls. Integral coving is not required in areas used exclusively for dining, point-of-sale, or the storage of UTENSILs or FOODs contained in the original **un-opened** container

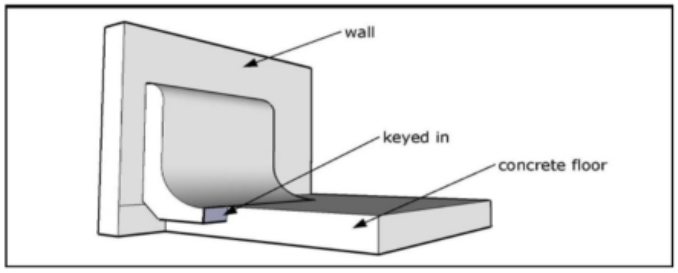
Floor Installation Diagrams



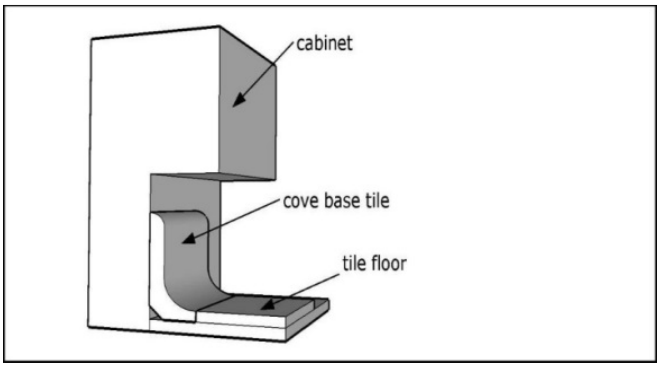
Example of quarry tile cove base.



Example of quarry tile cove base flush with floor.



Example of quarry tile cove base integral to concrete floor.



Example cove base; cabinet toe-kick

PEST CONTROL

All openings to the outside shall be effectively protected against the entrance of insects and rodents. All roller doors, sliding or bi-fold doors, or similar movable wall systems that are not self- closing and create a continuous opening to the exterior must have an effective means of pest control.

Some examples of effective barriers include:

- Solid, tight fitting, self-closing doors.
- Fixed or self-closing screens of #16 mesh or finer.
- Effective air curtains.

Example Air Curtain

This may not apply if a FOOD ESTABLISHMENT opens into a larger completely enclosed structure such as a coliseum, arena, warehouse, shopping mall, superstores, airport, or office building, where the outer openings from the larger structure are protected against the entry of insects and rodents.

A. Building

All masonry or cement foundations must be rodent proof. Seal all openings into the foundation and exterior walls, including openings & penetrations around wall and ceiling penetrations.

Cover all building vents with a minimum #16 mesh screen. Effectively seal all air ducts, skylight, transoms, and other openings to the outside.

B. Windows

Windows that open to the outside must be properly protected with minimum #16 mesh screen, with the exception of service windows.

Drive-thru and walk-up service windows must have effective means to prevent pest entry, to include minimum #16 mesh screens, properly designed and installed air curtains, or other effective means such as self-closing devices (spring-loaded, bump pad, electronic opener, or gravity operated).

C. Delivery, Customer, and Toilet Room Doors

Exterior doors: All outside doors shall be self-closing and tight fitting. Install a door sweep and weather stripping to prevent the entrance of insects and rodents. *Note: Daylight shall not be visible around the perimeter of the door.*

Garage Doors, Roller Doors, and Loading Docks: Garage and roller type delivery doors must be protected against pests. Loading docks shall have properly installed tight fitting dock seals at all loading bays. If the location of one of these doors exposes the kitchen or other FOOD service, air curtains will be required.

Toilet Room (Restroom) doors: All toilet rooms located in or adjacent to a FOOD ESTABLISHMENT shall be provided with tight fitting, self-closing doors. This requirement does not apply to a toilet room that is located outside a FOOD ESTABLISHMENT and does not open directly into the FOOD ESTABLISHMENT such as a toilet room that is provided by the management of a shopping mall.

D. Insect Control Devices, Design and Installation

Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device. These devices must not be located above FOOD preparation areas and installed to prevent the contamination of exposed FOOD, clean EQUIPMENT, UTENSILs, and LINENS, from insect fragments

MECHANICAL VENTILATION

A. Mechanical Ventilation Requirements

Commercial cooking or display EQUIPMENT, which produces smoke, steam, grease, mists, particulate matter, condensation, vapors, fumes, odors, or create sanitation or indoor air quality problems, will require a hood.

Hoods shall be designed and installed to prevent grease and condensation from collecting on walls, ceilings, and dripping into FOOD or onto FOOD contact surfaces. All hoods should comply with the current International Mechanical Code (IMC) and/or all local building and fire safety codes.

Balancing of the exhaust and make-up air must be ensured so that the system can be operated efficiently.

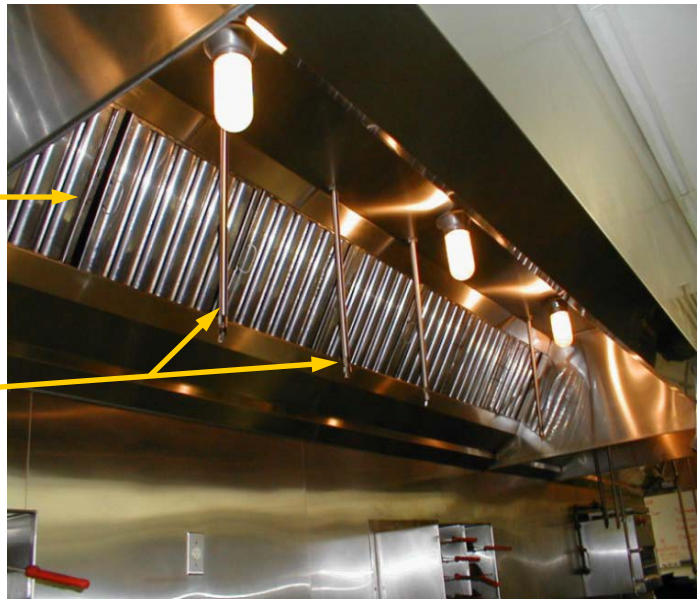
B. Mechanical Ventilation Hood Systems

Type I hoods are required over EQUIPMENT that produce grease, smoke, excessive steam, heat, condensation, particulate matter, odors, or create indoor sanitation or indoor quality problems. Examples of equipment requiring installation under a hood include: Kettles, pasta cookers, hot plates, salamanders, Mongolian-style grills, gas cooking EQUIPMENT, tableside cooking EQUIPMENT, such as Teppanyaki-style cooking, Tandoori ovens, rotisserie units, Panini grills, etc.

Type I Hood over Cook Line

Grease filters

Fire suppression system



The National Fire Protection Association provides a resource for FOOD ESTABLISHMENTS to reduce the potential fire hazard of commercial cooking operations. Refer to the NFPA link below or your local/State Fire Protection regulations.

http://www.nfpa.org/codes-and-standards/document-information-pages?mode=code&code=96

Type II hoods shall be installed over EQUIPMENT that produce steam, heat, mists, condensation, fumes, vapors, and non-grease laden FOODs.

Type II Hood over WAREWASHING Machine

Vapor hood

Vent less Hood Systems or ventilation systems integral to the cooking EQUIPMENT need to be reviewed and APPROVED by the local mechanical code, and other applicable fire safety codes.

Appendix A - MODEL PLAN REVIEW APPLICATION FOR FOOD ESTABLISHMENTS

TYPE OF APPLICATION: ☐ New ☐ Remodel ☐ Conversion	**Projected Start Date:**_____ **Projected Completion Date:** _____
TYPE OF FOOD OPERATION: ☐ Restaurant ☐ Institution ☐ Daycare ☐ Retail food store ☐ Other:_____	

FOOD ESTABLISHMENT INFORMATION

Name of Establishment:			
Establishment Address:	**City:**	**State:**	**ZIP:**

OWNERSHIP INFORMATION

Name of Owner:			
Address:	**City:**	**State:**	**ZIP:**
Email:	**Phone Number:**		

APPLICANT INFORMATION (e.g., ARCHITECT/ENGINEER)

Applicant Name:	**Contact Person:**		
Applicant Mailing Address:	**City:**	**State:**	**ZIP:**
Email:	**Phone Number:**		

FOOD OPERATION INFORMATION

Hours/Days of Operation	**Restaurant Seating Capacity**	**Type of Service (check all that apply)**	**Employees**
☐ **Sun:**_____ ☐ **Mon:**_____ ☐ **Tues:**_____ ☐ **Wed:**_____ ☐ **Thurs:**_____ ☐ **Fri:**_____ ☐ **Sat:**_____	# of Indoor Seats: _____ # of Outdoor Seats:_____ Square Feet of Facility: _____	☐ On-site consumption ☐ Off-site consumption ☐ Catering ☐ Single-use utensils ☐ Multi-use utensils ☐ Other:_____	Max per shift:_____ **Maximum meals to be served** ☐ Breakfast _____ ☐ Lunch _____ ☐ Dinner _____

The following documents must be submitted along with this application:

☐ Proposed menu or complete list of food and beverages to be offered (including seasonal, catering and banquet menus) – ***Standard Operating Procedures or HACCP plans may be required.***

☐ Plans must be clearly drawn to scale (minimum 11 x 14 inches in size) and include these items below:

- The floor plan must identify: food preparation, serving and seating areas, restrooms, office, employee change room, storage, warewashing, janitorial and trash area. Include location of any outside equipment or facilities (dumpsters, well, septic system-if applicable).
- Provide equipment layout and specifications, clearly numbered and cross-keyed with the equipment list. *Elevation drawings may be requested by the Regulatory Authority.*
- Identify handwashing, warewashing and food preparation sinks.
- Provide plumbing layout showing the sewer lines, cleanouts, floor drains, floor sinks, vents, grease trap or grease interceptor, hot and cold water lines, and direction of flow to sanitary sewer.
- Provide exhaust ventilation layout including location of hood and make-up air returns and ducts, if applicable.
- Lighting plan, indicating the exact foot candles for each area as required by the FDA Food Code (§6-303.11).
- Finish schedule showing floor, coved base, wall and ceilings for each area shown on the plans.

Note: A color coded flow chart may be requested by the Regulatory Authority demonstrating flow patterns for: food (receiving, storage, preparation, service); dishes (clean, soiled, cleaning, storage); trash (service area, holding, storage, disposal).

Signature:	**Date:**
Print Name:	**Title:**

Appendix B – REGULATORY COMPLIANCE REVIEW LIST
FOOD PREPARATION PROCEDURES

FOOD DELIVERY

1. How often will frozen foods be delivered? □ Daily □ Weekly □ Other: _____
2. How often will refrigerated foods be delivered? □ Daily □ Weekly □ Other: _____
3. How often will dry foods or supplies be delivered? □ Daily □ Weekly □ Other: _____

FOOD STORAGE* - Identify amount of space (in cubic feet) allocated for:

Dry Storage _____; Refrigerated Storage (41°F) _____; Frozen Storage _____; Utensil Storage _____

* Identify on plans where storage will be located.

INSTRUCTIONS: Describe the following with as much detail as possible. Indicate Not Applicable (NA) as appropriate.

PROCESS	IDENTIFY FOOD ITEMS	INDICATE LOCATION AND EQUIPMENT	MEETS CRITERIA (RA to circle and Initial)
Washing FDA Food Code §3-302.15			YES/NO
Thawing FDA Food Code §3-501.13			YES/NO
Cooking FDA Food Code §3-401			YES/NO
Hot Holding Hot food maintained at 135°F			YES/NO
Cooling Time/Temperature Control for Safety food will be cooled to 41°F within 6 hours; 135°F to			YES/NO
Reheating Food must be reheated to a temperature of 165° for 15 seconds within 2 hours			YES/NO

FINISH SCHEDULE

INSTRUCTIONS: Indicate which materials (quarry tile, stainless steel, fiberglass reinforced panels (RFP), ceramic tile, 4" plastic coved molding, etc.). Indicate Not Applicable (NA) as appropriate.

ROOM/AREA	FLOOR	FLOOR/WALL JUNCTURE	WALLS	CEILING	MEETS CRITERIA (RA to circle and Initial)
Food Preparation					YES/NO
Dry Food Storage					YES/NO
Warewashing Area					YES/NO
Walk-in Refrigerators and Freezers					YES/NO
Service Sink					YES/NO
Refuse Area					YES/NO
Toilet Rooms and Dressing Rooms					YES/NO
Other: Indicate					YES/NO
Identify the finishes of cabinets, countertops, and shelving:					

PHYSICAL FACILITIES

INSTRUCTIONS: Explain the following with as much detail as possible. Indicate Not Applicable (NA) as appropriate.

TOPIC	MINIMUM CRITERIA	MEETS CRITERIA (Circle and Initial)
Handwashing facilities	• Identify number of the handwashing sinks in food preparation and warewashing areas: _____Food Preparation _____ Warewashing Area • Type of hand drying device? Disposable towels □ Hand-drying device □	YES/NO
Warewashing Facilities	**MANUAL DISHWASHING** • Identify the length, width, and depth of the compartments of the 3-compartment sink: _____ • Will the largest pot/ pan fit into each compartment of the 3-compartment sink? □ Yes □ No If No, what will be the procedure for manual cleaning and sanitizing of items that will not fit into sink compartments? _____ • Describe size, location and type (drainboards, wall-mounted or overhead shelves, stationary or portable racks) of air drying space: _____ • What type of sanitizer will be used? □ Chemical Type:_____ □ Hot Water **MECHANICAL DISHWASHING** • Identify the make and model of the mechanical dishwasher:_____ • What type of sanitizer will be used? □ Chemical Type:_____ □ Hot Water • Will ventilation be provided? Yes □ No □	YES/NO
Water Supply	• Is the water supply public or non-public/private? public □ non-public/private □ o If private, has source been approved? Yes □* No □ o Attach copy of written approval and/or permit. • Is ice made on premises or purchased commercially? Made on-site □ Purchased □ • Will there be an ice bagging operation? Yes □ No □	YES/NO

Sewage Disposal	• Is the sewage system public or non-public/private? public □ non-public/private □ If private, has the sewage system been approved? Yes □* No □ Attach copy of written approval and/or permit. • Will grease traps/interceptors be provided? Yes □* No □ *Identify location on plan.	YES/NO
Backflow Prevention	• Will all potable water sources be protected for backflow? Yes □ No □ • Are all floor drains identified on the submit floor plan? Yes □ No □	YES/NO
Toilet Facilities	• Identify locations and number of toilet facilities: _____ • Hot and cold water provided? Yes □ No □	YES/NO
Dressing Rooms	• Will dressing rooms be provided? Yes □ No □ • Describe storage facilities for employee personal belongings_____	YES/NO
Linens	• Will linens be laundered on site? Yes □ No □ If yes, what will be laundered and where? _____ If no, how and where will linens be cleaned? _____ • Identify location of clean and dirty linen storage:_____ • How often will linens be delivered and picked up?	YES/NO
Poisonous/Cleaning Storage	• Identify the location and storage of poisonous or toxic materials • Where will cleaning and sanitizing solutions be stored at workstations? _____ • How will these items be separated from food and food-contact surfaces? _____	YES/NO

Pest Control	• Will all outside doors be self-closing and rodent proof? □ Yes □ No □ NA • Will screens be provided on all entrances left open to the outside? □ Yes □ No □ NA • Will all openable windows have a minimum #16 mesh screening? □ Yes □ No □ NA • Will insect control devices be used? □ Yes □ No □ NA • Will air curtains be used? If yes, where? _____ Note: All pipes and electrical conduit chases must be sealed to prevent rodent access.	YES/NO
Refuse, Recyclables, and Returnables	• Will refuse/garbage be stored inside? □ Yes □ No If yes, where _____ • Identify how and where garbage cans and floor mats will be cleaned? _____ • Will a dumpster or a compacter be used? □ Dumpster □ Compactor • Identify locations of grease storage containers:_____ • Will there be an area to store recyclables? □ Yes □ No If yes, where _____ • Will there be an area to store returnable damaged goods? □ Yes □ No If yes, where _____	YES/NO

PLAN REVIEW FORMULAS

WALK-IN REFRIGERATED STORAGE

$$\text{Estimated Space Needed (Cu. ft.)} = \frac{\text{Volume per Meal [Cu. ft.]} \times \text{Number Meals Served between Deliveries}}{0.40}$$

NOTE: Only 40% of any walk-in unit actually provides usable space

$$\frac{\text{Estimated Space (Cu. ft.)}}{\text{Height of Cooler (ft.)}} = \text{Size of Cooler Needed (Sq. ft.)}$$

Examples:

1. The number of meals between deliveries = 1000 (100 meals per day X 10 days between deliveries). Volume per meal = 0.1 cubic feet.

$$0.1 \text{ ft}^3 \text{ vol.} \times 1000 \text{ meals} = 100 \text{ ft}^3$$

$$\frac{100 \text{ ft}^3}{0.40} = 250 \text{ ft}^3 \text{ Usable Space Needed}$$

2. The usable space needed for the walk-in is 250 cubic feet. The cooler has a 6 foot high ceiling.

$$\frac{250 \text{ ft}^3 \text{ usable space needed}}{6 \text{ ft ceiling height}} = 41 \text{ ft}^2 \text{ Sized Cooler Needed}$$

REACH IN REFRIGERATED STORAGE

$$\text{Estimated Space Needed (Cu. ft.)} = \frac{\text{Volume per Meal [Cu. ft.]} \times \text{Number Meals Served between Deliveries}}{0.75}$$

NOTE: Only 75% of any reach-in unit actually provides usable space

Example:

1. The number of meals between deliveries = 1000 (100 meals per day X 10 days between deliveries). Volume per meal = 0.1 cubic feet.

$$0.1 \text{ ft}^3 \text{ vol.} \times 1000 \text{ meals} = 100 \text{ ft}^3$$

$$\frac{100 \text{ ft}^3}{0.75} = 133.3 \text{ ft}^3 \text{ Estimated Space Needed}$$

PLAN REVIEW FORMULAS

HOT WATER DEMAND

$$\text{Gallons Per Hour (GPH)} = \frac{\text{Sink Size in}^3 \times 7.5 \text{ gal/ft}^3 \times (\text{Number of compartments} \times 0.75 \text{ capacity})}{1728 \text{ in}^3/\text{ft}^3}$$

OR

$$\text{Sink Size in}^3 \times \text{Number components} \times 0.003255 \text{ in}^3$$

$$\text{British Thermal Units (BTU)} = \frac{\text{GPH} \times \text{°Rise} \times 8.33 \text{ lb/gal of water}}{\text{Thermal Efficiency}}$$

$$\text{Kilo-Watt (KW) Input} = \frac{\text{GPH} \times \text{°Rise} \times 8.33 \text{ lb/gal of water}}{3412 \text{ BTU per KW}}$$

Example:

1. How many BTU's or KW's will the booster heater need to raise the incoming hot water (140°F) to 180°F for the final rinse temperature if the dishwasher requires 64 GPH?

$$\frac{64 \text{ GPH} \times 40°\text{F Rise} \times 8.33}{0.70 \text{ (operating efficiency)}} = 30{,}464 \text{ BTU}$$

$$\frac{64 \text{ GPH} \times 40°\text{F Rise} \times 8.33}{3412 \text{ BTU per KW}} = 6.2 \text{ KW}$$

PLAN REVIEW FORMULAS

DRY STORAGE

$$\text{Required Storage Area (sq. ft)} = \frac{\text{Volume per Meal (0.1 cu. ft.)} \times \text{Number Meals between Deliveries}}{\text{Avg. Height of Area (ft.)} \times \text{Fraction of Usable Floor Area}}$$

Example: 7 ft. high ceiling, shelves 6" off the floor, 18" from ceiling
Usable Height 5 ft.

Usable Floor Space:
Depends on door swings, overhead sewer lines, electrical boxes, etc.

Examples:

1. The number of meals between deliveries = 1,000 (100 meals per day X 10 days between deliveries). A ***small fraction (3/10ths) of usable storage space*** in a store room that has 5 feet in usable height

$$\frac{0.1 \text{ cu. ft.} \times 1000 \text{ meals}}{5\text{ft} \times 0.3} = 66.67 \text{ ft}^2 \text{ Required Storage Area}$$

2. The number of meals between deliveries =1,000 (100 meals per day X 10 days between deliveries). A ***larger fraction (6/10ths) of usable storage space*** in a store room that has 5 feet in usable height

$$\frac{0.1 \text{ cu. ft.} \times 1000 \text{ meals}}{5\text{ft} \times 0.6} = 33 \text{ ft}^2 \text{ Required Storage Area}$$

LINEAR FEET OF SHELVING

$$\text{Linear Feet of Shelving Required (ft.)} = \frac{\text{Volume per Meal (0.1 cu. ft.)} \times \text{Number Meals between Deliveries}}{D \times H \times C}$$

D =Depth of Shelves (ft.)

H =Clearance bewteen shelves (ft.)

C =80% effective capacity of shelf height

Examples:

1. Assume 400 meals per day and a 10 day storage between deliveries = 4,000 meals.
   Volume of 0.1 cu. Ft. per meal, shelf depth of 18 inches, clearance of **12 inches** between shelves and 80% effective capacity of shelf height

$$\frac{0.1 \text{ cu. ft.} \times 4000 \text{ meals}}{1.5 \text{ ft.} \times 1 \text{ ft.} \times 0.80} = 333 \text{ ft. Shelving Needed}$$

2. Assume 400 meals per day and a 10 day storage between deliveries = 4,000 meals.
   Volume of 0.1 cu. Ft. per meal, shelf depth of 18 inches, clearance of **18 inches** between shelves and 80% effective capacity of shelf height

$$\frac{0.1 \text{ cu. ft.} \times 4000 \text{ meals}}{1.5 \text{ ft.} \times 1.5 \text{ ft.} \times 0.80} = 222 \text{ ft. Shelving Needed}$$

Appendix D Plan Review Web Links

These links are examples of resources available to the Food Establishment Applicant. The required plan, specifications and information must be approved by the Regulatory Authority to receive a permit to operate a food establishment.

Michigan Department of Agriculture and Rural Development

http://www.michigan.gov/mdard/0%2c4610%2c7-125-50772_45851-59764--%2c00.html

Wisconsin Department of Safety and Professional Services

http://www.dsps.wi.gov/Plan-Review

U.S. Food and Drug Administration Food Establishment Plan Review Guide

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm

North Carolina Public Health, Environmental Health Section

http://ehs.ncpublichealth.com/faf/food/planreview/app.htm

Minnesota Department of Agriculture

http://www.mda.state.mn.us/food/business/plan-review.aspx

Conference for Food Protection, Plan Review for Food Establishments

http://www.foodprotect.org/guides-documents/plan-review-for-food-establishments-2008/

Public Health – Seattle and King County

http://www.kingcounty.gov/healthservices/health/ehs/foodsafety/FoodBusiness/permanent.aspx

Harris County Public Health and Environmental Services

http://www.hcphes.org/divisions_and_offices/environmental_public_health/training_and_resources/information_for_food_establishments/food_establishment/

Florida Department of Health in Volusia County

http://volusia.floridahealth.gov/programs-and-services/environmental-health/food-hygiene/food-guide.html

8-201.12 Contents of the Plans and Specifications.
8-203.10 Preoperational Inspections.

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this FDA/CFP Food Establishment Plan Review Guide – 2000 has been used in the FDA State Training Team Plan Review courses. It can be accessed through http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operating

procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

(1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,

(2) Food is received from approved sources as specified under § 3-201.11,

(3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,

(4) Time/temperature control for safety food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under §§ 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with paragraph 2-103.11(N) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

Conference for Food Protection (CFP) Field Training Manual for Regulatory Retail Food Safety Inspection Officers (5-31-13 CFP Update)

» View Description of Available Documents

Crosswalk - Phases of Food Incident Response

This FSMAFederal-State Integration Team Crosswalk document is a visual representation of the essential response program components that address the roles and responsibilities of the food regulatory program at each phase of a food incident response.

» View Description of Available Documents

Crosswalk Requirements for Foodborne Illness Training Programs - Standard 5 (2021)

This Crosswalk document follows the Crosswalk-Phases of Food Incident Response. It provides information on where several foodborne illness training resources fit into the requirements of Standard 5 of the Voluntary National Retail Food Regulatory Program Standards.

Approved via Issue 2020-II-019 from the Program Standards Committee

» View Description of Available Documents

Crosswalk - Requirements for Foodborne Illness Training Programs Based on Standard 5 (2017)

This Crosswalk document follows the Crosswalk - Phases of Food Incident Response

» View Description of Available Documents

Emergency Action Plan for Retail Food Establishment

» View Description of Available Documents

Employee Food Safety Training Guidance Document

Identify what a food employee should know about food safety, prioritized by risk.

» View Description of Available Documents

Issue: 2020 II-033

Council Recommendation:	Accepted as Submitted		Accepted as Amended	**x**
Delegate Action:	Accepted	X	Rejected	

All information above the line is for conference use only.

Title:

Refer Standard 5 to Program Standards Committee for Review and Updating

Recommended Solution: The Conference recommends...

that the Program Standards Committee, a CFP standing committee, be charged with the following during the next biennium:

1. Conduct a thorough review of Standard 5 "Foodborne Illness and Food Defense Preparedness and Response of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);
2. The review should include comparing the Standard to other similar FDA standards in food;
3. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program;
4. Review Standard 5 "Data Review and Analysis" from a sampling of jurisdictions to determine if certain data analysis requirements typically have no or such limited data to make the information not valuable;
5. Review the Center for Disease Control and Prevention's National Environmental Assessment Reporting System (NEARS), Environmental Assessment Training Series (EATS), and Council to Improve Foodborne Outbreak Response (CIFOR) to consider inclusion of specific components.
6. Propose amendments to Standard 5 of the VNRFRPS;
7. Report back committee findings and recommendations to the next Biennial Meeting.

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

PSC Issue #3 list of supporting attachments:

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC3 & PSC5 2022 Program Standard 2 Appendix B-1

PSC Issue #4 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff

PSC Issue #5 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC3 & PSC5 2022 Program Standard 2 Appendix B-1
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC5 AFDO - Risk-Based Inspection Methods in Retail FD218
3. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC5 Course Descriptions and Objectives - FDA38 FDA39

PSC Issue #6 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC6 Draft Program Standard 2 – NCS Added

PSC Issue #6 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC 6 & PSC13 National Curriculum Standard

PSC Issue #13 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC13 Draft Program Standard 2 Additional Exam Based on NCS

PSC Issue #13 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC13 IFSS Framework Basic Advanced Feb 2021 Color Chart
3. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC13 IFSS Framework Basic Advanced Feb 2021 Descriptors tab
4. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC13 IFSS Framework Basic Advanced Feb 2021 first tab
5. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC6 & PSC13 National Curriculum Standard

STANDARD No. 2
Training Program

2.1 Purpose

This standard defines the essential elements of a training program for inspectors.

2.2 Requirement Summary

The State program uses a written training plan that promotes development and demonstrates that all inspectors who will conduct manufactured food inspections complete course curriculums, field training, and continuing education to adequately perform their work.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The State program uses a written training plan that ensures all inspectors receive training required to adequately perform their work assignments. The training plan includes course curriculums which provides for basic and advanced food inspection training as well as continuing education.

2.3.1.2 Appendix 2.2 or equivalent form must be used to document and summarize all training provided to inspectors.

2.3.1.3 The State program maintains a training history for active inspectors. The training history for all inactive inspectors must be kept for three years or per the state's record retention policy.

2.3.1.4 Appendix 2.3 or equivalent form must be used to document training for each inspector.

2.3.1.5 The State training record summary and individual training records must include the inspector's START DATE. Equivalent forms including electronic records may be used for required appendices.

2.3.2 Basic Food Inspection Training

The State program requires that each inspector complete a basic food inspection training curriculum that consists of coursework and field training described here.

2.3.2.1 Timeframe

The Basic Food Inspection Training course curriculum shall be successfully completed within 24 months of the inspector's START DATE with the manufactured food program.

2.3.2.2 Course Curriculum:

The Basic Food Inspection Training consists of coursework in the subject areas listed in this section.

2.3.2.2.1 Prevailing statutes, regulations, and ordinances
2.3.2.2.2 Public health principles
2.3.2.2.3 Emergency management
2.3.2.2.4 Communications skills
2.3.2.2.5 Microbiology
2.3.2.2.6 Epidemiology
2.3.2.2.7 Basics of HACCP
2.3.2.2.8 Allergen management
2.3.2.2.9 Basic food labeling
2.3.2.2.10 Food defense awareness training
2.3.2.2.11 Sampling technique and preparation

Note: States may further subdivide their basic training by identifying courses required for inspectors who only inspect non high risk warehouses. These courses must be clearly defined in the state training plan.

Note: Appendix 2.4 provides a list of available Basic Food Inspection Training Coursework that may be used to satisfy the requirements in 2.3.2.2.

2.3.2.3 Field training

2.3.2.3.1 Each inspector who will inspect general manufactured food firms must complete:
- 2.3.2.3.1.1 Ten JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.1.2 Of the ten, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.2 Each inspector who will only inspect non high risk food warehouses must complete:
- 2.3.2.3.2.1 Five JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.2.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or

EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.3 Inspectors who meet 2.3.2.3.2 and advance to conduct general manufactured food firms must complete:

2.3.2.3.3.1 Five additional JOINT FIELD TRAINING INSPECTIONS, FIELD INSPECTION AUDITS, or EVALUATIONS to fulfill requirements identified in 2.3.2.3.1; and

2.3.2.3.3.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.4 JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS/EVALUATIONS are conducted in firms that are representative of the firms to be inspected by the inspector. Each inspector will complete the minimum field training requirements prior to conducting independent inspections.

2.3.3 Advanced Food Inspection Training

The State program requires each inspector who will conduct specialized food inspections to complete an advanced inspection training curriculum which consists of relevant coursework and field training as described here.

2.3.3.1 Coursework

The state program requires each inspector who will perform specialized food inspections to successfully complete the coursework specific to the type of specialized food inspections they will be performing. Specialized food inspection courses include, but not limited to:

2.3.3.1.1 Acidified foods
2.3.3.1.2 Low acid canned foods
2.3.3.1.3 Juice HACCP
2.3.3.1.4 Seafood HACCP
2.3.3.1.5 Traceback Investigations[7]
2.3.3.1.6 Foodborne Illness Investigations[7]

2.3.3.2 Field training

[7] These advanced food inspection training courses are not subject to 2.3.3.2 Field Training requirements.

The State program requires that each inspector successfully complete the following before performing independent specialized food inspections.

2.3.3.2.1 Participate in two JOINT FIELD TRAINING INSPECTIONS;

2.3.3.2.2 After successful completion of the course participate in one EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR prior to conducting independent inspections; and

2.3.3.2.3 Within one year after being released to do specialized food inspections complete a second EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR in the area of specialty.

2.3.4 Experienced Inspectors

The criterion for conducting a minimum of 10 JOINT FIELD TRAINING INSPECTIONS and/or required coursework is intended for new employees or employees new to the food safety program. For CURRENT EXPERIENCED STAFF or NEWLY HIRED EXPERIENCED STAFF, a State program's training plan shall include the following unless the state determines in their training plan that all staff will be required to complete the program elements in 2.3.2 and 2.3.3:

2.3.4.1 CURRENT EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.1.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of the basic or specialized JOINT FIELD TRAINING INSPECTIONS.
2.3.4.1.2	Basic Course Work	Document training records available. Create a statement or affidavit explaining the background or experience that justifies a waiver of the missing Basic Course Work.
2.3.4.1.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.4.2 NEWLY EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.2.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of some or all of the basic or specialized JOINT FIELD TRAINING INSPECTIONS. Conduct two successful EVALUATION or FIELD INSPECTION AUDIT within 6 months of the Inspector's QUALIFIED DATE.
2.3.4.2.2	Basic Course Work	Document training records available. Statement or affidavit explaining the background or experience that justifies a waiver of the Basic Course Work.
2.3.4.2.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.5 Continuing education

Within the scope of this standard, the goal of continuing education and training is to enhance the inspector's knowledge, skills, and ability to perform manufactured food inspections. The objective is to build upon the inspector's knowledge base.

2.3.5.1 Each inspector must accumulate 20 CONTACT HOURS of continuing education in food safety every 36 months.

2.3.5.2 The 36-month continuing education interval starts at the QUALIFIED DATE, when the basic training cycle is completed.

2.3.5.3 The program may establish an alternate timeframe to track continuing education as long as the alternate timeframe and how that timeframe still meets or exceeds the intent of the standard (at least 20 CONTACT HOURS every 36 months) are clearly identified in program procedures.

2.3.5.4 The inspector qualifies for CONTACT HOURS for participation in any of the following activities that are related specifically to manufactured food safety or manufactured food inspectional work:

- Attendance at national or regional seminars / technical conferences;
- Professional symposiums / college courses;
- Food-related training provided by government agencies (e.g., USDA, State, local);
- Food safety related conferences and workshops;
- Distance learning opportunities that pertain to food safety; or

- Training approved by a QUALIFIED FIELD INSPECTION TRAINER.

2.3.5.5 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of ten (10) CONTACT HOURS may be accrued from the following activities:

- Delivering presentations at professional conferences;
- Providing classroom and/or field training to newly hired inspectors, or being a course instructor in food safety; or
- Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

2.3.5.6 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of four (4) CONTACT HOURS may be accrued for reading technical publications related to manufactured food safety.

2.3.5.7 Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation may include:

- Certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- Transcripts from a college or university;
- A letter from the administrator of the continuing education program attended;
- A copy of the peer-reviewed article or presentation made at a professional conference; or documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports; and
- An agenda and attendance roster.
- Documentation approved by the QUALIFIED FIELD INSPECTION TRAINER.

2.3.6 Coursework Sources

Basic, advanced, and continuing education coursework must be obtained from one of the sources listed here:

2.3.6.1 Training provided by a government agency (including in house training);

2.3.6.2 Distance learning, for example, satellite downlinks or web-based training[8];

2.3.6.3 Colleges, schools, research centers, and institutes;

[8] FDA/ORA U classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html

STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

STANDARD 4
UNIFORM INSPECTION PROGRAM

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STANDARD 4
UNIFORM INSPECTION PROGRAM

This standard applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.

Requirement Summary

Program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of laws, regulations, policies, and procedures.

Description of Requirement

1) Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. The quality assurance program shall:

   A. The quality assurance program shall assure that each inspector:
      1. Has required equipment and forms to conduct the inspection.
      2. Reviews the contents of the establishment file, including the previous inspection report, reported complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance.
      3. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met.
      4. Provides identification as a regulatory official to the person in charge and states the purpose of the visit.
      5. Interprets and applies the jurisdiction's laws, rules, policies, procedures, and regulations required for conducting retail food establishment inspections.
      6. Uses a risk-based inspection methodology to conduct the inspection.
      7. Accurately determines the compliance status of each risk factor and Food Code intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
      8. Obtains corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.
      9. Discuss options for the long-term control of risk factors with establishment mangers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans.
      10. Verifies correction of out-of-compliance observations identified during the previous inspection. In addition, follows through with compliance and enforcement in accordance with the jurisdiction's policies.
      11. Conducts an exit interview that explains the out-of-compliance observations, corrective actions, and timeframes for correction, in accordance with the jurisdiction's policies.

12. Provides the inspection report and, when necessary, cross-referenced documents, to the person in charge or permit holder, in accordance with the jurisdiction's policies.
13. Demonstrates proper sanitary practices as expected from a food service employee.
14. Completes the inspection form per the jurisdiction's policies (i.e., observations, public health reasons, applicable code reference, compliance dates).
15. Documents the compliance status of each risk factor and intervention (IN, OUT, NA, NO).
16. Cites the proper code provisions for risk factors and Food code interventions, in accordance with the jurisdiction's policies.
17. Documents corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.
18. Documents that option for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.
19. Compliance or regulatory documents (i.e., exhibits, attachments, sample forms) are accurately completed, appropriately cross-referenced within the inspection report, and included with the inspection report, in accordance with the jurisdiction's policies.
20. Files reports and other documentation in a timely manner, in accordance with the jurisdiction's policies.

B. The quality assurance program shall describe the actions that will be implemented when the program analysis identifies deficiencies in quality or consistency in any program element listed above in 1) (A).

2) The quality assurance program must achieve an overall inspection program performance rating for each of the twenty measured elements [Items1-20] of at least 75% using the self-assessment procedure and the appropriate table provided in the *Standard 4: Self-Assessment Instructions and Worksheet.*

An assessment review of each inspector's work shall be made during at least three joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports of the same inspected establishments, during every self-assessment period.

[*NOTE: *Staff members who are within their initial 24 months of training and have not completed all prerequisite courses, 25 joint inspections and 25 independent inspections as required in Standard 2, are exempt from the joint on-site inspections and file reviews used in the performance measurement rating calculation in the Standard 4 Self-Assessment Worksheet.*]

Outcome

A quality assurance program exists that ensures uniform, high-quality inspections.

Documentation

The quality records needed for this standard include:

1. A written procedure that describes the jurisdiction's quality assurance program that meets the criteria under the Description of Requirement section 1) (A), including corrective actions for deficiencies, and
2. Documentation that the program achieves a 75 percent performance rating on each element using the self-assessment procedures described above.

PSC Issue #7 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC7 Program Standards 2022 Standard 3 Requirements
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC7 Program Standards 2022 Std 3 Self-Assessment & Verification Audit form edits

PSC Issue #7 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC7 Program Standards 2022 Standard 3 Self-Assessment and Verification Audit form
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC7 2022 Program Standards 3 Inspection Program Based on HACCP Principles

PSC Issue #15 list of content documents

1) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC15 Proposed Revised Standard 3 Requirement to Include Plan Review
2) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC15 Proposed Revised Standard 3 SA VA Form to Include Plan Review

PSC Issue #15 list of supporting attachments

1) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC15 Annex 3 Ch. 8 Comp and Enf Const Insp and Approval 8-201.12 & 8-203-10
2) See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC14 & PSC15 Plan Review for Food Establishments Guide 2016

State Enforcement Policy

Keywords: STD-03, FDA

Issue Description

Background

As a result of 2019 legislation, our state implemented a new, progressive methodology for enforcement that became effective on January 1, 2020. This protocol takes into consideration not only the severity of the identified violation but also the prevalence of violations observed. The legislation provides for a uniform system to communicate inspection results which is based on an overall point system driven by assigned values of low, medium, and high pervasiveness. This point system establishes the criteria by which resources are to be directed for additional full re-inspections or enforcement activities.

Pervasiveness is the overall evaluation of specific issues observed to determine how prevalent the violation is. Using all available information such as active managerial control, previous inspection records, long term controls, and overall risk/severity of the specific situation, an inspector assigns a violation pervasiveness. This system then classifies routine and re-inspections into one of three ratings ("Pass," "Re-inspection," or "Closed") based on the total cumulative violations/ points. This rating is then used to determine the next required action: no required action (the next routine inspections is scheduled), a full facility re-inspection, or the immediate suspension of a license to operate. Facilities that score less than 50 points pass the inspection and do not have to demonstrate correction of risk factor or intervention violations through re-inspection or other follow-up activities.

We are seeking clarification for criteria 4 of standard 3 – the requirement for an implemented policy that requires on-site corrective actions or follow-up activities for out of compliance foodborne illness risk factors. The policies established in Standard 3 for onsite and long-term corrective actions link to Standard 6, Compliance and Enforcement. The violations in the Standard 6 CFP crosswalk outlines violations that should have corrective actions, these violations include interventions and core violations as well as risk factors.

Question/Problem

The CFP cross-walk contains very specific code citations within items 1-29 of the FDA inspection form for risk factors and interventions that include Priority, Priority Foundation, and Core violations. Are core and intervention violations intended to be included in the requirement for on-site corrective actions and follow-up activities?

Does our inspection program meet standard 3 if we do not require corrective action or follow-up activities for violations that pose a low risk to public health?

Rationale

Standard 3 specifically does not appear to align with Standard 6 for State and Local programs that have developed alternative systems of assessment that can also accomplish the same goal. There are situations where appropriate corrective actions cannot occur at the time of the inspection and the

violation has a low risk to the public's health. Because of the nuances in the code and a focus on mitigating risk and assessing active managerial control, it does not seem appropriate to require corrective action and follow-up activities for every situation in which risk-factors are out of compliance.

Standard 3 – Criteria 4

4. Corrective Action Policy

a) The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.

b) The jurisdiction has a written and implemented policy that requires discussion for long- term control of foodborne illness risk factors.

c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.

Response from the Clearinghouse (11-30-22)

No. Standard 3 requires that a jurisdiction develop and implement a policy that requires timely corrective actions as appropriate to the type of violation. In some cases, an actual physical visit to an establishment may not be necessary, however documented activities should lead to a desired outcome where a regulatory inspection system uses HACCP principles to identify risk factors and to obtain immediate and long-term corrective action for recurring risk factors. Core violations do not require an immediate on-site correction but follow up should be performed.

According to the 2017 FDA Food Code, the following is required: 8-406.11 Time Frame for Correction.
(A) Except as specified in (B) of this section, the PERMIT HOLDER shall correct CORE ITEMS by a date and time agreed to or specified by the REGULATORY AUTHORITY but no later than 90 calendar days after the inspection.
(B) The REGULATORY AUTHORITY may approve a compliance schedule that extends beyond the time limits specified under (A) of this section if a written schedule of compliance is submitted by the PERMIT HOLDER and no health HAZARD exists or will result from allowing an extended schedule for compliance.

STANDARD No. 2
Training Program

2.1 Purpose

This standard defines the essential elements of a training program for inspectors.

2.2 Requirement Summary

The State program uses a written training plan that promotes development and demonstrates that all inspectors who will conduct manufactured food inspections complete course curriculums, field training, and continuing education to adequately perform their work.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The State program uses a written training plan that ensures all inspectors receive training required to adequately perform their work assignments. The training plan includes course curriculums which provides for basic and advanced food inspection training as well as continuing education.

2.3.1.2 Appendix 2.2 or equivalent form must be used to document and summarize all training provided to inspectors.

2.3.1.3 The State program maintains a training history for active inspectors. The training history for all inactive inspectors must be kept for three years or per the state's record retention policy.

2.3.1.4 Appendix 2.3 or equivalent form must be used to document training for each inspector.

2.3.1.5 The State training record summary and individual training records must include the inspector's START DATE. Equivalent forms including electronic records may be used for required appendices.

2.3.2 Basic Food Inspection Training

The State program requires that each inspector complete a basic food inspection training curriculum that consists of coursework and field training described here.

2.3.2.1 Timeframe

The Basic Food Inspection Training course curriculum shall be successfully completed within 24 months of the inspector's START DATE with the manufactured food program.

2.3.2.2 Course Curriculum:

The Basic Food Inspection Training consists of coursework in the subject areas listed in this section.

2.3.2.2.1 Prevailing statutes, regulations, and ordinances
2.3.2.2.2 Public health principles
2.3.2.2.3 Emergency management
2.3.2.2.4 Communications skills
2.3.2.2.5 Microbiology
2.3.2.2.6 Epidemiology
2.3.2.2.7 Basics of HACCP
2.3.2.2.8 Allergen management
2.3.2.2.9 Basic food labeling
2.3.2.2.10 Food defense awareness training
2.3.2.2.11 Sampling technique and preparation

Note: States may further subdivide their basic training by identifying courses required for inspectors who only inspect non high risk warehouses. These courses must be clearly defined in the state training plan.

Note: Appendix 2.4 provides a list of available Basic Food Inspection Training Coursework that may be used to satisfy the requirements in 2.3.2.2.

2.3.2.3 Field training

2.3.2.3.1 Each inspector who will inspect general manufactured food firms must complete:
- 2.3.2.3.1.1 Ten JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.1.2 Of the ten, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.2 Each inspector who will only inspect non high risk food warehouses must complete:
- 2.3.2.3.2.1 Five JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.2.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or

EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.3 Inspectors who meet 2.3.2.3.2 and advance to conduct general manufactured food firms must complete:

2.3.2.3.3.1 Five additional JOINT FIELD TRAINING INSPECTIONS, FIELD INSPECTION AUDITS, or EVALUATIONS to fulfill requirements identified in 2.3.2.3.1; and

2.3.2.3.3.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.4 JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS/EVALUATIONS are conducted in firms that are representative of the firms to be inspected by the inspector. Each inspector will complete the minimum field training requirements prior to conducting independent inspections.

2.3.3 Advanced Food Inspection Training

The State program requires each inspector who will conduct specialized food inspections to complete an advanced inspection training curriculum which consists of relevant coursework and field training as described here.

2.3.3.1 Coursework

The state program requires each inspector who will perform specialized food inspections to successfully complete the coursework specific to the type of specialized food inspections they will be performing. Specialized food inspection courses include, but not limited to:

2.3.3.1.1 Acidified foods
2.3.3.1.2 Low acid canned foods
2.3.3.1.3 Juice HACCP
2.3.3.1.4 Seafood HACCP
2.3.3.1.5 Traceback Investigations[7]
2.3.3.1.6 Foodborne Illness Investigations[7]

2.3.3.2 Field training

[7] These advanced food inspection training courses are not subject to 2.3.3.2 Field Training requirements.

The State program requires that each inspector successfully complete the following before performing independent specialized food inspections.

2.3.3.2.1 Participate in two JOINT FIELD TRAINING INSPECTIONS;

2.3.3.2.2 After successful completion of the course participate in one EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR prior to conducting independent inspections; and

2.3.3.2.3 Within one year after being released to do specialized food inspections complete a second EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR in the area of specialty.

2.3.4 Experienced Inspectors

The criterion for conducting a minimum of 10 JOINT FIELD TRAINING INSPECTIONS and/or required coursework is intended for new employees or employees new to the food safety program. For CURRENT EXPERIENCED STAFF or NEWLY HIRED EXPERIENCED STAFF, a State program's training plan shall include the following unless the state determines in their training plan that all staff will be required to complete the program elements in 2.3.2 and 2.3.3:

2.3.4.1 CURRENT EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.1.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of the basic or specialized JOINT FIELD TRAINING INSPECTIONS.
2.3.4.1.2	Basic Course Work	Document training records available. Create a statement or affidavit explaining the background or experience that justifies a waiver of the missing Basic Course Work.
2.3.4.1.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.4.2 NEWLY EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.2.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of some or all of the basic or specialized JOINT FIELD TRAINING INSPECTIONS. Conduct two successful EVALUATION or FIELD INSPECTION AUDIT within 6 months of the Inspector's QUALIFIED DATE.
2.3.4.2.2	Basic Course Work	Document training records available. Statement or affidavit explaining the background or experience that justifies a waiver of the Basic Course Work.
2.3.4.2.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.5 Continuing education

Within the scope of this standard, the goal of continuing education and training is to enhance the inspector's knowledge, skills, and ability to perform manufactured food inspections. The objective is to build upon the inspector's knowledge base.

2.3.5.1 Each inspector must accumulate 20 CONTACT HOURS of continuing education in food safety every 36 months.

2.3.5.2 The 36-month continuing education interval starts at the QUALIFIED DATE, when the basic training cycle is completed.

2.3.5.3 The program may establish an alternate timeframe to track continuing education as long as the alternate timeframe and how that timeframe still meets or exceeds the intent of the standard (at least 20 CONTACT HOURS every 36 months) are clearly identified in program procedures.

2.3.5.4 The inspector qualifies for CONTACT HOURS for participation in any of the following activities that are related specifically to manufactured food safety or manufactured food inspectional work:

- Attendance at national or regional seminars / technical conferences;
- Professional symposiums / college courses;
- Food-related training provided by government agencies (e.g., USDA, State, local);
- Food safety related conferences and workshops;
- Distance learning opportunities that pertain to food safety; or

- Training approved by a QUALIFIED FIELD INSPECTION TRAINER.

2.3.5.5 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of ten (10) CONTACT HOURS may be accrued from the following activities:

- Delivering presentations at professional conferences;
- Providing classroom and/or field training to newly hired inspectors, or being a course instructor in food safety; or
- Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

2.3.5.6 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of four (4) CONTACT HOURS may be accrued for reading technical publications related to manufactured food safety.

2.3.5.7 Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation may include:

- Certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- Transcripts from a college or university;
- A letter from the administrator of the continuing education program attended;
- A copy of the peer-reviewed article or presentation made at a professional conference; or documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports; and
- An agenda and attendance roster.
- Documentation approved by the QUALIFIED FIELD INSPECTION TRAINER.

2.3.6 Coursework Sources

Basic, advanced, and continuing education coursework must be obtained from one of the sources listed here:

2.3.6.1 Training provided by a government agency (including in house training);

2.3.6.2 Distance learning, for example, satellite downlinks or web-based training[8];

2.3.6.3 Colleges, schools, research centers, and institutes;

[8] FDA/ORA U classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html

STANDARD No. 3
Inspection Program

3.1 Purpose

This standard describes the elements of an effective inspection program for manufactured food establishments.

3.2 Requirement Summary

The State program has a manufactured food inspection system. This system provides the foundation for inspecting food firms to determine compliance with the laws administered by Federal, State, and local governments. In addition, the State program has: (1) a risk based inspection program, (2) an inspection procedure, (3) an inspection report procedure, (4) a system to respond to CONSUMER COMPLAINTS, (5) a system to resolve INDUSTRY COMPLAINTS about inspections, (6) a recall system, and (7) a sampling procedure.

3.3 Program Elements

3.3.1 Risk-based Inspection Program

The State program has an inventory of food establishments for which the State has regulatory oversight. The inventory is categorized by the risk associated with the likelihood that a food safety or defense incident will occur.

3.3.1.1 Inspections are prioritized and frequencies assigned based on established risk categories. The State program has written procedure documenting their classification criteria and inspection frequencies.

3.3.1.2 The state program must use the risk factors and classification criteria as described in:

- Appendix 3.2; or
- FD&C Act, Section 421 (a)(1); or
- Develop its own risk factor and classification criteria. If the state chooses to develop its own risk factor and classification criteria a written rationale must be provided that demonstrates how public health is protected.

3.3.2 Inspection Procedure

The State program has a written procedure for inspecting food plants that require the inspectors to:

3.3.2.1 Review the previous inspection report and CONSUMER COMPLAINTS.

3.3.2.2 Have appropriate equipment[9] and forms (if necessary). Equipment must be verified and maintained as defined by the State's standard operating procedures or manufacture's recommendations.

3.3.2.3 Make appropriate introductions, and explain the purpose and scope of the inspection.

3.3.2.4 Establish jurisdiction.

3.3.2.5 Select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the plant is producing.

3.3.2.6 Assess employee practices critical to the safe and sanitary production and storage of food.

3.3.2.7 Properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded or otherwise in violation of applicable law.

3.3.2.8 Recognize significant violative conditions or practices, if present, and record findings consistent with State program procedures.

3.3.2.9 Distinguish between significant and insignificant observations, and isolated incidents versus trends.

3.3.2.10 Review and evaluate the appropriate records and procedures for the establishment's operation and effectively apply the information obtained from this review [during the inspection].

3.3.2.11 Collect adequate evidence and documentation to support inspection observations in accordance with State program procedures.

3.3.2.12 Verify correction of deficiencies identified during the previous inspection.

3.3.2.13 Behave professionally and demonstrate proper sanitary practices during the inspection.

3.3.2.14 Use current versions of applicable hazard guides or other guidance, to identify and evaluate the HAZARDS associated with product(s) and process(es) when conducting inspections of specialized food and processes.

3.3.2.15 Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation when required by regulation.

3.3.2.16 When appropriate review the firm's: scheduled process; HACCP plan or necessary process controls in the absence of a HACCP plan; food safety control plan and applicable monitoring, verification and deviation or corrective action records, including those related to sanitation.

3.3.2.17 Recognize deficiencies in the firm's monitoring controls and sanitation procedures through in-plant observations.

3.3.2.18 Use suitable interviewing techniques.

3.3.2.19 Explain findings clearly and adequately throughout the inspection.

3.3.2.20 Alert the firm's person in charge when an immediate corrective action is necessary.

[9] Standard number 8, Appendix 8.3 Inspection Equipment

3.3.2.21 Answer questions and provide information in an appropriate manner.
3.3.2.22 Write findings accurately, clearly, and concisely on the State document and provide a copy to the firm's person in charge.

3.3.3 Inspection Report

The State program has a written inspection report procedure that requires inspectors to:

3.3.3.1 Submit the inspection report within designated timeframes;
3.3.3.2 Complete the inspection report form completely and accurately;
3.3.3.3 Document violations and observations clearly, legibly, and concisely; and
3.3.3.4 Follow up with corrective action, compliance and enforcement.

3.3.4 Food Recalls[10]

The State program has a food recall system with written recall procedures for:

3.3.4.1 Sharing information about recalls with relevant agencies;
3.3.4.2 Ensuring recalled products are removed promptly from the market; and
3.3.4.3 Performing RECALL AUDIT CHECKS.

3.3.5 Consumer Complaints

The State program has a system for handling CONSUMER COMPLAINTS. The system contains written procedures for:

3.3.5.1 Receiving;
3.3.5.2 Tracking;
3.3.5.3 Evaluating;
3.3.5.4 Responding to; and
3.3.5.5 Closing CONSUMER COMPLAINTS.

3.3.6 Complaints Resulting from State Program Inspection Activities

The State program has a system for handling INDUSTRY COMPLAINTS about inspections. The system contains written procedures for:

3.3.6.1 Receiving;
3.3.6.2 Evaluating; and
3.3.6.3 Responding to INDUSTRY COMPLAINTS.

[10] Reference: PFP Best Practices for Improving FDA and State Communication During Recalls can be found: http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM460013.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

3.3.7 Sampling Procedure[11]

The State program has a written sampling procedure to ensure its SAMPLING PROGRAM is carried out in a manner that is consistent with state procedure. The sampling procedures must be reflective of the types of food and samples that the state collects and must include:

3.3.7.1 Procedures that require sample collectors to:

- 3.3.7.1.1 Use the appropriate method and equipment to collect the sample.
- 3.3.7.1.2 Record sample chain of custody per state procedure.
- 3.3.7.1.3 Handle, package, and ship sample using procedures appropriate to prevent compromising condition of the sample and ensuring security of the sample.
- 3.3.7.1.4 Deliver or ship sample to the appropriate laboratory program within prescribed timeframes.

3.3.7.2 Instructions for documenting the sample collection must include the following unless specified by the State's SAMPLING PROGRAM:

- 3.3.7.2.1 Date of Sample Collection
- 3.3.7.2.2 Product Identification Including:
  - 3.3.7.2.2.1 Name of Product
  - 3.3.7.2.2.2 Unique Manufacturing Identification references
- 3.3.7.2.3 Description of the product
- 3.3.7.2.4 Collection information including:
  - 3.3.7.2.4.1 Method of Collection
  - 3.3.7.2.4.2 Lot Sampled
  - 3.3.7.2.4.3 Lot Size
  - 3.3.7.2.4.4 Special Sample techniques if used to collect the sample
- 3.3.7.2.5 Location where sample was collected.
- 3.3.7.2.6 Name and address of responsible party, guarantor, possessor, or distributor.
- 3.3.7.2.7 Sample type
- 3.3.7.2.8 Analysis requested *if applicable*.
- 3.3.7.2.9 Product labels or specific labeling information that is collected or reproduced per state policies.

[11] Reference: PFP Food/Feed Testing Laboratories Best Practices Manual can be found: http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM404716.pdf

3.3.7.2.10 Identification of the sample with the sample number assigned by the sampler at the time of collection.

3.3.7.3 State programs are not required to have a written sampling procedure unless they collect samples. However, these programs must have a statement in lieu of sampling procedures that explains why a SAMPLING PROGRAM is not supported and how the public health is protected in the absence of such a program. An example may include: Stating that public health is protected because another state or federal agency collects samples and fulfills this need. The statement should include the name of the agency and the type of samples that it collects.

3.3.8 Records Retention

The State program must maintain records as required under Section 9.3.2.2 for the following:

3.3.8.1 Inspection reports which includes follow up activities;
3.3.8.2 Essential recall information;
3.3.8.3 CONSUMER COMPLAINTS;
3.3.8.4 INDUSTRY COMPLAINTS about inspections[12]; and
3.3.8.5 Documentation associated with sample collection.

3.4 Outcome

The State program is based on an inspection program that reduces the occurrence of foodborne illness, injury, or allergic reaction.

3.5 Documentation

The State program maintains the records listed here.

3.5.1 Appendix 3.1 Self-Assessment Worksheet
3.5.2 An inventory of food plants for which the state has regulatory oversight[13]
3.5.3 Written procedure documenting the classification criteria and inspection frequencies
3.5.4 Written rationale of the risk factor and classification criteria if a State program develops its own risk factor and classification criteria
3.5.5 Written procedures for inspecting food plants.
3.5.6 Written inspection reports procedure

[12] Records dealing with personnel actions are not subject to review during an ASSESSMENT.

[13] Refer to PFP Document Data Elements and Definitions for recommended but not required data elements for each food plant. http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM404717.pdf

3.5.7 Written inspection reports, which includes follow-up activities
3.5.8 Written procedures for food recalls
3.5.9 Essential recall information
3.5.10 Written procedures for CONSUMER COMPLAINTS
3.5.11 CONSUMER COMPLAINTS
3.5.12 Written procedures for INDUSTRY COMPLAINTS about inspections
3.5.13 INDUSTRY COMPLAINTS about inspections[14]
3.5.14 Written procedures for sampling or, in the absence of any SAMPLING PROGRAM, a statement stating how public health is protected
3.5.15 Sample collection reports
3.5.16 Documentation associated with sample collection

[14] Records dealing with personnel actions are not subject to review during an ASSESSMENT.

STANDARD 2 TRAINED REGULATORY STAFF

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STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1
Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2
Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual*.

STEP 3
Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1: Curriculum for Retail Food Safety Inspection Officers*.

STEP 4
Completion of a standardization process similar to the FDA standardization procedures.

STEP 5
Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 24 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: *The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.*

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre- requisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

> **Note:** *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*
>
> - *Logs/records that are completed based on sign-in sheets; or*
> - *Information validated from the certificate at the time-of-issuance; or*
> - *A college transcript with a passing grade or other indication of successful completion of the course; or*
> - *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
> - *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORAU courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or

2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or

4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: *Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1 – 3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: *The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."*

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead, and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant, and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

> **Note:** *The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*
>
> - *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
> - *The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

> **Note:** *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*
>
> - *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
> - *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 24 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following eight curricula areas, must be completed within this 24-month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology;
6. Hazard Analysis Critical Control Points (HACCP);
7. Allergen Management
8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 24 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

> **Note:** *The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: *The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually, regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge, and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors and communicates vital information about the inspection in a way that can be received, understood, and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 24- month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
    - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period[1].

Note: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

1. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

Note: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

Standard 2: Trained Regulatory Staff
APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

NOTE about course information: The courses listed below are updated and moved across different learning management systems over time. The latest information will be posted on the FDA Program Standards Landing Page at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019

For state, local, tribal, & territorial (SLTT) regulators to register on-line for free access to web courses, go to: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

Pre-requisite ("Pre") Curriculum Courses

(To be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

PUBLIC HEALTH PRINCIPLES

Courses	Course Number
1-Public Health Principles	FDA36 (90)

MICROBIOLOGY

Courses	Course Number
1-Overview of Microbiology	MIC01 (60)
2A-Gram Negative Rods	MIC02 (60)
2B-Gram-Positive Rods & Cocci	MIC03 (90)
3- Foodborne Viruses	MIC04 (60)
4- Foodborne Parasites	MIC05 (90)
Mid-Series Exam	MIC16 (30)
5- Controlling Growth Factors	MIC06 (90)
6-Control by Refrigeration & Freezing	MIC07 (60)
7A-Control by Thermal Processing	MIC08 (90)
7B- Control by Pasteurization	MIC09 (90)
10- Aseptic Sampling	MIC13 (90)
12-Cleaning & Sanitizing	MIC15 (90)

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Courses	Course Number
1. Basic Food Law for State Regulators	FDA35 (60)
2. Basics of Inspection: Beginning an Inspection	FDA38 (90)
3. Basics of Inspection: Issues & Observations	FDA39 (90)
4. An Introduction to Food Security Awareness	FD251 (60) A PDF/READABLE VERSION at (https://www.fda.gov/training-and- continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness) Note: Required exam is available via www.compliancewire.com.

5. FDA Food Code: Specific SLTT laws and regulations to be addressed by each jurisdiction.	**Note:** Some jurisdictions may require the FDA Food Code Course in addition to SLTT food code training.

COMMUNICATION SKILLS

Courses	Course Number
1. Communication Skills	CC8030W **NOTE**: Course must be accessed through LearnEd at: https:// fdaoted.csod.com/

Curriculum ("Post") Courses

(To be completed any time prior to Food Code Standardization AND within 24 months of hire or assignment to the regulatory retail food program)

MICROBIOLOGY

Courses	Course Number
7C-Control by Retorting	MIC10 (90)
8-Technology-Based Food Processes	MIC11 (120)
9-Natural Toxins	MIC12 (90)

HACCP

Courses	Course Number
1. Overview of HACCP	FDA16 (60)
2. Prerequisite Programs & Preliminary Steps	FDA17 (60)
3. The Principles	FDA18 (60)

ALLERGEN MANAGEMENT

Courses	Course Number
1. Allergens	CC8029W Course must be accessed through LearnEd at: https:// fdaoted.csod.com/

EPIDEMIOLOGY

Courses	Course Number
1. Collecting Surveillance Data	FI01 (90)
2. Beginning the Investigation	FI02 (90)
3. Expanding the Investigation	FI03 (90)
4. Conducting a Food Hazard Review	FI04 (90)
5. Epidemiological Statistics	FI05 (90)
6. Final Report	FI06 (30)

EMERGENCY MANAGEMENT – FEMA

Incident Command System and National Incident Management System: Course available from FEMA web link http://training.fema.gov/IS/NIMS.asp

Courses	Course Number
1. Introduction to Incident Command System	IS-100.C, Introduction to the Incident Command System, (180) ICS-100 for FDA
2. Basic Incident Command System for Initial Response	IS-200.C, Basic Incident Command System for Initial Response (180)
3. An Introduction to NIMS	IS 700.B, An Introduction to NIMS, (180) ICS-700

( ) Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

Estimated total hours for "Pre" courses are 42 hours.

Estimated total hours for "Post" courses are 26 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 68 hours

CFP – Employee Food Safety Training (EFST) Committee

Template approved: 7/13/2021

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME **CFP – EFST Committee**

DATE OF FINAL REPORT: 12/4/2022

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Tara Paster Cammarata and Ki Straughn

COMMITTEE CHARGE(S):

Issue # 2018-II-001

1. *Review the CFP "Employee Food Safety Training Guidance Document" for possible updates (assigned via Issue 2018-II-001); and*
2. *Report recommendations at the 2023 Biennial Meeting.*

COMMITTEE WORK PLAN AND TIMELINE:

- **A.** *Historical perspective review and acknowledgement of the 2016 - 2018 Employee Food Safety Training Committee Final Report*
- **B.** *Thank the past committee members for the completed work and recognize their commitment to CFP*
- **C.** *Welcome and organize the new committee members to complete the assigned charge using collaboration and transparency*
- **D.** *Divide and review the CFP "Employee Food Safety Training Guidance Document" for possible updates*

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

- ✓ *Friday, November 5, 2021*
  Ki Straughn, Dr. Ben Chapman from NC State, and Tara Paster Cammarata reviewed the historical perspective of the 2016 - 2018 Employee Food Safety Training Committee Final Report
- ✓ *Friday, December 10, 2021 – Committee Virtual Meeting*
  Recognized and thanked past committee members; Welcome; Orientation to Committee; Legal review; Expectations; Champions volunteered to lead the different sections of the Guidance Document and the committee accepted the plan calendar for success
- ✓ *Friday, January 14, 2022 – Committee Virtual Meeting:* ***Section 1***
- ✓ *Friday, February 11, 2022 – Committee Virtual Meeting:* ***Section 2***
- ✓ *Friday, March 11, 2022 – Committee Virtual Meeting:* ***Sections 2 & 3***
- ✓ *Friday, April 8, 2022 – Committee Virtual Meeting:* ***Section 4***
- ✓ *Friday, May 13, 2022 – Committee Virtual Meeting:* ***Section 4 and 5***
- ✓ *Friday, June 10, 2022 – Committee Virtual Meeting:* ***Sections 6***
- ✓ *Friday, July 8, 2022 – Committee Virtual Meeting:* ***Sections 5 and 6***
- ✓ *Friday, August 12, 2022 – Committee Virtual Meeting:* ***Sections 7***
- ✓ *Friday, September 9, 2022 – Meeting canceled because all sections were completed*
- ✓ *October 2022 – November 2022 –* ***Final review of all seven sections and development of issues*** *were completed via e-mail collaboration and consensus.*
- ✓ *Sunday, December 4, 2022 –* ***Final recommendations*** *were completed after receiving e-mail consensus.*

1. ***Overview of committee activities:***

*Section 1: Foundations of Food Safety review and updates were completed under the leadership of Champion **Janet Buffer**.*

*Section 2: Employee Health review and updates were completed under the leadership of two Champions **Ashley Eisenbeiser** and **Clay Hosh**.*

*Section 3: Personal Hygiene and Handwashing review and updates were completed under the leadership of Champion **Rachel Scanlan**.*

*Section 4: Preventing Cross-Contamination review and updates were completed under the leadership of Champion **Debbie Pickle**.*

*Section 5: Allergen Control review and updates were completed under the leadership of Champion **Jeff Hawley**.*

*Section 6: Time and Temperature Control for Safety (TCS) review and updates were completed under the leadership of Champion **Sharon Unkart**.*

*Section 7: Cleaning and Sanitizing review and updates were completed under the leadership of Champion **Tara Paster Cammarata**.*

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

   ***Yes**, the charges were successfully completed by the Employee Food Safety Training Committee Members.*

   ***Rationale:** One of the essential elements needed for protecting public health is food employee training. It is critical to take a proactive approach in preventing food employee skill gaps, this is done by imparting knowledge to further develop the food employee's new skills and providing updates on existing skills.*

   The Employee Food Safety Committee updated and addressed food employee knowledge, skills, and abilities (KSA) in the following areas:

   1. *Foundations of Food Safety*
   2. *Employee Health Outcomes*
   3. *Personal Hygiene and Handwashing*
   4. *Preventing Cross-Contamination*
   5. *Allergen Control*
   6. *Time and Temperature Control for Safety (TCS)*
   7. *Cleaning and Sanitizing*

The bench marking of food employee training assists in identifying KSAs; as well as any gaps that may exist. Once these gaps are identified then mitigation strategies can be performed ultimately strengthening the global food supply and protecting public health.

In closing, the Employee Food Safety Training Committee Members worked diligently on both charges according to our committee's calendar of events. The committee members are passionate subject matter experts with "excellence" as the standard. The enthusiasm and engagement are best-in-class with collaboration and consensus as the driving force to complete the committee work.

*The final recommendation of this committee is to **immediately publish** the "Employee Food Safety Training Guidance Document" on the CFP website for all to use.*

3. ***Charges INCOMPLETE and to be continued to next biennium:***

*None. The recommendation is to **disband** the Employee Food Safety Training Committee.*

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.

2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. ***Committee Issue #1***: *Employee Food Safety Training Committee Final Report*

   Acknowledging the Employee Food Safety Training (EFST) Committee final report with attachments and recognize by extending our sincerest gratitude and appreciation to the Committee members for their commitment and hard work.

   Attachments:

   Content Documents:

   Attachment: EFST Committee Final Report (Issues)

   Attachment: Employee Food Safety Training Guidance Document (2017 FDA Food Code)

   Supporting Attachments:

   Attachment: A 10.08.2021 Report

   Attachment: B 03.30.2022 Report

   Attachment: C 09.11.2022 Report

   Attachment: D Roster

2. ***Committee Issue #2***: *Publishing the "**Employee Food Safety Training Guidance Document** (2017 FDA Food Code)"*

   The Employee Food Safety Training (EFST) Committee recommends publishing the "Employee Food Safety Training Guidance Document (2017 FDA Food Code)" on the CFP website.

   Attachments:

   Content Documents:

   Attachment: Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Updated 12.04.2022

The Conference for Food Protection Employee Food Safety Training Committee was re-created and assigned **Issue #2018-II-01** from previous Issue 2016 II-001 that continued work initiated during the 2014 – 2016 biennium from the original Issue 2014-II-011.

The specific charges for the 2021-2023 biennium were to:

1. Review the CFP **"Employee Food Safety Training Guidance Document"** for possible updates; and
2. Report recommendations at the 2023 Biennial Meeting

Each topic category has been placed in its own section, grouped by contributing factor and foundational knowledge, based on the learning objectives. Objectives have been defined, as a roadmap for instructional designers and regulators; each objective has been assigned a KSA type (knowledge, skill, or ability).

KSA definitions:

- **Knowledge:** Understanding each of the Objectives and Measures in the Employee Food Safety Training program.
- **Skills:** Through training and experience, being able to apply each of the Objectives and Measures in the Employee Food Safety Training program.
- **Abilities:** Being able to apply effectively and efficiently each of the Objectives and Measures in the Employee Food Safety Training program in real-world applications.

One of the essential elements needed for protecting public health is **food employee training**. The Employee Food Safety Committee **updated** food employee knowledge, skills, and abilities (KSA)**.** In addition, the references to the 2017 FDA Model Food Code have been noted and specific measures provided in the following seven areas:

1. Foundations of Food Safety
2. Employee Health Outcomes
3. Personal Hygiene and Handwashing
4. Preventing Cross-Contamination
5. Allergen Control
6. Time and Temperature Control for Safety (TCS)
7. Cleaning and Sanitizing

This bench marking of food employee training assists in identifying KSAs; as well as any gaps that may exist. Once these gaps are identified then mitigation strategies can be performed ultimately strengthen the global food supply and protecting public health.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 1: Foundations of Food Safety

Section 1: Foundations of Food Safety	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
1.1	**K**	Identify food hazards (including biological, chemical, and physical).	**1-201.10** Definition: • Hazard	Lists known food hazards as it relates to employee duties: • Identifies foodborne illness as a disease transmitted to people through food.
	S	Applies methods to prevent the contamination of food from biological, chemical, and physical hazards.		• Implements appropriate corrective actions to reduce the risks of food hazards.
1.2	**K**	Identify employee role in controlling food hazards and the impact of their behavior.	**Preface ii**	• Describes the relationship between employee health and hand hygiene, time and temperature control, prevention of cross contamination, cleaning, sanitizing, allergen control and the prevention of cross-contact, and food safety.
1.3	**K**	Understands that some foods will **not** require a pathogen kill step prior to consumption.	**1-201.10** Definition: • Ready-to-Eat	• Explains ready-to-eat food as it relates to employee duties.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 2: Employee Health Outcomes

Section 2: Employee Health Outcomes	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
2.0	**K**	Identify the relationship between working when sick and foodborne illness and the importance of notifying management of reportable illness symptoms, diagnoses, or illness exposure.	**Annex 3** **2-201.11(E)**	• Recognizes that failing to notify management of reportable illness symptoms, diagnoses, and illness exposure may result in the transmission of a disease through food being prepared. • Explains role in reporting process (as required by FDA Food Code).
2.1	**K**	Identify illness symptoms, diagnoses (i.e., Big Six), and illness exposure, which are easily transmissible through food, that must be reported to management.	**2-201.11**	• Lists the illness symptoms, diagnoses, and exposures that must be reported to management.
2.2	**S**	Report required illness symptoms, diagnoses, and illness exposure to management.	**2-201.11(F)**	• Informs management when experiencing illness symptoms, diagnoses, or illness exposures that are reportable.
2.3	**A**	Food employees are aware that they are required to report required illnesses and symptoms to PIC.	**2-103.11(O)**	

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 3: Personal Hygiene and Handwashing

Section 3: Personal Hygiene and Handwashing	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
3.1	**K**	Identify the role of clean outer clothing in preventing contamination of food, equipment, utensils, linens, and single-service and single-use articles.	**2-304.11**	• Wears clean outer clothing.
3.2	**K, S**	Identify when, where, and how to wash hands according to the FDA Food Code.	**2-103.11(D)** **2-301.12** **2-301.14** **2-301.15**	• Washes hands according to the FDA Food Code.
3.3	**S**	Apply FDA Food Code standards for fingernails and jewelry.	**2-302.11** **2-303.11**	• Applies FDA Food Code standards for fingernails and jewelry.
3.4	**K**	Recognize where eating, drinking, and tobacco use is allowed.	**2-401.11**	• Eats, drinks, and smokes only in designated areas.
3.5	**K**	Identify when to use hair restraints to avoid food contamination and which restrains are appropriate according to the FDA Food Code.	**2-402.11**	• Wears appropriate hair restraints when necessary.

3.6	**K** **S**	Describe how to correctly cover a bandage, finger cot, or finger stall located on the wrists, hands, or fingers. Distinguish when and how to use and replace single-use gloves according to the FDA Food Code.	**2-401.13** **3-304.15**	• Covers bandages, finger cots, or finger stalls according to the FDA Food Code. • Uses and replaces single-use gloves according to the FDA Food Code.
3.7	**K**	Describe how to correctly cover infected wound on the hands or forearms.	**2-201.13(I)** **2-401.13**	• Covers infected wounds according to the FDA Food Code.
3.8	**K**	Understands food workers may not care for or handle animals.	**2-403.11**	• Food employees do not handle or care for animals unless allowed by the Food Code.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 4: Preventing Cross-Contamination

Section 4: Preventing Cross-Contamination	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
4.1	**A**	Prevent contamination of all food, including ice, during preparation, storage, and display. Prevent contamination of in-use utensils.	**3-304.12** **3-307.11**	• Prepares, stores, and displays all food in a manner that prevents contamination. • Store in-use utensils in a manner that prevents contamination.
4.2	**A**	Identify potential for food contamination associated with consumer self-service areas.	**3-306.13(B)** **3-306.13(C)** **3-304.17**	• Monitors and notifies a person in charge when a self-service area has potentially become contaminated.
4.3	**A**	Determine when to replace equipment and utensils with clean and sanitized equipment and utensils.	**4-601.11**	• Replaces equipment and utensils with clean and sanitized utensils.
4.4	**K**	Identify how to correctly store cleaned and sanitized utensils and equipment.	**3-304.12**	• Stores cleaned and sanitized utensils in a manner that prevents contamination.
4.5	**S**	Prevent contamination of fruits and vegetables by avoiding bare hand contact after washing raw, uncut fruits and vegetables.	**3-302.15**	• Washes raw, uncut fruits and vegetables prior to preparation or service and avoids bare hand contact once washed.
4.6	**S**	Describe proper storage of food, food containers, single service, and single use articles to prevent contamination.	**3-305.11** **3-305.12** **4-401.11**	• Properly stores food, food containers, single service, and single use articles to prevent contamination.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 5: Allergen Control

Section 5: Allergen Control	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
5.1	**K**	Identify the major food allergens as defined by the FDA Food Code 2017, which includes milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame (upon inclusion in the Food Code).	**1-201.10** Definition: • Major Food Allergen	• Lists the major food allergens as defined by the FDA Food Code.
5.2	**K**	Describe how food employees should communicate with customers to prevent allergic reactions.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, effectively executes on the training to prevent customer exposure to food allergens.
5.3	**K**	Identify methods for preventing cross-contact when preparing food.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, effectively executes on the training to prevent customer exposure to food allergens.
5.4	**K**	Recognize the signs of an allergic reaction and respond accordingly.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, and effectively executes on the training by properly describing how to respond to an allergen emergency.
5.5	**K**	Identify major food allergens on labels; is knowledgeable of proper allergen labeling.	**3-602.11 (B)(5)**	• Receives food allergen awareness training from person in charge, and effectively executes on the training by adhering to proper food allergen labeling.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 6: Time and Temperature Control for Safety (TCS)

Section 6 Time and Temperature Control for Safety	KSA Type	Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
6.1	**K**	Identify foods requiring time and temperature control to reduce the risk of foodborne illness.	**1-201.10** Definition • Time / Temperature Control for Safety Food	• Applies time/temperature controls to TCS foods such as but not limited to the following items: raw or heat-treated animal FOOD, plant FOOD that has been heat treated, raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified, or garlic in oil mixtures that are not modified.
6.2	**K**	Identify the requirements for noncontinuous cooking of TCS foods.	**3-401.14**	• Partially cooks TCS foods according to requirements.
6.3	**A**	Identify how to monitor TCS food temperatures using appropriate temperature measuring devices. Recognize that the temperature of TCS foods must be routinely monitored during cooking, holding, and cooling using a thermometer that meets requirements.	**1-201.10** Definition • Temperature measuring device **2-103.11(G)** **2-103.11(H)** **2-103.11(I)** **Annex 5:** The correct temperature measuring device and technique are essential in accurately determining the temperatures of TCS foods. The geometric center or thickest part of a product are the points of measurement of	• Use temperature measuring devices to monitor temperatures of TCS food. • Routinely monitors temperatures when cooking, holding, and cooling TCS food.

			product temperature particularly when measuring critical limits for cooking.	
6.4	**K**	Identify the appropriate cooking times and temperatures for TCS foods to reduce the risk of foodborne illness.	**3-401** (Raw animal FOOD) **3-401.13** (Plant FOOD for hot holding)	• Cooks TCS food to required minimum internal cooking times/ temperatures.
6.5	**S, A**	Identify the time/temperature requirements for cooling TCS food. Identify proper methods for cooling TCS food.	**3-501.14** **3-501.15**	• Cools TCS food according to time/temperature requirements. • Cools TCS food using a proper cooling method.
6.6	**A**	Apply corrective action to food that has fallen outside time/temperature control.	**3-501.18(A)(1)**	• Applies proper corrective action to food that has fallen outside time / temperature control.
6.7	**K**	Identify methods for safely thawing food according to the FDA Food Code.	**3-501.13**	• Thaws food safely following an approved method.
6.8	**K**	Identify time/temperature requirements for reheating TCS food for hot holding.	**3-403.11**	• Reheats TCS food for hot holding following time and temperature requirements.
6.9	**K**	Identify the time or temperature requirements for holding AND STORING hot and cold TCS food.	**3-501.16** **3-501.19**	• Holds and stores hot and cold TCS food according to time/temperature requirements.
6.10	**K**	Identify the requirements for date marking TCS food.	**3-501.17**	• Date marks TCS food according to requirements.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 7: Cleaning and Sanitizing

Section 7: Cleaning and Sanitizing	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
7.1	**K**	Identify the difference between cleaning and sanitizing.	**1-201.10** Definitions: • Easily Cleanable • Sanitization	Lists cleaning and sanitizing responsibilities as relates to employee duties: • Identifies equipment and facility cleaning activities • Identifies equipment and facility sanitizing activities.
	S	Applies appropriate cleaning and sanitizing methods to reduce the risks to food hazards.	**6-501.12** **6-501.13** **6-501.15** **6-501.16** **6-501.19**	• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards.
7.2	**K**	Identify the need to follow the specific procedures when using chemicals according to the manufacturer's guidelines and properly storing chemicals in a food establishment.	**7-101.11** **7-102.11** **7-202.11** **7-202.12** **7-203.11** **7-204.11**	• Follows manufacturer's guideline when using chemicals and properly storing chemicals according to the FDA Food Code.
	S	Applies appropriate procedures when using and storing chemicals in a food establishment.		• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards.

7.3	**K**	Identify food-contact surfaces.	**1-201.10** Definition: • Food-contact surface	• Lists food employee responsibilities and duties as it relates to food contact surfaces.
	S	Applies appropriate procedures on when and how to clean and sanitize food contact surfaces.	**2-103.11(K)** **4-601.11** **4-602.11** **4-602.12** **4-602.13** **4-603.11** **4-701,10** **4-702.11** **4-703.11**	• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when cleaning and sanitizing food contact surfaces.
7.4	**K**	Identify the need to follow the specific procedures when cleaning and sanitizing utensils and equipment.	**1-201.10** Definitions: • Utensil • Equipment • CIP cleaned in place • Counter-mounted equipment • Easily moveable **4-601.11** **4-602.11** **4-602.12** **4-602.13** **4-603.11**	• Follows specific procedures when cleaning and sanitizing utensils and equipment according to the FDA Food Code.

	S	Applies appropriate procedures when cleaning and sanitizing utensils and equipment.	**2-103.11(K)** **3-304.11**	• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards when cleaning and sanitizing utensils and equipment.
7.5	**K**	Identify the need to follow the specific procedures when using mechanical warewashing.	**1-201.10** Definition: • Warewashing **4-603.12** **4-603.13** **4-603.14**	• Follows specific procedures when using mechanical warewashing according to the FDA Food Code.
	S	Applies appropriate procedures when performing mechanical warewashing.		• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when performing mechanical warewashing.
7.6	**K**	Identify the need to follow the specific procedures when using manual warewashing.	**1-201.10** Definition: • Warewashing **4-301.12** **4-302.14** **4-603.14** **4-603.15** **4-603.16**	• Follows specific procedures when using manual warewashing according to the FDA Food Code.
	S	Applies appropriate procedures when performing manual warewashing.		• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when performing manual warewashing.

7.7	**K**	Identify the need to follow the specific procedures when using and storing wiping cloths.	**3-304.14**	• Follows specific procedures when using and storing wiping cloths according to the FDA Food Code.
	S	Applies appropriate procedures when using and storing wiping cloths.		• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards when using and storing wiping cloths.
7.8	**K**	Identify the need to follow specific procedures when responding to vomiting and diarrheal events in the food establishment.	**2-501.11**	• Follows specific procedures when responding to vomiting and diarrheal events in the food establishment according to the FDA Food Code.
	S	Applies appropriate procedures when responding to vomiting and diarrheal events in the food establishment.		• Recognizes that failing to follow appropriate procedures when responding to vomiting and diarrheal events in the food establishment may result in the transmission of a disease.

Template approved: 07/13/20/21

Committee Progress Reports are considered DRAFT until accepted by the Executive Board

The Conference Chair, Executive Director, Council Chair, or Issue Chair may return committee reports, Issues, or attached documents requesting edits to improve clarity or understanding, or to include missing information.

Committee-submitted documents may impact the image, credibility and integrity of the Conference as an organization. With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME: Employee Food Safety Training

DATE OF REPORT: ☒ ***Initial fall progress report*** ☐ ***Spring progress report*** ☐ ***Second fall progress report***
Date submitted: 10/8/2021 **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY:

COMMITTEE CHARGE(S):

Issue # 2018-II-001

1. *Review the CFP "Employee Food Safety Training Guidance Document" for possible updates (assigned via Issue 2018-II-001); and*
2. *Report recommendations at the 2023 Biennial Meeting.*

COMMITTEE WORK PLAN AND TIMELINE:

1. *Historical perspective review and acknowledgement of the 2016 - 2018 Employee Food Safety Training Committee Final Report*
2. *Thank the past committee members for the completed work and recognize their commitment to CFP*
3. *Welcome and organize the new committee members to complete the assigned charge using collaboration and transparency*
4. *Divide and review the CFP "Employee Food Safety Training Guidance Document" for possible updates*

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:***

   To be determined once committee is approved by the CFP Executive Board
2. ***Overview of committee activities:***

   Proposed committee roster attached pending CFP Executive Board approval
3. ***Charges COMPLETED and the rationale for each specific recommendation:***

   To be determined
4. ***Status of charges still PENDING and activities yet to be completed:***

   To be determined

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☐ ***Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.***
☒ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

1. *Please approve attached committee roster*

ATTACHMENTS:

1. ***Content Documents:***
   a. ***Committee Member Roster:*** ☒ ***See changes noted above under "requested action"*** ☐ ***No changes to previously approved roster***
   "Committee Members Template" (Excel) available at: www.foodprotect.org/work/ *Committee roster to be submitted as a PDF attachment to this report.*
   b. ***Committee Generated Content Documents (OPTIONAL):*** ☐ ***No draft content documents submitted at this time***

2. ***Supporting Attachments (OPTIONAL):*** ☐ ***Not applicable***

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COMMITTEE NAME: Employee Food Safety Training

DATE OF REPORT: ☐ ***Initial fall progress report*** ☒ ***Spring progress report*** ☐ ***Second fall progress report***
Date submitted: 3/30/2022 **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Tara Paster Cammarata

COMMITTEE CHARGE(S):

Issue # 2018-II-001

1. *Review the CFP "Employee Food Safety Training Guidance Document" for possible updates (assigned via Issue 2018-II-001); and*
2. *Report recommendations at the 2023 Biennial Meeting.*

COMMITTEE WORK PLAN AND TIMELINE:

1. *Historical perspective review and acknowledgement of the 2016 - 2018 Employee Food Safety Training Committee Final Report*
2. *Thank the past committee members for the completed work and recognize their commitment to CFP*
3. *Welcome and organize the new committee members to complete the assigned charge using collaboration and transparency*
4. *Divide and review the CFP "Employee Food Safety Training Guidance Document" for possible updates*

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:***
   - ***a.*** *Friday, November 5, 2021*
     Ki Straughn, Dr. Ben Chapman from NC State, and Tara Paster Cammarata reviewed the historical perspective of the 2016 - 2018 Employee Food Safety Training Committee Final Report
   - ***b.*** *Friday, December 10, 2021 – Committee Virtual Meeting*
     Recognized and thanked past committee members; Welcome; Orientation to Committee; Legal review; Expectations; Champions volunteered to lead the different sections of the Guidance Document and the committee accepted the plan calendar for success
   - ***c.*** *Friday, January 14, 2022 – Committee Virtual Meeting:* ***Section 1***
   - ***d.*** *Friday, February 11, 2022 – Committee Virtual Meeting:* ***Section 2***
   - ***e.*** *Friday, March 11, 2022 – Committee Virtual Meeting:* ***Sections 2 & 3***
2. ***Overview of committee activities:***
   - ***a.*** *Section 1: Foundations of Food Safety review and updates were completed under the leadership of Champion* ***Janet Buffer****.*
   - ***b.*** *Section 2: Employee Health review and updates were completed under the leadership of two Champions* ***Ashley Eisenbeiser*** *and* ***Clay Hosh****. This section took two meetings to complete.*
   - ***c.*** *Section 3: Personal Hygiene and Handwashing review and updates were completed under the leadership of Champion* ***Rachel Scanlan****.*
3. ***Charges COMPLETED and the rationale for each specific recommendation:***

   The Employee Food Safety Training Committee Members are working diligently on both charges according to our committee's calendar of events. The committee members are an all-star cast of ***passionate subject matter experts*** *with "****excellence****" as the standard. The enthusiasm and engagement are* ***best-in-class*** *with collaboration and consensus as our driving force to complete the committee work.*

4. ***Status of charges still PENDING and activities yet to be completed:***
   The Employee Food Safety Training Committee is absolutely an amazing group of professionals, and we are 100% on track to complete both charges on time.
   - ***a.*** ***Section 4*** *is schedules for review Friday, April 8, 2022.*
   - ***b.*** ***Section 5*** *is scheduled for review Friday, May 13, 2022.*
   - ***c.*** ***Section 6*** *is scheduled for review Friday, June 10, 2022.*
   - ***d.*** ***Section 7*** *is scheduled for review Friday, July 8, 2022.*

   Our committee would like to thank Jo DeFrancesco and Courtney Halbrook for their support and assistance.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.***

☐ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

ATTACHMENTS:

1. ***Supporting Attachments (OPTIONAL):*** ☒ ***Not applicable***

Committee Progress Reports are considered DRAFT until accepted by the Executive Board

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COMMITTEE NAME: Employee Food Safety Training

DATE OF REPORT: ☐ ***Initial fall progress report*** ☐ ***Spring progress report*** ☒ ***Second fall progress report***
Date submitted: 9/11/2022 **Date amended (if applicable):** *Click here to enter a date.* **Date accepted by Executive Board:** *Click here to enter a date.*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Tara Paster Cammarata

COMMITTEE CHARGE(S):

Issue # 2018-II-001

1. *Review the CFP "Employee Food Safety Training Guidance Document" for possible updates (assigned via Issue 2018-II-001); and*
2. *Report recommendations at the 2023 Biennial Meeting.*

COMMITTEE WORK PLAN AND TIMELINE:

1. *Historical perspective review and acknowledgement of the 2016 - 2018 Employee Food Safety Training Committee Final Report*
2. *Thank the past committee members for the completed work and recognize their commitment to CFP*
3. *Welcome and organize the new committee members to complete the assigned charge using collaboration and transparency*
4. *Divide and review the CFP "Employee Food Safety Training Guidance Document" for possible updates*

COMMITTEE ACTIVITIES:

1. ***Dates of committee meetings or conference calls:***
   - ***a.*** *Friday, April 8, 2022 – Committee Virtual Meeting:* ***Section 4***
   - ***b.*** *Friday, May 13, 2022 – Committee Virtual Meeting:* ***Section 4 and 5***
   - ***c.*** *Friday, June 10, 2022 – Committee Virtual Meeting:* ***Sections 6***
   - ***d.*** *Friday, July 8, 2022 – Committee Virtual Meeting:* ***Sections 5 and 6***
   - ***e.*** *Friday, August 12, 2022 – Committee Virtual Meeting:* ***Sections 7***
   - ***f.*** *Friday, September 9, 2022 – Meeting canceled because all sections were completed*
2. ***Overview of committee activities:***
   - ***a.*** *Section 4: Preventing Cross-Contamination review and updates were completed under the leadership of Champion* ***Debbie Pickle****.*
   - ***b.*** *Section 5: Allergen Control review and updates were completed under the leadership of two Champions* ***Jeff Hawley****.*
   - ***c.*** *Section 6: Time and Temperature Control for Safety (TCS) review and updates were completed under the leadership of Champion* ***Sharon Unkart****.*
   - ***d.*** *Section 7: Cleaning and Sanitizing review and updates were completed under the leadership of Champion* ***Lindy Wiedmeyer****.*
3. ***Charges COMPLETED and the rationale for each specific recommendation:***

   The Employee Food Safety Training Committee Members are working diligently on both charges according to our committee's calendar of events. The committee members are an all-star cast of ***passionate subject matter experts*** *with "****excellence****" as the standard. The enthusiasm and engagement are* ***best-in-class*** *with collaboration and consensus as our driving force to complete the committee work.*

4. ***Status of charges still PENDING and activities yet to be completed:***
   The Employee Food Safety Training Committee is absolutely an amazing group of professionals, and we are 100% on track to complete both charges on time.
   - ***a.*** ***Final Report including review of All 7 Sections*** *is scheduled for review Friday, October 14, 2022.*
   - ***b.*** ***Final Report Recommendation presentation*** *is scheduled for review Friday, November 11, 2022.*

Our committee would like to thank Courtney Halbrook for her support and assistance.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***Board Action is NOT required and therefore the report can be placed on the consent calendar for Board review and acceptance.***

☐ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

ATTACHMENTS:

1. ***Supporting Attachments (OPTIONAL):*** ☒ ***Not applicable***

2021-2023 Employee Food Safety Training
CFP Committee Roster

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Straughn	Ki	Chair	Regulatory - Local	PHSKC	Seattle	WA	2062638088	kstraughn@kingcounty.gov
Cammarata	Tara Paster	Co-Chair	Industry - Support	Paster Training, Inc.	Gilbertsville	PA	4844318240	tara.paster@pastertraining.com
Pickle	Debbie	Member	Regulatory - State	TN Department of Health	Nashville	TN	9312154527	Debbie.Pickle@tn.gov
Doherty	Brenden	Member	Regulatory - State	Florida DBPR - Division of Hotels & Restaurants	Tallahassee	FL	8507171260	brenden.doherty@myfloridalicense.com
Mickiewicz	Courtney	Member	Regulatory - State	VDACS	Virginia Beach	VA	7574780307	Courtney.Mickiewicz@vdacs.virginia.gov
Unkart	Sharon	Member	Regulatory - State	National Environmental Health Association	Denver	CO	7203413957	sdunkart@neha.org
Wiedmeyer	Lindy	Member	Regulatory - Local	City of West Allis Health Department	West Allis	WI	2623530344	lwiedmeyer@wesetalliswi.gov
Irving	Felicia	Member	Regulatory - Local	Harris County Enviromental Public Health	Houston	TX	8328400167	felicia.irving@phs.hctx.net
Barajas	Alexis	Member	Regulatory - Local	SNHD	Las Vegas	NV	7029278421	barajas@snhd.org
Henrichs	Amanda	Member	Regulatory - Local	Tulsa Health Department	Tulsa	OK	Need	ahenrichs@tulsa-health.org
Johnson	Jennifer	Member	Industry - Food Service	Yum!	Plano	TX	4077398555	jennifer.johnson@yum.com
Yoo	Joey (Woo Jin)	Member	Industry - Food Service	Compass Group USA	Charlotte	NC	4013270937	woojin.yoo@compass-usa.com
Morrison	Laura	Member	Industry - Food Service	Ohio Restaurant Association	Columbus	OH	6145634495	lmorrison@ohiorestaurant.org
Luebkemann	Geoffrey	Member	Industry - Food Service	Florida Restaurant and Lodging Assn	Tallahassee	FL	8508792581	gluebkemann@frla.org
Payton	Larry	Member	Industry - Retail Food	Tokyo Gardens Catering, LLC	Houston	TX	281515 3132	payton.larry@tgcsushi.com
Hsieh	Hsing-Yi	Member	Industry - Retail Food	Skogen's Festival Foods	De Pere	WI	9205405644	hhsieh@festfoods.com
Boyer	Ellen	Member	Industry - Retail Food	Wakefern Food Corp	Elizabeth	NJ	4843001637	ellen.boyer@wakefern.com
Hawley	Jeffrey	Member	Industry - Retail Food	Harris Teeter	Matthews	NC	7042360890	jhawley@harristeeter.com
Eisenbeiser	Ashley	Member	Industry - Support	FMI	Arlington	VA	2022200689	aeisenbeiser@fmi.org
Chapman	Bryan	Member	Industry - Support	StateFoodSafety	Orem	UT	8013606149	bchapman@statefoodsafety.com
Hosh	Clay	Member	Industry - Support	National Restaurant Association	Chicago	IL	8152630566	chosh@restaurant.org
Dolhanyk	Anne	Member	Consumer	STOP Foodborne Illness	West Linn	OR	3606014264	adolhanyk@gmail.com
Reich	Allen	Member	Academia	Northern Arizona University	Flagstaff	AZ	9288536340	allen.reich@nau.edu

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
		FDA Consultant	Regulatory - Federal					
		USDA Consultant	Regulatory - Federal					
		CDC Consultant	Regulatory - Federal					
McClellan	Hunter	Alternate	Regulator - State	Nebraska Department of	Lincoln	NE	4024716813	hunter.mcclellan@nebraska.gov
Walker	Matthew	Alternate	Regulator - State	Idaho Department of Health & Welfare	Boise	ID	2089855403	matthew.walker@dhw.idaho.gov
Huffman	Troy	Alternate	Regulator - State	Colorado Dept. of Public Health & Environment	Denver	CO	3036923664	troy.huffman@state.co.us
Hilton	DeBrena	Alternate	Regulator - Local	Tulsa Health Department	Tulsa	OK	9187201618	dhilton@tulsa-health.org
Woods	Yolanda	Alternate	Regulator - Local	Shelby County Government	Memphis	TN	19012229190	yolanda.woods@shelbycountytn.gov
Hernandez	Cris	Alternate	Regulator - Local	Washington County Environmental Health	Hillsboro	OR	5038907637	cris_hernandez@co.washington.or.us
Roughan	George	Alternate	Industry - Support	TAP Series	Westlake Vill	CA	8052178605	groughan@chimsol.com
Koester	Laura	Alternate	Industry - Retail Food	Harmons	Salt Lake Cit	UT	8013490407	laurakoester@harmonsgrocery.com
Allen	Consuelo	Alternate	Industry - Retail Food	Whole Foods Market	Austin	TX	15124268709	consuelo.allen@wholefoods.com
Mello	Wayne	Alternate	Industry - Retail Food	Ahold Delhaize/Retail Business Services	Scarborough	ME	2076329017	wayne.mello@retailbusinessservices.com
Buffer	Janet	Alternate	Industry - Food Service	Amazon	Mount Verno	OH	6145994541	jlbuffer@amazon.com
ONeal	James	Alternate	Industry - Food Service	Denny's	Spartanburg	SC	8034802079	joneal@dennys.com
Zaziski	Linda	Alternate	Industry - Food Service	Little Caesar Enterprises/Blue Line Distribution/Champion Food Service	Detroit	MI	5862436932	linda.zaziski@lcecorp.com
Hill	Michelle	Alternate	Consumer	Allergen Free Cooking	Woodbury	MN	6127014004	michelle@allergenfreecook.com
Chapman	Ben	Alternate	Academia	NC State University	Raleigh	NC	9198093205	bjchapma@ncsu.edu

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Updated 12.04.2022

The Conference for Food Protection Employee Food Safety Training Committee was re-created and assigned **Issue #2018-II-01** from previous Issue 2016 II-001 that continued work initiated during the 2014 – 2016 biennium from the original Issue 2014-II-011.

The specific charges for the 2021-2023 biennium were to:

1. Review the CFP **"Employee Food Safety Training Guidance Document"** for possible updates; and
2. Report recommendations at the 2023 Biennial Meeting

Each topic category has been placed in its own section, grouped by contributing factor and foundational knowledge, based on the learning objectives. Objectives have been defined, as a roadmap for instructional designers and regulators; each objective has been assigned a KSA type (knowledge, skill, or ability).

KSA definitions:

- **Knowledge:** Understanding each of the Objectives and Measures in the Employee Food Safety Training program.
- **Skills:** Through training and experience, being able to apply each of the Objectives and Measures in the Employee Food Safety Training program.
- **Abilities:** Being able to apply effectively and efficiently each of the Objectives and Measures in the Employee Food Safety Training program in real-world applications.

One of the essential elements needed for protecting public health is **food employee training**. The Employee Food Safety Committee **updated** food employee knowledge, skills, and abilities (KSA)**.** In addition, the references to the 2017 FDA Model Food Code have been noted and specific measures provided in the following seven areas:

1. Foundations of Food Safety
2. Employee Health Outcomes
3. Personal Hygiene and Handwashing
4. Preventing Cross-Contamination
5. Allergen Control
6. Time and Temperature Control for Safety (TCS)
7. Cleaning and Sanitizing

This bench marking of food employee training assists in identifying KSAs; as well as any gaps that may exist. Once these gaps are identified then mitigation strategies can be performed ultimately strengthen the global food supply and protecting public health.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 1: Foundations of Food Safety

Section 1: Foundations of Food Safety	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
1.1	**K**	Identify food hazards (including biological, chemical, and physical).	**1-201.10** Definition: • Hazard	Lists known food hazards as it relates to employee duties: • Identifies foodborne illness as a disease transmitted to people through food.
	S	Applies methods to prevent the contamination of food from biological, chemical, and physical hazards.		• Implements appropriate corrective actions to reduce the risks of food hazards.
1.2	**K**	Identify employee role in controlling food hazards and the impact of their behavior.	**Preface ii**	• Describes the relationship between employee health and hand hygiene, time and temperature control, prevention of cross contamination, cleaning, sanitizing, allergen control and the prevention of cross-contact, and food safety.
1.3	**K**	Understands that some foods will **not** require a pathogen kill step prior to consumption.	**1-201.10** Definition: • Ready-to-Eat	• Explains ready-to-eat food as it relates to employee duties.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 2: Employee Health Outcomes

Section 2: Employee Health Outcomes	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
2.0	**K**	Identify the relationship between working when sick and foodborne illness and the importance of notifying management of reportable illness symptoms, diagnoses, or illness exposure.	**Annex 3** **2-201.11(E)**	• Recognizes that failing to notify management of reportable illness symptoms, diagnoses, and illness exposure may result in the transmission of a disease through food being prepared. • Explains role in reporting process (as required by FDA Food Code).
2.1	**K**	Identify illness symptoms, diagnoses (i.e., Big Six), and illness exposure, which are easily transmissible through food, that must be reported to management.	**2-201.11**	• Lists the illness symptoms, diagnoses, and exposures that must be reported to management.
2.2	**S**	Report required illness symptoms, diagnoses, and illness exposure to management.	**2-201.11(F)**	• Informs management when experiencing illness symptoms, diagnoses, or illness exposures that are reportable.
2.3	**A**	Food employees are aware that they are required to report required illnesses and symptoms to PIC.	**2-103.11(O)**	

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 3: Personal Hygiene and Handwashing

Section 3: Personal Hygiene and Handwashing	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
3.1	**K**	Identify the role of clean outer clothing in preventing contamination of food, equipment, utensils, linens, and single-service and single-use articles.	**2-304.11**	• Wears clean outer clothing.
3.2	**K, S**	Identify when, where, and how to wash hands according to the FDA Food Code.	**2-103.11(D)** **2-301.12** **2-301.14** **2-301.15**	• Washes hands according to the FDA Food Code.
3.3	**S**	Apply FDA Food Code standards for fingernails and jewelry.	**2-302.11** **2-303.11**	• Applies FDA Food Code standards for fingernails and jewelry.
3.4	**K**	Recognize where eating, drinking, and tobacco use is allowed.	**2-401.11**	• Eats, drinks, and smokes only in designated areas.
3.5	**K**	Identify when to use hair restraints to avoid food contamination and which restrains are appropriate according to the FDA Food Code.	**2-402.11**	• Wears appropriate hair restraints when necessary.

3.6	**K** **S**	Describe how to correctly cover a bandage, finger cot, or finger stall located on the wrists, hands, or fingers. Distinguish when and how to use and replace single-use gloves according to the FDA Food Code.	**2-401.13** **3-304.15**	• Covers bandages, finger cots, or finger stalls according to the FDA Food Code. • Uses and replaces single-use gloves according to the FDA Food Code.
3.7	**K**	Describe how to correctly cover infected wound on the hands or forearms.	**2-201.13(I)** **2-401.13**	• Covers infected wounds according to the FDA Food Code.
3.8	**K**	Understands food workers may not care for or handle animals.	**2-403.11**	• Food employees do not handle or care for animals unless allowed by the Food Code.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 4: Preventing Cross-Contamination

Section 4: Preventing Cross-Contamination	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
4.1	**A**	Prevent contamination of all food, including ice, during preparation, storage, and display. Prevent contamination of in-use utensils.	**3-304.12** **3-307.11**	• Prepares, stores, and displays all food in a manner that prevents contamination. • Store in-use utensils in a manner that prevents contamination.
4.2	**A**	Identify potential for food contamination associated with consumer self-service areas.	**3-306.13(B)** **3-306.13(C)** **3-304.17**	• Monitors and notifies a person in charge when a self-service area has potentially become contaminated.
4.3	**A**	Determine when to replace equipment and utensils with clean and sanitized equipment and utensils.	**4-601.11**	• Replaces equipment and utensils with clean and sanitized utensils.
4.4	**K**	Identify how to correctly store cleaned and sanitized utensils and equipment.	**3-304.12**	• Stores cleaned and sanitized utensils in a manner that prevents contamination.
4.5	**S**	Prevent contamination of fruits and vegetables by avoiding bare hand contact after washing raw, uncut fruits and vegetables.	**3-302.15**	• Washes raw, uncut fruits and vegetables prior to preparation or service and avoids bare hand contact once washed.
4.6	**S**	Describe proper storage of food, food containers, single service, and single use articles to prevent contamination.	**3-305.11** **3-305.12** **4-401.11**	• Properly stores food, food containers, single service, and single use articles to prevent contamination.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 5: Allergen Control

Section 5: Allergen Control	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
5.1	**K**	Identify the major food allergens as defined by the FDA Food Code 2017, which includes milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame (upon inclusion in the Food Code).	**1-201.10** Definition: • Major Food Allergen	• Lists the major food allergens as defined by the FDA Food Code.
5.2	**K**	Describe how food employees should communicate with customers to prevent allergic reactions.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, effectively executes on the training to prevent customer exposure to food allergens.
5.3	**K**	Identify methods for preventing cross-contact when preparing food.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, effectively executes on the training to prevent customer exposure to food allergens.
5.4	**K**	Recognize the signs of an allergic reaction and respond accordingly.	**2-103-11(N)**	• Receives food allergen awareness training from person in charge, and effectively executes on the training by properly describing how to respond to an allergen emergency.
5.5	**K**	Identify major food allergens on labels; is knowledgeable of proper allergen labeling.	**3-602.11 (B)(5)**	• Receives food allergen awareness training from person in charge, and effectively executes on the training by adhering to proper food allergen labeling.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 6: Time and Temperature Control for Safety (TCS)

Section 6 Time and Temperature Control for Safety	KSA Type	Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
6.1	**K**	Identify foods requiring time and temperature control to reduce the risk of foodborne illness.	**1-201.10** Definition • Time / Temperature Control for Safety Food	• Applies time/temperature controls to TCS foods such as but not limited to the following items: raw or heat-treated animal FOOD, plant FOOD that has been heat treated, raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified, or garlic in oil mixtures that are not modified.
6.2	**K**	Identify the requirements for noncontinuous cooking of TCS foods.	**3-401.14**	• Partially cooks TCS foods according to requirements.
6.3	**A**	Identify how to monitor TCS food temperatures using appropriate temperature measuring devices. Recognize that the temperature of TCS foods must be routinely monitored during cooking, holding, and cooling using a thermometer that meets requirements.	**1-201.10** Definition • Temperature measuring device **2-103.11(G)** **2-103.11(H)** **2-103.11(I)** **Annex 5:** The correct temperature measuring device and technique are essential in accurately determining the temperatures of TCS foods. The geometric center or thickest part of a product are the points of measurement of	• Use temperature measuring devices to monitor temperatures of TCS food. • Routinely monitors temperatures when cooking, holding, and cooling TCS food.

			product temperature particularly when measuring critical limits for cooking.	
6.4	**K**	Identify the appropriate cooking times and temperatures for TCS foods to reduce the risk of foodborne illness.	**3-401** (Raw animal FOOD) **3-401.13** (Plant FOOD for hot holding)	• Cooks TCS food to required minimum internal cooking times/ temperatures.
6.5	**S, A**	Identify the time/temperature requirements for cooling TCS food. Identify proper methods for cooling TCS food.	**3-501.14** **3-501.15**	• Cools TCS food according to time/temperature requirements. • Cools TCS food using a proper cooling method.
6.6	**A**	Apply corrective action to food that has fallen outside time/temperature control.	**3-501.18(A)(1)**	• Applies proper corrective action to food that has fallen outside time / temperature control.
6.7	**K**	Identify methods for safely thawing food according to the FDA Food Code.	**3-501.13**	• Thaws food safely following an approved method.
6.8	**K**	Identify time/temperature requirements for reheating TCS food for hot holding.	**3-403.11**	• Reheats TCS food for hot holding following time and temperature requirements.
6.9	**K**	Identify the time or temperature requirements for holding AND STORING hot and cold TCS food.	**3-501.16** **3-501.19**	• Holds and stores hot and cold TCS food according to time/temperature requirements.
6.10	**K**	Identify the requirements for date marking TCS food.	**3-501.17**	• Date marks TCS food according to requirements.

Employee Food Safety Training Guidance Document (2017 FDA Food Code)

Section 7: Cleaning and Sanitizing

Section 7: Cleaning and Sanitizing	KSA Type	Food Safety Employee Training Objective	2017 FDA Food Code Reference	Example Measures *Possible ways to measure attainment of an objective*
7.1	**K**	Identify the difference between cleaning and sanitizing.	**1-201.10** Definitions: • Easily Cleanable • Sanitization	Lists cleaning and sanitizing responsibilities as relates to employee duties: • Identifies equipment and facility cleaning activities • Identifies equipment and facility sanitizing activities.
	S	Applies appropriate cleaning and sanitizing methods to reduce the risks to food hazards.	**6-501.12** **6-501.13** **6-501.15** **6-501.16** **6-501.19**	• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards.
7.2	**K**	Identify the need to follow the specific procedures when using chemicals according to the manufacturer's guidelines and properly storing chemicals in a food establishment.	**7-101.11** **7-102.11** **7-202.11** **7-202.12** **7-203.11** **7-204.11**	• Follows manufacturer's guideline when using chemicals and properly storing chemicals according to the FDA Food Code.
	S	Applies appropriate procedures when using and storing chemicals in a food establishment.		• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards.

7.3	**K**	Identify food-contact surfaces.	**1-201.10** Definition: • Food-contact surface	• Lists food employee responsibilities and duties as it relates to food contact surfaces.
	S	Applies appropriate procedures on when and how to clean and sanitize food contact surfaces.	**2-103.11(K)** **4-601.11** **4-602.11** **4-602.12** **4-602.13** **4-603.11** **4-701,10** **4-702.11** **4-703.11**	• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when cleaning and sanitizing food contact surfaces.
7.4	**K**	Identify the need to follow the specific procedures when cleaning and sanitizing utensils and equipment.	**1-201.10** Definitions: • Utensil • Equipment • CIP cleaned in place • Counter-mounted equipment • Easily moveable **4-601.11** **4-602.11** **4-602.12** **4-602.13** **4-603.11**	• Follows specific procedures when cleaning and sanitizing utensils and equipment according to the FDA Food Code.

	S	Applies appropriate procedures when cleaning and sanitizing utensils and equipment.	**2-103.11(K)** **3-304.11**	• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards when cleaning and sanitizing utensils and equipment.
7.5	**K**	Identify the need to follow the specific procedures when using mechanical warewashing.	**1-201.10** Definition: • Warewashing **4-603.12** **4-603.13** **4-603.14**	• Follows specific procedures when using mechanical warewashing according to the FDA Food Code.
	S	Applies appropriate procedures when performing mechanical warewashing.		• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when performing mechanical warewashing.
7.6	**K**	Identify the need to follow the specific procedures when using manual warewashing.	**1-201.10** Definition: • Warewashing **4-301.12** **4-302.14** **4-603.14** **4-603.15** **4-603.16**	• Follows specific procedures when using manual warewashing according to the FDA Food Code.
	S	Applies appropriate procedures when performing manual warewashing.		• Demonstrates proper cleaning and sanitizing procedures to prevent, eliminate, and reduce hazards to a safe level when performing manual warewashing.

7.7	**K**	Identify the need to follow the specific procedures when using and storing wiping cloths.	**3-304.14**	• Follows specific procedures when using and storing wiping cloths according to the FDA Food Code.
	S	Applies appropriate procedures when using and storing wiping cloths.		• Demonstrates proper cleaning and sanitizing procedures to reduce the risks to food hazards when using and storing wiping cloths.
7.8	**K**	Identify the need to follow specific procedures when responding to vomiting and diarrheal events in the food establishment.	**2-501.11**	• Follows specific procedures when responding to vomiting and diarrheal events in the food establishment according to the FDA Food Code.
	S	Applies appropriate procedures when responding to vomiting and diarrheal events in the food establishment.		• Recognizes that failing to follow appropriate procedures when responding to vomiting and diarrheal events in the food establishment may result in the transmission of a disease.

Template approved: 7/13/2021

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME Local Regulatory Representation

DATE OF FINAL REPORT: *11/09/22*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Chair Pieter A. Sheehan, Vice Chair, Jo DeFrancesco

COMMITTEE CHARGE(S):

Issue # 2020 II-10 To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:

- Examining the current Bylaws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
- Report back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
- Include representation from the Constitution and Bylaws Committee to assist in the development of recommendations and amendments from the findings determined in this charge.

COMMITTEE WORK PLAN AND TIMELINE:

1. Ongoing: Historical perspective review of CFP Constitution and Bylaws.
2. April 2022 :Organizational call
3. May 2022- July: Finalize survey and obtain recipient list. Survey current CFP local regulatory members to gather perspectives on the level to which CFP's organizational structure and biennial activities promote communication and collaboration among local regulators and between state and local regulators. Determine if there is outreach to locals from their elected representatives serving on the Executive Board; and is local regulatory participation extending beyond serving on the Board, Standing Committees, Council Committees, and Councils to voting representation on the Assembly of Delegates important to local regulators. Use survey results to inform committee's work to explore representation of local regulators on the Assembly of Delegates.
4. June 2022: Request assistance from Constitution & Bylaws/Procedures Committee for development of any recommendations to amend the Constitution & Bylaws or other governing documents based on outcome of work from charge #1.
5. July -August of 2022: review tentative survey data and determine further actions needed. Potentially survey other groups for information. Compile survey data and look for other ways to obtain local input on the issue.
6. September 2022: begin wrapping up survey activities and determine if enough data has been gathered to make a recommendation to change the Constitution and Bylaws. Begin work on any suggested changes.
7. October 2022: Committee met to discuss the final report to the board and any issues to be submitted.

8. November 2022: Prepare final report to the board and finalize issue from committee work.

, COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   04/26/22, 05/06/2022, 06/03/22, 07/15/22, 08/09/22, 09/05/22, 09/16/22, 10/07/22, 110/28/22, 11/4/2022

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

   Charge 1: Examining the current Bylaws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates. This work resulted in recommendations to the Board to consider rewriting the responsibilities of Executive Board members.

   Charge 2: Report back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium. The committee did report back to the Executive Board during the October, 2022 Executive Board meeting as charged in Issue 2020-II-010. That meeting resulted in the Board accepting rewritten responsibilities of Executive Board members.

   Charge 3: Include representation from the Constitution and Bylaws Committee to assist in the development of recommendations and amendments from the findings determined in this charge.
   Member of Constitution and Bylaws Committee was present on all calls beginning 05/06/22 and provided clarification when necessary. Mr. Sean Dunleavy served as the representative of the Constitution and Bylaws Committee.

3. ***Charges INCOMPLETE and to be continued until the next biennium: n/a***

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Local Regulatory Voting Representation

- Acknowledge the Committee report and thank the Committee members for their time.
- Acknowledge that the Committee did examine the current Bylaws, including a historical perspective and did explore methods to provide representation of local regulators on the Assembly of State Delegates, as charged in Issue 2020-II-010. This work resulted in recommendations to the Board to consider rewriting the responsibilities of Executive Board members.
- Acknowledge that the Committee did report back to the Executive Board during the October 2022 Executive Board meeting as charged in Issue 2020-II-010. That meeting resulted in the Board accepting rewritten responsibilities of Executive Board members.
- Acknowledge that the Committee did include representation from the Constitution and Bylaws Committee to assist in the development of recommendations and amendments from the findings determined as charged in Issue 2020-II-010. Mr. Sean Dunleavy served as the representative of the Constitution and Bylaws Committee.
- Disband the Committee as all charges from Issue 2020-II-010 have been completed.

a. ***Report – Committee Name:*** *Local Regulatory Representation Committee*

b. **List of content documents submitted with this Issue:** *Committee Member Roster*

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***

c. ***Other content documents:*** **List of supporting attachments:** ☐ ***Not applicable***

(c.i.1) **Survey Results II 22 10, PPT 22 11 10, Master Agenda and Minutes**

1. ***Committee Issue #2***:
2. ***Committee Issue #3***:

Committee Name: Local Regulatory

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Sheehan	Pieter	Co-Chair	Regulatory -Local	Fairfax County Health Department	Fairfax	VA	7032468470	pieter.sheehan@fairfaxcounty.gov
DeFrancesco	Joetta	Co-Chair	Industry-Support	NEHA	Tallahassee	FL	2394052211	jdefrancesco@NEHA.org
Carmody	Steve	Member	Regulatory- State	FDACS, Division of Food Safety	Orlando	FL	8507288849	stephen.carmody@fdacs.gov
Hutson	Jennifer	Member	Regulatory- State	WV DHHR Bureau for Public Health	Charleston	WV	(304)550-5292	jennifer.eb.hutson@wv.gov
Copeland	Deanna	Member	Regulatory -Local	Harris County Public Health	Houston	TX	713-248-4396	dcopeland@hcphes.org
Ferris	Leah	Member	Regulatory -Local	Clay County Public Health Center	Liberty	MO	8162605542	lferris@clayhealth.com
Walker	Stevan	Member	Regulatory -Local	City of Lubbock	Lubbock	TX	8067752116	mswalker@mylubbock.us
Sigler	Larry	Member	Industry - Food Service	Waffle House	Norcross	GA	(404) 518 – 2041	larrysigler@wafflehouse.com
Westbrook	Tim	Member	Industry - Retail Food	Publix Super Markets, Inc.	Orlando	FL	352-989-7314	tim.westbrook@publix.com
Guzzle	Patrick	Member	Industry - Support	National Restaurant	Boise	ID	208-515-8688	pguzzle@restaurant.org
Wood	Sharon	Member	Emeritus		San Antonio	TX	210-913-1333	spwood1983@outlook.com
Crawford, Ed.D.	Herman	Member	Academia	Nutri-Rific LLC	Webster	NY	9728850067	NUTRIRIFIC@GMAIL.COM

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Sudler	Robert	FDA Consultant	Regulatory - Federal	FDA	College Park	MD	240-402-1943	Robert.Sudler@fda.hhs.gov
Nattrass	Steve	FDA Alternate	Regulatory - Federal	FDA			860-240-4289 x 18	Steven.Nattrass@fda.hhs.gov
No appointee		USDA Consultant	Regulatory - Federal					
No appointee		CDC Consultant	Regulatory - Federal					
Dimaggio	Michele	Alternate	Regulatory -Local	Contra Costa County Environmental Health	Concord	CA	9253833053	michele.dimaggio@cchealth.org
Michael	Otzelberger	Alternate	Regulatory - Local	City of Milwaukee Health	Milwaukee	WI	414-708-1591	motzel@milwaukee.gov
Botsford	Jennifer	Alternate	Regulatory- State	ADHS	Phoeniz	AZ	6023643142	jennifer.botsford@azdhs.gov
McClellan	Hunter	Alternate	Regulatory- State	Nebraska Department of	Lincoln	NE	4024716813	hunter.mcclellan@nebraska.gov
Peri	Pearson	Alternate	Regulatory- State	Virginia Department of	Richmond	VA	8043047433	peri.pearson@vdh.virginia.gov
Modi	Rupesh	Alternate	Industry - Retail Food	HISSHO SUSHI	Charlotte	NC	6519556520	rmodi@hisshosushi.com
Sanchez	Angela	Alternate	Industry - Retail Food	AMAZON	Nashville	TN	951-201-4168	ajaynethomas@yahoo.com
Sweet	Bridget	Chair	Industry Retail Food	Amtrack	Providence	RI	4015985171	blsweet9@gmail.com

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 6-Non-voting alternates. Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 18-Non-voting alternates.*
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

Local Regulatory Representation Agenda and Minutes

10/28/22

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
    1. Examining the current by-laws to include a historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
    2. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
    3. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum – only 5 voting members present, Jo, Patrick Guzzle, Steve Carmody, Tim Westbrook, Herman Crawford

Reviewed Information on the Constitution and Bylaws pertaining to charges. Several Key items noted:

1) The Body of Delegates exists to ratify the votes that have already taken place in Council
2) Industry, Academia, and other constituencies also do have a vote on the Assembly of Delegates
3) The final guiding principle was the need to ensure that the Conference would provide a national and, to the extent possible, international dialogue on food safety on a regular, periodic basis, and that this dialogue would be among representatives of regulatory, industry, and other non-regulatory organizations.

Discussion on issues to submit to Council II.

1) Options were to reform the committee with better charges or dissolve the committee and make and respectfully make recommendations to the board in our final report. (Our final Report goes to the Board).

2) The consensus among the group on the call was to not reform the committee for the next biennium due to reasons listed below.

- Like Industry, Local Regulators can take part in the CFP process and have a voice by participating in committee work, and on councils.
- Local regulators can use the caucus process to aid in addressing concerns.
- We will ask the board to continue working towards increased communication with and to Local Regulators to promote greater involvement.
- Points 1 through 3 above
- This committee has been unable to obtain a quorum for the last several meetings thus making it harder to complete work or have in-depth discussion on issues. There has been minimal

committee participation throughout the last 6 months. It is hard to ask to extend the committee work with low attendance and participation.

Discussion for Call:

Reminder of information provided to Board at beginning of meetings on the Constitution and Bylaws

Constitution and Bylaws Discussion

- The rules for the Assembly of Delegates are spelled out in XIX (19) of the C&B
- All Delegates are required to list their alternate should they (Delegate) not be able to attend. The chosen alternate is at the discretion of the Delegate. There have been instances where the Delegate named a local regulatory representative to be the alternate Delegate and where a State Delegate named a neighboring State to be their alternate. (Side note: One possible consideration is to have the Local Regulatory Board members be Delegates. If this were decided, we would place that Local Regulatory Board member in a position where he/she is now responsible for representing hundreds of other local jurisdictions at the Delegates meeting. Additionally, let's suppose that Local Regulatory Board member is from Florida – we are now watering down Florida's vote to ¼ instead of the current 1/3 vote). It is possible that many members are not aware that all Delegates are required to list an alternate – and that the alternate is at the discretion of the Delegate.
- While the C&B is certainly open for revisions, the logistics of including local regulatory representatives in the Body of Delegates presents difficulty. Specifically, there are over 3300 local health departments in the United States and just over 50 state agencies. It should be recognized that trying to manage 50+ delegates is vastly easier than trying to account for the 3300+ local agencies.
- Page iii of the C&B describes the history in more detail – including the format and ratification process (which was modeled after the National Conference on Interstate Milk Shipments) that was decided in the 1980's. From page iii:
    - The final step in the decision to upgrade the Conference organization was taken at the 1986 Conference. The Program Committee reported that: "It was the unanimous view of the committee that the Conference should operate as an action organization, existing not merely to identify problems and formulate recommendations, but to resolve issues through the implementation of recommendations, much as the Weights and Measures Conference and the Interstate Milk Shippers do. Specific recommendations in this regard will be presented prior to the next Conference." (Page 410, Proceedings) To accomplish this, the 1986 Conference agreed: • To develop a state regulatory ratification mechanism whereby each of the 50 states will have one vote; and • To create a Constitution and Bylaws Committee to review the entire Constitution and Bylaws and to formulate recommendations for the Executive Committee to consider.
- Body of Delegates *ratifies* the vote that has already taken place in Council (where local regulatory representatives ARE involved in the vote)
- Pages iv and v of the C&B provide additional insight. From page iv:

    - The second principle that guided the review process was the need for the Conference to be more successful in promoting food safety, mutual respect, and uniformity. This was accomplished through the following changes: 1. The final actions taken by the Conference regarding such items as food safety controls, certification procedures, and Memoranda of Understanding, were to be adopted by the regulatory delegates of the Conference with the advice of industry and other non-regulatory members;
- Page v:
    - The final guiding principle was the need to ensure that the Conference would provide a national and, to the extent possible, international dialogue on food safety on a regular, periodic basis, and that this dialogue would be among representatives of regulatory, industry, and other non- regulatory organizations.

Discussion Points to turn into Potential Issues

The group produced several problems to be addressed when writing issues. They are placed into 3 categories

1) There is no Local Regulatory Representation voting during the Assembly of Delegates since only states are allowed to vote.
    - Many local jurisdictions are active in CFP and their state counterparts less so.
    - States and local jurisdictions may not use the same standards to protect food safety. (Local jurisdiction using the 2017 Food Code, the State still using 2005)
2) Communication to Local Regulators from States is usually top down and appears not to happen frequently, specifically on issues and voting.
    - States may not take into consideration the impacts of their votes on Local jurisdictions.
    - This could be potentially tasked to the Strategic Planning Committee on the board of Directors.

    Clarity is needed on the position description for members of the Assembly of Delegates (Is there one?) and a deep dive historical look at the Constitution and Bylaws and sates roles in the process. (This was addressed in first two meetings.)
    - Constitution and by-laws may be biased in favor of the states.
    - Constitution and by laws may make assumptions about the roles of both State and Local Jurisdictions in the CFP process as well as to what is occurring at the state level.

An additional idea, that had support is to ask the board if we can survey the members of CFP at the Biennium conference. The survey could be provided electronically or in paper form and, if approved the committee could man a table at the conference to gather as much input as possible.

Lastly a committee member reached out to Jo on bringing up the possibility of allowing the Regional Local representative to vote. Although this has been discussed I wanted to make sure all voices were heard

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10/07/2022

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
    4. Examining the current by-laws to include a historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
    5. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
    6. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting Agenda

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum
- Sharon Wood and Patrick Guzzle proposed that the committee suggest a change in the language of the Executive Board Member job description.
- Old Language:
    - Communicates with and updates their respective constituencies on the progress of CFP.
- Suggested New Language:
    - Actively and regularly communicates and reports CFP business and updates to their associated constituency using appropriate venues to include, but not limited to, professional groups, institutions, associations, newsletters, social media groups, and / or presentations to maintain a high level of knowledge on the status of CFP activities and pending issues being addressed.
- The group agreed to suggestions on the language change and to ask the board to reform the committee to be able to expand the study of the issue. This committee did not have a great deal of time, and the last few meetings did not have a quorum when voting was necessary
- Jo will put the two items to an e-vote and amend the report to the executive board.
- E- Vote to accept previous meeting minutes from 08.05.2022 and from 09.02.22 minutes accepted with 7 yes votes.
- The executive board voted to pass the change to the position description and understands that additional work is needed on Local Representation. A big thank you to Sharon and Patrick for their work on this matter.
- Discussion now needed on issue submission to reform committee and drafting charges to further guide the process.

09/16/2022

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
    7. Examining the current by-laws to include a historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
    8. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
    9. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting Agenda

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum – Quorum not present
- Current survey results – Still at 25
- From 09/02 Need someone to sort through information that we do have to determine if anything can be inferred. Steve Carmody will evaluate data and the group will discuss it on 09/16. Steve was unable to fully evaluate due to promotion.
- The committee discussed the survey and implications of information flow to local regulators.
- Sharon Wood and Patrick Guzzle proposed that the committee suggest a change in the language of the Executive Board Member job description.
- Old Language:
    - Communicates with and updates their respective constituencies on the progress of CFP.
- Suggested New Language:
    - Actively and regularly communicates and reports CFP business and updates to their associated constituency using appropriate venues to include, but not limited to, professional groups, institutions, associations, newsletters, social media groups, and / or presentations to maintain a high level of knowledge on the status of CFP activities and pending issues being addressed.
- The group agreed to suggestions on the language change and to ask the board to reform the committee to be able to expand the study of the issue. This committee did not have a great deal of time, and the last few meetings did not have a quorum when voting was necessary.
- The group recognizes the implications of changing the Constitution and Bylaws and the amount of time and effort it could take to adopt and implement any changes to include local representation

- Jo will put the two items to an e-vote and amend the report to the executive board.
- E- Vote to accept previous meeting minutes from 08.05.2022 and from 09.02.22 minutes accepted with 7 yes votes.

Reminder, final report is to be submitted to the Executive Board.
Call ended at 1:00 pm EST

09/02/2022 Minutes

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  10. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  11. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  12. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting Agenda

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum – Quorum not present until end of meeting.
- Antitrust Statement reminder- Jo
- Vote to accept previous meeting minutes from 08.05.2022 and from 09.02.22, e-vote

Reminder, final report is to be submitted to the Executive Board.

Survey

Current Results – Still at 25

- How do we obtain additional information prior to final report?
- Need someone to sort through information that we do have to determine if anything can be inferred. Steve Carmody will evaluate data and group will discuss on 09/16

Other Items

- Discussion needed on the impact of changes to the Constitution and Bylaws.
- Discussion on issues facing Local regulators and the impacts on knowledge of and involvement in CFP

- Jo will schedule call for 09/16 for discussion on survey data and ideas that can be presented to Executive Board in Lieu of changes to Constitution and By Laws. Group agreed on date.

08.05.2022 Minutes

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  13. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  14. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  15. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting Agenda

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum- quorum was present
- Antitrust Statement reminder- Jo
- Vote to accept previous meeting minutes from 05.06.22 and 06.04.22 due to lack of quorum on previous call – unable to vote no quorum present
- Online vote for meeting minutes 9 yes votes. Motion to accept minutes from 05.06.22 and 06.04.22 passes.
- Vote to accept previous meeting minutes from 07.15.22

Survey

- Current Status
  - Pieter to send out survey next week to CFP Local members.
- Need to try to reach larger audience. To that end we are reaching out to other potential groups of locals for input.
- Deadline to send out survey to other organizations and obtain results- end of September.
- Remember issue submission is fast approaching. We will need recommendations for potential realistic wording for representation and placement in Constitution and Bylaws.
- Discussion on ways to potentially get more information to use in the final report.
- Meeting Adjourned

07.15.2022

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  16. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  17. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  18. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting called to order

- Welcome – Jo called meeting to order
- Attendance- 7 voting members needed for a quorum- no quorum present
- Antitrust Statement reminder- Jo
- Vote to accept previous meeting minutes from 05.06.22 and 06.04.22 due to lack of quorum on previous call – unable to vote no quorum present

Survey

- Current Status
  - Link and voting information emailed out on 05.03.22
  - Pieter sent out survey next week to CFP Local members.
- Sam Gaber- Member of Pieter Sheehan's staff- gave brief overview of survey results and a couple key comments.
- Group discussed next steps with Survey-
- Need to try to reach larger audience. To that end we are reaching out to other potential groups of locals for input
  Michelle DiMaggio will reach out to NEHA
  Deanna Copeland will reach out to AFDO
  Pieter Sheehan will reach out to NACCHO
- New Overview/Intro Paragraph to be drafted – Hunter McClellan has agreed to draft
- Deadline for outreach to other organizations and for intro to survey set as Friday July 22nd. Please, report back to committee with information on outreach.
- A big thank you to everyone that has agreed to step up and help out.
- Once results are back we will need to determine actions needed to address issue.
  Jo reminded everyone to become familiar with the Constitution and By-laws
- Jo will start email thread to vote on minutes as well as discuss any needed committee work.
- Next meeting August 5th at 12:00.

Meeting adjourned 12:23

- Group to work on data- July Call
- Next steps for use of information?? Discussion
- Discussion to determine where changes may be needed in Constitution and Bylaws when survey is complete (LINK)

Increasing Local Regulatory Involvement in CFP and committee work

- Comment from voting process – will add to agenda of next call
- Discuss with group

New Business

- **It was brought up that the next call was right before a holiday weekend. Call Changed to the 15th of July to avoid any issues for people traveling for the Holiday.**

Motion to adjourn: Second:

Local Regulatory Representation Agenda

Local Regulatory Representation Minutes

06.03.22

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  19. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  20. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  21. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Meeting called to order

- Welcome – Jo
- Attendance- 7 voting members needed for a quorum- no Quorum 4 Voting members
- Antitrust Statement reminder- Jo
- Vote to accept previous meeting minutes from 05.06.22: Unable to vote will vote on next call

Survey

- Current Status
  - Link and voting information emailed out on 05.03.22

- Motion made by Steven Carmody to accept the Survey as it was currently written, Seconded by Deana Copeland
- Vote passed on 05/16 with 8 voting members agreeing to send out survey with adjustments from last call to CFP local members
- Survey has not yet been sent out to Local Members
- Pieter will send out survey next week to CFP Local members. Jo will resend list of emails

- Group to work on data- July Call
- Next steps for use of information?? Discussion

- Jo requested everyone work to become familiar with Constitution and By Laws to help determine where changes may need to be requested when survey is complete

Increasing Local Regulatory Involvement in CFP and committee work

- Comment from voting process – will add to agenda of next call
- Discuss with group

New Business

- **It was brought up that the next call was right before a holiday weekend. Call Changed to the 15th of July to avoid any issues for people traveling for the Holiday.**

Motion to adjourn: Larry Second: Michelle

Local Regulatory Representation Agenda

05.06.22

Charges

- To evaluate local regulator voting representation on the Assembly of Delegates and report to the Executive Board for consideration of the following:
  22. Examining the current by-laws to include an historical perspective and exploring methods to provide representation of local regulators on the Assembly of State Delegates.
  23. Reporting back to the Executive Board before the next biennium to make a recommendation for consideration for issue submittal during the next biennium.
  24. Including representation from the Constitution and By-laws Committee to assist in the development of recommendations and amendments from the findings determined in charges.

Jo DeFrancesco called the meeting to order at 12:05

- Welcome
- Attendance- 7 voting members needed for a quorum, 9 voting members present
- Antitrust Statement- Jo reminded group of statement.
- Jo reminded group the meeting is being recorded.
- Group was reminded that Courtney Halbrook was the new Council II Chair, and that Wendy Bell has stepped up as Vice Chair of the Council.

- It was announced that Sean Dunleavy would be attending the meetings as a representative of the Constitution and By-Laws Committee. Sean was present on the call to add input as needed.
- Discuss Survey and Feedback from group
    - Discussion – Led by Pieter Sheehan
        - Sharon Wood agreed to draft introductory statement giving issue background information to survey respondents. This was felt to be necessary by the group to aid in educating respondents.
    - Several Questions need minor clarification to ensure respondents understand the intent of the question.
        - Questions #3 and #5: Wording needs adjustment to change the sord issues to "topics" or similar.
        - Question #4: Group felt it would be appropriate to place CFP in front of the word Issue and capitalize the word Issue.
        - Questions 11 and 13 were perceived to be leading questions.
            - Suggestion was made to remove the language, "..we understand that you rely on state delegates…" on question 11
            - Suggestion was made to remove language and have it state, "Please, indicate your reasons for participating in CFP."
    - Jo will follow up with appropriate board members for mailing list.
    - Pieter and Jo will send out revised survey to Committee with a tight turnaround for discussion and voting. This will occur once suggested revisions are completed.
    - After vote survey will go out immediately.
- Future Committee Work
    - Future steps potentially include a second survey, should data from the current survey provide sufficient evidence to warrant, to local jurisdictions outside of CFP.
    - Suggest recommendations to be put in place for Local Representation voting process.
    - Coordinate with Constitution and By Laws Committee where/how to place recommendations
    - Draft Issues
- Scheduling remaining calls
    - Group agreed that Fridays at 12:00 EST is an acceptable time for meetings
    - Additional meetings are anticipated once survey results are in.

- New Business
    - None

- Motion to Adjourn: Patrick Guzzle
- Second: Tim Westbrook

Next Meeting: June 3, 2022 12:00 EST – Jo will send invite

ID	Start time	Completion time	Email	Name	Is your local jurisdiction adequately* represented by your State Delegate (ST-D)? *Note: Adequately refers to how state delegation communicates and represents your jurisdiction's specific needs o...	If you selected "no", please explain.	Does your jurisdiction have the opportunity to discuss big-picture items that effect your local food safety program with the State Delegate or representatives of the Delegate's agency/office durin...	Please indicate how often you meet with your State Delegates or representatives to discuss CFP Issues that impact voting decisions in the Assembly.	Does your State Delegate initiate dialogue regarding unique local, developing, or historically problematic concerns that require a "birds eye" view to get a solution?	If you selected "yes" to the previous question, what are some examples of concerns being discussed?	Does your local food safety program have the opportunity to discuss the impact of CFP Issues on your jurisdiction with State Delegate(s) in a regularly scheduled manner?	How often does your State Delegate(s) consult with your local jurisdiction when voting on CFP Issues? Are you always clear on the CFP Issues being discussed and evaluated?	How would you classify the intra-communication between your state and local agencies that handle food safety?	If you selected "ad-hoc" or "limited" to the previous question, please explain.	As an active local regulator and participant in CFP, would additional local voting rights in the Assembly of Delegates cause you to get more involved in CFP?	Please explain your answer to the previous question.	The Assembly of Delegates is made up of states and territories who have complete voting rights. As a local regulator, please indicate your reasons for participating in CFP.	Have you previously attended the regulator's caucus meetings during the Biennial Meeting in which the CFP Issues are discussed among all regulators?	Are you going to participate in the 2023 Biennial Meeting of the Conference of Food Protection?
1	6/13/22 14:33:37	6/13/22 14:42:43	anonymous		Yes		Yes	3-4 times per year and as needed.	No		Yes	As needed	Open		No	I am already actively involved	To give a local voice on a national level	Yes	Yes
2	6/13/22 14:39:56	6/13/22 14:45:31	anonymous		No	State does not communicate with local health dept.'s.	No	N/A	No	N/A	No	N?A	Limited		Yes	State needs to discuss CFP with locals. Most do not even know it exists.	To be part of the process.	Yes	Yes
3	6/13/22 14:39:15	6/13/22 14:49:34	anonymous		Yes		No	We have a regularly monthly state conference call on local issues but not exclusively on big picture CFP issues. It would be nice to connect quarterly with our state to bring everyone up to speed on the various committee work within each Council that LHJs may be working on.	Yes		No	Not sure unless you're heavily involved with CFP issues within each Council or following CFP issues?	Open	Regular monthly state conference calls with LHJs is being held in WA State especially now we're adopting the 2017 FDA Food Code.	Yes	But not at the expense of aligning with the State on issues and voting - need to communicate closely. Voting rights does not necessarily mean getting more involved with CFP as time constraints and subject matter expertise of the individual factors in more.	Dual purposes of contributing to the CFP issues and ultimately current Model Food Code final drafts but also to understand the science/issues of food safety and regulator oversight that makes sense to LHJs jurisdiction frontline impacts.	Yes	Yes
4	6/13/22 14:50:27	6/13/22 14:59:04	anonymous		Yes		Yes	Sometimes right before CFP vote if delegate is available.	No		Yes	Historically, CFP issues haven't been discussed between local and State delegate prior to voting on CFP issues. Mostly clear on CFP issues being discussed & evaluated but think that it would be valuable for state and locals to visit prior to voting to be sure that all things are considered regarding voting outcomes.	Open		Yes	If local voting rights were provided, would speak to issues that affect jurisdiction	To hear about what's happening on a national level and work to build consistent approaches with states and territories that have similar demographics and food establishments.	Yes	Yes
5	6/13/22 14:54:36	6/13/22 15:06:16	anonymous		No	I believe they have requested feedback on topics to bring to CFP but never hear anything else from them. We are the largest jurisdiction (population and facility count) in our State and have never been asked questions related to topics or concerns at CFP.	No	We do not. We meet regularly with them but it is always around issues we see in our community, not related to CFP issues	No		No	They have never consulted with us being the largest in the State. No, unaware of the CFP issues being discussed.	Limited	The State is currently down multiple employees so they attend our statewide meeting every other month though seem to only be collecting information not providing responses. This makes things incredibly difficult to run a program at the County level when we have to ask the State for guidance as it is a State-wide program.	Yes	I think so, yes		No	No
6	6/13/22 14:59:21	6/13/22 15:08:13	anonymous		No	State delegate does not adequately represent our jurisdiction and does not request feedback based on our community's needs and goals for public heath and food safety	No	never	No		No	does not clearly solicit feedback on issues under discussion	Ad-hoc	State only reaches out when they see a need. They do not ask if we need items addressed and there is only a single meeting each year for general conversation, no specific to CFP issues.	No	Since we are already actively involved, this would not increase our involvement. I do feel that it would better represent the community in our jurisdiction since many CFP issues to directly impact the community.	Interest in issues and committee work for addressing those issues.	Yes	Yes
7	6/13/22 16:00:03	6/13/22 16:11:29	anonymous		No	This past year, there was no-one to represent my State. In my state, there are many different local authorities that cover Retail food while the State covers Manufactured foods.	No	We do not meet.	No		No	N/A	Open	There is open dialogue between us and the state, however it is very rare. We have our own code, with our own authority.	Yes	If we had a seat at the table when voting it would be nice. Since we are not represented at all currently.	I got involved, because I believe its a good cause. It's fascinating to see everyone come together.	Yes	Yes
8	6/13/22 16:43:56	6/13/22 16:53:01	anonymous		No	I think the answer to this is "unsure" - I don't know who at the state attends these meetings and we are not consulted on issues they are voting on. We are not asked for input on issues or what local needs might be.	No	Never.	No		No	Never consulted. Only clear if I do research through the CFP website on items that interest me, that is, if I know about them through another source.	Limited	Communication with the state on food safety issues is extremely limited. There are no regularly scheduled meetings for this. I came from out of state and was surprised to find no solid network of food safety programs/program managers or department directors in the state. They do reach out if the food code is being updated, but that is not very often.	Yes	Yes. What is the point of attendance/involvement if I really don't have a say/vote? I can follow what is happening online if I need to.	To keep up on what is happening from a big picture standpoint, which could lead to a more progressive local food safety program. Additionally, the locals are the boots on the ground and have first-hand knowledge of the practicalities of how retail food establishments operate which should be considered when voting is happening. This could be very helpful to the process.	No	Yes
9	6/13/22 23:50:50	6/14/22 0:02:16	anonymous		No	Infrequent contact from state delegation on local health needs. The state rarely reaches out for our input and does not communicate on their dealings with CFP.	No	Never. In the 15 yrs I have been in the field the state delegates have never reached out to individual jurisdictions for their input.	Yes	Sous vide process, ROP	No	Never, no	Limited	State delegation does not ask for local input.	Yes	Since local health is never consulted for input by the state delegates, this is a deterrent to getting more involved.	To gain more knowledge of the FDA food code as CT uses a state code. To keep abreast of current issues that CFP addresses. To meet industry and government regulators for all over.	Yes	Yes

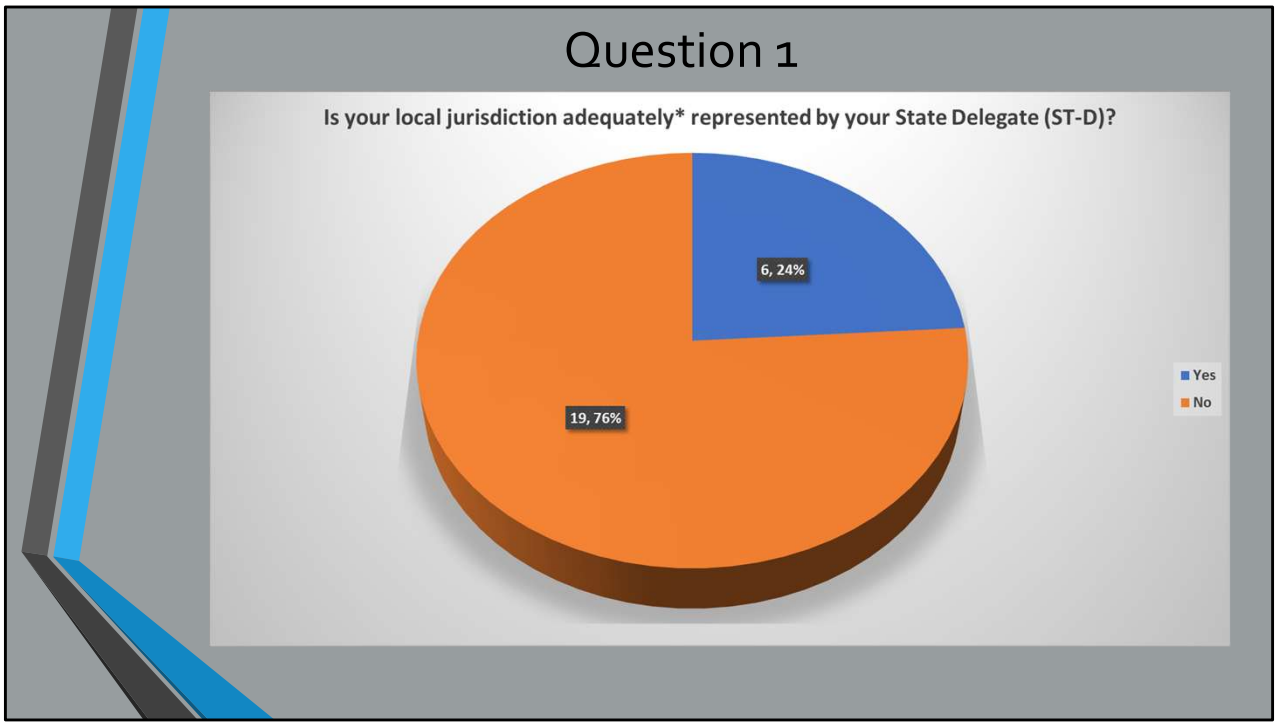
10	6/14/22 7:43:30	6/14/22 7:47:57	anonymous	Yes		No	never	No	No	Never, to my knowledge. No, not clear.	Ad-hoc	Communication as needed.	Yes	I'd try to understand the issues more than I do now, and that would cause me to be more involved in CFP.	Participation in the national organization that has direct impact on food safety regulations.	Yes	Yes
11	6/14/22 8:38:07	6/14/22 9:07:08	anonymous	No	The state does their thing and they vote with which I'm sure is their best choice. However, they did not reach out to us to hold a separate meeting to understand our viewpoints regarding each of the issues from those in our state. Historically, local regulators have only been allowed to attend the state caucus meetings so that a general understanding from all regulators regarding each of the issues could be discerned, especially amongst the state delegates who will be voting. The way it is currently set up, a local regulator has to do their own homework and lobby everyone to get their voice heard.	No	Whenever they decide that its a good time to conduct a training	No	No	I have not heard anyone from the state do so. I'm always clear on the issues because I do a lot of homework before hand and keep up with the actions taken by each of the councils	Ad-hoc	They provide presentation type of training when there is a code change. They are available by email if we have a question.	Yes	I have been involved with CFP for some time. I would love to have the opportunity to serve as a local regulator on the assembly of delegates.	To participate in the issue action discussion and voting process either as a council member or by working with those on the councils to ensure my viewpoints are expressed and provided.	Yes	Yes
12	6/14/22 8:58:05	6/14/22 9:11:55	anonymous	Yes		No	never	No	No	none that i know of	Limited	The state will have or set up meetings when the state wishes to communicate something down the line. Example, if the individuals at the state level thinks the local level may be communicating or doing something the state agency may not approve of, then the state will pass communication down the line letting the local agency know that they object to what is happening even when there was no guidance prior to the state reaching out to the local agency.	No	I do not think I have time to spend / work on issues at the CFP [illegible]	To read about issues other jurisdictions are having and what may be coming down the line.	No	No
13	6/14/22 9:34:17	6/14/22 10:00:54	anonymous	No	The Ohio Department of Health and the Ohio Department of Agriculture represent and advocate for their own best interests and have long been in a "them vs. us" relationship with local health departments. The delegates are their employees and are required to regard the desires of the agencies above all else, including the opinions of what local health departments think they need. This is unlikely to change.	No	Rarely - I can't recall any such meetings. Meetings with the state officials/ state delegates involve meetings where we *may* be permitted to observe - such as the Retail Food Safety Advisory Council (RFSAC) or where they are telling us what is going to happen during Food Safety Meetings. There are opportunities to ask questions, but these are by no means discussions. We are told what will happen and the questions are only in regard to clarification as to how they feel we should be interpreting or responding to situations. Our feedback as local health departments is deemed unnecessary. Feedback can be formally submitted during rule review, but that is only because it is required, not that it is seriously considered. The only way people know about CFP is if they engaged and found out about it on their own. It is not promoted or discussed by our state agencies. They don't want us involved at all.	No	There are none. They dc	No	Never. Have never been contacted or asked and I would be the person to ask at my department.	Limited	Non-existent needs to be an option. The state uses a top down management style. There is little involvement by the locals in what actually happens. There may be some "committees" to make it look like LHDs are involved, but there is little actually taken from them and put to use. They make all the decisions and we deal with them. They do not involve us in CFP related issues at all.	Yes	[illegible] to be more diversified so that more voices can be heard. If it truly is a unanimous decision, it would be the same result anyway wouldn't it? What would it hurt to have more voices? With the voting power only at the top state agencies and their delegates, currently, local health departments have no say, no power, and really no incentive to want to be involved in CFP. I think we need to get the word out that Locals CAN make a difference and CAN play a role in how our codes are made. The state likes to make people think otherwise. This can be a collaborative effort. The state agencies are	It is important to understand how everything fits into the big picture. Even though we are a small part of the puzzle, we each contribute to a greater whole and can influence what happens. If few people care enough to be involved, we all will suffer when decisions are made by limited perspectives. Additional perspectives, can provide insights that we may not have been aware of. That can help us make more informed decisions. What we do keeps our communities and families safe. That is important and a valuable use of time.	Yes	Yes
14	6/14/22 10:28:36	6/14/22 10:32:49	anonymous	No	Our State is not involved in CFP or the FDA Program Standards.	No	Our State is very hands off. Little to no communication about anything. We basically do what we want and govern ourselves.	No	No	State does not discuss.	Limited	State does not do anything to support local efforts.	Yes	We are already heavily involved in CFP through committees and council membership. We just do not get to vote or have any input after that.	To help develop Food Code policy, provide input from actual 'boots on the ground' individuals, and to learn more about food law.	Yes	Yes
15	6/14/22 10:48:25	6/14/22 10:56:25	anonymous	No	In Nevada, there are 4 jurisdictions, three local county health districts that cover environmental health for their respective counties and the State of Nevada that covers all other rural counties within in the state. Each jurisdiction is separate with their own regulations, etc. The state delegation committee does not communicate important retail food issues to our jurisdiction and does not have an understanding of our needs and issues at the local level.	No	Had one meeting prior to the last CFP meeting, but no other outreach from the State Delegates regarding CFP issues.	No	No	So far, just one meeting prior to the 2020/21 CFP.	Limited		No	We already have several staff on committees and have participated on council. We would continue to be involved with CFP regardless of having local voting rights.	Our agency has been active in CFP for several years as we want to be informed of immerging food safety issues that effect our local community.	Yes	Yes
16	6/14/22 12:56:40	6/14/22 13:10:03	anonymous	Yes		Yes	Upon request by either party	No	Yes	The local representation has dialogue and opportunity sharing to come to consensus prior to vote. Ultimately, as is known, the state votes accordingly to what they believe is accurate for the entire state.	Open		No	I'm already actively involved and our delegation of authority is granted by the state.	I agreed to represent the local regulators in the SE on the EB board. It is of service to the profession.	Yes	Yes
17	6/14/22 16:58:44	6/14/22 17:14:19	anonymous	No	In the past we would have meetings and work groups to talk about the issues submitted to the CFP. Last two CFP Annual meetings there was no coordinated meetings or work groups to discuss the presented issues prior the CFP annual meeting.	No	Have not meet for the last few years.	No	No	Only at the CFP regulatory meetings.	Limited	Haven't had meetings regards CFP Issues for a long time.	Yes	We are already pretty involved with CFP but would like to become more involved with local participation.	Being able to be involved on working committees, and councils. Being able to listen to the dialogue of issues being presented to the three councils.	Yes	Yes

18	6/14/22 17:52:38	6/14/22 18:02:35	anonymous	No	Locals represent themselves best and make decisions more efficiently. There is an association that brings all the locals together with the State agency but the State does not make the necessary decisions in a timely manner to allow locals to progress in their decision making.	Yes	These meetings are scheduled once a month. They are not exclusively for CFP related items but if there are any, they would be discussed at this meeting.	No		Yes	As stated above, if they do come up, it would be at the monthly meetings. Our local jurisdiction has multiple members of CFP so we are aware through direct participation.	Ad-hoc	Our State agency does not have the expertise nor the decision making processes in place to lead food safety topics and issues.	Yes	Understanding that our voice could directly be heard, would increase participation. Our large local agency is the most influential food safety agency within the State. The State relies on the locals a lot but does not provide the necessary leadership.	To be part of the discussion in how our industry approaches regulations and the direction food safety programs should be progressing in.	Yes	Yes
19	6/14/22 17:51:28	6/14/22 18:09:33	anonymous	No	There is little to no communication between our jurisdiction and the State Delegate regarding CFP issues.	No	We may run into them at the CFP Biennial Meeting. A "formal" meeting is not scheduled.	No		No	We usually aren't even informed of who the State Delegate is. The State does not reach out to us regarding CFP Issues. Any communication takes place at the Biennial Meeting if we run into each other, such as at the regulator caucus or in the halls at breaks.	Limited	We do not have regularly scheduled meetings or communication with our State.	No	I am sufficiently involve, additional voting rights would not cause me to get more involved.		Yes	Yes
20	6/14/22 15:42:53	6/15/22 14:34:46	anonymous	No	The state does not solicit information/feedback from the counties regularly and the counties often take topics to the state for discussion and receive no feedback or untimely feedback. When the state is engaged on a topic, they often defer to the counties so they are not involved. In addition, the state mostly regulates correctional institutions and behavioral health facilities. The local counties regulate more than 90% of retail food facilities and have the greatest experience.	No	The state attends a monthly meeting with all of the counties but CFP and how the State will vote on CFP items is not a routine agenda item. The state does not engage the counties in discussing issues or proposing issues in advance of the biannual meeting.	No	This dialogue is typically	No	This interaction is infrequent and we may discuss items that end up at CFP but the conversation is not typically geared towards preparing for CFP voting or discussions. The state also lacks in-house expertise of the regulations.	Limited	The counties often approach the state with food safety topics but the response is often to handle it on our own or the state says they will get back with us and it does not happen timely or at all	Yes	Local representation could speed things up for regulators and our stakeholders, but we risk diluting the importance of the states participating in the process.	We have participated in councils to discuss the issues. We have also provided comments on proposed issues.	Yes	Yes
21	6/15/22 14:58:16	6/15/22 15:12:31	anonymous	No	We are very seldom asked or given the opportunity to participate in any meetings determining regulatory activity.	No	Never	No		No	Never	Limited	We are contracted by the state and the state makes all of the decisions.	Yes	I would be able to provide insight to my staff and have a better understanding of how decisions are made regarding regulatory issues.	I wanted to get more involved and have more knowledge of how decisions are made.	No	Yes
22	6/16/22 8:16:09	6/16/22 8:33:03	anonymous	No	Our state delegates do not communicate with the local jurisdictions in our state regarding issues, needs, requests, or CFP involvement.	No	zero	No		No	zero	Ad-hoc	There are no regularly occurring meetings or communication. Conversations are initiated at the local level on an as needed basis. As a home rule state, our state department of health does not have oversight of our program.	Yes	As a local regulator, we are as active as can be in the current structure on councils and committees. We have not observed or participated in a closing session as we have no impact or input at that level.	Changes made to the Food Code and Program Standards have the greatest impact on local jurisdictions. I want to have a voice in the changes that are made that affect food safety. When change is made and passed down to locals, often locals do not embrace these changes and this contributes to the inconsistency of the food safety regulatory structure at all levels across the country.	Yes	Yes
23	6/16/22 12:34:12	6/16/22 12:42:43	anonymous	No	It appears that most of the items passed through the councils or recommendations by the council tend to pass in the assembly and the assembly of delegates is more of a formality but I also don't know who my state delegates are which kind of says to me that there is a barrier there if there is no opportunity to speak to them. I know this may be more possible in our "region" meetings that occur during CFP, but if these states delegates don't attend those meetings, how are we supposed to know who they are or network with them?	No	Leading back to the last question, our jurisdiction may just be getting more involved in these discussions and there are instances when our department works with the state but I'm not sure if there are instances where we meet with the state specifically for this purpose.	No	Not that I know of.	No	Not that I know of.	Limited	Again, I as a local member have not had any insights or guidance on even having a discussion with our state people so maybe I'm just super new but no idea.	Yes	I think people may be more inclined to be involved when they know they are contributing to the decision. Again, I think that being involved in the committees is good enough for me and I haven't seen anything shot down by what the committees are doing by the assembly so I think local regulators do have some power, it may just come down to how that is marketed. Also I get the sense that many local authorities see this as more of a hindrance rather than an opportunity to grow as an employee. My local gov employer has not decided if my involvement is really allowed based on my job title. I tend to clock out during the CFP	I like to give our perspective at the local level in the field to help make decisions on ways to standardize or simplify processes to make it easier for all of us. It's tough when local regulations tend to be different in regions and being able to have these discussions to talk them out may be helpful for everyone involved. I like to be involved in these as it helps me get a whole view sense of the process which I believe helps me become a better inspector.	Yes	Yes
24	6/18/22 10:17:50	6/18/22 10:32:22	anonymous	No	Attendance by my state at the Biennial Meeting has not been consistent over the last decade, and most local inspectors in my state do not understand the function of the CFP, the Biennial Meeting or the way that the Food Code is updated.	No	Rarely, if ever, mostly due to the lack of local involvement in the Biennial Meeting.	No		No	Never	Limited	In my state, experienced food safety employees are retiring and there is a lack of experienced inspectors at both the state and local level. Because my state does not use the Food Code, the mechanism to field train and certify inspectors is dissicult and there is a back-log of new inspectors needing certification.	No	Local inspectors in my state (CT) are responsible for all environmental oversight: wells, septic, salons, pools, housing, etc. and do not have time to get involved in CFP or focus with any debth on food safety.	I used to work for a Tribal Health Dept. and had time to devote to CFP. Since returning to local health during the pandemic, it is not possible do to the huge workload.	Yes	No

25	6/22/22 13:38:08	6/22/22 13:56:09	anonymous	No	As a local regulator in my state highly involved with CFP over the past years I have never had my ST-D reach out to my department and ask for requests to bring up to the CFP. We have also never had information or updates from the CFP in our state.	No	This has never occurred in my state.	No	Yes	There has been no consultation with local jurisdiction.	Ad-hoc	Local jurisdictions contact the state agency only when there is a question, scenario, or new procedure that requires state guidance on.	No	if we start to allow local regulators to have voting rights within CFP there may be the possibility of conflict of interests (many local regulators may be involved/married into families of large industry companies etc. and may start to push for their agendas), disagreements with local regulators and state agencies/delegates, and an opening to undermining future CFP work. I am a local regulator and against having voting rights traditionally held by our state delegates. I do ask for updates from our state delegates about work being done at the CFP	I like to know what is going on at a national level. I like to be involved with committee work and helping contribute to national changes. I enjoy policy-making work and ensure things are carried out with DEI work in mind also.	Yes	Yes

Local Regulatory Committee Survey

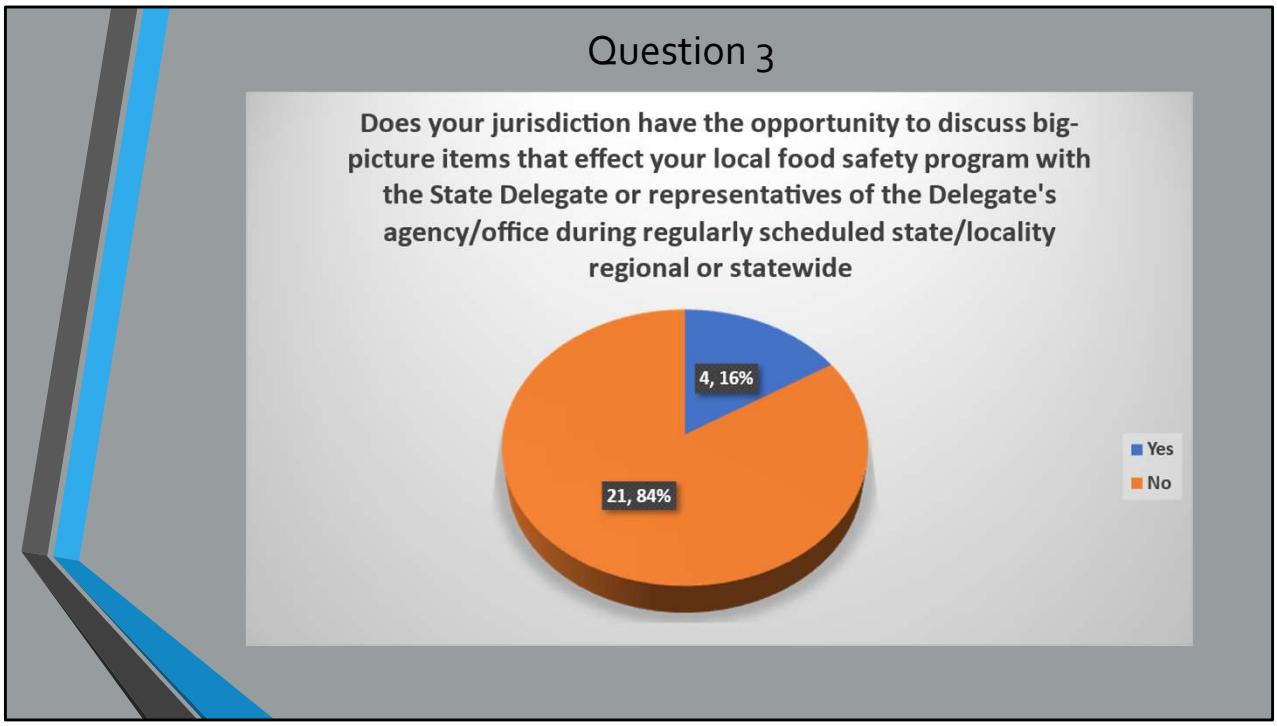
Prepared by Samuel Gaber



Observation: Little to no communication between the states and locals.

Example:

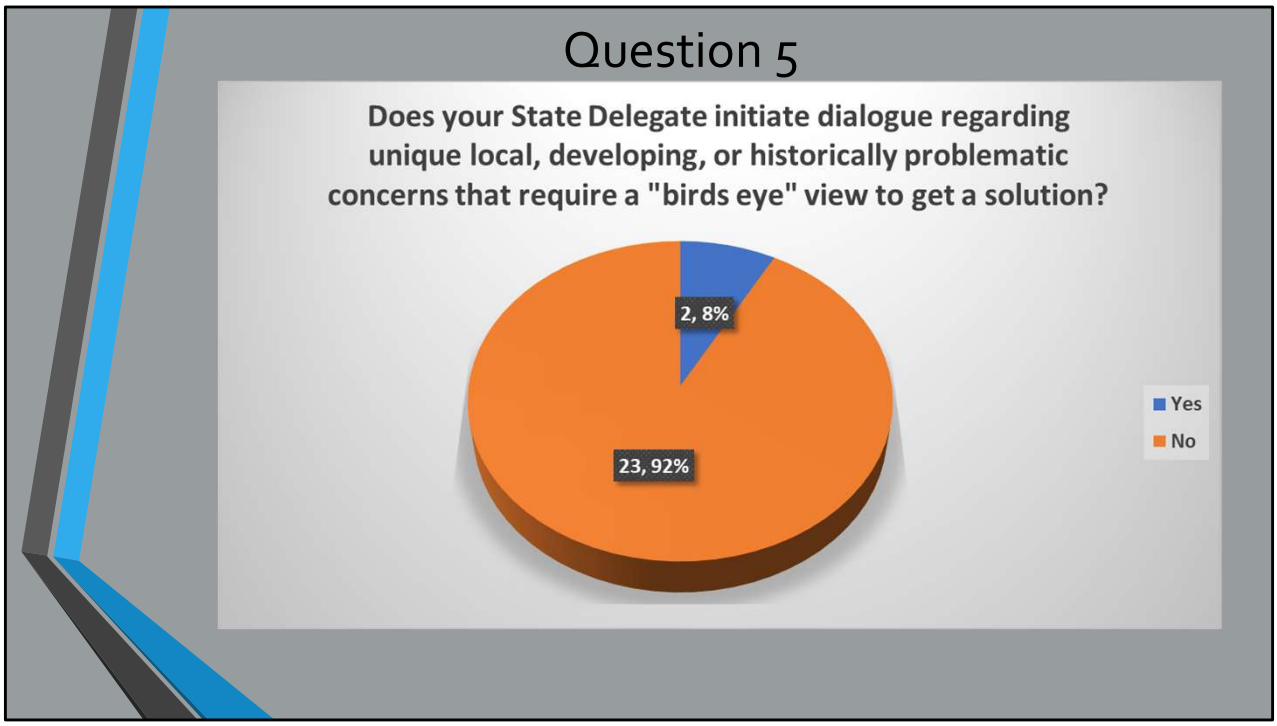
- State does not communicate with local health dept.'s.
- There is little to no communication between our jurisdiction and the State Delegate regarding CFP issues.
- There appears to be some confusion over **who** should be communicating information to the Local Regulators is it the state? The Delegate?



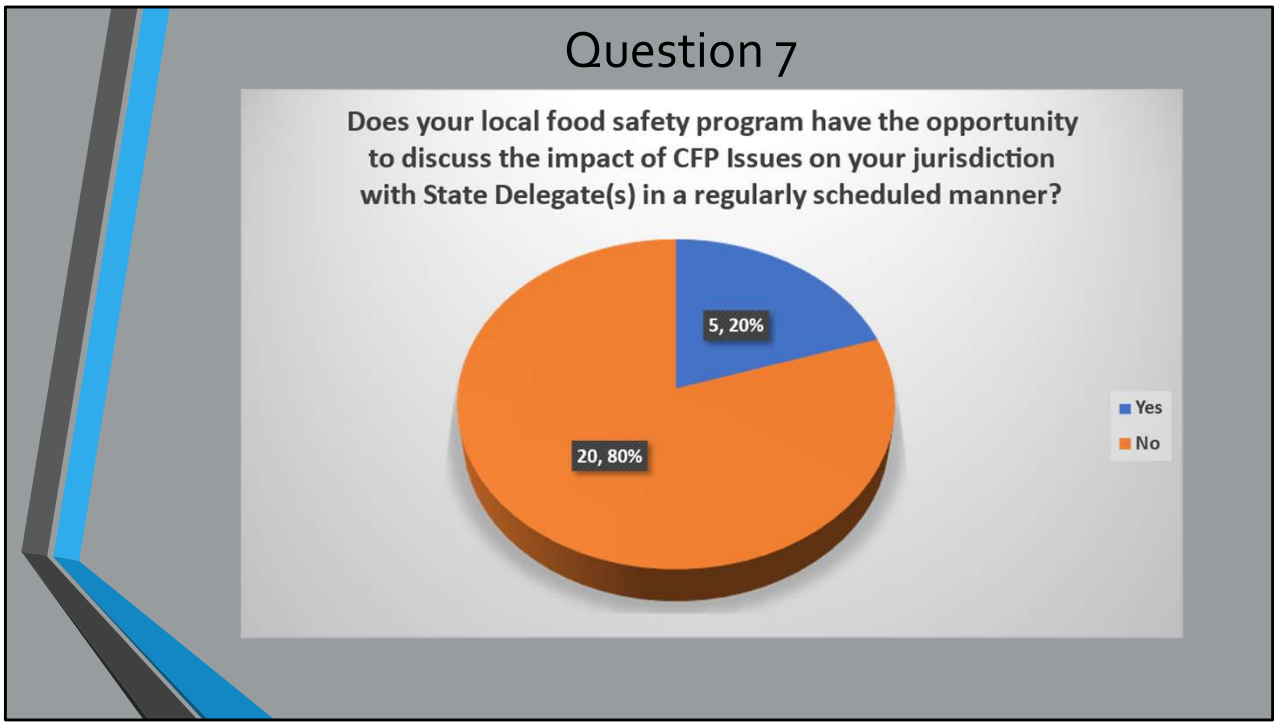
Observation: Official meets are not happening between states and locals.

Example:

- This has never occurred in my state
- We may run into them at the CFP Biennial Meeting. A "formal" meeting is not scheduled.
- We do not. We meet regularly with them but it is always around issues we see in our community, not related to CFP issues
- We have a regularly monthly state conference call on local issues but not exclusively on big picture CFP issues. It would be nice to connect quarterly with our state to bring everyone up to speed on the various committee work within each Council that LHJs may be working on.



Same two as previous question

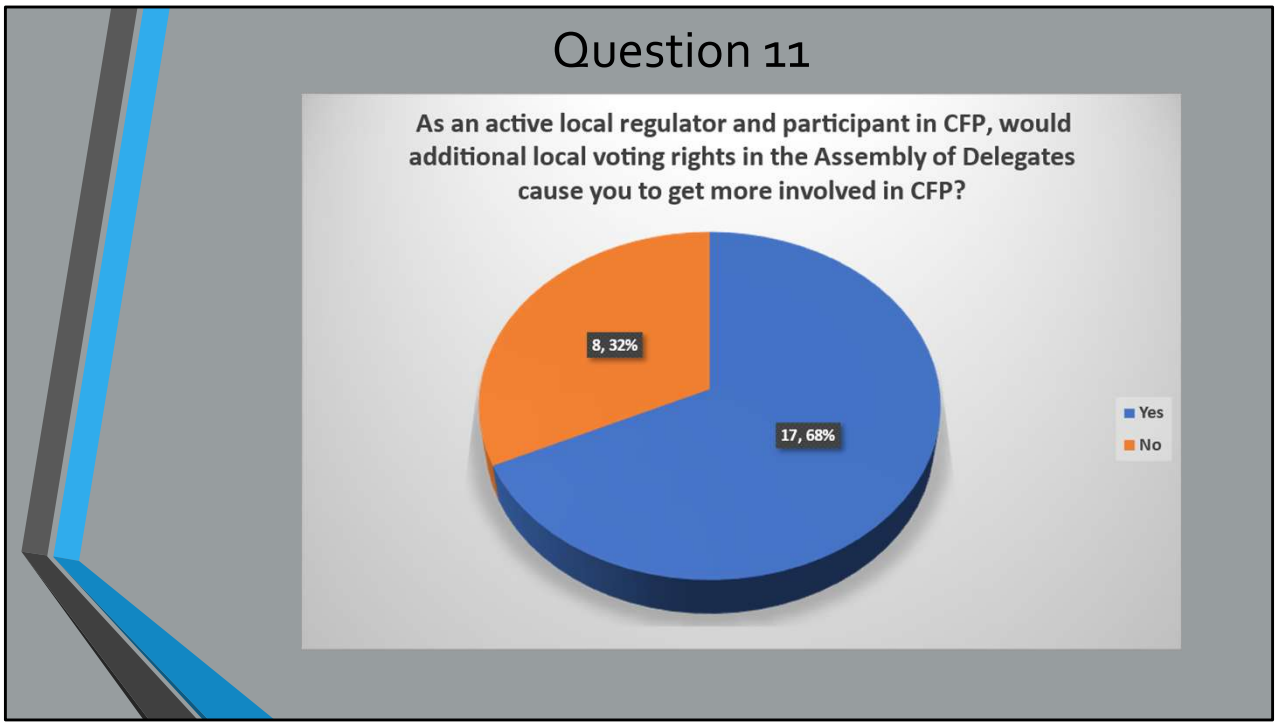


Observation: Little to no communication between the states and locals.

Example:

- There are none. They don't want our opinions or for us to be involved at all.
- Not sure unless you're heavily involved with CFP issues within each Council or following CFP issues?
- Historically, CFP issues haven't been discussed between local and State delegate prior to voting on CFP issues. Mostly clear on CFP issues being discussed & evaluated but think that it would be valuable for state and locals to visit prior to voting to be sure that all things are considered regarding voting outcomes.

General comments reflect a top down approach to any messaging between state and local.

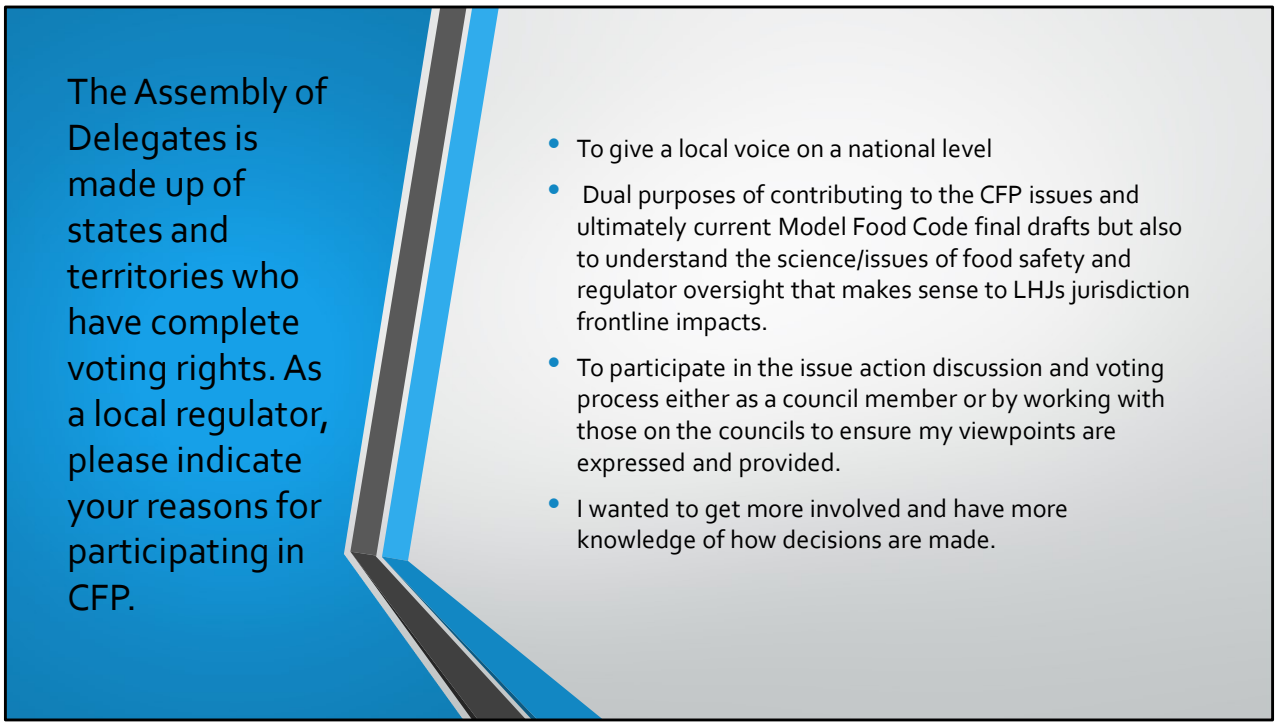


Observations: Locals want to participate
Of those that answered no 7 of them said they were already active and one said they didn't have time.

Example:

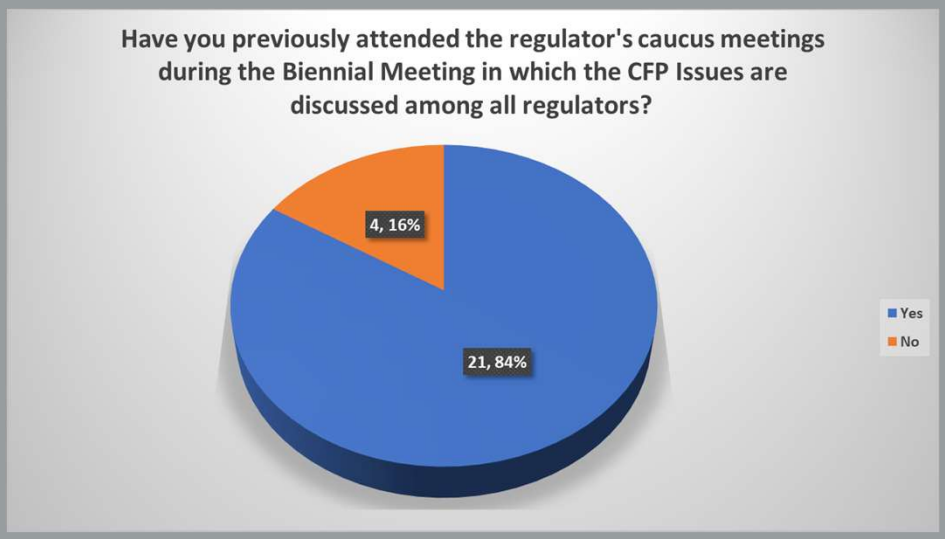
- To give a local voice on a national level
- To participate in the issue action discussion and voting process either as a council member or by working with those on the councils to ensure my viewpoints are expressed and provided.
- But not at the expense of aligning with the State on issues and voting - need to communicate closely. Voting rights does not necessarily mean getting more involved with CFP as time constraints and subject matter expertise of the individual factors in more.
- If we start to allow local regulators to have voting rights within CFP there may be the possibility of conflict of interests (many local regulators may be involved/married into families of large industry companies etc. and may start to push for their agendas), disagreements with local regulators and state agencies/delegates, and an opening to undermining future CFP work. I am a local regulator and against having voting rights traditionally held by our state delegates.

- I do ask for updates from our state delegates about work being done at the CFP level from time-to-time. This should be happening, but is not.



Observations:
The general vein of the answers to this were almost all along the same vein. To be part of the process, to have their voice heard and to have a say in the decisions being made

Question 14


Have you previously attended the regulator's caucus meetings during the Biennial Meeting in which the CFP Issues are discussed among all regulators?
4, 16%
21, 84%
Yes
No

Remarkably, even with communication issues noted the data shows the majority of participants will attend the next biennial conference.

PSC Issue #8 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC8 RPS Standard 2 Trained Staff Instructions and Worksheet for a VA
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC8 RPS 2022 Program Standards 6 Compliance Enforcement Inst and Worksheet for a VA

PSC Issue #9 list of content documents

1. 1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 Program Standards 2022 Standard 5 Edits
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 Program Standards 2022 Definitions Edits

PSC Issue #9 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 & PSC17 Standard 5 FBI and Food Defense Preparedness and Response

2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 2022 Program Standards Definitions

PSC Issue #16 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC16 Standard 5 Roadmap draft 10 22
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC16 Standard 5 Data Collection Template

PSC Issue #17 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC17 Program Standards 2022 Standard 2 with Crosswalk added
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC17 Program Standards 2022 Standard 5 with Crosswalk added

PSC Issue #17 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC 4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC9 & PSC17 2022 Program Standards 5 FBI and Food Defense Preparedness and Response

PSC Issue #18 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC18 www.foodprotect.org – Crosswalk Screenshot

PSC Issue #19 list of supporting attachments

1. PSC1 Program Standards Committee Report, Attachment title: PSC19 Issue 2020 II-033

PSC Issue #10 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC10 Draft Standard 6 Establishment File Worksheet Food Code Form 3A Based

PSC Issue #11 list of content documents

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC11 Draft Standard 6 Standardized Key Crosswalk to the 2017 FDA Food Code

Clearing House Question STND 6

State Enforcement Policy and Corrective Action

Keywords: STD-06, FDA

Issue Description

Background

As a result of 2019 legislation, our state implemented a new, progressive methodology for enforcement that became effective on January 1, 2020. This protocol takes into consideration not only the severity of the identified violation but also the prevalence of violations observed. The legislation provides for a uniform system to communicate inspection results which is based on an overall point system driven by assigned values of low, medium and high pervasiveness (identified in the attached document "19-09 Requirements for Communicating Inspection Ratings"). This point system establishes the criteria by which resources are to be directed for additional full re-inspections or enforcement activities.

Pervasiveness is the overall evaluation of specific issues observed to determine how prevalent the violation is. Using all available information such as active managerial control, previous inspection records, long term controls, and overall risk/severity of the specific situation, an inspector assigns a violation pervasiveness. This system then classifies routine and re-inspections into one of three ratings ("Pass," "Re-inspection," or "Closed") based on the total cumulative violations/ points. This rating is then used to determine the next required action: no required action (the next routine inspections is scheduled), a full facility re-inspection, or the immediate suspension of a license to operate. Facilities that score less than 50 points pass the inspection and do not have to demonstrate correction of risk factor or intervention violations through re-inspection or other follow-up.

Question/Problem

The current enforcement system in our state focuses on comprehensive compliance with the food code through a points-based rating system. Establishments that achieve a "Pass" rating during an inspection will not be required to show resolution for any out-of-compliance risk factor or intervention violations. Does this enforcement system meet the intent of Standard 6, Compliance and Enforcement?

Rationale

It is possible to have a risk factor violation that was unable to be corrected on-site at a facility that did not receive enough accumulated points to warrant a full re-inspection and actually achieved a "Pass" rating. At the time of the inspection, a "Pass" rating requires no further action by the operator to demonstrate correction of a violation and the next routine inspection will be scheduled. The "Pass" score during a full risk-based inspection has demonstrated that the operator had an overall effective control of the food safety risks. The system in Colorado was designed to allow regulatory resources to be focused on the operators that have significant food safety risks (resulting in a full "Re-inspection" or "Closure" of the facility) and not on those facilities that have their food safety risks under control (resulting in a "Pass" score) and have demonstrated active managerial controls are in place.

The desired outcome is to focus resources to effectively achieve compliance with regulatory requirements at facilities that have a significant lack of control over risk factors and interventions. Point values are reflective of risk factors and interventions and are given more emphasis based on prevalence.

Standard 6 – Criteria 1

1. Compliance and Enforcement Procedure

a) The jurisdiction has written step-by-step compliance and enforcement procedure that describes what actions and tools (i.e. forms, documents, interventions) are to be used to achieve compliance

<u>Clearinghouse Response</u> (11-30-2022)

No. The intent of Standard 6 is to evaluate the effectiveness of a jurisdiction's compliance and enforcement policy. Compliance and enforcement activities should result in follow up actions for out-of-control risk factors and timely correction of code violations. The program must demonstrate credible follow up for each violation noted during an inspection with particular emphasis placed on risk factors that most often contribute to foodborne illness.

PSC Issue #12 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC12 2022 Program Standards 8 Program Support and Resources
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC12 Issue 2020 II-017 Packet

FTE DATA CALCULATION

Calculate productive hours per year for an employee doing 100% food inspections

Information For One Employee		Hours/Year	Hours/Day	Total Hours
Annual FTE Hours Per Year: Industry Standard				2080
	Local Holiday Hours Per Year			0
	Local Vacation Leave Hours Per Year			0
	Local Sick Leave Hours Per Year			0
	Local Family-Personal Leave Hours Per Year			0
Productivity Factoring Per Year				
	Travel Time For Inspection			2080
	Administrative Work (in-office work)			2080
	Break time			2080
	Others			2080
Personal Development Time Per Year				
	Professional Development			2080
	Others			2080
Productive Annual FTE Hours Per Year (FTE Conversion Factor)				**2080**

FOOD SAFETY INSPECTION HOURS PER YEAR

Position Title	Percent of time spent on food inspections	Number of Employees	Total Hours
			0
			0
			0
			0
			0
			0
Total Food Safety Inspection Hours			**0**
Total Current FTE			**0.00**

Actual working days	Actual working weeks
260	52

Alter

STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION

	Low Risk Establishments	Frequency of Low Risk Est Inspections Per Year
Routine and Permitting		1.00
Follow Up Inspections/Reinspections (Assumes 15% of total)		
Foodborne Illness Complaints (Assumes 1% of total)		
Other (Assumes 10% of total)		
Total Number of Required Inspections		
Hours Spent Per Inspection	0.75	
Total Inspection Time	0	
Total Required FTE		
Standard 8.1 Staffing Level		

Sources
-2017 Subcommittee # 2 - Survey 1 and 2
-2019 Pilot Study

Moderate Risk Establishments	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishments	Frequency of High Risk Est Inspections Per Year	Total
	2.00		3.00	0
				0
				0
				0
				0
1.25		2.00		
0		0		0
				0.00
				Standard not met

STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION		
	Very Low Risk Establishments	**Frequency of Very Low Risk Est Inspections Per Year**
Routine and Permitting	0	1.00
Follow Up Inspections/Reinspections (Assumes 15% of total)		
Foodborne Illness Complaints (Assumes 1% of total)		
Other (Assumes 10% of total)		
Total Number of Required Inspections		
Hours Spent Per Inspection	0.75	
Total Inspection Time	0	
Total Required FTE		
Standard 8.1 Staffing Level		

Sources
-2017 Subcommittee # 2 - Survey 1 and 2
-2019 Pilot Study

Low Risk Establishments	Frequency of Low Risk Est Inspections Per Year	Moderate Risk Establishments	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishments
	2.00		3.00	
1.00		1.25		2.00
0		0		0

Frequency of High Risk Est Inspections Per Year	**Total**
4.00	0
	0
	0
	0
	0
	0
	0.00
	Standard not met

Conference for Food Protection
2020 Issue Form

Issue: 2020 II-018

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2016 II-020; new or additional information has been included or attached and the recommended solution has been revised.

Title:

PSC Issue #2 New assessment tool for Standard 8 Staffing Level Criteria

Issue you would like the Conference to consider:

The Program Standards Committee has addressed the charges outlined in Issue 2018 II-018: Continue Revision of Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 8 Staffing Level Criteria. The Committee has proposed a recommendation that the FDA modify the Standard 8 "Staffing Level" criteria by including the proposed model assessment tool as a secondary option to assess compliance based on the findings of the 2018 - 2020 Program Standards Committee, Subcommittee #2.

Public Health Significance:

The VNRFRPS offer a systematic approach to, through a continuous improvement process, enhance retail food regulatory programs. The VNRFRPS define and provide a framework designed to accommodate both traditional and emerging approaches of regulatory programs operating within an integrated food safety system. The Program Standards Committee established a subcommittee to address the specific charges in Issue 2018 II-018. The subcommittee, with support from staff from Harris County Public Health, created a new proposed model assessment tool, ensured it to be statistically sound, and completed a pilot study among 19 jurisdictions to test the proposed model. The information collected provided the means to: (1) Improve the proposed model assessment tool that was initially created by the Standard 8 Subcommittee in Issue # 2016 II-020; (2) Validate the statistical soundness of the proposed model by confirming there was no relationship found between times and frequencies provided by "high" and "low" performing jurisdictions; (3)

Determine if the proposed model assessment tool could be used in the real world setting by conducting a Pilot Study to assess the functionality of the model among varying jurisdictions; and (4) Utilize data from the study to recommend the proposed model assessment tool be included in the Standard 8 "Staffing Level" criteria as an alternative way to determine compliance.

Recommended Solution: The Conference recommends...:

The Conference recommends that a letter be sent to FDA asking them to modify the "Description of Requirements" for "Staffing Level" in Standard 8 by including the proposed model assessment tool as an alternative option to assess compliance for the VNRFRPS.

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Supporting Attachments:

- "PSC Issue #2 list of supporting attachments"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

PSC Issue #2 list of supporting attachments

1. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC2 CFP Issue 2020 II-031
2. See Issue titled: PSC1 Program Standards Committee Report, Attachment title: PSC2 2022 Program Standards 1 Regulatory Foundation

Template approved: 7/13/2021

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME *Food Defense Committee (FDC)*

DATE OF FINAL REPORT: *12/2/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Albert Espinoza and Jennifer Bonsky

COMMITTEE CHARGE(S):

Issue # 2020 II-009

1. *Identify current food defense references to be included in Appendix 2, Section 4.*
2. *Recommend whether an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments is appropriate.*
3. *Report the committee's findings and recommendations back to the Conference at the next Biennial Meeting*
4. *The Committee would work closely with the FDA Food Defense and Emergency Coordination staff in CFSAN*

Issue # _____

1.
2.
3.

COMMITTEE WORK PLAN AND TIMELINE: CO-CHAIRS CONTINUED TO WORK THE PLAN AND TIMELINE IN ACCORDANCE WITH CHARGES SINCE OCTOBER 2021.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***
   - Initial meeting in November 2021 after committee membership approval.
   - Routine meetings held on: 11/22/21, 12/06/21, 01/18/22, 1/31/22, 02/14/22, 02/28/22, 3/28/22, 4/11/22, 4/25/22, 5/23/22, 6/6/22, 7/18/22, 8/1/22, 8/15,22, 8/29/22, 9/12/22, 9/26/22, 10/10/22, and 10/24 via Teams.
   - Since January 2022 our committee completed two participant surveys. First survey obtained members Yes/No and comments on Charge 2 – whether an additional knowledge area under 2-102.11(C) relating to Food Establishments is appropriate. Second survey, more specific on participant recommended verbiage.
   - With 80% Yes on recommending additional knowledge area, specific to Food Defense and 100% Yes on proposing the FDA definition for Food Defense be added.
   - Charge 1 – FDA and USDA consultants provided their updated website links, participants reviewed and provided comments to update Annex 2, Section 4, will be submitted for Council consideration.
   - Our committee worked on an employee orientation checklist for Food Defense to completion. This document is to be submitted as an issue for Council consideration.
   - Charge 4 – We want to thank our FDA and USDA consultants for being on our virtual sessions, working closely with our committee. The FDA Food Defense and Emergency

Coordination staff, Julia Guenther and Jon Woody attended our meetings, providing input periodically and being available to assist with our drafted issues to be submitted.

Our Charge - that a FDC be reestablished to evaluate ways to improve Food Defense awareness for both operators and regulators in food establishments.

Charges for the committee are:

- Identify current food defense references to be included in Annex 2, Section 4.
- Recommend whether an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments is appropriate.
- Report the committee's findings and recommendations back to the Conference at the next Biennial Meeting.
- The Committee would work closely with the FDA Food Defense and Emergency Coordination staff in CFSAN.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***

a. Charge 1 - Identify current food defense references to be included in Annex 2, Section 4. This charge is completed with providing Annex 2, Section 4 updated information.

b. Charge 2 - Recommend whether an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments is appropriate. After discussion, two surveys and a final vote our committee completed this charge. Our participants are in favor of Food Defense awareness by employees be provided by the Person in Charge.
Approved language by vote on 7/18/2022:
ADD- FDA Food Code- 2-102.11 Demonstration (C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation.

18) Explaining steps that are taken to prevent intentional ADULTERATION by CONSUMERS, FOOD EMPLOYEES, or other persons including monitoring operations, ingredients, supplies, and finished products for unusual or suspicious activities, and similar FOOD DEFENSE activities.

ADD- FDA Food Code – 2-103.11 Person in Charge the PERSON IN CHARGE shall ensure that: (Q) EMPLOYEES are aware of food defense, such as signs of intentional acts of ADULTERATION as it relates to their assigned duties and report suspicious activity to the PERSON IN CHARGE.

ADD- FOOD DEFENSE Definition: FOOD DEFENSE is the effort to protect food from acts of intentional ADULTERATION.

c. Charge 3 - Report the committee's findings and recommendations back to the Conference at the next Biennial Meeting.
Our committee co-chairs will submit our findings and approved recommendations as CFP 2023 issue(s), forwarding to our Council II Chair, Vice Chair for comment, then submit to our CFP issue receiver.

d. Charge 4 - The Committee would work closely with the FDA Food Defense and Emergency Coordination staff in CFSAN.

   Our committee wishes to thank our FDA Consultants, some of whom represent the FDA's Food Defense and Emergency Coordination staff in CFSAN. They actively participated in our committee meetings and discussion. USDA was also present for our meetings, provided Annex update and actively participated with input during discussion of our charges.

3. ***Charges INCOMPLETE and to be continued to next biennium:***

   There are no incomplete charges, our committee completed work on the four charges provided by Council II.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

1.

2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1: Report – Committee Name:*** **List of content documents submitted with this Issue:**
Committee Member Roster:

☒ ***See attached revised roster PDF*** ☐ ***No changes to previously approved roster***

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

FDC Membership roster is updated to include alternate members requested by Co-Chairs to participate as voting members. Participants who have resigned from the committee are noted with a strikethrough.

(1) ***Other content documents:***

b. List of supporting attachments: ☒ ***Not applicable***

(b.i.1)

1. ***Committee Issue #2***: Amend Food Code – add Food Defense requirement under 2-102.11(C).
2. ***Committee Issue #3***: Amend FDA Model Food Code Annex 2, Section 4 Food Defense references.
3. ***Committee Issue #4:*** Approval and Posting of Food Defense Guidance Document

Food Defense

Employee Orientation

Establishment Name: _____ **Employee ID#:** _____

Food Employee Name: _____

Employee Awareness Checklist: The purpose of this checklist is to provide a guideline to help raise employee awareness pertaining to Food Defense. This can be used during employee orientation or during routine employee training to help document Food Defense discussions.	**Employee Initials**
Be a responsible employee. Communicate any potential food defense issues to your manager.	
Be aware of your surroundings and pay close attention to customers and employees who are acting suspiciously or are not where they belong	
Limit the number of personal items you bring into your work establishment and keep items secure in a designated area	
Be aware of who is working at a given time and where (in what area) they are supposed to be working.	
Periodically monitor the food display and food service areas (like salad bar, food displays, and other self-service foods.)	
Make sure chemicals are labeled an in their designated storage or sales area. Notify manager if large amounts of chemicals are missing.	
Know your company guidelines and follow them. If you have questions or believe company guidelines are not being followed, request assistance from your manager.	
Take all threats seriously, report any verbal or social media threats made by other employees or customers to your manager.	
If the back door is supposed to be locked and secure, **make sure it is!**	
If something doesn't look normal, **stop** using the product and **notify** your manager **immediately**. For example, if a food product or chemical you use looks different than it usually does	
If an ex-employee or non-employee enters an **"employees only"** area, let them know they have entered an "employee only" area, ask if they need help, escort them out of the employee area. Notify the person in charge or a manager.	
Cooperate in all investigations and notify management or corporate office. This could mean answering questions from the police or other government officials	
Do not talk to the media; refer all questions to your manager, person in charge, or corporate office.	
If you are aware of a hoax, prank, or social media challenge, notify your manager **immediately**.	
CUSTOMER AWARENESS SOP:	
Be aware of any unattended bags or briefcases customers bring into your operation, notify your manager **immediately**.	
If a customer walks into an **"employee only"** area of your operation, ask the customer politely if he or she needs help, then notify a member of management.	
VENDOR AWARENESS SOP:	
Check the identification of any vendor or service person that enters restricted areas of your operation and do not leave him or her unattended. Make sure management is aware of any after-hour vendor services or deliveries.	
Monitor all products received and look for any signs of tampering.	
When a vendor is making a delivery, never accept more items than what is listed on your invoice. If the vendor attempts to give you more items than listed, **notify your manager**.	
When receiving deliveries: **Step 1.** Always ask for identification. **Step 2.** Stay with the delivery person. **Step 3.** Do not allow the person to roam freely throughout your operation. **Step 4**. Delivery vehicle must always be attended or locked when the driver is away delivering products.	
FACILITY AWARENESS SOP:	
Report all equipment, maintenance, and security issues to your manager.	
Document any equipment, maintenance, and security issues.	
Be aware of the inside and outside of your facility, including the dumpster area, and report anything out of the ordinary.	
ESTABLISHMENT SPECIFIC FOOD DEFENSE (OPTIONAL):	

EMPLOYEE SIGNATURE DATE OWNER/MANAGER SIGNATURE DATE

Resourced by: SURE, Food Defense Manager Manual For food service and retail establishments

NEW EMPLOYEE ORIENTATION

1. It is the recommendation that food establishment employees complete this Food Defense Employee Orientation form within 30 days of hire. This includes anyone that serves or sells food, including volunteers, owners, and managers, regardless of whether they have been trained in food safety.

2. The Food Defense Employee Orientation should be completed in its entirety.

3. The food establishment employee should complete the top section which includes Establishment Name, Name of Employee, and the Employee ID Number (if applicable).

4. Food establishment employee should read and initial all the statements listed under each topic.

5. Please make sure that both the owner/manager and food employee sign and date the form.

6. Completed Food Defense Orientation forms should be maintained as part of the food establishment's operating records and kept for two years. You are encouraged to keep the original completed forms for the duration of the employee's employment.

7. This form should be completed only one time by each food establishment employee. If you wish to review this information again in the future with an employee who previously completed the form, follow these steps. Review the information and have the employee sign and date the back of the form.

Committee Name: Food Defense

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email	
Espinoza	Albert	Co-Chair	Industry - Retail Food	H-E-B	San Antonio	TX	210-8845783	espinoza.albert@heb.com	
Bonsky	Jennifer	Co-Chair	Regulatory - State	Michigan Department of Agriculture & Rural Development	Lansing	MI	517-614-0149	bonskyj@michigan.gov	
Inman	Adam	Member	Regulatory - State	Kansas Dept. of Ag	Manhattan	KS	785-5646764	adam.inman@ks.gov	
Morris	Travis	Member	Regulatory - State	Florida Department of Health	Tallahassee	FL	850-9016498	travismorris10@hotmail.com	
~~Harrison~~	~~Lisa~~	~~Member~~	~~Regulatory - State~~	~~Indiana Department of Health~~	~~Indianapolis~~	~~IN~~	~~317-4122106~~	~~lharriso@isdh.in.gov~~	~~Notified her CC Chairs she accepted another opportunity. Jennifer confirmed her email no longer active.~~
Vauls	Patricia	Member	Regulator - State	Maryland Department of Health	Baltimore	MD	410-7678447	patricia.vauls@maryland.gov	Patricia Vauls accepted position as Regulator -State voting member. 11/17
Bell	Wendy	Member	Regulatory - Local	Mecklenburg County Public Health	Indian Trail	NC	980-257-3999	Wendy.Bell@MecklenburgCountyNC.gov	
Villareal	Rolando	Member	Regulatory - Local	County of Sacramento	Sacramento	CA		surfvillareal@gmail.com	
Baroudi	Dr. Al	Member	Industry - Food Service	The Cheesecake Factory	Thousand Oaks	CA	818-8715890	abaroudi@thecheesecakefactory.com	
Morrison	Laura	Member	Industry - Food Service	Ohio Restaurant Association	Columbus	OH	614-5634495	lmorrison@ohiorestaurant.org	
Waldroop	Hillary	Member	Industry - Retail Food	Publix Super Markets	Lakeland	FL		hillary.waldroop@publix.com	
~~Ciarimboli~~	~~Ellen~~	~~Member~~	~~Industry - Retail Food~~	~~Hy-Vee Inc~~	~~West Des Moines~~	~~IA~~	~~515-7793553~~	~~eciarimboli@hy-vee.com~~	
~~Allen~~	~~Consuelo~~	~~Member~~	~~Industry - Retail Food~~	~~Whole Foods Market~~	~~Austin~~	~~TX~~	~~512-4268709~~	~~consuelo.allen@wholefoods.com~~	
Brown	Bob	Member	Industry - Retail Food	Whole Foods Market	Austin	TX	512-9447405	robert.brown@wholefoods.com	
Summers	Christine	Member	Industry - Vending and Distribution	Compass Group - Cantee	Belmont	NC	425-2816397	christine.summers@compass-usa.com	
Lindholm	Jeffrey	Member	Industry - Support	iCertainty	Chevy Chase	MD	240-9084111	jeff.lindholm@icertainty.com	
Collins	Alicia	Member	Industry - Support	Steritech	Charlotte	NC	707-208-4399	Alicia.Collins@Steritech.com	
~~Baker~~	~~Rance~~	~~Member~~	~~Industry - Support~~	~~NEHA~~	~~Denver~~	~~CO~~	~~303-3241161~~	~~rbaker@neha.org~~	
Kincheloe	James	Member	Consumer	Center for Science in the Public Interest	Washington	DC	707-490-7087	jkincheloe@cspinet.org	

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email	
Dutilly	Devin	FDA Consultant	Federal	FDA			301-348-1980	Devin.Dutilly@fda.hhs.gov	
Wanucha	Donna	FDA Consultant ALT	Regulatory - Federal	FDA			678-616-5600	Donna.Wanucha@fda.hhs.gov	
Clark	Carrie	USDA Consultant	Regulatory - Federal	USDA-FSIS				carrie.clark@usda.gov	
Hanson	Patricia	Alternate	Regulator - State	FDACS	Tallahassee	FL	850-6669090	patricia.hanson@fdacs.gov	
~~Davis~~	~~Diane~~	~~Alternate~~	~~Regulatory - Local~~	~~Harris County Public Health~~	~~Missouri city~~	~~TX~~	~~713-2746367~~	~~diane.davis@phs.hctx.net~~	
~~English~~	~~Amber~~	~~Alternate~~	~~Regulatory - Local~~	~~Washoe County Health Distric~~	~~Reno~~	~~NV~~		~~aeenglish@washoecounty.us~~	~~Withdrew, 11/1/2021~~
Graham	Julian	Alternate	Industry - Food Service	Centerplate	Lutherville Timonium	MD	407-7120481	julian.graham@me.com	
Millwood	Corey	Member	Industry - Retail Food	Publix	Marietta	GA	678-6728703	corey.millwood@publix.com	
Melichar	Wayne	Alternate	Industry - Vending and Distribution	Feeding America	Elmhurst	IL	312-3995281	WMELICHAR@FEEDINGAMERICA.ORG	
Cammarata	Tara Paster	Alternate	Industry - Support	Paster Training, Inc.	GILBERTSVILLE	PA	484-4318240	tara.paster@pastertraining.com	
Guzzle	Patrick	Alternate	Industry - Support	National Restaurant Association	Boise	ID	208-515-8688	pguzzle@restaurant.org	
Kantrowitz	Sarah	Alternate	Academia	Perkins&Will	Boston	MA	914-5230757	sarah.e.kantrowitz@gmail.com	
Wilson	David	Alternate	Consumer (organizations)	After School Matters	La Grange	IL	708-5820022	d.wilson180@my.chicago.chefs.edu	
Garren	*Donna*	alternate	Processing	Institute	Arlington	VA	703-6630252	dgarren@affi.com	
committee size is standing									

Food Defense

Employee Orientation

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Committee Name: Food Safety Management Systems

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Sedlak	Mandy	Chair	Industry - Food Service	EcoSure, a Division of Ecolab	Naperville	IL	612-271-4935	mandy.sedlak@ecolab.com
Sylvis	Christine	Co-Chair	Regulatory - Local	Southern Nevada Health District	Las Vegas	NV	7027590507	sylvis@snhd.org
Huffman	Troy	Member	Regulatory - State	Colorado Dept. of Public Health & Environment	Denver	CO	3036923664	troy.huffman@state.co.us
Jackson	Jeff	Member	Regulatory - State	Arkansas Department of Health	Little Rock	AR	8708477619	jeff.jackson@arkansas.gov
Smith	Colleen	Member	Regulator - State	NH DHHS	Concord	NH	16032714858	colleen.smith@dhhs.nh.gov
Sanders	Heather	Member	Regulator - State	Pennsylvania Department of Agriculture	Harrisburg	PA	717-836-2115	hesanders@pa.gov
Pollock	Evelin	Member	Regulatory - Local	Harris County Public Health	Houston	TX	713-248-5691	evelin.pollock@phs.hctx.net
Woods	Yolanda	Member	Regulatory - Local	Shelby County Government	Memphis	TN	19012229190	yolanda.woods@shelbycountytn.gov
Monique	Crawford	Member	Regulator - Local	Harris County Public Healh	Houston	TX	8328402522	monique.crawford@phs.hctx.net
Boyles	Chris	Member	Industry - Support	Steritech	Charlotte	NC	704-968-3822	chris.boyles@steritech.com
Rossow	Todd	Member	Industry - Retail Food	Publix Super Markets, Inc.	Lakeland	FL	8637977659	todd.rossow@publix.com
Edelen	Jeffrey	Member	Industry - Retail Food	Whole Foods Market	Austin	TX	737-932-1143	jeff.edelen@wholefoods.com
Whitlock	Lisa	Member	Industry - Retail Food	Lisa Whitlock Retail Food Safety Consultant	Loma Rica	CA	(530) 770-1953	kitchencooker63@gmail.com
Tew	Dan	Member	Industry - Food Service	Yum! Brands	Prosper	TX	5026193447	daniel.tew@yum.com
Okenu, Ph.D.	Dan	Member	Industry - Food Service	H-E-B Grocery Company	San Antonio	TX	(404)805-2221	okenu.daniel@heb.com
Hsieh	Hsing-Yi	Member	Industry - Retail Food	Skogen's Festival Foods	De Pere	WI	9205405644	hhsieh@festfoods.com
Zaziski	Linda	Member	Industry - Food Service	Little Caesar Enterprises/Blue Line Distribution/Champion Food Service	Detroit	MI	586-243-6932	linda.zaziski@lcecorp.com
Nutt	Elizabeth	Member	Industry - Support	Association of Food and Drug Officials	Tuilsa	OK	9182711420	enutt@afdo.org
Quam	Susan	Member	Industry - Support	Wisconsin Restaurant Association	Madison	WI	6082162875	squam@wirestaurant.org

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Otto	CRD Jessica	FDA Consultant	Regulatory - Federal	FDA			240-402-1876	Jessica.Otto@fda.hhs.gov
Marcello	John	FDA Alterante	Regulatory - Federal	FDA			480-829-7396 x 2035	john.marcello@fda.hhs.gov
Wittry	Beth	CDC Consultant	Regulatory - Federal	CDC			770-488-7333	Xks5@cdc.gov
Otto	Mark	CDC Consultant Alternate	Regulatory - Federal	CDC			404-498-6400	rwv3@cdc.gov
Smith	Melissa	Alternate	Industry - Food Service	TPC Training - State Food Safety	Buffalo Grove	IL	5037295667	melissa.smith@statefoodsafety
Temke	Laura	Alternate	Industry - Retail Food	Sendik's Food Markets	Milwaukee	WI	4147327585	laura.temke@sendiks.com
Wildey	Laura	Alternate	Industry - Retail Food	National Environmental Health Association (NEHA)	Denver	CO	3026685403	lwildey@neha.org
ZENLEA	JEREMY	Alternate	Industry - Retail Food	EG America	Westboro	MA	6035832506	jzenlea@cumberlandfarms.com
Bussiere	Vanessa	Alternate	Industry - Support	Aspire Food Safety Solutions LLC	Tacoma	WA	253-334-5181	vanessa@aspirefoodsafety.com
Dohnal	Theodore	Alternate	Industry - Support	Huginn Consulting LLC	Big Rapids	MI	231-349-3322	tdohnal@huginnconsultingllc.com
Eisenbeiser	Ashley	Alternate	Industry - Support	FMI	Arlington	VA	2022200689	aeisenbeiser@fmi.org
Flusberg	Martin	Alternate	Industry - support	Powerhouse Dynamics	Newton	MA	617 680 2471	martin@powerhousedynamics.com
Seminara	Mario	Alternate	Industry - Support	Food Safety Works LLC	Lakewood	CO	7206811615	mario@foodsafetyworksll.com
Follett*	Emilee	Alternate	Industry - Support	State Food Safety				efollett@statefoodsafety.com
Wilson	David	Alternate	Consumer (organizations)	After School Matters	La Grange	IL	17085820022	d.wilson180@my.chicago.chefs.edu
Crawford, Ed.D.	Herman	Alternate	Academia	Nutri-Rific LLC	Webster	NY	9728850067	NUTRIRIFIC@GMAIL.COM
Dunleavy	Sean	Alternate	Regulator - State	Michigan Department of Agriculture and Rural Development	Howell, MI 48855	MI	15172438895	dunleavys@michigan.gov
Wallingford	Shelly	Alternate	Industry - Food Service	First Watch Restaurants	Bradenton	FL	(720) 456-5702	swallingford@firstwatch.com

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 6-Non-voting alternates.*
Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 18-Non-voting alternates.
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

*added at the direction of Conference Chair and not eligible as a voting member until approved by the Executive Board

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

The Conference Chair, Executive Director, Council Chair, or Issue Chair may return committee reports, Issues, or attached documents requesting edits to improve clarity or understanding, or to include missing information.

Committee-submitted documents may impact the image, credibility, and integrity of the Conference as an organization. With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME: Food Safety Management Systems (FSMS) Committee

DATE OF FINAL REPORT: December 2, 2022

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Mandy Sedlak, Committee Co-Chair Industry
Christine Sylvis, Committee Co-Chair Regulatory

COMMITTEE CHARGE(S):

Issue: 2020 II-030

1.Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.

2.Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.

3.Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:

a) the hurdles/challenges involved in such a requirement; and

b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.

4.Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.

5.The committee should report its findings and recommendations at the next Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.

COMMITTEE WORK PLAN AND TIMELINE:

The committee met monthly from November 2021 through November 2022. Workgroup documents were shared via FoodSHIELD, CFP Microsoft Teams/SharePoint, and attached to calendar invitations. Microsoft Teams was used for monthly meetings and for the working document. The following milestones were established: identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code by January 2022; identifying solutions for overcoming the identified barriers and provide recommendations for how to promote the solutions by August 2022; conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code by September 2022; and developing recommendations on next steps to promote universal development and implementation of documented FSMSs by October 2022. Periodic reports were prepared and submitted in October 2021, March 2022, July 2022, and November 2022, in accordance with the CFP master calendar.

COMMITTEE ACTIVITIES:

1. Overview of committee activities:

Council II Vice Chair Drafted initial proposed membership roster which was approved by the Board.

Dates of committee meetings or conference calls: The committee has met on November 16, 2021, December 14, 2021, January 18, 2022, February 14, 2022, April 19, 2022, May 17, 2022, June 24, 2022, July 26, 2022, October 18, 2022, and November 15, 2022, November 18, 2022. A subcommittee was created to organize identified barriers into subcategories and consolidate and edit the barriers. Additional subcommittees were created to review the solutions submitted by barrier subcategory (economic, people, and training), and to identify pros and cons.

The initial meeting November 16, 2021, included committee member introductions, a review the committee charges, a timeline for addressing the charges was agreed upon, and it was decided that FoodSHIELD will be used for document sharing.

During the meeting December 14, 2022, work being conducted on FSMSs by other groups such as the food safety management survey that the Association of Food and Drug Officials (AFDO) in conjunction with the FDA Retail Food

Safety Regulatory Collaborative was discussed, an overview of FoodSHIELD and the working document was provided, and committee members were encouraged to submit new barriers and barriers submitted.

During the meeting January 18, 2022, the categories to organize barriers (economics, training, processes, accountability, people) were discussed and an overview of the AFDO food safety management industry survey was provided.

During the meeting February 14, 2022, the barriers listing, as organized by the subcommittee, were reviewed. The committee determined that the terms in Annex 4 of the Food Code (Food Safety Culture, Food Safety Management Systems (FSMS), and Active Managerial Control (AMC)) needed to be clarified and defined prior to moving forward with solutions.

During the meeting April 19, 2022, a definition for AMC was decided upon and work on a definition for FSMS was commenced.

During the meeting May 17, the format for the solutions listing was decided upon and three subcommittees, with leads for each of the related barrier categories were created (economic, people, training). Work on a definition for FSMS continued.

During the meeting June 24, 2022, the definition for FSMS was completed and an example of how to implement a FSMS was discussed. Review of solutions to economic and people barriers were complete. The co-chairs met with FDA Advisor, John Marcello, on June 24, 2022, to discuss the direction of the Committee and future actions/charges of the FSMS. The co-chairs met with Council II Chair and Vice-Chair, Courtney Halbrook, and Wendy Bell, on July 13, 2022, to discuss the progress of the Committee and recap the discussion with the FDA Advisor to ensure it aligned with the charges of the Committee.

During the meeting July 26, 2022, a quorum was not established so the definition of FSMS could not be voted upon. Options for the future direction of the Committee was discussed and work on Charge #3 commenced.

During the meeting September 20, 2022, the committee discussed and voted on changes to the roster. The roster changes were necessary to form a quorum to vote in future meetings as a result of non-attendance and individual requests. The roster update consisted of removing voting members Mark Speltz (Regulator – Sate) and Naomi Macias (Regulator – Local) who respectfully asked to be removed from the committee due to a new job responsibility. Moved voting members Sean Dunleavy (Regulator – State) and Shelly Wallingford (Industry- Food Service) to non-voting members due to missing at least three consecutive meetings and not responding to an email regarding future participation. Transferred Troy Huffman and Hsing Yi from non-voting members to voting members to replace those listed in 1 and 2 above. Transferred Evelyn Pollak to an alternative voting member. The committee also voted/approved the proposed FSMS definition. The committee also established a special meeting on September 29, 2022, to finalize pros and cons. A reminder was made that the committee would vote on accepting the proposed solutions and barriers on the October 18, 2022, meeting. There was also discussion around the future of the FSMS committee.

During the October 18, 2022, meeting, a quorum was established, and the committee voted and approved the proposed barriers and solutions. The committee discussed the development of prospective Committee Issues to present to Council II Chair and Vice Chair by November 18, 2022. The committee also discussed consideration for recreating the FSMS Committee with proposed committee charges and the idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about submitting an Issue to establish a joint Standing Committee to encompass the work of the FSMS and DFSS Committees. Next steps, co-chairs met with stakeholders for considering recreating with the DFSS committee. Committee co-chairs Mandy Sedlak and Christine Sylvis will draft charges report and issues for review by the FSMS committee before the November 15, 2022, meeting.

During the November 15, 2022, meeting, the committee voted/approved to accept the Pros/Con report as written to be included in final report submission. The next discussion was around developing recommendations on how to promote universal development and implementation of documented FSMSs consistent with Annex 4. The committee started with 2 options. 1. Consider recreating FSMS Committee – creating committee charges using the Barrier's list as a starting point. 2. Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, submitting an Issue to establish a Standing Committee to encompass the work of the FSMS and DFSS Committees. The will of the FSMS committee was to request a standing committee (w/o digital committee). A motion was made to recreate the committee as council committee w/chargers and to create a separate issue to change from a council committee to a standing committee w/duty as stated by constitution and bylaws. Motion passed. The final discussion of the meeting was around the charges for FSMS Committee during 2023-2025 biennium. The considerations for charges were:

- Risk Factor for PIC provision
- Cost benefit analysis (NACCHO/collaborative)
- Develop a toolbox, develop verbiage to outline prerequisites (SOPs) that are not covered. Review results of EHS-Net/CDC collaboration and incorporate into toolbox
    - Focus on Employee Health, Healthy people
    - Use the school USDA/HACCP SOPs as a possible guide/tool; consider reviewing #4 "Guidance for School Food Authorities, "Developing a Food Safety Program based on the process approach to

HACCP Principles" Consider having CDC provide an overview of project and what tools may come out of this down the road.
    - CONSIDER: Piloting a FSMS for Employee Health program to see how it might work. Find industry volunteer to develop FSMS; site visits to support and verify effectiveness. Industry/Regulatory Partner. Note this is something that CDC is already using this approach/project. Initialed via EHS-Net
    - Get understanding of EHS-Net project as how it relates to FSMS committee work and consider collaboration and providing guidance based on the results of the study.
    - The overarching thread of these suggestions is that we need to increase awareness, communication and idea sharing with initiatives already underway. A committee may not be well suited to do a pilot study themselves but give the results they could give guidance.
- Reviewing the previously identified pros and cons to barriers to the universal voluntary development and implementation of documented FSMS and provide additional remedies
- Items not covered in our current charges
- Complete gap analysis of PIC Provision
- Committee Charge to fill in the gaps between all areas working on aspects of employee health and all aspects of collaboration/projects currently being done.

During the November 18, 2022, meeting, the committee discussed how to and where to suggest the addition of the approved FSMS definition into the Food Code. After much discussion, the committee proposed that it be added in the public health significance section. (The Definition be incorporated into chapter 1, and that FSMS and its definition be incorporated into to AMC.) The committee voted to include FSMS, AMC into code w/voluntary use terminology, the motion passed. Mandy and Christine edited the draft issues to improve clarity and style as discussed and shared the issues with all members. The final report was submitted to Council II Chair and Vice Chair on November 18, 2022

In addition to monthly meetings additional Subgroup Meetings took place on the following dates:

- 01-11-2022
- 02-02-2022
- 02-08-2022
- 02-28-2022
- 03-22-2022
- 04-14-2022
- 05-13-2022
- 07-13-2022
- 08-25-2022
- 9-29-2022
- 10-31-2022
- 11-02-2022

Collaborative Meetings:

- 09-13-2022
- 11-04-2022

2. Charges <u>COMPLETED</u> and the rationale for each specific recommendation:

a. (Charge 1) Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.
    i. The Committee met on several occasions including subcommittee work to identify barriers to the universal voluntary development and implementation of documented FSMSs. The barriers are documented in the Committee Findings Report.

b. (Charge 2) Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.
    i. The Committee met on several occasions including subcommittee work to identify solutions for

overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions. The solutions are documented in the Committee Findings Report.

c. (Charge 3) Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on: a) the hurdles/challenges involved in such a requirement; and b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.
    i. The Committee met on several occasions including subcommittee work to identify pros/cons assessment of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code. The pros and cons are documented in the Committee Findings Report.

d. (Charge 4) Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.
    i. The Committee met on several occasions including subcommittee work to develop recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4. The Committee is submitting an Issue for the 2023 CFP Biennial Meeting to include the definitions of Active Managerial Control and Food Safety Management Systems into Chapter 1 of the Food Code and incorporate these systems into Chapter 2 of the Food Code in § 2-103.11. It is also being recommended that the future FSMS Committee continue to develop recommendations on additional steps to promote universal development and implementation of documented FSMSs.is

e. (Charge 5) The committee should report its findings and recommendations at the next Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.
    i. The Committee is submitting an Issue for the 2023 CFP Biennial Meeting to acknowledge this final report with attachments containing meeting minutes and the Committee Findings Report which includes the findings and recommendations.

3. Charges <u>INCOMPLETE</u> and to be continued to next biennium:

All charges are complete, however continued work is needed to promote universal development and implementation of documented FSMSs.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☐ ***Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.***

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. ***Issue #1:*** **Report – Food Safety Management System (FSMS) Committee**

List of content documents submitted with this Issue:

- 2021-2023 FSMS Committee Roster
- 2021-2023 FSMS Committee Final Report
- FSMS Findings Report

Committee Member Roster:

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***
"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) ***Other content documents:***

a. List of supporting attachments: ☐ ***Not applicable***

- 2021-2023 FSMS Committee Meeting Minutes
- 2021-2023 FSMS Committee Attendance Log

2. ***Committee Issue #2***: Re-create – FSMS Committee

3. ***Committee Issue #3***: Create FSMS Committee as Standing Committee

4. ***Committee Issue #4:*** Amend Food Code – Include Active Managerial Control and FSMS

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ISSUE 2020-II-030

Title: **Creation of a Food Safety Management System (FSMS) Committee**

Committee Recommended Solution: The Conference recommends...:

a Food Safety Management System (FSMS) Committee be created and work with stakeholders such as but not limited to the Retail Food Safety Regulatory Association Collaborative to identify recommendations for developing and implementing documented, HACCP principles-based Food Safety Management Systems (FSMSs) in all food establishments to support FDA's blueprint for a New Era of Smarter Food Safety. The FSMS Committee should consider:

1. Identifying barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.
2. Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.
3. Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:
   a) Hurdles/challenges involved in such a requirement; and
   b) Recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.
4. Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.
5. The committee should report its findings and recommendations at the next Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.

CHARGE 1: BARRIERS

Economic Barriers

Economic related barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.

1. **Resource Barriers**
    a. Insufficient supervision/oversight of staff (such as a Certified Food Protection Manager (CFPM)) during all hours of operation.
    b. Lack of resources (time, personnel) to develop and implement SOPs and train on FSMSs.
    c. Implementing FSMSs is costly and difficult.
    d. Lack of expertise and direction by staff to create FSMSs.
    e. Costs associated with technology upgrades (electronic monitoring on refrigeration, electronic logs/recordkeeping, databases) to capture data and report findings.
2. **Time Barriers**
    a. Staff and management do not have enough time dedicated for monitoring and recordkeeping.
    b. Lack of time for development, implementation/training, maintenance, and continuous improvement.
    c. FSMSs are not addressed during the plan review process. Regulators place emphasis on physical facilities over operational elements (AMC and FSMS) during plan review
3. **Cost Barriers**
    a. Concern that FSMSs will increase costs due to an increase in corrective actions.
        i. Training costs associated/especially with high turnover and staff shortage.
        ii. Costs for development, implementation/training, maintenance, and continuous improvement (Labor, Materials, Support, Training).
        iii. Cost/benefit (return on investment) of FSMSs is hard to quantify.
    b. Cost of foundational prerequisite programs (i.e., facility, equipment, pest management, cleaning).

People Barriers

People related barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.

1. **Buy-in Barriers**
    a. Resistance to change.
    b. Disconnect between food safety behaviors and the occurrence of foodborne illness.
    c. Lack of knowledge of the “why” for food safety related to business case.
    d. Food safety is behavioral so getting staff (leadership and front-line) to buy in to it is difficult.
    e. Lack of operator motivation to implement and maintain more processes. FSMSs are perceived as extra work.
    f. Voluntary FSMSs without tangible incentives will probably not be followed. Voluntary perceived as not important or necessary.

g. Development of a FSMS will vary for different types of food establishments (chain/independent, quick service/full service, process 1/2/3, etc.). Although the principles are the same, model templates may not apply to all types of food establishments.
h. Resistance of leadership to invest in FSMSs, people, and processes to help maintain food safety.

2. Leadership/Accountability Barriers

a. Lack of management commitment.
b. Competing priorities.
c. Lack of management setting expectations and holding people accountable.
d. Lack of a champion.

3. Values Barriers

a. Lack of trust and understanding between industry and regulatory folks.

4. Cultural/Ethnicity Barriers

a. Language and literacy barriers (spoken and written).
b. Lack of belief in the science and causes of foodborne illness.

Training Barriers

Training related barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code

1. Training Barriers

a. Lack of training/time for regulatory time to coach, offer guidance to industry
b. Lack of dedicated time to develop procedures that are prerequisites of FSMSs, train food handlers on procedures, review their level of understanding, monitoring, and coaching to improve
c. Lack of training for industry on understanding, developing, and implementing a FSMS.
d. FSMS is not a defined or universally understood/consistent term. Inconsistent use of Food Safety Culture, Food Safety Management Systems, and Active Managerial Control.

2. Knowledge Barriers

a. Lack of knowledge of hazards, risk factors, interventions, and corrective actions.
b. Lack of understanding of the science and causes of foodborne illness.
c. Perception that they “have it covered”.
d. Lack of technical ability to create a FSMS.
e. Upper management may not be clear on the importance of food safety and current food safety conditions.

3. Processes Barriers

a. Some food establishments currently have an unstable foundation of prerequisites (pest control, sanitation, crisis management, etc.) and are not set up for success for developing and implementing FSMSs.
b. Businesses are different, significant process variability. Not a one-size fits all approach.
    i. Type of Operation (Retail food, Sit down Restaurants, Quick serve Restaurants, Convenience Stores)
    ii. Size of operation (# of locations, Franchise operation, Regional vs. national company)

c. Who oversees and manages food safety? Managed at Corporate level vs at the restaurant/store location

4. **System Development/SOPs Barriers**
    a. Lack of standardized processes (across multiple stores, regional, company locations (decentralized management)).
    b. Lack of resources (implementation guides, creation examples, messaging, templates, sample SOPs, guidance documents and tools) to get a FSMS program started.
    c. Annex 4 is not an 'easy-read.' Terminology needs to be defined and used consistently between courses (FD215, FD218), the Food Code, and other materials. There have been significant advancements in the availability of tools since it was drafted.
    d. Lack of capturing and monitoring key food safety data points then using the data to maintain and improve food safety and quality
5. **Code Differences Barriers**
    a. Inconsistent terminology used with industry vs. regulatory.
    b. Many states don't adopt Food Code Annexes.
    c. Alignment between Federal, State, and local authorities.

CHARGE 2: SOLUTIONS

Economic Solutions

1. **Lack of resources (e.g., time, personnel, expertise) to develop procedures, implement and train procedures, and monitor ongoing implementation of procedures.**
    a. Provide tools for regulators to educate and assist operators. Provide guidance to regulators on how an inspection might differ for locations that have implemented voluntary a FSMS. Encourage regulatory agencies to schedule visits with operators to promote the adoption of voluntary FSMSs.
    b. Update FDA Food Code Annex to clarify what a FSMS is, how operators can implement them effectively, and how regulators can support them during visits.
    c. Create a starter kit that regulators can provide to operators (such as at the time of initial permitting.) Where appropriate, leverage existing FDA materials, posters, and videos for educating frontline workers. Include:
        i. Education on the basic concepts of FSMSs.
        ii. Examples of procedures, training and monitoring specific to each industry segment (restaurant, grocery, convenience store, etc.)
        iii. Examples of signage and job aids
        iv. Templates for logs
    d. Information on types of technology that can support FSMSs (electronic monitoring for refrigeration, electronic logs/recordkeeping, digital task management, etc.)
    e. Develop an industry-focused marketing campaign to promote FSMSs. Leverage resources and communication channels through the Retail Food Safety Collaborative. Include:
        i. Purpose and value of FSMSs, including cost benefit analyses with case studies and examples.
    f. Available tools and templates for FSMS components.

g. Develop a regulatory-focused marketing campaign to promote FSMSs. Leverage resources and communication channels through the Retail Food Safety Collaborative. Include:
    i. How to communicate the purpose and value of FSMSs.
    ii. Available tools and templates for operators.
    iii. Guidance for how to encourage the voluntary adoption of a FSMS.

2. **Perception that implementing FSMSs is costly and difficult.**
    a. Update ANSI CFPM requirements to include training on FSMSs to promote a more universal understanding of basic FSMS processes and how voluntary adoption improves food safety.
3. **Facilities are not designed to support FSMSs.**
    a. Provide support and training for regulators conducting the plan review process so that they can guide operators toward plans and specifications support voluntary FSMSs now and in the future.
    b. Provide training and materials for regulators conducting the plan review process, such as charts that illustrate FSMSs and encourage forward thinking about how preparation procedures, facility layout, and equipment choices provide a foundation for voluntary FSMSs.
4. **It is difficult to quantify the return on investment for a FSMS and demonstrate that the cost justifies the benefit.**
    a. Create a guidance document that operators can use to design, implement, and evaluate a Case Study to justify the cost effectiveness of FSMSs. Create specific versions for industry segments where appropriate.
        i. How do you create an effective study design?
        ii. What are the costs?
        iii. How do you quantify the benefit for employees, customers, the company?
        iv. How can results from recent FDA Risk Factor Studies be leveraged, e.g., over 60% fewer high-risk issues when managers had strong knowledge of their FSMS?
    b. What is the value proposition in terms of risk mitigation? In terms of quality?
        i. The cost avoidance of prevented foodborne illness outbreaks due to implemented FSMSs.
    c. Create a cost benefit analysis example to educate operators on the benefits of implementing FSMSs. Leverage the Retail Food Safety Regulatory Association Collaborative's "Active Managerial Control Incentive Programs Assessment Report" as a model. (Possibly engage the Collaborative to conduct this work.)
    d. Fund pilot programs to study and quantify the impact of implementation of FSMSs in the real world. Then publish results as detailed cases studies with costs, benefits, and lessons learned.
    e. Leverage the cost benefit analysis to organize and sponsor a collaborative marketing campaign aimed at operators around the cost benefit analysis to encourage voluntary adoption. Publicize through Collaborative and Industry organizations to ensure broad communication across stakeholders.
    f. Provide tools to educate regulatory food inspectors on how to leverage the cost benefit analysis when working with operators to encourage voluntary adoption of FSMSs.

People Solutions

1. Buy-in Barriers

a. For regulatory agencies and industry trade organizations to conduct a general cost benefit analysis for Code Compliance inspections and inspections focused on Risk Based incorporating FSMSs. Identify the return on investment for each type of inspection:
    i. Include stories and case studies of actual foodborne illnesses.
    ii. Create a sample business case that includes benefits to employees, customers, organization, quality, risk mitigation and costs, etc.
    iii. Reframe the role of FSMSs as a good practice that supports other elements of an operation, such as employee retention, training, cost controls to support and market FSMSs.
    iv. To conduct a study of actual costs of implementing FSMSs by the industry with impact changes.
    v. To conduct a study of actual costs of implementing FSMSs training and policy by the regulatory agencies doing risk- based inspections with impact changes as compared to Code Compliance inspection costs.
    vi. Develop simple communication messages that can be used to influence upper leadership. Communicate previous situations where companies did not invest and the negative effects. Several well-known examples exist. The use of facts and statistics can support the messages and can be used as a persuasion tool to increase interest in and creation of a FSMS.
    vii. Use the cost benefit analysis to educate the operator on reasons why they can't afford not to implement a comprehensive FSMSs designed to control hazards associated with foodborne illness risk factors in their businesses.
    viii. For regulatory authorities and industry members to build relationships focused on risk factors and FSMSs via networking meetings, new business start-up kits, virtual meetings, advisory group meetings…coffee with your health department, etc.
b. Identify individuals or groups of individuals within a food facility of industry and/or regulatory community that are food safety ambassadors and advocate for safe food handling practices and procedures that support FSMSs across the industry.
c. Increase in industry member awareness and participation in food safety as it relates to their job.
d. Recommend industry training of front-line workers incorporate the "FDA Retail Food Protection Industry Education Materials -Posters and Videos" into their new hire training plan or use similar training material that illustrate the consequences of poor behavioral food safety practices along with traditional training that describes how to do the procedure correctly.
e. Encourage regulatory agencies to conduct risk factor studies that use Food Code critical limits as part of the study of regulated businesses on a routine basis in partnership with the industry. Identify risk factors in need of priority attention, develop intervention strategies designed to control those problematic risk factors and publicize the initiative and results within the community.
f. Encourage regulatory agencies to implement the criteria in the FDA Voluntary National Retail Food Program Standards for improving their food programs.

g. Regulatory partners should provide outstanding customer service by being helpful and providing appropriate resources to the industry that support the implementation of a FSMS as part of their permit in a consistent and dependable manner.
h. Food safety regulators should tell stories of actual foodborne illness cases studies during their inspections to encourage industry member buy-in of implementing FSMSs. Use social media and commercials to increase industry and consumer awareness about the correlation between FSMSs and compliance of risk factors and how implementation of FSMSs can make a difference. Get statistics to support this message from FDA, CDC, Olmstead County, MN, and other agencies.
i. Consider the use of incentive programs or other systems that motivate good food safety practices. These motivators could include, but may not be limited to: public recognition, certificates/awards for achievement, positive feedback on inspection reports, etc. Examples:
    i. Inspector following up every month or so for first 6 months to a year to support Risk Control Plan for FSMS implementation.
    ii. Incentive programs for AMC of risk factors that includes model templates and examples which are easily accessible by industry members and regulatory authorities. The Retail Food Safety Regulatory Association Collaborative has examples at these links:
    https://ActiveManagerialControlincentiveProgramsAssessmentReport-RetailFoodSafetyCollaborative
    https://www.retailfoodsafetycollaborative.org/tools/active-managerial-control-incentive-programs-examples-from-jurisdictions-leading-the-way
j. Regulatory agencies recognize industry efforts who implement FSMSs successfully in their businesses. For example, regulatory agency could develop web-based public recognition of the business so it pops up whenever someone electronically searches for that business which can be removed by the regulatory agency as necessary. Another example -industry who implements FSMSs and control all hazards associated with foodborne illness risk factors that are in compliance at the time of regulatory inspections might get a permit fee reduction or inspected less frequently if they are routinely in compliance.
    i. Identify incentives for regulatory agency using FSMSs. For example -Inspectors who routinely provide training on FSMSs during inspections might get recognition from their Agency, especially if they are making a difference in their district.
    ii. Include FSMSs component in the application for the Crumbine Award and other state/national awards to recognize regulatory agency efforts in promoting the implementation of FSMSs by the regulated industry and getting improved long-term compliance of risk factors

2. Leadership/Accountability Solutions

a. Provide free guidance and resources through multiple collaborations (FoodSHIELD, Retail Food Safety Collaborative, FMI, NRA, etc.)
b. Encourage both bottom-up and top-down approaches to training, education, and communication on the importance of FSMSs. Create accountability at all levels for well-developed and executed FSMSs.
c. Food service establishments may consider hiring a consultant with expertise in FSMSs to assist in the development, execution, and improvement of the facility FSMS.

d. Define routine corporate level food safety reporting to the Corporate Suite along with recommendations for improvement.
e. Regulatory inspections can support industry efforts in implementing their FSMS by assessing compliance of hazards associated with foodborne illness risk factors at the time of inspection as priority over good retail practices in their limited time

3. Values Solutions

a. Build relationships between regulatory authorities and industry members so they:
    i. Share a common goal to focus on AMC of risk factors and FSMSs.
    ii. Educate on what a FSMS is and how to build/apply/improve.
    iii. Work collaboratively on solving problems around the control of hazards.
b. Regulatory inspectors can support industry efforts in implementing their FSMS by assessing compliance of hazards associated with foodborne illness risk factors at the time of inspection as priority over good retail practices in their limited time.
c. During and after Plan Review:
    i. Recommend industry use preoperational plans and/or inspections as a time to discuss FSMSs with the regulatory authority. Include a review of facility construction and design; menu items and food preparation process based upon how many times a menu item moves through the temperature danger zone, which is between 41 F and 135 F; food handling practices and behavior that may affect equipment needs and facility layout; training and education provided by whom; and current SOPs to support a comprehensive FSMS.
    ii. Operators are encouraged to work with their inspector to identify alternative food safety practices and behaviors to control hazards associated with foodborne illness risk factors after opening day as necessary. Such as, changing from a complex food process that involves cooling and reheating to same day service process that shouldn't require as much refrigeration or facility space.
d. Encourage food safety regulators to engage with food handlers and managers during inspections to explain the importance of food safety concepts using relatable language and storytelling, to foster understanding and buy-in of FSMSs.
e. Recommend regulatory authorities provide classroom and/or field training during onsite inspections that includes education for the industry using the "FDA Retail Food Protection Industry Educational Materials -Posters and Videos" or similar training materials that illustrate the consequences of poor behavioral food safety practices along with traditional training that describes how to do the procedure correctly. Additional option is to conduct/offer virtual training sessions/solution meetings" (This would allow for individualized interaction/topic specific training tailored for the operators needs/deficiencies. While still building the positive relationship between regulatory and business) - may also be a helpful tool to accommodate businesses who operate on second and third shifts.
f. For regulatory agencies to update their inspection reports and standardization procedures to include the assessment of FSMSs. For example, Olmstead County, MN developed a PTV Package (Discussion and Observation Guide and information poster showcasing the results of two in-depth studies) that they use, make appointments with the manager to sit down and have a discussion about food safety during non-busy time. They first began developing

their program in the late 1990's. Another example is FDA FSMSs assessment of foodborne illness risk factor areas to identify correlations between PTM and compliance of risk factors during their most recent risk factor studies.

g. Regulatory to look at incorporating/developing a separate consultative service who work exclusively with industry to assess/develop FSMSs. This division would operate separate from enforcement. OSHA and State OSH programs utilize this concept very effectively for workplace safety -examples: https://www.osha.gov/consultation, http://169.62.82.230/documents/dleg/.wsh_cet0165_216929_7.pdf. MIOSHA for example also utilizes an Alliance program to partner with organizations/businesses to promote/reward safety practices. http://www.agcmichigan.org/uploads/.1/0/6/5/106585507/infosheet_onsite_consultation_services_guideline.pdf. For the alliance, Associations like ASSP (American Society of Safety Professionals) has local chapters that will partner/sign an alliance with MIOSHA to promote and provide community-based services to members/nonmembers and community. This concept could be used/developed to promote effective FSMSs.

4. Cultural/Ethnicity Barrier Solutions

a. Encourage the use of translation services and/or storyboards to effectively communicate messages in multiple languages. The storyboards should illustrate the consequences of the improper food safety practices behavior as well as the desired food safety practices behavior. As an example, the FDA worked collaboratively with many regulatory agencies and industry members to develop storyboards in multiple languages for foodborne illness risk factors.

b. Seek feedback for solutions from other industry peers, food associations, your HR department, Risk Management, and Insurance Providers (as both of these divisions have enormous amounts of data, statistics, program assessments, stories, etc.) etc.

Training Solutions

1. Training Solutions

a. Provide training materials
   i. Assess current FSMSs implementation and focus on vulnerabilities/gaps
   ii. Illustrate the consequences of poor behavioral food safety practices
   iii. Traditional training materials for front line employees based on their job responsibilities

b. Recommend regulatory agencies
   i. Be trained in FSMSs process to be a valuable resource and provide support to the industry for training, materials, consultations, etc.
   ii. Promote incentive programs to facilities with FSMSs leading to decreased inspection frequency
   iii. Evaluate FSMSs during the plan review process
   iv. Assess the uniformity of FSMSs based on the operations and food processes
   v. Include FSMSs in risk classification, potentially leading to less frequent inspections for well-managed locations.

c. Update FDA OTED courses (FD215, FD218, FD312) as necessary to include what a FSMS is, how to verify during routine inspections, and how retail food inspectors can provide guidance on FSMSs to the operator based on inspectional findings.

d. Update CFP Field Training Manual to include verifying knowledge of FSMSs on the Training Plan and evaluate understanding on the Training Worksheet.
e. Update FDA Standardization Procedures to include verification that the candidate has an understating of FSMSs as a performance area.
f. Request SME when reviewing the job task analysis for the CFPM exam to determine if knowledge development of FSMSs should be expected of every CFPM/PIC

2. Knowledge Solutions

a. Increase awareness of the need for FSMSs through a marketing campaign including:
    i. Major causes of foodborne illness in retail
    ii. Control of hazards associated with foodborne illness risk factors
    iii. Use of case studies
    iv. What success looks like in different types of businesses/sizes (risk factor PTM data)
    v. Promote continuous improvement of food safety programs

3. System Development/SOP Solutions

a. Develop an operational toolbox
    i. Create a FSMS Team and assign roles/establish ownership and accountability
    ii. Implementation guidance document (promote parallel development of FSMSs during startup of retail food businesses),
    iii. User friendly/easily implemented training aids,
    iv. Templates,
    v. Coaching and communication, accountability ideas, reinforcement approaches
    vi. Create a tiered system of tools based on establishment processes (considering independents/small chains to large corporate/franchisee)
b. Include ""Managing Food Safety -A Manual for the Voluntary use of HACCP Principles for Operators of Food Service and Retail Establishments"" as a resource
c. Use available resources such as: state/local regulatory authority websites, CFP, universities (i.e., NC State, University of FL, University of GA), professional organizations (IAFP, NEHA, AFDO, NACCHO), Key service providers, Business associations (FMI, NRA, etc.)
d. Review, update and streamline info in Annex 4.
    i. Focus on process with flexible approach rather than prescriptive
    ii. Define elements of FSMSs
    iii. Explain what is foundational vs. best practices
    iv. Explain how to apply principles
    v. Link FSMSs to Inspections

CHARGE 3: PROS/CONS ASSESSMENT SOLUTIONS

PROS of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code.

1. FSMSs are very beneficial because research documenting a PIC's strong working knowledge of their FSMS correlates to fewer occurrences of foodborne illness risk factor violations during an inspection. These findings were highlighted in various studies including but not limited to FDA Risk Factor Studies.

2. Operators understand the food safety hazards in their processes and how to control them which would advance AMC and reduce risk factor violation occurrence and prevent foodborne illness.
3. Having all operators and regulatory agencies working toward this common goal of voluntary FSMS implementation could encourage collaboration across the industry and regulatory community. A minimum expectation of FSMSs that control risk factor occurrence can be identified with specific goals for respective partners.
4. Developed and implemented FSMSs have the potential to make onboarding and training new employees easier for industry and regulatory staff.
5. Requiring FSMSs would allow for review of operational components and evaluation during plan review providing regulators and operators with earlier intervention and educational opportunities.
6. Flexible FSMSs could foster an effective food safety culture.

CONS of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code.

1. FSMSs are an emerging topic in retail food not widely understood. There is a need for training of regulators and industry on the concept of developing, evaluating, and assessing FSMSs with an emphasis on how FSMSs may differ to address the differences in corporate infrastructure and diversity within the retail and food service industries prior to including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code.
2. The requirement for the development and implementation of documented FSMSs in a future edition of the Food Code would be difficult for many. Some reasons include:
    a. Small businesses just starting out, or businesses with English as second language to may have limited resources to develop FSMSs.
    b. One size does not fit all types of operations that are regulated under the Food Code.
    c. Extra resources to ensure fairness and equity among types of food establishments would be needed.
    d. It will be a challenge to write the requirement in such a way that all types of operations (large national corporations, to non-English owner operator facilities) will be able to comply with the requirements.
    e. If implemented FSMSs are too simple, it may not achieve the outcome of a well written plan that results in active managerial control.
3. Regulators would need the training and experience and program infrastructure to evaluate/assess the customized and individual FSMSs. In addition, there would need to be an agreement/understanding that format and content is operationally specific and would not have to exactly match a model template or Annex 4.
4. Crafting the verbiage to allow enforceable language may be difficult.
5. This could add time or cost to health departments food programs, and create industry push back/variance requests, etc.
6. It is a large project for any company or location. Many people are likely unfamiliar with the term, so making it "required" will be a large step. This is especially true if the requirement includes that FSMSs be documented. Industry may view this as overregulation even though many are already doing it. If it starts as voluntary, large organizations might pave the way and

create example systems that smaller operators can use as templates. Perhaps industry groups could be leveraged to facilitate this process and openly share examples.

7. The cost to industry to develop FSMSs and the cost to regulators to review industry FSMSs for compliance.
8. Jurisdictions that adopt the food code could exclude or modify this provision, resulting in inconsistencies.
9. Brands may not want proprietary documents and components of their customized FSMS shared in a public document such as a plan review.

2021-2023 CFP
Food Safety Management System (FSMS) Committee

Meeting Number: 1
DATE: November 16, 2021
TIME: 3:00 EST

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisors: Jessica Otto and John Marcello
CDC Advisor: Beth Wittry and Mark Otto
Scribe: Christine Sylvis

Agenda

	AGENDA ITEM	PRESENTER	
1.	Welcome, Call to Order	Christine Sylvis and Mandy Sedlak	
2.	Rollcall	Christine Sylvis	
3.	Conference for Food Protection, Inc. Antitrust Statement	Mandy Sedlak	
4.	Food Safety Management Systems Definition	Christine Sylvis	
5.	Review of Committee Charges	Christine Sylvis	
6.	Review CFP Timeline for Committee Work:	Mandy Sedlak	
7.	Suggested Schedule	Mandy Sedlak	
8.	Overview of Committee Working Plan	Mandy Sedlak & Christine Sylvis	
9.	Action Items	Christine Sylvis	
10.	Next meeting date	December 14, 2021	

MEETING MINUTES:

1. **Meeting Called to Order:**
   - Sylvis FSMS Committee meeting called to order at (time),

2. **Roll Call FSMS Committee:**
   - Roll Call Conducted by Christine Sylvis
     - Co-chair introduction
     - Voting Member introduction
     - FDA Consultant and Alternate introduction
     - CDC Consultant and Alternate introduction
     - Non-Voting Member introduction
   - *See attendance spreadsheet*

3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Read by Mandy Sedlak
     - Moving forward, statement will just be referenced
     - PowerPoint will be kept so statement can be referenced at any time. A copy will also be placed in FoodShield.

4. ***Food Safety Management Systems***
   - Definition of FSMS along with resources
   - References to what committee will be discussing in the next year

5. **Review of Committee Charges:**
   - 5 charges

        - First charge tentatively due January 2022
    - First charge: Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.

6. **Review CFP Committee Work Timeline/Calendar:**
    - March 2022
        - Reports for Executive Board Meeting due to ED
    - July 2022
        - Reports for Executive Board Meeting due to ED
    - November 2022
        - Final Committee Reports and prospective Committee Issues due to Council Chairs for preliminary review
        - Revised Final Committee Reports and Issues submitted to Issue Chairs for preliminary review and comment
    - December 2022
        - Issue Submission for 2023 Biennial Meeting opens online for 30 days

7. **Suggested Schedule**
    - Deadline is November 2022 for 2023 Council Meeting
    - Exactly a year to get 5 charges completed
    - Tentative/Suggested Schedule
        - First Charge complete by January 2022
        - Second Charge Complete by April 2022
        - Third Charge Complete by July 2022
        - Fourth Charge Complete by October 2022
        - Final Committee Report Due November 2022

8. **Overview of Committee Working Plan/Administration/Meetings:**
    - Monthly Schedule; 2:00 pm CST every third Tuesday
    - Meeting Frequency?
        - starting out monthly and adjusting as needed
    - Each charge might have separate meeting
    - Meeting Platform?
        - Teams Meeting acceptable
    - Shared Documents?
        - Set up FoodSHIELD group and invite team members

9. **Action Items/Next Steps**:
    - Verify that FoodSHIELD works.
    - Send out Teams invitation for December 14, 2021 with a backup link
    - Identifying barriers – first committee charge before talking about hurdles to overcome them (second charge).
    - Put a live document on FoodSHIELD to add in barriers for first charge.
    - Feedback by December 13, 2021 for next meeting on December 14, 2021.

10. **Next Meeting Date**:
    - December 14, 2021

2021-2023 CFP
Food Safety Management System (FSMS) Committee

11. Identify a Scribe for 12/14/21 meeting:
- Todd Rossow

Meeting Number: 2
DATE: December 14, 2021
TIME: 3:00 – 4:00 pm EST

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisors: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Todd Rossow

Agenda

11. Welcome, Call to Order		
12. Rollcall,	Christine Sylvis	
13. Conference for Food Protection, Inc. Antitrust Statement	Mandy Sedlak	
14. Identify a Committee Scribe:	Todd Rossow	
15. Review CFP Timeline for Committee Work:	Mandy Sedlak	
16. Review of Committee Charges:	Mandy Sedlak	
17. Overview of Committee Plan of work:	Mandy Sedlak and Christine Sylvis	
18. Action Items:	Christine Sylvis	
19. Determine next meeting date:	January 18, 2023	

MEETING MINUTES:

1. **Meeting Called to Order:**
   a. Second FSMS Committee meeting called to order at (time),
      i. Motion accepted (identify members). Todd motioned to open the meeting with a Second by Mark
2. **Roll Call:**
   a. Roll Call Conducted by Christine - She has a maintained spreadsheet of the voting and (alternate) non-voting committee members
3. **Conference for Food Protection, Inc. Antitrust Statement**
   a. Mandy referred to this document and that it is posted to our FoodSHIELD site.
4. **Identify a Committee Scribe:**
   a. Todd was identified as the scribe for this call.
5. **Review CFP Committee Work Timeline:**
   a. Mandy reviewed the Suggested Schedule from the 20211116 presentation
   b. We are currently reviewing Charges 1 to the Barriers to the universal development and implementation of documented FSMSs consistent with Annex 4 of the Food Code. – January 2022
   c. We also reviewed the expected deliverables from the Charge on April 2022, and those due on July 2022, Oct 2022, and the final report due November 2022.
   d. Meeting invites are to be sent out to all with the defined schedules
   e. Meeting was requested to be recorded
6. **Review of Committee Charges:**
7. **Overview of Committee Working Plan:**

a. We will maintain the original direction to hold monthly calls and follow the Schedule to address the Charges.
b. We discussed the AFDO Food Safety Management Survey worked on in conjunction with the FDA Retail Food Safety Regulatory Collaborative
    i. Elisabeth Nutt and John Marcello shared some highlights of the survey.
    ii. The survey was constructed by an AFDO cross-functional working group.
    iii. It has 2 Parts – Part 1 (Food Safety Culture and Employee Health Policy) and Part 2 (Active Manager Control and Food Safety Management Systems).
    iv. The last part of the survey was sent out Dec 1 and will close out at the end of 2021.
    v. Survey was sent to industry and key associations (National Restaurant Assoc, National Association of Chain Restaurants, FMI, Grocers Assoc, etc.) These associations relayed the survey out to their member.
        1. Comment – AFDO should consider sending the survey to State associations too.
    vi. The survey was also sent to key food industries (grocery, C-stores, restaurants, etc., both large and small).
    vii. The survey results will be used to find best practices, what is the industry doing and what are they not doing around these four topics.
    viii. Data to be available at the end of March 2022.
    ix. The FDA Retail Food Safety Regulatory Collaborative objectives will be shared with the CFP FSMS committee. These results of the survey will help support the New Era of Smarter Food Safety as part of FDAs initiative.
    x. Part of the Retail Collaborative Grant is to pursue FSMS and AMC.
    xi. There are no direct connections of the survey questions to the CFP FSMS committee. The Committee can look at the questions and which may best serve the CFP FSMS committee. Elisabeth Nutt will share with the committee the survey questions.
    xii. Again, the results from the survey will be back in the spring of 2022 and will be shared with the CFP FSMS committee.
c. Submit the barrios and solutions, not all members submitted. The summitted comments shared so far were reviewed.
d. Food Shield Overview to see the submitted – Foodsheild.org
e. Go to Groups and see the groups you are part
f. Christine reviewed the committee's folder and where out documents are located
g. There are still some that can't gain access to FoodSHIELD. Email Christine if you are having issues gaining access.
h. John Marcello – He shared some about the AFDO survey on behave of the Retail Collaborative. The survey data collection will be completed by the end of Dec and will have some results to be shared at the January meeting, primarily about Best Practices.
i. The committee members were asked to review the barriers submitted.
j. We need to consider a White Board to collect some common ideas to Barriers.

8. Action Items:

a. Set up a small subgroup to review the Barriers and Solutions comments and help bucket for best organizations. The following volunteered to help. (Venessa B and Jeff J). Others interested should connect with Mandy and Christine. **Christine and Mandy** will set up a call to review these items for consolidation.
b. **Christine** will get the excel sheet with the committee members recorded Barriers and Solutions posted to FoodSHIELD. Each week she will update with additional feedback.

c. **All committee members** should review the Charges, go to FoodSHIELD and review the recorded Barriers and Solutions and be prepared to contribute to the conversation on the January call.
d. **Elisabeth Nutt** will share with the committee the AFDO survey questions.

9. **Motion to adjourn** – Troy H made a motion and second by Mark S.
10. **Next Meeting Date**:
    a. January 18, 2022.
    b. Linda Z will be the scribe for this coming meeting in January (Venessa B also stepped up to help, if needed (via Chat)

Meeting Number: 3
DATE: January 18, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisors: Jessica Otto
CDC Advisor: Beth Wittry (Jona Johnson filling in while Beth Wittry on leave)
Scribe: Linda Zaziski

Agenda

20. Welcome, Call to Order	Christine Sylvis	
21. Rollcall	Sylvis/Sedlak	
22. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
23. Review barriers identified	Mandy Sedlak	
24. AFDO Industry Survey Overview	Mandy Sedlak	
25. Action Items:	Mandy Sedlak and Christine Sylvis	
26. Next meeting date: February 15, 2021 3:00pm EST	Christine Sylvis	

MEETING MINUTES:

1. **Meeting Called to Order:**
    a. Third FSMS Committee meeting called to order at 3:01pm EST
2. **Roll Call:**
    a. Roll Call Conducted by Christine Sylvis, documented by Mandy Sedlak
3. **Conference for Food Protection, Inc. Antitrust Statement**
    a. Reminder by Christine Sylvis
4. **Review barriers to the universal voluntary development and implementation of documented FSMSs identified**
    a. Subgroup met to identify "categories" of barriers and are working on grouping
        i. 97 barriers have been initially identified
        ii. Categories for barriers identified: economics, training, processes, accountability, people
            1. Sub-committee Divided document into 3 main buckets to assist in consolidation/analyzing/organizing
                a. **Economics** (resources, cost, time, equipment)
                b. **People** (buy-in, staffing, cultural)

                Training (Knowledge of Regulators and Industry) System Development, SOPs Accountability (leadership)
    b. Next Steps:

i. Review barriers Get through barriers by end of January 2022
ii. Address Solutions component: Target Date: April 2022

5. **AFDO Industry Survey overview:**
   a. Presented by Elizabeth Nutt
      i. Background:
         1. Task for collaborative to look at food safety culture
         2. Help industry and regulatory what is active managerial control and what is needed for a good food safety system.
         3. Mick Micklos; NRA, FMI, NCS, NCRS. Industry input 4-part survey management systems, employee heath, food safety systems, food safety culture.
         4. Roll-out done in 2 installments. (Early Nov/2nd Part just closed 1/10)
         5. Iowa State validating survey, looking at how and which data can be used/comparisons
         6. Survey taken by – IAFP, Industry Trade Organizations, AFDO
      ii. Types of Questions
         1. Questions shared with the group
         2. Surveys to be posted to Food Shield. – for committee use.
      iii. TBD – how to use data: actionable, best practice
      iv. Looking to distribution to regional facilities or single operators. To get a good cross functional look to see where these groups are at.
      v. TBD: Findings Report-out. Collaborative wants to convene face-to-face meeting w/industry leaders to share findings/work groups, publication to follow.
      vi. Information may be useful for charges of this committee. – independent research and initiatives can add value to each other
6. **Action Items**:
   a. Subgroup to group barriers and review to consolidate
   b. Committee to review barriers and solutions by next meeting. Provide suggestion to edits/additions
   c. Entire Group - To review barriers before meeting
7. **Next Meeting Date**:
   a. February 15, 2021, 3:00pm EST
   b. Identify a Committee Scribe: Linda Zaziski
   c. Meeting ended 3:25pm; Subgroup stayed on to work on barrier consolidation

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Meeting Number: 4
DATE: February 14, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak
FDA Advisors: Jessica Otto
CDC Advisor: Beth Wittry/Jen Otto
Scribe: Linda Zaziski

Agenda

27. Welcome, Call to Order	Mandy Sedlak	
28. Rollcall	Mandy Sedlak	
29. Conference for Food Protection, Inc. Antitrust Statement	Mandy Sedlak	
30. Review CFP FSMS Solutions Pro/Cons Next Steps 20220209	Mandy Sedlak	

31. Comments/Discussion/Formatting; Solution Considerations Next Steps	Mandy Sedlak	
32. Action Items: See minutes	Mandy Sedlak	
33. Next meeting date: March 15, 2021 3:00pm EST	Mandy Sedlak	

MEETING MINUTES:

1. **Meeting Called to Order:**
    a. Forth FSMS Committee meeting called to order at 3:04pm EST
2. **Roll Call:**
    a. Roll Call Conducted/Documented by Mandy Sedlak
    b. Christine is on vacation
3. **Conference for Food Protection, Inc. Antitrust Statement**
    a. Reminder by Mandy Sedlak
4. **Review Committee prepared excel: CFP FSMS Solutions Pros/Cons Next Steps 20220209**
    a. Woot! Woot! Shoutout to the participants of the subcommittee
        i. **Feedback regarding the solutions pro/con next step document**
            1. Concern: Under training barriers: FSMS is currently not clearly defined as a universal term consider prioritizing as most important
                a. Jessica Otto to provide terminology used in the recent surveys.
                b. Elizabeth – Risk factor 'pillars of risk factors" Policy/Procedures in writing, training and Follow-up Accountability
                c. Important not to confuse performance systems reactive control/active managerial control. Active managerial definition is laid out in Annex 4.
                d. Some confusion has been noted regarding Annex 4; culture, food safety management systems and active managerial control
                e. **ACTION: First Priority of Next Working Group**- Better define/Clarify definitions in Annex 4 (Food Safety Culture, Food Safety Management Systems and Active Managerial Control)
                    i. Question are we taking a regulatory approach or an industry approach. Looking at 2 different approaches to the same thing. Voluntary vs Regulatory how is supporting industries efforts to develop a food safety management system.
                    ii. Picture may become clearer once definitions are clarified – differences and similarities between food safety culture, management systems and active managerial control.
                    iii. What are action items that industry can do? What can regulatory do to support? Within the Deli Study as an example: There were 2 steps that were leaned in on: one for industry and one to regulators.
                    iv. Elizabeth Nutt – Update: Industry survey has been closed, sent to Iowa University for assessment. Information to be shared with group as it becomes available.
                    v. Focus on how industry defines
                    vi. Volunteers sought for working group. Suggested meeting date March 1 3:00pm EST
        ii. **Formatting**
            1. Some struggles: Some of the items crossed over to multiple buckets (People, Training, Economics)
            2. Still open for formatting comments, suggestions

iii. **Solutions**
1. **ACTION** – send solution suggestions over to Mandy and Christine to capture in master document.
   a. Review barriers and how they are classified
   b. Can put solution suggestions next to the barrier or in format that is easiest for you.

b. **Next Steps:**
i. **Sub Committee to work on/develop definitions from Annex 4 – Mandy to set up meeting**
ii. Review barriers submit solutions for capturing in the master documents.
iii. Continue to Address Solutions component: Target Date: April 2022

5. **Action Items**:
   a. **Definition Subgroup–** Mandy to set up; March 1, 2022, at 3pm EST
   b. **Entire Group** to review barriers document. Submit solutions to Mandy/Christine by next meeting

6. **Next Meeting Date**:
   a. March 15, 2021, 3:00pm EST
   b. Identify a Committee Scribe: Linda Zaziski
   c. Meeting ended 3:40pm

Meeting Number: 5
DATE: April 19, 2022
TIME: 3:00pm EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisors: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

1. Welcome, Call to Order	Christine Sylvis	
2. Rollcall,	Christine Sylvis	
3. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
4. CFPM and AMC Definitions	Christine Sylvis	
5. Action Items:	Christine Sylvis	
6. Next meeting date: May 17, 2022, 3:00pm EST	Christine Sylvis	

MEETING MINUTES:

1. **Meeting to Order:**
   - Sixth FSMS Committee meeting called to order at (3:02pm),

2. **Roll Call:**
   - Roll Call Conducted by Christine Sylvis
   - Mandy Sedlak not able to attend. Kudos given to Alternates for participating/attending 😊
   - 8 voting members present. No Votes anticipated

3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis

4. FSMS and AMC Definitions

- Review FSMS and AMC Definitions from workgroup 4/14/21
  - Definition documents sent to group. Document is available on the CFP team site for FSMS
  - Committee agreed the CFP AMC definition was a good definition.
  - Some additional sources with additional information – subcommittee, comments, FDA and some references to risk factor studies in delis and other references w/links that have other documents that have similar information in them. Marking instruction on procedures training and monitoring.
  - Definition of FSMS and Procedure (oral/written) w/ examples, Training/Monitoring to follow same example. Notes/Thoughts can be found on document – not full sentences, just thoughts/work in process (so concepts and ideas did not get lost.
  - Consider have one-line definitions with examples listed below and have an example that would show steps from procedure to monitoring/training.
  - Floor opened for discussion:
    - Question asked: Written/verbal – do we need to include these for monitoring
    - Group left off - with training.
    - Monitoring was next bucket to be looked at. Definition was taken from the risk factor study. Has not been word-smithed yet.
    - Suggestion: Use similar language under procedures for monitoring (for consistency purposes) Example could be digital thermometers to tie monitoring piece into paragraph.
    - Monitoring may be more visual then oral.
    - Monitoring – assess knowledge of person; are they following the concept. Can we incorporate 'assessing knowledge'
    - All for ease of system, monitoring just an oral/visual process or is it recorded to ensure that it is being completed. Or are we placing that at the AMC level?
    - FSMS – continuously improved, wrapped up to include continuous improvement process.
    - Monitor and verify. If do not record will be difficult to get to improvement part. Feel recording should be included. Hard to prove or demonstrate corrective action effectiveness w/o proof.
    - Go back to written procedure that monitoring would meet the intent. What's going to differentiate accidental vs purposeful. Procedures like training could be stepped not necessary as an essay in paragraphs.
    - Wall charts and job aids can be part of training
    - Looking at definition – training procedures and monitoring. Putting it into a procedure basics then put into next steps of training, monitoring and improvement. Current definition is a bit confusing.
    - Can have written procedure or can have an oral procedure - i.e. this is how you wash your hands (opposed to written) but would have either demo by PIC or posted job aides/posters. Training how you give information to food employees.
    - Group thinks that oral should be taken out… not sure how to monitor oral
    - Would be challenging for manager to document handwashing; so visual would be a good way to assess/monitor. Lends flexibility
    - Perhaps general statement conducted visually; records of monitoring are the best way to verify completion/compliance.
    - Couldn't record be just a yes or no; wouldn't that be an acceptable record?
      - Depends on how specific the group wants to get
      - Applicable as we can get to put into action in establishment
    - Example from Mark (from chat box) was dropped into Christine's working documents.

- Question: Are we trying to move beyond oral procedures? Ideal or goal would be to have written but oral procedures would be acceptable – this would impact all food establishments, not just restaurants.
- Really looking at how process would be applied.
- Suggestion: Monitoring example for digital temperature where logs, review process by PIC during their shift may be a good place to include these concepts.
- Caution: The more we include - written records, may lose those who truly work in an oral culture. Documented is stronger, but oral is a FSMS. Does not seem like the message we want to say. A well-developed written FSMS is one thing; but oral culture can be a FSMS
- Isn't this in fact one of the barriers that we need to overcome and work through
- For FDA to develop a system that can be used by everybody. Maybe we need to encourage that next level of FSMS.
    - Some mom/pop shops struggle. The monitoring piece is crucial and makes a difference. Know what they are supposed to be doing, but monitoring is not happen. Agree with some of written, some of monitoring should be written. Not necessarily one size fits all. Some may allow documenting others may not (i.e., air monitoring). Is there a way to say that? Written procedure on how something is monitored.
    - Would have something to verify against.
- Is next level having a written process? Is that our charge? Yes, charge does say written FSMS.
- May be conducted visually, monitored with a goal of having a well-documented FSMS program. (i.e., tying in hand washing poster with steps as an example)
- Combination of things – regulatory remember history. Elements of good FSMS and HACCP, inroads of concepts to incorporate. All or nothing. Developing the tools to do root cause analysis. Businesses along process – where are they will be based on how you ask the questions. I.e. some may have written/training may need emphasis on monitoring. Elements can assist in incrementally improving FSMS
- Visual and recording. Procedures and Training then implement more visually. Routine/process then institutionalize and introduce charts/systems that work for the operation. Validation doing process reaches the validated method to ensure the process works and works for the operation.
- Consider using terminology "move towards' opposed to 'have'
- Incorporate the goal, complete and consistent primarily written.
- Examples provided – do we like list? edits, removal, additions?

5. **Overview of Committee Working Plan:**
    - Button up definitions, send out to group for review
    - Christine/Mandy to send out email requesting participation/meeting dates to continue work on solutions to barriers.

6. **Action Items**:
    - Next Steps:
        - Christine to massage examples make sure everything matches; will send updated document out to group.
        - Heads up – We are coming up to our deadline to review 'solutions' for FSMS
        - Completed first set of barriers, next step to work on solutions then move on to pros/cons;

- Additional dates/sub-committee meetings may be established/sent out to begin this work prior to the next formal meeting. All are welcomed to join/participate.

7. **Next Meeting Date**:
   - May 17, 2022, 3:00pm EST
8. **Adjourned at 4:02pm EST**

Meeting Number: 6
DATE: May 17, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

1. Welcome, Call to Order	Mandy Sedlak and Christine Sylvis	
2. Rollcall	Mandy Sedlak and Christine Sylvis	
3. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
4. Review work completed by working group on Solutions/Next Steps	Mandy Sedlak	
5. Review Final Definition of Food Safety Management System	Mandy Sedlak	
6. Review of Committee Charges	Mandy/Christine	
7. Overview of Committee Plan of work	Mandy	
8. Action Items	Mandy	
9. Next meeting date:	Christine/Mandy	

MEETING MINUTES:

1. **Meeting Called to Order:**
   - 7th FSMS Committee meeting called to order at 3:02pm
2. **Roll Call:**
   - Roll Call Conducted by Christine Sylvis, documented by Mandy Sedlak
3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis
4. **Review work completed by working group on Solutions:**
   - Meeting 5/13/22
   - New sheet “Solutions full list” on working Excel document. Updated version in Food Shield 2022-0516.
   - Decided on format of “Solutions” - Assign solutions into 3 barriers “buckets” (color coded)
     - Economic (blue)
     - People (yellow)
     - Training (green)
   - Visual representation shared with attendees on meeting. Various workbooks on workbook.
     - Created new page. Decide How to propose the solutions
     - Using the 3 lists Barriers, People and Training have one list for each set of solutions for these barriers

Solutions next steps:

- Divide into 3 groups to work on solutions, one group per bucket. To locate document: Working, Barriers, Solutions Workbook – go to versions and download. 2.0 version; most current version will have all columns filled out.
- Group Leads: Chris Boyles – Economic; Lisa Whitlock – People; Mandy – Training
- Working groups for each bucket – attached below.

Economic		Training		People	
Chris	Boyles	Elizabeth	Nutt	Mark	Speltz
Sean	Dunleavy	Dan	Okenu, Ph.D.	Dan	Tew
Jeffrey	Edelen	Susan	Quam	Shelly	Wallingford
Jeff	Jackson	Todd	Rossow	Lisa	Whitlock
Naomi	Macias	Heather	Sanders	Yolanda	Woods
Monique	Crawford	Colleen	Smith	Linda	Zaziski
Vanessa	Bussiere	Martin	Flusberg	Melissa	Smith
Herman	Crawford, Ed.D.	Hsing-Yi	Hsieh	Laura	Temke
Theodore	Dohnal	Troy	Huffman	Laura	Wildey
Ashley	Eisenbeiser	Evelin	Pollock	David	Wilson
		Mario	Seminara	JEREMY	ZENLEA

- Review Solutions, decide if appropriate, combine like Solutions, wordsmith as needed
- Original milestone to have Solutions completed: April 2022 (Note: We are a bit behind to work on definition of food safety management systems)
- Goal: Complete Solutions lists by May 31, 2022 and return to Mandy Sedlak and Christine Sylvis.
    - An updated version will be sent to the full committee for review.
    - Mandy Sedlak and Christine Sylvis are available to schedule and join meetings.

5. Review the Definition of Food Safety Management System

- References for definition development
- April 14th version – Almost complete w/FDA feedback
- Documented 4/20 – Review
    - Procedures for Procedures, Training and Monitoring.
    - Final Version reviewed as group
        - Change maintain to ‘follow’
        - Under monitoring, include technology (monitoring/automatic) systems.
        - A written FSMS indicated better compliance. Under procedures, “oral’ can you document. Concern the word oral waters down the intent
            - Careful not to get bogged down, some of industry may not be able to do everything, may have procedures of culture, even though the system is primarily oral. Group goal is to help move bar. Delicate balance to consider diversity, and open to other approaches that are out there.
            - Something written does not need to be complicated reference to manual of dishwasher, fact sheet from local HD/written. Something written not huge/beautiful but right direction.
            - If we want to make progress take into account, there are several ways to do things. Which would include oral. Not everything written down; less prescriptive.

- Have had extensive conversations lending to the definition listings allowing oral, written, job aids, posters w/steps, SOP etc… last sentence – Ultimate goal is – while not discounting the other types of methods/modalities.

- Training – discussion on verbiage; add goal is to…
  - Add specific/assigned to the employee's job duty (what they do).
  - Consider not singling out.
  - Add including allergen and awareness
  - Shouldn't this be more general then specific?
  - PIC needs to know all so they can monitor and ensure that all employees are doing what they need to. But specific employees only need to know what their specific job duties would require. (ie dishwasher would not necessarily know temperature to cook food)
  - Concern raised regarding others doing multiple jobs
  - Broader the more encompassing. Broad brush approach allows industry operator to put together a system to effectively train their employees.
  - Job duties is broad, that employee needs to be trained in all duties they are responsible for.
  - Consider using Jessica's verbiage; consider including the word document/documenting. (being the ultimate goal)
  - Refresher and frequency important to include.
  - Straw poll – 'All' was the most preferred verbiage

6. **Review Committee Charges**
7. **Overview of Committee Working Plan:**
   - Next milestone, July 2022: Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:
     a) the hurdles/challenges involved in such a requirement; and
     b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries.
     The committee should also consider a gap analysis of § 2-103.11 as a starting point.
8. **Action Items:**
   - Subgroups meet and complete Solutions Lists, return to Mandy Sedlak and Christine Sylvis by May 31, 2022.
   - Review updated Solutions List for the three buckets of Barriers sent out after June 1, 2022 to discuss at the June 21, 2022 meeting.
   - ACTION For all Members– Review definition and review the barrier buckets/solutions
9. **Next Meeting Date: June 21, 2022, 3:00 EST**
10. **Meeting Adjourned 4:00pm EST**

Meeting Number: 7
DATE: June 23, 2022
TIME: 10:00AM EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

1. Welcome, Call to Order	Mandy Sedlak and Christine Sylvis	

2. Roll Call	Mandy Sedlak and Christine Sylvis	
3. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
4. Review work completed by working groups on Solutions/Next Steps	Mandy Sedlak	
5. Review of Committee Work Plan	Mandy Sedlak	
6. Action Items	Mandy Sedlak	
7. Next meeting date: July 19, 2022	Christine/Mandy	

MEETING MINUTES:

1. **Meeting Called to Order:**
   - 7th FSMS Committee meeting called to order at 10:04am
2. **Roll Call:**
   - Roll Call Conducted by Christine Sylvis, documented by Mandy Sedlak
3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis
4. **Review work completed by working group on Solutions:**
   - Main committee divided into 3 working groups (leads in Red)

Economic		Training		People	
Chris	Boyles	Elizabeth	Nutt	Mark	Speltz
Sean	Dunleavy	Dan	Okenu, Ph.D.	Dan	Tew
Jeffrey	Edelen	Susan	Quam	Shelly	Wallingford
Jeff	Jackson	Todd	Rossow	Lisa	Whitlock
Naomi	Macias	Heather	Sanders	Yolanda	Woods
Monique	Crawford	Colleen	Smith	Linda	Zaziski
Vanessa	Bussiere	Martin	Flusberg	Melissa	Smith
Herman	Crawford, Ed.D.	Hsing-Yi	Hsieh	Laura	Temke
Theodore	Dohnal	Troy	Huffman	Laura	Wildey
Ashley	Eisenbeiser	Evelin	Pollock	David	Wilson
		Mario	Seminara	JEREMY	ZENLEA
		Christine	Sylvis		
		Mandy	Sedlak		

   - Economic and People working groups each met and submitted consolidated solutions.
   - Kudos to Economic and People group for work done!
   - **ACTION:** Training group needs to meet.
   - **ACTION for all members:** Review people and economic solutions consolidated list for discussion at next meeting

5. **Review Committee Work Plan**

Definition of Food Safety Management System; Most Current Version

- Goal: Feedback/Incorporation and Agreement/Vote on definition moving forward
- Discussion on where this definition came from
  - Definition for the National Retail Study
  - FSMS can be in any form; more documented more sustainable. But documentation is not required.

- Most were happy with procedures, still working through the training portions
- **Procedure's component**… Positive reaction from group
- **Training Component:**
    - Do we need to mention risk factor interventions in this section?
    - Might be narrowing things by too much
    - Focus on critical limits.
    - There are some hazards not included that would be related that would be controls (ie Covid). Can FDA comment
    - Add in beginning over food safety risk factors.
    - Are we getting in the weeds? Conceptualize the groups work to work on barriers/solutions.
    - Pre requisition programs, GMP, other areas are important as well.
    - Continue to keep interpretations broad. Allow for maximum flexibility. Group Agreed
- **Monitoring Component**
    - Adequately and consistently – is it too definitive?
    - Change verbiage "Conveys adequate amount of knowledge to …
    - Original Charge – asking us to make recommendations to creating documented HACCP Based Food Safety Management System. Are we meeting intent of our charge?
        - Clarification on issue itself; right above numerical listing.
        - **ACTION**: Add full listing of charges on spread sheet
        - Beginning paragraph is the crem dela crème – slow process that would begin to facilitate a forward movement towards a food safety management system. Baby steps not all or nothing… Be wary of approach.
        - 30,000 not narrowing change down any further. May later be parched out into smaller sections.
        - Group in agreement; that tier approach as first step; going in right direction.
        - Starting a food safety management system is better than having nothing at all.
    - Add Jessica language
    - Group agreed with verbiage changes as presented.
- **Examples Section**
    - Examples provide ideas on how to incorporate. To have procedure, a diagram could contain steps.
    - Really not writing a procedure here. Well-developed procedure would be to have the diagram above the 3-compartment sink
    - Point of Clarification: Where diagram is, procedures should include recontamination; is why that was added in might need some word smithing. Having a nice diagram can be your written procedure (do not need written SSOP)
    - Is the example helpful? Or does it need to be more streamlined.
    - Example - Way to detailed. (not have as specific SOP)
    - Take off prewash to air dry
    - Trepidation – those written procedures too much; making simplest solution ie poster could serve as procedures. Does not need to be difficult.
    - Simplistic – Beneficial pointing back to the food code. Food code will answer all of the questions. Use that as a resource/reference.
    - In the procedure – procedures can be as simple as posted visual reminders?
    - Evolution of definition – did have within definition; getting too long – hence example was created to demonstrate how all those steps could be incorporated. Goal to control length and complexity of the definition.

- Example – too prescriptive (small retailer and regulatory) getting pretty prescriptive. Way too much work – I am not doing this. Having an example this detailed setting the bar too high/expectation of regulatory. Is biggest concern. Might be doing the opposite of what we are trying to achieve.
- Conceptually agree on FSMS
- Example may be better suited for barrier or solution section.
- Q&A section better way to use example piece.
- Examples sometimes thought as a benchmark (one size does not fit all)
- Biggest challenge to try and break this down in bite size pieces. IE Employee Health as one section. How to package this back to the conference.

- **NEXT STEPS**: Christine will send out final version w/o examples, group review; Will Vote on definition next meeting. Continued incorporation and discussion of examples

6. **Overview of Committee Working Plan:**
    a. Next milestone, July 2022: Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:
    a) the hurdles/challenges involved in such a requirement; and
    b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries.
    The committee should also consider a gap analysis of § 2-103.11 as a starting point.
7. **Action Items:**
    a. **ACTION: Training Subgroup** needs to meet to complete Solutions Lists, (ASAP)
    b. **ACTION For all Members** – Continue to review consolidated People and Economic Solutions Lists for discussion next meeting
    c. **ACTION For all Members** – Review definition of FSMS – Vote Next Meeting

8. **Next Meeting Date: July 19, 2022, 3:00 EST**

Meeting Adjourned 11:03pm

Meeting Number: 8
DATE: July 26, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Mandy Sedlak/Linda Zaziski

Agenda

1. Welcome, Call to Order	Christine Sylvis	
2. Rollcall	Christine Sylvis	
3. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis	
4. Charge #3	Christine Sylvis	
5. Review of Committee Work Plan	Christine Sylvis	
6. Action Items	Christine Sylvis	
7. Next meeting date: July 19, 2022	Christine/Mandy	

2021-2023 CFP
Food Safety Management System (FSMS) Committee

MEETING MINUTES:

1. Meeting Called to Order:

- 8th FSMS Committee meeting called to order at 3:10pm

2. Roll Call:

- Roll Call Conducted by Christine Sylvis, documented by Christine Sylvis
- Quorum not established – all votes put on hold (only 6 voting members present); Voting via email discussed; to be coordinated by Sylvis/Sedlak

3. Conference for Food Protection, Inc. Antitrust Statement

- Reminder by Christine Sylvis

4. Commence work on Charge #3:

Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:

a) the hurdles/challenges involved in such a requirement; and
b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.

Plan to complete Charge #3:

- Mandy Sedlak and Christine Sylvis met with Courtney Halbrook, Council II Chair, and Wendy Bell, Council II Vice Chair and John Marcello regarding the progress of the committee and the charges. They were very impressed with the amount of work already completed by the committee! They agreed with assessing Charge #3 at an overview level. They acknowledge that this committee will likely be reformed (or a similar one formed) and encourage for us to think about those next steps and suggest charges.
    - Suggested that Charge 3 as an overall broad umbrella. Suggested Pro/Cons be developed/looked with an overall perspective Overview
    - List of barriers, pros, cons with really nothing coming out of it. To help expediate. Looking at pro/cons at an overview level
    - Coming up with a project of sorts that would show FSMS as it is being implemented
    - Liked example for manual ware washing on how easy it is to initiate a FSMS with more details in documentation/SOPs
    - The committee could do the committee a great favor of coming up with more then just a list.
    - FDA developed an employee health policies w/tool kit tying it in w/Norovirus. Perhaps that type of recommendations that an association or entity develop a project with learnings be rolled into a national strategy.
    - Take a microcosm on what we learn with would have a drastic impact on public health.
    - Tool out of this group from industry on how they need to work/manage a toolkit or step by step process on how to roll out/develop in business-based concept. Industry can provide helpful insight into development – voluntary approaches.

- Consider/suggest charges for a newly formed committee resulting from 2023 CFP
- Assess lessons learned on pros/cons and barriers/solutions before making suggestions on how to proceed. How can we incorporate our experiencing into context?
- Annex 4 of the food code. Incorporate Pros/Cons having FSMS as a requirement in the food code. Once barriers are solved items/topics FSMS incorporated into the Food Code.
- Provision – FSMS; responsibilities on the PIC have various controls and KSA of employees. High Level approach. If group took a look at that provision discussed strength and weakness of how it exists in the Food Code. Are jurisdictions using this provision if so, how, if not why-not? How is industry seeing use of this component? This be the starting point as it is already in the food code. (2-103.11)
- Not about putting more content in the code. How does the PIC – support or positively impact retail.
- How is regulatory authority applying this provision when inspecting the food code. For example: temperature violation is observed, mark cooking violations. If PIC portion on FSMS is marked, is there a double violating. How is this assessed?
- Suggestion: Helpful if Food Code had defined term for FSMS. Definition will provide a criterion on how to evaluate PIC. Annex 4 written more in industry vernacular then regularity speak.
- FSMS mentioned 54 times, all in Annex 4.
- What is experience with PIC provision? Challenges/How applied. Make sure all members have read PIC provision.
- Hesitancy to double dip citations. Identify a problem not driving to the underlying problem. Consultative way but not as a citation/regularity enforcement mode. Never found a way to address w/o alienating industry. The way it is written there are things intertangled not just concise or aligning well with Annex 4. Not a connective method to jive with other documents.
- Jurisdiction – the only time double debited. If failed, then PIC would be marked. Not for temperature violation only if they failed the inspection.
- Underutilized marking due to double dipping.
- One agency developed a flow chart on when to use PIC violation. Did use a lot more; had framework for not double dipping and not beating up on industry. Not written in code or pushed to regularity/industry. Can this template be shared?
- Data from AFDO on how often PIC demonstrates knowledge is marked. One of top 5 violations cited. Counts really climbed. Considerations and causes of this. Demonstration and Duties (Mandy has data via a presentation)
- There is some guidance for using 2-103.11 in marking instructions of Annex 7, but it is worded broadly. (Con) The section, does discuss PIC citations as being a judgement call.
- Send pros/cons in broad fashion. Something to meet changes then individual project for Charge 5. Include some experiences of what we learned
- Food code already requires a FSMS by practice does not explicitly state. Does ask that management make sure employees are following a program.

5. **Status of Committee Charges**
   - **a.** Definition of Food Safety Management System – vote next meeting
   - **b.** Work on “Training solutions” continues
6. **Action Items:**

a. Training Subgroup needs to meet to complete Solutions Lists, (ASAP)
b. **ACTION – All Members Send to Mandy:**
   - A listing of the hurdles/challenges (pros/cons) of Including FSMS into the food code specifically hurdles and challenges of the requirement and recommendations on how to best incorporate into the food code.
   - Also include Recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. Use § 2-103.11 as a starting point. Include: Suggestions on how this provision can be used. What and how it is currently being used or not being used. Provide any info sheets/guidance documents/flow charts that may exist.
c. **ACTION For all Members** – Continue to review consolidated People and Economic Solutions Lists.
d. **ACTION For all Members – Review definition of FSMS**
e. This is the last week to submit applications for Council membership at the 2023 Biennial Meeting: deadline 11:30 p.m. EST on Wednesday August 3, 2022. A final message will be sent out next week to let people know the application deadline has been moved to Friday, August 5.

7. **Next Meeting Date: August 16, 2022, 3:00 EST**

Meeting Adjourned: 3:59pm

Meeting Number: 9
DATE: September 20, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Mandy Sedlak/Linda Zaziski

Agenda

7. Welcome, Call to Order	Christine Sylvis
8. Rollcall	Christine Sylvis and Mandy Sedlak
9. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis
10. Committee Roster Update	Christine Sylvis and Mandy Sedlak
11. Vote on FSMS Definition	Christine Sylvis and Mandy Sedlak
12. Completed Charges Format	All
13. Status of Committee Charges	Christine Sylvis and Mandy Sedlak
14. Future of FSMS Committee	Christine Sylvis and Mandy Sedlak
15. Action Items	Christine Sylvis and Mandy Sedlak
16. Next meeting date: October 18, 2022	Christine Sylvis and Mandy Sedlak

MEETING MINUTES:

1. **Meeting Called to Order: 3:02pm**
   - 9th FSMS Committee meeting called to order at 3:00 EST
2. **Roll Call:**
   - Roll Call Conducted: Quorum Established
3. **Conference for Food Protection, Inc. Antitrust Statement**

- Reminder by Christine Sylvis

4. **Roster Update**
   - Remove voting members Mark Speltz (Regulator – Sate) and Naomi Macias (Regulator – Local) who respectfully asked to be removed from the committee due to a new job responsibilities.
     i. Elizabeth Nutt - **MOTION** made to remove Speltz/Macias at their request: Seconded: Dan Okenu. Vote: No opposition: **MOTION APPROVED**
   - Remove voting members Sean Dunleavy (Regulator – State) and Shelly Wallingford (Industry- Food Service) due to missing at least 3 consecutive meetings and not responding to an email inquiring about future participation.
     i. Elizabeth Nutt made friendly amendment - **MOTION** to move Dunleavy/Wallingford to alternate/non-voting; Seconded Dan Okenu. Vote: No opposition: **MOTION APPROVED**
     ii. Discussion regarding how both were contacted; to verify non-interest, if not needed for full vote. Suggested to move forward then make contact; then work on reinstating/bringing back to group. Perhaps move to non-voting roll by committee then reach out. Move members around to have voting structure.
   - Transfer Troy Huffman and Evelin Pollock from alternate members to voting members to replace those Speltz/Macias.
     i. **MOTION** by Dan Okenu to move Troy Huffman (regulatory) from non-voting representative to voting representative. Seconded by Elizabeth Nutt. Vote: No opposition: **MOTION APPROVED**
     ii. **MOTION** by Elizabeth Nutt to move Evelyn Pollak from an alternate to a voting member (regulatory) Pending Pollak acceptance. Seconded by Jeff Edelen. Vote: No opposition: **MOTION APPROVED**
     iii. Possible industry representatives to voting position: Hsing Yi, Laura Tempke, Laura Wilding
     iv. **MOTION** by Jeff Edelen to move Hsing Yi from alternate to voting member Troy Huffman seconded Voting: No opposition: **MOTION APPROVED**

5. **Vote on FSMS Definition:**

FSMS refers to a specific set of actions (e.g., procedures, training, and monitoring) to help achieve active managerial control.

Procedures (P): A defined set of actions adopted by food service management for accomplishing a task in a way that minimizes food safety risks. Procedures may be oral or written and include who, what, where, when, and how a task should be performed. The goal is to move toward complete, consistent, and primarily written procedures and may include topics such as when to wash your hands, how to set up a 3-compartment sink, how food temperatures are achieved and maintained/monitoring food temperatures.

Training (T): The process of management's informing employees of the food safety procedures within the food service establishment and teaching employees how to carry them out. Information may be presented in formats such as a set of instructions/illustrations, recipe cards with process instructions, wall charts, wallet cards, or live demonstration. The goal is to provide and document training for all food safety tasks in a format and frequency adequate to ensure employees have the knowledge to carry out the procedures consistently and effectively.

Monitoring (M): Routine observations and measurements conducted to determine if food

safety procedures are being followed. Monitoring systems should include who, what, where, when, and how monitoring is to be performed and may be conducted visually or documented in writing. The goal is to move toward a well-documented system that can be verified and may include use of automated systems, digital thermometers, logs, charts, checklists, and other job aids and tools

- Elizabeth Nutt made **MOTION** to accept the definitions as presented. Motion Seconded by Hsing Yi. Motion amended to add verbiage under "training": Information may be presented "in formats such" as a set of instructions/illustrations…" for Voting: No opposition: **MOTION APPROVED**
    - Excellent start to begin our discussion on FSMS. May have some wordsmithing but great start.
    - Consider adding on-line/virtual verbiage. Consider not putting in these words to keep broad. Consider adding word "such as"

6. **Completed Charges Format:**
    - Changed format of barriers and solutions
    - Currently in list format included all buckets and sub buckets (took everything we had and put it in one listing)
    - Suggestions on other method to format? Consider a table or chart with each bullet being a table. Same format in table opposed to bullet. Group agrees that bullets are good for formatting.
    - Recommendation to use numbers instead of bullets to be able to identify topics as individual discussion points.
7. **Status of Committee Charges:**
    - Review pros and cons submitted.
        i. Special Meeting: September 29, 2022, at 8:00 Pacific/11:00 Eastern
    - Vote next meeting: Charge 1 (Barriers), Charge 2 (Solutions) and Charge 3 (Pros/Cons)
    - Discuss Charge 4 (recommendations on next steps) next meeting.
    - Develop prospective Committee Issues to present to Council II Chair and Vice Chair by November 2022.
    - Revised Final Committee Reports and Issues submitted to Issue Chairs for preliminary review and comment by November 2022.
    - Issue Submission December 2022.
8. **Future of FSMS Committee**
    - Summary of Retail Food Safety Regulatory Association Collaborative project and possible resource/assistance by David Lawrence.
        i. David Lawrence and Brenda Bacon; Introduction and high-level overview of Collaborative.
        ii. Collaborative working with NACCHO for project funding; CFP Board currently in discussion to accept funded program.
        iii. Brenda and David asked to attend future FSMS meetings so that they can be in know of committee activity/recommendations so that through the Collaborative's partnership with NACCHO - documents/information developed by the committee can be made publish-ready. Allows them to get a pulse for what is going on and how their partnerships can get ahead of the curve to make the process more streamlined while tying in possible resources.

iv. Objectives of this committee and the Collaborative dovetail very well together.
v. FDA request to truly involve the Collaborative.

- Consider recreating FSMS Committee – Committee Charges will need to be developed. Barrier's list can be used as a starting point
- Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about submitting an Issue to establish a Standing Committee to encompass the work of the FSMS and DFSS Committees.
    i. Any movement forward on this initiative will be taken up by the FSMS in collaboration with the DFSS Co-Chairs and in consultation with Council II Chairs.

9. **Action Items:**
    - **ACTION For all Members –** Conduct a final review on consolidated pros/cons list. Send any recommended changes to Many and Christine. Plan to vote on final list at next meeting.
    - **ACTION For all Members** – Conduct a final review of consolidated People, Economic, and training Solutions and Barriers Lists. Send any recommended changes to Many and Christine. Plan to vote on final list at next meeting.
    - **ACTION For all Members** – Think about Issues regarding FSMS that may be submitted for the 2023 CFP. Possibly Recreate committee
    - NEHA AEC abstract submission contact Laura Widley
10. **Next Meeting Date:** October 18, 2022, 3:00 EST

Meeting Adjourned: 4:00pm

Meeting Number: 10
DATE: October 18, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

17. Welcome, Call to Order	Christine Sylvis
18. Rollcall	Christine Sylvis and Mandy Sedlak
19. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis
20. Changes Document	Christine Sylvis and Mandy Sedlak
21. Charge 4	Christine Sylvis and Mandy Sedlak
22. Status of Committee Charges	Christine Sylvis and Mandy Sedlak
23. Future of FSMS Committee	Christine Sylvis and Mandy Sedlak
24. Action Items	Christine Sylvis and Mandy Sedlak
25. Next meeting date: October 18, 2022	Christine Sylvis and Mandy Sedlak

MEETING MINUTES:

1. **Meeting Called to Order: 3:01pm**
    - 10th FSMS Committee meeting called to order at 3:01pm EST
2. **Roll Call:**

- Roll Call Conducted; Quorum Established

3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis
4. **Completed Charges Document:**
   - Changed format of Barriers and Solutions to use numbers instead of bullets to be able to identify topics as individual discussion points.
   - No comments received on Barriers and Solutions.
   - Vote: Charge 1 (Barriers), Charge 2 (Solutions)
     i. Items still in red:
        1. (2) Comment/discussion questioned group to put under equipment or cost barriers. Put under cost barrier subset vs a standalone. Suggestion made to Bucket out. Group good with leaving as a standalone
        2. Process Solution Bucket for sub processes – number 3 was removed
        3. Idea for additional cost: unacknowledged cost if a foodborne illness incident occurs. People do not recognize a cost if something does not occur … more of a solution piece (4a iii, or add as a subset under bullet 4 under b). Group agreed/added in.
   - Christine will ensure that all formatting is consistent
   - **Vote**: Lisa made motion to approve solutions and barriers (Charges 1 and 2) accept the documents; Troy Seconded. Discussion: non. Vote; no objections or abstentions. **Charges 1 and 2; Motion Passed**

5. **Charge 4:**
   - Charge 4: Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.
     i. Retail Food Safety Regulatory Association Collaborative/NACCHO project resources. Also: AFDO/NEHA (Active Managerial Control), Plan Review Committee
        1. Cost/benefit analysis of implemented FSMSs
        2. Toolbox resources (draft SOPs, job aids, case studies, etc.)
           Note: David Lawrence mentioned the year one goals of collaborative. Document to be shared with group on current status and support for present and forward movement. Added to teams site and Food Shield.

     ii. CDC EHS-Net project on Employee Health Policy
     iii. Retail Food Safety Specialists – Train the Trainer type program
   - Develop prospective Committee Issues to present to Council II Chair and Vice Chair by November 2022.
     i. **Consider recreating FSMS Committee –** Committee Charges will need to be developed. Barrier's list can be used as a starting point
     ii. Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about **submitting an Issue to establish a Standing Committee to encompass the work of the FSMS and DFSS Committees.**

1. Do not need to recreate committee every year. Charges would be included in the bylaws.
2. Standing committee
    - Can be explored as an option if we can pin-point criteria. The other committees usually have some oversight of standards with ANSI/reviewed yearly. Lots of overlap.
    - More research may be necessary regarding standing committees or when a committee moves into a standing option.
    - Big thing outside of FSMS – regulated to conference administration vs standard maintained as long as CFP has that standard. may be new territory to create a new standing committee that would not have a sunset every two years.
    - Executive committee will need to have a discussion on. Standing committee reports to executive committee. Board tracking constitutionals charges, plus charges from board meeting or from conference. Constant maintenance and other charges, benefit rational two council committees doing similar to bring both committees together. Argument in background. Constitutional bylaws outlined. Procedures document to the board. Rational is there.
    - Putting into the issue along with the background. Retail foods is also a standing committee. Constantly maintaining program as well. Huge amount of work.
    - Large committee with multiple subcommittees to support to spread out work.
    - Prepare a case and get some feedback from others with experience to see if we are on the right track with fall back in council. Committee were to propose, would this be an issue or would it go through the executive board. Not pan out then there would be some charges to move forward. Issues submitted for acknowledgement in November. This would be seen by board to garner support. Would be an issue by one of two committees Christine/Mandy and Ben/ co-submitting. Get all players with co-chair of to committees. Publication committee was the last standing committee that was formed. (in Richmond).

6. **Status of Committee Charges:**
    - Special Meeting: September 29, 2022, at 8:00 Pacific/11:00 Eastern reviewed Pros
    - Complete review of Cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code October 21, 2022 at 8:00 Pacific/11:00 Eastern.
    - Vote next meeting: Charge 3 (Pros/Cons)
    - Revised Final Committee Reports and Issues submitted to Issue Chairs for preliminary review and comment by November 2022.
    - Issue Submission December 2022.

7. **Future of FSMS Committee**
    - Summary of Retail Food Safety Regulatory Association Collaborative project and possible resource/assistance by David Lawrence.
        i. David Lawrence and Brenda Bacon; Introduction and high-level overview of Collaborative.
        ii. Collaborative working with NACCHO for project funding; CFP Board currently in discussion to accept funded program.
        iii. Brenda and David asked to attend future FSMS meetings so that they can be in know of committee activity/recommendations so that through the Collaborative's partnership with NACCHO - documents/information developed by the committee can be made publish-ready. Allows them to get a pulse for what is going on and how their partnerships can get ahead of the curve to make the process more streamlined while tying in possible resources.
        iv. Objectives of this committee and the Collaborative dovetail very well together.
        v. FDA request to truly involve the Collaborative.
    - Consider recreating FSMS Committee – Committee Charges will need to be developed. Barrier's list can be used as a starting point
    - Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about submitting an Issue to establish a Standing Committee to encompass the work of the FSMS and DFSS Committees.
        i. Any movement forward on this initiative will be taken up by the FSMS in collaboration with the DFSS Co-Chairs and in consultation with Council II Chairs.
8. **Action Items:**
    - **ACTION For all Members** – Think about Issues regarding FSMS that may be submitted for the 2023 CFP. Possibly Recreate committee or standing committee
    - **ACTION For all Members – Special meeting on Oct 31 review cons and complete**
    - **ACTION: Smaller/Identified members/guests** to discuss standing committee option prior to the 31st. (Becky, Todd, Mandy, Christine, David, Devine)
    - **ACTION For all interested Members: Meeting prior to the 15th to create the issue submission for vote on the 15th.**
    - **ACTION for Voting Members/Others:** Meeting scheduled for November 15th – Vote on Charge 3 Pros/Cons and Charge 4 Next Steps.
9. **Next Critical Voting Meeting Date:** November 15, 2022, 3:00 EST

Meeting Adjourned: 3:55pm EST

Meeting Number: 11
DATE: November 15, 2022
TIME: 3:00 EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

26. Welcome, Call to Order	Christine Sylvis
27. Rollcall	Christine Sylvis and Mandy Sedlak
28. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis
29. Changes Document – Pros and Cons vote	Christine Sylvis and Mandy Sedlak
30. Charge 4 – Future of the Committee	Christine Sylvis and Mandy Sedlak
31. Charge 4 - Issues for next Committee	Christine Sylvis and Mandy Sedlak
32. Issue – Final Report	Christine Sylvis and Mandy Sedlak
33. Issue – FSMS Definition	Christine Sylvis and Mandy Sedlak
34. Status of Committee Charges	Christine Sylvis and Mandy Sedlak
35. Action Items	Christine Sylvis and Mandy Sedlak
36. Adjourn	

MEETING MINUTES:

1. **Meeting Called to Order: 3:02 pm**
    - 10th FSMS Committee meeting called to order at 3:02pm EST
2. **Roll Call:**
    - Roll Call Conducted; **Quorum Established**
3. **Conference for Food Protection, Inc. Antitrust Statement**
    - Reminder by Christine Sylvis
4. **Completed Charges Document:**
    - Thank you to those who attended the Special Meeting on September 29, 2022. Pros and Cons were completed!
    - Edited Barriers and Solutions to use FSMS/FSMSs correctly and consistently
        i. Unbolded items and single/plural consistency
        ii. Con #2; wordsmithing to address all the bullets/flow
    - Added Pros and Cons to the document.
    - No comments have previously received regarding Pros and Cons.
        i. Discussion by Group
            1. No Discussion
        ii. Other Comments:
            1. Clarification regarding revisiting some charging for this group to look at charges not directly dealt with due to time constraints Yes, future of committee and/or standing committee can address open ended items/unaddressed items
    - **VOTE:** Elizabeth Nutt; **Motion to Accept Pros/Con report as written to be included in final report submission.** Second Yolanda Woods. No Discussion; Vote: No Dissentions, No abstentions. **MOTION PASSED**
5. **Charge 4 Future of the Committee:**
    - Charge 4: Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4
    - 2 Options:
        i. Consider **recreating FSMS Committee** – Committee Charges will need to be developed. Barrier's list can be used as a starting point
        ii. Consider idea presented by Eric Moore and Ben Chapman, Digital Food Safety Systems (DFSS) Committee Co-Chairs, about submitting an Issue to establish a **Standing Committee to encompass the work of the FSMS and DFSS**

Committees. Meetings have been held with Council II Chair (Courtney Williams) and Vice Chair (Wendy Bell) and with CFP Constitution and Bylaws Committee Chair (Daveen Sarrocco-Smith), Issue 2020-II-030 submitter (John Marcello), and DFSS Committee Co-Chairs (Eric Moore and Ben Chapman). A Standing Committee is a practical option.

iii. Discussion:

1. Standing Committee well received by members
2. Are we already incorporating the merging of all of those groups?
3. Standing committee would incorporate FSMS and Digital Committee The new committee would have charges in both.
4. It is very difficult for committees to deal with charges when merging groups. Concern what is being suggested is bandwidth of committee to deliver and move bar forward.
5. Sustainably of Food Safety Management Systems, if it did get put into the food code.
    - Envision 4 years down the road.
    - Aspects of FSMS in pieces into the food code.
    - The thought was that incremental editions will be made into the food code over a longer period of time.
    - On-going changes as time goes along.
    - Not as big as programs standard committee but would have charges to committee.
    - Sustainability was discussed based on interest for committees. Would 2-4 committee formed be enough interest to join committees
6. Question: Would considerations be made for standing committee w/o combining with the Digital Food Safety System Committee work
    a. What is the vision for synergize of both committees combining?
        i. Component of FSMS, having digital portion incorporated into it
        ii. Christine shared charges of collaborative on how digital would fit into FSMS
7. Suggestion was to have standing committee for FSMS as standalone standing committee w/o having them work as one
8. The 4 deliverables of the collaborative are tied to new era for food safety. Listed separately for scope under broad idea of FSMA. Standing committee would need sub committees and workgroups. Complexed need lots of work but need lots of symmetry.
9. 2 thoughts standing committee for FSMA. Digital as standalone or combining with separate charges/combining them perhaps at a later time.
10. If they go separate; not likely to get 2 standing committees; be sure to give that some consideration. 2 is very unlikely.
11. Not sure that that would matter. We can request, if not standing, then request to be a continued committee. To be prepared for that; Standing Committee let digital address their own perspective. To be proactive, our

committee should be proactive if we are not looking to be a standing committee then look at a recommendation for reforming/extending

12. If both ask to be a standing committee; then executive committee could recommend to combine.
13. **Will of Committee:** Request standing committee (w/o digital committee) if that does not look favorable then default fall back to council committee. Council members for council 2 would need to recommend be recreated as a council committee
14. Council 2 FSMS Members; (Courtney WIlliams, Chair) Christine and Ashley Eisenbeiser

iv. Recommended solution language/other thoughts:

1. Add Active Managerial Control of Risk Factors
2. Charges in the Public Health significance need to be in Solution. What is the committee going to work on. Charges and recommended are in the solutions point.
3. Advise from Daveen, one issue to create committee to change bylaws then a separate issue to recreate w/charges of committee.
4. Consider recreation of committee then based on public health significance to standing committee. Council Chairs determine what order issues are addressed in. They determine order the CFP ordering system. Once council beings they can change order w/recommendation and vote.
5. Some of the charges for this new committee next biennium will be solution on other charge/issue on charges would be incorporated into next biennium and explaining on why this needs to be a standing committee. Council chair confers with council members on order. Has been standard, not impossibility to this order.
    a. Good idea; insure committee gets created. If becomes standing committee that is another issue, but at least the committee will continue.
6. Recreate committee w/ charges. Separate issue submitted to create as standing committee. (Might be more straight forward to do it this way)
7. Charges on public health significance – carry over some of the items on initial FDA and CDC studies FSMA have strongest statistical correlation to reduction of FBIs
8. Health People; Norovirus reduction. Developing health policies program. Better focus on one specific area. Number one case of FBI at retail level with focus of employee health

- **VOTE** Lisa Whitlock made motion to recreate the committee as council committee w/chargers with separate issue to change from council committee to a standing committee w/duty as stated by constitution and bylaws. Jeff Jackson seconded. No objections, no abstentions **MOTION PASSED**

6. Charge 4: Charges for FSMS Committee during 2023-2025 biennium

- Considerations for Charges:
    i. Risk Factor for PIC provision

ii. Cost benefit analysis (NACCHO/collaborative)
iii. Develop a toolbox, develop verbiage to outline prerequisites (SOPs) that are not covered. Review results of EHS-Net/CDC collaboration and incorporate into toolbox
    1. Focus on Employee Health, Healthy people
    2. Use the school USDA/HACCP SOPs as a possible guide/tool; consider reviewing #4 "Guidance for School Food Authorities, "Developing a Food Safety Program based on the process approach to HACCP Principles" Consider having CDC provide an overview of project and what tools may come out of this down the road.
    3. CONSIDER: Pilot a FSMS for Employee Health program to see how it might work. Find industry volunteer to develop FSMS; site visits to support and verify effectiveness. Industry/Regulatory Partner. Note this is something that CDC is already using this approach/project. Initialed via EHS-Net
    4. Get understanding of EHS-Net project as how it relates to FSMS committee work. Consider collaboration
    5. The overarching thread of these suggestion is that we need to increase awareness, communication and idea sharing with initiatives area underway. A committee may not be well suited to do a pilot study themselves but give the results they could give guidance.
iv. Reviewing a charge for Barriers, Pros/Cons provide solutions/remedies
v. Items not covered in our current charges
vi. Complete gap analysis of PIC Provision
vii. Committee Charge to fil in the gaps between all areas working on aspects of employee health and all aspects of collaboration/projects currently being done.
viii. NOTE: Christine typed up charges and read as written
ix. Items to be word smithed; Charges Can Vote to have 4 items incorporated into the charges submitted for the reformation/standing committee

7. **Review Issue to submit committee final report**
8. **Review Issue to include where FSMS definition fits into Food Code**
    - Where does definition of FSMS belong in the Food Code discussion
    - Annex 4, under active managerial control
    - Place after AMC, put in FSMS definition
    - Soft roll-out in code: Put somewhere under the radar; time to include into definition Chapter One for the Food Code. PIC duties, que Employees begin using FSMS to begin voluntary implementation of systems to reduce FBI.
9. **Status of Committee Charges:**
    - Final Committee Report to be submitted to Council II Chair and Vice Chair by November 18, 2022.
        i. Thank you, Linda Zaziski, for reviewing!!
    - Revised Final Committee Issues submitted to Council II Chair and Vice Chair and Issue Chairs for preliminary review and comment by November 2022.
    - Issue Submission December 2022.
        i. Summary of Issues to be submitted

1. 1. Accept FSMS Committee Final Report
2. 2. Recreate FSMS Committee
3. 3. Create FSMS as a Standing Committee
4. 4. Charges for FSMS Committee during 2023-2025 biennium.

10. Action Items:

- **ACTION For Christine and Mandy** – Finalize final report and issues and submit to Council II Chair and Vice Chair within deadlines
- **ACTION For all Members –** Thank you for your outstanding work and dedication to this committee and your dedication to food safety every day and adjourn.
- **ACTION– For All Voting Members: Need to determine where definition falls into Food Code. (Vote needed)**
  - **i. Next meeting November 18, 2022 at 10:00 EST**

11. Meeting Adjourned 5:03pm

Meeting Number: 12
DATE: November 18, 2022
TIME: 10:00am EST
Conference Call: via Teams

Co-Chairs: Mandy Sedlak and Christine Sylvis
FDA Advisor: Jessica Otto
CDC Advisor: Beth Wittry
Scribe: Linda Zaziski

Agenda

37. Welcome, Call to Order	Christine Sylvis
38. Rollcall	Christine Sylvis and Mandy Sedlak
39. Conference for Food Protection, Inc. Antitrust Statement	Christine Sylvis
40. Location of FSMS in the Food Code	Christine Sylvis and Mandy Sedlak
41. Charge 4 - Issues for next Committee	Christine Sylvis and Mandy Sedlak
42. Issue – Final Report	Christine Sylvis and Mandy Sedlak
43. Action Items	Christine Sylvis and Mandy Sedlak
44. Adjourn	

MEETING MINUTES:

1. **Meeting Called to Order: 10:03am**
   - 10th FSMS Committee meeting called to order at 3:02pm EST
   - Quorum Established
2. **Roll Call:**
   - Roll Call Conducted; Quorum **Established**
3. **Conference for Food Protection, Inc. Antitrust Statement**
   - Reminder by Christine Sylvis
4. **Location of FSMS Definition in Food Code**
   - Term Active Managerial Control around for 20 plus years. Not made its way into definition of food code. Think time to put on radar going hand in hand with FSMS. Employees begin using AMC by using FSMS. Deal with compliance. Allows for a soft roll-out. No specification gives wiggle room but gets the ball rolling. Time to be in codified portion in the food code.

- If definition in food code, if in annex can it be in the definition. Terms defined n codified section. If you want it in Chapter 1. Language needs to be in codified section so it can appear in purpose and definition. Excellent definition and concept. Do not need to be prescriptive in definition. FDA please incorporate as appropriate.
- Council will need vision to move forward
- If in multiple sections Chapter 1, 2 and annex; Council chairs recommended do multiple issues. Don't include too many in a single issue. Multiples allow options. Annex a no-brainer. If we want to get it in the food code – optional at this stage. Making it an "and: (hard call) Making it an "or" – more receptive
- FSMS are actual things… tend to lead to AMC; makes it difficult/tricky
- Proposed mechanism/intent; less on where it is placed. Angle of intended outcome. Want it to be codified. opposed to danker with language.
- Active managerial control in definition. PIC use FSMS as an example fo what they can do to achieve AMC
- PIC responsible for developing the FSMS. PIC would be the executer of the system. In the italicized section is more of explanation; call out permit holder implement some type of FSMS. Interesting angle –
- Agree on FSMS definition. Grappling with where does it go? Struggle; what does this look like. Duties of AMC is FSMS, how do we rationalize the PIC provision. Struggle may be related to the work that is still needed.
- 2-101.11 best place to include. Section P, written plans where specified required (health policy/vomit clean-up) FSMS is not always written… goal for written. Permit holder would develop.
- FSMS members in committee support concept and code concept/definition inclusion. May get pushback from industry.
    i. Teaching concept in food safety classes to include small industry
    ii. Many SOPs for larger organizations already refer to PIC/systems
- 2-101.11 Duties, Assignment, AMC in 2-111.2
- If several avenues, list several for consideration; in code somewhere not sure where in code. Not sure where it would fit just that you want it in there. Options to consider.
- there are concurrent Issues to be submitted by the Program Standards Committee to add plan review with a FSMS perspective to Standard 3 and to re-create the CFP Plan Review Committee to update the Food Establishment Plan Review Guidance Document to be inclusive of FSMS
- It would be a big challenge during plan review to have a full menu developed to drive a complete FSMS but I could see some components being available then.
- could go under responsibilities of the permit holder in Chapter 8
    i. Some agencies do not adopt Chapter 8. But then again everyone can pick and choose any code provision.
    ii. Need to find out why regulatory agencies are not using Chapter 8 – need deeper dive
    iii. Many not using Annex's

- Appears that we are moving too quickly. AMC must go hand in hand with FSMS. FSMS used widely. Is there a way we can move AMC into definitions then our task will be to develop a more clear perspective on what a FSMS. AMC in codified section.
- FSMS is a tool to achieve AMC
- Want to have in the code, but more to be done on development and interpretation of getting FSMS in code.
- Options: 2-103.11 incorporate FSMS AMC into duties but not be prescriptive or 2-101.11, chapter 8 incorporating AMC this go around.
- Under 2-103.11: **The Person In Charge shall maintain Active Managerial Control by ensuring:....** Will also allow for definition of AMC in codified.
- FSMS tool – massage them to work together. FSMS to become mandatory . Tool of choice to obtain AMC. Consider a FSMS to achieve AMC
- Could you add FSMS into 2-103.11 (P) Written procedures and plans, where specified by this Code and as developed by the FOOD ESTABLISHMENT or those created as part of a FOOD SAFETY MANAGEMENT SYSTEM, are maintained and implemented as required.
- VOTE Motion – would require specificity, perhaps later in the future.
- Let FDA find location.
- Submit issue provides AMC and FSMS in the code by ensuring really conveys the concept. Not worry about where it goes, probably the best use of groups time.
- Incorporate AMC into 2-201.11 and 2 other asks - define AMC and include FSMS defined in the code.
- Motion/friendly amendment to recommend verbiage presented on Charge 4 Incorporating **"voluntary use"**
- AMC is already in code that 'shall ensure' by including the AMC; already in code – hence reason why deep dive is needed and addressed as group.
    i. A through P is this in a nutshell.
    ii. FSMS is not well defined, required. AMC is getting a title and a definition
    iii. New names to old interventions.
- How to get the definition into the code.
    i. Into Annex 4, right after AMC
- Have defined FSMS; not have to decide exactly where it goes. Perhaps in public health significance section. Definition be incorporated into chapter 1 and that FSMS and definition incorporated into to AMC
- **VOTE: Motion to include FSMS, AMC into code w/voluntary use terminology** made by Jeff and seconded by Lisa. Discussion, no objections, no abstains **MOTION PASSED.**
- Vote was on inclusion to the food code; actual verbiage does not require vote.

5. **Charge 4; Issues for next committee**
    - Draft issues shared on screen - verbiage as currently written.
    - Based on conversations today, these items will be wordsmithed and then shared with all members.
6. **Final Committee Report – Submission Due November 18**
7. **Action Items:**
    - **ACTION For Christine and Mandy** – Finalize final report and issues and submit to Council II Chair and Vice Chair within deadlines (Deadline Nov 18)
    - **ACTION – For Christine/Mandy and All Voting Members: Christine will wordsmith and send final issue verbiage to committee members. Please review ASAP.**

- **ACTION For all Members –** Thank you for your outstanding work and dedication to this committee.
- **ACTION For all Members – Need new Co-Chair Committee for next biennium all members encouraged to consider this opportunity.**

8. **Meeting Adjourned: 11:06am**

Committee Name: Demonstration of Knowledge

Y=In Attendence **N=Not in Attendence**

Last	First	Committee Position	Meeting 1 11/16/21	Meeting 2 12/14/21	Meeting 3 01/18/22	Meeting 4 02/14/22	Meeting 5 04/19/21	Meeting 6 5/17/2022	Meeting 7 06/24/22	Meeting 8 07/26/22	Meeting 9 9/20/2022	Meeting 10 10/18/2022	Meeting 11 11/15/2022	Meeting 12 11/18/2022	
Sedlak	Mandy	Co-Chair	X	X	X	X		X	X	X	X	X	X	X	0
Sylvis	Christine	Co-Chair	X	X	X		X	X	X	X	X	X	X	X	0
Boyles	Chris	Voting	1	1	1	1	1	1	1	0	1	1	1	1	9
~~Dunleavy~~	~~Sean~~	~~Alternate~~	0	0	1	0		0	0	0	~~NA~~	~~NA~~	~~NA~~	~~NA~~	~~1~~
Edelen	Jeffrey	Voting	1	1	0	0		0	0	0	1	1	1	1	4
Jackson	Jeff	Voting	1	0	1	1		1	1	0	0	0	1	1	5
~~Macias~~	~~Naomi~~	~~Voting~~	~~0~~	~~0~~	~~0~~	~~0~~		~~0~~	~~0~~	~~0~~	~~0~~	~~0~~	~~0~~	~~NA~~	0
Crawford	Monique	Voting	1	1	1	1	1	1	1	0	0	0	1	0	7
Nutt	Elizabeth	Voting	0	1	1	1		1	1	1	1	1	1	1	8
Okenu, Ph.D.	Dan	Voting	1	1	1	1		0	0	1	1	1	1	0	7
Quam	Susan	Voting	0	0	1	1		1	1	1	0	1	1	0	6
Rossow	Todd	Voting	1	1	1	1		0	1	1	1	1	0	1	8
Sanders	Heather	Voting	1	1	1	1	1	1	1	0	1	1	1	1	9
Smith	Colleen	Voting	1	1	1	1		1	1	0	0	0	1	1	6
~~Speltz~~	~~Mark~~	~~Voting~~	~~1~~	~~1~~	~~0~~	~~0~~	~~1~~	~~0~~	~~0~~	~~0~~	~~0~~	~~1~~	~~0~~	~~NA~~	4
Tew	Dan	Voting	1	1	1	1		1	0	1	1	1	0	1	8
~~Wallingford~~	~~Shelly~~	~~Alternate~~	~~0~~	~~1~~	~~0~~	~~1~~		~~0~~	~~0~~	~~0~~	~~NA~~	~~NA~~	~~NA~~	~~NA~~	2
Whitlock	Lisa	Voting	1	1	0	1	1	1	1	1	0	1	1	1	8
Woods	Yolanda	Voting	0	1	1	1	1	0	0	0	1	1	1	1	6
Zaziski	Linda	Voting	1	1	1	1	1	1	1	1	1	1	1	1	11
Huffman	Troy	Voting	NA	NA	NA	NA	NA	NA	NA	NA	1	1	0	0	
Pollock	Evelin	Voting	NA	NA	NA	NA	NA	NA	NA	NA	0	0	1	1	
Hsieh	Hsing-Yi	Voting	NA	NA	NA	NA	NA	NA	NA	NA	1	0	0	1	
			12	14	15	15	7	10	10	7	11	13	13	13	
Otto	CRD Jessica	FDA Consultant	0	1	1	1		1	1	1	1	1	0	1	8
Marcello	John	FDA Alterante	1	1	1	1	1	1	1	1	0	0	1	1	8
Wittry	Beth	CDC Consultant	0	1	Fill in	Jana Johnson	1	1	0	0	1	0	0	0	4
Otto	Mark	CDC Consultant Alternate	1	1	1	1	1	1	1	1	1	1	1	0	10
Bussiere	Vanessa	Alternate	1	1	1	0		0	1	0	0	0	0	0	4
Crawford, Ed.D.	Herman	Alternate	0	1	1	0	1	0	0	1	1	0	0	0	5
Dohnal	Theodore	Alternate	0	1	1	0		0	1	1	1	1	0	0	6
Eisenbeiser	Ashley	Alternate	1	1	1	1	1	1	0	1	1	1	1	0	9
Flusberg	Martin	Alternate	1	1	1	1		0	1	1	1		0	0	7
~~Hsieh~~	~~Hsing-Yi~~	~~Alternate~~	1	1	0	1	1	1	1	1	1		0	0	8
~~Huffman~~	~~Troy~~	~~Alternate~~	1	1	1	0	1	0	1	0	1		0	0	6
~~Pollock~~	~~Evelin~~	~~Alternate~~	1	1	1	1	1	1	1	1	0		0	0	8
Seminara	Mario	Alternate	0	1	0	0		0	1	0	0		0	0	2
Smith	Melissa	Alternate	1	1	0	0		0	0	0	0		0	0	2
Temke	Laura	Alternate	1	1	0	1		0	0	0	1		1	0	4
Wildey	Laura	Alternate	1	1	1	1	1	1	1	1	0		0	0	8
Wilson	David	Alternate	0	0	1	0		0	0	0	0		0	0	1
ZENLEA	JEREMY	Alternate	0	1	1	0		0	0	0	0		0	0	2
Dunleavy	Sean	Alternate											0	0	
Wallingford	Shelly	Alternate											0	0	
			11	17	14	10			11	10	10		4		83
Johnson	**Jona**	**CDC Consultant fill-in while Beth Wittry on leave**					1								1

															0
NOTES:															0
Vanessa Bussiere emailed 8/3/22, she missed a few meetings due to family issues and send pros and cons															0
Mark Speltz emailed 5/25/22 that due to a new job assignment that will take up a significant amount of time he will no longer be able to participate in the committee.															0
															0
															0
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															0

***** Serving in the consumer group slot under a temporary waiver appoved by

Large documents posted online (e.g., Food Code) are to be referenced only by the web address along with a notation of the specific page and/or section numbers; large publicly available documents are NOT to be attached in their entirety.

The downloaded document is too large, and we were unable to save.

We were unable to insert a web address.

Attachment link:

https://www.fda.gov/media/117509/download

References for FSMS #4 – Create FSMS Committee as Standing Committee:

- FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-service Restaurants, 2013-2014 (2018). https://www.fda.gov/media/117509/download
- Cormier, R.J., Mallet, M., Chiasson, S., Magnusson, H., and Valdimarsson, G. (2007). Effectiveness and Performance of HACCP-based Programs. Food Control, 18(6), 665-671.
- Luning, P.A., Bango, L., Kussaga, J., Rovira, J., and Marcelis, W.J. (2008). ComprehensiveAnalysis and Differentiated Assessment of Food Safety Control Systems: A Diagnostic Instrument. Trends in Food Science & Technology, 19(10), 522-534.
- Luning, P.A., Marcelis, W.J., Rovira, J., Van der Spiegal, M., Uyttendaela, M., and Jacxsens, L. (2009). Systematic Assessment of Core Assurance Activities in a Companyspecific Food Safety Management System. Trends in Food Science & Technology, 20(6), 300-312.
- Ropkins, K., and Beck, A.J. (2000). Evaluation of Worldwide Approaches to the Use of HACCP to Control Food Safety. Trends in Food Science & Technology, 11(1), 10-12.

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME *Digital Food Safety Management Systems*

DATE OF FINAL REPORT: *11/10/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: ERIC MOORE AND BEN CHAPMAN

COMMITTEE CHARGE(S):

1. Identifying best practices, existing guidance documents, and research that relate to the use of digital food safety management systems including digital temperature monitoring equipment.
2. Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Food Safety Management Systems (DFSMS) including digital temperature monitoring equipment.
3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 4 (Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors), Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
4. Reporting the committee's findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

COMMITTEE WORK PLAN AND TIMELINE:

Workplan:

- *Monthly full committee meetings (Started in Nov. 22)*
- *Collect existing literature, guidance, and research documents related to Digital Food Safety Management System (DFSMS)*
- *Create basic best practice guidance document from document research findings for use as a working outline*
- *Create two working subcommittees to edit working outline*
- *Sub-Committee meetings started 06/01/2022*
- *Meetings scheduled to occur by-weekly*
- *Committee review and approval of best practice guidance document*
- *Create sharing plan*
- *Report findings and recommendations*

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

- *Committee determined that monthly full committee calls (when feasible) were appropriate.*
- *Created file and document sharing process for committee members access and use for research documents and working group documents.*
- *Committee identified several existing documents (research, industry articles, regulatory guidance) during the research discovery.*
    - *Received and reviewed over 30 documents and publication*
- *Committee determined the need to develop alignment around terminology of what a Digital Food Safety Management Systems (DFSMS) and Digital Temperature Monitoring Equipment (DTME) is and is not. This was accomplished by creating definitions that the committee came to consensus on.*
- *Committee agreed that a good starting point for a Best Practice Guidance document would be to use an existing regulatory guidance document as a starting point (FDA-Guide to Inspections of Computerized Systems in the Food Processing Industry) for the committees work on developing a best practice document to simplify format and approach with an existing regulatory best practice document.*
- *Committee determined the need to establish two working subcommittees to revise/edit the existing guidance document with the goal of developing an appropriate retail focused best practice guidance document.*
    - *Two subcommittees were created; one to focus on DFSMS, and the other to focus on DTME*
    - *Subcommittees determined that bi-weekly meetings (when possible) would be needed to complete necessary edits/revisions.*

Subcommittees also agreed to providing progress reports on monthly full committee calls.

- *Subcommittee outputs were combined into a single document: General Best Practice Guidance for Food Establishments and Regulatory Authorities for Digital Food Safety Management Systems.*

- *Chairs of this committee have been in communication with the CFP liaisons for the Retail Food Regulatory Association Collaborative on future steps (such as FDA grant funded industry research) and deliverables of this* committee's *work. These efforts focus on a grant objective to encourage the application of digital tools and incentives that prompt desired behaviors (e.g., handwashing) in collaboration with retail food and foodservice industry trade organizations.*

- *On 12/12/2022 a 2-day voting member electronic vote to Approve the final version of the DFSMS Best Practice document was initiated for all 19 voting members.*
  - *Voting closed on 12/14/2022.*
  - *Voting member quorum was obtained (18 yes, 1 no),*

COMMITTEE AND SUBCOMMITTEES MET ON THE FOLLOWING DATES: *NOVEMBER 16, 2021 – FEBRUARY 8, 2022 - MARCH 18, 2022 - APRIL 29, 2022 - MAY 23, 2022 - JUNE 17, 2022 - JULY 1, 2022 - JULY 15, 2022 - AUGUST 12, 2022 - SEPTEMBER 7, 2022 - SEPTEMBER 9, 2022 - SEPTEMBER 23, 2022 - OCTOBER 7, 2022 - NOVEMBER 2, 2022 - NOVEMBER 4, 2022 - NOVEMBER 7, 2022* - DECEMBER 8, 2022

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. All charges completed
3. ***Charges INCOMPLETE and to be continued to next biennium:***
   a. None

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***
☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**
1.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. ***Committee Issue #1: Report – Digital Food Safety Systems Committee***

   List of content documents submitted with this Issue: ***Committee Member Roster:***

   ☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***
   "Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

   (1) ***Digital Food Safety System Committee Final Report***
   (2) ***Digital Food Safety Management Committee Member Roster***
   (3) ***Draft General Best Practice Guidelines for DFSMS***

   a. **List of supporting attachments:** ☐ ***Not applicable***

   (1) ***Attachment 1_Original CFP ISSUE)2020_II_021***
   (2) ***Attachment 2_DFSSC Meeting Minutes***
   (3) ***Attachment 3_DFSSC Definitions Accepted***
   (4) ***Attachment 4_Computerized Systems in Food Processing FDA***
   (5) ***Attachment 5_SubCommittee DRAFT DFSMS Best Practices Doc***

2. ***Committee Issue #2: Approve/Post General Best Practice Guidelines for Digital Food Safety Management Systems***
3. ***Committee Issue #3: Amend Food Code Annex to Include Reference to General Best Practice Guidelines for Digital Food Safety Management Systems***

Committee Name: Digital Food Safety

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Moore	Eric	Co-Chair	Industry	Testo Solutions	West Chester	PA	215.806.4717	emoore@testo.com
Chapman	Ben	Co-Chair	Academia	N.C. State	Raleigh	NC	919.809.3205	bjchapma@ncsu.edu
Brandt	Matthew	Member	Regulatory - State	Colorado Department of Public Health and Environment	Denver	CO	720.550.0322	matthew.brandt@state.co.us
Samples	Jarryd	Member	Regulatory - State	Idaho Department of Health and Welfare	Boise	ID	208.866.0934	jarryd.samples@dhw.idaho.gov
Splawn	Travis	Member	Regulatory - State	Oklahoma State Department of Health	Oklahoma City	OK	405.535.5813	traviss@health.ok.gov
Vauls	Patricia	Member	Regulatory - State	Maryland Department of Health	Baltimore	MD	443.609.3072	patricia.vauls@maryland.gov
Matulis	Katie	Member	Regulatory - State	WI DATCP	MILWAUKEE	WI	414.551.2510	katie.matulis@wisconsin.gov
Nord	Jennifer	Member	Regulatory- Local	University of Michigan OSEH	Ann Arbor	MI	734.709.7582	harrisjl@umich.edu
Pascucilla	Michael	Member	Regulatory- Local	East Shore District Health Department	Guilford	CT	203.619.1286	mpascucilla@esdhd.org
Coffman	Vanessa	Member	Consumer	Stop Foodborne Illness	Chicago	IL	971.409.4968	vcoffman@STOPfoodborneillness.org
Abney	David	Member	Industry	Pizza Hut	Plano	TX	405.210.1278	david.abney@yum.com
Abouchar	Julie	Member	Industry	Whole Foods Market	Peachtree	GA	678.255.1202	julie.abouchar@wholefoods.com
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Jenkins	Matthew	Member	Industry	McDonalds	Chicago	IL	312.405.4631	matt.jenkins@us.mcd.com
Roberson	Michael	Member	Industry	Publix	Lakeland	FL	863.688.1188	michael.roberson@publix.com
Yoo	Joey	Member	Industry	Compass Group	Charlotte	NC	401.327.0937	woojin.yoo@compass-usa.com
Yang	Lilly	Member	Industry	Acheson Group	Blacksburg	VA	808.646.1554	Lily.Yang@AchesonGroup.com
Owen	Gina	Member	Industry	Ecolab	Greendboro	NC	336.688.5461	gina.owen@ecolab.com
Ruiz Espejo	Jonathan	Member	Industry	Retail Business Services	Salisbury	NC	704.640.7015	m
Last Name	**First Name**	**Position on Committee**	**Constituency**	**Employer**	**City**	**State**	**Phone**	**Email**
Sudler	Robert	FDA Consultant	Regulatory - Federal	FDA			240.402.1943	Robert.Subler@fda.hhs.gov
Wittry	Beth	USDA Consultant	Regulatory - Federal	USDA			770.488.7333	Xks5@cdc.gov
Kramer	Adam	CDC Consultant	Regulatory - Federal	CDC			404.498.1228	ank5@cdc.gov
Last Name	**First Name**	**Position on Committee**	**Constituency**	**Employer**	**City**	**State**	**Phone**	**Email**
Bhatt	Chirag	Alternate	Industry - Support	HealthSpace USA	Houston	TX	281.684.6883	chirag.bhatt@hscloudsuite.com
Ciarimboli	Ellen	Alternate	Industry - Retail Food	Hy-Vee Inc	West Des Moines	IA	515.453.2789	eciarimboli@hy-vee.com
Davis	Brianna	Alternate	Industry - Food Service	Savory Restaurant Fund	Lehi	UT	801.642.3800	brianna@savorymanagement.com
Edsall	Jean	Alternate	Industry - Support	Matrix Sciences	Centreville	VA	330.432.4078	jean.edsall@kroger.com
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Martin	Eric	Alternate	Industry - Food Service	Texas Roadhouse	Louisville	KY	502.515.7382	ericm@texasroadhouse.com
Melichar	Wayne	Alternate	Industry - Vending and Distribution	Feeding America	Elmhurst	IL	312.399.5281	WMELICHAR@FEEDINGAMERICA.ORG
Nardone	Angela	Alternate	Industry - Support	Share-ify	Longwood	FL	805.907.2233	nardone@share-ify.com
Pascoe	Roxanne	Alternate	Industry - Retail Food	Metropolitan Market	Seattle	WA	206.549.5613	rpascoe@metropolitan-market.com
Scott	Kevin	Alternate	Industry - Support	Ayro Inc	Stephens City	VA	540.974.2092	kevin.scott@ayro.com
Seaman	Charles	Alternate	Industry - Retail Food	Hy-Vee, Inc.	Racine	WI	262.488.3131	pokie102@gmail.com
Sperber	Michael	Alternate	Industry - Support	UL	Simi Valley	CA	818.388.9890	michael.sperber@ul.com
Wiser	Darrell	Alternate	Industry - Retail Food	Ecolab	Lehi	UT	479.426.5738	darrell.wiser@ecolab.com
Wynnw	Rebecca	Alternate	Industry - Food Service	Darden	Denver	CO	303.895.4042	rwynne@darden.com
Woodbury	Thomas	Alternate	Industry - Support	ComplianceMate	Holladay	UT	801.330.9511	thomas.g.woodbury@gmail.com

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise;*

Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 36 -Non-voting alternates.

Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

General Best Practice Guidance for Food Establishments and Regulatory Authorities for Digital Food Safety Management Systems

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A. Introduction and Scope

The use of Digital Food Safety Management Systems (DFSMS) within the retail food industry, regulated by the Food and Drug Administration (FDA), continues to gain widespread interest, acceptance, and use. The use of DFSMS is expected to continue to grow in the retail food industry as technology improves and components become more readily available. As technology advances the retail food industry continues to replace paper-based records associated with traditional food safety management systems with digital documentation. Recent FDA Risk Factor study results have shown that utilizing a robust management system leads to a reduction in food safety risk factors.

An oft-used component of a DFSMS, Digital Temperature Monitoring Equipment (DTME) can improve awareness, response, and documentation of temperature conditions. This technology allows more accurate, reliable, and efficient food and equipment temperature control impacting safety and quality improvements. As DFSMS and DTME become more common in the retail food industry, the visibility, awareness, and availability of information that these systems and technology can provide should support improvements in controlling food safety risk factors in food retail.

This guidance will outline food safety management approaches specific to the implementation and use of technology in food retail. Best practices provided in this document serve as a foundational guide for the collection of accurate, consistent, and reliable data that can be used to make risk-reduction decisions. This document has been written with the assumption that a food retail establishment has a food safety management system and that they have identified and addressed HACCP Principles 1, 2 and 3 as referenced in Annex 4 of the most recent version of the U.S. FDA Model Food Code.

B. Definitions

Digital Food Safety Management System (DFSMS)

An interactive, digital, or electronic archive intended to collect, store, and analyze data that supports a food safety management system as defined in Annex 4 of the most recent version of the U.S. FDA Model Food Code. DFSMS specifically supports ongoing quality control and assurance, monitoring and recordkeeping of specific food safety goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the most recent version of the FDA model Food Code. A DFSMS employs active user-based workflows that support decision making, that can be reviewed and acted upon, and may be housed locally (on-premises) or be accessed remotely using off-site servers or cloud storage.

DFSMS may include but are not limited to functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports (i.e., Trends over time)

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital Temperature Monitoring Equipment (DTME)

Automated purpose-built temperature measuring device(s) that often includes sensors capable of generating and capturing temperature data for analytical use. This equipment may include the functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time that may connect to a system that may be capable of delivering alerts and exception reports.

Software

Software is the term used to describe the total set of programs, procedures, rules, and any associated documentation pertaining to the operation of a technology-based system that

includes, but is not limited to application, operating system, and utility applications used by the computerized system.

C. Prerequisites

Best practice for a DFSMS is to employ purpose-built hardware and software when designing and implementing an approach. The appropriateness of hardware and software should meet the goals of any RCP. Maintenance of the system and the proper replacement of system hardware is critical for it to function as designed. Design specifications of the hardware and software should be determined and periodically reviewed to ensure the system and its functional components do what is intended to support food safety.

This document recognizes that DFSMS are built and utilized to support the most recent version of U.S. FDA Model Food Code, Annex 4, HACCP Principles specifically:

Principle #4: Establish Monitoring Procedures
Principle #5: Establish Corrective Actions - implementation of the corrective action specifically
Principle #6: Verification/Sharing for equivalency for regulatory checks
Principle #7: Record keeping procedures and documentation

Personnel operating, maintaining, and programming DFSMS should have adequate training to complete their assigned duties. Determine the extent of operator, system managers, and software system technical personnel training in the functions, requirements and operation of the computerized system.

Examples of training may include but are not limited to:

- system operation
- malfunctions
- regulatory requirements
- system changes
- security procedures
- manual operation of the system
- documentation of system errors

D. DFSS Inputs

Digital Food Safety System Equipment (DFSSE)

DFSSE typically include various purpose-built and designed stationary and handheld measurement instruments, tools, and sensors capable of the collection, storage, and

transmission of data into software. The food contact surface of DFSSE must meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent. Examples may include but are not limited to mobile device(s), sensors, thermometers, RFID/QR Code scanner/receiver, etc.

Stationary Monitoring Devices

Purpose build devices which are permanently or semi-permanently affixed, mounted, installed, attached to equipment or surface using food grade mounting/installing materials, maintained free of accumulated soil, and cleaned per manufacturer instructions. When devices do not include an external measurement display, access to the measurement data should be easily accessible and viewable. These devices when appropriate should meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent.

> *Note: DFSS Stationary temperature monitoring devices must meet the requirements outlined in the most recent version of the U.S. FDA Model Food Code 4-204.112 Temperature Measuring Devices*.

Device examples may include but are not limited to equipment or wall mounted data loggers, humidity sensors, door open/close sensors, camera's, etc.

Data access examples may include but are not limited to: Software report on mobile, desktop, tv monitor/screen, etc.

DFSSE Accuracy

Handheld and stationary temperature measurement instruments must meet the most recent version of the U.S. FDA Model Food Code 4-203.11 & 4-203.12. In the event that a handheld or stationary temperature device does not have a display; the operator should be able to easily demonstrate/record the reading/actual monitored temperature (value) for review and record. Follow OEM recommendations & guidelines and follow their procedures.

DFSSE Functionality

Regular and ongoing equipment and system operation functionality are recommended to be conducted (refer to manufacturer for frequency) to verify that DFSMS, DFSSE and DTME in use are operating as intended, if/when issue(s) are identified appropriate action is taken to correct issue(s).

Examples of device functionality issues are but are not limited to:

- Power loss
- Improper device installation
- Device damage/defective

- Software communication/connectivity
- Device communication/connectivity

It is recommended that records of software and equipment functionality verification be maintained and readily available.

Examples of functionality verification may include but are limited to:

- Handheld measurement device accuracy & functionality
- Stationary measurement device accuracy & functionality
- Software and device connectivity/communication

E. Data and System Infrastructure

DFSMS data are the measurement values and user inputs captured by DFSSE, DTME and DFSMS users that are then stored in DFSMS software. Data storage may be stored locally (on-site) or virtually (cloud storage) but access to this data must be readily available for use and display on-site. This makes it possible to retrace which value occurred at which time.

Examples of, but not limited to, measurement values that may be recorded and stored as data in a DFSMS:

- Time points and Account IDs which are assigned to certain quality checks
- Description of the area
- Description of the equipment
- Description of the products/product categories
- Description of the measurement locations of the equipment
- Description of suppliers
- Check lists/Quality handbook
- Tasks (Daily, Shift, On-Demand)
- Reports (Daily, Shift, On-Demand)
- Product specific quality and safety measurement data points (Temperature, pH, TPM, PPM, humidity, time)
- Alerts (alerts are notifications to users)
- Alarms (is the result of an unacceptable software or hardware reading)
- Alert recipients
- Corrective actions associated with checklists and measurement points
- Manual data entry (for immutability and data integrity)

When DFSSE, DTME or a DFSMS user completes a measurement this value is stored in DFSMS software. Each measurement value represents a unique permanent data point represented in the DFSMS software, additional or new data (including that which is associated with an existing or old data point) are then stored in a sequential manner allowing for the original data point to remain. This can be described as a time-based progression of record keeping. The DFSMS software should also be capable of recording all previously recorded data should be readily accessible and documented when changed and available for reporting.

Digital Temperature Monitoring Equipment (DTME) Data

There are three broad ways of capturing temperature and humidity data; they are commonly identified as hand-held, stationary, or Integrated temperature measuring devices. An important consideration for DTME is that devices have the ability to cache/store data locally when connectivity is interrupted, if/when data connectivity is interrupted a DTME device should have the ability to push/send cached/stored data to the DFSMS system when connectivity is restored.

Verification / Immutability

A retail food business may have measures in place to ensure that data captured by the computerized system cannot be altered without a digital signature record or other means of tracking history of inputs. If provisions are made to allow correction of data entries, the entry may identify the person making the changes, the reason for the change and reference to the originally captured data.

Data and System Integrity and Access

Data Integrity and Access are both important aspects of a DFSMS that should be considered to ensure that quality of the information collected by the system is accurate and reliable. To support the integrity of a DFSMS it is recommended that reasonable controls are in place to ensure that stored and/or in-process data is not able to be altered in an unauthorized manner, and that any changes to the DFSMS and/or the stored/in-process data is captured.

Data access is also a way to support effective data integrity. Access to a DFSMS should be controlled and limited only to those persons to whom permission is granted. All data and information should be protected through reasonable use of encryption protocols.

Examples of encryption may include, but are not limited to:

- Utilizing passwords,
- User management and,
- User rights.

Examples of information and/or data for encryption include but are not limited to:

- Passwords
- Proprietary business information
- Data transferred between the input devices and local/cloud-based reporting and storage programs/locations.
- Login occurrences
- Access to information within the DFSMS should also be tailored according to a user's role and responsibilities, writing, or reading rights.

Manual Data Entry

Determine if and how manual interventions are documented; a separate log may be kept of such interventions. The computerized system may be such that it detects, reacts to, and automatically records manual interventions. It is important that system operators are trained in manual backup systems as a best practice this should be documented and conducted prior to DFSMS usage. To ensure business continuity, it is recommended that users have their own SOP for review (redundancy) to ensure practices are being enacted.

Manual Back-Up

A manual back-up system is frequently utilized as a function of business continuity in the event of a computerized system (e.g., hardware or software) failure. Functions controlled by computerized systems may sometimes also be controlled by parallel manual backup systems. As a best practice, functions that are manually controlled and/or manually backed up should be identified and noted re: the firm’s protocols or the system’s protocol. Critical process controls are particularly important. Determine the interaction of manual and computerized controls and the degree to which manual intervention can override or defeat the computerized function. The firm's operating instructions should describe what manual overrides are allowed, who may execute them, how and under what circumstances.

F. DFSMS Outputs

System Outputs and Notification(s)

Typical DFSMS and DTMS include the capability to include user level notification(s) tailored around programmable components of an organization's Standard Operating Procedures (SOP), see What Data is Stored section above for measurement examples that may be involved.

Examples of user level system notification(s) may include but are not limited to the following:

- Reports
- Trends
- Automated emails
- SMS or text message
- Phone calls
- Visual indicators (lights)
- Audible indicators (sounds)

A best practice is to associate one or more corrective actions with an alert. To assure corrective actions are completed in a timely fashion, alerts can be escalated when corrective actions are not completed within a set timeframe.

G. Committee Members

Academia/Industry Members				Regulatory Members	
Ben	Chapman	Eric	Moore	Justin	Asberry
Vanessa	Coffman	David	Abney	Robert	Sudler
Julie	Abouchar	Amanda	Douglas	Beth	Wittry
Jaime	Estes	Julian	Graham	Adam	Kramer
Matthew	Jenkins	Michael	Roberson	Matthew	Brandt
Joey	Yoo	Lilly	Yang	Jarryd	Samples
Gina	Owen	Jonathan	Ruiz Espejo	Travis	Splawn
Chirag	Bhatt	Ellen	Ciarimboli	Patricia	Vauls
Brianna	Davis	Jean	Edsall	Katie	Matulis
Martin	Flusberg	Jeffery	Lindholm	Naomi	Macias
Eric	Martin	Wayne	Melichar	Jennifer	Nord
Angela	Nardone	Roxanne	Pascoe	Michael	Pascucilla
Kevin	Scott	Charles	Seaman		
Michael	Sperber	Darrell	Wiser		
Rebecca	Wynnw	Thomas	Woodbury		

Conference for Food Protection
2020 Issue Form

Issue: 2020 II-021

Council Recommendation:	Accepted as Submitted		Accepted as Amended	**x**	No Action		
Delegate Action:	Accepted		Rejected				

All information above the line is for conference use only.

Title:

Creation of a Digital Food Safety System Committee

Recommended Solution: The Conference recommends...:

the creation of a Digital Food Safety System Committee to complete the following charges and report its findings at the next CFP Meeting.

The Committee will be charged with:

1. Identifying best practices, existing guidance documents, and research that relate to the use of digital food safety management systems including digital temperature monitoring equipment.
2. Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Food Safety Management Systems including digital temperature monitoring equipment.
3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 4 (Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors), Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
4. Reporting the committee's findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 1
DATE: 11/16/21
TIME:11am – 12:30pm (Est)

Co-Chairs: Eric Moore & Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Eric Moore

Agenda

1. Welcome, Call to Order
2. Rollcall,
3. Conference for Food Protection, Inc. Antitrust Statement
4. Identify a Committee Scribe:
5. Review CFP Timeline for Committee Work:
6. Review of Committee Charges:
7. Overview of Committee Plan of work:
8. Action Items:
9. Determine next meeting date:

MEETING MINUTES:

1. **Meeting Called to Order:**
    - First D0K Committee meeting called to order at 11:10am,
        - Motion to begin meeting: Eric Moore
        - Motion accepted 1st Matt Brandt, 2nd Tom Woodbury
    - Committee chairs thanked all members for interest and agreement in being part of this working committee
    - Active participation in committee work was stressed given the condensed work timelines
    - Councill II Chair (Joetta Defrancesco) will be speaking to CFP leadership to get a clear understanding around the level of access for committee members to use Teams as a preferred file sharing platform. More details to be provided during the next meeting.
2. **Roll Call:**
    - Roll Call Conducted by Eric Moore
    - Roll call will be completed using Teams participant list to check for voting member quorum
    - Current voting member quorum requirement is 11 voting members
    - Attendance record captured on committee attendance log
3. **Conference for Food Protection, Inc. Antitrust Statement**
    - Full CFP Antitrust read by Ben Chapman
    - Complete antitrust statement review will be suspended for future meeting
    - Brief review of CFP-Antitrust will be completed for all future full & sub-committee meetings
4. **Identify a Committee Scribe:**
    - Lily Yang agreed to be committee scribe
    - Julian Graham agreed to be stand-by scribe to ensure continuity
5. **Review CFP Committee Work Timeline:**
    - Meeting was not recorded due to committee chairs not having Teams recording access
    - Current plan is to have full committee calls completed monthly, beginning in December

        - A straw poll about full committee monthly calls was with unanimous support.
    - Review of CFP Master Calendar identified the following key dates:
        - October 2021 – 1st Periodic report sent to Council Chair (PDF copy provided to committee)
        - March 2022 – 2nd Periodic report due to Council Chair
        - July 2022 – 3rd Periodic report due to Council Chair
        - November 2022 – Final report due to Council Chair
6. **Review of Committee Charges:**
    - Committee charges review completed
    - Committee was reminded that the charges are not able to be changed
    - Chairs provided a note of caution related to “Scope Creep” away from the charges
7. **Overview of Committee Working Plan:**
    - Full committee call all frequency to be monthly
    - 7 full committee meeting meets are going to be planned over the next 12 months
    - These meetings will act as a review/report out of sub-committee actives
        - Sub-committee meetings will occur in between these meetings
    - Meeting 0: Introductions
    - Meeting 1: Define committee focus, identify sub-committee needs, members, etc.
    - Meeting 2 & 3: Focus on work completed around charges 1 & 2
    - Meeting 4: Determine structure of documents identified in Charge 3
    - Meeting 5 & 6: Review of documents
    - Meeting 7: Review of Final Report
        - Slide deck was used to provide work plan details
        - Deck was provided to all committee members for reference
8. **Action Items**:
    - Charis to provide a voting member meeting poll to be sent out to determine most appropriate reoccurring monthly meeting dates & time
    - Committee members we requested to notify chairs of any committee conflicts that a member may have that will limit a member's active engagement.
    - Committee members were requested to:
        - Further review the committee charges
        - Think about how to define:
            - Digital Food Safety System
            - Digital Temperature Monitoring System
9. Questions – The following questions were asked by committee members:
    - Q1: How will meeting frequency be determined?
        - A1: Through voting member feedback
    - Q2: Will the use of organizational “Use-Case” documents be appropriate for use by committee?
        - A2: All documents are welcome for review and use by the committee
    - Q3: To reduce the potential for committee member work duplication around document research, will it be possible to have industry members and regulatory members focus on documents and information specific to constituency?
        - This is a great idea and will be part of further committee conversations
    - Q4: Is there a project management tool (ex-Smart Sheets) that could be used by the committee to support better transparency of work progress
        - A4: Great idea, committee chairs will look into if this is possible

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

-

10. Next Meeting Date:

- TBD after voting member poll is completed

Meeting Number: 2
DATE: February 8, 2022 **TEAMS and phone in options in calendar invite**
TIME: 10am ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Julian Graham (on behalf of Lily Yang)

Agenda

1.	Welcome, Call to Order
2.	Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
3.	Discuss Definitions
4.	Discuss documents collected by committee members (is anything missing? Next steps)
5.	Review FDA computerized document as a model for our committee guidance?
6.	Refine/add to/further outline what else would be captured
7.	Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: March 18, 2022 1pm ET

I. Welcome, Call to Order

Eric called meeting to order
Michael Robison call
Tom Woodburry second

II. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

Eric did roll call
Eric reviewed antitrust statement & shared link in the chat

III. Discuss Definitions

Eric shared screen
Ben lead discuss
1st charge

Digital food safety management system: A digital or electronic collection of policies, procedures, data, monitoring actions, cloud-based functionality including real-time alerting, automated reporting, and supporting documentation to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food and food products intended for human consumption. .,

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Digital temperature monitoring equipment: Electronic sensors/devices capable of automatically measuring, monitoring, storing, transmitting, documenting and sharing the temperature (and potentially other characteristics) of food, air, or water. Monitoring equipment allows for the capture and storage of temperature data over a period of time and connects to a system capable of delivering alerts and exception reports.

Highlighted cloud-based functionality including real-time alerting not all system need to be cloud based some organization do not house data in the cloud.

Open Committee Discussion on Definitions:

Michael Roberson - I recommend striking "cloud based." Not all digital systems will be cloud based, especially when companies work to address data security concerns. Larger companies have their own servers and will not place all data into the cloud due to these data concerns.
Woodbury, Thomas - As a "Teams" novice... if you need to zoom in on the text displayed, hold down control/command and use your mouse wheel to scroll to zoom in/out
Rebecca Wynne - Added visibility
Angela (Guest) - Added capture/recording
Michael Roberson - I agree with Ben, as the Food Safety Management System is inclusive of all parts - policies, procedures, records, and monitoring actions. YES to recalls.
Adam Kramer - What should be the minimum requirements be.
Michael Roberson -Policies on a company intranet is one component. It may be helpful to have separate core components. Policies alone would not necessarily constitute having a digital food safety management system. Likewise, having an electronic recall system, without any policies and procedures, would not constitute having a digital food safety management system. Think "Active Managerial Control" components that are actively engaged on a regular basis.

Justin Asberry: Wanted to drop in the definition from the Food code for a FSMS:

Elements of an effective food safety management system may include the following:
• Certified food protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
• Standard operating procedures (SOPs) for performing critical operational steps in a food preparation process, such as cooling
• Recipe cards that contain the specific steps for preparing a food item and the food safety critical limits, such as final cooking temperatures, that need to be monitored and verified
• Purchase specifications
• Equipment and facility design and maintenance
• Monitoring procedures
• Record keeping
• Employee health policy for restricting or excluding ill employees
• Manager and employee training
• On-going quality control and assurance
• Specific goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors.

Conesus on removing Animal Foods

Angela - Is “auditable” a sufficient replacement for “legally defensible”

Edsall, Jean V - There are existing legal precedents regarding recordkeeping systems. This may already expand to digital recordkeeping systems.

Travis Splawn - Agree with others. Not sure if "Legally defensible" is the best language, or used elsewhere.

Asberry, Justin - Let me ponder on that legally defensible question.

Travis Splawn - Perhap use something like "has an audit tracking feature"?

Asberry, Justin (Guest) - I will consult with FDA-CFSAN as well to give a Food Code Interpretation on the legal defensible conversation.

Moved on to 2nd Definition:

Digital temperature monitoring equipment: Electronic sensors/devices capable of automatically measuring, monitoring, storing, transmitting, documenting and sharing the temperature (and potentially other characteristics) of food, air, or water. Monitoring equipment allows for the capture and storage of temperature data over a period of time and connects to a system capable of delivering alerts and exception reports.

Engaging conversation on both definitions. Ben & Eric will share final definition to all members for Reminder to review documents between meetings.
Motion to adjourn

Thomas Woodbury - Strike other characteristics

Comments collected by committee members (is anything missing? Next steps)

IV. Review FDA computerized document as a model for our committee guidance?

V. Refine/add to/further outline what else would be captured

VI. Wrap-up

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 3
DATE: March 18, 2022 **TEAMS and phone in options in calendar invite**
TIME: 1pm ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

8.	Welcome, Call to Order
9.	Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
10.	Past meeting minutes
11.	Voting member Definitions Poll Results Review
12.	Discuss FDA computerized document as a model for our committee guidance?
13.	Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: April 29, 2022 1pm ET

VII. Welcome, Roll Call

- Eric conducted roll call!

VIII. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- Ascertained that all individuals are comfortable of Antitrust. If anyone is uncomfortable with it, please do let Eric Moore know.

IX. Welcome, Call to Order

- Amanda Douglass approved meeting to be in order
- Julian Graham seconds
- Chirag – we may not need to do this next time as other CFP committees are *not* doing this.
- Eric – this meeting is being recorded; if anyone has questions around this, can discuss OFFLINE
    - Ben is currently unable to join today and sends his regards

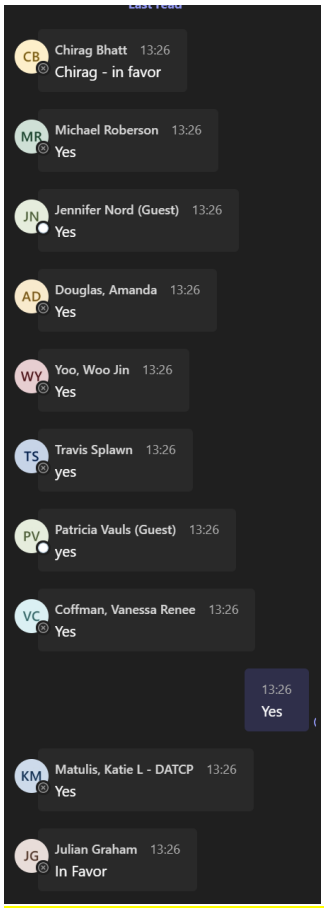
X. Last Meeting Recap

- Good discussion around the definitions that were shared with everyone for feedback. There was a lot of good discussion and Julian captured the comments accordingly.
- In the last meeting, committee discussed both definitions that were identified that were part of Charge 1
- First Definition for Digital Food Safety Management System
- Second Definition for Digital Temperature Monitoring Equipment
- With some post-editing per discussion with Eric/Ben, definitions were put into a place that everyone could be comfortable with. Yesterday, voting members completed a poll (agreement/disagreement) with the definitions that were made.
    - Consensus of vote:

    - Yes: Voting members of the committee agree with the definitions.
- (see “Discuss Definitions”)

XI. Discuss Definitions

- Eric – extends appreciation for Michael Roberson (email to Ben and Eric) stating that in a few areas, the definition used the word “must” as opposed to using another type of word. The intent, originally, was not to make rigid definitions
    - Perhaps the reason why one member voted “NO” may be due to the word “must”
    - Question for Voting Members: Do voting members feel that it would appropriate for an additional revision to the two definitions to edit the words that are very constrictive (i.e. ‘must’) and replacing with lighter words (i.e. ‘shall’) OR are voting members in agreement (now) with minor editorial revisions?
    - Michael Roberson –
        - “words matter” especially once issues and recommendations get to the Council.
        - For Council – often comes down to the wording
        - Is good with the content but did want to bring to the Committee’s attention of “the use of extremes; when we can provide flexibility, it helps”.
    - Eric – agrees with Michael – there shouldn’t be an issue with removing “most” and replacing with “shall”
- Michael Roberson, brings motion to floor: “To allow Chair and Vice-Chair Editorial Positions to address some of the words like “must” to make amendments to provide flexibility” for the two definitions.
    - Jennifer Nord seconds that motion
    - Jean (in comments)
    - Chirag: I agree with what Michael says. In order to avoid the lengthy discussion and Council discussion, it is probably in our best interest to change that word. And as we al know, Michael has been in CFP for a long time”
    - Robert Sudler: “To add to what Chirag and Michael have said. As I look at the definition themselves, the word ‘shall’ does really make a difference. We don’t want to regulate through definition”.
- Eric: “Let’s call the vote for the motion that has been provided” – votes are done via “text” in text window (see figure below).



- **Conclusion of Vote: There is voting member quorum to allow Chair and Vice-Chair editorial lee-way to replace terms like "must" with terms like "shall"**

XII. Review FDA computerized document as a model for our committee guidance?

- Is any of what is currently there usable? Any section? Content? Let's have a discussion around "that" [usability] and begin to identify – as in Charge 2 of Committee Charges – create guidance document around best practices specific to:
  - Use of Systems,
  - What these systems are (or aren't), and
  - How Regulatory Bodies can Assess Validity (including: if current system in place is viable or not)
- We all agree that a digital FSMS is *not* a PDF on a mobile device; it's more than that. Hence why we created the aforementioned two definitions.
- FDA's "Computers Systems in the Food Processing Industry" (link)
  - One of the questions – was anybody aware of the existence of this document?
    - Is it appropriate for the Committee to recommend, back to FDA, to make revisions to the existing document in relation to what our goals are OR

        - Is it better for the Committee to use it as a starting point for what we've been charged w/ creating and submitting *the created* at Biennium.
    - Michael Roberson – I don't recommend editing existing regulatory documents. Better to stick to what Council charge is. Use doc as a starting point.
    - Robert Sudler – agrees with Michael. He recently reviewed the article and noted it was updated last in 2014. Although it was created by ORA but also CFSAN. Justin (ORA) and him (CFSAN) will do their due diligence to identify if there is an update flying around.
        - This should be used as a starting point – needs to be tailored to what *we* want to focus on. There's a lot, he believes, of work that needs to be done.
    - Eric – Just to be clear, if Committee identifies portions/components of this document, are we (we are) allowed to choose portions of the verbiage, right? Since this is public domain documentation; want to ensure there is no potential issues with.
        - Robert Sudler – "It's a public facing document that's out there for people to use. Certainly nothing wrong with what you've described. No, no problem"

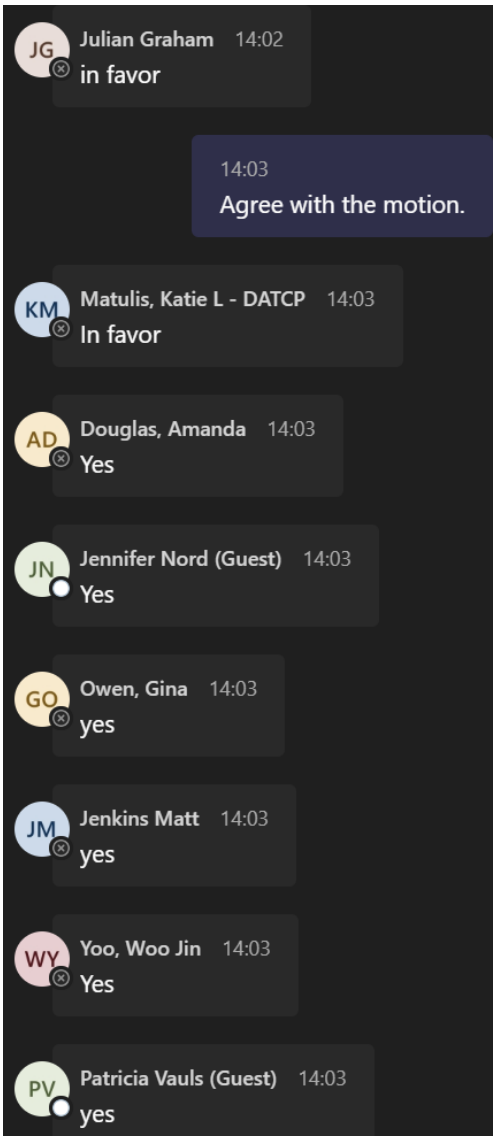
XIII. Discussion Time re: above

- Eric – for those that were able to go through this (he read it 4X):
    - What did you like?
    - What did you *not* like?
    - Is the format of this, appropriate? Format being – how the TOC is laid out ← is this format what we, as a committee, think will be appropriate for us to develop for the two documents to be created as part of the Charge? OR do we need to blow the format up and think of something new and different?
- LY: Wanted to better understand, are you referring to Chapter?
    - Eric: Right, this is the question – do we want it to mirror like that? "This has a very federal feel to it. Is that format appropriate for what we want to produce? OR does anybody have any suggestions for a different format that would be user-friendly for industry and/or regulatory individuals"
    - Robert Sudler - "is your attempt to modify or create a similar document that's geared towards the retail sector? Is that the eventual goal –that is able to cite Food Code provisions?"
        - Eric: In essence, yes. To replace wording. But we all know that isn't a possibility Leading to the next question – what portions of this document do Committee members are appropriate for Use or Adaptation for what *we* want to create?
            - Ask the latter question first.
            - Response for above re: formatting (LY) – it needs to be revised b/c it's not really useable
- Eric – Table formatting, let's focus on CONTENT
- Current Document - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/computerized-systems-food-processing-industry
    - Provided segregation of topics based on HARDWARE, SOFTWARE, PROCESS, PERSONNEL
        - Do we want to copy these topics over? Or do we want to reorganize parts of it?
        - Does there need to be sections of "Technology Overview" and such sections?
    - Julian – does not believe that this is the best approach to reading the document.
        - Explore from the Different Buckets. Thinking about a "DFSMS", there's some autonomous measurements that happen (e.g. IoT systems, people-driven

systems wherein handheld BT probes may be used, to digital version of checklists) – Using those three buckets

- Eric: What do people feel like? Hypothetically (below list) are the core sections of the document that we will create which mirror **Chapter 2** of document.
    - Overview
    - Hardware/peripherals
    - Software
    - Data storage and access/sharing
    - Maintenance and calibration
    - User/training/knowledge
- Chapter 2 seemed to have the most useful information to both BC & EM to move the project forward
    - Are there any buckets missing, from above? Or are any of them subsets of one/other?
- Jean Edsall
    - Has paged through document and while it has good definitions and descriptions of hardware and software and with rapid changing of technology (and the out-dated ness of this – what we write must be more generic and not as specific).
    - On proposed topic – there needs to be a MANAGER's piece of it for discussion management systems.
        - What's the manager's role and responsibilities
        - Who is responsible for it?
    - Eric: So looking at "User/training/knowledge" ← let's consider revising *this* title to have discussion
        - Adding "manager role and responsibilities" underneath
    - Jean: What are acceptable substitutions? How do you prove to regulatory? And how does regulatory utilize this document to assess that things are done right
        - What is industry moving towards?
        - What is regulatory going to use to assess the systems.
    - Eric – do you think that the above are subsets or a new section?
        - Jean – we need more feedback
- Eric:
    - While this document is outdated, a lot of the information within the current FDA document is not applicable to what is being created.
    - Example: should we include "inspection concepts" as part of that list?
    - Robert Sudler: Something to consider – if you're making a guidance document, one thing to focus on should be…if someone was reading the Food Code, what is missing and what doesn't currently fall in the Food Code.
        - When it comes to the Food Code, what is currently falling short & it should be addressed in the guidance document.
        - Ultimately this document should be able to assist with what may be missing and address potential gaps.
- Jin Woo Yoo –
    - It wouldn't hurt to add regulatory compliance section. Under the regulatory compliance section, we can add the details of the regulation that we can provide to regulator. It can act as a good chain-of-custody & be able to provide guidance for what to provide to regulators.

    - Jennifer Nord: To add to that, we not only need to think about regulators, but also how industry will be using/doing with this guidance.
- *Current updated List* @ 13:54 ET
    - Overview
    - Hardware/peripherals
    - Software
    - Data storage and access/sharing
    - Maintenance and calibration
    - User/training/knowledge
        - Manager role and responsibilities (person in charge – FC)
    - Regulatory Compliance
        - From Katie Matlulis - we could make a regulatory compliance checklist with the main points from the guidance document (more of a cheat sheet)
        -
- Justin Asberry (w/ FDA)
    - "How would the two definitions from last call fit into this document? In the beginning? In the definition?"
    - Eric: Yes. Ben and I chat that while we were creating the list above, we do all need to ensure that these definitions also cover the overlapping document itself
        - Yes, a definition aspect needs to be included for sure
- Katie Matulis DATCP (in chat):
    - A suggestion, we could make a regulatory compliance checklist with the main points from the guidance document (more of a cheat sheet)
    - Eric: great idea!
- Looking at the other sections of *List* – any opinions, perspective, recommendations for what would fall within each of the *Sections* – portions of this existing FDA document could begin to incorporated if Committee would like to do that!
    - Eric: We need to conceptually and mentally aware that we will be creating two different documents. The definition exercise was the generator for the document(s) that we would need to create. Each of the lists – one for DFSMS & another for Best Practice for digital temperature monitoring equipment – would be addressed.
        - Moving into a final place (from editing & finalizing perspective), can probably blend the two; however, for right now's ease of workstream, if Committee agrees that it may make the most sense to split into two subgroups to focus on each of the areas separately with the intent that it'll become a whole overarching document.
    - Amanda Douglas – Agrees, there should be two
    - Eric: While there may be some redundancy, needs to be considered separately.
        - We need to be aware of the usability & real-world application that companies are in.
        - Not everyone is going to need to use both at the same time.
        - Sounds like two working committees will be what makes sense!
        - Should we make motions to start the two subcommittees?
- Amanda brings a motion that we start the process to split into two subcommittees to work within the second Charge
    - Julian Graham – seconds.
    - Voting members vote through chat window



    -
    - Matt Brandt = Yes
    - Travis Splawn = Yes
  - **Voting members have approved the creation of two subcommittees to begin to work on addressing Charge #2**
- Establishing Members of Those Committees:
  - Option 1 – Provide polls to
    - 1) voting members – needs continuity between both subcommittees & voting member quorum – once established
    - 2) At-Large Members – poll will also be out there to identify which workstream to be involved with
  - Does anyone have other suggestions?
    - “Silence means acceptance” - Eric
    - Julian & Amanda & Lily think above option are great!

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Digital Food Safety System Committee
Meeting Minuets

XIV. Refine/add to/further outline what else would be captured

- Committee meeting got through what Eric & Ben wanted to discuss
- OR do we want to discuss FDA documents that the Committee agrees for what the two subcommittees will be allowed to moving in it.
- We will need to start working on this expeditiously! – "Thanks, COVID"
- Julian – can we discuss the Timeline for the Subcommittees? What's our expectation for time, etc.?
    - Eric: Hope to get the poll out early next week (Week of March 21) for Voting Members – complete this ASAP – executed by end of next week (Week of March 21).
        - Secondary poll can be finalized by end of March 2022.
    - On next call, can identify:
        - Subcommittee completion times
        - Subcommittee reporting to the larger Committee
    - Subcommittees:
        - Will need to work independently of each other
        - However, must provide monthly progress updates.
- Which voting members would like to be Chairs of Subcommittees?
- Courtney (on phone) –
    - When you send out the poll, also let people vote who wants to self-nominate
    - Also believes it's a good idea for people to read the FDA document to figure out pieces.
    - With poll, remind people on what the Charge is and what needs to happen (since this is both for industry & regulatory – needs to be general so it's not just "old technology")
        - Will be useful to have experts lean on the sections
        - For those not as focused in this, let them ask the questions
    - Email from Joetta – deadline reminder progress report by 25th of March
        - Please be comfortable with where things are before sending in.
        - Eric – will have this part completed before next Wednesday (3/23)
- Katie Matulis (in chat) –
    - It may be useful to open up the FDA document for comments on the shared teams page/google documents/
        - Julian will convert the PDF doc to a Google Doc to allow for comments!
- Eric:
    - If you don't get the FDA podcast alerts that are coming out, there is going to be a new podcast that the FDA is pushing out that has absolute relevance to what we listen to.
    - Podcast Link (release on March 21): https://www.fda.gov/food/cfsan-constituent-updates/fdas-third-techtalk-podcast-will-be-artificial-intelligence

XV. Wrap-up

- Able to get 12 minutes back! 😊
- We will talk in a few weeks – keep an eye out for the polls!
- **Next meeting – April 29, 2022 from 1PM – 2:30PM ET**

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 4
DATE: April 29, 2022 **TEAMS and phone in options in calendar invite**
TIME: 1pm ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

14. Welcome, Call to Order
15. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
16. Past meeting minutes review
17. Sign-Up Reminders: a. Sub-Groups b. Future meeting dates/times
18. CFP Executive Meeting Overview
19. CFP Support of Future (2025) Committee Activities
20. Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: TBD

XVI. Welcome, Roll Call

- Justin Asberry does not always receive the things they are hoping to receive (from either Ben or Eric) – Ben uses the Calendar invite for meetings (that might be the meeting and not having that).
- Completed w/ Quoroum

XVII. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

XVIII. Welcome, Call to Order

- Don't need to be following protocols for Robert's Rules
- Antitrust statement by Eric

XIX. Last Meeting Recap

- If anyone has specific questions as it relates to the last meeting, raise them NOW or email Ben and/or Eric

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

- Access last meeting notes here: https://drive.google.com/drive/u/0/folders/1F7XyuNLXR5s8AepF7BjgQvQkaYblPGuz Committee documents - Google Drive

XX. Sign-up Reminders

XXI. Sub-Committee

- **Please complete by next Tuesday**
- Question: Can you see on the back end which committee we picked?
    - YES. Your email is logged
- Link: https://docs.google.com/forms/d/e/1FAIpQLSdgA5Qssxbwd0a9lCKRxs6Rx8JCfQWSvZCvz08lalAxm2utYw/viewform?usp=sf_link

XXII. Future Meetings

- **Please complete ASAP.**
- Want to get a few more, in the books
- Meeting 4 (May) - http://whenisgood.net/89m3de8
- Meeting 5 (June) - http://whenisgood.net/hrff9hx

XXIII. CFP Executive Meeting Overview

XXIV. Wendy Bell (Council 2)–

- The former Council II chair is no longer in the regulatory role.
- Courtney Halbrook (vice-chair) has stepped into Council 2 chair position
- Wendy Bell has been brought on as the new Vice-Chair for Council 2

XXV. Overview of Executive Board Meeting

- Our committee came up in a number of discussions – focusing around publications, sharing, what to do with "best practices" guides going forward
- There is a plan to release the next iteration of the Food Code in 2022
    - As we think about our recs for the 2023 bi-annual, there is a goal by FDA (supplements, not full updates) – so if there are things we'd like to recommend Food Code related, there is a potential that is on a quick turn-around
- There is a Publications Commtitee for CFP looking at the best way to distribute information to stakeholders from what comes out of conference
- Potential that CFP website will be updated

XXVI. CFP Support of Future (2025) Committee Activities

- CFP is currently in the process of applying to different funding sources to supprot a vaariety of activities
- Group who was responsible for this had reached out to inquire if there were any potential needs for funds
- We can decide/discuss what the system/interface should be for (a) temperature recording; (b) digital management systems

  - We won't be able to get to: Implementation & Barriers around these systems
    - As there is exploration for grants – do we want to get public health grants or interns that could do some exploration/research into what is available for mid- and small businesses
    - Explore barriers to implementation?
- Put together some proposals that when/if this committee is reofrmed, we can put those into the charges
  - There is a high likelihood that this committee will be reformed
- CFP has been working with NEHA and others to bolster the ability to do inside-the-organization-help-for-resaerch-committees
- Julian: How would the money be used? What are some of the ideas, when we are out there, to do X? What is X?
  - Ben: When supporting a change in implementation – what are some problems people may have achieving best practices? Is it time, resources, lack of understanding and knowledge? Funds can provide starting point to fill gaps. As we're writing the best practices documents, we are making a bunch of assumptions.
  - This might allow us to park some of the assumptions and learn, somehow – through interviews or focus groups or visits or surveys – what the reality is across the industry (as opposed to speculation).
  - Likewise, could be working across the regulatory world about implementation.
  - Or utilization of resources (either Intern, or Consultant, or Contract) who can answer the questions about the implementation of the best practices
  - Often there are gaps that are filled by people outside of this process that committees use to move forward; but, maybe there are ways for CFP to support next steps for this committee
  - Eric – right out of the gate for this undertaking, it's working with FDA to CFP – we are the "guinnea pigs"
- Once we get an adequate number of voting members divided between the two subgroups, Ben and Eric will start the process by providing each committee with a general template that will be loosely framed and based to incorporate some components of the FDA document that was previously discussed to place comments within (via G-Drive)
  - **Please provide comments on the Google Document – re: Guide to Inspections of Computerized Systems**
  - **https://docs.google.com/document/d/1OlanY6xpA1WzLEo0eNsNR5hmQByuiaIN/edit**

XXVII. Wrap-up

- **Next meeting – TBD**

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 5
DATE: May 23, 2022 **TEAMS and phone in options in calendar invite**
TIME: 2pm ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Julian Graham

Agenda

1.	Welcome, Call to Order
2.	Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
3.	Past meeting minutes review
4.	Review of revised definitions
5.	Introduce sub-committee leads
6.	Sub-Group: a. Introduce leads b. Review charges c. Discuss meeting frequency
7.	Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: TBD

XXVIII. Welcome, Roll Call

- Some Members At Large & Voting are traveling
- Completed w/ Quoroum

XXIX. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

XXX. Welcome, Call to Order

- Don't need to be following protocols for Robert's Rules
- Antitrust statement by Ben

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

XXXI. Last Meeting Recap

- If anyone has specific questions as it relates to the last meeting, raise them NOW or email Ben and/or Eric
- Access last meeting notes here: https://drive.google.com/drive/u/0/folders/1F7XyuNLXR5s8AepF7BjgQvQkaYblPGuz Committee documents - Google Drive

XXXII. Review of revised definitions

No Comments on latest revision
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit

Digital food safety management system (DFSMS): An interactive, digital or electronic archive intended to collect, store, and analyze data that supports a food safety management system. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the FDA model food code. A DFSMS employs active user-based work-flows that support decision making, report generation (including trends over time) that can be reviewed and acted upon, and may be housed locally (on-premise) or be accessed remotely.

DFSMS should include but not limited to may havemust have functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports, for exampleand trends over times

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital temperature monitoring equipment: Automated temperature measuring device(s) that shouldmust include electronic sensors capable of generating and capturing temperature data for analytical use. This equipment may include the functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time may connect to a system that may be capable of delivering alerts and exception reports.

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

XXXIII. Introduce sub-committee leads

XXXIV. Systems

lily.yang@achesongroup.com (co-lead)
jonathan.ruizespejo@retailbusinessservices.com (co-lead)
brianna@savorymanagement.com
patricia.vauls@maryland.gov
harrisjl@umich.edu
Matt.jenkins@us.mcd.com
Katie.matulis@wisconsin.gov
michael.roberson@publix.com
RWynne@darden.com

XXXV.

XXXVI. Charge

Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for systems based on our consensus definitions.

XXXVII. Equipment

Julian.Graham@sodexo.com (co-lead)
jaime.estes@albertsons.com (co-lead)
wmelichar@feedingamerica.org
Amanda.douglas@wawa.com
traviss@health.ok.gov
matthew.brandt@state.co.us
ECiarimboli@hy-vee.com

XXXVIII. Charge

Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for digital temperature monitoring equipment on our consensus definitions.

XXXIX. Format

Using existing FDA Document as scaffolding and bullet points/outline of best/good practices.

XL. General Discussion

- Ben and Eric will lead expectation meeting with Co Leads
- Co Leads will identify scheduling with the group
- Ben and Eric will share meeting invites with the entire committee, everyone is welcome to drop in.
- Edsall, Jean V

  how would you like non-voting members to join the sub-committees?

You may join either group as a non-voting member. Please email Ben if you have strong preference on subcommittee.

XLI. Wrap-up

- **Next meeting – TBD**

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 6
DATE: September 7, 2022 **TEAMS and phone in options in calendar invite**
TIME: 2PM ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

UPDATED Agenda:

8. Welcome, Call to Order
9. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
10. Past meeting minutes review
11. CFP Reporting Deadline Review
12. Sub-Committee Progress Report Out: a. Digital Food Safety Management System i. Q&A b. Digital Temperature Monitoring Systems i. Q& A
13. General Q&A
14. CFP & NACCHO Research Grant Overview
15. Wrap-up

Link to definitions document:
https://docs.google.com/document/d/1uUsCjqeYG65sSG3oTYy738I7QG9JJhpSq70KY_kR3Wk/edit
Link to Google Drive for resources
https://drive.google.com/drive/u/0/folders/1jcAkf4fypF1pxEsiOUwYcW3FgV0sdIZg
Next Meeting Date: TBD

XLII. Welcome, Roll Call

- Do not have Voting Member Quorum
- Will continue to have the meeting
- Eric will run through Voting Member Names quickly that isn't marked off.
- Agenda
- Need to change certain individuals for names and positions (USDA v CDC)

XLIII. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- Operating under CFP Anti-Trust operations – no talk about pricing & customers and all that goodness.

XLIV. Past Meeting Minutes Review

- Reviewed. Need to change a date

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

XLV. CFP Reporting Deadline Review

- Periodic review for Fall Meeting must happen by end of tomorrow (9/8/2022) because that document is due to CFP Executive Director by October 13, 2022 in preparation for OCT 5 & 6th Grand Rapids MI Board Meeting
- Coming up on due-dates very very quickly!
- Issues open December 19, 2022 (for 30 days)
- April 23 – 28 – Biannual Meeting

XLVI. Subcommittee Progress Report Out

- Digital Temperature Monitoring
    - They have mostly completed
    - They will have a cleaner version of the document by next week for everyone to review
    - Do you feel that subcommittee member engagement is adequately supporting the process as things are progressing?
        - Yes.
    - Do you think things are achievable within 4 – 5 weeks.
        - Yes. Taking a "simple" approach. Should get a version of that quickly
- Digital Food Safety Management
    - Taking each section and wordsmithing and eliminating verbiage and writing comments. As a group we have regular communication between the two sub-committee chairs and within group for providing comments
    - More than halfway through the document and at a good pace to complete in 5 weeks.
    - Handheld and stationary device*

XLVII. General Q&A

- Question from David & Brenda Bacon – to clarify – DFSM is editing the FDA Guidance Document that the edits are being made to?
    - Yes. Both Committees are using the original document from FDA 2001
- David Lawrence: for follow up to Eric – this subcommittee work will be two separate documents?
    - Yes. At this time, we don't have a voting member quorum, but we could have asked the committee (today) to vote whether or not there would be value in two independent documents (one on software component and other on hardware technology component) OR if it would be better to bring them back together into one final product. But since we can't vote today; we are mentioning this as something for Committee to think on and consider.
- Doing a Straw-Poll or Any Comments on the above?
    - Thomas Woodbury – generally deployment should be together for both aspects, he would vote to do a combined document
- 09/09/22 AMMENDED NOTES:

- During the call I mentioned that a vote may need to be conducted to determine if the documents our 2 subcommittees are working on should be combined into a single document or left as two standalone documents. I apologize but was not correct and a vote will not be required to combine the two documents into a single document. According to our second committee charge (see below or attached) our committee is charged with creating a single document, not multiple. Sorry for any confusion this may have created.
  - *DFSMS Charge 2) Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Food Safety Management Systems including digital temperature monitoring equipment.*

XLVIII. CFP & NACCHO RESEARCH GRANT REVIEW

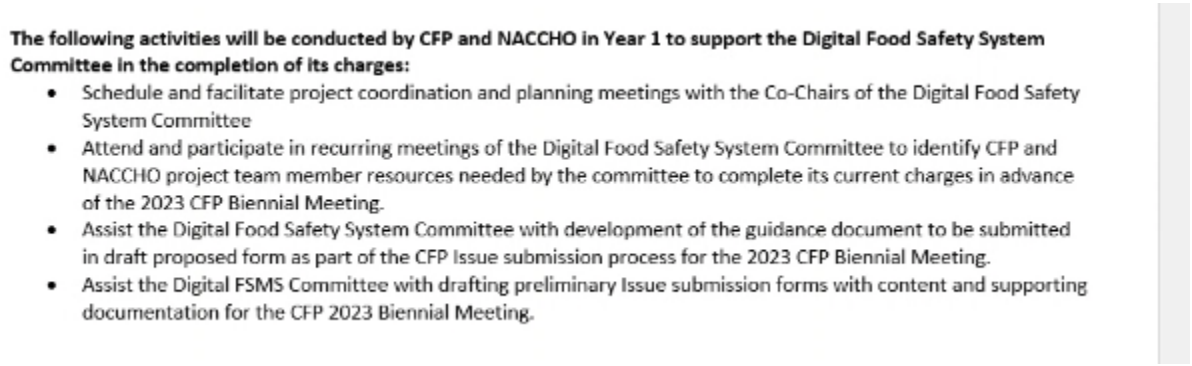
New Update: Retail Food Regulatory Association Collaborative (www.retailfoodsafetycollaborative.org) -- discussion the CFP & NACCHO research grant that has been awarded related to research incorporating what is being done in this Committee work (2 parts)

- Brenda and David want to thank everyone (including Ben & Eric) for being on this call.

- Regarding this Collaborative – long term objectives and priorities for the collaborative (multiple partners). There are ways to create grant funding.

  - If you don't know about the Collaborative already, there are many resources from Cycle 1, etc. FDA/CDC/etc that is maintained by NEHA) in the website.
  - Love the opportunity to market the Collaborative and what it's doing
  - The FDA funding has provided much needed support to complete Objectives
- There are two grant cycles for funding.
- Year 1 of Grant Cycle 2 = started August 1st – Year 1 is guaranteed funding for research funding strategy.
  - Works supporting Specific Aim #5 – 4 Objectives
    - Brenda & David working on this work
    - Angie Wheeler & Dr. McSwaine work together in a research team
- Provide assistance for grant funding and ability to leverage resources beyond CFP (like from NACCHO) to support charges of committees – including this one!
- As we are forming issues, if we want to continue this committee, what additional continuation would we have? What would we add to these charges?

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets



The following activities will be conducted by CFP and NACCHO in Year 1 to support the Digital Food Safety System Committee in the completion of its charges:

- Schedule and facilitate project coordination and planning meetings with the Co-Chairs of the Digital Food Safety System Committee
- Attend and participate in recurring meetings of the Digital Food Safety System Committee to identify CFP and NACCHO project team member resources needed by the committee to complete its current charges in advance of the 2023 CFP Biennial Meeting.
- Assist the Digital Food Safety System Committee with development of the guidance document to be submitted in draft proposed form as part of the CFP Issue submission process for the 2023 CFP Biennial Meeting.
- Assist the Digital FSMS Committee with drafting preliminary Issue submission forms with content and supporting documentation for the CFP 2023 Biennial Meeting.

-
    - The first bullet is already being worked on
    - The second bullet is happening today.
- There are changes that might happen to this guidance document but timeframe that occurs after the Biannual meeting to get ready for publication/posting, that's what we've asked NACCHO help us with to help achieve final publication standpoint.
- Brenda:
    - David and her are not part of the committee; they are here to help support the committee as it runs parallel to our committee. Don't want to be disruptive to our committee work – want to be supportive and assist as much as we'd like in being prepared for the biannual in 2023.
- Eric – Due to this condensed timeline, your support will be invaluable. Supportive of all the cooks in the kitchen.

Get on track for where things are going with the workstreams. Get on the subcommittee documents and provide documents.

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 7
DATE: October 07, 2022 **TEAMS and phone in options in calendar invite**
TIME: 4 PM ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

Agenda:

16. Welcome, Call to Order
17. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
18. Past meeting minutes review
19. CFP Reporting Deadline Review
20. Sub-Committee Progress Report Out: a. Digital Food Safety Management System i. Q&A b. Digital Temperature Monitoring Systems i. Q& A
21. General Q&A
22. Wrap-up

XLIX. Welcome, Roll Call

- Do not have Voting Member Quorum
- Status update

L. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- http://www.foodprotect.org/administration/policies/antitrust-policy/

LI. Past Meeting Minutes Review

- Reviewed. Need to change a date

LII. CFP Reporting Deadline Review

- Moving things forward on the Best Practices Update
- Committee Update for Timeline (Now and when Report is Due on November 18)
- Engagement from the Entire Committee

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

LIII. Subcommittee Progress Report Out

- Current Version of Combined Best Practices Document Link: https://docs.google.com/document/d/1ICYp069DJSqQOJKezzlbjfp2gmBj7zDLLpiu8Qc00wM/edit
- Opening up **TWO WEEK REVIEW TIME (October 21st) FOR ADDITIONAL COMMENTS/SUGGESTIONS/EDITS** to Best Practices Document Draft (above)
    - Document is ~8 pages of content – digital food safety systems & digital monitoring equipment
    - Identifying best practices per charge
    - Ben and Eric feel that this is practical; however, utilize next two weeks for feedback and discussion on holes/gaps in document that need to be included (or cut)
- After October 21st, David Lawrence and Brenda will work as part of the Retail Food Safety Collaborative to support with writing
- **By October 31st, want it to be ready for voting by the entire committee.**
- **Proposition for vote on November 2nd (as next planned meeting)**

- Review by David Lawrence – to review content as the whole committee has done and to provide editorial revisions – no intent to change content/information included

- Ben: Is two weeks enough time to review and provide additional feedback?
    - Jenn Nord – two weeks is perfect. Anymore time, it'll slip away from people
- David Lawrence – End of Business (Oct 21) is end of the review/comment period. Afterwards, is that when things will be cleaned up and ready for vote?
- Lily:
    - Shout-out to DFSM Sub-committee, you know who you are
    - If you, as a reader, are confused by any of the "techy" terms, please let us know. Part of the document is supposed to allow for tech people to ultimately understand the food safety of things. If things aren't understandable (especially as it comes to the food safety management system aspect), please comment and we'll address
- Julian:
    - Shout-out to Temperature Sub-Committee, you know you are
    - The section on "Guidance to Inspector" – decided that this part shouldn't be in this document and/or that it is necessary to complete this document.
        - Bringing up to the group at large to have this discussion.
- Ben: next agenda item was to tackle the "Do we need guidance for inspector"? – is this what we should talk about now or discuss in G-Document?
    - This document is an adaptation of existing FDA document on Digital Systems (aimed at processors – and in that document, there was a section on what inspector should know).
    - Need consensus on this

  - David Lawrence (CFRP): I am aware that the Program Standards Committee is looking at adding a food safety management system perspective to the plan review process conducted by regulators
    - Has been brought to the Program Standards Committee and sees that there is in-tandem as collaborative focus
- Any specific thoughts for the regulators? >> No response
- Does anyone feel strongly that it should (or shouldn't) be included in best practices document?
  - Julian: Subcommittee looked at hardware components of the digital food safety management system, and decided that it would be very hard to evaluate a data logger that didn't have a screen (and the efficacy of it working) other than "looking" at it. The hardware components that make up the food system are so different
    - Also included OEM as a means of capturing that data? Because some municipalities would find it different or difficult.
      If we do it, would be hard.
  - David: I'm thinking for the regulatory assessment of digital systems that might be used for specialized food processes like ROP
- Ben/Eric – Feel we are in a good spot to meet our charge and meet the charge on-time.

LIV. General Q&A

- Question from David Lawrence (CFP) on chat:

[16:09] David Lawrence, CFP (Guest)

- Ben & Eric, I would like to have the CFP Collaborative grant team take a look at this for feedback and comment if that is okay with the committee.
- Courtney Halbrook – did you propose of where the document will be posted?
  - Will be part of the November 2nd meeting
- David Lawrence: Are we trying to ensure that tech people can understand food safety?
  - Lily: Yes, because ultimately those will be the people to "put those things into place" and still have the food safety people (validation, verification, etc.) understand as a mainstay.
  - Ben: Yes, we are trying to bridge the gap of the people who are managing the DFSMS & those that'll be doing the IT behind that. That pathway between those two – so it's not just about, "this is what's important from food safety" but also incorporating the knowledge for the people who will be incorporating the systems from behind-the-scenes.
  - David – Definitely want to know that there is someone in the background who is managing the system/IT. Don't have to go looking for it.
- Courtney Halbrook - how do you want to collect that feedback in the document?
  - Ben: Yes. Everything that goes into the document, at this time, will be "comments and suggestions" – however you feel comfortable.
- Eric – if any individual will suggest a deletion or removal of sentences/sections; instead of just suggesting "Delete", please provide some comments/perspectives as to "why you don't feel this is appropriate and/or could be placed somewhere else"

- Chirag – The document is very comprehensive. Do you want everyone to do grammatical suggestions?
- Very close to being done! Just a little bit more work and we'll seal the deal – there have been no big Kerfuffle!!!

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 8
DATE: November 2, 2022 **TEAMS and phone in options in calendar invite**
TIME: 2 PM ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler
USDA Advisor: N/A
CDC Advisor: Adam Kramer
Scribe: Eric Moore

Agenda

Agenda:

23. Welcome, Call to Order
24. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
25. Past meeting minutes review
26. Review & Discuss Outstanding Document Questions
27. Issues Overview: a. Issues to submit i. Final report, supporting docs and member recognition ii. Approval and posting of draft guidance on CFP website iii. TBD – committee reformation as a sub-committee of the larger FSMS standing committee b. Proposed Issue(s) i. Combine DFSMS Committee with FSMS Committee ii. Create new FSMS Standing Committee
28. Next Steps: a. Volunteers for writing Issues b. E-vote on final document c. Create Final Report
29. Key Dates: a. 11/18/22 – Draft Final reports due to Council Chair b. 12/2/22 – Revised Final Reports due to Council Chairs c. 12/19/22 – 01/22/23 Issue Submission

LV. Welcome, Roll Call

- Do not have Voting Member Quorum

LVI. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- http://www.foodprotect.org/administration/policies/antitrust-policy/

LVII. Past Meeting Minutes Review

- Reviewed, no changes

Review & Discuss Outstanding Document Questions

- Process started to review the editorial revisions completed by Committee Chairs (Eric & Ben), each paragraph was provided to members to view on screen for comment.

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

- Introduction & Scope comment(S):
    - Robert Sudler - Hyper link to FDA Retail Risk Factor Study Homepage provided in chat
    - David Lawrence – Does the most recent risk factor study highlight Digital FSMS?
        - Robert Sudler – It does not mention Digital no edits required
    - Adam Kramer – Would the Annex 4 number change with a new version of the food code?
        - Robert Sudler – Annex number would not change with a new food code version of the food code
- Definitions Comment(s):
    - David Lawrence – It's likely that FDA will release 2022 FDA Food Code by years end and suggested removing 2017 Food Code reference in DFSMS definition and replacing with "most recent version of the FDA Model Food Code"
- Best Practices Comments(s)
    - Eric raised question around the need for the mention of ieee & siia in the DTME paragraph.
        - Suggested change provided by Brenda Bacon. to remove the term back-end to eliminate confusion
- Handheld Devices Intended for Direct Food Contact Comment(s):
    - Eric updated the food code reference to include "most recent version of the FDA Model Food Code"
    - Robert Sudler – If this section is intended to focus only on food thermometers the specific section of the code should be reference
        - Ben & Eric – Intent of the section is to focus on more than just food thermometers, pH meters and humidity for example.
        - Robert – It is ok as stated if intended to be inclusive of other devices
- Integrated Temperature Measuring Devices Comments(s):
    - There was much discussion on the intent of this paragraph and the inclusion of OEM devices, the need for redundant thermometers in the food code
        - Robert Sudler & Adam Kramer – No specific requirements in the food code for 2nd thermometers
        - Katie Matulis - A secondary thermometer is not required with an OEM thermometer, but an OEM thermometer/digital readout is still required with a DFSMS (sensors, etc.).
    - Ben and Eric plan to make revisions based on the discussion and bring back to whole committee for further discussion.
    - **This is where discussion stop due to time**
        - **Follow Meeting to be scheduled to occur as soon as possible to review additional changes and the remaining sections of the document.**

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

LVIII. Issues Overview:

1. Issues to submit
    I. Final report, supporting docs and member recognition
    II. Approval and posting of draft guidance on CFP website
    III. TBD – committee reformation as a sub-committee of the larger FSMS standing committee
2. Proposed Issue(s)
    I. Combine DFSMS Committee with FSMS Committee
    II. Create new FSMS Standing Committee

LIX. Next Steps:

I. Volunteers for writing Issues
II. E-vote on final document
III. Create Final Report General Q&A

Key Dates:

a. 11/18/22 – Draft Final reports due to Council Chair
b. 12/2/22 – Revised Final Reports due to Council Chairs
c. 12/19/22 – 01/22/23 Issue Submission

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

Meeting Number: 9
DATE: November 07, 2022 **TEAMS and phone in options in calendar invite**
TIME: 3 PM ET
Co-Chairs: Eric Moore and Ben Chapman
FDA Advisors: Robert Sudler & Justin Asberry
USDA Advisor: Beth Wittry
CDC Advisor: Adam Kramer
Scribe: Lily Yang

Agenda

This meeting is being scheduled to pick-up where Call 7 (11/2/22) left off:

- Revised document will be sent out before end of day tomorrow for full committee review and comment on Monday
- We realize that this date/time may be a challenge but please do your best to attend if your schedule permits

Agenda:

1. Welcome, Call to Order
2. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement
3. Past meeting minutes review
4. Review & Discuss Outstanding Document Questions
5. Issues Overview: a. Issues to submit i. Final report, supporting docs and member recognition ii. Approval and posting of draft guidance on CFP website iii. TBD – committee reformation as a sub-committee of the larger FSMS standing committee b. Proposed Issue(s) i. Combine DFSMS Committee with FSMS Committee ii. Create new FSMS Standing Committee
6. Next Steps: a. E-vote on final document b. Create Final Report
7. Key Dates: a. 11/18/22 – Draft Final reports due to Council Chair b. 12/2/22 – Revised Final Reports due to Council Chairs c. 12/19/22 – 01/22/23 Issue Submission

2021-2023 CFP
Digital Food Safety System Committee
Meeting Minuets

LX. Welcome, Roll Call

- Do not have Quorum – only 8 voting members (Quorum is for 11 voting members)
- Will be conducting voting member polls to move the document into its finished stage for "time being"

LXI. Rollcall/ Conference for Food Protection, Inc. Antitrust Statement

- Operating under CFP Anti-Trust Rules
- http://www.foodprotect.org/administration/policies/antitrust-policy/

LXII. Past Meeting Minutes Review

- Finished to General Usage Section

LXIII. Review of Document

- Changing "system faults (bugs)" to "system malfunctions"
- Include Food Code #s – there may be changes in the future; unlikely that these will be changed. But doc should be reviewed every 4 years (Robert Sudler) – then these numbers will need to be updated; and any cross-references that mention the Code, if they change, also will be noted. Not something tht needs to be updated or worried about now; but definitely long-term, needs to be kept on the radar to review (don't wait 10 years). Need to include that these documents will be updated and reviewed periodically
- Data Storage – that system has some type of programming that is not acceptable despite what it is that it doesn't overwrite what was originally recorded (need to make sure)
- Finished review of document
- Review last week's edits from inputs:
    - Edited "Inputs – Digitl Food Safety Management System Equipment"

LXIV. Issues Overview

- Straw Poll of voting members? Will they accept as it is right now? – 8 of 8 YES (in agreement)
    - Non-voting members – are you also comfortable with the document? YES – 6 of 7 non-voting are in agreement
    - Total: 15 members

LXV. Issues to Submit

LXVI. Proposed Issues

- Request that *this* specific committee be reformed to further explore and work on identifying research information (work with Collaborative) to do a funded research study for the next biannual.
- In parallel, Ben & Eric – along with food safety Council 2 chair/vice-chair & David Lawrence & David McSwane have discussed the possibility of Food Safety Management Committee transitioning to a standing committee to identify specific charges to discuss formation of Standing Committee to begin during the next biennium.
    - Standing FSM Committee
    - Sub-committee standing - for digital food safety

    - To ensure alignment in wording and approaches moving forward
- Does anyone see any issues with this committee falling under a Food Safety Management Systems Committee (not yet proposed) – currently no one on the team feels negatively about this

LXVII. Next Steps:

- Co-Chairs to make minor document changes determined during today's meeting
    - Revisions completed 11/8/22
- Draft Final reports due to Council Chair
    - To be sent to Council Chair tomorrow 11/9/22
- Voting Member e-vote on Final Report
    - TBD based on Council Chair feedback
- Final Reports due to Council Chairs (12/2/22)
- Biennial Issue Submission (12/19/22 – 01/22/23)

Digital Food Safety System Committee Definitions

Digital Food Safety Management System (DFSMS): An interactive, digital, or electronic archive intended to collect, store, and analyze data that supports a food safety management system. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the FDA model food code. A DFSMS employs active user-based work-flows that support decision making that can be reviewed and acted upon, and may be housed locally (on-premise) or be accessed remotely.

DFSMS should include but not limited to functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports, for example trends over time

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital temperature monitoring equipment: Automated temperature measuring device(s) that should include electronic sensors capable of generating and capturing temperature data for analytical use. This equipment may include the functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time may connect to a system that may be capable of delivering alerts and exception reports.

Computerized Systems in Food Processing Industry

Pavan Sandeep Kuli

Content sourced as of 17/03/2026

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INTRODUCTION

One of the computerized systems within the food processing industry regulated by the Food and Drug Administration (FDA) continues to increase. The use of computerized control system technology is expected to continue to grow in the food industry as the cost of components decrease, as companies are continually improved to withstand the rigors of the food processing environment, and as computerized systems are used to replace facilities equipment and manufacturing processes in an attempt to produce high quality, high value products. Now process design will strive to achieve safe quality products, while at the same time minimizing production costs. The use of computerized control systems in the production of food products will be vital to fulfilling these goals.

As computer systems become instrumental in providing for the safety of FDA regulated products, the FDA will need to develop expertise to evaluate computerized systems, to examine, comment and validate records on computerized systems, and to conduct on-site storage inspections.

The purpose of this course is to examine the FDA investigation into conducted inspection of regulated food firms that use computers and computer software to control manufacturing processes. Chapter 1 will review the FDA regulations. Chapter 2 will look into reviews by the Office of Regulation Affairs (ORA), Division of Emergency and Investigational Operations (DEIO) and the Center for Food Safety and Applied Nutrition (CFSAN) of computerized systems in food processing establishments. Chapter 3 will examine the criteria for good processing manufacturing quality and conformance, plus communication your written comments or suggestions to DHEO, ORC (or send an e-mail to Internal Bureau address to). DEIO/ORA/FDA/5600 Fishers Lane/HFC-132

CHAPTER 1: REGULATIONS OF COMPUTERIZED SYSTEMS

A. FOOD, DRUG AND COSMETIC ACT

FDA's authority to regulate the use of computers in food plants is derived from the Food Drug and Cosmetic Act (FD&C Act). Section 402 (a) (3) of the Act states: "A food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have become injurious to health." Section 402 (a) (4) states: "A food shall be deemed to be adulterated if the methods, facilities, or controls used for its manufacture, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such food is not unsafe or lacks sufficient quality and is not properly labeled under section 403 (a) (1) and food shall be deemed to be adulterated if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have become injurious to health." Section 701 (a) authorizes the issuance of regulations for the efficient enforcement of the Act. Section 520 (f) (1) (B) authorizes the issuance of regulations for the control of methods used in, and the facilities and controls used for, the manufacture, processing, and packing of human food.

Before discussing the use of computerized systems under the FD&C Act, it is useful to review the related sections of the Act.

Section 201 (g) (1) defines the term drug to include articles "(B) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, in man or other animals; and (C) intended to affect the structure or any function of the body of man or other animals."

Section 201 (h) defines the term device to include articles "(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

Section 201 (s) defines the term "new drug" as any drug "the drugs, constituents, and conditions of use prescribed, recommended, or suggested in the labeling thereof, as are not held, by such experts, to be established safe, or any other contaminants."

Section 201 (ff) defines the term "**Subpart F Supplement, sun-gel** which is "any food which contributes consumption from any source." It continues to **sub-Pa (3) (A) (i)** to "any food manufacturing ... shall be conducted under such conditions and controls as are necessary to minimize the potential for growth of microorganisms, or for the contamination of food."

Implied and explicit references for the need to have computerized controls for accurate and reliable may be found in other Sections of the FD&C Act. For example, see the function of the computerized system in the food process.

PART 113 SUBPART A: THERMALLY PROCESSED FOOD AS ASSORTED LOW-ACID CANNED FOODS

FDA's General Food Safety and Regulation Division (GFSRD) has determined that the use of computerized systems to control processing operations is necessary to assure the safe production of low-acid canned foods. **Low-acid canned foods (LACF) are foods packaged in hermetically sealed containers, such as CYN Part 113, Thermally Processed Low-Acid Canned Foods in Hermetically Sealed Containers** except for: sealed, aseptic processing systems, and containers that are processed before they are sealed.

Computer equipment makes this task to control computer systems to help control food record keeping functions and to perform real time process deviation corrections, have been used in the food processing industry for many years. Examples of these uses have been:

- a. to aid in FDA by the systems vendor or user to explain the operation of the computer system,
- b. to aid by FDA in the vendor to examine the hardware and software development, validation and documentation procedures, and
- c. to aid by FDA in production to evaluate the computerized record maintenance and change control procedures.

To ensure vendors who submitted their computer systems to FDA for review and were found to be satisfactory, received a letter stating that FDA found the computerized system, as evaluated, to meet the intent of the regulations. Use of this voluntary submission of computerized systems to FDA for evaluation subjected the vendor to FDA's policy and procedures for the review of these systems. Upon receipt of a vendor's system, a requirement that FDA investigators would be provided on site access to the vendor's computer equipment software operating instructions, and a requirement that the vendor would maintain confidentiality of any trade secrets revealed by FDA's computer software and equipment.

Food manufacturers that used CYN Part 113LF computer controlled recording and real time process deviation corrections, have been used in the food industry for many years. The use of computerized systems to control processing operations is necessary to assure the safe production of low-acid canned foods. Low-acid canned foods (LACF) are foods packaged in hermetically sealed containers, such as cans, flexible pouches, and aseptic processing systems, except for: containers that are processed before they are sealed.

The function of the system as it operates can be used to determine if critical factors such as retortchon per minute (rpm), vent time, initial temperature, process, thermal process deviations, and documentation are being controlled by the computerized system. Operation of the FDA's computer equipment software operating instructions, and a requirement that the vendor would maintain confidentiality of any trade secrets revealed by FDA's computer software and equipment. As food product deviations will not have to be reported to FDA, as long as the computer system is functioning properly and properly documented, it will not record the systems functions. This is the automatic food or food process of performance. The only way to develop confidence that the computer system is going to perform correctly is to have a validation program as part of the design, check, or test. The validation program should encompass the entire computer system, including:

The investigator must keep in mind the limitations of specific regulations regarding the use of computers in food processing plants. Most of the current FDA food regulations in the FD&C Act of specific authority to examine computer software and computer hardware records. Section 704 authorizes FDA to conduct factory inspections to determine if a food manufacturer or the activities of a manufacturing process, the manufacturer is operating in establishing that the computerized system functions as it was intended to function. The investigator is not authorized to examine computer software. The investigator is entitled to be provided with the computer software that was intended to be used by the computer system as designed. It is important to remember that computerized systems are used to control the food manufacturing process, quality and consumer controls.

The investigator should evaluate the operations of computerized systems during the inspection to determine if the use of the computer software may lead to adulteration of the finished food product. Many companies used in the food industry may not have the in-house capability to write computer software programs. For example, if there was a misunderstanding on a bill of lading between a purchaser and a seller, the criticality of the inspectional control function may be a matter of reading in a batch of ingredients. Another example of a critical control function would be the temperature maintenance of a lot of process. A review of the computerized formulas provides consistent and reliable performance. HACCP (Hazard Analysis Critical Control Point) computer software programs are used to control critical control points in food processes. Documentation steps established by a computerized system.

This is an important to find out if the operator or management can override any of the computer control functions. If operators/management can override control functions, what are possible details on how this is done, what overrides are possible, and how overrides appear in the processing record should be determined.

The investigator should find out how the system handles deviations from an or expected operations. Does the computer automatically shut down the process, automatically generate parameters, calculate new manufacturing instructions or choose alternate programmed procedures the investigator must determine the parameters for computing or selecting the alternate procedures.

During inspection of food firms using computerized systems to control and monitor critical control points, investigators should review the computer software and hardware documentation to record other factors related to the food process. Examples of these factors are:

- a. The equipment specifications for software and hardware.
- b. The critical factors controlled by the system.
- c. Does the critical factors are controlled?
- d. How does the firm ensure that the microprocessor or computer is indicating the correct information (validation)?
- e. How and how often is the equipment calibrated and/or checked for accuracy?

Investigators should review the computer software documentation to determine responses to the authorization of a food product will take, and whether it fits in the documentation. Development of evidence of food adulteration caused by the operations of a computerized system is also discussed in Chapter 4 of the Compliance Program Guidance Manual.

During the inspection of food processing facilities the responsibility of the food manufacturer to establish that the computerized system functions as it was intended and the critical audit aspects of food manufacturing should be discussed with the facilities management. The FDA investigator should make the firm's management aware that a computerized system is subject to FDA inspection and that the firm must have the procedures required to operate the system. Management of the firm should be made aware that the computerized systems should be validated to place under actual operating conditions by the firm **Close Surface on Computerized System Validation.**

The applicable sections of the listed references should be used, in addition to this guide when inspecting firms using complex computerized systems.

CHAPTER 2: COMPUTER SYSTEM TECHNOLOGY

A. TECHNOLOGY OVERVIEW

In recent years digital electronic controllers have replaced the relays and analog switches that were used to control processing operations. Digital controllers are electronic devices that receive data input from the single loop controller to complex high-end computer systems.

If the function is for controlled consists of numerous sequential (logical) steps, the controlling device can be a fixed-level computer that is often called a logic controller. The logic controller may be set up as a single loop controller.

A single loop controller could be responsible for controlling one function, such as temperature, pressure, or flow. Single loop controllers could be programmable, and could be built-in temperature within set temperature parameters. The loop would consist of the temperature controller, a temperature sensor, a power source for the steam valve that controls the steam flow.

Digital single loop controllers contain Read Only Memory (ROM) which is manufactured into the controller or programmed into the controller by the manufacturer. Random Access Memory (RAM), Erasable Programmable Read Only Memory (EPROM) or Electronically Erasable Programmable Read Only Memory (EEPROM).

PROMs is field programmable by the manufacturer or customer once only by burning out the internal fuses. EPROMs and EEPROMs are erased by exposing the chip to ultraviolet light. EEPROMs are erased by electrical means. EEPROMs are programmed by exposing the chip to ultraviolet light sources that erase the original chip configuration. EEPROM memory is programmed by applying a voltage to the chip. Programmable logic chips (PLC) chip. RAM is normally used to control functions, the values of the parameters of an operator do not need to be changed. Random Access Memory (RAM) using battery backed memory to maintain the values of the parameters during power outages. This requires a power supply for both RAM and its replacement.

Superimposing, Advanced microprocessor or computer systems would normally use a combination of ROM and RAM to program control processing functions.

A more advanced system would use a programmable logic controller (PLC) which could allow the operator or firm to alter the control functions to meet the particular **close Approach** The type of controller would use algorithms in programmed procedures for solving a control problem. Algorithms are a set of logical steps that are performed in order to solve a logical sequence of events for solving a problem **Appendix 3A**

Control of multiple parameters such as temperature, pressure, pumping rate, rotation, etc. would require the application of several logic controllers connected to a PLC or microprocessor or computer.

Companies are different from hardwired controls to three major categories. To provide for adequate control of critical control points in food processing and/or documentation. The design of the computerized controls must address these three major areas:

- a. Proper, conventional hardwired systems, which provide for full-time monitoring of critical functions, the computer performs its task sequentially, and the computer monitors the critical functions on a time-shared basis. Should the system fail, it can malfunction(s) or become long before the computer to carry out these through its task), the critical sensor is not monitored. Normally this is not a problem, because the computer scans the critical sensors at a rate that is sufficient for the control. The problem occurs when the processing computer is directed from its task by another computer, or the computer software program is changed, or a defect occurs in the software. Should this occur, the food processing control computer may stray from its control or monitoring functions.
- b. In a computerized system the control logic may be easily changed if the computer software can be easily changed. Some security measures are needed to limit that the changes.
- c. Some computer experts have stated unequivocally that in computer software can be written error-free. While this may be true for very large software routines with thousands of lines of code, most of the software routines used for control and monitoring functions are relatively short and relatively simple. Because of this, these routines become critical to food safety and should be kept error-free.

B. COMPUTERIZED SYSTEM HARDWARE

Input Devices. Equipment that translates external information into electrical pulses that the computer can understand. Examples are thermocouples, RTDs (thermistor resistance temperature devices), pressure, flow, and conductivity transmitters, pH probes, and switches, such as limit switches, flow rate/y touch screens and operator keyboards.

Examples of hardware are:

- a. Thermocouple/RTD provides temperature input for operation of a retort.
- b. Pressure transmitter provides pressure input for operation of a retort.
- c. Operator keyboard used to input batch, menu number and other processing information.

Output Devices. Equipment that receives electrical pulses from the computer and either causes an action to occur, generally by controlling the manufacturing process functions, or displays data. Examples are chart recorders, valves, motors, printers, CRTs, video (CPU), printers, and alarms. Examples of hardware are:

- a. Solenoid activates the impeller of a mixer.
- b. Valve controls the amount of steam delivered to a thermal process.
- c. Printer records significant events during a sterilization process.
- d. Alarm (buzzer, bell, light, etc.) sounds when operator intervention is or lacking is/ds drops below the desired temperature.

Most output devices will be governed by a low food processing equipment under control, but not necessarily. Due to the CPU. Some output devices such as printers may be located remotely from the computer equipment.

Signal Conversion. Many input and output devices operate by transmitting or receiving electrical signals that are in analog form. These analog signals must be converted to digital form (A/D) before the computer can use them. Similarly, digital signals must be converted into analog signals for use by analog devices (D/A). Examples of hardware are:

- a. Thermocouple/RTD provides temperature input for operation of a retort.
- b. Pressure transmitter provides pressure input for operation of a retort.
- c. Operator keyboard used to input batch, menu number and other processing information.

**Computer Hardware

connections between complete computer systems that are geographically distant or they may consist of computer systems on a local area network (LAN) in the same facility.

If the firm is on a computer network it is important to know:

a. What output, such as batch production records, is sent to other parts of the network;
b. what kinds of input (instructions, software programs) are received;
c. the identity and location of establishments that interact with the firm;
d. the extent and nature of monitoring and controlling activities exercised by remote on-net establishments; and,
e. what security measures are used to prevent unauthorized entry into the network and possible unwarranted food process alteration, or obliteration of food process controls and records.

Peripheral Devices: All computer associated devices external to the CPU can be considered peripheral devices. This includes the previously discussed input and output devices. Many peripheral devices can be both input and output, they are commonly known as I/O devices. These include CRTs, printers, keyboards, disk, modems and tape drives.

C. ENVIRONMENTAL/EMI HAZARDS

Location: Potential problems have been identified with location of CPUs signal transmission lines and peripheral devices. These Include:

Hostile Environments: Environmental extremes of temperature, humidity, static, dust, power feed line voltage fluctuations, and electromagnetic interference should be avoided. Such conditions may be common in certain operations and the investigator should be alert to locating sensitive hardware in such areas. Environmental safeguards may be necessary to ensure proper operation.

Electromagnetic Interference (EMI): Low voltage electrical lines from input devices to the CPU are vulnerable to electromagnetic interference. EMI may result in inaccurate or distorted input data to the computer. Therefore, peripheral devices should be made immune to electromagnetic interference (EMI) such as electrical power lines, motors, portable telephones, walkie-talkies, radio/TV broadcasts, and fluorescent lighting fixtures. Peripheral devices and signal transmission lines should be located as far as possible from sources of electromagnetic interference. Shielding of signal transmission lines, grounding, filters, circuit design and proper design of the device's cabinet or housing are acceptable methods to prevent EMI.

Distance Between CPU and Peripheral Devices: Device proximity to the PLC/computer may be important concerning loss of signal due to electrical resistance of the signal transmission lines. To correct this problem the device may be located near the PLC/computer or signal transmission lines having less electrical resistance (i.e. 2 wire vs. 4 wire RTD) may be used.

Proximity of Input Devices to Food Processing.

Input devices such as employee interfaces should be located as close as possible to the operation being controlled.

D. MAINTENANCE/CALIBRATION

Computer systems normally require a minimum of complex maintenance. Electronic circuit boards, for example, are usually easily replaced and cleaning may be limited to dust removal. Diagnostic software is usually available from the vendor to check computer performance and isolate defective integrated circuits. Maintenance procedures should be included in the firm's standard operating procedures. The availability of spare parts and access to qualified service personnel are important to the operation of the maintenance program.

The firm should use replacement parts which meet the specifications of the original computer system design or the system should be revalidated to document that the replacement parts perform as per the original specifications of the computer system.

Sensors used as part of the computerized system, monitoring or controlling process functions, should be checked for accuracy in the set operating range of the function being controlled or monitored during production. For example if an RTD is used to sense the temperature of a retort system operating at 250 F, the RTD should be accurate at 250 F and not just at some lower temperature, such as at 212 F.

Computerized systems used to control, monitor or record functions that may be critical to the safety of a food product should be checked for accuracy at intervals of sufficient frequency to provide assurance that the system is under control. If part of a computerized system that controls a function critical to the safety of the food product is found not to be accurate, then the safety of the food product back to the last known date that the equipment was accurate must be determined. (e.g., an RTD is providing a signal which indicates that a thermal process is operating at 95oC, when is fact the process is operating at 90oC. If 90oC is below the firms established critical limit for food safety, the safety of the food may be in question. If this was noted on March 23 and the RTD was last checked for accuracy on January 1, the food processed from January 1 to March 23 should be evaluated for safety).

The manufacturers/vendors of computerized system components normally recommend minimum maintenance schedules including accuracy checks of their components.

E. COMPUTERIZED SYSTEM SOFTWARE

Software is the term used to describe the total set of programs, procedures, rules, and any associated documentation pertaining to the operation of a computerized system and includes: application, operating system, and utility software used by the computerized system **(see Glossary of Computerized System and Software Development Terminology, August 1995).**

Name: Software routines are usually named with some relationship to what they do, i.e., Production Initiation, Batch Production or Alarm. The name of the software may be followed by a version number (i.e., DOS 6.0) that indicates where that particular software version falls in the release history of the software (i.e., between DOS 5.2 and DOS 6.2)

Function: Software routines should have a defined function or purpose, i.e., start production, record and print alarms, or calculate Fo.

Input: Inputs, such as thermocouple signals, timer, or analytical test results should be identified.

Output: Output signals generated by the software may result in a form of mechanical action (valve actuation) or recorded data (generation of records). Outputs should be identified.

Fixed Set point: This is the desired value of a software function variable that cannot be changed by the operator during execution. Determine major fixed set-points, such as desired time/temperature curve, desired pH, etc. Time may also be used as a set point to stop the computer controlled process to allow the operator to interact with the system.

Variable Set point: This is the desired value of a software function variable that may change from run to run and must usually be entered by the operator. For example, entering the initial temperature of a LACF thermal process for each retort load.

Fuzzy Logic: Computerized systems utilizing fuzzy logic are increasingly being developed and used in food processing. Fuzzy logic differs from conventional logic in that the information used to control the system is neither definitely true nor false. Fuzzy logic control is carried out by implementing linguistic decision rules that come from the experience of operators or the knowledge of industry experts. Input from several sources may be used by the fuzzy logic controller to form the output decision of the computer system. A complete discussion of fuzzy logic control systems is beyond the scope of this document, the investigator should however be aware that this type of logic controller may be found in food manufacturing. Examples of everyday equipment using fuzzy logic would be: Television sets with automatic color control, hand held camcorders that compensate for operator movement and anti-lock braking systems used on automobiles. Potential problems with these type of control systems is that they can be programmed where there is no fixed set point by which the software function is controlled. When fuzzy logic controllers are used to control factors critical to the safety of a food manufacturing process a more detailed review of the control system is warranted. Determine if a record is made of control of the critical factor by the computerized system. A permanent record or an alarm function may be used to verify that a fuzzy logic controller controls each critical factor at or beyond its critical limit.

Edits: Software may be written to reject or alter certain input or output information that does not conform to some predetermined criterion or otherwise fall within certain pre-established limits. This is an edit and it can be a useful way of reducing errors; for example, if a certain piece of input data must consist of a four-character number, software edits can be used to reject erroneous entry of a five-character number or four characters comprised of both numbers and letters. On the other hand, edits can also be used to falsify information and give the erroneous impression that a function is under control. For example, a software output edit may add a spurious "correction" factor to temperature values that fall outside the Pre-established limits, thus turning an unacceptable value into an "acceptable" value. It is, therefore, important to attempt to identify significant software edits during the inspection, whenever possible. Sometimes such edits can manifest themselves in unusually consistent input/output information.

Software Over-rides: Software may be designed so that the sequence of programmed events or edits can be overridden by the operator. For example, a function controlling routine may cause an ingredient auger motor to stop when the weigh scale contents reach a predetermined weight. The software may prevent the auger motor from resuming activity until the weight has dropped back to the established set point. However, the same software may allow an operator to override the stop and reactivate the auger motor even at a weight that exceeds the set point limit. It is therefore important to know what overrides are allowed, if they conflict with the firm's operating instructions and how the system documents the override event(s).

Software Development: During the inspection determine if the computer software used by the firm has been purchased as "off the shelf" from outside vendors, developed within the firm, prepared on a customized basis by a software producer, developed by a third party vendor or some combination of these sources. Some software is highly specialized and may be licensed to food establishments. If the software used by the firm is purchased or developed by outside vendors, determine which firms prepared the software.

Sometimes "off the shelf" or customized software may contain segments (such as complex algorithms) which are proprietary to their authors and which cannot normally be readily retrieved in program code without executing complex code breaking schemes. In these cases the buyer should obtain validation documentation from the supplier to ensure that the software will perform as designed. If the food manufacturer is using such software to control or monitor a critical control point in the food process, determine what steps the firm has taken to verify that the software is performing as it was designed. Where food firms develop their own application software, review the firm's documentation of the approval process. This approval process should be addressed in the firm's written development instructions. It may be useful to review the firm's development (English) documents that formed the basis of the computer software (See Software Development Activities, July 1987, U.S. Department of Health and Human Services, Food and Drug Administration).

Software Security: Determine how the firm prevents unauthorized software changes and how data is secure from alteration, inadvertent erasures, or loss. Determine whom in the firm has the ability and/or is authorized to write, alter or have access to software. The firm's security procedures should be in writing. Security should also extend to devices used to store software, such as tapes and disks. Determine if accountability is maintained for these devices and if access to them is limited.

An important part of software security is change control. The firm should have in place a written procedure by which changes are made to software. This will include identification of a software error, how it was corrected, who performed the correction, did the changes influence any other portions of the software program, were the changes validated specifically and then as they related to other portions of the software program, and how the changes were documented. Software has a circular life-cycle that requires a defined maintenance procedure be followed (See Computerized System Validation).

F. PERSONNEL QUALIFICATIONS

Personnel operating, maintaining and programming computerized control systems should have adequate training and experience for performance of their assigned duties. Determine the extent of operator, system managers, and computer system technical personnel training in the functions, requirements and operation of the computerized system. Training should include not only system operation but cover the significance of system faults (bugs), regulatory requirements, system changes, security procedures, manual operation of the system, and documentation of system errors. Training of computerized system personnel should be documented by the manufacturing firm.

The investigator should determine the key computerized system personnel during the inspection. This may include not only the firm's own employees but outside vendors or consultants. For each of the key employees, determine to the extent possible, that employee's responsibility for the computerized system. It is important that technical personnel are available or can be reached during computerized system failures.

G. PROCESS DOCUMENTATION

Most computerized systems are capable of generating accurate and detailed documentation of the food process under computer control. What is important is that the computer generated records contain all of the information required by the CGMPS. For example, if production records are generated by computer, determine if they contain all of the information required to be in each record(s).

The firm should have security measures in place to insure that data captured by the computer system cannot be altered. If provisions are made to allow correction of data entries, the entry should identify the person making the changes and the reason for the change should be identified. For example an operator misreads a temperature indicator and enters the information into the system. The computer system then alarms the operator that the entry is out of the correct range. The operator then enters the correct temperature which is accepted by the system. All of the above should be captured on the firms records. For those firms storing records electronically, provisions should be made to store the records in a format which cannot be easily altered.

Computerized systems generating critical control monitoring records must be capable of recording the lowest and/or highest value (depending upon the critical control limits) occurring between two recording points. (for example, the sensor sends a vessel pressure to a computer continuously, even though the signal is recognized by the computer every few milliseconds, it is only printed out once every 2 minutes, it may be critical to know the lowest vessel pressure during that 2 minute period).

Electronic records must be maintained in a format that can be presented to the investigator in a readable form. This could be in the form of electronic data that can easily be accessed and read by common computer software or in the form of accurate hard copy documents produced from electronic records maintained by the firm.

Electronic Signatures if used should be controlled by the firm under written operating procedures, which insure that the electronic signature is a valid representation of the individual making the entry. Operator entry codes should be protected so that they can be used only by the person assigned that code. Electronic signatures should meet all of the requirements of FDA's final rule, 21 CFR Part 11, regarding electronic signatures.

CHAPTER 3 COMPUTERIZED SYSTEM VALIDATION

A computerized system includes: the computer hardware, computer software, peripheral devices, personnel, and computer system documentation (including computer hardware and software manuals, specifications for peripheral devices and standard operating procedures).

The computerized system used to control critical functions in food processing should be validated in its entirety.

The suitability of a computerized system for the tasks assigned to food production should be shown through appropriate tests and challenges. The depth and scope of computerized system validation will depend upon the complexity of the system and its potential effect on food safety. The validation program need not be elaborate but should be sufficient to support a high degree of confidence that the computerized system (software, hardware, personnel and operating procedures) will consistently perform as it is supposed to **(See System Testing Reference "Software Development Activities Report)**. Although various components of the computerized system may be tested separately (qualification), the total computerized system should be validated. Validation requires the system, as it will be configured and used in production to be shown to behave as expected (defined or specified) not only for normal conditions and inputs, but importantly that it continues to provide control and useful, meaningful outputs when unusual, or unexpected conditions and events occur and when inputs occur at the specified ranges or boundaries. That is, worst case conditions must be identified and tested. It is vital that a firm have assurance that software routines, especially those that control critical manufacturing functions, consistently perform as they are supposed to within pre-established operational limits. Determine who conducted the computerized system validation and how key computerized system routines were tested.

In considering computerized system validation, the following points should be addressed:

1. Does the capacity of the hardware match its assigned function? For example, in a system using an RTD for temperature control, is the RTD capable of sensing temperatures through out the processing control range, has the RTD been checked for accuracy in the operating temperature range(s), does the computer receive an accurate signal from the RTD, and does the computer react to the RTD signals as designed?
2. Have operational limits been identified and considered in establishing production procedures? For example, a PLC may be able to only receive input from two thermocouples at one time. This would limit the number of locations at which temperatures could be obtained in this manufacturing process.
3. Does the software match the assigned operational function? For example, if software is assigned to generate complete thermal processing records for a LACF process, then it should account for all of the information required to be recorded for that retort system as required by the GMPs Part 113.
4. Have test conditions simulated "worst case" production conditions? A computerized system may function well under minimal production stress (such as in a vendor's controlled environment) but falter under high stresses of equipment speed, data input overload or frequent or continuous multi-shift use, unexpected sequences or order of events and a harsh environment. Therefore, it is insufficient to test the computerized system for proper operation during a short interval, when the system will be called upon in worst case conditions to run continuously for days at a time. Some firms may test the circuits of a computer by "feeding" it electrical signals from a signal simulator. The simulator sends out voltages designed to correspond to voltages normally transmitted by input devices. When simulators are connected to the computer, the software program should be executed as if the emulated input devices were actually connected. These signal simulators can be useful tools for equipment qualification; however, they may not pose worse case conditions and their accuracy in mimicking input device performance should be established. In addition, validation runs should be accomplished on line using actual input devices.
5. Have computerized system tests been repeated enough times to assure a reasonable measure of consistent reproducible results? In general, at least three consecutive, successful test runs should be made to cover different operating conditions. If test results are widely divergent they may indicate a software bug or an out of control state.
6. Has the validation program been thoroughly documented? Documentation should include a validation protocol and test results that are specific and meaningful in relation to the attribute being tested. For example, if a temperature sensor's reliability is being tested, it would be insufficient to express the results merely as "acceptable," without other qualifying data such as temperatures observed, duration of the test, and the temperature range tested. The individual(s) responsible for conducting, reviewing and approval of the system validation should be identified in the documentation.
7. Are documented systems in place to initiate revalidation when significant changes are made to the computer system or when computer system errors are noted? Documentation should include the reason for the system change, the date of the system change, the changes made to the computerized system, and identification of who made the changes. Revalidation is indicated, for example, when a major piece of equipment such as a circuit board or an entire CPU is replaced and when software changes such as time, temperature, sequence of routine events, data edits or data handling are made. Sometimes identical hardware replacements may adequately be tested by using diagnostic programs available from the vendor. In other cases, such as when different models of hardware are introduced, more extensive testing under worst case production conditions, is indicated.

Computerized system vendors routinely perform an installation qualification to ascertain that the equipment is functioning within the hardware manufacturers specifications after being installed. However, hardware qualification is only part of the verification process and the complete computerized system should be validated.

The ultimate responsibility for suitability of the computerized system used in food processing rests with the food manufacturer. Computerized system validation data and protocols should be kept at the food manufacturer's facility. When validation information is produced by an outside firm, such as the computer vendor or software developer, the records maintained by the food establishment need not be all inclusive of voluminous test data; however, such records should be reasonably complete (including system specifications, protocols and general results) to allow the food manufacturer to assess the adequacy of the system validation. A mere certification of suitability from the vendor, for example, may be inadequate.

CHAPTER 4 MONITORING OF COMPUTERIZED SYSTEM OPERATIONS

A. INPUT/OUTPUT DEVICE OPERATION.

The accuracy and performance of these devices are vital to the proper operation of the computer system. Improper inputs from thermocouples, RTDs, pressure gauges, etc., can compromise the most sophisticated microprocessor controlled system. These sensors should be systematically calibrated and checked for accurate signal outputs.

Input to and output from the computer system should be checked by the processing firm for accuracy. While this does not mean that every bit of input and output needs to be checked, it does mean that checking must be sufficient to provide a high degree of assurance that input and output is accurate. In this regard there needs to be some reasonable judgment as to the extent and frequency of checking based upon a variety of factors such as the complexity of the computer systems. The right kinds of input edits, for example, could mitigate the need for extensive checks.

During the inspection determine the degree and nature of input/output checks and the use of edits and other built-in audits.

Input/output error handling has been a problem in computerized systems. Determine the firm's error handling procedures including documentation, error verification, correction verification, and allowed error overrides.

An illustration of inadequate input/output checks and error handling would be where a firm used a computer to sense and record retort temperatures during the thermal processing of an LACF. Failure of the firm to verify that the computer is providing an accurate reading of the correct temperature by independent observations of the Mercury-in-Glass thermometer during the thermal process would be a lack of adequate input checks. Failure of the firm to respond in some way to differences between the recorded (computer sensed temperature) and the observed temperature would indicate inadequate error handling. Determine the degree to which the firm's personnel monitor computerized operations. Is such monitoring continuous or periodic, what functions are monitored? For example, a firm's computer system may be used to maintain the pH in a mixing kettle, but if the firm does not sufficiently monitor the system they may fail to detect a hardware problem that allows the pH to go out of tolerance. During the inspection, where possible, spot-check computer operations such as:

1. Calculations; compare manual calculations of input data with the automated calculations or ask the firm to enter a given set of input values and compare automated results against known results.
2. Input recording; compare sensor indications with what the computer indicates, for example. As mentioned previously, some signals may be incorrectly converted and built-in software programming edits may alter input data. For example, a thermocouple indicating 80 C may read out on a view screen as 100 C or any other temperature if the signal converter is malfunctioning.
3. Time keeping; where computers are reporting events and controlling a function in real time, spot-check the time accuracy against a separate time piece; accurate time keeping is especially important where time is a determinative or limiting factor in a food manufacturing process such as during pasteurization or sterilization. It should be noted that some computer systems run on a 12-hour clock whereas others run on a 24-hour clock. When a host computer system is used, determine if the host or the process computer controls the time during process function control, record printing etc. Time keeping conflicts can arise when more than one of the computers is responsible for keeping or indicating time.

   The firm should have a requirement for the computer clock to be reset at predetermined intervals to insure that the system is using the correct time of day. This may be important in continuously operating systems and in those systems documenting the production time of day.
4. Automated cleaning in place (CIP); determine the procedure used, how the firm assures adequacy of cleaning, and residue elimination.

B. ALARMS:

A typical computer system will have several built-in alarms to alert personnel to some out-of-limits situations or malfunctions. Determine what functions are linked to alarms. For example, alarms may be linked to power supply devices, feedback signals to confirm execution of commands, and food process conditions such as empty or overflowing tanks. Determine the alarm thresholds for control of critical functions and whether or not such thresholds can be changed by the operator. For example, if the temperature of water in a pasteurization tank is linked to an alarm which sounds when the temperature drops below 95oC, can the operator change the threshold to 93oC?

Determine how the firm responds when an alarm is activated. This should be covered in the firm's written operating procedures. Determine the types of alarms (lights, buzzers, whistles, etc.) and how the firm assures their proper performance. Are they tested periodically and equipped with in-line monitoring lights to show they are ready? Because an activated alarm may signal a significant out of control situation it is important that such alarm activations are documented. Determine how alarms are documented in production records, in separate logs or automatic electronic recording, for instance. Can all alarm conditions be displayed simultaneously or must they be displayed and responded to consecutively? If an employee is monitoring a CRT display covering one phase of the operation, will that display alert the employee to an alarm condition at a different phase? If so, how? The operation of the computerized systems alarms should be validated as part of the complete computerized system under actual operating conditions.

C. MANUAL BACK-UP SYSTEMS:

Functions controlled by computerized systems may sometimes also be controlled by parallel manual backup systems. During the inspection find out what functions can be manually controlled and identify manual backup devices. Critical process controls are particularly important. Determine the interaction of manual and computerized controls and the degree to which manual intervention can override or defeat the computerized function. The firm's operating instructions should describe what manual overrides are allowed, who may execute them, how and under what circumstances.

Determine if and how manual interventions are documented; a separate log may be kept of such interventions. The computerized system may be such that it detects, reacts to and automatically records manual interventions and this should be addressed during the inspection. It is important that system operators are trained in manual backup systems. Determine the extent of the operator training and if the firm has any procedures for testing the manual backup system on a routine basis (e.g., computer controlled systems would be manually operated for several hours once every month).

D. SHUTDOWN RECOVERY:

How a computer controlled function is handled in the event of computer shutdown (e.g., power failure) is significant and can pose a problem. Shutdown recovery procedures are not uniform in the industry. Some systems, for example, must be restarted from the initial step in the software routine sequence and memory of what has occurred is lost. Other systems have safeguards whereby memory is retained and the control function is resumed at the point where it was halted. Newer systems may have limited battery back-up which will allow the firm to complete the control and/or documentation function or to step the manufacturing process through a safe shutdown procedure. Determine the disposition of the computer's memory content (program and data) upon computer shutdown.

Determine the firm's shutdown recovery procedure and if, in the event of computer failure, the food manufacturing process or control function is brought into a "safe" condition to protect the product. Determine such safeguards and how they are implemented. Where is the point of restart in the cycle - at the initial step, a random step or the point of shutdown? Look for the inappropriate duplication of steps in the resumption of the process. The time it takes to resume a computerized process or switch to manual processing can be critical, especially where failure to maintain process conditions for a set time (e.g. temperature control during the thermal processing of LACF) compromises product integrity. Therefore, note recovery time for delay-sensitive functions and investigate instances where excessive delays compromise product safety or where established time limits are exceeded. Many systems have the ability to be run manually in the event of computer shutdown. It is important that such backup manual systems provide adequate function control and documentation. Determine if backup manual controls (valves, gates, etc.) are sufficient to control the food manufacturing process and if employees are familiar with their operation. Records of manual operations may be less detailed, incomplete, and prone to error, compared to computerized documentation, especially when they are seldom exercised. Therefore, determine how manual operations are documented and if the information recorded manually conforms with CGMP requirements.

The computerized systems shutdown and recovery process should be validated as part of the validation of the computerized system under actual operating conditions.

REFERENCES:

Software Development Activities Report, Feb. 1987, U.S. Food and Drug Administration, Office of Regulatory Affairs.

Guide to Inspection of Computerized Systems in Drug Processing, Feb. 1983, U.S. Food and Drug Administration, Office of Regulatory Affairs.

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Glossary of Computerized System and Software Development Terminology, August 1995, U.S. Food and Drug Administration, Office of Regulatory Affairs.

Guide to Inspection of LACF Manufacturers - Part 1 - Administrative Procedures/Scheduled Processes, November 1996; Part 2 - Processes/Procedures, April 1997; and Part 3 - (currently in draft, not yet released), U.S. Food and Drug Administration, Office of Regulatory Affairs.

Guide to Inspections of Dairy Product Manufacturers, April 1995, U.S. Food and Drug Administration, Office of Regulatory Affairs.

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Inspectional Methods (Interim Guidance), October 1996, U.S. Food and Drug Administration, Office of Regulatory Affairs.

FDA Final Rule on Electronic Signatures, 21 CFR Part 11, published March 20, 1997.

Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula; Proposed Rule, Federal Register July 09, 1996.

APPENDIX 1 - QUICK GUIDE TO EVALUATION OF COMPUTERIZED SYSTEMS USED IN FOOD PROCESSING

This appendix is provided as a quick reference guide for use by FDA investigators conducting inspections of food manufacturing plants using computer control/documentation systems. The guide should not be used without a through understanding of the information provided in the main text of the Guide To Inspection of Computerized Systems in the Food Processing Industry.

1.) Determine the critical control points in the food process using HACCP concepts. Examples would be:

Pasteurization

Sterilization

pH control

Nutrient control/weighing

Nutrient analysis

Record keeping

Control of microbiological growth

2.) For those critical control points controlled by computerized systems determine if failure of the computerized system may cause food adulteration. Is the critical control point covered by GMP's or the FD&C Act?

3.) Identify computerized system components including:

Hardware:

Input devices

Output devices

Signal converters

Central Processing Unit

Distribution system

Peripheral devices

Alarms:

Types (visual, audible etc)

Functions

Records

Software:

Documentation:

Manuals

Operating procedures

Personnel:

Type

Training

4.) For computer hardware determine the manufacturer, make and model number.

5.) Obtain or make a simplified drawing of the computerized system control loop including:

Sensors

CPU

Signal converters

Actuators

Peripheral devices

6.) Software:

a. For all critical software determine:

Name

Function

Inputs

Outputs

Set-points

Edits

Input Manipulation of Data

Program Over-rides

b. Who developed software.

c. Software security to prevent unauthorized changes.

d. Firms checks on computerized systems inputs/outputs.

7.) Observe the system as it operates to determine if:

Critical processing limits are met

Records are accurate

Sensor input is accurate

Time keeping is accurate

Personnel are trained in systems operations and functions

8.) Determine if the operator or management can override computerfunctions. Explain.

9.) Explain how the system handles deviations from set or expected results.

10.) Determine the validation steps used to insure that the computerized system is functioning as designed.

a. Was the computerized system validated upon installation?

Under worst case conditions?

Minimum of 3 test runs?

b. Are there procedures for routine maintenance and revalidation?

Does the equipment in-place meet the original specifications?

c. Is validation of the computerized system documented?

d. How often is system:

maintenance performed

revalidated

calibrated

11.) Are system components located in a hostile environment which may effect their operation?

12.) Determine if the computerized system can be operated manually. Explain.

13.) Automated CIP (cleaning in place).

How does firm ensure that cleaning is adequate.

Documentation of CIP steps.

14.) Shutdown Procedures

Does firm use battery backup system?

Is computer program retained in control system?

What is firms procedure in event power is lost to computer control system?

15.) Does the firm have a documented system for making changes to the computerized system which explains:

The reason for the change

The date of the change

The changes made to the system

Who made the changes

16.) Document computer functions which are causing or may cause food products to be adulterated or misbranded.

APPENDIX 2 DIAGRAM OF LOGIC CIRCUIT

APPENDIX 3 DIAGRAM OF ALGORITHM

REPRESENTATIVE DIAGRAM OF A PORTION OF AN ALGORITHM FOR A WATER IMMERSION RETORT WHICH CONTROLS THE PROCESS TIME AND TEMPERATURE

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Combined DFSSC Sub Committee DFSMS Best Practice Guidelines

General Best Practice Guidance for
Food Establishments and Regulatory Authorities
for
Digital Food Safety Management Systems

Prepared by the Digital Food Safety Management System Committee
2021 - 2023 Conference for Food Protection

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A. Introduction and Scope

The use of digital food safety management systems (DFSMS) within the retail food industry, regulated by the Food and Drug Administration (FDA), continues to gain widespread interest, acceptance and use. The use of DFSMS is expected to continue to grow in the retail food industry as technology improves and components become more readily available. As technology advances the retail food industry continues to replace paper-based records associated with traditional food safety management systems with digital documentation. Recent FDA Risk Factor study results have shown that utilizing a robust management system leads to a reduction in food safety risk factors.

An oft-used component of a DFSMS, Digital Temperature Monitoring Equipment (DTME) can improve awareness, response and documentation of temperature conditions. This technology allows more accurate, reliable and efficient food and equipment temperature control impacting safety and quality improvements. As DFSMS and DTME become more common in the retail food industry, the visibility, awareness and availability of information that these systems and technology can provide should support improvements in controlling food safety risk factors in food retail.

This guidance will outline food safety management approaches specific to the implementation and use of technology in food retail. Best practices provided in this document serve as a foundational guide for the collection of accurate, consistent and reliable data that can be used to make risk-reduction decisions. This document has been written with the assumption that a food retail establishment has a food safety management system an that they have identified and addressed HACCP Principles 1, 2 and 3 as referenced in Annex 4 of the U.S. FDA Model Food Code (2017)

B. Definitions

Digital food safety management system (DFSMS)

An interactive, digital or electronic archive intended to collect, store, and analyze data that supports a food safety management system as defined in Annex 4 of the most recent version of the U.S. FDA Model Food Code . DFSMS specifically supports ongoing quality control and assurance, monitoring and recordkeeping of specific food safety goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the most recent version of the FDA model Food Code. A DFSMS employs active user-based work-flows that support decision making, that can be reviewed and acted upon, and may be housed locally (on-premise) or be accessed remotely using off-site servers or cloud storage.

DFSMS may include but are not limited to functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports (i.e.trends over time)

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital Temperature Monitoring Equipment (DTME)

Automated purpose-built temperature measuring device(s) that often includes sensors capable of generating and capturing temperature data for analytical use. This equipment may include the

functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time may connect to a system that may be capable of delivering alerts and exception reports.

Software

Software is the term used to describe the total set of programs, procedures, rules, and any associated documentation pertaining to the operation of a technology based system that includes, but is not limited to: application, operating system, and utility applications used by the computerized system.

C. Prerequisites

Best practice for a DFSMS is to employ purpose-built hardware and software when designing and implementing an approach. The appropriateness of hardware and software should meet the goals of any RCP. Maintenance of the system and the proper replacement of system hardware is critical for it to function as designed. Design specifications of the hardware and software should be determined and periodically reviewed to ensure the system and its functional components do what is intended to support food safety.

This document recognizes the that DFSMS are built and utilized to support the current version of U.S. FDA Model Food Code, Annex 4, HACCP Principles
Specifically:
Principle #4: Establish Monitoring Procedures
Principle #5: Establish Corrective Actions - implementation of the corrective action specifically
Principle #6: Verification/Sharing for equivalency for regulatory checks
Principle #7: Record keeping procedures and documentation

Personnel operating, maintaining, and programming DFSMS should have adequate training to complete their assigned duties. Determine the extent of operator, system managers, and software system technical personnel training in the functions, requirements and operation of the computerized system.
Training may include but are not limited to:

- system operation
- malfunctions
- regulatory requirements
- system changes
- security procedures
- manual operation of the system
- documentation of system errors

D. DFSMS Inputs

Digital Food Safety Management System Equipment (DFSMSE)

DFSMS Equipment typically include various purpose-built and designed stationary and handheld measurement instruments, tools and sensors capable of the collection, storage, and transmission of data into software. The food contact surface of DFSMS Equipment must meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent. Examples may include but are not limited to: mobile device(s), sensors, thermometers, RFID/QR Code scanner/receiver, etc.

Stationary Monitoring Devices

Purpose build devices which are permanently or semi-permanently affixed, mounted, installed, attached to equipment or surface using food grade mounting/installing materials, maintained free of accumulated soil, and cleaned per manufacturer instructions. When devices do not include an external measurement display, access to the measurement data should be easily accessible and viewable. These devices when appropriate should meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent.

Note: DFSMS Stationary temperature monitoring devices must meet the requirements outlined in the most recent version of the U.S. FDA Model Food Code 4-204.112 Temperature Measuring Devices.

Device examples may include but are not limited to: equipment or wall mounted data loggers, humidity sensors, door open/close sensors, camera’s, etc.
Data access examples may include but are not limited to: Software report on mobile, desktop, tv monitor/screen, etc.

DFSMSE Accuracy

Handheld and stationary temperature measurement instruments must meet the most recent version of the U.S. FDA Model Food Code 4-203.11 & 4-203.12. In the event that a handheld or stationary temperature device does not have a display; the operator should be able to easily demonstrate/record the reading/actual monitored temperature (value) for review and record. Follow OEM recommendations & guidelines and follow their procedures.

DFSMSE Functionality

Regular and ongoing equipment and system operation functionality are recommended to be conducted (refer to manufacturer for frequency) to verify that a DFSMS, DFSMSE and DTME in

use is operating as intended, if/when issue(s) are identified appropriate action is taken to correct issue(s). Examples of device functionality issues are but are not limited to:

- Power loss
- Improper device installation
- Device damage/defective
- Software communication/connectivity
- Device communication/connectivity

It is recommended that records of software and equipment functionality verification be maintained and readily available. Examples of functionality verification may include but are limited to:

- Handheld measurement device accuracy & functionality
- Stationary measurement device accuracy & functionality
- Software and device connectivity/communication

E. Data and System Infrastructure

DFSMS data are the measurement values and user inputs captured by DFSMSE and DFSMS users that are then stored in DSFMS software. Data storage may be stored locally (on-site) or virtually (cloud storage) but access to this data must be readily available for use and display on-site. This makes it possible to retrace which value occurred at which time. The following are examples of, but not limited to, measurement values that may be recorded and stored as data in a DFSMS:

- Time points and Account IDs which are assigned to certain quality checks
- Description of the area
- Description of the equipment
- Description of the products/product categories
- Description of the measurement locations of the equipment
- Description of suppliers
- Check lists/Quality handbook
- Tasks (Daily, Shift, On-Demand)
- Reports (Daily, Shift, On-Demand)
- Product specific quality and safety measurement data points (Temperature, pH, TPM, PPM, humidity, time)
- Alerts (alerts are notifications to users)
- Alarms (is the result of an unacceptable software or hardware reading)
- Alert recipients
- Corrective actions associated with checklists and measurement points
- Manual data entry (for immutability and data integrity)

Combined DFSSC Sub Committee DFSMS Best Practice Guidelines

When DFSMSE or a DFSMS user completes a measurement value this value is stored in DFSMS software. Each measurement value represents a unique permanent data point represented in the DFSMS software, additional or new data (including that which is associated with an existing or old data point) are then stored in a sequential manner allowing for the original data point to remain. This can be described as a time-based progression of record keeping. The DFSMS software should also be capable of recording All previously recorded data should be readily accessible, and documented when changed and available for reporting.

Digital Temperature Monitoring Equipment (DTME) Data

There are three broad ways of capturing temperature and humidity data; they are commonly identified as held, stationary, or Integrated temperature measuring devices. An important consideration for DTME is that the devices often have the ability to cache/store data locally when connectivity is interrupted, if/when data connectivity is interrupted a DTME device should have the ability to push/send when connectivity is restored. The infrastructure shall refer to information technology industry cache/storage best practices at the time (such as ieee.org).

Verification / Immutability

A retail food business may have measures in place to ensure that data captured by the computerized system cannot be altered without a digital signature record or other means of tracking history of inputs. If provisions are made to allow correction of data entries, the entry may identify the person making the changes and the reason for the change and what previous data was.

Data and System Integrity and Access

Data Integrity and Access are both important aspects of a DFSM that should be considered to ensure that quality of the information collected by the system is accurate and reliable. To support the integrity of a DFSM it is recommended that controls are in place to ensure that stored and/or in process data is not able to be altered data in an unauthorized manner, and that any changes are captured. Data access is also a way to support effective data integrity. Access to a DFSMS should be controlled and limited only to those persons to whom permission is granted. All data and information should be protected through the use of encryption protocols. Examples of encryption could include, but are not limited to, utilizing passwords,user management and user rights. While examples of things needing encryption include but are not limited to:

- Passwords
- Proprietary business information
- Data transferred between the input devices and local/cloud-based reporting and storage programs/locations.
- Login occurrences
- Access to information within the DFSMS should also be tailored according to a user's role and responsibilities, writing or reading rights.

Manual Data Entry

Determine if and how manual interventions are documented; a separate log may be kept of such interventions. The computerized system may be such that it detects, reacts to, and automatically records manual interventions. It is important that system operators are trained in manual backup systems; as a best-practice this should be documented and conducted prior to DFSMS usage. To ensure business continuity, it is recommended that users have their own SOP for review (redundancy) to ensure practices are being enacted.

Manual Back-Up

A manual back-up system is frequently utilized as a function of business continuity in the event of a computerized system (e.g. hardware or software) failure. Functions controlled by computerized systems may sometimes also be controlled by parallel manual backup systems. As a best practice, functions that are manually controlled and/or manually backed up should be identified and noted re: the firm's protocols or the system's protocol. Critical process controls are particularly important. Determine the interaction of manual and computerized controls and the degree to which manual intervention can override or defeat the computerized function. The firm's operating instructions should describe what manual overrides are allowed, who may execute them, how and under what circumstances.

F. DFSMS Outputs

System Outputs and Notification(s)

Typical DFSMS and DTMS include the capability to include user level notification(s) tailored around programmable components of an organization's Standard Operating Procedures (SOP), see What Data is Stored section above for measurement examples that may be involved. Examples of user level system notification(s) may include but are not limited to the following:

- Reports
- Trends
- Automated emails
- SMS or text message
- Phone calls
- Visual indicators (lights)
- Audible indicators (sounds)

A best practice is to associate one or more corrective actions with an alert. To assure corrective actions are completed in a timely fashion, alerts can be escalated when corrective actions are not completed within a set timeframe.

G. Committee Members

Academia/Industry Members				**Regulatory Members**	
Ben	Chapman	Eric	Moore	Justin	Asberry
Vanessa	Coffman	David	Abney	Robert	Sudler
Julie	Abouchar	Amanda	Douglas	Beth	Wittry
Jamie	Estes	Julian	Graham	Adam	Kramer
Matthew	Jenkins	Michael	Roberson	Matthew	Brandt
Joey	Yoo	Lilly	Yang	Jarryd	Samples
Gina	Owen	Jonathan	Ruiz Espejo	Travis	Splawn
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Brianna	Davis	Jean	Edsall	Katie	Matulis
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Kevin	Scott	Charles	Seaman		
Michael	Sperber	Darrell	Wiser		
Rebecca	Wynnw	Thomas	Woodbury		

DRAFT

Template approved: 7/13/2021

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COMMITTEE NAME: Council II Allergen Committee

DATE OF FINAL REPORT: *12/5/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☒ ***Council II*** ☐ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Co-Chairs: Dr. Amani Babekir and Michelle Hill CP-FS

COMMITTEE CHARGE(S):

Issue # _2020-II-011__

1. Develop an operational framework for food allergy prevention and control using existing research and other evidence-based materials (for example: CDC guidance in schools and guidance developed by retail food industry) in retail food establishments including:

- **a.** A written template retail food establishments can use to reduce the risk of food allergy reactions and respond to any reactions that do occur. The template can incorporate findings, lessons, materials, etc. from items b-f.
- **b.** Steps to take during a food allergy emergency and identify key components of food allergy emergency plans.
- **c.** Food allergy training for food workers and identify educational content and training needs based on employees' assigned duties.
- **d.** Findings, recommendations, and materials from the 2018 Allergen Committee to ensure retail food establishments have tools to notify customers when menu items contain major food allergens.
- **e.** Food-handling practices, policies, and procedures to prevent food allergens from unintentionally contacting another food.
- **f.** Equal considerations for alternate food sources, such as food pantries and food banks, to ensure equity and access.

2. Recommend changes to the Food Code that support retail food establishments to operationalize framework to prevent and control food allergic reactions.

3. Report back findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

COMMITTEE WORK PLAN AND TIMELINE: The committee charges are completed; the committee will meet as needed to finalize the documents after the Council II Co-Chair review process.

COMMITTEE ACTIVITIES: *Dates of committee meetings or conference calls:*

A) Allergen Committee: 3/31, 4/14, 4/28, 5/12, 6/9, 6/23, 7/7, 8/4, 8/18, 9/1, 9/15, 9/29, 10/13, 10/27, 11/10, 12/5

B) Sub-group meetings, week of: 3/20, 3/27, 4/3, 4/10, 4/17, 5/8, 5/15, 5/22, 5/29, 7/10, 8/14, 8/21, 8/28, 9/4, 9/8

1. *Overview of committee activities:*

Completed the Framework after addressing the Federal Partners comments.

Finalized the Issue language recommending changes to the Food Code.

Completed the Issues to submit to Council II.

2. *Charges <u>COMPLETED</u> and the rationale for each specific recommendation:*

All charges are completed and the guidance documents, “Major Food Allergen Framework” and “Summary – Major Food Allergen Framework” were produced through the Committee’s hard work.

3. ***Charges INCOMPLETE and to be continued to next biennium:***

   All charges have been completed.

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ ***No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.***

☐ **Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

Issue #1: Allergen Committee (AC) Final Report

List of content documents submitted with this Issue: Committee Member Roster:

☐ ***See attached revised roster PDF*** ☒ ***No changes to previously approved roster***

“Committee Members Template” (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) *Other content documents:*

a. List of supporting attachments: ☐ ***Not applicable***

(a.i.1) “Major Food Allergen Framework” document

(a.i.2) “Summary – Major Food Allergen Framework” document

(a.i.3) Meeting Minutes

(a.i.4) Meeting Attendance Records

1. ***Committee Issue #2***: Publish “Major Food Allergen Framework” and “SUMMARY – Major Food Allergen Framework” to CFPs website.
2. ***Committee Issue #3***: Amend the Food Code.
3. ***Committee Issue #4***: Re-create the Allergen Committee

Committee Name: Allergen Committee

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
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Baldwin	James	Member	Industry - Retail Food	The Golub Corporation - Price Chopper/Market32	Schenectady	NY	518-379-1516	jimbaldwin@pricechopper.com
Thoma	Libby	Member	Industry - Retail Food	H-E-B	San Antonio	TX	210-425-3390	thoma.libby@heb.com
Wagner	Ben	Member	Industry - Retail Food	Target	Minneapolis	MN	612-280-1452	ben.wagner@target.com
Potts	Amber	Member	Industry - Support	National Environmental Health Association	Denver	CO	2143845981	apotts@neha.org

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
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Lapore	Nicole	Alternate	Industry - Retail Food	Albertsons	Devon	PA	973-886-7783	nicole.lepore@albertsons.com
Algeo	Susan	Alternate	Industry - Support	WinWam	Mt. Laurel	NJ	610-322-7665	susanalgeo@winwam.com
Meinhardt	Christina	Alternate	Industry - Food Service	Aramark	Philadelphia	PA	267-939-4894	meinhardt-christina@aramark.com
*Larsen	Tom	Alternate (recommended)	Industry - Support	Accounts Coordinator of State Food Safety	Orem	UT		tlarsen@statefoodsafety.com
Noller	Aubrey	Alternate	Industry - Retail Food	Food Lion	Salisbury	NC	8646402760	aubrey.noller@retailbusinessservices.com

*This Alternate member is being added to the roster at the direction of the Conference Chair. Will require Executive Board approval before being moved into a voting position

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Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise;*
Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 36 -Non-voting alternates.
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

Major Food Allergen Framework

Conference for Food Protection
2023 Biennium
Council II: Allergen Committee
Publication Date: _____

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Contents

Introduction

PURPOSE This document is to serve as a voluntary operational framework for FOOD ALLERGY[1] prevention and control of the MAJOR FOOD ALLERGENS[2] (as defined below) using existing research and other evidence-based materials for FOOD ESTABLISHMENTS[3] and OTHER COMMUNITY FOOD SOURCES[4]. Readers should be aware, however, that people may have other allergies beyond the major food allergens, and food establishments may employ the same practices outlined in this document to assist CONSUMERS[5] with allergies, FOOD INTOLERANCE/SENSITIVITY[6] beyond those listed herein.

Readers should be aware that consumers may have other food allergies, intolerances, or sensitivities (such as celiac disease, Crohn's disease, IBS/IBD, and others) which, although not technically allergies, are triggered by ingestion of particular foods.

SCOPE This document covers food allergy training of FOOD HANDLERS[7]; food handling policies and practices; consumer notification tools for food allergens; a food allergy reaction and emergency response guide; and equal consideration for other community food sources.

BACKGROUND A food allergy happens when a person's immune system overreacts to a food protein. Approximately thirty million people in the U.S. have food allergies, leading to 200,000 emergency department visits per year. FOOD ALLERGIC REACTIONS[8] vary in severity, from mildly itchy skin and lip swelling to severe, life-threatening symptoms (ANAPHYLAXIS[9]) and death. In the United States, 51% of adults and 42% of children with food allergies have experienced a severe reaction.

1 "Food allergy" means the reaction of the body's immune system to certain proteins in food. Reactions can vary in severity from mild symptoms involving hives and lip swelling to severe, life-threatening symptoms, called anaphylaxis, which may involve shock and fatal respiratory problems.

2 "Major Food Allergen" mean the allergens in foods that cause over 90% of allergic reactions: milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.

3 "Food establishment" means an operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

4 "Other community food sources" means food sources that are made available to the public on a need basis, e.g., food bank, food shelf, food pantry.

5 "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale

6 An adverse reaction to a substance in food that does not involve the immune system, e.g., the inability to process or breakdown a certain food such as the milk sugar lactose which can lead to discomfort or have ill effects.

7 "Food handler" means a person who handles food utensils or who prepares, processes, or serves food or beverages for people other than members of their immediate household.

8 "Food allergic reaction" means an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. The immune response can be severe and life-threatening.

9 "Anaphylaxis" means a life-threatening allergic reaction due to over-release of certain chemicals in the body resulting in shock when a person with an allergy is exposed to an allergen. Allergies to food, insect stings, medications, and latex, are most frequently associated with this type of severe response, and may include skin symptoms or swollen lips, difficulty breathing, reduced blood pressure, and gastrointestinal symptoms.

The **Major Food Allergens** that cause over 90% of all allergic reactions in people are these types of food:

- Milk
- Eggs
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans
- Sesame[10]

This guide includes example procedures, considerations, and resources that a food establishment can use to respond when someone notifies the food establishment about a food allergy or reports an allergic reaction. It also provides a framework for providing consumers accurate information about food ingredients so they can make informed decisions when ordering.

Although comprehensive, this guide might not provide everything that needs to be considered for a food allergy reaction and emergency response plan. It might also contain materials that are not relevant to every food establishment, so please consider internal procedures or standard operating procedures when using this material.

10 Sesame has been added to the list of Major Food Allergens via the FASTER Act of 2021, effective January 1, 2023.

A. Training

PURPOSE This is a framework to educate food handlers about (1) the Major Food Allergens – milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame; and (2) other allergy and intolerance issues they may encounter.

Duties in food establishment (intensity of training increases with responsibility)

1. PIC - Person in Charge (PIC)[11]

Training should include

a) Definitions for food allergy, food intolerance/sensitivity, and CROSS-CONTACT[12].
b) List of the symptoms of a food allergic reaction, including anaphylaxis.
c) List of the Major Food Allergens in FDA's Food Code.
d) Dangers of food allergens and how to prevent cross-contact.
e) Using proper cleaning methods, such as wash, rinse, and sanitize, to prevent cross-contact.
f) How and when to communicate with consumers and staff about food allergens.
g) Special considerations related to food allergens for workstations and SELF-SERVICE[13] areas.
h) How to handle food allergy requests.
i) How to deal with food allergy emergencies.
j) Proper food preparation for guests with food allergies.
k) How to read a food LABEL[14] and understand the importance of food labels.
l) Personal hygiene practices to prevent cross-contact.
m) How to receive and store foods that contain Major Food Allergens to prevent cross-contact.

2. Front of house; wait staff, hostess/host, to-go personnel

Training should include

a) Definitions for food allergy, food intolerance/sensitivity, and cross-contact.
b) List of the symptoms of a food allergic reaction, including anaphylaxis.
c) List of the Major Food Allergens in FDA's Food Code.
d) How to handle food allergy requests.
e) How to deal with food allergy emergencies.

3. Back of house; Food handler *(as defined in FDA's Food Code)*

Training should include

a) List of the Major Food Allergens in FDA's Food Code.
b) Dangers of food allergens and how to prevent cross-contact.
c) Cleaning and personal hygiene practices to prevent cross-contact.
d) In-depth knowledge of MENU[15] items and preparation as it relates to assigned duties.
e) Proper food preparation for consumers with food allergies.
f) How to read a food label and understand the importance of food labels.

11 "Person in Charge (PIC)" means the person present at a food establishment who is responsible for the operation at the time of inspection.

12 "Cross-contact" means the unintentional transfer of an allergen from a food or food-contact surface containing an allergen to a food or food-contact surface that does not contain the allergen.

13 "Self-service" means areas where a food handler is not present to serve a consumer and the consumer is responsible for serving themselves. Examples: buffets, salad bars, sushi bars, or display cases.

14 "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and any word, statement, or other information that appears on the outside container or wrapper of the retail package.

15 "Menu" means all written and verbal lists of foods prepared and offered in a food establishment.

4. Understanding Labels

a) Manufacturers of PACKAGED FOOD[16] products that contain a Major Food Allergen are required by law to list that allergen on the product label – including if they are, or are a component of, a flavor, color, incidental additive, or spice (i.e., sesame paste).
b) There are several ways the allergen can be listed, so CONSUMERS[17] must read product labels carefully.
   i. The allergen may be listed in a 'Contains' statement.
   ii. If the product does not have a 'Contains' statement, consumers should review the entire ingredient list.
   iii. A 'may contain' or 'produced in a facility' marking is a voluntary, separate allergen advisory statement when there is a chance that a food allergen could be present. Anything labeled in this manner should be considered to have an allergen present.
c) Common allergens can have other names. For example, caseinates (in all forms), and whey (in all forms) are all milk proteins.
d) Although the same allergen can be present in multiple ingredients, its "food source name" (for example, milk), or common or usual name, must appear in the ingredient list just once to comply with LABELING[18] requirements.

SUPPLY CHAIN CONSIDERATIONS Manufacturers change their ingredients and production methods continually and without warning; it is especially important to read the ingredient label, and ingredient statement, for the presence of major food allergens with each shipment. Contact the manufacturer in advance if you have questions about food allergens that may be in a product.

e) Major food allergen labeling information can be found within:
   - FDA's "21 CFR 101", https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101
   - USDA's "Allergens – Voluntary Labeling Statements," https://www.fsis.usda.gov/guidelines/2013-0010
   - USDA's **"**FSIS Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling," https://www.fsis.usda.gov/sites/default/files/import/Allergens-Ingredients.pdf

16 "Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food handler, upon consumer request.

17 "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

18 "Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

B. Food-Handling Policies & Practices to Help Consumers with Food Allergies

PURPOSE Example policies and practices are provided here that will reduce the risk of a consumer being exposed to a food allergen.

With food allergens, it is **very important** to avoid having **even small amounts** of an ingredient to which a consumer is allergic come into contact with their food, utensils, tableware, and packaging. The unintentional transfer of an allergen from a food or food-contact surface containing an allergen to a food or food-contact surface that does not contain the allergen is called **cross-contact**. Sometimes it is obvious when an allergy-causing ingredient has gotten into a food through cross-contact because the ingredient can be easily seen, but other times it is not obvious, and great care should be taken to avoid these situations.

Following these guidelines, which apply to **all food handlers** who come into contact with food, beverages, and any food preparation surface, can help consumers with allergies avoid potentially life-threatening allergic reactions.

Train relevant staff in the following procedures

1. Food & Ingredient Storage

a) **Label** and segregate unpackaged foods containing one or more of the Major Food Allergens away from each other, and store separately from other foods and ingredients. *Make sure to read ingredient labels to check for the presence of allergens before labeling and segregating.
b) Spills of any of the Major Food Allergens should be cleaned up immediately, following the usual cleaning procedures used in the food establishment. If any Major Food Allergen accidentally comes into contact with other food ingredients that do not contain that allergen, these ingredients should be excluded from use.

2. Self-Service Items

a) For food items that were made on site, **label** the food items, or place **signs** next to the food items, that clearly identify the presence of one or more of the Major Food Allergens, or keep ingredient lists on site that identify the presence of one or more of the Major Food Allergens.
b) Labels and signage should be in both English and Spanish, and/or other languages appropriate to either the establishment, or the geographic area.

3. Taking a Food Order

a) When a consumer informs staff they have a food allergy, intolerance, or sensitivity, immediately **notify** the Person in Charge (PIC) or designated person (manager, chef, or key employees).
b) Help the consumer **identify** menu items that contain ingredients to which they are allergic and offer suggestions for alternative menu items.
c) If no alternative menu options are available, politely **inform** the consumer.
d) If it is possible to **modify** a menu item so that it does not include ingredients the consumer must avoid, inform the consumer, and ask if the modification would suit their needs.
e) **Verify** with the food handler that the proposed menu item modification is possible, feasible, and can be done safely for the consumer.
f) Make a **note** on the consumer's order that they have a food allergy/intolerance/sensitivity and which ingredients they must avoid so that other food handlers are aware.

4. Preparing a Food Order

a) Thoroughly clean all areas and equipment that will be used for preparing the allergic consumer's meal, even if those areas had already been cleaned for normal use.
b) Wash hands thoroughly before preparing the allergic consumer's meal. In some situations it may be necessary to change apron/chef coat, if previously soiled with potential allergens.
c) Use dedicated equipment or physically separate products to prevent cross-contact.

i. Use color-coded or specially marked supplies, uniforms, equipment, and utensils designated for preparing allergen-free meals.
ii. Avoid using the same cooking medium (e.g., oil or water) and surface (e.g., grill, prep table) when handling ingredients with and without allergens.

d) Use ingredients that do not contain the allergen(s) to which the consumer is allergic. Check ingredient labels for packaged foods.
e) Prepare food in a manner that eliminates cross-contact. All preparation, including garnishes, should be done by only one food handler who is dedicated to ensuring the meal is allergen-free, and who is not preparing other consumers' meals at the same time.

i. **If a mistake is made**, and an ingredient to which the consumer is allergic is accidentally included in the meal, it is **not sufficient** to simply remove the offending ingredient, because cross-contact will have occurred. In case this happens, **re-make** the consumer's meal.
ii. Wash your hands with soap and water before continuing preparation to avoid potential, or additional, cross-contact.

f) Cover the meal with a clean lid to prevent cross-contact and mark the meal as "allergy" so other staff are aware.
g) Notify the PIC, or designated food handler once the allergen-free meal is prepared and ready for service.
h) Wash, rinse, and store special equipment for allergen-free meals to be ready for next use.
i) Wash your hands with soap and water before touching anything else if you have handled a food allergen.

5. Delivering a Food Order

a) Verify with the food handler who prepared the meal that it does not contain the allergen specified by the consumer.
b) Ensure no cross-contact with other meals occurs during transport of the meal to the consumer.
c) Use a separate meal tray to deliver the meal.
d) VERIFY with the consumer that the meal meets their needs.
e) Discard the meal and offer to re-make it for the consumer if the meal contains ingredients to which the consumer is allergic. **Notify** the PIC. **Review** procedures and **retrain** the food handler(s) who prepared and handled the meal on these procedures **before** allowing them to re-make the consumer's meal.

C. Tools to Notify Consumers about Major Food Allergens

PURPOSE The purpose of this guidance is to provide examples of how to give consumers accurate information about food ingredients that are, or that contain, Major Food Allergens so they can make informed decisions when ordering. Giving incorrect or incomplete information can put consumers at risk for allergic reactions.

Consumers with food allergies depend on accurate allergen information when deciding what to eat. It is most effective to tell the consumer both verbally and in writing (e.g., on labels and menus) about the presence of food allergens and the risks of cross-contact.

1. Food Allergens in Menu Items & Self-Served Food[19] Items

a) Review your menu and source ingredients.
b) Use a table (see "Figure 1: Example Food Allergen Matrix" below), listing each menu item and noting the presence of major food allergens including all ingredients such as egg washes, sauces, garnishes, etc. Remember, a food might have more than one allergen.
c) Print "Figure 2. Allergen Matrix – Major Food Allergens Present in Menu Items" (following page) and use it for staff and consumers.
d) Assign a person in charge to regularly, at least once a year, review the food allergen table and update it as needed to verify the ingredients have not changed. Review and update when ingredients, suppliers or processes have changed, and/or a new item has been added to the menu. Consider off-menu items, seasonal and specialty items.
e) Have accessible the full list of ingredients for menu items for consumers with allergies or intolerances beyond the top nine. Consumers may be allergic to ingredients beyond the Major Food Allergens, like gluten. Understanding the full list of ingredients may help you better assist these consumers.

2. Create a Food Allergen Matrix *(based upon your current menu items)*

Figure 1. Example Food Allergen Matrix

Food Items*		Major Food Allergens								
		Egg	Fish	Milk	Peanut	Sesame	Shellfish	Soybean	Tree Nut	Wheat
Breads or Breaded	Bagels	X		X		m		m		
	Gluten Free biscuit	X		X				m	m	
	Sourdough bread									
	Croutons	X		m		m			m	
	Onion rings	X		X						
	Chicken nuggets	X						m		
	Mac and cheese	X		X						
Cheese	American			X						
	Provolone			X						
	Cheddar			X						
	Peanut oil in fryer				X			X		
Lettuce Salad	no Dressing									
	with Dressing	X		X				X		

"X" Contains this allergen.

"m" May contain this allergen or is processed in a facility with this allergen.

19 "Self-served food" means Restaurant-type food that is available at a salad bar, hot food bar, buffet line, cafeteria line, or similar self-service facility, and is served by the consumers themselves. Self-service food also includes self-service beverages, such as drinks dispensed from a soda fountain and coffee available on a self-service basis

Figure 2. Allergen Matrix[20]

Major Food Allergens Present in Menu Items

Food Items *	Major Food Allergens									Other Components			
	Egg	Fish	Milk	Peanut	Sesame	Shellfish	Soybean	TreeNut	Wheat				

"X" Contains this allergen.
"m" May contain this allergen or is processed in a facility with this allergen.
** Include off-menu items, seasonal and specialty items.*

Created on:_____ Reviewed on:_____ Next review:_____

20 A table such as this could be customized for gluten-free and other food intolerances and sensitivities by utilizing the “Other Components” column.

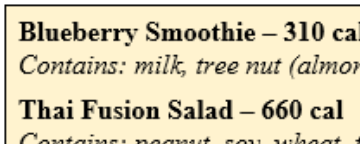
3. Menus & Signage

Design and update existing menus (including those for online ordering, catering, specials, and take-out) to ensure names and descriptions of **all** food items include Major Food Allergens present in each food. For example:

a) Have signage to notify consumers and food handlers an allergen menu exists.
b) Next to each menu item, include text to specify allergens (e.g., *Contains egg, milk*).
c) Use images (or "icons") of food allergens next to menu items where they are present. Include a key so consumers know what the icons represent. Links to websites with pre-made icons are included below.

Figure 3. Examples of notifications

Example 1: In-menu allergen notification.



Example 2: Allergen icons.

4. Talk with Consumers

a) Encourage staff to **ask consumers** about any food allergies they might have.
b) **Provide a list** of menu items and their ingredients for food handlers and consumers as a reference.
c) **Appoint at least one trained food handler per shift** to respond to consumer requests and questions about food allergens.

5. Other Ways to Inform Consumers

a) **Static clings** on display cases provide Major Food Allergen information in consumer view. **Tags or tents** next to food items also work well.
b) **Counter cards, table-talkers, or signs** at the point-of-sale or pick-up to inform consumers.
c) Consider **placing a sign in a prominent location**, when contact with a Major Food Allergen is possible or unavoidable (e.g., French fries prepared in the same fryer as breaded [wheat-containing] items).
d) **Websites** where you can find graphics and other icons for food allergens include:

i. International Association for Food Protection (IAFP) Food Allergen Icons
https://www.foodprotection.org/resources/food-allergen-icons/
ii. StateFoodSafety Allergen Icons
https://drive.google.com/drive/folders/1z_Ie5yxvWq5vFLnWnR7FeIXZDQePhygI?usp=sharing
iii. Erudus Food Allergy Icons
https://erudus.com/standardised-food-allergy-icons/

D. Food Allergy Reaction & Emergency Response Guide

PURPOSE This section is to serve as a resource for food establishments when writing a food allergy reaction and emergency response plan. This guide includes example procedures, considerations, and resources that a food establishment can use to respond when someone reports an allergic reaction. Although this section was written specifically for food allergies, some parts are applicable to reactions caused by other exposures, such as bee stings. Example informational posters are included for you to use within your food establishment.

1. What an allergic reaction may look like

Allergies are complex and allergic reactions can vary from person to person.

Allergic reactions can present in many ways. Food allergic reactions vary in severity, from mildly itchy skin and lip swelling to severe, life-threatening symptoms (anaphylaxis) and death. Some signs and symptoms only affect one part of the body (for example, hives around the mouth). Some signs and symptoms mean that multiple areas of the body are affected (for example, dizziness).

Even within the same person, reactions can differ from food-to-food and day-to-day. For example, a person might experience itching around the mouth after eating an almond, but they could have difficulty breathing and require emergency care after eating a peanut. Even reactions to the same food on different eating occasions can cause different symptoms in the same person.

Different people, including children, experience different symptoms too. For example, not everyone experiences nausea or diarrhea during a reaction. Likewise, it is possible to have a severe life-threatening reaction (anaphylaxis) without any skin symptoms, such as a rash or hives.

2. Allergic reactions in children and adolescents

Children can experience serious food allergic reactions, with an alarming number of fatal anaphylactic reactions occurring during adolescence. Milk, egg, wheat, and soy allergies are more common in childhood than adulthood.

Children can have difficulty communicating what they are experiencing during a reaction. Some children put their hands in their mouths or scratch at their tongues. Their voices may change (for example, becoming hoarse or squeaky), and they might slur their words.

3. If someone reports an allergic reaction

These are **examples** of potential actions to take when a person reports an allergic reaction. Procedures may differ depending on the severity of the reaction. Food establishments should evaluate their need for internal procedures or additional steps. based on corporate policies or other circumstances.

*** When in doubt, call 911 ***

a) Clearly direct one person to dial 911 and report an allergic reaction.
b) Follow the directions of emergency services personnel and the food establishment's food allergy emergency response plan.

4. Epinephrine auto-injectors

a) What is an auto-injector?
EPINEPHRINE AUTO-INJECTORS[21] are medical devices for injecting a measured dose of epinephrine directly into a person experiencing an allergic reaction. The devices are designed to be given through clothing. Multiple brands of auto-injectors are available in the United States, and other countries, and may look slightly different. In the U.S., you cannot buy an epinephrine auto-injector unless you have a prescription from a health care provider. Food establishments will not be able to stock an auto-injector for general use.
Epinephrine auto-injectors have specific directions for use printed directly on the device. **Always follow the instructions printed on the auto-injector**. Always call emergency services when an auto-injector needs to be administered, as a relapse is possible.

b) Here are some example images of what an epinephrine auto-injector might look like; not all auto-injectors will look like these.

Figure 4. Examples of Epinephrine auto-injectors (EAIs)

5. Additional considerations for the food establishment

The following questions and scenarios may be used to develop a detailed food allergy reaction and emergency response plan and/or can be used as a practice drill. Not all questions and scenarios will apply to a food establishment and some food establishments might have additional questions to consider.

a) What ingredient information will be provided to a consumer if they ask? Will this information be written or verbal?

i. If a person experiences a reaction, their first question will be if the allergen was present in any of the food(s) they ate.

b) The exact numbers to dial to reach emergency services should be clearly posted by all telephones.

i. Is there an additional number to dial or extra step to get an outside line?

c) Each person should be aware of any role they play during an emergency. You may consider who will:

i. Be the primary person in charge and ensure each person is performing their duties.

21 A device for injecting oneself with a single, preloaded dose of a drug. The device typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body.

ii. Call emergency services and relay information.
iii. Direct and meet emergency medical services? Are there clear instructions available on how to find the food establishment?
iv. Interact with and physically assist the consumer, if necessary.
v. Keep the area around the person experiencing the reaction clear.

d) Will the food establishment keep any allergy-specific supplies (for example, antihistamines or itch creams) on hand? If yes, when will they be used?

REMINDER Epinephrine is the only medication that can treat a severe allergic reaction and must be prescribed by a health care provider.

e) Will staff have permission to search a person's belongings for an epinephrine auto-injector if they are unable to assist?
f) Can staff administer epinephrine auto-injectors? If yes, which people have permission?
g) Is there an automated external defibrillator ("AED") available? If yes, are staff trained to use it?
h) What are the procedures if the person experiencing a reaction does not want to call an ambulance? If the person leaves before the ambulance arrives, who will pay for any charges incurred?
i) Is there a debriefing and/or reporting requirement after the incident? If yes, include those steps in the allergic reaction response plan.
j) Modify the response plan, as necessary, to better prepare for future incidents.

6. Examples of Posters *(that can be placed within your food establishment to support food allergy preparedness and emergencies)*

E. Equal Consideration for Other Community Food Sources

Other community food sources provide healthy, nutritious food to those in need. For individuals with food allergies, it can be difficult to find safe foods. People with food allergies may need additional support and it is important to consider the food sources' ability to do the following:

- Have at least one well-trained person that is available to speak with those who have allergy concerns. It is important to identify foods that do not contain *at least* the Major Food Allergens so appropriate suggestions can be made.
- Allow consumers the opportunity to review original food packaging so they can read the labels. Know the importance of reading every label, every time, as ingredients can change without warning.
- Make sure staff understand the dangers of cross-contact and how to avoid it. Find out what procedures are in place to avoid cross-contact in the storage and/or preparation of food, if it is being prepared on site, so it can be shared readily.
- If food is cooked and/or served on the premises, be sure workers knows how to recognize the signs and symptoms of anaphylaxis and what the protocols are for a food-allergic emergency.

When offering foods/meals to large groups, encourage preparation of meals that are free of the Major Food Allergens.

- If foods or meals with food allergens are served, provide materials (e.g., signage, labels, tags, tents) in prominent and visible locations to inform consumers.
- While most sections of this document are applicable to both food service venues as well as other community food sources, special attention should be paid to the understanding of how allergens are listed on food labels and the availability of food label information.

Food Sources During an Emergency and Disaster Preparedness

Whether an earthquake, hurricane or wildfire, natural disasters, in addition to man-made ones, can happen at any time, often with little notice. Establish procedures for accessing allergen-friendly foods during an emergency. A crisis is never a time to experiment with a new food or product.

Fig

Food Allergy Reactions

Nine Major Food Allergens

- Milk
- Eggs
- Fish
- Shellfish
- Tree nuts
- Peanuts
- Wheat
- Soybeans
- Sesame

Symptoms of a Severe Allergic Reaction

LUNG
Short of breath, wheezing, repetitive cough

HEART
Pale, blue, faint, weak pulse, dizzy

THROAT
Tight, hoarse, trouble breathing/ swallowing

MOUTH
Significant swelling of the tongue and/or lips

SKIN
Many hives over body, widespread redness

GUT
Repetitive vomiting, severe diarrhea

OTHER
Feeling something bad is about to happen, anxiety, confusion

OR A COMBINATION
of symptoms from different body areas.

FOR **MILD SYMPTOMS** FROM **MORE THAN ONE** SYSTEM AREA, GIVE EPINEPHRINE.

If someone is having a SEVERE ALLERGIC REACTION…

INJECT EPINEPHRINE IMMEDIATELY

Follow the instructions on the device.

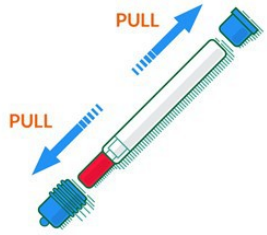
CALL 911

Tell them the individual is having an allergic reaction.

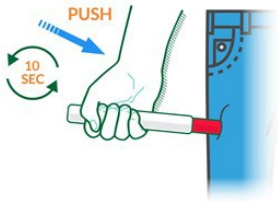
LAY them down.

If breathing is difficult or they are vomiting, let them sit up or lie on their side.

STEP 1. Prepare the epinephrine auto injector for injection by following the instructions on the device.



STEP 2. Administer the injection by firmly push the needle into the leg until a click is heard or felt. Hold the device there.



Written allergic reaction response plan is can be found here: _____

Adapted from Michigan Department of Agriculture and Rural Development, Michigan Restaurant Association, https://www.foodallergy.org/living-food-allergies/food-allergy-essentials/food-allergy-anaphylaxis-emergency-care-plan, and https://www.fda.gov/food/food-labeling-nutrition/food-allergies

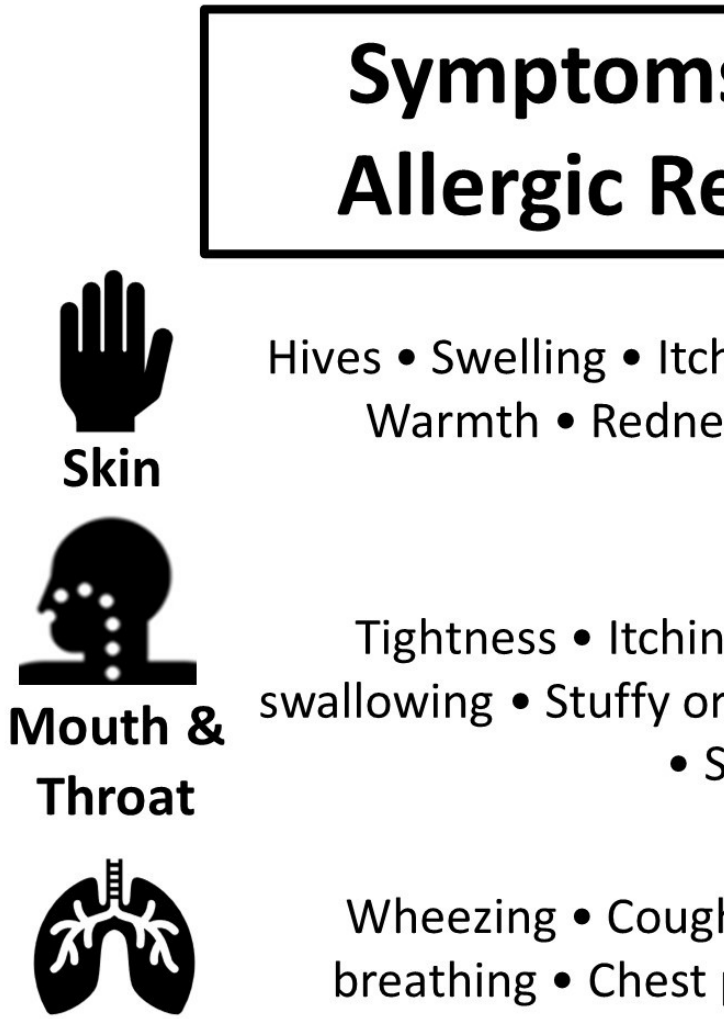


Figure 6. Symptoms of an Allergic Reaction

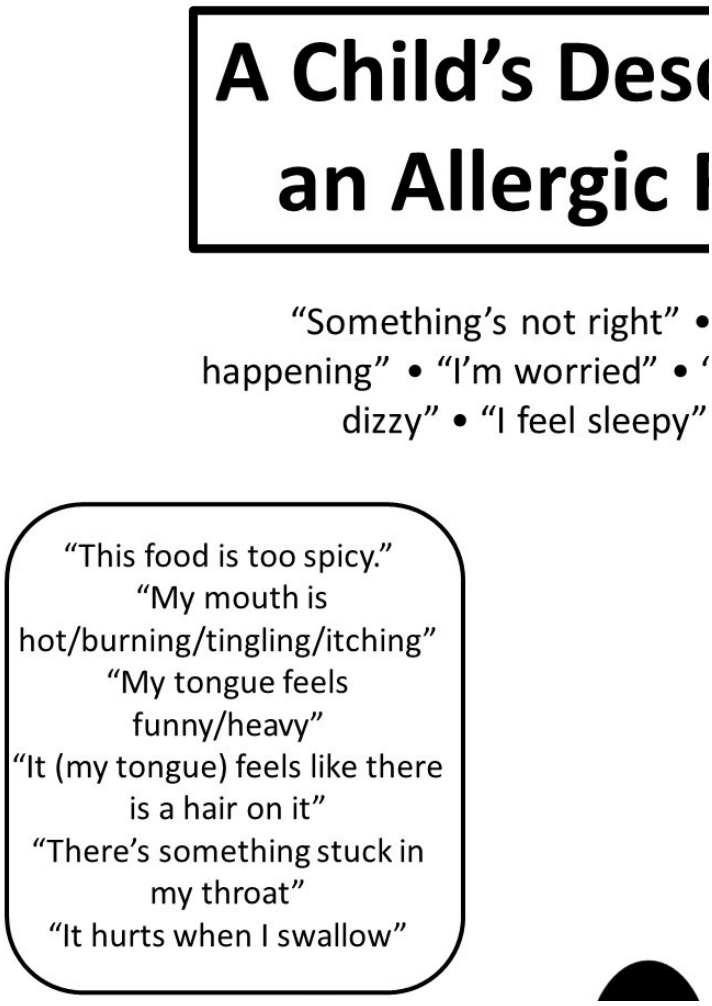


Figure 7. A Child's Description of an Allergic Reaction

Figure 8. Food Allergy Aware - Six that save lives

FOOD ALLERGY AWARE

SIX THAT SAVE LIVES

1

The Symptoms

Signs of a serious food allergy reaction – known as anaphylaxis – are 2 or more of the following after eating a suspect food:

- Hives, itching and/or skin redness
- Swelling of the tongue, lips or throat
- Breathing difficulty, wheezing or coughing
- Stomach cramps or vomiting or diarrhea
- Feeling faint / drop in blood pressure (If only this 1 symptom, it is still anaphylaxis.)

2

In Anaphylaxis: Use the auto-injector right away. Call 911 and report a food allergy emergency.

Epinephrine shots are given via the auto-injector to the outer thigh muscle. This is considered a very safe drug. Antihistamines are acceptable as secondary medication only. They won't halt anaphylaxis. Allergists say: err on the side of using the auto-injector.

3

Time is of the Essence

In studies of those who have died of anaphylaxis, they did not receive an epinephrine injection, or they got it too late, after a reaction had progressed. In anaphylaxis, prompt use of the shot is always essential.

4

Go to the Hospita

A person who had an eme epinephrine shot must be to hospital for observation. transport, IF symptoms ha improved within 10 to 15 n a second auto-injection s be given.

5

Reclining is Best

During the ambulance r the person having the se reaction should be lying d with the legs raised (this im blood flow). NIAID guidel recommend the patient re oxygen and IV fluid.

6

Don't Go It Alone

No person should be exp to be fully responsible fo administration of an epine auto-injector. Assistance anaphylaxis is crucia

From allergicliving.com. Based on guidelines from NIAID and the Canadian Society of Allergy and Clinical Immunology.

Definitions

Anaphylaxis
A life-threatening allergic reaction due to over-release of certain chemicals in the body resulting in shock when a person with an allergy is exposed to an allergen. Allergies to food, insect stings, medications, and latex, are most frequently associated with this type of severe response, and may include skin symptoms or swollen lips, difficulty breathing, reduced blood pressure, and gastrointestinal symptoms.

Consumer
A person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

Cross-contact
The unintentional transfer of an allergen from a food or food-contact surface to a food or food-contact surface that does not contain the allergen.

Epinephrine auto-injector
A device for injecting oneself with a single, preloaded dose of a drug. The device typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body.

Food allergic reaction
An adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. The immune response can be severe and life-threatening.

Food allergy
The reaction of the body's immune system to certain proteins in food. Reactions can vary in severity from mild symptoms involving hives and lip swelling to severe, life-threatening symptoms, called anaphylaxis, which may involve shock and fatal respiratory problems.

Food establishment
An operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

Food handler
A person who handles food utensils or who prepares, processes, or serves food or beverages for people other than members of his or her immediate household.

Food intolerance/sensitivity
An adverse reaction to a substance in food that does not involve the immune system, e.g., the inability to process or breakdown a certain food such as the milk sugar lactose which can lead to discomfort or have ill effects.

Label
A display of written, printed, or graphic matter upon the immediate container of any article; and any word, statement, or other information that appears on the outside container or wrapper of the retail package.

Labeling
All labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

Major Food Allergen
The allergens in foods that cause over 90% of allergic reactions: milk, egg, fish (such as bass, flounder, or cod), Crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, sesame, and soybeans.

Menu
All written and verbal lists of foods prepared and offered to consumers.

Other community food sources
Food sources that are made available to the public on a need basis, e.g., food bank, food shelf, food pantry.

Packaged food
"Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. (2) "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food handler, upon consumer request.

Person in Charge (PIC)
The person present at a food establishment who is responsible for the operation at the time of inspection.

Self-served food
Restaurant-type food that is available at a salad bar, hot food bar, buffet line, cafeteria line, or similar self-service facility, and is served by the consumers themselves. Self-service food also includes self-service beverages, such as drinks dispensed from a soda fountain and coffee available on a self-service basis.

Self-service
Areas where a food handler is not present to serve a consumer and the consumer is responsible for serving themselves, such as at a buffet, salad bar, sushi bar, or display case.

References

Conference For Food Protection. (2021). Food allergen notifications: A guidance for industry. http://www.foodprotect.org/media/guide/cfp-allergen-notification-guidance-8-22-2019-10-27-21.pdf
FARE: Facts and Statistics
https://www.foodallergy.org/resources/facts-and-statistics
UC Davis: Food allergies in children: Pediatric guidelines, diagnosis and more (ucdavis.edu)
https://health.ucdavis.edu/blog/good-food/food-allergies-in-children-pediatric-guidelines-diagnosis-and-more/2021/07
Serbes 2022: Serbes et al. Clinical features of anaphylaxis in children. Allergy Asthma Proc.
FARE/Child: How a Child Might Describe a Reaction | Food Allergy Research & Education
https://www.foodallergy.org/resources/how-child-might-describe-reaction
SNHD: HACCP-Based SOPs (southernnevadahealthdistrict.org)
https://www.southernnevadahealthdistrict.org/download/FERL-Resources/SOP-ALLERGY-TRAINING-AND-RESPONSE-20190102.pdf
Significant portions of this guidance were informed by materials developed by the Southern Nevada Health District.
https://www.southernnevadahealthdistrict.org/permits-and-regulations/food-establishment-resource-library/food-allergy-awareness-materials/
FARE: Navigating Food Assistance Programs with Food Allergies
https://www.foodallergy.org/resources/food-banks-and-soup-kitchens
FDA: Have Food Allergies? Read the Label
https://www.fda.gov/consumers/consumer-updates/have-food-allergies-read-label

Train relevant staff in the following procedures:

1. Food & Ingredient Storage

a) Label and segregate unpackaged foods containing one or more of the Major Food Allergens away from each other, and store separately from other foods and ingredients. *Make sure to read ingredient labels to check for the presence of allergens before labeling and segregating.

b) Spills of any of the Major Food Allergens should be cleaned up immediately, following the usual cleaning procedures used in the food establishment. If any Major Food Allergen accidentally comes into contact with other food ingredients that do not contain that allergen, these ingredients should be excluded from use.

2. Self-Service Items

a) For food items that were made on site, label the food items, or place signs next to the food items, that clearly identify the presence of one or more of the Major Food Allergens, or keep ingredient lists on site that identify the presence of one or more of the Major Food Allergens.

b) Labels and signage should be in both English and Spanish, and/or other languages appropriate to either the establishment, or the geographic area.

3. Taking a Food Order

a) Encourage staff to ask consumers about any food allergies they might have.

b) When a consumer informs staff they have a food allergy, intolerance, or sensitivity, immediately notify the Person in Charge (PIC) or designated person (manager, chef, or key employees).

c) Provide a list of menu items and their ingredients for food handlers and consumers as a reference.

d) Help the consumer identify menu items that contain ingredients to which they are allergic and offer suggestions for alternative menu items.

e) If no alternative menu options are available, politely inform the consumer.

f) If it is possible to modify a menu item so that it does not include ingredients the consumer must avoid, inform the consumer, and ask if the modification would suit their needs.

g) Verify with the food handler that the proposed menu item modification is possible, feasible, and can be done safely for the consumer.

h) Make a note on the consumer's order that they have a food allergy/intolerance/sensitivity and which ingredients they must avoid so that other food handlers are aware.

4. Preparing a Food Order

a) Thoroughly clean all areas and equipment that will be used for preparing the allergic consumer's meal, even if those areas had already been cleaned for normal use.

b) Wash hands thoroughly before preparing the allergic consumer's meal. It is necessary to change apron/chef coat, if previously soiled with potential allergens.

c) Use dedicated equipment or physically separate products to prevent cross-contact.

   i. Use color-coded or specially marked supplies, uniforms, equipment, and utensils designated for preparing allergen-free meals.

   ii. Avoid using the same cooking medium (e.g., oil or water) and surface (e.g., grill, prep table) when handling ingredients with and without allergens.

d) Use ingredients that do not contain the allergen(s) to which the consumer is allergic. Check ingredient labels for packaged foods.

e) Prepare food in a manner that eliminates cross-contact. All preparation, including garnishes, should be done by only one food handler who is dedicated to ensuring the meal is allergen-free, and who is not preparing other consumers' meals at the same time.

   i. If a mistake is made, and an ingredient to which the consumer is allergic is accidentally included in the meal, it is not sufficient to simply remove the offending ingredient, because cross-contact will have occurred. In case this happens, re-make the consumer's meal.

   ii. Wash your hands with soap and water before continuing preparation to avoid potential, or additional, cross-contact.

f) Cover the meal with a clean lid to prevent cross-contact and mark the meal as "allergy" so other staff are aware.

g) Notify the PIC, or designated food handler once the allergen-free meal is prepared and ready for service.

h) Wash, rinse, and store special equipment for allergen-free meals to be ready for next use.

i) Wash your hands with soap and water before touching anything else if you have handled a food allergen.

5. Delivering a Food Order

a) Verify with the food handler who prepared the meal that it does not contain the allergen specified by the consumer.

b) Ensure no cross-contact with other meals occurs during transport of the meal to the consumer.

c) Use a separate meal tray to deliver the meal.

d) VERIFY with the consumer that the meal meets their needs.

e) Discard the meal and offer to re-make it for the consumer if the meal contains ingredients to which the consumer is allergic. Notify the PIC. Review procedures and retrain the food handler(s) who prepared and handled the meal on these procedures before allowing them to re-make the consumer's meal.

6. If someone reports an allergic reaction

*** When in doubt, call 911 ***

a) Clearly direct one person to dial 911 and report an allergic reaction.

b) Follow the directions of emergency services personnel and the food establishment's food allergy emergency response plan.

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Meeting Number	Meeting Date	Meeting Time
01	**11/12/21**	11:00 am EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair; Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	CFP Antitrust Statement	Amani Babekir
iv.	Identify a Committee Scribe	Michelle Hill (via Teams transcription service)
v.	Review CFP Timeline for Committee Work	Michelle Hill
vi.	Review of Committee Charges	Michelle Hill
vii.	Overview of Committee Plan of work	Amani Babekir
viii.	Action Items	Amani Babekir and Michelle Hill
ix.	Determine next meeting date	Tuesday, Nov 23, 2021, 2 pm EST
x.	Adjournment	Amani Babekir
xi.	Attachments to Minutes	Yes

MEETING MINUTES

i. Call to Order – Amani Babekir

This first meeting of the CFPs Council II Allergen Committee will now come to order at 11 am EST on November 12, 2021 … As this is our first meeting there are no minutes to approve.

ii. ROLLCALL – Michelle Hill - 15/19 Voting Members present [*9 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – Read out by Amani Babekir

This Antitrust Statement is to inform the Conference for Food Protection (CFP) Executive Board members and the general membership of CFP that whenever competitors within an industry gather together, appropriate care must be taken to ensure that violations of antitrust laws do not take place.

CFP functions, be they conferences, board or committee meetings, by their very nature, bring competitors together. To avoid antitrust allegations it is necessary to avoid discussions of sensitive topics. Agreements to engage in product boycotts, restrictive market allocations, refusal to deal with third parties and price-restraining activities are automatically illegal under antitrust laws.

An antitrust violation does not require proof of a formal agreement. There need not be written or verbal agreement to collude. Also, conversations regarding any of these sensitive areas may be construed as implicit violations. As a result, those attending CFP-sponsored functions should remember the importance of avoiding not only unlawful activities but even the appearance of unlawful activity.

The antitrust laws – the Sherman Act, Clayton Act, and the Federal Trade Commission Act – are intended to ensure free and open competition. Violations of these laws can have serious consequences for CFP and its members. Violations are felonies that can result in severe penalties and significant litigation expenses for CFP and its members. Even if a government or private suit is successfully defended, the cost and disruption of the litigation can be overwhelming. Taking antitrust precautions, therefore, is not only advisable but imperative.

For your protection, the Conference for Food Protection recommends that, should one of these subjects be brought up, it would be in your best interest to voice your objection and disassociate yourself from the discussion if it continues.

iv. Committee Scribe

Michelle Hill will vet meeting minutes and curate the file moving forward. Meeting minutes to be approved at the start of the next meeting.

v. Review CFP Timeline for Committee Work – Michelle Hill

This timeline was produced by the 2023 Biennium Executive Board. As we all are aware, we are operating on a condensed timeline for this biennium. We have just over 12-months to address and complete the charges assigned to this committee.

The EB has yet to publish a more specific timeline. As more information is made available, we will be sharing exact dates.

As you can see from this list, we have deadlines dictating the completion and submission of our work to our Council II Chairs, Co-Chairs, and EB.

Committee reports are due in March, July, September, and November.

2022	March	**Due: Committee Reports submitted to Council (14-days prior to EB-mtg)**
	April	EB Meeting – Westin Galleria - Houston TX
	May/June	Opens: 30-day period to apply online for Councils for 2023 Biennium
	July	**Due: Committee Reports submitted to Council** Review: Council Chairs review 2023 Council Applicants Due: Recommendations for Council - 30-days prior to EB Meeting
	August	EB Meeting: TBD EB Approve: Council Members for 2023 Biennium Due: 2023 *draft* Registration Packet for EB review Finalized: Registration Fees for 2023 Biennium Sponsorship categories, benefits, fees Consider: Workshop topics for 2023 Biennium
	September	Send: Notification to Council Applicants **Conference Call: Issue Chair hosts call with Council and Standing Committee Chairs and Co-Chairs** Site Visits: for future Biennial Meeting 2025/2026 Midwest Region TBD Due: Meeting venue contract negotiations for EB approval.
	October	Released: 2023 Issue Pre-submission form; Issue submission guidelines Distribute: Registration Packets
	November	Send: Delegate Letters – 150-days prior to Biennial Meeting (mandated) **Due to Council Chairs for Review: Final Committee Reports; Prospective Committee Issues** Send to EB for Review: Standing Committees Documents Due: Feedback to Committee Chairs from Conference Chair/EB/Council Chairs Submit: Revised Final Reports submitted to Issue Chairs for review and comment Submit: Revised Issues submitted to Issue Chairs for review and comment
	December	Opens online: 30-day submission period for 2023 Biennium
2023	January	Close: Issue submission mandated to close not less than 90-days prior to Biennial Meeting
	February	Deadline: Submit Official State Delegate Voting Form Finalize and Assign: Issue Committee completes review and assigns each to a Council for deliberation
	March	Available: Director produces Issue Packets, mandated at least 40-days prior to Biennial Meeting Due: Reports for EB due to Director
	April	21st -28th Biennial Meeting – Westin Galleria -Houston TX

vi. Review of Committee Charges – read out by Michelle Hill

1. Develop an operational framework for food allergy prevention and control using existing research and other evidence-based materials (for example: CDC guidance in schools and guidance developed by retail food industry) in retail food establishments including:
   a. A written template retail food establishments can use to reduce the risk of food allergy reactions and respond to any reactions that do occur. The template can incorporate findings, lessons, materials, etc. from items 2-6.
   b. Steps to take during a food allergy emergency and identify key components of food allergy emergency plans.
   c. Food allergy training for food workers and identify educational content and training needs based on employees' assigned duties.
   d. Findings, recommendations, and materials from the 2018 Allergen Committee to ensure retail food establishments have tools to notify customers when menu items contain major food allergens.
   e. Food-handling practices, policies, and procedures to prevent food allergens from unintentionally contacting another food.
   f. Equal considerations for alternate food sources, such as food pantries and food banks, to ensure equity and access.
2. Recommend changes to the Food Code that support retail food establishments to operationalize framework to prevent and control food allergic reactions.
3. Report back findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

vii. Overview of Committee Work Plan/Timeline – Amani Babekir

a) collect materials and resources … complete by the end of November.

b) sorting of collected materials

c) categorize it into categories and then we assign workgroups to these categories.

d) workgroups will evaluate resources and determine the materials … to construct framework.

e) Collection and analysis completed by end of March

f) April - write template to be used by … retail food … to manage the risk of allergy … template is also going to be part of the framework.

g) Framework to complete by … July the 30th.

h) Identify possible change to the food code by the end of October – clear Framework written and reviewed.

i) Finalize Committee work – by end of December 2022.

Steps to Completion	Completion Date
Collect materials/resources	November 30
Assign work groups	December 30
Evaluate materials/resources	March 30
Write a template	April 30
Written framework	July 30
Changes to the Food Code	October 30
Final Report	December 30

Amani Babekir: I'm opening the floor for discussion from all of you. So, if you have a point or suggestion or comments, please raise your hand.

Michelle Hill: Madam Chair, I don't see any hands raised.

Amani Babekir: I would like to have a motion to accept or decline the workplan. Can I get first and a second on this motion please?

Michelle Hill: I move to accept this workplan.

Vinson, Scott: Second … the motion.

Babekir, Amani: And let us proceed with the vote on the motion … To make it simple … voting YES for **non-acceptance**. …if anyone opposed to the motion please say no or raise your hand … Do we have any abstain … motion pass to accept the committee work plan. Thank you.

viii. Action Items – Amani Babekir

Amani Babekir: Per our work plan we need to complete the collection of the material and resources … by the end of this month. THANK YOU FOR CONTRIBUTING: James Baldwin, Jennifer Green, Ben Wagner. From the beginning of this committee work we are looking to add extra resources and materials to the research FDA and CDC, USDA … local regulatory … if you are aware of any resources, please send it to us. You could send the link or the PDF file.

Cartagena, Mary: clarification …. Is it any resource on allergens or is there something specific that you're looking for?

Amani Babekir: Yes … it's more about controlling allergy in education about allergen and managing allergy in public setting or in food service areas.

Michelle Hill: We have not yet been able to set up a collection point on … Teams … as soon as we're able … start pulling all those resources in one - we'll send out an email when completed - you can go and check it out and we don't repeat effort.

Resource	Completed
Previous CFP Committees	✓
Research	
FDA/CDC	
USDA	
Industry	
Food Retail	
Regulatory	

ix. Meetings Schedule for 2022 / 2023

- Bi-weekly meeting
- Thursday's
- 2 - 3 pm EST, 1 - 2 pm CST, 12 - 1 pm MST, 11 am – 12 pm PST
- Teams – configure access and data storage

Amani Babekir: [Opens Discussion around the proposed Committee Meeting Schedule]

Mortiz, Erin – makes suggestion regarding meeting times, alternating days of week so if you cannot attend one you may be able to attend another.

Amani Babekir: set up recurring meeting every Thursday … will monitor your emails and responses to every meeting and invitation as it approaches … those who cannot attend … could suggest a better time or day …. to move it. [Request for questions / discussion]

Thoma, Libby – Yes, I was wondering if it's possible to have a proxy attend in our place if we have a desk, one dedicated person to fill in as our backup. If we're not able to attend.

Courtney Halbrook – I serve as vice chair of Council 2 and … The correct answer is I'm not 100% certain … so we'll get back to you. But it's a great question. Will find an answer.

Babekir, Amani – That sounds good. Thank you, Courtney … we will send out an email once Courtney clarifies. Any further suggestions or a question? [silence] I would like to have a motion to accept or decline the timeline proposed here. Can I get first and second on this motion?

Vinson, Scott – I move to accept this schedule.

Baldwin, James – … I … second.

Babekir, Amani - Thank you, so let's proceed with the vote on this motion. Is there anyone opposed to the motion? Please say no or raise your hand? [silence] Do we have any abstaining? [silence] Thank you so Motion passes … we will accept this schedule and adjust it as it needed. Thank you. I would like have a motion … to accept or decline the next meeting Tuesday, November 23rd from 2:00 to 3:00. … Can I get a first and second on this motion?

Vinson, Scott – Moves the motion

Ben Wagner – Seconds the motion.

Babekir, Amani - Thank you, let's just proceed with the vote on the motion … anyone opposed motion, please say no. [silence] Do we have any abstaining? [silence] The motion passes - we will have our next meeting Tuesday, November 23rd from 2:00 to 3:00 Eastern Time. **ACTION** – Co-Chairs will send out email invites for meetings.

x. Meeting Adjourned – Amani Babekir

xi. ATTACHMENTS to Minutes

American College of Allergy, Asthma & Immunology, http://acaai.org/

Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).

Food Allergy & Anaphylaxis Connection Team, http://www.foodallergyawareness.org/

Food Allergy Research & Education, http://www.foodallergy.org/

FDA 2017 Food Code https://www.fda.gov/media/110822/download

Retail Allergen Resource Document: https://www.fmi.org/docs/default-source/food-safety/retail-allergen-resource-document.pdf?sfvrsn=6

Asthma and Allergy Foundation of America: https://www.aafa.org/food-allergies/

Food Allergies / FDA: https://www.fda.gov/food/food-labeling-nutrition/food-allergies

Restaurant Food Allergy Practices – Six Selected Sites, United States, 2014: https://www.cdc.gov/mmwr/volumes/66/wr/mm6615a2.htm

McAdams, B., Deng, A., & MacLaurin, T. (2018). Food allergy knowledge, attitudes, and resources of restaurant employees. *British Food Journal, 120*(11), 2681-2694. http://dx.doi.org/10.1108/BFJ-01-2018-0028

FDA, Food Allergens, www.fda.gov/food/ingredientspackaginglabeling/foodallergens/default.htm FDA, Food Allergen Labeling and Consumer Protection Act of 2004, www.fda.gov/Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm

Food Standards Agency, Allergy and Intolerance, https://www.food.gov.uk/science/allergy-intolerance

IDDBA, Food Allergens in the Bakery, www.iddba.org/training-materials/pdfs/job-guides-food-allergens-bakery

Food Allergy Research & Education, Resources for Food Manufacturers, www.foodallergy.org/resources/food-manufacturers

https://www.foodstandards.gov.au/consumer/foodallergies/foodallergenportal/Pages/Allergy-information-for-the-food-service-industry.aspx

https://www.afgc.org.au/industry-resources/food-labelling-and-allergen-guide

https://info.allergenbureau.net/

https://allergenbureau.net/resources/

https://vital.allergenbureau.net/

https://allergyfacts.org.au/allergy-management/food-industry/food-service

FSIS Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling

Food Allergies Webpage

Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common (BIG 8) Food Allergens - Revision 2

Allergens- Voluntary Labeling Statements

Availability of FSIS Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration Through Labeling (79 FR 22083)

Meeting Number 02	Meeting Date **11/23/21**	Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair; Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	CFP Antitrust Statement	Included via attachment to Meeting Invitation email.
iv.	Identify a Committee Scribe	Michelle Hill (via Teams transcription service)
v.	Meeting Minutes	Michelle Hill
vi.	Accessing Teams	Amani Babekir
vii.	Collect Resources	Michelle Hill
viii.	Action Items	Verify access to Teams and the Resources folder
ix.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order

ii. ROLLCALL - 16/19 Voting Members present {*9 required for quorum}*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Committee Scribe

Michelle Hill will vet meeting minutes and curate the file moving forward. Meeting minutes to be approved at the start of the next meeting.

v. Approve previous Meeting Minutes (11/12/21)

Motion passed via voice vote.

vi. Accessing the folder of Resources for evaluation – Amani Babekir

Showed the committee members how to access the Resource folder within Teams.

The FDA members are not able to access the Teams folders so have requested another method of distribution. We agreed to send documents, when needed, via email attachment, and also recommended that members access document via the SharePoint interface of Teams.

Two additional document repository services were recommended to try – Dropbox and Adobe Cloud.

vii. Overview of Collected Resources – Michelle Hill

Showed the committee members the folder of Resources that need to be reviewed. We opened the floor for discussion, and it was suggested that we choose an evaluation method to screen documents for further evaluation. Additional resources were shared by committee members via the Chat in Teams.

viii. Action Item

Co-chairs agreed to send out two options to access documents: Teams and SharePoint; requested members email the Co-Chairs with access issues so they can be addressed before the next meeting.

xi. Meeting Adjourned – Amani Babekir

Meeting Number 03	Meeting Date **12/09/21**	Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair; Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	CFP Antitrust Statement	Included via attachment to Meeting Invitation email.
iv.	Meeting Minutes	Michelle Hill (via Teams transcription service)
v.	Review Committee Work Plan	Amani Babekir
vi.	Access to Resources	Michelle Hill
vii.	Evaluate Collected Resources	Amani Babekir
viii.	Assign Documents for Evaluation	Michelle + Amani
ix.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order

ii. ROLLCALL

18/19 Voting Members present {*10 required for quorum}*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Meeting Minutes

Michelle Hill will vet meeting minutes and curate the file moving forward. Meeting minutes to be approved at the start of the next meeting.

Motion to approve Meeting Minutes made by NAME, seconded by NAME, approved via voice vote.

v. Review of Committee Work Plan

Steps to Completion	Completion Date
Collect materials/resources	November 30
Assign work	December 30
Evaluate materials/resources	March 30
Write a template	April 30
Written framework	July 30
Changes to the Food Code	October 30
Final Report	December 30

vi. Access to Resources

Three Ways to Access Documents

- CFP Teams > Files > Council II > Allergen Committee > Members > Collected Resources

- CFP SharePoint via Teams
- Email attachments

vii. Evaluate Collected Resources

Collected Resources

Folder Name	#
CDC related	2
CFP related	6
FDA related	20
International	39
Regulations	18
Regulatory – State and Local	21
Research 1. Allergen control 2. Allergen Labeling 3. Allergens educating about 4. Allergens general info	 28 14 20 133
USDA related	9

1. Co-chairs evaluate documents using the "Evaluating Information Source" form
2. Files that meet criteria will be assigned to reviewers

Deadline 12/30/21

Evaluation Form

Evaluating Information Sources

Criteria	(Yes/No)
Document Purpose	
Provide information, persuade or advocate	Yes
Intended audience	
Food retail, food service, food industry, public, researchers	Yes
Authority and credibility	
the resource has authority/credibility	Yes
Accuracy and reliability	
The information well researched?	Yes
Currency and timeliness	
The information is not outdated or updated/revised in another version?	Yes

If you answer "Yes" to all of the criteria items, please proceed to the information collection step using the "**Information Collection Form**"

Information Collection Form

Allergen Committee –Information Collection Form

Name: Amani Babekir	
Document Title/Date: Food Allergen Notifications: A Guidance for Industry / 2020	
Document Source: CFP 2020 – Allergen Committee	
Document Pass Information Criteria (Yes/No): Yes	
Allergy emergency	
Steps during allergy emergency	
Components of food allergy emergency plans	
Employee Training	
Education content	
Training per assigned duties	
Food-handling practices to prevent cross-contact	
Policy	
procedures	
Equity access	
Alternative food sources	
Tools for retails to notify customers about item containing allergen (CFP previous committee)	
• A combination of verbal and written allergen notifications. • Notifications should be specific to menu items and the major food allergens they contain, rather than generic warnings that may apply to the entire menu or food preparation environment. • Food allergen notifications should address all ingredients containing major food allergens, including "hidden ingredients," such as egg washes, sauces, garnishes, etc. • If food operation is not able to accommodate an allergen-free order. Be open and honest with the consumer about the limitations of the establishment in controlling food allergens. **More illustration/details in the documents**	

viii. Assign Documents for Evaluation

- Members will be notified by email of the documents to evaluate.
- The assigned document will be sent by email to each reviewer.
- Forms will be sent to each reviewer by email
- Forms and documents will be available in Teams
- Objections and Discussions – Darby's statement and request to just begin by writing a draft framework ….

ix. Meeting Adjourned

Next meeting: December 23, 2021 - 2:00 EST

Meeting Number 04	Meeting Date **12/23/21**	Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair; Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	CFP Antitrust Statement	Included via attachment to Meeting Invitation email.
iv.	Meeting Minutes	Michelle Hill (via Teams transcription service)
v.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL – Michelle Hill

8/17 Voting Members present {*10 required for quorum}*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Meeting Minutes

Michelle Hill will vet meeting minutes and curate the file moving forward. Meeting minutes to be approved at the start of the next meeting.

- Assign Documents for Evaluation
- Objections and Discussions – Darby's statement and request to just begin by writing a draft framework ….

v. Meeting Adjourned

Next meeting: Jan 6, 2022 – 2:00 pm EST

Meeting Number	Meeting Date		Meeting Time
05	**01/06/2022**		2:00 pm EST
Co-Chair; Meeting Chair	Co-Chair	Scribe	Council II Chairs
Amani Babekir	Michelle Hill	Amber Potts	Jo DeFrancesco/Courtney Halbrook
Advisory - FDA	Advisory – FDA		Advisory - FDA
Greg Abel	Devin Dutilly		Mary Cartagena
Advisory - CDC	Advisory – CDC		
Erin Moritz	Jenna Seymour		
Advisory - USDA			
Jennifer Green			

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Rollcall	Michelle Hill
iii.	Meeting Scribe	Amber Potts
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Reconsider Work Plan	Amani Babekir and Michelle Hill
vii.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order

ii. ROLLCALL - 15/17 Voting Members present {*10 required for quorum}*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

There were no meeting minutes for call held 12/23/2021 as there was not a quorum. Meeting minutes for 12/09/2021 were voted on. Motion to approve Meeting Minutes 12/09/2021 as is made by Scott Vinson, seconded by Ben Wagner, approved via voice vote. Today's meeting minutes scribed by Amber Potts.

v. Reconsider Work Plan

The original process was to use the form created to evaluate the documents and a form to collect information needed. The resources would be split into sections and assigned out.

Madam Chair *entertained a motion* regarding reviewing only the shared resources, attached to the email meeting invitation. The shared resources are those added by the committee only.

No motion to proceed. Motion dies.

Several committee members expressed issues with accessing the resource link on the shared resource document stating there are issues with security risks on the document, unable to open the link, some links were not working. Vy Goddard suggested all members to list the resources by charges and see if everyone's match.

Madam chair *entertained a motion* to proceed as Vy suggested.

Steven von Bodungen motioned to proceed. Amanda Garvin seconded.

Discussion opens. Michelle Hill asks Vy to repeat the suggestion. Vy clarifies that we would all review the shared resource document and assign links to specific charges, the groups would be assigned charges. This would negate the need for any collection forms Vote on motion: 0 opposed, 0 abstain. *Motion passes.*

Vy screen shared to show example. Groups would compile everything then vet resources at the next meeting. Vy would begin working on this.

Scott Vinson raises a question: For charges 1a, it states relating to items 2-6. There are no items 2-6.

Michelle Hill clarifies it means b-f, all items below 1a or the remaining part of the list. Charge 1 refers to SOPs and 1b are the steps to take. Looking at the Australia and New Zealand resources, they have implemented allergen training modules at the Federal level for specific retail establishments: hospitals, restaurants, schools, etc. They have methods and modules we can use to build our framework.

Amani mentions that we are vetting the resources because they are going to be the components of the framework.

Scott Vinson comments: Allergy training is one of *many* trainings for employees. Due to the high turnover and limited period for training Scott suggests that what ever materials we prepare should be concise and conveyed quickly.

Steven von Bodungen backs up the comment and agrees materials should be concise and to the point.

Amber Potts also agrees, and the materials should be in plain language. Vy suggests making flyers, stickers, and magnets. Cassandra Mitchell agrees with Vy, there are many languages spoken so pictures would be great.

Libby Thoma mentions to look in the ServSafe exam. There is limited information on allergens and ServSafe is not focused much on food production. ServSafe should be added to the resource page. ServSafe has an online allergen module.

Crystal Eisner says she would look into Responsible Training, link already on the shared resource page.

Scott Vinson suggests that the workers in food service ask if the consumer has any food allergies or to post a sign to encourage customers to let the server know of the allergy. For customers to take more responsibility. Several members agree and it is suggested that conversation happen with the PIC or the manager, not necessarily the server.

Amani Babekir asks if we should begin preparing the framework at the next meeting to add in these points made. Several members agree.

David Read raises a question if we should not just limit the allergen training and this framework to focus on worker but also for managers and even up to the corporate level?

> Scott suggests not bringing it to the corporate level and to focus on the workers. He recommends listing the most common allergens with graphics so they can quickly see them.
>
> Christine Sylvis says there are a lot of resources from SNHS we can use. She shares her screen so we can view the Big-8 infographic. The smaller 'Just Ask' infographic was not successful in their local campaign.

Amanda Garvin likes SNHD and states we should base our material on their resources; Suggests the dairy allergen graphic be something other than a glass of milk.

Scott Vinson also likes SNHD and proposes *to move a motion.*

Madam chair *entertains a motion* that on the next call we will review all the SNHD resources and decide which to incorporate into the work project.

> Michelle Hill motions to proceed. Amanda Garvin seconds.

Motion opens for discussion. Christine Sylvis is happy to share all the information in a format that we can utilize, Word document etc. Amber Potts mentions that NEHA has a Canva account and can make infographics.

Vote on motion: 0 opposed, 0 abstain. *Motion passes.*

vi. Next call

- We will look into SNHD resources. Christine to send resources in an email.
- Armani and Michelle will begin building out the framework.
- Vy clarifies that we will no longer be reviewing the shared resource document.

Amanda Garvin raises a question: Is our work directed toward industry and not inspectors and only to change the food code?

Greg Able answers yes. Reminds us that this is for all institution types in the retail setting: grocery, deli, restaurants, schools, food trucks etc.

Libby Thoma asks if we can see the work completed from the 2018 committee?

Amani answers work can be viewed from CFP website, ask for all issues and attachments.

vii. Meeting Adjourned - Next meeting January 20th 2022. .

Meeting Number	Meeting Date		Meeting Time
06	**01/20/2022**		2:00 pm EST
Co-Chair; Meeting Chair	Co-Chair	Scribe	Council II Chairs
Amani Babekir	Michelle Hill	Amber Potts	Jo DeFrancesco/Courtney Halbrook
Advisory - FDA	Advisory – FDA		Advisory - FDA
Greg Abel	Devin Dutilly		Mary Cartagena
Advisory - CDC	Advisory – CDC		
Erin Moritz	Jenna Seymour		
Advisory - USDA			
Jennifer Green			

AGENDA

i. Rollcall – Michelle Hill

ii. Scribe (Volunteer) – Amber Potts

iii. CFP Antitrust Statement – Amani Babekir

iv. Meeting Minutes Approval – Michelle Hill

v. Review SNHD Resources - Committee

vi. Framework Points - Committee

vii. Adjournment – Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL – 13/17 Voting Members present [*10 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

Madam Chair *entertained a motion* to approve previous meeting minutes from 1/6/2022 meeting.

Scott Vinson moved to approve minutes.

Jim Baldwin seconded the motion.

Madam Chair opened the floor for discussion. Michelle Hill recognized Amber Potts for a god job on previous meeting minutes.

Vote on motion: 0 opposed, 0 abstained. *Motion passed* to accept previous meeting minutes as they were submitted.

Christine Sylvis asked about icons from the 2018 Allergen Committee. She is unable to find the icons and would like for us to see them

Madam Chair said she will look into finding the icons.

Amber Potts scribed today's meeting minutes.

v. Review SNHD Resources

Madam Chair screen shared SNHD resource page we received by email. We began reviewing links in resource page one at time. Question raised by Scott Vinson; should we click on the links in the documents? Madam chair answered yes.

Allergy Aware Poster:

Michelle Hill- the poster is an excellent resource and categorized correctly and associated with charges.

Michelle Hill – will SNHD be updating for sesame? Christine Sylvis answered, yes SNHD can update to include sesame.

Amber Potts – maybe we should change photos? Is this intended for food handlers? Answers is yes, it's for food handler. So, we could put in more specific photos to show the kinds of food these allergens are present in.

Jennifer Green – seconds changing photos to things we eat that have the allergen in them.

Michelle Hill – thirds. To look for alternative graphics.

James Baldwin – Recommends storing the poster with food as reminder and to create awareness and be used as a training tool [by inspectors] when on site to explain major allergens and what a food handler's role is. Will illicit awareness and quick reference and what to do, how to recognize a reaction.

Scott Vinson – Pictures aren't going to be the way those appear in a restaurant. Some are additives to food items that aren't able to be seen. We may have a hard time finding pictures to represent this.

Erin Moritz – agree with Scott. Unless we want an exhaustive list we may want to stick with them [current graphics]. If we make food specific photo it may be seen to the food worker as the only thing to worry about, example being bread.

Amanda Garvin– Answer will lie somewhere in the middle. Agree about changing milk picture as dairy, but maybe have a few more things. This will not work without some sort of training – combined with training. Answer of including (example dairy) has three main ingredients casein, whey, and lactose as proteins people are allergic to. List proteins people are allergic to.

Scott Vinson– Wheat is its own challenge. When customers say they have a wheat allergy they probably mean they have celiac disease, which is not the same as an allergen. Whey, barley, oats etc. Not sure how to visually depict wheat. What is our committee charge on gluten or related celiac disease, not an allergy?

Erin Moritz– agree simpler is better. End result is to not expose customers to what they can't eat. In training, it would be worth to introduce, at a very high level, that celiac is a different outcome than with someone with a food allergy. Allergy vs sensitivity vs celiac.

Vy Truong – keep things simple. Resources specific to PIC can be more thorough than with food worker. The PIC can narrow it down to what they have in their facility.

Amanda Garvin – We do need something simple, quick but where do we draw the line of simple? We need to take things forward before we know the line. Agree that we should define a few things to eliminate confusion. So we can help break myth that people who aren't allergic will not die if they are exposed.

Jenna Seymore – The problem is that within the restaurant world a lot of restaurant tell the customer to say you have an allergy so it alerts people and increases seriousness even if it's not an allergy.

James Baldwin – Referring back to a comment in last meeting by Scott regarding practicality and simplicity and competing training. Most food establishments don't have labs or scientist – recommend we be simplistic about 8 major allergens. Can't make it too complex or it will not work well.

Cassandra Mitchell – concur with Vy to keep it simple and training will be essential. Ask Cristine – how has this been received at SNHD establishments?

Christine Sylvis– Received really well. Did this as intervention strategy, the risk factor survey identified we weren't doing a good job about educating on allergens. Did include industry in creating strategy. Response always poster is a good idea. SOP good idea. Having a logo or something to say we are educated on allergens was not received well, thought there was liability on their part. Inspections talked about allergens and importance and things food hander could do. Promotional to handout purple marker to hand write allergen orders. Discussion about allergens – sees posters up, helps with PIC knowledge. Statistics show a significant improvement on allergy awareness on follow up study.

Madam Chair asked if we can more forward with using the poster as a resource. Several members said yes we want to use poster.

Allergy Awareness Video

Amber Potts – There may be an issue with using video for training due to language barrier.

Scott Vinson in chat: I think it's a great video and I watched nearly the whole thing, but I think it might be a bit long for our purposes.

James Baldwin – Is the intent to use the video as part of the process -or use ideas from the video in the frame work (recommend second)? There are states that require managers allergen cert requires food handlers to view video and take a test and completed annually.

Madam Chair proceeded to next resource.

Allergen Guide

Scott Vinson in comments: I think it's a useful resource and we should include it

Crystal Eisner agrees and says it's a good tool.

James Baldwin – Provides an allergen guides helps them make an informed decision on what to eat. Customer informs server and lets the cooks know to prepare item to spec using clean utensils. This is a good part of training. Not so much all on restaurant but gives guest a chance to talk – partnership.

Madam Chair proceeded to next resource.

Food Allergen Warning Sign

Amber Potts – This seems like a liability statement on restaurants, I don't think it would be helpful.

Scott Vinson agrees – not helpful and doesn't provide training. But we can use it if our charges require this kind of resource.

Christine Sylvis – agrees with Scott – not favorite thing but industry asked for it.

Crystal Eisner – Can be a tool in toolbox that most rest require them to post that. Can still be part of the tool box.

Vy Truong – good start to bring awareness to consumers – could reword it. Include cross contact to be aware that the other foods are in the establishment.

Madam Chair proceeded to next resource.

Logo for Allergy Awareness

Amber Potts- similar to previous and not sure how well it would be received. And to be used when the facility is certified in allergen training.

Scott Vinson in chat: I think it's fine. It's an efficient way of getting 8 words into a square shape.

Madam Chair proceeded to next resource.

SOP – Allery Free Meal Prep

Amber Potts and Vy Truong agree to use

Madam Chair proceeded to next two resources.

[Via Chat]

Vy Truong - I think this resource will be helpful. I think all three SOPs are great

Scott Vinson - Allergy is spelled incorrectly at top

Amber Potts - I love SOPs but I am not sure how useful they are in a restaurant setting.

Scott Vinson- I agree -- I frankly don't think the typical restaurant will use these last three documents

Cassandra Mitchell - I think the SOP are great. I like the break down of the instructions in different segments

Committee did not have time to discuss the Framework Points.

Madam chair asked for any final comments before we adjourn.

Libby Thoma asked if we can get access to SafeFood program's training on allergens to review.

Madam Chair said she would check to see if we have access to the resources, which should be listed on the resources page.

vi. Next call

We will discuss framework points and working groups and brainstorm to see how we can cover all the charges.

vii. Meeting Adjourned. - Next meeting February 3, 2022.

Meeting Number	Meeting Date		Meeting Time
07	**02/03/2022**		2:00 pm EST
Co-Chair; Meeting Chair	Co-Chair	Scribe	Council II Chairs
Amani Babekir	Michelle Hill	Amber Potts	Jo DeFrancesco/Courtney Halbrook
Advisory - FDA	Advisory – FDA		Advisory - FDA
Greg Abel	Devin Dutilly		Mary Cartagena
Advisory - CDC	Advisory – CDC		
Erin Moritz	Jenna Seymour		
Advisory - USDA			
Jennifer Green			

AGENDA

i. Call to Order – Amani Babekir
ii. Rollcall – Michelle Hill
iii. Scribe – Amber Potts
iv. CFP Antitrust Statement – Amani Babekir
v. Meeting Minutes Approval – Michelle Hill
vi. Framework Points – Committee
vii. Next call
viii. Adjournment – Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL 11/17 Voting Members present [*10 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

Madam Chair *entertained a motion* to approve previous meeting minutes from 1/20/2022 meeting.

Cassandra Mitchell moved to approve minutes; Scott Vinson seconded the motion; Madam Chair opened the floor for discussion.

Vote on motion: 0 opposed, 0 abstained. *Motion passed* to accept previous meeting minutes as they were submitted. No other discussion ensued.

v. Framework Points

Madam Chair screen-shared the framework point document. At the requests of members, Amani emailed the document so we could follow along.

Amani gave a summary of this framework document:

Noted that the targeted timeline is July 2022.

She divided up the section into 6 workgroups to present draft work to the committee to frame out the final framework. These workgroups would meet separately then come together at the committee meetings to discuss progress. Workgroups will have leaders who decide on work and when to meet.

Ben Wagner asked to clarify the sequential due dates, does that mean workgroups cannot get started at the same time? Amani answered that it depends on the workgroup and suggested all workgroups begin work at once.

Erin Moritz commented that some workgroups will have more work than others and we may want to keep that in mind when we decide how many are in each group.

Emergency Plans Group:

Volunteers = Erin Moritz, Mary Cartagena, Libby Thoma, Crystal Eisner

Lead = Erin Moritz

Training:

Volunteers = Vy Goddard, Dave Reed, Nicole Lepore, Amber Potts, Jennifer Seymour, James Baldwin, Greg Abel

Lead = Amber Potts

Notification Tools:

Volunteers = Cristine Sylvis, Cassandra Mitchell, Erin Moritz, Mary Cartagena, Christina Meinhardt

Lead = No one volunteered so Amani will request more members through email and then we will come back to decide a leader.

Practices:

Volunteers = Ben Wagner, Scott Vinson, James O'Neil, Aubrey Noller, Greg Abel, Amani Babekir

Lead = Scott Vinson

Equal Consideration:

Unidentified member asked what this workgroup is. Amani explained that it is finding an alternative food source and to include this in your (the food establishment's) operational plan.

Discussion Ensued:

Scott Vinson and Erin Moritz disagreed with Amani and interpreted 'equal consideration' to mean we need to come up with allergen resources for entities that are not typical food establishments (not restaurants). Scott thought the charge should have read 'alternative' not 'alternate.' Food source means other food establishments such pantries and banks. So, our charge is to come up with allergy awareness resources used in food settings other than retail foods.

Mary Cartagena asked are food banks/pantries not considered retail food establishments? Scott Vinson answered that retail means they sell food. Amber Potts clarified that the Food Code says 'convey' and has nothing to do with if they charge or not.

Erin Moritz commented that whatever resources we develop can be adapted for locations other than restaurants and grocery stores. Scott Vinson agreed. Scott suggested eliminating this as a workgroup suggested the CFP included it to cover equity considerations. Jennifer Green (?) disagreed with the CFP equity statement and added that people who work in these alternate establishments are often volunteers, older and less aware of allergen issues. There is a difference so we should include different resources for them, it's important to think about this sector – donated food. Vy Truong agreed with Jennifer adding that workers are not trained and it is a good idea to have a few things on hand for them for the volunteers (basic allergen training).

Cassandra Mitchell suggested we come back to this workgroup. Erin agreed and added that we could consider developing other materials and come back. Or instead of forming a formal workgroup we designate individuals to keep this consideration in mind as work through our charges. Vy Truong and Jennifer Green volunteered as well. Amani agreed and asked the group if we can appoint them for this position. Group agrees.

Template (must include all sections we develop and to be used by the establishments):

Volunteers = Erin Moritz, Ben Wagner

Lead = Ben Wagner

No additional thought or comments were made about the workgroups or framework document.

Amani reminded everyone that we do have resources already approved in the Teams folders.

- SNHD resources
- Shared resources
- Collected resources

Amani asked about the ServSafe resources and if we are allowed to use them. There is a charge to access the platform. Jo DeFrancesco said she would meet with Amani separately about this.

Amani asked about the Responsible Training resources (generic allergen awareness training). There is also a charge. Crystal Eisner answered that she has emailed the owner and is awaiting an answer. But she would pay the cost to access the training.

Amani will send out email and contact list so workgroup members can start their work and begin scheduling meetings.

No final comments were made.

vi. Next call

Framework.

vii. Meeting Adjourned. - Next meeting February 17, 2022.

Meeting Number 08	Meeting Date **02/17/2022**	Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair and Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour	

AGENDA

i. Call to Order – Amani Babekir

ii. Rollcall – Michelle Hill

iii. Scribe – Michelle Hill

iv. CFP Antitrust Statement – Amani Babekir

v. Meeting Minutes Approval – Amani Babekir

vi. Sub-committees – Progress Reports for groups b, c, d, e

vii. Adjournment – Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL 13/17 Voting Members present [*10 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

Madam Chair *entertained a motion* to approve previous meeting minutes from 2/03/2022 meeting.

Crystal Eisner moved to approve minutes; David Read seconded the motion; Madam Chair opened the floor for discussion.

Vote on motion: 0 opposed, 0 abstained. *Motion passed* to accept previous meeting minutes as they were submitted.

No other discussion ensued.

v. Sub-Committees – Progress Reports

- During our previous meeting, we voted to:
- divide into 6 workgroups to present draft work to the committee to frame out the final framework. These workgroups would meet separately then come together at the committee meetings to discuss progress. Workgroups will have leaders who decide on work and when to meet.
- Madam Chair requested the leader of each sub-committee report on their progress.

Emergency Plans (Due date Feb 16, 2022):

- Members Erin Moritz, Mary Cartagena/Devin Dutilly, Libby Thoma, Crystal Eisner
- Lead Erin Moritz

Status report given by E. Mortiz – held 1st meeting last week, will meet again tomorrow.

- Currently group is tasked with gathering already-published Allergy - Emergency Control Plans.
- Will gather the documents, review, and use them to inform our plan creation.

b. Training (Due date March 2, 2022):

- Members Amber Potts, Vy Truong, David Read, Nicole Lapore, Amanda Garvin, Greg Abel, Jennifer Seymour, James Baldwin

- Lead Amber Potts

Status report given by V. Truong – held two meetings this week.

Defined 3 categories of training, organized as a tier system for amount and type of training for each tier.

1. PIC – most training. Will create/acquire Allergen awareness materials based on allergens on site; will train others on how allergens appear in the food being offered. Can use posters, printed materials, and video-learning for training. (Southern Nevada Allergy Materials; FAAN videos)
2. Food Handler/Prep – Must be able to name all major allergens and how they appear in the food being served; will learn safe-handling practices for allergens. Can use posters, printed materials, and video-learning for training. (Southern Nevada Allergy Materials; FAAN videos)
3. Wait Staff – Must know what allergens are present for menu items and if and how they can be excluded or replaced. Will use primarily video-based training (FAAN videos, etc.)

Vy Truong asked what the expectations are for sub-committees for work completion. Madam Chair declared that the sub-committees are expected to produce DRAFT framework around their charges.

c. Notification Tools (Due date March 16, 2022):

- Members Cristine Sylvis, Cassandra Mitchell, Erin Moritz, Mary Cartagena/Devin Dutilly, Christina Meinhardt, Michelle Hill, Scott Vinson, Amani Babekir
- Lead Amani Babekir

Status report – given by A. Babekir – held 1st meeting this week. The group acknowledges the hard work of previous Allergen Committees within the CFP. Selected the 2020 Allergen guidance as published on the CFP website as a base starting point to develop this part of the framework.

It was determined that the document has been well-prepared and will allow us to make informed decisions moving forward. The idea is to reduce words when able and move towards a shorter, more visual presentation for this information.

The use of ICONS to visually represent allergens was discussed. It was agreed that the ICONS included in the previous CFP work were acceptable to use and to encourage others to use.

Anne D – speaking as a Consumer, finds the ICONS very helpful in making decisions.

V. Truong – Agreed with Anne. Prefers visual over written words as it can reach all people. Visual ICONS are easily recalled later.

E. Moritz – Suggested the committee provide the ICONS as part of the Framework so that entities can choose to use those they find to be appropriate.

d. Practices (Due March 30, 2022):

- Members B Scott Vinson, Ben Wagner, James Baldwin, Aubrey Noller, Greg Abel, Amani Babekir, James O'Neal
- Lead Scott Vinson

Status report – given by A. Babekir – held 1st meeting yesterday. Group agreed to combine 2 SOPs from Southern NV Health District for clarity sake. Considering ICONS.

e. Template Group (Due date April 27, 2022):

- Members Ben Wagner, Michelle Hill, Erin Mortiz
- Lead Ben Wagner

Status report – given by A. Babekir – Has not met yet – will wait until work has been submitted by the other sub-groups and then begin the process of porting it all into the Framework.

vi. Next call - Subcommittee Status Reports - March 3, 2022.

vii. Meeting Adjourned. - Next meeting.

Meeting Number 09	Meeting Date **03/03/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Scribe Susan Algeo	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Devin Dutilly Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		

AGENDA

i. Call to Order – Amani Babekir

ii. Rollcall – Amani Babekir

iii. Scribe – Susan Algeo

iv. CFP Antitrust Statement – Amani Babekir

v. Meeting Minutes Approval – Amani Babekir

vi. Committee charges review - Amani Babekir

vii. Working group update – group leaders

viii. Adjournment – Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL 9/16 Voting Members present [*9 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

David Read- Motion to accept previous meeting minutes, second James O'Neal, no discussion. Motion passed to accept last meeting minutes.

v. Discussion regarding questions that came up during sub-committee meetings

Questions about charge #2: Will the framework we create be referenced in the food code or will it act as guide for retail food establishments?

[Opens the floor for discussion]

James Baldwin- are we trying to determine the charge? Recommendation is guidance.

Amber Potts- agree they are very different things and if it was for the food code, we would need specific language. Recommend it is referenced as a guide but that the food code require sometime of framework.

Jo DeFrancesco- we can make a recommendation that the FDA includes it and offer language that can be modified.

Scott Vinson – are we supposed to recommend specific language?

David Read – recommend what we do could be included as guidance in the Food Code Annex, which does not change the codified Food Code language. The Annex is guidance

Greg Abel- support not recommended for food code and do it as a framework and/or annex. This is because it's about bringing awareness for allergens. Because if it's in the food code, can it/will it be enforced?

Scott Vinson- given what we heard about enforcement; are the guidance documents enforceable provisions?

Jo- talked about different ways to submit the documents (whitepapers, annexes, CFP website) without it being codified

James Baldwin- recommend whitepapers to be posted on CFP website.

- Subgroups
- Emergency Plans

Devin Dutilly- Continue to work, meeting every Friday. Things are going well and should meet the deadline.

Training

Amber Potts- shared document they are working with. They need an extension for deadline. They started questioning if we want an SOP for an allergen free meal based on the document they had started with.

Question for larger group: how in depth should we be going?

Scott Vinson suggested condensing the document (their group had used the same document) into one or two pages. To make it as simple as possible for food workers to understand and food managers to be able to train.

They will go back and make it a more generalized document about major allergens and symptoms.

James Baldwin cautioned the group on whatever is put together here applies to the retail industry across the board (supermarket vs. restaurant). Be careful to not make it very specific to table service.

Amanda Garvin- is there a different term for food handlers in grocery stores??

Greg Able- FDA refers to retail as anywhere the consumer gets their hands on the food. Recommended Food Employee (which would be consistent with the food code).

Discussion about definition of food employee and who will be trained on allergens.

Amber asked if the training group is supposed to recommending increased allergen training??

Erin Moritz- in general we want to provide as much as we can. Seems there are not a lot of training that are available.

C. Notification Tools

Amani Babekir- Making good progress. Prepared documents on previous committees work and added extra materials about how to check food allergens in menu items

They would like to add Spanish language icons/posters to the materials.

Practices

Scott Vinson- they are making good progress for the March 30th deadline

First draft is put together. They want the document to be readable and something that can be copied and displayed in food establishments. They have written about storage, taking the order, preparing, and serving the food. They are still working on pairing it down so it can be concise and fit on one page.

Greg Abel asked about how useful documents posted on the wall will work for visual learners? And mentioned many employees won't read something posted. Scott mentioned there are icons that IAFP had created that may be useful; they do plan on having graphics in addition to verbiage.

Question for the group: Should they be developing only visual?? And let the training group deal with the verbiage?

Scott made the point we need to make the documents understandable for everyday people, by using plain language and simplified documents.

Devin Dutilly suggested looking up plain language there are resources that can assist.

Templates

If other groups come across forms or tools that could be useful for the templates group, please send to the group. At the end of the month the Templates group should be able to start their work.

NRA/ServSafe

What exactly do we want to use their content for and what is the outcome of using them?

James Baldwin- the way allergens are currently covered in CFPM courses is very basic information.

Amani asked, do we need the materials?? James did say the materials have been vetted and accepted by stakeholders. Erin mentioned having them review our documents after they are completed?

Do we need to be coordinating more between the subgroups so we are all staying in our lane and not doing double work? Amani suggested that training starts sharing their work. But even if we do create extra materials, it will still all be put together and will be revised. It's better to start with too much information

vi. **Next call -** Subcommittee Status Reports - March 17, 2022.

vii. **Meeting Adjourned. -** Next meeting.

Meeting Number 10	Meeting Date **03/17/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Amber Potts	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Scribe	Amber Potts
iii.	CFP Antitrust Statement	Amani Babekir
iv.	Previous Meeting Minutes	Amani Babekir
v.	Framework Points	Amani Babekir
vi.	Subgroup Update	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

i. Call to Order – Amani Babekir

ii. ROLLCALL 09/17 Voting Members present [*10 required for quorum]*

iii. Conference for Food Protection, Inc. Antitrust Statement – incorporated by reference; sent with each meeting notice via email message.

iv. Previous Meeting Minutes

David Reed made a correction in the minuets: page 23 comment from David Reed on the bottom of the page should say that what we do we include in the Food Code Annex, which does not change the Food Code. Annex is only guidance, where the framework would possibly live.

Amani asked for him to email the changes.

Devon from FDA thanks David for his comments and clarifies that the Food Code is the both annex and codified language, which cannot be changed.

Amani entertained a motion to approved previous meeting minuets. David Reed moved to approve minuets. Libby Thoma seconds the motion. Amani approved meeting minutes as amended by David.

No further discussion about the minutes.

Amani – proceed to vote on motion. Opposed = 0. Abstain = 0. *Motion passed* to accept minutes as amended.

v. Framework Points

Feedback from team members and FDA consultants about the framework.

Amani shared screen. We need to finalize first draft from each work group by the end of March. Training and Practices finalized draft. Working on notification and emergency team.

Discussion that framework to be a guidance for CFP website. We could reference or support the Food Code by referencing in the Annex of the Food Code. We may have to submit in a separate issue, Joe to check on that.

Comments/thoughts about framework? None.

Recommendation to look into FARE org has about allergens as resources and into different sections, similar to sections we are working on in subgroups. Each subgroup looks into their section through website and look into contents. Foodallergy.org/resources

- Consider adding anything missing.

- Add references to drafts (end section listing references used to create the draft). Then work later on how we will add it in the document.
- Need consistent terms throughout all drafts.
- Food Code defines some terms: Major Food Allergen, Food Employee, Food Establishment, …
- Which definition do we want used in the framework? Need volunteers to work on terms and intro section to framework.

Terms subgroup volunteers = None in chat.

Leaving to subgroup members to add more terms that need a definition. Feel free to add terms to list.

Recommendation to do a further review to review framework by FDA consultant and if we could get access to ServSafe/AllerTrain to look into framework to look at what we will create.

vi. Subgroup update:

Emergency – Erin Moritz Screen shared draft framework

Reviewed sections and key decisions.

7 sections:

- Section 1 poster/flyer posted where staff can see it
- Sections 2 - 3; learn more about allergic reactions, emphasized every allergic reaction and symptoms are different with different severities. Poster of potential symptoms of allergic reaction. Additional considerations
- Section 4 - dedicated to children
- Section 5 - procedural when customer reports a reaction
- Posters included as examples
- Section 6 - what is an epi-pen including pictures of examples and how to administer one with graphics

How does the larger group feel about using the brand name Epi-Pen? Other comments

Scott Vinson – comprehensive. Suggests we make sure this guidance remains ever green, so it does not have to be updated often, chances are it won't. Try to make them applicable and relevant for the longer term. Graphics may change, colors may change etc. Keep that in mind for lengthy descriptions of auto injectors.

Erin agrees. All from US other countries may have own brands. Good idea to add something about how not all Epi-pens will look like this.

Scott – maybe just include a brief section on the fact that these exist. No photos or maybe just one. Not really the food services role to be responsible for administering them, helpful to let staff know they exist. Not necessary to go into lengthy description of what they are and images. Document is very long and thought we agreed to keep them concise as possible, and this is just one subcommittee. Thinks to take a second look.

Erin – Establishment to decide if it's their role to administer the pen, they can disregard the entire section, but some establishments may want this information. It is our role to make the decision?

Libby – the first part says this is to be crafted to establishment own policies.

Erin – yes, we said that under purpose. Purpose to serve as a resource.

Libby read purpose. Erin – can add that you may not need all these materials based on situation. Libby – not meant to be 100% prescriptive.

Devin - any sections that are applicative in other workgroups? So, we can reduce document size.

Erin – to took entire framework and then shorten it.

Scott shortened document because they originally included emergency.

Amani – include everything and then reduce as a whole.

Mitchell, Cassandra - I have found that a couple of the training courses identify the epi pens generally as Auto-Injector Devices

Amani – any further questions?

Erin – would be interested if sections are not needed put those in the chat and we can discuss those. A draft is not ready to send out will send after the meeting tomorrow afternoon.

Amani – next section Training.

Amber went over the training draft.

Amani – please review all draft as they relate to their charges and make sure all components are covered.

Notification Tools Group – working on draft, received several comments and suggestions and also thank you Scott for making in plain language. Meeting tomorrow to finalize comments and draft and will send it out to larger committee.

Point about Icons and Spanish language – CFP does not have capability to offer this service, but we can explore if the committee members could provide this. Backup we can look for resources.

Amber – we have adobe stock we can use

Amani – no members who speak Spanish – ask larger council to see who speaks Spanish.

Move to Practices group

Scott Vinson – member companies said it's very important to have those for staff.

Already shared with full committee. Important that all staff members see this, so we added sentence to include that. Kept it concise and brief and plan language. One divergence from language – supposed to use term unpackaged food, did not include this term because we want to make sure not to forget food items made in the store. They won't be labeled from the manufacturer, avoided that term.

Should this group include signage to include in back of house? If so, another group may need to help. What font should we use?

Erin – regarding icons, Erin can help out with that. Would be helpful if there is which section you want an icon for.

Scott – we should use all the same icons. Color ones weren't as good. Choose at full committee level. Maybe Amani can provide those so we can all use the same ones.

Amani – add icons to draft and we can discuss to whole team.

Devon – clarify that definition of packaged in food code, under label section covers food packaged in a food establishment.

Amani – thank you and asking for volunteers for terms group.

vii. Meeting Adjourned.

Next meeting March 31, 2022.

Meeting Number 11	Meeting Date **03/31/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Subgroup Update	Amani Babekir
viii.	Adjournment	Amani Babekir

MEETING MINUTES

Call to Order

Babekir, Amani: Hello everyone and thank you for giving us this time to join our meeting. This meeting will now come to order. We would like to do the roll call, Michelle.

Roll Call

Michelle: Yes, I would be happy to. Thank you, Madam Chair. <calls roll for voting members> OK, I will try to keep my eye out if any of these other people arrived that haven't said yes, I'll add them in Madam Chair. We have a quorum of ten.

Scribe – Michelle Hill agreed to take notes that will be verified via transcript issued by Teams.

CFP Antitrust Statement

Babekir, Amani: And I would like to remind you that it is the Conference for Food Protection. Antitrust statement is active in this call. And just keep it in mind. And if you want to reference it, please find it in the attachment of this meeting Invitation.

Previous Meeting Minutes

Babekir, Amani: I will entertain a motion regarding the minutes of our last meeting.

Mitchell, Cassandra: motion that we accept the Minutes as written.

Garvin, Amanda: I second..

Babekir, Amani: Is there any discussion or question about the Minutes? So now we could proceed to the vote on the motion … is there anyone opposed to the motion? Please say no or raise your hand. Do we have anyone abstain? Nay. The motion passes to accept the document as it is. Thank you.

Framework Points

Babekir, Amani: Now we could move to the second item in the agenda. Let me share my screen. I have a couple of points I wanted to bring to all of you to discuss and see if you have any suggestions about it. Those points came out of the review process. We have right now in the draft which we generated as part of our subgroups work on these drafts. I sent out drafts for your review, and we received some comments and really, we appreciate your review. If you did not get a chance to review these drafts, please try to do so. It is really very important to make sure that we covered all the essential components of this framework.

One of the questions is about research that looks into the icons which are used to notify consumers about the allergy - are those icons sufficient. Do they convey the right message? All of the issues that might be around the icons, has anyone evaluated them.

Michelle: The paper that I'm going to be referring to, Icon based digital food allergen labels is the shortened title. It is a conference paper that was published in June of 2020. It is particular to a device - a handheld device where you scan the barcode of food products and receive information about allergen content. The study was specific to Wheat.

People were more responsive to an icon for allergen representation versus it being written out, and the clear choice was for Icon, and they have good data to show that that's the most responsive way that people can - most recognizable way for people to view allergen on a label. And in this case, it was being displayed digitally. I would be happy to distribute this paper, after the meeting today and give you an idea of what we are looking for as far as research as well, if anybody else wants to look around to find good data on what is a better way to transmit information, pictographic, icon versus written language. It was particularly preferred by people that were traveling and not native to the country. That, or did not have the speech or language ability for the country that they were in. It is a study that was done in Germany, in German. People in Italy as well as Switzerland, using the tool as well. And they saw quite a substantial percentage of people that really preferred the iconography over the written word.

Babekir, Amani: Thank you, Michelle. And this is just one example of the studies. Yes, Scott.

Vinson, Scott: I really liked the icons that the previous Allergen Committee group had included in their document. Maybe it was Erin, but they shared it with - I think on our last full Committee call. I thought those icons were really good. To Michelle's research, I yeah, I think it's pretty obvious that if you're traveling in a foreign country and you don't read the language you would like to see icons. I know when I'm traveling in a foreign country and I don't speak the language, I always appreciate seeing icons on packaged food when I'm buying it at the grocery store because I have celiac disease so that stands to reason. But Erin, do you have the icons that you had included in your work group document that you could share? I thought they were really good.

Moritz, Erin: Yeah, I can pull it up. Is that alright, Amani?

Babekir, Amani: Yes, please.

Michelle: I just wanted to add here really quick, and I failed to mention that they also use color coding. Yellow was used for likely possibility of there being an allergen present and red was absolutely that allergen is present, so it helped to address the preferential allergen labeling question as well.

Moritz, Erin: Sounds like a really interesting study, Michelle. The icons in our particular section – are these ones you are referring to?

Vinson, Scott: Those are really great.

Moritz, Erin: These are just kind of cobbled together from - they're not from one specific source. I'd have to go back and find where I pulled the images from. But we could certainly develop our own set from existing sources as well, if that's something that the group feels would be beneficial.

Vinson, Scott: No, why? Why remake the wheel? I think the work is already done. I think these are perfect. They have both an icon and the words in English next to them. Why don't we just include these and use them across all of our subcommittee work products?

Michelle: Scott, I like your suggestion there. I do want to mention that the previous allergen committee did provide a set of icons and they were the standardized set from the International Association of Food Protection. And they're what are used across Europe. I don't know if that's something we care to match, but they do exist. They're very similar to these. They are triangle shaped and we wouldn't have to follow that necessarily, but very similar to these.

Vinson, Scott: Oh, the ones that were in the triangle. Yeah, I've seen those several times. I looked at the IAFP link when we were preparing our work product document and those are good. But whatever we choose, we should just use them across all of our subgroups and then - put them in our final work product at the committee level.

Michelle: Absolutely.

Babekir, Amani: And do we think that we need a requirement for those icons - just to give it to the food facility in case they did not use those specific icons?

Vinson, Scott: Remember, we're creating a guidance document. This is not regulation.

Michelle: I do agree with you, Amani, with the question that they should be provided as an optional set that could be used in the case that they are not already using a recognizable set.

Moritz, Erin: Yes, is that what you were asking, Amani?

Babekir, Amani: That is correct, and I would like to satisfy the question that came from our FDA consultant. Devin maybe will elaborate into his comments about the icons. In general, if we specify that the icons need to be word and image, the image needs to be colored or black and white. Devin, could you give us more details about your comments regarding the icons?

Dutilly, Devin: Yes. Thank you, Amani. Thank you everybody on the call for the discussion with the icons. It is really great to see that the work group is moving forward with highlighting and bringing awareness to the nine major food allergens … these are the most recognizable and the team members mentioned that the other ones were also recognizable. It begs the question from all of us, perhaps we should be considering, if we're looking at uniform use of allergen icons or notification systems. How is that going to be interpreted across the United States, from different parts, the United States, different cultures that are within the United States. It's just something to think about whether icons are chosen, the ones that are on the screen or any other ones. It's just something to think about - the uniform acknowledgement of one image representing the allergen of choice here. But this is something to consider. Thank you.

Vinson, Scott: What are you saying? Are these not universally recognized? What do you suggest?

Moritz, Erin: If I might jump in here, I think Devin is saying that specific images aren't going to be universally recognized across the US because we don't have one set that the US has all agreed on using. Is that what you were trying to say, Devin?

Dutilly, Devin: Yes, and that would likely require quite a bit of research and investigation to establish something like that.

Moritz, Erin: Yeah, I think that's way above kind of you know our charges. I feel like that would be an entire separate conference maybe.

Dutilly, Devin: Thank you.

Michelle: When I was doing research to try and find anything about allergen icon use and recognizability, the Codex Alimentarius had industry specific icons that it's been using for a long time and there's good research for that. And it says right on there that they're not meant to be used at the consumer level. And my question would be why not? They look very similar to these. I could see if I could pull those up, but are you guys involved with that at all with the Codex Alimentarius and the USA Codex? Or is that not in your purview?

Moritz, Erin: I doubt anybody at CDC is involved with that. Jenna, I don't know if you know if somebody, please feel free to jump in.

Seymour, Jennifer (Jenna): I don't.

davidread2861: I'm pretty sure FDA is a member of the Codex.

Dutilly, Devin: There's a number of folks that are involved with it. You're right. Jennifer and Erin from the FDA side of it. So those are good points you bring up - so it's been done before.

Michelle: I'm guessing the research would be there. They were presented at the official conference recently and like Scott was saying, if it's already existing, maybe we could just point to that and use that.

Dutilly, Devin - I guess just to take a step back - the Codex is internationally focused, you know, organization - FAO and WHO? The food code is going to be targeted towards domestic, right? So that would be those are two different populations within that scope. So that that would be the difference. FDA does have representation, as Jennifer and Erin had mentioned, on multiple Codex Panels and committees.

Michelle: To that point, are they available to be used? I know that we're speaking about the United States. However, parity across is not a bad idea. If within the larger world, and if it's already recognizable when people travel, perhaps it's a good set. That was just what I was thinking.

Dutilly, Devin:. Michelle sounds like a great suggestion to perhaps include that as an option or an example within the document. So great suggestions. I'm glad you were able to find that research and bring it up, so it's definitely a valuable comment for the group to discuss. So, thank you very much Michelle.

Babekir, Amani: Also, I have a question about the food industry. Sometimes they do use icons in their product. Are there standard icons or is it up to the manufacturer? Do you know anything about that? CDC or FDA?

Moritz, Erin: I do not know. If I had to guess, I would say that. It's probably, as Michelle said, industry specific, not standardized across all food sources and all food users.

Vinson, Scott: Speaking for industry, it is not, and I think that's kind of what we're doing with this document. We're trying to provide resources for industry.

Moritz, Erin: Yes.

Vinson, Scott: This is a guidance document for Food establishments, retail food establishments. So, we should probably ask people like me representing the industry. And I think that these icons here are pretty recognizable. And if you want to go ahead and include the icons that are used by the Codex Alimentarius, that would be fine too. For people who travel internationally a lot like me, that's probably not a huge part of the population, we throw it in there. Why not? But you know, giving more options, I suppose to industry is fine, but I don't see a problem with these unless somebody can point out something specific about these, then I don't think we need to do a lot of research about whether people can tell whether this is a fish or not.

Michelle: But to earlier points - there are concerns especially around the appearance of a milk bottle for that dairy allergy - it's casein that's the issue. It's a hard thing to represent and I guess what I was just really getting at is that if there's a standard that people are used to seeing already, whether its industry based or not, perhaps it's a good standard. I don't take issue with these icons. I think they're demonstrative of what they are. But I do know that discussion early on was about how representative are they? You know, do they actually transmit what we need to transmit?

Thoma,Libby: I would like to just pop in and say in our from retail, we also in H-E-B we use Boards across all of our departments within the store to communicate to our customers that anything made in store is going to have one of these top nine allergens and they're all listed. They are icons and then they have the verbiage and these are easily their placards. They're displayed throughout our stores - our goal is to make sure that our non-English speaking customers understand what those are as well because it has, you know the descriptions along with the icon and they're color coded but. Honestly, ours are color coded based on aesthetics - I wouldn't say that they're based on anything that has anything to do with the actual food itself.

Michelle: Are they similar to this icon set?

Thoma,Libby: I can. I'll send you one when I get home. I'm driving right now.

Michelle: Thank you.

Vinson, Scott: On the black and white versus color issues for the icons I we need to look at this from the perspective of an individual operator. So, in actual food service establishments, not all of them may have color printers on site. And if we're expecting people to print these off and post them in the back of the kitchen or the back of the house and the kitchen area, food prep areas, they may only have a black and white printer. I would suggest we not do color.

Michelle: Absolutely, I agree.

Thoma,Libby: I agree too.

Babekir, Amani: Hey, thank you very much for this discussion. Any extra points about the icons - I see Erin, you put your point in the chat. You made a very good point. Any extra comments?

Vinson, Scott: I have a question about Erin's question here. She writes in my mind there are two decisions we will have to make as a committee - which icons to use in our final document, and which to provide as resources to establishments. Shouldn't they be the same?

Moritz, Erin: There's multiple sources of icons available, and so we'll have to pick one to use within just our document that we're providing - if we include links to the last committees deliverable - it has three or four resources. I don't see anything wrong with that and that way the establishments can choose which ones they prefer. We'll just have to just decide on one set that we are going to use in this particular document and if it matches one of the resources we are providing, that's great.

Vinson, Scott: It isn't the document we're producing. We're presenting this document to the CFP.

Babekir, Amani: Yes, Scott, I think what Erin meant here, is to make it consistent through the whole document. What icons are we going to use on that document? Besides providing additional resources to the food facility for these icons.

Michelle: What I am hearing here is a difference between whether we're dictating an icon set to be used across industry versus an icon set that we're going to use within the CFP guidance.

Moritz, Erin: Yes. And I think deciding a set across industry is well beyond the charges for this committee.

Michelle: So perhaps we offer the icon set that we use as the standard within our document, and like we've said earlier, just giving references that link out, not necessarily including that icon set as a part of our document - just links to those icons.

Moritz, Erin: So an establishment might read our document and say these look great, this is good for us, we're going to use them. Another establishment might say, I don't like the milk bottle. I'm going to use something else, and we have provided those resources for them to look for other images.

Michelle: OK, so there should be a spot within the guidance documentation that says here's a source for other allergen icons and give the link, not necessarily depicting the icons within our document just for clarity's sake. Is that?

Moritz, Erin: That's a good question. I assumed that we would include those, but because those were from the previous committee, maybe that's beyond our group. Yeah, I didn't think of it that way, Michelle. That's a great question.

Babekir, Amani: Yes, we do have the notification sections and one of the main sections on that section is to provide various resources for these icons just to diversify the options for the food facility. Yes. Which option they would use.

Moritz, Erin: OK. Yes, that's right.

Babekir, Amani: And to make those icons consistent through the document. We are going to leave that to the template group because the template group is the one who's going to work on the format and finalize the look of the framework. So, whatever icons we are going to add to our drafts, we are going to send it over to the template team and then they will look over it and decide after they discuss it with the whole team which icons they're going to use through the whole document. Does that sound like a good suggestion? Scott, I see your hand.

Vinson, Scott: Yes. So, my understanding is that the document the Subgroups and the committee is producing that so will turn into CFP has one audience. Not two separate audiences. The one audience is retail food establishments. We are producing an operational framework for retail food establishments to help them with allergy awareness and so forth. We don't have a document that's audience is CFP and then stuff within the document that's audience is retail food establishments, the whole work product we are coming up with, the audience is retail food establishments.

Babekir, Amani: That is correct.

Vinson, Scott: OK. Thanks.

Garvin, Amanda: But we do turn in reports to CFP, correct?

Michelle: Correct. There are specific things that we need to talk about - it's basically benchmarking on how far we are within our charge.

Babekir, Amani: Yeah, we already submitted, we do submit Periodic reports to the CFP and we already send the second report to the progress of our work and then at the end of the whole work, we going to submit a final report and that's going to be approved by the CFP, and one of the components of that report is this framework. But the main objective of the framework is to address the control and prevention of the allergen within the food facilities. So, any extra points or suggestions before we move to the next point?

Subgroup Updates

The next thing is about training, and Amber is not with us, but I would assume there is a team member from her subgroup which could help with this question. Let me share my screen here one more time. OK, the question is about how to ensure proper training. How do we ensure the proper training? Is there any requirement, any kind of assessment we would like to suggest - Anything like that? I'm not sure if that is being covered in the training subgroup. During their discussions, I know at some point they were looking into a standard way to evaluate the components of a training. But I'm not sure how far they went through this discussion. So, I'm opening it for the whole team and also for the Members in the training subgroup if they have any comments about this one.

Michelle: Just to clarify, Madam Chair, are we looking for ideas around how to assess a person's knowledge, or are we looking at how to assess the material as it is presented?

Babekir, Amani: Yeah, it's either way, just we are looking for if there is a way we could add to this framework - to assess the knowledge, or to assess the quality of the training that is going to be provided. I would assume at the end its going to fall on the person who is trained, how we're going to assess his training - his knowledge. Do you have anyone from the training subgroup in our meeting today?

davidread2861: I'm on that committee - something has been mentioned is how do you assess whether the training is sufficient or not? But we didn't discuss any further details about that. I do know that if it's online training, often there are assessments included periodically and maybe a quiz or something at the end, but it's not like a proctored exam or anything. It's just to measure progress and knowledge as you go through, for example, an online course.

Michelle: Being part of that training Subcommittee, is there an element that you guys have introduced that would allow that opportunity or a recommendation for that to occur? Just maybe stating that that's necessary, that there be an assessment of knowledge in some way.

davidread2861: But it seems like there needs to be some sort of assessment, but that's just my opinion. I don't think we've gone into detail in the committee about that, which would be ideal because everyone could get the same type of training and then you could have an assessment process built into that training.

Michelle: Much like ServSafe does with their allergen certification.

davidread2861: Most online training has that and if you're doing in person training as well. Don't know if you need to be developing, you know, separate testing processes - I guess a lot of this could be done as online training.

Michelle: That and as opposed to what we could just ask for, is that there be an assessment that's done and leave it open to what they might think that could be. But the fact is that we need to assess how well trained that person, you know, if they've been trained properly.

davidread2861: Right.

Michelle: So maybe a framework of assessment, you know, please know these things.

davidread2861: I agree.

Michelle: Which is I guess is what our framework is maybe, already.

davidread2861: I know we were building online training for the regulatory community and it's based on competencies. So, you'll look at what competencies are needed to perform certain tasks and then you develop your training and assessment around those competencies.

Vinson, Scott: I'm sorry we are talking about creating test materials to include in this guidance document.

Michelle: I don't know that that's the intent of the conversation. I think that it's more centered around whether we recommend that there be an assessment of knowledge as part of the framework.

Vinson, Scott: I'm going to say I would say no. I think that's beyond the scope of our charge - we are supposed to create an operational framework that can be used in retail food establishments to help with allergy awareness. I don't think we need to be creating testing materials or you want to call them, assessments, whatever.

Michelle: We would advise that they perform an assessment - is what we would be talking about - not actually saying this is the assessment you must adhere to. Just advise that they assess that person's knowledge in whatever way they find would be applicable to their circumstance. It's so varied.

Vinson, Scott: Folks, I think we need to be a little bit realistic. We need just a reality check here for a moment. And I've talked about this before on other calls. The retail food industry is under tremendous pressure right now. Labor shortages supply chain. Ingredient shortages it it's a mess. We need to be very careful about layering on additional regulation. The devil to deal with, particularly medium and smaller sized establishments, so.

Michelle: I agree with you Scott.

Vinson, Scott: I would be against that. I would be against.

Michelle: It's a very valuable opinion that you're sharing, Scott, and the load is there for those people. However, just making sure that reminding them that they need to know if that person has understood what they've been told. What we're after here is just acknowledgement that they understand. Maybe it's they sign a document saying they've been trained; it could be as simple as that.

Vinson, Scott: And an additional document. And then that document would be kept where?

Michelle: It would be up to the Food establishment how they deal with that, like everything else, how you document and how you store it.

Vinson, Scott: Like storing documents on site, every single requirement has - there's a domino effect.

davidread2861: Well, I think the food code actually has some training requirements in it right now and I would assume there's some way that facility would have to track that. I mean, they have to show that people have been trained.

Michelle: It could be added to it.

Vinson, Scott: So, you have these things.

Michelle: Absolutely. It's part of your operating procedures typically. Standard operating procedures are. I've seen that most commonly, and it's usually one single form, and there's several items on that form you have been made aware that you need to inform about personal illness, then how that pertains to food production. It's knife work - that you understand how to use a knife, it's agreement to report illness within the home. It could be added to that - that I acknowledge that these are the nine allergens, and we deal with them … and you know I'm not trying to give language here, I'm just saying it could be part of that and they're already retaining that. Most likely so if they've got good procedures in place they would be.

Babekir, Amani: These are good discussions? I will collect all these points from our recording, and I will send it over to the training subgroup. And then they're going to discuss it and decide how they're going to address these comments, because the question about the training assessment is based on just the feedback we got after reviewing the draft of our documents, so that is the reason

for this question. Thank you everyone - and before I continue, just to the next step, I want to open the floor to the subgroups update. I know that you have done fantastic jobs on your drafts. Really, very good job combining and completing those drafts. I'm going to call the subgroups and give them the chance if they have any questions to the larger group - the emergency plan group - Erin, do you have any questions or any update?

Moritz, Erin: No, no questions. We got a few limited comments back and we've made changes based on those suggestions. And I think we need to go through and make sure the formatting makes sense, but other than that I think it's good to go. We are certainly open to other folks to still review it if you have a chance.

Babekir, Amani: And do you think you could send the draft?

Moritz, Erin: Yes, I think that's doable. We have a meeting tomorrow and I guess my plan at least was just to go through and make sure the formatting looks good and check spelling and all you know little stuff like that. And then I think it'll be good to go.

Babekir, Amani: Thank you, Erin, and uh, the emergency plan members. Now I'm going to move to the training subgroup. I know that is a draft being sent out for review from the training subgroup - Amber is not with us. Are there any comments from the group members about the progress of the draft?

Amber: Do you mean the draft itself - I sent the draft to you when we were done with it.

Babekir, Amani: OK. Thank you. So, I'm going to move to the notification tools group. We're going to have a meeting this Friday and we're going to go over some of the comments we received just to make further updates to our final draft. And then I'm going to move to the practice group. Scott, do you have any update?

Vinson, Scott: Yep, we finished our document and I sent it to you the other day.

Babekir, Amani: Thank you. I have all the drafts now ready and we still have a chance - if you want to review it and give us extra feedback, please feel free to do so. What our next step is going to be, let me just share my screen here one more time.

Michelle: Is there a central place that could we put those most up to date versions in our repository on Teams in the Teams folder for the allergen committee.

Babekir, Amani: Yes we could do that, thank you. What's our next step? My suggestion is to continue the subgroup meetings, just keep the block you have in your calendar for those meetings. Keep it on because what's going to happen? While we are reviewing it, we're going to come up with some questions, and we can receive comments and we are going to send it to the subgroups and you're going to work on addressing those comments or additions to your draft. So just keep those meetings in your calendar. If there is no request being sent to you, you could just cancel that meeting. But at least keep it on. We are going to compile all of these drafts together, put it in one draft, review it and validate it against ServSafe contents. Michelle has access to these contents, so she's going to review what we generate. It again is the components of the ServSafe allergy and training. Are we going to identify if there is anything we need to add? If there is anything we need to edit based on this review?

Also, we need to review it with FARE, so I'm going to go over the components of the FARE training and see if there are any additions we need to address in our drafts. The third one we suggested in our discussion is that we need to look at and also compare it to our documents is the AllerTrain. We don't have access to this training. If there is any member who has the contents of their training or materials and could help us to review and compare it to our draft.

Michelle: I'll reach out to Betsy Craig, the owner of AllerTrain and request access.

Babekir, Amani: Thank you, Michelle. And would you be able to do the review or?

Michelle: Most likely not, but I could put her in touch with whoever would be able to volunteer to do that.

Amber: Yeah, I can review that. That's our training.

Babekir, Amani: Thank you, Amber. So, do you have suggestions about any other materials to review and compare to our draft?

davidread2861: Are you looking for other online training?

Babekir, Amani: It could be online.

davidread2861: I know that FMI does have an allergen training course as well.

Michelle: I think we're looking for our hole, is what our goal here is.

Babekir, Amani: Yes - do you have access to the FMI training material?

davidread2861: I don't specifically. That training is available on the IFPTI website. I could inquire about its availability.

Babekir, Amani: OK. Thank you. Any extra points or suggestions about the review? We are hoping to complete the compilation and then the review within two to three weeks. And then we will send it over the template team to work on their charge. We're going to

work on the terms - and thank you very much to the notification subgroup members that agreed to continue working on the terms. We're going to be working on these and will provide it to the template team. If you want to volunteer to work with us on this term subgroup, please put your name on the chat or let me know through email. That is all I have, and I open it to all of you, if you have any extra suggestions or discussion?

Moritz, Erin: When you talk about terms, just to clarify, this is the group that will be deciding when we talk about and establish we're going to use the word food retail establishment or just establishment. When we talk about, you know, basically the definitions team, is that correct?

Babekir, Amani: That's correct, yeah.

Moritz, Erin: Ok, thank you.

Meeting Adjourned.

Babekir, Amani: Any extra suggestions or ideas? I think that concludes our meeting today and thank you, everyone, and I'm going to send any comments or feedback that I receive to the subgroup that is related to those comments and thank you very much for continuing to work on your drafts. Thank you. Have a nice afternoon.

Next meeting Thursday, April 14, 2022.

Meeting Number 12	Meeting Date **04/14/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Subgroup Update	Amani Babekir
viii.	Adjournment	Amani Babekir

MEETING MINUTES

Call to Order

Babekir, Amani: Hello everyone and thank you for giving us this time to join our meeting. This meeting will now come to order. We would like to do the roll call, Michelle.

Roll Call

Michelle: Yes, I would be happy to. Thank you, Madam Chair. <calls roll for voting members> We have a quorum of eleven.

Scribe – Michelle Hill agreed to take notes that will be verified via transcript issued by Teams.

CFP Antitrust Statement

Babekir, Amani: And I would like to remind you that it is the Conference for Food Protection. Antitrust statement is active in this call. And just keep it in mind. And if you want to reference it, please find it in the attachment of this meeting Invitation.

Previous Meeting Minutes

Babekir, Amani: Now we could move to approving the Minutes. Could you please go to the version I sent out yesterday? To the end of the document, you will see our last meeting notes. I will give it 2 minutes for your review. And then we could entertain a motion. So I will entertain a motion regarding the minutes of our last meeting.

davidread2861: I just sent you some edits to the comments that I made to try to clarify at least what I thought I was saying.

Babekir, Amani: OK, that is great. Any other? To wait till we make the change on the minutes, and then we proceed with entertaining a motion on it or I will entertain a motion regarding the Minutes.

Michelle Hill: Madam Chair, perhaps somebody could make a motion to approve the amended minutes in our next meeting. So people have time to review that.

Babekir, Amani: OK.

Michelle Hill: What's the will of the committee?

Ben.Wagner: I motion to approve the amended meetings in the next meeting.

davidread2861: I second.

Babekir, Amani: Thank you. Any further suggestions? OK, so let's proceed to the vote on the motion. Is there any one opposed to the motion? Please say no or raise your hand. Thank you. Do we have anyone abstaining? Thank you. So the motion passes to approve the minutes next week, after amendment OK. Thank you.

Framework Points

Babekir, Amani: So now we could move to the second item in our agenda. Just they want to give you an update about the progress in the framework, and share my screen. What we did here, we put together all the sections we received from the subgroups. Thank you very much for your effort and the time you spent working on those documents. So as of now, we have the initial draft of the framework. So that is very good progress to our committee work. We put it all together. The first section is the training and then we added the handling piece. And here is the notification section. And then the third one is the allergic reaction.

We are also working on the definition section - the subgroup meets every Friday. We made good progress on listing all the possible terms that are commonly used in our draft and we are working on adding definitions to those terms. And thank you very much for Michelle and Devin and also for the subgroup members - they really put an effort and time into doing this. Another thing I want to say if you want to volunteer on the definitions of group, please send me an email. We are planning to conclude the work on those definitions within two weeks, so we will be able to send a draft to Devin. He volunteered to give it a revision on it from his side before we proceed with formatting the document and sending it out to the template team.

Any comments about the progress we have so far on the actual draft? And definitely we're gonna have a lot of discussion about it after this. I'm gonna hand off to Michelle and also I'm gonna tell you how I compare this document with the first sources by showing you all the sections in one draft. Do you have any questions, any comments about it?

Michelle Hill: Madam Chair, I see a hand raised - Jennifer.

Green, Jennifer - FSIS: I was able to review two or three sections - I'm not sure how many total sections it will be, but will we get a chance to review the entire document like this one, this version here that has everything included.

Babekir, Amani: That is for sure, Jennifer. After the end of this meeting, I will send out this version to all of the team members, so you will have a chance to review it and do comparison with whatever resource is available for you. So that is a good thing.

Green, Jennifer - FSIS: OK, awesome. Thank you.

Babekir, Amani: Any additional comments? Thank you. And I will give you an idea about how I compare it with the FARE resources. Let me share what I used here - I'm going to walk you through the FARE website and the resources I saw there.

I found a couple of resources - mainly for avoiding cross contact. They do have a portion for the emergency care plan. How to read a food label, and also they have Spanish versions. I tried to see if they have signage or icons in Spanish, and I did not see documents or procedures in Spanish, but we could reference it in our document. Going over these resources, I found that we covered everything in our draft. The only thing I added there is that they say to avoid the cross contact is to wash hands before preparing the allergen free meal - so I added that because I don't think we had it there in the best practices section. But other than that we are aligned with the FARE contents. Any discussion or note about this. OK. Thank you.

And now I'm gonna hand it to Michelle. Michelle has done a very good job - an awesome job on reviewing our contents against ServSafe. She added a lot of feedback and suggestions there and I will give her the floor to just walk us through our notes and discuss it with you.

Michelle Hill: I took some time and nitpicked through the ServSafe food allergen training modules that they offer on their website - it is a paid service. I teach this material frequently so it was fairly simple to go through and see how we matched up. I did not find any glaring omissions with the exception of defining anaphylaxis. I know that will be one of our definitions, but I think that we should probably say a little bit more about what anaphylaxis is, and I've made a note to that effect here on the right - That it's a serious allergic reaction that occurs rapidly and may cause death. That is how ServSafe defines it. And this is all up for debate. You don't have to use any of this or all of this. I'm just letting you know what I saw when I went through it. Any place you see A tag here, it's where I found actual language specific to those ideas addressed by the ServSafe curriculum. As I said, the biggest potion that was missing would be talking about anaphylaxis and then also the flow. We might consider changing the flow of this document. In particular, we start with the person in charge, which I think is appropriate. However, it seems like it flows much better if we go to the front of the House next and then the back of the House. And maybe it's because that's the experience that customer has that it makes more sense that way. But a lot of the trainings that I did observe all had the flow in that manner.

So it's just a how we feel about it, how it flows as far as the contents, everything looked really good. I didn't see, like I said, I didn't see anything that was a glaring omission. You are more than welcome to take time to look through this when you have time. And I was only able to complete this early this morning. So it's not a lot of time for people to be able to really walk through it. I'm not sure if you want me to go through each point here or if that's something we do offline. I'm open to any kind of questions or feedback regarding this. Madam Chair, is this what you were expecting for me to do, or would you like me to go through each comment I've made?

Babekir, Amani: Yeah, I think that is good. What is going to be our next move is I'm gonna send these documents to all of our committee members to comment on it, and definitely I encourage the subgroup leaders to talk to their group members to see if there is anything they need to address or make any change to their draft. Based on Michelle's comments, as far as she said, we don't need to add anything new. But if we see that we need to adjust some of the language, we need to do anything extra, we're gonna give the subgroup a chance to do that, and we are opening it for your suggestions also, If you have any.

Michelle Hill (Guest): Madam Chair, I guess the biggest thing I've noticed is that we don't really prescribe specific language and how these things should be spoken of. I don't know if that's something that is in our purview or if we just recommend that they obtain knowledge in that way - a framework for the knowledge is what I'm seeing it as. A lot of the comments that I've made give full blown descriptions of how it would be taught,, so I guess that's something we need to consider - how much of that do we actually include in the framework?

Babekir, Amani: Thank you. I'm opening it for discussion here. Michelle, could you go to the top of the document? Maybe we could go over some of the comments and see the feedback and then we could complete it if it is a definition.

Michelle Hill: Perhaps we do list symptoms, although this is addressed later on in this document, in the framework itself, it would fall under this area here how to recognize and respond - I think that that's cared for well in that latter part. I did break out each specific allergen from it just being an itemized list to being actual numbers to again reiterate that there are nine allergens.

Babekir, Amani: I see your comments about the guest - Keeping your guests safe starts before guests. Even walk through the door.

Michelle Hill (Guest): Yes.

Babekir, Amani: Could you walk us through this one?

Michelle Hill: This speaks to how to prevent cross contact and also to how to be more aware of what's gonna hit your door before it comes, especially if you're a facility that can take a reservation, this wouldn't necessarily be for retail food. And we're looking more at a sit down restaurant here. But either way having a clear policy ahead of time on what allergens are special requests that we can reasonably accommodate. And then having clear policies to communicate that information. Everybody in the operation should know what they can accommodate and not - within given reasoning. I mean, if you're making homemade bread on site, I don't think you're going to say you can accommodate gluten free. Or gluten sensitive.

Babekir, Amani: I know in our best practices section we did not address or we don't. We did not call out that there needs to be clear policy and communicated. Do we need to consider that point?

Michelle Hill: I think so. I think that maybe having a little bit more language using some of these ideas to fill in the blanks as far as specific things that we would like them to undertake - activities to undertake. I'd like feedback from the larger committee on this.

Babekir, Amani: Practice subgroup members, do you have any feedback or comments about this? You're gonna have some time to discuss it later - we have a very quiet team today.

Michelle Hill (Guest): I think it's a lot to process. You know, in our special ordering process, how do we actually handle these orders? Maybe being specific about how we do that? Although I believe that if you read our entire flow, it is addressed throughout each designation/segment of workers. I would like to see back of the house be third and front of the House to be second - I think the flow would be a lot better. That's something we could change right now if people agree to it - if they think it makes sense.

Babekir, Amani: Do we have any further discussion about the comparison with ServSafe? And how do we feel about the contents we produce and that we aligned with their content?

Eisner, Crystal (PHS): I feel it's aligned well.

Babekir, Amani: That's good. Thank you.

Michelle Hill: Are you speaking to the order of ideas here, or just overall that we've aligned well with ServSafe?

Eisner, Crystal (PHS): Overall with ServSafe.

Michelle Hill: OK. How do you feel about changing the order of how we talk about the training modules? Do you think it matters that we have a definite flow - maybe I'm the only one that thinks this flow is awkward.

Eisner, Crystal (PHS): Can you Scroll down? And so it's training and then you have person in charge and then what's the next?

Michelle Hill (Guest): The next one is back at the house and then it's followed up with front of the house. I would recommend that we do front of the House prior to back at the House. That's my only big idea.

Eisner, Crystal (PHS): You're doing it like the flow - as if you walk into a restaurant from the front door. Is that how you're doing it?

Michelle Hill: That's what I was thinking. It's the way a lot of other written material approaches this for training is that they go from the flow of a customer and so I think it makes sense, just for clarity sake, to have the two items swapped.

Eisner, Crystal (PHS): Yeah, that's the standard - why not stay with the standard?

Michelle Hill: Thank you. I do agree with that. Is that something we can just do or do we need to have this go back to the subgroup with that comment?

Babekir, Amani: We have Members from the training subgroup - in this portion of the training, that's right. Michelle, on the training section.

Michelle Hill: Correct. This is the training subgroup. If we'd like to take a, maybe somebody could make a motion to make this change. If you're comfortable as a group.

Eisner, Crystal (PHS): Is there anyone for that subgroup on the call right now? Maybe they had a certain reason why they did it in this order.

Babekir, Amani: Amber is not able to join us, but we welcome comments from other subgroup members.

Goddard, Vy (VDH): I'm on that sub group. I don't remember a specific reason for the flow that is really significant, so I'd be OK with changing the flow, but I'm only one person on that committee, so fine by me.

davidread2861: I was on that group as well, and I don't recall any specific reason for the way it was listed, so changing it would be fine.

Michelle Hill: Madame chair, how would you like to proceed? Do you think we need to have a vote on this or is this something that is a matter of course and I can just make the change and we'll move forward with this document for review?

Babekir, Amani: I think we could make the change and then we will leave it to the template team to work on the flow of the document, because this is gonna be their task. We have Amber with us, but she's not able to see the screen. But if you can hear us, Amber, just give us your feedback in the chat.

Michelle Hill (Guest): The change has been made, the flow is now within training. Number one, PIC, number two, front of House, number 3 back of house, and then the 4th recommended changes to the wording and this would be the food code Annex specifically - not the food code itself. I think this is good. I think it'll be important for people to really take some time and look at the comparisons that have been done. And you know, if we feel like there needs to be more language added in around certain ideas, just to flesh them out, if it's agreed that that's necessary, then we can do that.

Babekir, Amani: Yes, Scott.

Vinson, Scott: Michelle, can you scroll through the whole document so we can get a sense for the whole thing?

Michelle Hill: Absolutely. I'll start at the top. It's 19 pages.

Vinson, Scott: Is this a consolidation of all of the subgroups work?

Michelle Hill: It is. This is the training component that was produced by the training work group. This is the verbiage produced by the policies and Practices Group here. Here's the tools to notify, as provided by the subgroup. I did adjust this table - I recreated it because it was painful. And I did go through and drop in where the ServSafe material would align with the same ideas throughout the entire document - not just the beginning part. And then here's a blank example form they can use. The very last section is the emergency response guide and that includes several pictures or posters that people can print and use.

Here's the flow of what to do if something happens. And ServSafe is not very verbose on that - basically says make sure the person … it steps through exactly what we've done here for the most part, it's a lot lighter even than this, as far as what they tell people to do. This is more specific, which I think is good. And then here are the posters, with references of course.

How a child might describe it? I thought this was quite good. Actually this was a very nice graphic here - explanatory, and the references for each section - each part of the framework carries a references section.

Subgroup Updates

Vinson, Scott: Is there a section with sample Posters with icons - the notification group.

Michelle Hill: Yes. That is right here. It is part of the food allergy reactions - how to recognize and respond. So here's the 9 icons that we spoke of last meeting. These have not been adjusted in any way from the last meeting. They're intact as is.

Babekir, Amani: For the notification sections we have links, but we haven't added any actual icons there. I think Amber's team also gathered icons.

Michelle Hill: This is what we have right now is part of the framework. This is what it includes.

Babekir, Amani: Correct.

Michelle Hill: Did that answer your question, Scott?

Vinson, Scott: Yes - just scroll up to that page a minute ago - Symptoms of an allergic reaction. So this page here. You've got this section here. Symptoms of a severe allergic reaction. And then if you scroll down again on the next page, it's repeated.

Michelle Hill: It is - this would be intended to be hung separately. I think that the intention of this group was that it be found in both places? So just options I guess for people.

Vinson, Scott: And one is labeled symptoms of a severe allergic reaction and the other one is labeled symptoms of an allergic reaction. So is there a difference?

Michelle Hill: There can be - the severity matters. The question is, are they tipping into anaphylaxis or not?

Vinson, Scott: Well, I mean, but do we need the word severe - people are gonna notice that it's on one section and not the other. And they're gonna wonder why there's a difference. So maybe just make them the same.

Michelle Hill: I can make that as a note. Is that what I should be doing?

Babekir, Aman: Yes please.

Michelle Hill: OK.

Dutilly, Devin: To take a look at the number of work group members are on the call now. If you take a look at the each of those documents - I think some of the intent - like you had said Michelle very nicely - they will have them printed off and hung, and each of the documents can serve different purposes within the food establishment. Different locations that they are placed or hung. So that was kind of the intent for it. And so there's a little description above it. I believe that talks about that. Thank you.

Vinson, Scott: OK. So maybe somewhere on these pages if these are meant to be hung on the wall or posted somewhere maybe. Maybe that should be noted somewhere.

Michelle Hill: There is a list up here that calls out - it says below the below posters and Flyers are designed to be placed within your food establishment in locations such as, and then they give advice as to where each poster could appear that would make sense.

Vinson, Scott: Ah. Good.

Michelle Hill: So that's a good suggestion. They did a really good job on this, referring back out. In fact, any time that they had a spot that they could refer the user or the reader to a resource, they did so with this picture call out and then what it is - it was well done. The other part I liked about this is that they did layout examples of potential reactions and then what we do is that initial assessment of how severe is it? If they can talk or not, we do this. If they're unconscious, we do this, or semiconscious … and that in itself speaks to the severity and how we deal with it.

Vinson, Scott: I have one other suggestion. I've noticed that the word individual is used frequently in these pages. I would just suggest replacing the word individual with either person or people if it's plural. I find the word individual to be dehumanizing.

Michelle Hill: I can. I'll put that in absolutely as a suggestion to be considered as a Global change.

Babekir, Amani: Any additional thoughts or comments - and how do you feel about the length of the document? How many pages do we have, Michelle?

Michelle Hill: It's 19 pages in length, but we have to consider the fact that the final three or four pages, I believe 4 pages are posters - the cover page also wouldn't necessarily need to be always printed, so that would bring us down to 15 pages of actual framework.

Babekir, Amani: It's good. And we're gonna have the definition sections. So one of the ideas is are we going to have the introduction and then the definition section. The idea is do we need to put it in the front of the document or as an appendix? The end of the document - what are your thoughts on this? We're going to have around 15 Definitions. Do you think it's best to put it at the beginning or the end of the document as an appendix?

Michelle Hill: I typically see things like that defined ahead of time, but that's just me.

Goddard, Vy (VDH): I agree. I think up front would be great.

Babekir, Amani: At the beginning.

Michelle Hill: What I'm hearing is we would have an introduction page basically saying what we're doing, why we're doing it and then right after that the definitions, Correct?

Babekir, Amani: Yeah, that's correct. Yes, Scott.

Vinson, Scott: Normally I would agree. But in this instance, given our audience, and given the length of this document, I think having an introduction that is concise but approachable and maybe friendly and folksy in tone will be very good. But, then to have that

immediately followed by a lengthy definition section, I think it's going to be off putting if a person who's running a restaurant who's already stressed out, is immediately confronted with a very lengthy document like this, and then it has a page or two of definitions. They're going to - their eyes will glaze over and they'll just stop. So I would get right into the meat of the stuff first, and put the definitions at the end or in some other section. But to immediately start confronting people with a document that looks very technical in nature is going to be off putting.

Michelle Hill: To that, Scott, would it make more sense for us to call out the definitions as we flow through the document or would you just recommend that we have it be at the end and people can reference them as needed?

Vinson, Scott: Well, that's a good idea. Maybe having it woven in - maybe each time the word is used then you just put the definition in parentheses after it. Maybe that would be a better approach depending upon how long the definitions are.

Goddard, Vy (VDH): If I find a word no, I wanna be able to go to the beginning of the end and find that and not have to look through the documents and find the one place definition might be.

James O'Neal: Well, and we can continue this part of the conversation, I had a thought about the training piece. So however you wanna do that?

Babekir, Amani: Thank you, Jim.

Thoma,Libby: I agree with Scott - when we write our technical documents for our audiences, both in manufacturing and in our retail world, we put the definitions at the end. So let's just kind of a standard way that we do it in retail.

Babekir, Amani: Thank you. David?

davidread2861: I agree with that. I think it should be more like a glossary than maybe even calling it definitions. And that would be at the end.

Green, Jennifer - FSIS: At the end would be a good.

Babekir, Amani: Thank you. So the group of the template Ben - Ben you are the leader of the group. That correct? I don't have the list in front of me now.

Ben.Wagner: Yes, I am.

Babekir, Amani: Would you take the burden of Putting the document together and having. The option, it seems like we are leaning into putting the definitions by the end of the document, but it's hard to tell. Would you like to take the burden of Deciding on that with the team When you are working on the document, so you bring it here to our meeting and they could vote on it if they wanted this way or not.

Ben.Wagner: That works.

Babekir, Amani: Thank you.

Babekir, Amani: Yes, James.

James O'Neal: Looking at the training, it looks like a lot of it is a certain set of basic information that would be applicable to anybody that works there. Am I reading that correctly?

Michelle Hill: Absolutely, yes.

James O'Neal: And so just a thought. Would it be a good idea to say this is a training for anyone who works within the restaurant and then have it broken down into specific training for back of house front of house so it's not? I mean, it's really important, but it kind of looks repetitive. If I were to pick up this document and read through it the first time.

Babekir, Amani: Yes. Thank you - we could add a note, then we could refer it to the training subgroup to look into it.

Michelle Hill: If I can capture the essence - State that this is training for all who handle the food. Break out training.

James O'Neal: Yes, bullet Point C - list the major food allergies. It's the same for all of them. So if you could have just a section where kind of a general training and then if there's anything different for a backup House employee that they would need to know kind of the gist of what I was looking at.

Babekir, Amani: That's good.

Michelle Hill: I see. So we could say this is for instance, we could talk about there being general knowledge that everybody should have. And then specific knowledge of the job duty. Is that right?

James O'Neal: Yeah, exactly. Yeah.

Michelle Hill: I think that's a really good suggestion. I too found it repetitive. But I think that the intent here- I'm not on this subcommittee, so correct me if I'm wrong - the intent here was to be specific about what each segment of duties these people need, what they need to know to do their job correctly, as far as allergen control.

Goddard, Vy (VDH): Yeah, yeah, that was the intent. And there was like, if it were gonna be separated out, then they would have all the parts - we can talk about it within our group.

Michelle Hill: Yes, that's a good place for that, yes.

Babekir, Amani: It's good. Any further suggestions? I'm going to send out this document. Michelle, could you please send it out to the whole team members?

Michelle Hill: Yes.

Babekir, Amani: Please feel free to work with your subgroup on your section and just address the comments or anything that's added in the document. And we are gonna work on the definitions. And also if you are not even a member of any of the subgroups, if you have any additional thoughts, please send it to us. I'm going to give it like 2 weeks before we send the document to Ben. So if you feel like the change needs to be addressed by the template team, you could leave it and just leave a note - and they will handle it. Yes, Scott.

Vinson, Scott: Amani so now that the document is consolidated into one, is the work of the individual subgroups completed and we no longer need to have our subgroup meetings.

Babekir, Amani: Yes, I am going to send it to you. So we are still gonna have - from now and then - some meetings because it's gonna be a continuous process of editing the document. And I don't like to do all the work just in our general meeting. Just probably the subgroups will be better. To focus on each section individually and make the changes needed. I would say for example when I send out the documents, you probably need to call a meeting with your subgroup members to just go over the comments which are placed in your section.

Vinson, Scott: OK, alright. So someone will either Michelle or you will be sending this out to everyone and then the subgroup chairs should look at our sections and address any comments made in our section.

Babekir, Amani: That is correct. I would expect to receive four versions of the document - one from each subgroup after they address the comments that were placed on the document.

Vinson, Scott: OK.

Babekir, Amani: Within two weeks before our next meeting.

Michelle Hill: If I may mention - it might be useful - don't just spend time on your own section. It's very important that that section be right of course, to your subgroups liking, but comments are also welcome throughout the document, especially if you feel like it would add to the clarity and the conciseness of the information as it's presented.

Meeting Adjourned - Next meeting is April 28, 2022.

Babekir, Amani :That's correct, yeah. So any additional points or suggestions before we conclude our meeting today. So thank you everyone for joining us today. Have a very nice rest of the day.

Meeting Number 13	Meeting Date **04/28/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Jo DeFrancesco/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Framework Points	Amani Babekir
vi.	Previous Meeting Minutes	Amani Babekir
vii.	Adjournment	Michelle Hill

MEETING MINUTES

Meeting Call to Order

Amani Babekir: This meeting will now come to order. Michelle could you please take the roll call and see if we have quorum?

Roll Call

Michelle Hill: [takes roll call of voting members]. Madame chair, we have a quorum.

Scribe – Michelle Hill agreed to take notes that will be verified via transcript issued by Teams.

This meeting is now being recorded.

CFP Antitrust Statement

Amani Babekir: I'll just remind you the conference for food protection antitrust statement is active in this call, so just keep that in mind and for your reference, it's attached to all our meeting invitations.

Framework Points

Amani Babekir: The first topic here we wanted to discuss is the draft of the Equal Consideration Section. They really took their time to write down this draft and I would like to get your opinion on it and see if we need to make any changes to it before we add it to the framework draft. I'm going to share my screen and if you have an issue following on the screen – you could open the documents I sent out. Can you see my screen?

Michelle Hill: Yes.

Amani Babekir: You can see here the documents – Vy is not able to join us today for this meeting, but you could provide your comments about this document. Please let anyone into the meeting as I'm not able to do that while I'm sharing my screen.

First, a summary about the allergens. And then in the knowledge section, just pointing out the sections we have in the framework. Here's handling the cross contact. And then food preparation and understanding the label - it's More like a generic thing, but that which could be used in food pantries and food banks. Just open it for your discussions if you have any comments. Any suggestions? And do you think this is sufficient to meet the charge? Consider this section: Equal Consideration

Devin Dutilly: Thank you again for welcoming me and thank you for all the hard work that everybody has put into this document and all the other work. I really appreciate it. And I think everybody on the call does as well. Could you just give a little background for the equal consideration in this document and how it's going to fit in with the rest of the framework?

Amani Babekir: I can - let me share the charges.

Devin Dutilly: Yeah, that would be great. Thank you very much, Amani.

Amani Babekir: Here is the first charge which is talking about developing a framework for the food facility and they said that they needed to consider several points and one of these points is F. And on that one, it says equal considerations for alternate food sources such as food pantries, food banks to ensure equity and access. And during our initial discussions, we felt like we needed separate subgroups to develop contents for each point. But for this one, one or two of us could just compile a couple of graphs and couple of sentences that will address these equal considerations.

Erin Moritz: If I'm remembering correctly, the purpose of subsection F was really to make sure that what we end up submitting is helpful not just for retail food establishments, but for also these other kinds of establishments. Is that correct, Amani?

Amani Babekir: That is what I understood, yeah.

Erin Moritz: Through the lens of knowing that a food pantry or a food bank might experience additional challenges beyond what a retail food establishment experiences or maybe just different challenges, not necessarily more.

Amani Babekir: Any additional point about the understanding of the f part of the charge?

Devin Dutilly: That's helpful. Thank you.

Amani Babekir: Based on this we felt the need to have just a separate minor section that addresses these facilities.

Devin Dutilly: If we go back to the definitions that we used, and if we do choose to use the definition from the food Code on food establishments, the facilities that are mentioned above would be encompassed in that definition. It depends on the definition this document chooses to go with, but if we are using the food code definition, the FDA would likely have comments on that, making a distinction between this type of establishment having different needs than another type of establishment. Although there is a distinction between the establishments I think when it comes to the requirements within the food code, the requirements would hold for both of those types of establishments because they all fall underneath through establishment, and if we could apply it to all food establishments So I don't think there's an objection to creating this, but just a just as a note, the food code covers to all of these, and so anything that would apply to one would also apply to the other.

Amani Babekir: And it seems from the developed draft here, most of the components refer to specific pages of the framework which we already developed, so other than understanding labels, seems like this is a different section here. Do we think that when it comes into the preparation and the training and knowledge and handling, the cross contact, do we need a section, a separate section? What are the equal considerations?

Ben Wagner: I'm not sure that we do. Looking at this - the understanding labels - is that to train the staff members to understand labels and if so, would we not use that elsewhere for retail food establishments to understand the labels of their ingredients? I don't know. To me this seems like we're reiterating, just to reiterate. Is there anything in here that is novel to food pantries, food banks, etcetera?

Erin Moritz: I think when we very first started discussing this, two of the main points were, just concerns, maybe additional difficulty communicating with the patrons, and then also having volunteers who maybe have less of a background in food safety. Someone will have to remind me if there were other concerns. I think what we have probably covers it technically, but I'm wondering if It may be good to call out those considerations at the beginning of this particular document, and I like the idea of pointing out specifically where they can go in the document to address those issues. And I don't - is there anybody from the group who worked on this document on the call?

Amani Babekir: We don't have an actual subgroup for this part of the charge.

Erin Moritz: OK.

Amani Babekir: I think there was Jennifer with her, but we couldn't recognize which Jennifer. Not sure if there is anyone who volunteers on that subgroup or that team …

Erin Moritz: It'd be interesting to me to see if she found some sort of resources pointing out specifically additional or different challenges within the food banks, and maybe there's not, but if there are additional or different challenges than it may be worth pointing those out at the beginning of this section

Amani Babekir: OK. Any additional points on this?

Ben Wagner: It's minor, but where it says for food is prepared on site I would say for foods prepared or repackaged on site.

Erin Moritz: Yes. This reminds me - that was another comment made way back - that a lot of these types of facilities will have a package of crackers or something that they'll open and repackage for distribution.

Crystal Eisner: Understanding labels from manufacturers of packaged food. And then are required by that too -

Amani Babekir: OK. And do you think understanding the label is it an important piece to add to our framework – should be considering adding it to the whole framework? Seems like it's ...

Crystal Eisner: It's general information. I think it's good to understand the label. As far as may contain or production facility – this is maybe, overall concern, not just this area - is this anywhere in our framework?

Amani Babekir: Yes - it's not. I don't think we have detailed information about understanding the labels.

Erin Moritz: I think if we did want to keep the section, we'd have to tie it back to specific challenges in in food banks or food pantries.

Amani Babekir: But would it be worth adding it to the whole document? Especially this program just understanding the labels?

Crystal Eisner: Alright.

Erin Moritz: I do like the that bullet. Eat all that differentiates. Contains versus may contain. I think that's worth putting in the main body of the document

Crystal Eisner: And just like the common allergies can have other names, for example. But for the dairy, the casein and so forth, unfortunately, we had a little girl where my daughter goes to school. Her grandmother bought her something online - juice that said dairy free, but it can't contain casein - and she actually passed away from a severe allergy. Yes, I think that's a good. Sorry, I haven't gone through all the bullets, but if we have not stated that elsewhere, I think that it is a good idea to.

Amani Babekir: OK.

Michelle Hill: I just wanted to mention I'm back finally. FYI and, if you were speaking about casein being listed, I'm all for it. It's necessary

Amani Babekir: That's good.

Devin Dutilly: And just as a general comment - we would, the cautionary, the PALs, the cautionary allergen labeling that is listed here - this is not something that we have issued a specific guidance on. It's not something that we would comment on or you use it, something that could be in lieu of good manufacturing practices or cleaning sanitation practices within a retail establishment Thank you.

Amani Babekir: Thank you.

Erin Moritz: I'm wondering if it's worth adding something? Another bullet, - something to the extent that Devin just said, note that simply saying something may contain an allergen is not an acceptable alternative when trying prevent cross contact.

Ben Wagner: So, was the concern that a food shelf would be labeling something themselves? Is that the concern?

Erin Moritz: I just don't know enough about food pantries and food banks to really know the best content for this section.

Devin Dutilly: We have a representative on the call here that is part of one of those groups or a represents one of those groups, I think Vincent, Scott - he represents a lot of large facilities - is he on the call? I think he had some comments about other groups he represents and I think you captured a lot of different groups that are in his organization as he happened to be on the call.

Amani Babekir: He's not able to attend.

Devin Dutilly: Probably valuable. OK. Any anybody else who represents those groups or have a large of volume?

Michelle Hill: I can speak from a person that's worked in the food bank before and it's not that we would label necessarily on the shelf that something has an allergen, but we would definitely be wanting to help assist them to determine if a packaged food did. And in this case, I believe we're talking to the presence of casein and not dairy or not lactose. You know, understanding what the true allergen is. And I think that's what we're trying to get at here is that. Does that answer part of your question?

Ben Wagner: I think quite honestly, we're all over the board on this. There's been comments about the fact that it may contain statement does not give a production facility a get out of jail free card for doing proper GMP, which production facilities understand. I don't know if food shelves do - I don't know if food shelves – that if they break something down and repack it, put their own labels on it or not. I think this is good information for anybody working in the Food service side of things, whether it's a food bank or a restaurant. Well, the question is, Is this information good information that should be for anybody reading the document and then we can refer back to it when we're talking to food service or not food banks specifically, or this equal considerations portion? Specifically.

I have an additional question. The bolded statement above – The understanding labels says have a staff member that's knowledgeable about allergens. Review the ingredients on the label with the customer to ensure … You wouldn't expect somebody to do that in a grocery store? Would you expect somebody to do that in a food bank?

Amani Babekir: OK, so I'm going to highlight this section here to discuss it later. Michelle, would you like to proceed - if there is any extra discussion on this and then move to voting on approving the Minutes.

Michelle Hill: Absolutely. I'd be happy to, Madam Chair.

Amani Babekir: OK, so please continue the discussion if there are any extra points regarding this part. And just to give you an update about the framework right now, we are in the process of sending it out to the template team and the target date is May 4 - we will compile it send it to the template team after we review it with the ServSafe comments.

Michelle Hill: Thank you, Amani. One quick question, Amani, what we have remaining then is to decide about this document, as far as closing discussion, and then voting on the previous two meeting minutes and then we adjourn.

Amani Babekir: That's correct, yes.

Previous Meeting Minutes

Michelle Hill: What is the will of the people present here? Would you like to continue the discussion on this document? I'd like to entertain a motion to either continue to discuss or to table it until we have more information about this particular section.

Ben Wagner: I put out a motion to table it until we have more information.

Michelle Hill: Thank you. Ben, do I have a second?

Darby Greco: This is Darby. I'll second that.

Michelle Hill: Thank you, Darby, so noted. We will reach out to Vy, and perhaps the next time we come around to this, we'll have her on the call. Thank you for your patience on this, everyone. I apologize for my absence from the meeting. I don't really know what happened, but that's what the transcript is for, right? At this point, if you could please pull up, and if need be, review the minutes from the previous two meetings. We had a request to make a correction to the document. What we would like to do now is take a moment to review those and then we'll come back. And I'd like a motion to be made possibly for us to approve those minutes as they appear or whatever discussion needs to ensue about the Minutes. So let's take 2 minutes to review those documents and hopefully everybody got them – Amani sent them out pre meeting.

Michelle Hill: The meetings that the Minutes that we need to approve start on page 33, this is meeting number 11 and it was held on March 31st and there were edits. There were a couple words that were edited, and corrections made. We were asked to hold off on approving these minutes until people could see those updates. And so that's what this document is. It runs through page 40.

Michelle Hill: And then the next set that we need to approve are from the meeting we had two weeks ago, April 14th, and this is the first time we were attempting to approve these minutes. they're quite long. These meaning there's got to page 49, 41 to 49. When you feel comfortable, if you'd like to make a motion to either table or to approve or whatever …

Ben Wagner: I motioned to accept both sets of the meeting minutes

Michelle Hill: Thank you, Ben.

Ben Wagner: As written.

Michelle Hill: So noted. Thank you, Ben.

Crystal Eisner: Then what was your motion? Sorry, I missed it – was reading.

Ben Wagner: I was moving to accept both sets of meeting minutes as written

Crystal Eisner: I second that.

Michelle Hill: Crystal, Ben, thank you. We have a motion on the floor if you would like to vote.

Michelle Hill: Unless I see or hear a number or an abstain. I will say that this motion passes to approve minutes. From both meetings as written Alright, I appreciate that. Thank you so much.

Meeting Adjourned

Michelle Hill: As usual, you guys are a great team. I really enjoy being part of this committee and I'm really very pleased to see the level of attendance at today's meeting and I look forward to seeing everybody again in the next two weeks when we meet again. Please feel free to reach out with any questions, comments, and concerns, and when you do send communication, please make sure you include both Amani and I on that email message If there's nothing else, I would like to adjourn this meeting.

Next Meeting set for Thursday, May 12, 2022.

Erin Moritz: Hey, thanks everyone!

Meeting Number	Meeting Date		Meeting Time
14	**05/12/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

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vi.	Previous Meeting Minutes	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Meeting Call to Order

Babekir, Amani: I now call this meeting to order. I will proceed with the roll call.

Roll Call

Babekir, Amani: [takes roll call of voting members] Let me count – So we have 8, missing one for the quorum.

Hill, Michelle: I see a Wendy Bell on the call - do we know you? I'm sorry. I don't mean to be rude. I don't recognize your name.

Bell, Wendy: Hi yes, I don't know if you saw Courtney's email, but I was moved into the vice chair role.

Hill, Michelle: Oh! Welcome!

Babekir, Amani: Welcome to the Committee, Wendy, we're glad to have you with us.

Hill, Michelle: Can we count her towards our quorum?

Babekir, Amani: Yeah, I don't think so. I wish we could do that.

Bell, Wendy: No, no.

Babekir, Amani: We can proceed with the with the agenda and then by the end of the meeting, if we have a quorum, Michelle if you see voting Members waiting to join our meeting that might help meet our quorum.

Hill, Michelle: Good.

Scribe – Michelle Hill agreed to take notes that will be verified via transcript issued by Teams.

This meeting is now being recorded.

CFP Antitrust Statement

Babekir, Amani: Thank you. And just I would like to remind you that the Conference for Food Protection Antitrust statement is active in this call. So just please keep that in mind during the discussions and the activity in this call.

Framework Points

Babekir, Amani: The next thing here in our agenda is to give you an update about the framework.

Babekir, Amani: I sent out the framework to the templates team along with the definitions, and I am so glad that we have Ben us today. I wasn't able to join the initial meeting, so hopefully Ben will be able to give us an update of the progress.

Wagner, Ben: You want that now, OK. So the team has met, we took the three documents that were provided by the larger committee.

The main framework, the definitions and the additional thoughts for food banks, etcetera. Sorry, I'm not thinking of the official titles. Anyway. We started to put everything together. We're going to place the definitions at the end of the document. We are currently working with pulling information throughout the document for the purpose and scope of the overall document as well as an introductory paragraph to the rest of the work.

We'll continue to meet on this about once a week through the rest of the month and then we're hoping to have some progress that we can show back to the group.

Babekir, Amani: Do you have any questions or do you need any extra volunteers to help with the work?

Wagner, Ben: I feel like the group that we have is pretty good. We will probably be bringing things, as we as we look at what we can clean up in the document, one thing that we did note is that nine major allergens are listed repeatedly throughout the document. Now we are thinking we can make the document shorter by having that laid out in the beginning of the document and then referencing back to it.

But we wanted to bring that to the various groups that had created their portions just to verify that they are with that they didn't have a reason for calling them out again in full list.

Babekir, Amani: Thank you. Thank you, Ben. There is any questions or comments to them?

Babekir, Amani: We can proceed to the next item on the agenda, which is the equal considerations document.

I know in our previous meeting we did not complete the discussion on this topic; we wanted to get more information from Vy Truong.

The information she gathered on the document – if she sees something that is different than the larger scope of the document we created, which related to them Equal consideration and the food banks. So that is one of the questions we had for you. What's your thought on it?

Truong, Vy (VDH): Hi - I tried to skim through the meeting notes right beforehand and I see that you guys made some good suggestions. Thank you. I don't have a lot to add, I'm not actually very familiar with food banks. I just wanted to make sure that this topic wasn't dropped, so I volunteered to get something drafted. And yeah, I noticed that I do reference the document a lot because I didn't want to be repetitive and so I felt like the only new thing to really add would be reading labels - however you guys want to incorporate that.

And I was thinking that for food banks, they might not want to read the whole document depending on how long it ends up being - that maybe they could pull just that portion.

I guess I'm still not sure exactly how the framework's going to end up working at the end; if it'll be like pullable sections like that could just be dedicated to other types of food service, or food banks for example, and they could pull those couple of pages and not have to sort through everything. So however, you guys want to put it together in the final stages of this, is perfectly fine with me. I'm not committed to anything in particular. I do think that some food banks prepare food on site, so a lot of the stuff that we had already created was great for that. And then the only new thing I thought that was really important was to understand those labels. So, if you guys have suggestions on rewording that or things that take away or add, feel free to do whatever you guys want with that draft.

Babekir, Amani: Thank you. Michelle collected very good suggestions about this section – Michelle?

Hill, Michelle: Thank you, Amani. I have a compatriot here in Minnesota - his name is John Carrillo, and he just retired from Aramark. He's been in food for a long time. He's been dealing with food banks in and out throughout his career. I did just speak with him briefly about what we had in our framework. And he responded very nicely to me. He pointed out that the best time to give allergen information would be when the person is picking up their food and it could be as simple as a slip of paper mentioning that the food they're received may or can contain food allergens, and that it may cause an allergic response, and again that could be based on what's in the actual container or box or bag, whatever they're collecting it in. In particular he deals with Second Harvest, which is a big outfit here locally. I don't know. I think their nationwide, but he says that they as an entity, they do a good job letting volunteers who sign up for corporate community days or general volunteering, where they pack bulk foods, they repack bulk foods. They're very open about the fact that they may contain allergens and ask people that have known allergens to do something else, so they enforce strict hand washing. They change aprons and gloves between tasks. People who may have an allergic reaction are given tasks away from handling that bulk food. So the big piece that I think we may want to add to this would be like what Vy said, maybe it's a simple sheet of paper that would tell them real quick. These are the allergens in your box. I don't know. Maybe that's too specific, but that's the feedback I got. I know it's one person, but that's what I have. Thank you.

Babekir, Amani: Thank you, Michelle. Any comments from the team?

Truong, Vy (VDH): Yeah, I think that that's great, because if we make it too complicated, it's just going to get lost. Some sort of handout? And I don't know how to do that because food banks are so varied. If it is one sheet of paper - should we list all the allergens? Because, it's not going to be able to be specific to a box because we don't know what is going to be in each of the boxes. I'm not really sure I haven't handle that.

Hill, Michelle: If I may - what he suggested - it would be as simple as, we provide them the nine allergens like as a grid and they would just check the box if they know that there's a known allergen. And so it would be really be a simple sheet that would say, here's the nine allergens check which ones are present and maybe even a half sheet that they just throw in the box and say be aware. That doesn't have to be what it is, but that's what he recommended.

Truong, Vy (VDH): I think that's a really good idea, but it's also really important to remember that some food banks like his are really big and really well organized, and some are a lot smaller. And what if they miss one of the allergens? Just because they're not aware, that could be pretty dangerous if someone was like, oh, there's no wheat, and there is.

So, I don't know somehow whatever we create, just making sure that we address - maybe giving them a checklist, but also addressing that there could be unknown allergens.

Hill, Michelle: I think that's excellent - that they, we, would note that the other thing he said is that when they do break out the bulk food, if it is allergy, they label it for allergens and again, like you're saying, this is Second Harvest, so big dog, but it's good advice.

Babekir, Amani: So are we good with having a section for the equal consideration in the Framework?

Wagner, Ben: I feel like it it's a good idea.

Hill, Michelle: I do too, yes.

Truong, Vy (VDH): I agree.

Babekir, Amani: Ben, would you like to take the effort of adding this section , with your team, to the framework?

Wagner, Ben: I think we already had decided that we were going to do something like that. Yes, with the information that we already have, plus if we get any other Experts that we can talk to that might have further information we want to incorporate and then we can bring that back to the larger group to approve.

Babekir, Amani: OK. Vy, would you like to join to join these efforts?

Truong, Vy (VDH): Sure ,I can. Or, if you just need anything from me, just feel free to reach out.

Wagner, Ben: I think we'll reach out if we need you. How's that sound?

Truong, Vy (VDH): Sounds perfect.

Babekir, Amani: That sounds good. Thank you very much

Babekir, Amani: Michelle, you could forward those comments to Ben so he will have it in his records?

Hill, Michelle: Yes, I am also on the template committee with Ben. So yes, will do.

Previous Meeting Minutes

Babekir, Amani: I think that is all the items I have in the agenda today. We are going to postpone the voting for approving the Minutes until our next meeting. Are there any additional thoughts or questions about the progress of the work, or any other thing?

Hill, Michelle: Amani, if I may - please take the time to review the meeting minutes and if you do have changes let me know prior to our next meeting and we can get those put in so that we can approve, you know have an easier time of approval if there are needed changes.

Meeting Adjourned

Babekir, Amani: OK. I think that's it. We made a very good progress and I think we're going to make our deadline, which is the end of this month, so we can send it out for the FDA to review, and hopefully by July we'll have our framework complete, and then we will proceed with what suggestions we have for changes to the Annex to the FDA Model Food Code. Thank you everyone. Hopefully see you in our next meeting. Next Meeting is set for Thursday, May 26, 2022.

Meeting Number	Meeting Date		Meeting Time
15	**06/09/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Call to Order

Babekir, Amani: This meeting will now come to order. Michelle, would you like to do the roll call today.

Roll Call

Michelle Hill (Co-Chair): Certainly. Thank you. Madam Chair, we have a quorum of nine.

CFP Antitrust Statement

Babekir, Amani: OK, that's great. Thank you, Michelle. We just want to remind you that the Conference for Food Protection antitrust statement is active during this call, so let's just keep it in mind and we can proceed to the first item in the agenda, which is approving the last meetings minutes.

Previous Meeting Minutes

Michelle Hill (Co-Chair): Madam Chair, I cancelled the May 26th meeting we would have had two weeks ago because it was the day before Memorial Day weekend, and it was not a date that was listed on our master schedule. Today we need to approve two sets of previous meeting minutes.

Babekir, Amani: Two sets, OK.

Michelle Hill (Co-Chair): I do believe so, as we did not have quorum for the most-recently held meeting, and we couldn't vote on the previous meeting because there had been edits to that set of minutes that needed to be reviewed and approved.

Babekir, Amani: OK. Thank you, Michelle, for reminding us of this. Let's review the last two sets of meeting minutes as part of the documents which I sent out yesterday. I will give it 2 minutes so you can go over it before we vote.

Michelle Hill (Co-Chair): Madam Chair, just for clarity's sake, we will be voting on minutes from the meeting from April 28th meeting #13, which beings on page 47. The second set of meeting minutes is for the May 12th meeting #14, begin on page 53.

Babekir, Amani: Thank you, Michelle. OK. I will entertain a motion regarding the minutes of the last two meetings.

Michelle Hill (Co-Chair): Madam Chair, shall we entertain a motion for just the meeting minutes from April 28th to start?

Babekir, Amani: OK, let's do that.

Ben.Wagner: This is Ben. I motion to approve the meeting minutes from April 28th. Thank you.

Michelle Hill (Co-Chair): So noted. Thank you, Ben.

James O'Neal: And this is James. I'll second the motion.

Michelle Hill (Co-Chair): Thank you, James O'Neal, so noted.

Babekir, Amani: Thank you. Is there any discussion on the Minutes, any questions? No? Let's proceed to the vote on the motion. Is there anyone opposed to the motion? Please raise your hand. Do we have anyone abstaining? The motion passes to accept the Minutes as is. Thank you. So now I will entertain a motion regarding the minutes of the last meeting.

Ben.Wagner: This is Ben again. I move to approve the meeting minutes from the last meeting.

Michelle Hill (Co-Chair): Thank you, Ben, so noted. The meeting date is May 12th that we're speaking about.

Vinson, Scott: I second the motion.

Babekir, Amani: Thank you, Scott.

Michelle Hill (Co-Chair): So noted.

Babekir, Amani: Is there any discussion on the Minutes? Any questions? Thank you. Let's proceed to the vote on the motion. Is there anyone opposed to the motion? Please say no or raise your hand. Do we have anyone abstaining? The motion passes.

Framework Points

Babekir, Amani: OK, so now we will move to the second agenda item. I would like first to start by thanking the template team. They put together the framework, the different sections in just one document and they went over it and investigated creating additional sections, like the Introduction and the Table of Contents.

Devin Dutilly (FDA) is going to lead the comments regarding reviewing this document. He will have an internal review of the document and we are hoping that we're going to get FDAs comments by July 15. I'm going to give the floor to Ben, and all of you, to discuss the framework piece by piece. But I would like to bring up to you one of the suggestions which I received. Amber suggested that the document is very long. It might be very useful to small restaurants. And we probably need to create a kind of handout or more concise document than this one.

So first we want to discuss this point before we go into discussing all the sections of the unified document. What do you think about this suggestion? Yes, Michelle.

Michelle Hill (Co-Chair): Thank you, Madam Chair. I think it's an incredibly good point. I personally would recommend that we keep our long document but develop something that maybe is a single sided or a double-sided sheet of paper and perhaps it's as simple as we have a nice set of icons or pictographic representation of symptoms of allergy, as well as icons for representing allergens. Thank you.

Babekir, Amani: Thank you, Michelle. Yes, Erin?

Mortiz, Erin: I'm a big fan of more pictures and fewer words. Before we get started on that, it would be good to formalize what perspective we want this document to be from. We kind of ran into some of this when we were formatting it, but right now I think it's sort of written as an educational document. In some sections I think the original idea was to make it a template that an establishment could either print out or use or fill in their own information if they wanted to do something different than what's already in the document. And I think some sections are a very high-level list of, we should be including this in an establishment's plan. I think nailing down what perspective we're coming from and exactly how we want the establishments to be able to use this. We might want to establish that first before we do anything else.

Babekir, Amani: Thank you. Yes, Amber?

Amber Potts: Hello. So let me explain what I'm meaning. I like the framework and I think we should keep that document, but in addition, a smaller like pamphlet-type thing and I'll show you something I did to give you a visual, but just from experience – for the majority of small businesses, English isn't the first language. These second-language speakers may have a very difficult time implementing this or even understanding it.

Just even personally, I got about 14 pages in, and I had to stop and do something else, then come back to it because it's just a lot of information. I do think that the document could be trimmed down a little bit. I think there's some repetitive spots. Can I share my screen and give you an example of what I was thinking about?

Babekir, Amani: Yes, please.

Amber Potts: OK, so you may have seen these business plan type things, but just a quick flip through pamphlet of what this document says on a high level, of course, this isn't the final one, but I put together a flip book.

We could list everything here. You could see the major food allergens, and then some of them I put like casein for milk, and stuff like that.

Kind of just a more fun document, I guess to read and something that maybe is more digestible and could be easily translated into another language.

Babekir, Amani: Thank you. Yes, Scott?

Vinson, Scott: I think that's a neat and generous offer. I think it would be useful to some of the smaller establishments than even not so small. If Amber is generous enough to make the offer to create something like that, I would be in support of it.

Babekir, Amani: Thank you, Scott. Yes, Michelle?

Michelle Hill (Co-Chair): I think it's a great idea and it's I like the idea of it kind of pulling it out of being such a formal, serious presentation, not that it's not serious, but kind of like fun facts. You know, so really neat! Is that a template, Amber, that you developed that we could just plug into?

Amber Potts: Yeah. So here at NEHA and personally I use Canva. It's a website that they give you templates and then you just plug and play.

This was the one I found. It was in red. I turned it all into purple because I felt like that was food allergy, and then it popped up yellow to kind of bring attention to certain areas. Once the framework is more finalized and more final, I can basically plug and play on this document, and then send it over for review, definitely. By December this is doable, sure.

Mortiz, Erin: The goal for, we'll call it Amber's document, may be just for ease, especially like smaller establishments. Print it out and have it as a resource without doing anything to it. Is that kind of the goal with that?

Amber Potts: Yeah, that that was my goal.

Mortiz, Erin: OK.

Amber Potts: And then not necessarily even printing. It could be something digital. People could have easy access to.

Mortiz, Erin: Sure. OK.

Amber Potts: What is the access? It would be nice if we could have it translated into other languages – that would be pretty neat too.

Mortiz, Erin: Definitely agree.

Babekir, Amani: Right, thank you. And Amber, do you think you're going to need any help at any point?

Do you need an extra volunteer with you? Or you could handle it by yourself.

Amber Potts: Yeah, it would be nice to have one other person to kind of go back and forth with.

Babekir, Amani: OK.

Amber Potts: I'm not sure how to give them access into the NEHA Canva account, but it's as simple as me downloading it and doing it that way is fine too. It's going to be really relatively simple for me to just basically copying and pasting what's already in the framework. I'm not adding anything. And then Canva has a wide variety of stock photos to use, and then of course if we have any photos we could put in there, but just someone else to look at it and make sure I didn’t install anything wrong or miss copy or anything like that would be nice.

Babekir, Amani: That is cool. Yes, Scott.

Vinson, Scott: I'm happy to help with that Amber, if you like.

Amber Potts: Oh yeah, sure.

Babekir, Amani: Those great thank you, Scott. OK. Yes, Michelle.

Michelle Hill (Co-Chair): And if you wouldn't mind having a third, I am happy to help out with that as well.

Amber Potts: Yes, awesome.

Babekir, Amani: Thank you, Michelle. So that's great. We can proceed with working on our original documents and while Amber is getting ready to prepare her template for the other document and also, I think beside Amber's document, if we feel down the road, that we might need to add extra handout. Any additional documents also feel free to suggest as we could add it as an attachment to our original document.

I think now we could proceed to the second point in our agenda, which is reviewing the framework draft. Ben, would you like to lead this one?

Ben.Wagner: If you wish, so is the expectation that we're going to go through and make comments as a group or just an overview, or what are we looking for here?

Babekir, Amani: Yeah, if you could walk us through the changes you made to the document and if you have any comments or question or suggestion about a specific section, feel free to ask it to the team and then to discuss it, and then proceed to the second point on the document.

Ben.Wagner: High level, we did put a table of contents together for the document. We also put together an introduction section with a purpose and scope for the entire document.

This symbol means that there's an image available within the document that can be used. And then it goes immediately into the various sections for the charges we were given. The only changes we tried to do is to put a purpose in where it seemed appropriate. Other than that, not much has changed. I guess I was hoping the larger group would take a look at the overall flow of the document and see if, once again, like we've mentioned, if it's too wordy in spots, or if it seems not wordy enough in other spots. I don't have all the mark-up language showing here just because it is really chaotic. When you show all the markup, but the data is still there. If you want to look on Word for what markup is happened. Some of these notes that remain from me could probably be deleted. I didn't realize this version was going to go out to the whole group immediately without those being deleted. I don't have much else to say at this point, except at the bottom of the entire document we get into a short paragraph about equal consideration for alternative community food sources. I don't know if that needs to be beefed up. I would love for that group to look at this and make suggestions as to how that can be edited or changed or added to a lot of the information we were originally provided was also provided elsewhere in the documents. We kind of referred back to that. And we actually included it in another section. There was a part about reading labels. And we included that in a previous section where we thought it would fit. If that doesn't work for the entire group, please speak out. We have this Definitions Section. And then we go down to references and these were just references pulled from the various sections and concatenated, and I tried to put them in. A format that I thought looked appropriate once again, not an expert at that, so somebody else wants to take a crack at it, feel free. I'm open to any feedback people have. If you just want to let me know where you want me to focus on the document while I'm sharing, or I can stop sharing my screen.

Babekir, Amani: Thank you, Ben. Yes, Scott.

Vinson, Scott: It's been a while since I've looked at this document and now, I'm looking at it with fresh eyes again and in the food handling policies and practices section starting on page.

6, scroll down to page 7. There's a section at the top under 22D, I guess it's just new section D use ingredients that have been designated as allergen free on their packages, or otherwise determined to be safe for allergen free meals. So, in looking at this section again, I'm wondering if that should be included. If the person is preparing, you know, food service workers, preparing someone's meal they're trying to exclude specific allergens that the customers told them they need to avoid. So, if we're directing the Food service worker to do what is written in line D, does that mean they're going to be maybe confused and exclude any type of allergen, even though the customer might not be allergic to that particular ingredient? The way this reads in section D, it looks like we're telling the food service worker to just make the food, free of every major food allergen. I'm not sure that's what we're intending to say here.

Abel, Greg: No, you're intending to say, uh, not to use the offending proteins for that particular order.

Vinson, Scott: Well, that's not what it says.

Abel, Greg: Yeah, we have to somehow fix that, I think.

Vinson, Scott: Yeah, because it makes it look like they're supposed to only use ingredients that are labeled allergen free.

Mortiz, Erin: And is there such a thing as allergen free?

Abel, Greg: No.

Michelle Hill (Co-Chair): No.

Abel, Greg A: Yeah, we don't want to be making up a term here that's doesn't exist.

Vinson, Scott: Yeah, I think that section is really confusing and is going to confuse food service workers.

Michelle Hill (Co-Chair): Can we just delete it? I mean because the next statement I think is pretty clear.

Vinson, Scott: Yeah, yeah. I think we should just delete it.

Mortiz, Erin: And just for reference, this you know sort of the formatting group. Our charge was not to actually look at content. It was more just to make it flow a little bit better.

Abel, Greg: I would recommend not removing it at this point, but rather maybe rewriting it, because I think that's an important piece - using correct ingredients. I'm trying to think of what would work better there.

Vinson, Scott: Just say something like don't put anything the customers are allergic to in the meal.

Abel, Greg: Right, or maybe something like ensuring ingredients do not contain …

Dutilly, Devin: You could put free. You could put free from.

Abel, Greg: Yeah, and certainly.

Ben.Wagner: So, does the group want to bring suggestions to Scott on how that could be altered? And then Scott, do you want to take that? And once you have something you think is sufficient, bring it back and we can insert it, and change it.

Vinson, Scott: Sure. But frankly, I don't think we need specific instructions because it's superfluous.

Michelle Hill (Co-Chair): I think so too. Brevity is our friend.

Vinson, Scott: Yeah, somebody's earlier in the call said that the documents too long. I don't know, but we should be looking at parts to omit.

Michelle Hill (Co-Chair): Or that are redundant or obvious.

Vinson, Scott: Yes.

Babekir, Amani: I think here this piece is about ingredients. Have we covered anything related to the ingredients in the upper sections? You could scroll up here.

Vinson, Scott: Yeah, but I mean, it's just common sense. They've been told to avoid a certain ingredient because the customer is allergic to it. They're not going to put that ingredient in the meal, and you don't need to write it out. This is common sense. It doesn't need to be set.

Michelle Hill (Co-Chair): Maybe the intention of the statement originally was that you make sure that the ingredient you're going to use doesn't have that allergen.

Mortiz, Erin: Yeah, I was going to say if, let's say you use you use like a store-bought salsa or something. That's kind of how I took the purpose of that particular statement, although I was confused by it as well. Do we say any place else in this section to check the ingredients of the ingredients, so to speak? Or let's say there's like a sauce that goes into a recipe you have the ingredients of the recipe, but then if there's a sauce that's premade or something you also need to make sure that this sauce does not have the food allergen in it as well.

Vinson, Scott: Ohh, I think I see what you're trying to get at. So, I think the issue here is processed foods. So, if the food preparer is using an ingredient that is processed and might have its own set of ingredients, they should check them too.

Michelle Hill (Co-Chair): Isn't it two or more ingredients you must label?

Abel, Greg: That's it - yes.

Thoma,Libby: Hi, this is Libby. I just want to say, as common sense as it seems to be, I do think we need to make a statement that says, don't put allergens in the food.

Michelle Hill (Co-Chair): Yes.

Susan Algeo: Great.

Thoma, Libby: Today I went to a Taco restaurant. I ordered a Taco that is described on their menu board as being prepared on a corn tortilla. And when it came to me, it was on a flour tortilla. So, I said this is on a flower tortilla and he goes, Yes, ma'am, it is. Do you want it on corn? And I said, I do because that's how it's described on your menu board.

And he was like, Oh, OK, well, we'll fix it. But they intentionally made it not according to their advertised. recipe. So as basic as that is, I do think we need to make sure that they are following their procedures, so that the customer isn't misled.

Abel, Greg: So, what you're saying there for D is ensuring the foods and ingredients used are free of that offending protein.

Michelle Hill (Co-Chair): Correct. I like that.

Susan Algeo: Yeah.

Dutilly, Devin: You might want to consider using a term like, unexpected sources of food allergens

Vinson, Scott: I just put something in the chat that's concise and to the point.

Babekir, Amani: Thank you. Any other suggestion or comments about this point? Ben, would you like to scroll up to the beginning of the document and then we could go over the comments with the team. See their suggestions – I left peoples because I thought maybe we just need to bring them here to the team and see if they have any additional thoughts.

If any of your comments are not needed, please delete.

Ben.Wagner: Is everybody happy with that phrasing of what the term Food Service employees?

Michelle Hill (Co-Chair): I would recommend food workers because then you're including people that are volunteering.

Vinson, Scott: I agree.

Susan Algeo: I think we talked about this before. Doesn't the Food Code define a food employee versus an employee, and food employee encompasses all that food service. I can check but I think that I mean the food could have the definition, so I just didn't know if we want to get confusing.

Michelle Hill (Co-Chair): No, that's an important point.

Babekir, Amani: What do we have in the definition section then? We have one. As in food service or food employ.

Susan Algeo: I was just looking at, didn't see we have food employee. It's food employee this food handler in there.

Babekir, Amani: So do we want to keep it food employee on the whole document?

Michelle Hill (Co-Chair): Could we add a definition that's food worker that combines the employee and handler ideas? Where were these pulled from? Is this from the food code from the Model Food code?

Babekir, Amani: Yeah, that's from the Food Code.

Babekir, Amani: And we previously discussed this one as Susan said and we agreed to use the food employee.

Michelle Hill (Co-Chair): Oh, OK.

Mortiz, Erin: And do we? What was the objection to food worker? Did we? Talk about that at all. I can't remember.

Babekir, Amani: I think because it was listed under the definitions, the food employee and also, we had, I think, the food workers and then we said, it's a difference in the Food Code to make it consistent with the language of the Food Code. Let's just stick to the food employee.

Mortiz, Erin: OK. I do like food worker better at sounds a little bit more plain language but being consistent with the Food Code is also beneficial.

Babekir, Amani: Thank you.

Susan Algeo: The Food Code only has, from what I can see, food employee. They don't define food handler that I see in here, so that might have been from another source.

Michelle Hill (Co-Chair): Well, and what's highlighted on our working document here is Food service employee, so.

Susan Algeo: Right, so we show.

Michelle Hill (Co-Chair): We would move that, yeah, OK.

Susan Algeo: Probably swap that to food employee, right?

Michelle Hill (Co-Chair): Correct. Yeah, that's my assumption too.

Susan Algeo: OK.

Babekir, Amani: Yes, Amber.

Amber Potts: The question under scope right here, isn't all of this covered in the table of contents? Do we need to say it again?

Ben.Wagner: I'm sorry, what's covered in the table of contents.

Amber Potts: Uh, where it says scope. The document covers these topics. You go to the table of contents. You can see what the document covers. I don't know if we need to say it twice.

Susan Algeo: I think when we put it together, Ben and Erin, correct me if wrong. I think we were just trying to match other pages that had the purpose, scope and intro, so I think we're just following that concept.

Amber Potts: Ah, I see.

Mortiz, Erin: I'm fine with deleting it.

Susan Algeo: I mean, I am too, except for just keep in mind, I don't think most people read a table of contents. They might just jump into it. But agreed there's some repetition in here.

Mortiz, Erin: And I'm not sure lay audience is going to understand the difference even between a purpose and a scope.

Vinson, Scott: I don't understand the difference.

Amber Potts: Yeah, I think we need to be cognizant of our audience. I mean, high up corporate food safety, they're going to understand this. But that's not the majority of restaurants. But then again, the additional pamphlet we're going to put together may alleviate that. I don't know what the best thing to do is.

Mortiz, Erin: And I vote for deleting the scope from the introduction, with my non-voting member vote.

Vinson, Scott: I support that.

Michelle Hill (Co-Chair): I do as well.

Susan Algeo: Amani. Did you say that FDA was going to look this over? Once we've completed stuff and they're going to give us feedback or they have a current document?

Babekir, Amani: They have the current document, is that correct, Devin?

Dutilly, Devin: Yes, the document that was sent out on 6/6. So that document is the one that's been used for comments? That's what we're currently using.

Susan Algeo: We just want to be careful if we change too much, then uh, we might need to wait for that feedback.

Babekir, Amani: Yes.

Amber Potts: So I guess I wasn't here for that meeting. We sent this to the FDA to review. OK.

Dutilly, Devin: Sorry I didn't announce myself – I am Devin Dutilly with the FDA, with the with staff here. I've been one of the consultants along with Greg Abel. And then we also have CDC consultants on the call and then USDA representative as well. So we've all been kind of participating with and engaging actively across the board here so I think, we're just taking some time to provide some comments from other individuals within our agencies as well as just looking at the document now that's been put together in a complete framework.

Amber Potts: Yeah, that just makes me nervous cause it's I don't think it's written to the level that the FDA would - if the FDA was our audience, this would not be sufficient. It's not written like code language either, which I know it's not code, but it's OK. I'll just wait for the comments.

Dutilly, Devin: I think these comments are helpful, right. So I think it's great to work through questions, concerns within the group, so I think that's been fruitful discussion right now. I don't think that you should be discouraged from commenting right now.

Michelle Hill (Co-Chair): We actually might be like minded on what we want to change.

Susan Algeo: Umm.

Amber Potts: I think one other quick comment I had is just an editing thing. When we say major food allergens, sometimes we capitalize all the M and the F and the A and sometimes we don't. I just think we need to be consistent throughout.

Abel, Greg: Agree.

Vinson, Scott: Makes sense?

Babekir, Amani: Thank you.

Michelle Hill (Co-Chair): I did want to ask the larger group here under the intro, the first statement declaring that it's an immune system overreaction to a food protein isn't the fact that the immune system is reacting at all the problem? It doesn't necessarily indicate overreaction, it just means it's reacted. And it maybe it doesn't matter, but it did bother me …

Abel, Greg: Where are you? At what paragraph?

Michelle Hill (Co-Chair): There you go, you've highlighted it – Overreacts. It's the fact that it's reacting at all, that is the problem is it's not an overreaction, it's just a reaction.

Mortiz, Erin: Well, it's.

Amber Potts: Yeah. And it's written differently down in the emergency section, the sentence is written twice in different ways. I notice that as well.

Mortiz, Erin: So I think. In in my mind it it's an overreaction because it is reacting to something that's harmless.

Michelle Hill (Co-Chair): I see.

Mortiz, Erin: I can't remember if I was involved in writing this sentence or not. I do kind of like the overreacts because it adds a little bit more urgency.

Babekir, Amani: So what do we have?

Vinson, Scott: Given our intended audience is food service workers, maybe we can just avoid the issue altogether by just saying, People who have allergies to certain foods must avoid those foods in order to avoid getting very sick. Something like that. You don't really need to explain the medical issue, they just need to know that it that it makes him sick.

Babekir, Amani: I agree with that, and we already have a definition for food allergy in the definitions or technical definition. So you could use a simple term here.

Michelle Hill (Co-Chair): We could say something such as a food allergy happens when a person consumes a food they're allergic to.

Mortiz, Erin: That to me is kind of circular.

Michelle Hill (Co-Chair): It is.

Abel, Greg: Right, I think you want to be kind of prescriptive of what it actually is because you know, people need to get educated at some point to actually know what it is to so they can react properly. You know to make it so simple, might belittle the importance of it maybe.

Mortiz, Erin: Yeah, I remember having jobs as a teenager and a young adult. You know, there's always that little voice in the back of my head, at least where I just wanted to know why, otherwise I wasn't going to take it seriously. I think having a medical line about it is helpful, because otherwise it's just like, well, now you're just telling me what to do by saying they can't be exposed.

Michelle Hill (Co-Chair): To speak to that point too, Erin, I think that also it's such a muddy play, the definition food allergy is - people don't all agree on what it means. We have people tell us all the time they got an allergy, when really it's an intolerance.

Mortiz, Erin: Yeah.

Michelle Hill (Co-Chair): So I do like having clarity around the terminology because it it's a big difference between.

Mortiz, Erin: Right.

Michelle Hill (Co-Chair): You're not going to drop dead if you have an intolerance, so.

Babekir, Amani: So we have in the definition section, we have like two long sentences explaining the food allergy. Maybe we need just to look at it and see exactly how we want to rebuild it and bring it there - the section which we are discussing now.

Michelle Hill (Co-Chair): If I may real quick, I just realized we could delete that entire first sentence and still have a very good introduction.

Mortiz, Erin: Yeah. I mean, if we define it elsewhere in the document. Yeah, we could just start the intro at approximately … We just have to define it somewhere in the document, which I think it should be in the definitions table.

Vinson, Scott: Yeah, I have to jump off in just a few minutes and I'm I wanted to ask the group about a couple other things I found in on page 7. Before I have to jump off, I'm wondering if we've included things that maybe shouldn't be there on page 7, at the end of Section 4. It's right above taking food to the customer. That line, wash your hands with soap and water before touching anything else if you have handled a food allergen. Wondering if that is needed there, because presumably the food worker has just finished preparing and allergen free meal so do we need to direct them to wash their hands again?

Babekir, Amani: Before.

Vinson, Scott: Right after they just washed the equipment. It seems like an extra repetitive step that might annoy people and be unnecessary. What do you think?

Michelle Hill (Co-Chair): I would strike it, I don't see that it has a purpose either. It's not logical flow.

Vinson, Scott: Yeah.

Susan Algeo: Yeah, we're saying the meals complete then, yeah. They would move on to the next one and that step wash their hands.

Vinson, Scott: I don't know how it ended up, but it ended up there if I if I put it there, it was my mistake.

Susan Algeo: And we love encouraging people to wash their hands!

Babekir, Amani: Have we mentioned washing hands before preparing the meal on step number one?

Abel, Greg: Yes, that's the problem.

Michelle Hill (Co-Chair): Yes, it's always the first thing, hopefully.

Vinson, Scott: Yes, it's 4B.

Vinson, Scott: It looks like we can just get rid of 4 (i) and then my next question before I have to run. In Section 5, taking food to the customer, 5E, Review procedures and retrain the staff who prepared and handled the meal on these procedures before allowing them to remake the customers meal. OK, so I'm just seeing I've been in these situations before where I've been the customer. I've been very diligent about telling the person who took my order about my gluten intolerance and the meal comes out and it has gluten in it and I get the waiter's attention, or take it back to the counter and tell them about it. If they must, it's already taken a lot of time, and if I'm eating with other people, they're like halfway through the meals by this point, if the person who has to prepare the meal has to review the procedures and be retrained by someone. Again, before remaking my meal, it's going to take forever. And at that point, I mean, I've been in these situations where I've they bring out the meal, it takes them so long. By the time they get it to me, everybody else in my dining party is already done. And I just say sorry, you know. Thanks, but no thanks. We're going to leave. So I'm wondering if that should be omitted there and or saved for a later step because you want to get the meal by this time you've annoyed the customer because you've brought out a meal that has the allergen. So you want to remake it quickly. Of course, it's important not to screw it up again, but reviewing procedures and retraining that seems a little time consuming.

Michelle Hill (Co-Chair): Perhaps, Scott, we could say something such as corrective action must be employed and that corrective action phrase to a CFPM would be I'm retraining as I go. We teach to correct as you go, and maybe that's the intention of that part of the statement.

Vinson, Scott: Or yeah, or you could just put something in the preceding clause from in the previous sentence. Offered to remake the meal, allergen free, for the customer or something like that. But if I'm the customer, I don't want to wait until the person gets retrained, you know? Or it'll. It'll take too long.

Michelle Hill (Co-Chair): That or if you go to a sub shop and ask for gluten free bread in the middle of lunch and they break the machine down so they'll clean the slicer ...

Baldwin, James: Should not be referred to as a follow up corrective action.

Michelle Hill (Co-Chair): I beg your pardon. I think that's how we teach it.

Baldwin, James: Should that be referred to as a follow up corrective action? So not scarily good in process, but doing it as a corrective action after.

Vinson, Scott: Yeah.

Vinson, Scott: Yeah, I wouldn't use the words corrective action cause it sounds too formal and again we need to remember our audience here. I would put it in conversational language. Umm, but you know it can be added as a step.

Vinson, Scott: If after you deliver the allergen free meal, remade allergen free meal to the customer, then make sure that everyone knows the proper procedures.

Babekir, Amani: Or maybe we just need to delete before allowing them to remake the customers meal?

Michelle Hill (Co-Chair): That's exactly what should happen.

Vinson, Scott: Yeah. OK, thanks everyone for indulging me. By jumping ahead. I've got to run. Good luck.

Babekir, Amani: Thank you, Scott.

Michelle Hill (Co-Chair): I suspect that that whoever worked on this phrase was hoping that we would have this be a teachable moment, is probably the intention there.

Babekir, Amani: That is true. So, Ben, are you good with this one? Do you like to remove just Before allowing them to remake the customer meal, maybe you could add that on your comments there.

Ben.Wagner: I'm sorry. Can you send me the language you would like? I'm not making any changes on this right now. I'm just putting everything in comments. Initially, when our team went through this, the content we weren't concerned about it. So I feel like, if you guys want contact me, the groups that created the individual section content can make the changes.

Michelle Hill (Co-Chair): It's a good point, Ben.

Mortiz, Erin: Yeah, I would rather have the groups review their own sections again and send us the changes - like I said, we really did not look at content in the formatting group.

Michelle Hill (Co-Chair): Not at all, Ben. I think that what we could set how to satisfy this possibly would be to state in your comment strike before allowing them to remake the customers meal. That's the recommendation currently is what's in front of us.

Babekir, Amani: OK, so it seems. Thank you, Ben. It seems we are running out of time. So what we could do? I'm going to give it extra one week for you to review. And if you have any comments to add it to the document. And then I could send it out to the teams so they could go over their sections and make the needed changes. Does that sound like a good plan to all of you?

Michelle Hill (Co-Chair): Amani, just for clarity, does that mean when you say extra week, can you clarify?

Babekir, Amani: Yes, because I haven't received a lot of comments on the document. So I'm going to give it extra week or maybe two weeks. By then we will also have the comments from Devin and his colleagues. And please try to give it some time to go over the documents and make any comments about any suggested changes or any formatting we need to consider. After two weeks, I will send it out to the original subgroups so they could work on their sections and addressing those comments. That sounds like a good plan.

Michelle Hill (Co-Chair): Thank you. Yes.

Babekir, Amani: I'm going to give you one week for you to go over it, add your comments and suggestions before I send it out to the subgroups to work on editing.

Michelle Hill (Co-Chair): Our directive at this point is to provide you with our comments on the document as it is and then they'll be compiled and then we'll return it to committees, subcommittees to discuss and change.

Babekir, Amani: Yes. OK.

Thoma,Libby: Thank you.

Adjournment

Babekir, Amani: So thank you everyone. Thank you and have a good rest of the week and nice weekend.

Meeting Number	Meeting Date		Meeting Time
16	**06/23/2022**		2:00 pm EST
Co-Chair; Meeting Chair	Co-Chair	Meeting Scribe	Council II Chairs
Amani Babekir	Michelle Hill	via Teams Transcript	Wendy Bell/Courtney Halbrook
Advisory - FDA	Advisory – FDA		Advisory - FDA
Greg Abel	Devin Dutilly		Mary Cartagena
Advisory - CDC	Advisory – CDC		
Erin Moritz	Jenna Seymour		
Advisory - USDA			
Jennifer Green			

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Amani Babekir
iii.	Scribe	
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

1. Roll call
2. Framework update
3. Proposed issues
4. Proposed Food Code addition
5. Adjourn

Meeting Number 17	Meeting Date **07/07/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

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v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Call to Order

Amani Babekir: I will now call this meeting to order. Michelle, could you please take the roll call?

Roll Call

Michelle Hill: Yes, Madame chair. [takes the roll call]. We have a quorum; we can proceed with the day's business.

CFP Antitrust Statement

Babekir, Amani: I would like to remind you that the Conference for Food Protection antitrust is statement is active in this call. So just want us to keep that in mind.

Previous Meeting Minutes

Babekir, Amani: And we could proceed to our first item in the agenda. We want to approve the previous meeting Minutes – the most recent is still being processed, so we will vote on the Minutes from June 9th. I sent it out just a couple of minutes before this meeting. If you could please open it and I will give like 2 minutes to review. And then we're going to proceed with the discussion and voting. OK, so I will entertain a motion regarding the minutes of our last the meeting from the June 9th.

Hill, Michelle: And just for clarity's sake, they run from page 57 to 71 of the Word document that was emailed by Amani.

Ben.Wagner: This is Ben. I move to approve the meeting minutes.

Babekir, Amani: Thank you.

Garvin, Amanda: I will second.

Babekir, Amani: Thank you. So, is there any discussion on the Minutes, before we proceed to vote? [long pause] Anyone opposed to the motion, please say no, or raise your hand. [long pause] Do we have anyone abstaining? [long pause] The motion passes to approve the Minutes as is. Thank you.

Framework Points

Babekir, Amani: And we could proceed to our first item in the agenda. We want to approve the previous meeting Minutes – the most recent is still being processed, so we will vote on the Minutes from June 9th. I sent it out just a couple of minutes before this meeting. If you could please open it and I will give like 2 minutes to review. And then we're going to proceed with the discussion and voting. OK, so I will entertain a motion regarding the minutes of our last the meeting from the June 9th.

Hill, Michelle: And just for clarity's sake, they run from page 57 to 71 of the Word document that was emailed by Amani.

Ben.Wagner: This is Ben. I move to approve the meeting minutes.

Babekir, Amani: Thank you.

Garvin, Amanda: I will second.

Babekir, Amani: Thank you. So, is there any discussion on the Minutes, before we proceed to vote? [long pause] Anyone opposed to the motion, please say no, or raise your hand. [long pause] Do we have anyone abstaining? [long pause] The motion passes to approve the Minutes as is. Thank you.

Babekir, Amani: So now we could go to the second item in the agenda, which is to continue reviewing and working on the framework. I sent out the latest version of the framework, and now let me share it with you. You could follow me on the screen if you want, or you could open your version. Can you see my screen?

Hill, Michelle: Yes, Madam Chair.

Babekir, Amani: OK. Thank you. So, I'm just going to go over some of the comments that we got from the previous meeting and add the notes to it. One of the things I noticed is that after we finalize the draft, we need to go back and change the table of contents because we deleted some of the sections and all of that. So, if the template, A team, is going to take care of this.

Hill, Michelle: I know how to do that, Amani. I'd be happy to assist in having that be completed.

Babekir, Amani: OK. Michelle, would you like to do it by yourself or ... Ben?

Hill, Michelle: I can work with Ben, if that's OK?

Ben.Wagner: This is Ben. That's fine.

Babekir, Amani: OK, that's good. Then the second one - we got a suggestion to make the document shorter than it is, and to highlight the definitions in the footnote of the document. So, per each page, if we see any word listed in the Definitions, we add it to the footnote of the page. What are your comments on this suggestion? Do you think it's better than the way it is right now, or we keep it as it is?

Ben.Wagner: So would that be replacing the basic dictionary at the end, or would it be just adding footnotes to every page and still having the dictionary at the end?

Babekir, Amani: I think from what I understood from the suggestion - and Devin, I'm not sure if he's with us today - is to replace the definition section, yes.

Dutilly, Devin: I'm here in the call, yes. I think the comment that I was passing along related to having it in the footnotes, in addition to having it in the in the definition section, just so that folks wouldn't have to flip to that section, or if they chose - on previous calls, someone had mentioned that somebody might just choose to print off 1 section and they may have it, or they might choose to, you know, print off only a small portion of it and not the entire document. They would still have some reference to what the definition meant, so both locations.

Ben.Wagner: I would just like to point out that it's not going to make the documents smaller, which, either way is fine, but I know that that's what the group seemed to try to be doing.

Hill, Michelle: I think that is an important point that's being made here. However, because I often print off one page of something and it's super nice to have that information contained at the bottom, it could be as small as six-point type.

Moritz, Erin: I kind of like the idea of having it in both places. I'm wondering if there's a way to, you know like Michelle is getting at, have it in smaller and maybe a lighter font, so it's less visually obtrusive. But I think we definitely need to keep the section at the back because they're all listed alphabetically - a quick reference there.

Babekir, Amani: Thank you. Any other point? OK. Thank you. So, I hear that the agreement is to have the some of the definitions in the footnote. Myself, I don't have experience doing that, who is going to take care of this one?

Hill, Michelle: I can work with Ben again. I've done a lot with this type of thing in Word.

Babekir, Amani: OK.

Hill, Michelle: Or anybody else is welcome. I'm just saying I'm happy to help.

Babekir, Amani: So, Ben, is that OK with you - that's to be taken care of under your subgroup, with Michelle.

Ben.Wagner: Yes, I think the subgroup can take it on.

Babekir, Amani: OK. That's good. Thank you.

Ben.Wagner: As long as you'll put a comment in here somewhere that that's what we're doing, so we don't forget.

Babekir, Amani: OK. We probably need to even give an idea here, or add the words that need to be added, under the footnote. They could be ...

Ben.Wagner: I think what the framework team can do is take the dictionary that we already have, do a search on the terms wherever the terms show up. We can mark that we need a footnote and then go from there.

Babekir, Amani: OK.

Moritz, Erin: Yeah, maybe with the exception of like food worker or something, I don't necessarily know if that has to be on every page.

Babekir, Amani: OK. Thank you. In the other point – here – we have couple of suggestions here - under this section, and Erin, I'm glad you are with us on this call. One of the suggestions is to - in this section additional consideration for the establishment is to make it simpler by just converting it to a checklist so it will be easy to read and the way it is right now. And also, we requested references when we were in the first draft round, but we probably wouldn't need it here. Just for the sake to make the contents here more simple. So, what do you think Erin and your group? You think that's something you will take care of? And if you have any other different opinion, please let us know.

Moritz, Erin: Yes, I think a checklist we can certainly try. I guess my hesitation is that I'm not sure all of these will apply in all situations and establishments. Would bullets be better? Any better than like A and 1?

Hill, Michelle: Perhaps it needs to be more of like a flow chart if then.

Hill, Michelle: That's a whole can of worms, isn't it?

Babekir, Amani: Yes.

Moritz, Erin: Again, I think a lot of these will overlap. Not all of them will be applicable in all situations. I saw one or two hands up.

Babekir, Amani: Yes - could you please speak up? I can’t see the hands.

Vinson, Scott: This is Scott. I have a question. It might be on the next topic we're getting to, I'm guessing, but the references.

I noticed Amani you highlighted some of the references in here. I think that's a reference to the Southern Nevada Health District. I'm wondering if we need the references in the body of this document, maybe they would be better placed at the end. I think we have two different audiences with this document. The first is really the folks at CFP who gave us our committee charge to come up with this document – I think they want to see our references - where we came up with this. Our other audience is the reader of the document, the ultimate reader, which will be the retail food workers. They're probably not really going to be that interested in seeing references in the body of the document. Maybe it's OK to leave it at the end if they're really interested, but they probably really don’t care about references, so maybe we should just put them all at the end.

Moritz, Erin: Yes, I think that's what we ended up doing for the other references. I think we probably just missed this section.

I agree. I think you know we have one Section - one short section at the end - with the References used to create this document.

Babekir, Amani: Yes, and we have …

Ben.Wagner: This is Ben. We did actually take any sections that were labeled as Reference sections from the individual groups and put them all as one at the end. Anything that was an inline reference we didn't touch.

Babekir, Amani: We do have a section where you have all the references combined, and even the breakdown by different sections, so it would be easy to refer to.

Moritz, Erin: Yes, I think that's fine. Just stay consistent with just keeping them all at the end.

Babekir, Amani: OK, that is good. So now we're going to come back to the point of making this section more concise because we have several points here. On our previous call, the agreement was let's work on trying to make this document more concise so the readers are comfortable going through it, I would say. We wanted to think about how we could put this section in a different way.

Moritz, Erin: So, to me this is at least when we were creating this, to me this is basically like a laundry list of things that establishments can think about when they're developing their plans and so I think anytime I see something that's a laundry list, I kind of expect it to be long because this is where we're getting very detailed and this is where somebody who is really thinking about the nitty gritty of their plan. They are the ones who are going to be reading this, so that was our thinking behind it because there are so many considerations, and those scenarios are going to be different based on the kind of establishment and where it is. We're certainly open to suggestions, but that was the point of this particular section, if somebody's really sitting down and thinking about what their plan is going to look like, these are things that that could help them.

Babekir, Amani: OK. And I agree that building an emergency plan is at the core of our charges. Any other suggestions about presenting this section in a different way? [silence] Could it be in a different or are we OK with it?

Garvin, Amanda: This is Amanda Garvin. Somebody had mentioned a checklist, an option for the checklist might be kind of something we do for a facility, and we have, like these are the SOP's that pertain to all facilities and then we have a list of, this is what pertains to some facilities so only included if applicable. So that might be an option.

Moritz, Erin: OK. So, kind of group it based on.

I don't know if these are specific enough to try to narrow down and say, this is good for a full-service restaurant, This is good for a Taco truck. Although that's one possible thing that we could consider doing. Thanks.

Hill, Michelle: Oh wait, we could know it for this section, like as a prelude to it, that it's meant to be used in that way, that you might not have answers to all of these questions. There. You do. You do say that might have additional questions to consider.

Moritz, Erin: We could certainly try to shorten the paragraph - I think that's doable. And then similar to - Michelle, what you were just saying? I wonder if there's some words we could add or change in the section title that just make it more like, If you're just reading this for general interest, don't bother with this section.

Hill, Michelle: Perhaps we could say something as easy as if you were intending to form an allergen plan - isn't this really targeting an allergen response plan? - so if you're looking to have that for your organization, that this would be what you need.

Moritz, Erin: Yes.

Babekir, Amani: And this is …

Hill, Michelle: Something similar. Right, yes.

Moritz, Erin: Writing a detailed plan, because this is very detailed stuff.

Babekir, Amani: And this is one of the elements of the charges, to show the customer how to walk through, or the restaurants staff how to walk through building these emergency plans.

Dutilly, Devin: Just commenting, I think that about shortening the document and some of the discussion right now, is there a need to do a small section - like a summary, an executive summary type document and then have the rest of the document exists … or something like that. I don't know if that's going to be helpful or not. Is it because the intent is to have it in a detailed emergency? Because you all had just said this is not an action plan or an emergency plan, detailed one, right. So, it's just the detailed one. And then is there some way we can go through each section and just scratch certain things and then make it a summary of what's in there that is also useful but not detailed. So, then we have like two documents, one is like an executive summary document and then one is like this. Based on what we already - not to creating more information - just using the existing language and wording and just scrapping certain text. It's just a thought.

Babekir, Amani: Amber has suggested to create like a short document from this version.

Moritz, Erin: And I think for this particular section, the poster that we developed kind of serves it as that executive summary.

Dutilly, Devin: OK. That makes sense.

Moritz, Erin: That's kind of where we were going with that poster.

Hill, Michelle: Quick. But.

Dutilly, Devin: Yes. OK, great, good.

Hill, Michelle: We might talk about how this is a detailed inventory of what you would need you know in order to do the plan or to comply with the chart - the poster, which I think is very effective, by the way.

Moritz, Erin: Yes, I like the idea of scratching that paragraph and maybe doing one sentence saying that this particular section is designed for – has detailed considerations for …

Hill, Michelle: Sorry. The final line might be enough. These questions and scenarios may be used as a practice drill for your food establishments staff or don't have to - maybe not even practice drill, but …

Moritz, Erin: We could just keep that sentence and say these questions, that scenarios may be used to develop a detailed emergency - allergen reaction and response plan, and can be used as a prep. And then delete the rest of that paragraph

Hill, Michelle: Yes.

Hill, Michelle: And may also be used as a practice drill.

Babekir, Amani: But now? Could you say the sentence one more time?

Moritz, Erin: OK. These questions and scenarios may be used to develop a detailed Emergency … Allergy reaction? What did we officially call it? An emergency response plan. And that gets to the other things I wanted to discuss about the section that you guys deleted. But let's finish up with this first.

Babekir, Amani: We could do that.

Moritz, Erin: And – can be used as a practice drill ...

Babekir, Amani: For your food establishment staff.

Moritz, Erin: Yes, I think the rest of the sentence is OK.

Hill, Michelle: As I said, you could strike, you could just say period after drill. I mean, it's obvious we're talking about your staff, but the …

Moritz, Erin: Yes, that's true.

Babekir, Amani: Do you want to make any change on the title?

Moritz, Erin: How about, could we use the word detailed in the title again?

Hill, Michelle: Forming a detailed response …

Moritz, Erin: Detailed considerations for the establishments.

Babekir, Amani: Or, for developing emergency response plan.

Hill, Michelle: Yes. Is that our charge? Let's call it what our charge is.

Babekir, Amani: Are you OK? So detailed. Consideration. It's not additional, is that right? Have we? Umm.

Moritz, Erin: We can remove additional, I think. I think really what we were going for was detailed instead of additional. I think that's good.

Babekir, Amani: Any point or any suggestion before we proceed on this section, are we good with it?

Hill, Michelle: If we're intending this to be a form, let's say that somebody could take and fill in. I don't know if that is the intention, but this could be set up with little boxes that could be checked as I move through and have spots to write. I don't know if that's our intention though, but if we wanted them to be able to just copy it and use it, that's something we might want to consider.

Moritz, Erin: Yeah, I'm not necessarily opposed to that. My only hesitation is some of these will be applicable to some establishments while others might not. But you know, it's certainly up to the establishment to decide if they're applicable or not. We could try a text box or a checkbox - otherwise you know even if bullet points might be a little bit less intimidating than the letters and the numbers. And you know, open to feedback from the group.

Hill, Michelle: But I've been looking to work on this with the template team. If or maybe Erin directly.

Moritz, Erin: Yes. OK.

Babekir, Amani: OK. That's good. So, we could proceed to the next point. Erin, you said you have a comment about one of the sections we deleted here from.

Moritz, Erin: Yes.

Babekir, Amani: From your part.

Moritz, Erin: All right. Can you guys all see this? For the most part, I was fine with, you know, all the suggestions here. I do want to take a moment to explain the rationale of why we kind of broke this down into different scenarios. Allergic responses look very different, and so lots of people when they think of an allergic reaction, they think of somebody sitting at the table clutching their neck because they can't breathe, but there's a really wide continuum of consciousness - ability to communicate. There're people like me, I have a peanut allergy, but it's very mild. So, I would actually be pretty mad if an establishment called an ambulance for me and be especially angry if I got stuck with a bill for it. And so, I'm definitely OK with deleting this kind of detailed suggestions. Basically, a flow chart but with words - but I do think we really need to work in somewhere else that a person could be alone, they could be with a group. And what do you do with them? They could be unconscious, which obviously you call an ambulance. But if somebody says, I ate a peanut from your dish, I'm just going to take a Benadryl. I think you know we want to basically draw attention to the fact that there's really wide continuum of severity and so I'm thinking it would make the section we were just trying to shorten a little bit longer, but I'm wondering if we could add this first.

Add somewhere in here, something like think about what role your establishment would play if the person is alone versus with a group. If they're in distress versus in distress but can still communicate. So, it would not be necessarily this kind of prescriptive steps

to take, but I do really want to get establishments thinking about beyond that sort of classic sitting at the table gasping for air, if that makes sense.

Hill, Michelle: I think it's really important, the point you're making, Erin, because they do present very differently, especially when you consider children versus older groups.

Moritz, Erin: Right. And so, if we do - like I said, I'm fine with deleting, you know, these step-by-step things, but we need to put it in here somewhere that it's not always going to be the diner sitting at the table turning red, clutching their throat.

Babekir, Amani: I'm wondering if this section or the message on this section being addressed is in the training section. Is Amber with us?

Amber Potts: I'm here.

Babekir, Amani: Have your team addressed you know the different level of reactions in your section and just to bring awareness about this.

Amber Potts: No, no we didn't.

Moritz, Erin: If we wanted to add a little blurb about that in the training section, that would be good. But like I said, I'd be happy if we mention it in the section that we were just working on too. I don't know if any other members of the emergency subcommittee are on – if they have thoughts.

Hill, Michelle: I don't know that they would be much point in graphics of people actually experiencing allergic responses. To show that there's a huge variation. Or is that just too difficult or too much?

Moritz, Erin: It's not a bad idea. I think it would be included in a very specific, day long allergy training.

Hill, Michelle: Yes.

Moritz, Erin: I think what we're putting together is a lot more broad than that, but I do like the idea, of course, I always like the idea of graphics.

Hill, Michelle: Picture says 1000 words.

Moritz, Erin: Yes.

Babekir, Amani: So, Erin, do you think you could … Yes, Amber, go ahead.

Amber Potts: I like the idea of keeping it broad as this is not the training. We're not developing a training per se, just a, you know, a document to help them write their own allergy plan. And so we, I think we should at least mention it, but I don't want to - and we have to remember they have no medical training. So, I don't want to put that kind of responsibility on a restaurant owner or server. And then I don't want them to interpret that as such either, so I think it's just a general statement. Basically, it's like if you've ever done lifeguarding - the drowning isn't as you see in the movies where it's splashing and yelling, there's no - it's silent. So, just an acknowledgement that you may not see what you think you're going to see - something like that - and then leave the training - when they take that training - for it to be a more in-depth kind of training.

Moritz, Erin: Yes, and what I do really want these restaurants to think about is there's going to be these wishy-washy scenarios where their staff are not going to be sure if they should call the ambulance. Like if somebody reports a reaction but they don't want an ambulance but they're turning red - you know these are these are actually the much more likely scenarios that they're going to come across. And so, they just need to be thinking about it. And even just be aware, like you said, Amber that you know … you're not gonna be splashing around in the pool yelling for help, metaphorically.

Babekir, Amani: Yes, Scott.

Vinson, Scott: Maybe this is already in the document, I can't see it at the moment, but maybe put something in there about, ask either the customer, or someone with the customer, if they would like the facility to call an ambulance. Because, like someone said a moment ago, you have some customers that might be annoyed if the establishment calls an ambulance, and they didn't want them to. Maybe they get stuck with a giant bill. So, is that in there? Oh yeah, there it is.

Moritz, Erin: And that's what we had here, but maybe that is too specific - it's I feel like that's an important enough question.

That if we for example, put an additional, you know bullet point down here, we could just call that out as like a sub bullet.

Vinson, Scott: But that's really all the establishment can do if the customer says no, or the person they're with says no. Then the restaurant can't do anything else - they can't constantly monitor the customer for possible other signs that aren't necessarily obvious signs that someone having an allergic reaction. I think we need to keep this.

Moritz, Erin: Some establishments might be willing to do that though.

Vinson, Scott: They might, but I don't think we need to spend a lot of time or take up a lot of space in this document writing about it. The main point we want to get across to the establishment is somebody might be having allergic reaction. Beyond the classic signs, there might be other signs. Ask the person or whoever is with him if you if they want you to call an ambulance, and then move on. They have a business to run.

Babekir, Amani: And we have it on #5. If you scroll to number 5. Here we have it. If someone reports an allergic reaction, I think that's where it is. Start is when the customer says I have an allergic reaction and then they will proceed with their steps. Do we need to add any clarification about the level of allergic reactions. and then ask them to first, ask the customer if he wants us to call the 911 or not?

Vinson, Scott: It really has to depend on what the customer wants. And this part in here. When in doubt always call 911 I from what I heard a moment ago from whoever said it, they don't want that necessarily. So maybe we should take that part out.

Moritz, Erin: Well, this is when in doubt.

Vinson, Scott: Well, yeah, and there's.

Moritz, Erin: Like if I was a business and somebody told me not to call 911, but then they stopped breathing.

Vinson, Scott: Well, that's just common sense.

Hill, Michelle: It is, and it isn't, though. I mean, what we're really asking here is what's the liability?

Vinson, Scott: If you put both messages in there, it's going to get confusing for these workers. If you put when in doubt, always call 911. But then you also say ask the person whether they want you to call 911. Which is it?

Hill, Michelle: I think that maybe it's personal discretion. The way we talk about this. What is the liability if somebody in your restaurant - they eat something and they drop dead. Are you responsible for that?

Vinson, Scott: No.

Babekir, Amani: What if …

Moritz, Erin: They told you that they had an allergy though.

Babekir, Amani: Yes, I think there ...

Moritz, Erin: I think I would assume the liability would depend on whether the customer mentions a food allergy.

Babekir, Amani: Yes.

Moritz, Erin: Like if they don't mention it then, well, that's a whole. I don't know. I'm not a lawyer, so will stop talking.

Babekir, Amani: Yes.

Hill, Michelle: So, it's a sticky wicket, I think really.

Moritz, Erin: It's very sticky wicket, yes.

Babekir, Amani: Yes, but there could be liabilities, especially if they label it in their menu, like for example, these dishes, gluten free. And then when I eat it, it turns out it is not, and I have reaction. Yes, that will bring them some liability.

Hill, Michelle: That's like misbranding …

Babekir, Amani: And we have it here on this section, on the first, on the second sentence, saying that procedures may differ depending on the severity of the reaction, so maybe just we need to add more clarification here. To address all of these doubts between calling 911 or asking the customer.

Moritz, Erin: So maybe I can draft - what? I would suggest - I hate to, you know, keep everybody talking about this for hours and hours - send it around to the emergency response group and then we can, you know, tweak it as needed and send it back to you, Amani. Does that sound OK?

Babekir, Amani: Yes, that sounds good.

Moritz, Erin: OK.

Babekir, Amani: And are you OK about the other deletions? Do you have any extra comments, Erin? Because there are additional things we might need also to delete in the section.

Moritz, Erin: Let me - I think there is only one other thing I wanted to kind of get your take on and I can just share it - share my screen again since I have it right up here - we have this particular poster …

Babekir, Amani: Yes, that was my question - about this poster.

Moritz, Erin: I think we like it because it did have some like facts underneath it and it's certainly one that a restaurant might want to print out and post somewhere if they like it. So basically, we could leave it in there as a potential resource for them. But I guess I'm OK with removing it if the rest of the subgroup is as well. It's just another resource that the establishment can use.

Babekir, Amani: Are there any comments about this one? Are we OK with keeping it?

Hill, Michelle: I think it's necessary.

Moritz, Erin: OK.

Babekir, Amani: Thank you, Michelle.

Moritz, Erin: OK.

Vinson, Scott: Wait a minute. Can you go back to that poster? Step four says go to the hospital. So, is that for? This isn't for retail food workers. They're not going to go to the hospital with them.

Moritz, Erin: No, this is a general yeah. This is a general.

Vinson, Scott: So, this a sign that we envision the establishment maybe posting, a customer facing sign, somewhere in the restaurant or facility?

Hill, Michelle: Yes.

Moritz, Erin: If they yes, they want to. It does make some good points. But yeah, it's not specific to retail food establishments.

Hill, Michelle: I really like it because it covers the full bases. If it's a true, you know if it ends up being a true anaphylactic response that you have to treat with an EPI pen. It covers all the bases.

Moritz, Erin: But I can kind of see where it might - it would be confusing. Now you know, we don't expect anybody from the food establishment to go to the hospital with the customer.

Vinson, Scott: So, this is really for people who have food allergies.

Moritz, Erin: It yeah, it's definitely possible, since it's from an ID.

Vinson, Scott: I'm not sure it belongs in this document. Then we're supposed to be developing guidance for the establishment.

Garvin, Amanda: I suggest a better place for it.

Babekir, Amani: Sorry, Amanda. What did you say? Couldn't hear you.

Garvin, Amanda: Sorry about that. I'd have to agree with that. I think that this is not quite the correct place for it, and I have. Like it's sounding like some of the stuff we've already said in different areas, so. I'm not sure if this is something we could just get rid of, and I do hear that you know it is important. As a response to definitely have the right responses, but I think this is another one kind of confusing it up again of don't call 911, call 911, wait, send up to the hospital. Oh, what should I go with them? I think we just need to kind of tone it down a little on this and, what can we do to get them to think about - when should you do the things?

Babekir, Amani: Thank you, Amber. Any other point?

Moritz, Erin: Does anyone very strongly oppose removing it?

Abel, Greg A: I have one point to consider.

Moritz, Erin: Sure.

Abel, Greg A: You looking at some surveys? I read someone where 65%. Of the surveyed say they wouldn't know how to cope if faced with the customer suffering an allergic reaction. So that's over half a staff and this was - the study was dropped at food service workers, so with that. With the 65% not knowing how to cope, you know, are we taking anything away from that guidance that would not benefit someone who is having an allergic reaction.

Hill, Michelle: To that point. That's why I like this document. Because there tends to be a lot of mystery - when I teach, I ask them how many people have actually seen a response.

Abel, Greg A: Mm-hmm.

Hill, Michelle: And especially the variance of response. I like that this addresses that. What's their experience? Maybe it needs to be called something else. Referenced in a different way.

Babekir, Amani: Ask. But.

Vinson, Scott: This poster is directed toward people who have food allergies. So, it's not really for the establishment or the people who work in the establishment. I'm going to actually call for a vote on this page.

Moritz, Erin: Sorry, could you say that again? I didn't quite catch it.

Babekir, Amani: You want to call for a vote.

Moritz, Erin: Oh OK. I do think you know, we throughout this entire document, you know, we do kind of have to balance. Of course, we'd like to include boatloads of information and make it 8000 pages long. That would be ideal if people would read it. But we also want to limit confusion as well and people don't like to read anymore. So yes, I certainly see both points of view.

Babekir, Amani: OK.

Hill, Michelle: You know, perhaps this would be better as a hot link at the end, saying these are some resources that we like, or we could recommend and maybe it lives there as a hot link or something they can follow if they choose.

Moritz, Erin: To me that's a happy compromise.

Babekir, Amani: Yes, or as a supplement to the document, because beside this draft, we're going to have the short version.

Moritz, Erin: Right.

Babekir, Amani: Of the work of the framework and we could have extra documents like this. As an attachment.

Hill, Michelle: I keep forgetting about that - the short version.

Babekir, Amani: Yes. So, are we fine with that? To delete it but still keep it as either attachment or add a link to it if we have a reference.

Hill, Michelle: Scott has his hand up, Madam Chair.

Babekir, Amani: Yes, Scott.

Vinson, Scott: I forgot it was still up. I think I still would like to call for a vote on this document. I don't think we need to include it as an attachment because it's not directed to our audience. It's directed to people who have food allergies, and I'm one of them.

Babekir, Amani: OK.

Vinson, Scott: So, I'm calling for a vote.

Babekir, Amani: OK. That is, that is good. So, let's do that before the end of the call.

Dutilly, Devin: What is the vote for? What is the question that you're asking to vote on?

Babekir, Amani: I will entertain a motion regarding this poster. Scott, you could proceed with your motion.

Vinson, Scott: I move that we vote on whether to include this, Food allergy aware - six that save lives page in our document.

Moritz, Erin: Or link can we specify cause now we have two potential solutions which would be – one, include as a supplement or a link, and then one solution would be deleted completely and move on with our lives.

Vinson, Scott: This is going to be a paper document in these facilities, so I don't think links will be very helpful.

Dutilly, Devin: I think that that was why some people were thinking of including the poster.

Hill, Michelle: Exactly. I was thinking about the suggestion we had about turning this into a smaller Canva-type app that there could be some dynamic linking there as well. If we were to include it in that space versus printed.

Babekir, Amani: So. I'm not clear very clear …

Vinson, Scott: I'll repeat it. I move that we vote on whether to include this document in whatever form. Bully printed page or link or whatever. I don't think this document is addressed to our audience.

Babekir, Amani: OK. Thank you, Scott. So, the motion is Do we need to include it in whatever version or not. Anyone 2nd?

Garvin, Amanda: 2nd.

Babekir, Amani: Thank you. So. You already heard the discussion about this, so I'm going to proceed to the vote. Is there anyone who opposed to the motion? Please say no or is raise your hand. Probably it will be easier to raise your hand so we could count it.

Ben.Wagner: I am confused as to what we're voting, if we vote yay.

Vinson, Scott: Just to clarify the motion is not whether to - the motion is to exclude this document from our guidelines.

Ben.Wagner: So, yay vote is to exclude, and nay vote is to include. Got it?

Vinson, Scott: Correct.

Babekir, Amani: So, the motion is to exclude, as he's said. So, if there anyone opposed to the motion. Which is to exclude this document. You can raise your hand so we could count.

davidread2861: So, this is to exclude it if you vote. If you raise your hand, you're voting to exclude it.

Babekir, Amani: You are voting. To not exclude it because I'm asking about, is there anyone opposed to this motion?

Moritz, Erin: So, the question is keep or exclude?

Babekir, Amani: That is right, and the motion is to kill it. So, if you are not with killing it, please raise your hand. Michelle, can you see the all the hands?

Hill, Michelle: Yes, Madam Chair. I see 4 to keep it and the rest to exclude.

Dutilly, Devin: I think there wasn't a vote for other side, right, there needs to be a vote for the other side.

Babekir, Amani: OK.

Vinson, Scott: Amani, you kind of, you kind of did it backwards, Amani, by asking for the no votes. You probably should just ask for yes votes. People who support the motion. The motion is to exclude. So ask for of the voting members. Who votes yes for the motion to exclude.

Babekir, Amani: OK so - Yes for excluding this poster from the document. Please. Raise your hands.

Hill, Michelle: Madam Chair, I see three hands that are in the yay for exclusion.

Babekir, Amani: So who abstains - any abstains?

Hill, Michelle: I do not see any hands raised.

Babekir, Amani: OK. So the motion is passed.

davidread2861: I thought there were four votes to keep it as well. You said there are only three votes to exclude it.

Hill, Michelle: I was under the impression that we were voting from the start all over again, and when she asked the question, I counted three hands raised in the affirmative to exclude.

davidread2861: Right. But I thought when you first did it - those that didn't want it excluded - there were four hands.

Babekir, Amani: The three is to exclude - the three are with the exclusion.

davidread2861: And four were to keep it.

Babekir, Amani: Yes, the motion failed.

Vinson, Scott: So the motion failed. Amani. You really need to vote Amani. You need you need as the chair to conduct a vote you need to ask for yay votes and nay votes. You need to ask for the yay votes first. There were three yay votes for the motion. The motion was to exclude and then the next step is to ask for the Nay votes. And I think there were four Nay votes. But you might wanna do it again, because I think there was some confusion.

Babekir, Amani: OK, let's do it again, because the way we usually doing it, we first ask about the person who is no say no to the motion, and then we count those people.

Vinson, Scott: Well, that's backwards.

Hill, Michelle: OK.

Moritz, Erin: Can I make an additional suggestion?

Babekir, Amani: Yes.

Moritz, Erin: Can we? I don't know if we can do this, but I'm wondering if it would be less confusing to say, the motion is to keep it. And that way if you vote yes, that means you like it. And if you vote no, that means you don't. But that might confuse things even more at this point.

Hill, Michelle: No, I think it's clarity. I think that would be clear. So if you're voting, if you raise your hand, you're to keep it, if you're lowering it, you're to get rid of it.

Babekir, Amani: OK. So I want to entertain another motion. I would like to entertain a motion.

Vinson, Scott: Did you?

Babekir, Amani: Regarding this poster.

Vinson, Scott: Did you dispense with my motion?

Hill, Michelle: No, we just changed it from a double negative to a positive. That's all we've done.

Babekir, Amani: Yeah, we because it seems like, you know, the Members here are confused about what we are doing because we kept jumping from yes, no, no, yes. So, we wanted to redo it again. So, it will be more clear.

Vinson, Scott: OK, I withdraw. I withdraw my original motion.

Babekir, Amani: OK. Thank you, Scott. So. I will entertain a motion regarding this poster. So, I want to hear the motion that say we want to keep this poster so we can vote on it. Erin would like to move?

Hill, Michelle: No.

Moritz, Erin: Am I allowed? I'm. I'm not. I'm a non-voting member.

Hill, Michelle: How about Scott?

Ben.Wagner: This is Ben. I move that we vote to include this poster in some form in our documentation - our document.

Babekir, Amani: Thank you. Wait a second.

davidread2861: I'll second it.

Babekir, Amani: Thank you. So, let's proceed to the vote on the motion. Is there anyone opposed to the motion? Please say no. I don't want to keep. Or raise your hand.

Vinson, Scott: I think everyone is confused by the way you pose the question you asked for. People who are opposed to the motion.

Babekir, Amani: Yeah.

Vinson, Scott: This is not parliamentary procedure - I think that's part of the confusion. The way you were conducting votes seems to be backwards.

Hill, Michelle: Madam Chair, if I may, perhaps we could ask for those that are in favor of the motion to exclude, to raise their hands.

Babekir, Amani: OK, people.

Ben.Wagner: The motion is not to exclude the motion is currently to include.

Babekir, Amani: The motion is to include – and watching this thing so the people who are in favor for this motion, please raise your hand.

Moritz, Erin: And the motion is to include.

Babekir, Amani: That's right.

Vinson, Scott: And this is only voting members, right?

Babekir, Amani: That's right.

Abel, Greg A: On the chat, Amber Potts had to leave but she voted to remove the poster whenever you get there, that's what that was counted or not.

Hill, Michelle: It was not. Thank you, Greg.

Hill, Michelle: I see five hands, Madam Chair.

Babekir, Amani: OK. So. I would see that the motion is passed, to include the poster.

Hill, Michelle: I think we have to ask for those to raise their hand that are not in favor of the motion. Am I incorrect about that?

Babekir, Amani: It's already passed, but I think we need to ask about abstaining. Is anyone abstaining?

Hill, Michelle: OK. I don't see any hands, Madam Chair.

Babekir, Amani: Yeah. Thank you. So, the motion passed to keep this poster and we keep, we can keep discussing how we want to include it. Do we want it to include in the actual document or move it somewhere else

Adjournment - Babekir, Amani: Anything else before we conclude our meeting today. OK. Thank you everyone.

Meeting Number	Meeting Date		Meeting Time
18	**08/04/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Meeting Call to Order

Babekir, Amani: I call this meeting to order.

Roll Call

Babekir, Amani: Michelle, would you like to start with the roll call?

Michelle Hill: [Takes roll call of Voting Members] Madam Chair, we have a quorum. Our new quorum is 8. We do have 8.

Babekir, Amani: OK, that is great. Thank you, Michelle.

CFP Antitrust Statement

Babekir, Amani: I would like to remind you that the Conference for Food Protection Antitrust statement is active in this call. So just keep it that in mind during our discussions.

Previous Meeting Minutes

Approval of previous Meeting Minutes was tabled by the group as the processing for these documents is not yet complete.

Framework Points

Babekir, Amani: And let me first start by bringing up our agenda for today. I will share my screen. Can you see my screen?

Michelle Hill: I can.

Babekir, Amani: What we're going to do today is we will review the timeline of our work and introduce the FDA and the USDA comments that we received on the framework and decide on how we want to proceed with working on those comments and refining the framework. First, just looking back at our timeline, which we built together when we started our meetings. We are done writing the framework and now we need to refine it because we have other things to do - which is deciding on what changes we need to recommend for the food code. I remember from our previous calls we decided on working on indicating this framework in the Annex section of the Food Code, but we still need to refine our discussions on this part, so we need to dedicate time to do that. The suggested timeline - we need to keep in mind that we need to finalize working on the comments and finalize the framework by the middle of September. Because as I said, we need to work on the second charge and also our final reports need to be submitted. And Michelle, could you remind us about when the final report is due?

Michelle Hill: Certainly. There is an interim report due shortly here, that Amani and I are working on. It is the report to the Executive Board about how we've moved through the work pertaining to our committee's charges. The report will be published on the CFP

website at foodprotect.org. You are welcome to view our previous filing, which was the Spring report, to see the type of information and how will be reporting that.

As far as when our actual work is due, the master calendar has us slated to have everything completed and sent to our Council Chairs by the end of December 2022. The Council chairs prepare and suggest improvements to the report that are needed in order for the report to be submitted to the Executive Board to be included in the next biannual meeting in April.

Babekir, Amani: That's good. Thank you, Michelle.

Michelle Hill: Certainly.

Babekir, Amani: Any questions about the timeline, any points you want to bring up?

Vinson, Scott: Amani, this is Scott – I have a question. It looks like we're going to be missing the July 30th deadline to have the written framework completed, because we still have this review of the FDA feedback to complete, which you're saying is due by September 15th.

Babekir, Amani: Yes, that is the reason we must agree on a revised timeline - trying to complete it by September 15.

Vinson, Scott: Is there a way we can do all - track these things - or do they have to be done sequentially?

Babekir, Amani: This is what we'll discuss as the second topic - how we want to proceed. I emailed you each the documents with the comments we received from the FDA and the USDA. Would someone open voting – make a motion – like, do we want to do this in our general meeting or in our subgroups and it will be faster if we are able to do it in the subgroups because we could work all of us on it at the same time on the on the document.

We're will decide on that a little bit later in our meeting - just keep it in mind. If we are working within subgroups, that is the fastest way to meet our deadline.

Vinson, Scott: If we do the work in the subgroups, and by that we mean have each subgroup review this new FDA feedback. People who aren't on a particular subgroup won't necessarily get to see what the feedback was and have a voice on it. Is that right?

Babekir, Amani: Yes, so the general Group, if it's kind of format or stuff minor like that, could work on it together. If it's something essential the subgroup could suggest the change that they would like to make and bring it into the general meeting. That's what we are planning to do. Are we OK with that? And we could proceed that way.

Vinson, Scott: Well, speaking for myself, I think I would prefer and maybe we can do it on this call. I would prefer that if maybe the people from FDA who proposed or gave the feedback documents to you - I don't know if they're on this call or not, but maybe they could just sort of speak up as to each individual comment. Maybe if we could go through the 24-page document, just sort of page by page before the entire group, so that everyone has benefit of seeing what these proposed changes from FDA were. These documents sort of came as a surprise to me because I thought we had already done all of this reviewing and then for these documents to sort of come in after we already had two previous full committee calls to review all the pages – I wasn't anticipating that.

Michelle Hill: Well, wait now – we did announce that.

Babekir, Amani: We announced that, and we were expecting it because we kept checking in with Devin, our FDA consultant, about their timeline to give us their feedback. We were waiting for it while we were working on refining the draft on our side. We meant to make it a parallel effort, so we could save time and consideration of the comments wouldn't hurt our progress with the framework.

Michelle Hill: We have been waiting on the feedback. We've talked about it in several previous meetings. The meeting minutes are forthcoming for prior meetings - they are being worked on and will be out shortly.

We did discuss this, and I think this is part of the greater issue that we're talking about. You know that we're going to address is how do we move forward with this? Do we do it as a full committee? And I respect what you're saying, Scott, I think it's very important that everybody has a voice in how this ends up, at least looking in the end. But we've also sent these documents out with comments for quite a period of time now. You've had them in, everybody's had them in their possession, I think at least three weeks. Am I wrong on that Amani?

Babekir, Amani: That is correct. Once we received it, we send it out.

Michelle Hill: I was hoping that people would have been able to take time between then and now to have a good idea of what was being said so we could have a productive conversation. I like the idea of reviewing each one with the consultants here, but perhaps that's something we do in two weeks when we give them time to actually prepare to do that - just a suggestion. Thank you, Madam Chair.

Babekir, Amani: Thank you.

Vinson, Scott: Well, this is Scott again responding to Michelle. Yeah, I appreciate the fact that Amani did send these documents out a couple weeks ago at least, but some of these changes may be controversial. I don't know. This is something that really should be discussed and considered by the group as a whole, rather than forcing Amani to sort of take every - you know, there are a lot of people on this committee and to have everyone go through each of these three documents and give the thumbs up or thumbs down to each individual change that might be proposed - I'm not quite finished - change that might be proposed would be a lot of work for Amani. It just seems to make sense to me to just do it on one of these calls. Perhaps this one - we have a full hour. And whoever proposed them from FDA can just say here's what we're proposing here. If they're just minor things like, you know, formatting or syntax or whatever, I don't think anybody is probably going to object. But if there's substantive changes, that should be discussed for the before the entire committee.

Babekir, Amani: Yes.

Michelle Hill: If I may, Amani and I work on this together and it's not just her doing the function. She communicates because she has the ability to do that. So, I just wanted you to know that we are together, Amani and me. We co-chair this committee. The other part I wanted to say is that we are able to talk about this within the meeting. I think that's a very good idea. I don't know how - I guess this would be the point where we would ask Devin, and the other people that contributed to the review, to speak as to whether they're prepared for this today, we didn't let them know that this was what was going happen.

Babekir, Amani: Yes. I would like to add a note here, before we open the floor to Devin, really this is the communication I received from Devin and the group who added comments on the framework - that is all these comments are suggestions and just things we need to consider when we are refining our framework. So, it is not binding statements from any organization. These are the things that are highlighted, and I'm really appreciative of Devin, and also for Lauren from USDA, for walking me through their comments; How to understand it on the documents with the different colors and their suggestions on each point. We need to open the floor for Devin, and any other Federal Partner, to go over these comments 1 by 1 - that is something we could do also here.

But I want to also hear from the other committee members because all our idea is we need to work right away on those comments. Do we want to work on this as one group, including our FDA and USDA representatives? Going through these comments one by one and working on it in the general meeting, or we want it to do it in the subgroups?

That is something we could do - I'm going to need a motion on it, but before that, I open the floor to Devin and Jennifer, if you want to add anything or any points about your comments.

Devin Dutilly: Thank you, Amani and everybody else. This is Devin. Erin is raising her hand as well.

Maybe I'll make it just a brief comment and let Erin and Jennifer comment. Just as a point of clarification, the comments that I submitted, me being with FDA, they weren't just FDA comments, there are comments from other federal partners. So, these are federal partner comments, so USDA, FNS, FDA, FSIS, Erin included, and some other partners from CDC.

They all commented on the Framework, and I compiled the comments from the agencies and pass them forward. So, the comments weren't just from FDA, they were compiled comments from all three agencies.

It is exactly right to say they're just comments to consider and suggestions myself, Erin, Jennifer and Greg, and others from FDA, USDA and CDC have been working throughout this process to kind of express some of our thoughts as we move forward. And we do really appreciate the collaboration and partnership to help raise the awareness and to provide resources for our stakeholders when it comes to Allergens.

So, Erin had her hand raised, and she's been a great partner in this as well. And Greg as well is here, and Jennifer - so thank you.

Moritz, Erin: I was just going to ask if it's worth kind of doing a hybrid. You know, separate it out into the subgroups to, I guess deal with sort of the low hanging fruit that maybe doesn't need the entire committee to discuss, and then leaving it up to the groups to turn over any larger, sort of thorny issues that can be discussed with the larger committee. That was just kind of kind of my thought as to how to proceed. Over.

Babekir, Amani: Thank you. Jennifer, I think I heard something.

Green, Jennifer: I do appreciate the opportunity to contribute, and I look forward to seeing how everything's going to progress.

Babekir, Amani: Thank you, Jennifer. Now we're getting to the point to decide. And thank you, Erin, for your suggestion to decide how we're going to proceed. I sent an email poll, but unfortunately the quorum is 14 and I got just seven responses - 6 within the group working on the subgroup and one is working on the general meeting, so we need to vote on it now.

I would like to entertain a motion about how we're going to proceed with addressing the FDA and the USDA comments.

Vinson, Scott: Madam Chair, I have a motion.

Babekir, Amani: Yes, please.

Vinson, Scott: I move that the full committee now on this call just consider the comments.

On the three documents that you circulated and if Devin or someone else from FDA wants to speak to the suggestions that's fine. We can probably dispose of this fairly quickly, I'm guessing.

Babekir, Amani: OK.

Devin Dutilly: Yes, and just to clarify, I think that we tried to make the comments as clear as possible. So, you know we can - there's a number of us on the call, so we can try to clarify anything that might be needed. But we tried to make the comments as clear as possible and make any suggestions in there. I'm happy to walk through the documents on this call as an FDA consultant, I'm happy to offer any clarification on the comments that were compiled by the three federal agencies. Amani had asked the question, would somebody be prepared to help us walk through the comments today? And the answer would be yes. Thank you.

Babekir, Amani: Thank you. I just would like also to keep in mind, if we're going to work on it in the general meeting, we need to move the meetings to weekly instead of biweekly to be able to meet our deadline, so I have a motion on the floor to work on it in the general meeting. Can I hear a second?

Moritz, Erin: Can I quickly clarify something about the motion - Scott would the motion be to work on all the comments in the general meeting starting today, but potentially, move into weekly meetings at the same time as that, correct?

Babekir, Amani: That is correct. So instead of having biweekly, it's going to be at the same time weekly meeting.

Moritz, Erin: OK.

Vinson, Scott: Actually, that was not part of my motion.

Moritz, Erin: OK.

Babekir, Amani: I know it's not part of your motion, but just something to keep in mind if we're going to do it in the general meeting, we need to move the meetings to weekly because we wouldn't be able to meet our deadline.

Michelle Hill: Perhaps what we should do is vote on whether we want to do it in the larger meeting and then we'll vote on how we proceed with that motion. Is it weekly? Is it biweekly?

Babekir, Amani: We'll work on the motion working on the comments in the general meeting. Any second?

Amber Potts: [Seconds the motion]

Babekir, Amani: Thank you. Any discussion, any points on the motion? OK, so let's proceed to the vote on the motion. If you agree with the motion to work on the comments in the general meeting, please say yes. All raise your hand. And Michelle, could you monitor?

Michelle Hill: I have six people that have voted in favor - Voting members that voted in favor.

Babekir, Amani: OK. We'll give it extra one minute.

Michelle Hill: Amani, please remind me, do you and I vote on this? I can't remember. I don't think we do, do we? We do. OK. Alright.

Babekir, Amani: Is there anyone abstaining?

Babekir, Amani: Do you see any hands, Michelle?

Michelle Hill: I do not.

Babekir, Amani: OK, so the motion did not pass. We need 8.

Michelle Hill: That is correct, yes.

Babekir, Amani: Yeah. OK.

Any further comments or suggestions from the committee members? I know Erin you raised suggestion before. Any reactions or other suggestions to be presented - this question for the all the committee members.

Michelle Hill: So, we voted not to do it today, as a larger group, but we didn't necessarily agree on how to proceed moving forward. We should we perhaps entertain a motion regarding that.

Babekir, Amani: Do we want Erin’s suggestion to be a motion or there is any other suggestion or motions you want to present here?

Moritz, Erin: I can't raise.

Babekir, Amani: Correct.

Moritz, Erin: I can't raise a motion and I'm a non-voting member but, do you want me to repeat what I was suggesting and then somebody could motion on that?

Babekir, Amani: Yes, please.

Moritz, Erin: OK. My suggestion was to first start with subgroups reviewing the comments from the federal partners within their own subgroups and address any comments that they're able to address there. Any outstanding issues that they'd like the feedback from the larger group would be taken to the larger committee.

David Read: OK. I'm just curious if we do this in subgroups, if somebody from FDA would be willing to participate in some of those. Otherwise, it seems like it's easier almost to do it in a group, but if you do it by subgroups - rather than flounder around, if there's questions, it might be nice if we could have FDA on those subgroup calls.

Michelle Hill: Since they some of the subgroups are headed by our federal partners, so they're present in, and if they're not, we could certainly invite them.

Babekir, Amani: We have federal partners on our subgroups - the emergency plan we have Devin, and the training we have Greg, in the notification we have Devin, in the practices we have Greg, and on the template, we have Erin.

Babekir, Amani: We have a good representation for them on the subgroups and if we want to add more members, volunteers, that also could be done. I'm open also the opportunity now for that to be done. Do you think that is sufficient, David?

David Read: Yes, that'd be fine. I just know that they're busy and maybe haven't been able to make all of the subgroup calls, so.

Devin Dutilly: I think we, if needed, can figure out how to provide coverage. If one of us can make a meeting or something like that, we work together to provide comments on the documents. We, from FDA and I think I can speak for USDA and CDC as well, appreciate the partnership and we're here to support CFP and this progress. We'll definitely support, wherever we can and whenever we can - we'll provide coverage for sure. Thank you.

Babekir, Amani: Thank you. OK. We could define the members of each subgroup later in the meeting, but we still have to decide on maybe on how we want to proceed. I would like to entertain a motion. [Long silence]

Michelle Hill: Which means somebody has to make a motion for us to move forward - A voting member?

David Read: I'm sorry, could you repeat?

Eisner, Crystal: Yes, what was that? Can you repeat it?

Babekir, Amani: We need to have the motion to decide how we want to proceed. Erin suggested that we work on the comments in the subgroups, and then if there are any outstanding issues, we could bring it to the general meeting to discuss it. That is a suggestion that has been brought up, and the previous motion did not pass, which is working on the comments in the general meeting, so I would like to hear motion. What if you want to further discuss it – I would also like to hear it - about how we want to proceed, how we want to work on the comments.

Libby Thoma: To clarify, we have two options. One, we work in our subgroup with our regulatory partner, or we do it together in a in the total group, but that didn't pass, correct?

Babekir, Amani: That's correct.

Libby Thoma: I motion that we work through these comments in our subgroups, Madam Chair.

Babekir, Amani: Thank you.

Eisner, Crystal: And I second the motion.

Babekir, Amani: OK. Thank you. Is there any discussion, or any additional point on this motion?

Moritz, Erin: I do want to clarify that my suggestion was not just working on the comments with the subgroups, but it also includes if there are any comments that the subgroups do not feel confident making decisions with, we could still bring it to the larger group.

Babekir, Amani: Thank you. Libby, would you like to amend your motion to incorporate this or ...

Libby Thoma: Yes, I amend my motion to include that if there are any outstanding issues, we bring those to the large group.

Babekir, Amani: Thank you. OK. Any second?

Eisner, Crystal: This is Crystal, I second it again.

Babekir, Amani: Thank you, Crystal. OK. Let's proceed to vote on the motion. If there is no further discussion. If you agree with on working on the comments in the subgroup and bring any outstanding issue to the general meeting, please raise your hand or say, yes.

Michelle Hill: [Voting members vote] Thank you. I have 7 yeses.

Babekir, Amani: Thank you. Anyone abstain?

Vinson, Scott: Madam Chairman, point of clarification.

Babekir, Amani: Yes, Scott.

Vinson, Scott: How many voting, how many voting members do we have in the call?

Babekir, Amani: We have 8.

Vinson, Scott: And for a motion to pass, does it require a majority of voting members or a majority of people in the call?

Babekir, Amani: Eight, we need 8. Eight of the voting members.

Vinson, Scott: So, we need every voting Member on this call to vote in favor of something for it to pass.

Babekir, Amani: That's correct, yeah.

Vinson, Scott: Oh dear.

Babekir, Amani: Do we have any abstaining? Michelle, do you have any counts?

Michelle Hill: I have seven in favor. No abstentions. So, the assumption is that we should collect the No votes.

Babekir, Amani: Yes. This did not pass, we need 8. So, it seems like we need to find a way to be in the middle to bring both groups together.

Michelle Hill: Perhaps we begin the review – bring up the documents so we can all of us get a good look at them together and maybe entertain a motion to do at least that part today, with everybody still on this call. And then we can decide after we look at it, what kind of work is in front of us and form a plan … someone has to make a motion.

Vinson, Scott: Trying to move it, I move what Michelle just said.

Babekir, Amani: Yes, I think I think we need to do it that way. OK. So, Michelle, could you access the documents because we hosted all the documents, we received with the comments in the Teams side.

Michelle Hill: I got it fine with the call, but I have no access to any CFP files on Teams.

Vinson, Scott: Madam Chair, I have that e-mail open. I can share my screen if you'd like.

Babekir, Amani: But we were hoping to work on the same documents. If there is a way anyone of you could access the Teams side the CFP …

Babekir, Amani: The idea was if we are going to work on it in the subgroup, at least one member could be able to access the documents and help the team members to work on it. But it seems like we are not able to access it while we are in the call.

Vinson, Scott: Madam Chairwoman, this is Scott. I just shared my screen. Is this one of the documents you are referring to? This was in that e-mail you sent around.

Babekir, Amani: No, that is just the summary for the comments from the USDA. It's the other one which has the actual comments.

Vinson, Scott: OK, here it is. I think I've found it. Is this correct?

Michelle Hill: You've got it! Turn on comments or scroll down to see if comments are turned on. Oh, there they are.

Babekir, Amani: I don't think that is - what is that? Could you open the other one? You could start with that one.

Vinson, Scott: OK. Can you see this one?

Babekir, Amani: That is the one.

Michelle Hill: Thank you so much. If we can start making - reviewing at least the first beginning part of this right now, you could just send me your document. I'll make sure it gets left loaded where it needs to live. Is that OK with you Amani?

Babekir, Amani: Yes, that is OK. Let's start with the first comments. Could you maybe click on it so you could show the whole comment?

Vinson, Scott: Oh yeah, there.

Babekir, Amani: We could give it like a minute just to go over the comments and then we can discuss it.

Michelle Hill: Yes.

Babekir, Amani: OK. Let me now open the floor for the discussion on this comment.

Eisner, Crystal: The comment says consider changing it to major food allergen framework, but then it says, can you also include non-major food allergens?

Moritz, Erin: So, regarding the suggestion to change it to major food allergens, I think one of the key questions is if somebody comes in and says, I have an allergy to Jell-O, which is not one of the major food allergens. Do provide guidance here that can be used for non-major food allergens.

Michelle Hill: Am I wrong in assuming that the point of calling it a major food allergen framework is, that is the verbiage that appears in the food code - Is that right?

Abel, Greg A: Correct.

Libby Thoma: Correct.

Abel, Greg A: That's correct. And the document only applies to the major food allergens, the eight soon to be 9, correct.

Michelle Hill: Correct. Thank you.

Babekir, Amani: Also, would like to remind that our charge is addressing the major food allergens.

Eisner, Crystal: We should probably name it the same.

Michelle Hill: Do we need to entertain a motion to make this change?

Babekir, Amani: I think that will take long time.

Vinson, Scott: Maybe it'd probably be faster just to ask if anyone has any objections to any of these suggestions.

Michelle Hill: That's good advice.

Babekir, Amani: Are we good with the change? Are we good with changing the document title to major food allergen?

Vinson, Scott: Yes.

Babekir, Amani: OK. Any other point? OK. So, Scott, could you type that please?

Seymour, Jenna: I do hope that this other point within that comment is not missed about just having something somewhere that points people, like in this case with Celiac disease that came up a lot in discussions. Just pointing people to the gluten intolerance group. It's not like this document would have to say anything about it except to say if this is also a concern,

go here [insert GiG website address]. Just do not ignore what is obviously something that a lot of restaurants are hearing about and wanting to address.

Michelle Hill: We perhaps also could refer to the FDA advice on what is gluten free. That might be a good part of it too.

Devin Dutilly: I think that in addition, the broader question would be what Erin had said about these procedures these techniques, these points may also apply to other allergens as well, so you know it's not a major change to the document, but that's what the comment essentially is capturing - is that you don't need to make major changes, or perhaps you might need to make major changes, but small tweaks.

Babekir, Amani: To what?

Moritz, Erin: I think a long time ago, we did have some kind of verbiage in here about how this, even though this is the charge, is specifically for major food allergens, a lot of the materials are relevant to you know gluten sensitivities or any other food sensitivities.

And so maybe just a sentence or two in the introduction and then pointing, since gluten is such a such a prominent sensitivity, pointing to some gluten sensitivity resources.

Babekir, Amani: Do you think we could point to this in the introduction of the document.?

Moritz, Erin: To me, that's kind of where it fits most, because it's before we are even getting into the main purpose of the document. Or maybe if we end up doing a references page at the end possibly? Certainly open to other suggestions.

Michelle Hill: I did notice that the comment below the one we're working on also dealt with a similar or same issue. I'm wondering if it would inform our process.

Babekir, Amani: OK. And Scott, could you please change the title on the document to Major? Thank you.

I'm going to give it 30 seconds to go over the second comment.

Michelle Hill: And this might be how we achieve what we're trying to achieve, which is they're saying to add possibly a disclaimer on the scope of this document. We could say, yes, it deals with the nine major food allergens. However, it's also applicable to, fill in the blank, really.

Babekir, Amani: It seems like it's the opposite. It's like you disclaim that it is just the nine major food allergens.

Moritz, Erin: We'll have to state somewhere whether everything in here is just for the nine food allergens. And if we're saying that some of the parts can be used for others, then maybe it's not necessary to consider it a disclaimer. We just have to write something somewhere.

The key question is what we want to do about the fact that some of the stuff is going to be applicable to other food allergens and other sensitivities.

Babekir, Amani: But is it enough and sufficient for the other Allergens? If we want to generalize the document and say this is for major food allergens, but it could be applicable for other type of allergens, do you think that's a fair statement?

Moritz, Erin: I think we use wishy washy words like, it could be applicable to other food allergens and other sources of food sensitivities, etc.

Michelle Hill: Including celiac disease, perhaps.

Seymour, Jenna: I get a little uncomfortable with that one just because …

Moritz, Erin: OK.

Seymour, Jenna: That's why it was me that put that gluten intolerance group into the into the comment because they do training for restaurants on specifically how to deal with Gluten intolerance and celiac disease.

Michelle Hill: Yes, they are awesome - I was really glad to see that.

Vinson, Scott: I was going to try to add an asterisk here and then put down at the bottom what we just talked about a disclaimer, but I can't seem to figure how to do it, so maybe it would be better done on page 4 in the verbiage of the introduction.

Babekir, Amani: So do we want to say it's just for the 9 Major food allergens or it's also applicable to the others?

Moritz, Erin: I don't know how often this would happen, but I would hate for somebody to.

Say, I learned all this stuff and I have all this stuff, but somebody came in with a Jell-O allergy; now what do I do? And Jell-O allergy being an example of something that not many people have.

Michelle Hill: No, it's that allergy to gelatin, and I happen to have it – it is obscure.

Moritz, Erin: Oh, you do. OK. I'm sorry. I was trying to think of something very obscure.

Michelle Hill: The question I keep thinking of is would we change our behavior if we knew other information other than, Is it an allergy? and we would take hopefully the same precautions that we do for allergy that we would for Celiac.

Moritz, Erin: In anaphylactic shock to gelatin and your emergency response, I think should not be any different than if it were for one of the nine.

Michelle Hill: No.

Vinson, Scott: If we had that type of language, are we going beyond the scope of our charge?

Moritz, Erin: I think we would be dipping our toe beyond the scope. In in my mind, as long as we don't go in depth and discuss other scenarios. I guess it's just common sense to me that we could say something like that and be OK.

Vinson, Scott: How about something like this?

Moritz, Erin: Certainly, certainly open to other, you know, other opinions.

Babekir, Amani: I need to end the meeting at 3:00 pm because I have another meeting and I wouldn't be able to stay on the call. We need to stop it here and we could proceed on the other comments the next meeting.

Babekir, Amani: Do we want us to make this weekly meeting? I think we need ….

Michelle Hill: We didn't reach a consensus, did we?

Babekir, Amani: I hate to delay working on it for two weeks.

Moritz, Erin: For what it's worth, I think we're going to have to meet more often, especially if this is kind of the direction that we're going in, in terms of how we're going to address these.

Babekir, Amani: Please send me your suggestion if you think it's better, we move to the weekly meeting instead of bi-weekly so I can set-up a meeting for the next week at this time. We need to convene now.

Abel, Greg A: One quick comment – the document that was reviewed by the federal partners here was an older version, and I know you guys met two more times to revise the document. So, what you might have in the current version of the document may have changed since the comments on this revision, from what I understand.

Babekir, Amani: There are some changes here and we could look at it and compile it into one document.

Abel, Greg A: OK.

Babekir, Amani: Yes - before we proceed with the comments.

Michelle Hill: Thank you for making us aware of that. I'll work with you on that, Amani. I'll be happy to.

Babekir, Amani: Yes. Thank you, everyone. Scott, please send to us this version and see you either next week or the following week.

Michelle Hill: Stay tuned. We'll be asking your opinion on how we should move forward via e-mail.

Adjournment

Babekir, Amani: This meeting is now adjourned. Thank you.

Meeting Number 19	Meeting Date **08/18/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
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MEETING MINUTES

Babekir, Amani: Michelle, would you like to do the roll call?

Michelle Hill: Yes, Madam Chair. I can do that. [takes roll call of Voting Members] We have a list of seven and I do believe that's our current quorum so we can proceed with the business of the day.

Babekir, Amani: OK. Thank you, Michelle.

Babekir, Amani: I would like to remind you that the Conference for Food Protection Antitrust statement is active in this call. So just keep that in mind.

Babekir, Amani: Let me share our agenda for today. I'm going to give you an update about our voting members.

So we could you could see how we ended up with the seven as our quorum.

Babekir, Amani: OK. So we're going to postpone approving the minutes of the previous meetings to the next meeting, so we're going to have almost like, 3 or 4 Minutes to approve, so hopefully we could do that in our next meeting.

Babekir, Amani: I want to also give you an update about our voting members. So two of our voting Members are not with us anymore. Vy has moved to a new job and is not able to serve in our committee and Cassandra, she retired. So they are very active members in our committee and it's a big loss for us. We should all the best to them. Both of them are representing the local regulatory, and we want to keep the balance of the floating members. So we moved one of our alternate members from local regulatory - Christine - to the voting members. So I'm really glad Christine has agreed to be a voting member in our committee. Hopefully this will make our voting process easier, and we will meet our quorum in our meeting. Any questions before I move to the next item in the agenda? [no questions are asked]

About the timeline.

I received a couple of questions about “what is our timelines” and we are looking into the extra work we need to do with the framework, we really got a little bit worried about our timeline. So, the updated timeline - that is per November 18 - we need to submit the final reports, the final documents and also the Issues we want to submit to the Council for the next Biennium.

All of these need to be ready for a round of review from the Council members, and then we're going to have a chance to make a second round of edits before the final solid submission. But this is the deadline - November 18th, so we need to be ready with all of our documents by then.

What we propose to do in order to finalize our work in the framework, because we're going to need also some time to spend on our Issues, we going to dedicate kind of four weeks to review the comments we received from our federal partners. In these four weeks we are hoping, and I sent an e-mail about this, we are hoping that we do some work or even just go over these suggestions and see which one we want to address.

Which one we think we could refer to maybe a future committee's charges. Or we could disagree with it and have a different opinion than doing any change on the framework. For the sake of time, we thinking what will be the way to do it? And because we couldn't come to an agreement in our last meeting, as to having a portion of the comments to be worked on the subgroups, and some portion we review it in our large meeting.

And thank you to Michelle. She put all of the comments in one document. And this way we could review it in our meeting, just look into the comments, see which one needs to be discussed here in our large meeting, which one we could, you know assign to the subgroups just by doing it so quickly.

And we did do this initial kind of work, me and Michelle, we worked through all of the comments, and we thought, OK, this one is one of the basic things that we need all of us to discuss in our large meeting. Some of it is format or just extra information needs to be added, which could be handled with the subgroups. Thinking about what we sent in the e-mail and what we suggested right now, I'm opening the floor for any suggestions, any comments and any points you want to raise before we move forward with reviewing the comments.

And I can't see any hands. Michelle, if you see hands.

Amber Potts: Scott has his hand up.

Vinson, Scott: Can I share my screen?

Babekir, Amani: Yes, please.

Vinson, Scott: OK, so I'm the leader of the group E, which focuses on Practices, and I will share my screen. So these people are in Group E practices, Ben Wagner, James Baldwin, Aubrey Noller, Greg Abel, Amani and James O'Neill Amani, you're on, I'm on, I didn't hear during the roll call many of the other folks in my Group E on the call - did I miss anyone who's maybe on?

Babekir, Amani: Yes, I know. Ben Wagner is traveling, so He is not able to join us on the call.

Vinson, Scott: James, are you on?

James O'Neal Yeah, I'm here, Scott.

Vinson, Scott: OK. Amani and Michelle, how many people does it take? How many people do you need to have a quorum on a Group to have a call?

Michelle Hill: I think it's just simple majority.

Vinson, Scott: Supermajority. OK. Well, I don't think we have it cause it's just me, James, Amani. I was going to ask my Group E if we could meet following this call at 3 pm or whenever this call ends, so we can perhaps dispose of some of the comments from our federal partners. Let me share my other screen to show my Group what they are. So I have reviewed the comments from Devin Dutilly: , one of our federal partners. Let me share my screen so you can see what they are. Here it is. So group E, we are actually "section B Food handling practices" in the framework document, and our section comprises two pages, pages six and seven of the framework.

Devin has submitted 20 - I counted them up across 2 pages - comments, most of them are picayune, and merely like suggestions or observations and don't require a great deal of any consideration? Some do, but I was wondering if my Group could maybe quickly dispose of them, act on them on a call after this call.

Does it sound like we have enough people to do that? I'm going to be out for the next two weeks. This is August, which is vacation time for people involved in the public policy making apparatus in Washington. It's and surrounding areas. So this is the time when we're out because Congress is out. So this. I can't work on it the next two weeks. I know you would want the subgroups to take it from here.

I guess we'll have to come back in early September to do it, if that's OK with you, Michelle and Amani.

Michelle Hill: One thing I wanted to point out, Scott is, and I don't know that this is the case, but there's more than just Devin's comments that are part of the considerations. So there were comments from FSIS.

Devin Dutilly: Yes.

Babekir, Amani: Yes.

Michelle Hill: Devin had condensed a bunch from other federal partners under his own name, so some of that data, of course, came from other agencies like USDA. Is that right, Devin?

Babekir, Amani: Yes.

Vinson, Scott: Well.

Devin Dutilly: Yes. Thank you for. Thank you for clarifying it, Michelle, that's correct. So the comments that were submitted, I submitted the comments and as we discussed previously, those comments were comments from USDA, FSIS, USDA, FNS and CDC as well as FDA.

So the comments that are underneath my name are compiled comments from the federal partners. So they're federal partners comments, even though my name appears. And we don't have ability yet to change who submits them, so they're all submitted underneath mine. So I compiled all the comments that were submitted, and we discussed the comments as federal partners. So those are federal partner comments. Thank you. Thanks, Michelle.

Vinson, Scott: OK.

Babekir, Amani: Also, Scott on the e-mail which I sent, I sent the version of the framework with merged comment because also we have comments from the USDA.

Vinson, Scott: That's what this document says at the top of the screen, doesn't it, merge comments?

Babekir, Amani: Ah, yes. That is the one, OK.

Michelle Hill: Ah, that's not the most recent one we sent, though. We sent one that was laid out in a landscape fashion with all the comments for everybody at the bottom. I did a clipping of each part where the comments pertained to and then they're all in a grid below the picture of what you're commenting on, or what the comments were on. Does that make sense?

Vinson, Scott: This is the document that Amani sent out last night.

Babekir, Amani: That's correct. Yes. So this is the actual framework with the comments, the document Michelle referring to is that second document on the e-mail which includes the list of all the comments. But Scott, you are good. That is the document you need to work on with your subgroup.

Michelle Hill: Even though no other partner comments are on that one?

Babekir, Amani: That should have all of the - that should have the merged comments.

Vinson, Scott: OK, so there are three documents in the e-mail you sent out last night. I'm sharing it on my screen here. I don't care if everyone sees.

Michelle Hill: What you should be looking at is federal partner comments.

Vinson, Scott: OK. Well then that was confusing, so I should be looking at this one.

Michelle Hill: In your attachments, there's one titled federal partner comments 8/12/22.

Babekir, Amani: Yeah, but that, that one, Michelle, that's contained just the comments, but if they are going to start working on the actual framework document, they need that one with both comments because we merged it together.

Vinson, Scott: OK, now I'm confused. So I think the document that I was originally sharing on my screen that said merged comments with all the comments in the right margin, I think that's the one we're that the subgroups are supposed to consider, correct?

Babekir, Amani: That's correct.

Vinson, Scott: OK, so I was right.

Babekir, Amani: Yes.

Michelle Hill: OK. And the one that I'm talking about it? Can you bring that up, please, Scott? Because there is some important information on that that I want people to be aware of.

Vinson, Scott: Which one is it called?

Michelle Hill: Federal partner comments 8/12/22.

Vinson, Scott: OK, let me pull up that e-mail again. So this one.

Michelle Hill: Yes.

Vinson, Scott: Federal comments.

Michelle Hill: Correct.

Babekir, Amani: When we were planning to review it, to go over that document just after Scott's point, yeah, we want to go over the list of these comments and then show you which one we think we need to discuss it here in our meeting and which one we could assign to the subgroups.

Michelle Hill: This seems like it's crazy because it's 57 pages, but, what was done was the information that the comments pertained to was clipped and pasted above as a static picture, so you can't actually change the data and then the first column there “D” that means it came from, you know, the Devin Dutilly: labeled stuff, and then you know what they said. And then in the far-right column, it's what Amani went through, and we decided, OK, or we thought about. You can of course suggest any changes, but we just did a quick look and thought, OK, who should work on this? Is it a whole group issue? Is it a template group issue? And Amani color-coded based on is it a? Is it a formatting particular or is it - what was the green again, Amani? I don't remember what the bluish green was.

Babekir, Amani: Yes, so these one that's we need to consider, we need to think about and the yellow is formatting changes or the blue also might refer to like text addition.

Michelle Hill: That third column would be used to actually make the language changes or suggestions. And then we can meet as a group and merge it all together. That was the thinking. You don't have to use this, but we've already done some of the vetting and we're just trying to improve the flow in the process. And so at some sections get repeated because they had multiple sets of comments. So if you see repeating same data, it's because there's still comments that have to be addressed.

Vinson, Scott: I am now totally confused.

Babekir, Amani: What we're trying to do with this one, which including all the comments, is to look at it here in our larger group and think about it. But as a subgroup, you need to work on that document, Scott, to look and see the comments. We want to ensure that you are using the right comments which have both the FDA and also the USDA comments together in the same document.

Michelle Hill: And FNS was separate ...

Babekir, Amani: Yes - so all the partners.

Michelle Hill: The original one you were showing.

Vinson, Scott: This one.

Babekir, Amani: Yes, do you see other comments beside the Devin comments? Do you see other comments with other names?

Vinson, Scott: No, they all have Devin's name. Click on each one. But he said that is just because he merged all of the agencies - Federal partners - into one under his name.

Babekir, Amani: Yes, you should see all the comments and labels.

Vinson, Scott: Well, there's one, yeah. There's one.

Babekir, Amani: OK, so that means you're good. Yes – FNS - that is another comment. So we merged both of them into this one document.

Michelle Hill: OK, I'm really glad you made that clarification, Amani, because all I was hearing was that it contained only Devin comments. So I'm glad to see FNS would be part of that too. So good - thank you, Scott.

Vinson, Scott: So the subgroups are to use this document that I have open now - that you all see on your screen - and each group should go to their section of the framework and consider so for example , you know the training group should consider each one of the comments.

Michelle Hill: Yes.

Vinson, Scott: OK.

Babekir, Amani: That's correct.

Vinson, Scott: So I don't have, it looks like enough people in the practices Group E to do this today. So my question for you, Amani and Michelle, is, is it OK if our group waits until early September?

Babekir, Amani: September? So you're going to have like early September, that's mean you're going to have like 2 weeks to complete it. Do you think this could be done within two weeks?

Vinson, Scott: Well, my group, we only have 2 pages. And it's 20 comments. Many of them are fairly innocuous - don't seem to require - I mean this is more a comment than anything that requires action. This section could be applied to all food allergens, but our regs are specific only to major food allergens. OK, and your point is, I don't know, but I imagine our Group is going to just say, OK, whatever. But there are some that are substantive, but I don't think it'll take two weeks or probably take one call.

Babekir, Amani: OK, that sounds good.

Michelle Hill: So Amani should we put a deadline on that like we would like to have data back by September 15th perhaps or?

Babekir, Amani: Yes, we agreed that this is going to be done within four weeks. So that means by September 18, we need to be complete, yeah.

Vinson, Scott: And so just so we all know all the group leaders know how many people do we need on our group calls to have a quorum.

Michelle Hill: I think they're subgroups, do they? Isn't it just a simple majority?

Babekir, Amani: Yeah, you don't need quorum because you're not going to be voting. But if you have enough people that you feel comfortable to proceed with, you know the change.

Vinson, Scott: Well, we may well be voting.

Babekir, Amani: You may, I don't ... Wendy? I think Wendy is with us. Hi, Wendy, can you hear me? Are you with us?

Bell, Wendy: Yes, I can hear you. And it's so I believe Michelle is correct as far as the subgroups, I would assume that you would bring your decisions to the main group if there's something that needs additional attention and just the nature of how many Members we have. And on this committee, it's I think we just need to proceed forward. And then if there's an issue we can bring it to Michelle and Amani and we can move forward from there.

Vinson, Scott: So we are not to vote in the subgroups we are to reach consensus on whatever we can where we can't reach consensus, we need to bring it to the full group.

Michelle Hill: That's awesome, yes.

Babekir, Amani: Yes, that's correct. That will make your job easier, without stress. Because we're going to have a chance to review the subgroup work in our large meeting. We're going to have two or three meetings to do that. So it's any critical things, any additional points, because now we're going to go to the document Michelle just discussed. Any additional points about the subgroup work?

Michelle Hill: I think it was Amber who said in the Chat that she would like to follow the same thing for her group. Is that right, Amber?

Amber Potts: Yeah, I agree. And ours is even smaller or like a page and a half. So it'll probably just take one meeting to go through the comments and that would be it. So I'll send a "when it's good for my group?".

Babekir, Amani: If that is good and for the notification group, I have a meeting this Friday and I moved it to, I think 3:30, so I could give Devin a chance to join us. Scott, would you be able to join if we move it a little bit later? I know you did not accept it or you're going to be on vacation. You are going to be out.

Vinson, Scott: What date are you talking about?

Babekir, Amani: Tomorrow at three.

Vinson, Scott: I'm on vacation. I'm traveling.

Babekir, Amani: OK, so it will be fine. So for the notification subgroup, we're going to meet tomorrow , and that should be the other one. Michelle is going to take care of the equal considerations' subgroup. So, Michelle, are you good with that one?

Michelle Hill: Yep. Thank you for reminding.

Babekir, Amani: Thank you. And I'm gonna send an e-mail to Ben for his subgroup and Erin, are you good with the starting your emergency plan group?

Moritz, Erin: Yeah, I'm gonna send out a "when is good" poll and just put some meetings on the calendar based on that.

Michelle Hill: Erin, I think you already do invite me, but could you for sure invite me for those?

Moritz, Erin: Yes, absolutely.

Michelle Hill: OK. Thank you.

Babekir, Amani: Thank you. It's great. And let me share that document which including all the comments together just to give it a look. So here are all the comments and I'm glad that we resolved the first two comments good with that one.

All these comments are related to formatting and having a footer section, so that will be taken care of by the template team. And this one - the one which you see I put committee on - we need to discuss it here.

These comments are about the title of the document, which is the retail food establishment.

Do we need retail on it? Amber, we discussed this one before here. Do we need it to keep it retail food establishment or … ? Consider all other all retail food establishment are not specifically called out in terms of special consideration for this type of food establishment. Do we need to think about other names or add any additional comments to the document? Just give yourself some time to go through these comments, which I'm just highlighting.

Eisner, Crystal: What's the current title?

Babekir, Amani: Now the title of our framework is "At retail food establishment" here, and also, we have it here, retail food establishment.

Moritz, Erin: Do we have the definition of that anywhere? We put that in our definitions?

Amber Potts: The food code calls it food establishment.

Babekir, Amani: We have it as food establishment, not retail. Even in the definition section.

Amber Potts: I think we should just put it as food establishment.

Moritz, Erin: I'm good with just food establishment.

Babekir, Amani: Thank you. Now we could move to the second one. So talking about food intolerance and sensitivity. Just take a moment to go through it.

Amber Potts: I think the only comment I would think is I don't like gluten intolerance. I would prefer like with I'm, I'm assuming it's referencing Celiac. Which is more severe? You know, I have a lactose intolerance, but if I eat it, I'm not gonna get severely ill. I think

don't we already have something that mentions it? I feel like we should mention it, but Celiac is it called a gluten intolerance? Is that what it's called?

Vinson, Scott: I have Celiac disease and it's referred to interchangeably as Celiac disease or gluten intolerance.

Moritz, Erin: Are there degrees of severity where you can be intolerant, but it doesn't rise to the point of Celiac disease?

Michelle Hill: Yes, and that's referred to as gluten sensitivity, not intolerance.

Moritz, Erin: I see, Celiac disease and gluten intolerance are synonymous. So, I think if anything, to be correct, we would refer to it as gluten sensitivity or Celiac/gluten intolerance, I guess, if people aren't familiar with the term Celiac disease.

I don't think that's really getting at what this comment is addressing. I don't know if we want to say it's not intended for gluten sensitivities.

Michelle Hill: You know, because really logic would dictate you don't treat them any differently. The answer is complete exclusion of the protein from the meal. So, is the behavior different?

Amber Potts: No.

Moritz, Erin: Yeah, that's a tough one.

Amber Potts: I don't know this much about food science. Can you have a product with wheat but not with gluten? And can you have a product with gluten and not with wheat?

Vinson, Scott: Yes.

Michelle Hill: Wheat is the greater allergy. Yes. And gluten. There are some wheat grains that are gluten, low gluten or no gluten. And that is the difference. So it's Gliadin across the board and then you can also have the Gluten as part of it, or separately.

Seymour, Jennifer: So I just, I just wanted to correct something because I was feeling like what was just said before, was not right. So I just checked, to back me up, that gluten intolerance is not the same thing as Celiac disease when they're talking about gluten intolerance, which is talking about people with issues of bloating, etcetera, that is not Celiac.

Vinson, Scott: I mean, look, the advocacy groups, there are several advocacy groups for people with Celiac disease, some of them call themselves the Gluten Intolerance Group.

Seymour, Jennifer: Right. Although I'd take GiG does work on addressing issues for people with gluten intolerance as well as Celiac, which might be why GiG is called that.

Vinson, Scott: Look, I think I'm probably the only person on the call who actually has Celiac disease, so maybe.

Seymour, Jennifer: No, I do also, sorry I do.

Babekir, Amani: I do, I also have it, Scott.

Vinson, Scott: OK, well, when we were diagnosed, we were diagnosed with Celiac disease, right?

Seymour, Jennifer: Yes.

Vinson, Scott: And our doctors also referred to it as gluten intolerance. Gluten is a protein that is found in wheat, rye, barley and sometimes oats, due to cross contamination.

Babekir, Amani: To address the intolerance and sensitivity, and also to consider mentioning gluten specifically so, do we want to do that?

Amber Potts: I think it's worth a mention.

Moritz, Erin: Yeah, I think so. There's what we call it, which ultimately, we'll have to come up with something we agree on, but the larger comment is whether we feel comfortable saying that what we've put together can be used to prevent exposure.

Amber Potts: Right.

Moritz, Erin: People from being exposed to gluten? So there's kind of two questions that were discussing.

Michelle Hill: The point I was trying to make earlier is if the behavior is different then we need to talk about it differently. But if it's the same behavior you're gonna employ to control the problem we could say, the concepts contained here, or the advice is guidance. It effectively, when implemented well, will effectively control for Celiac, gluten intolerance, whatever you're going to say, … I don't know if that's agreeable, but ...

Moritz, Erin: I think that's the goal of what we set out for at the beginning … was to have it be helpful in both situations.

Michelle Hill: Yes

Michelle Hill: And from a person that teaches this stuff it just seems like the confusion is around boots on the ground. Confusion is, "Is my behavior different? And if the behavior keeps the allergenic protein controlled, you still need the same skill set. Reading the label, knowing the how it is prepared, what's its flow …

Vinson, Scott: Right.

Babekir, Amani: But is it? Is it sufficient? So is it sufficient to control gluten – the information we include here? Or could it be used as part of the gluten control?

Michelle Hill: Well, really any allergy.

Vinson, Scott: It's probably not. I mean our charge was to control for the eight allergens. Rye and barley aren't among the eight Major or nine major allergens. So we probably should just include a sentence in here, something like ….

Michelle Hill: They don't exclude Rye, Barley, because those are types of wheat grains. They're in the grass family. So those are descriptions or examples of how we talk about that allergen in the food flow and labeling.

Vinson, Scott: Say that again, Rye and Barley are types of wheat.

Michelle Hill: They're in the wheat family. And so when, for instance, when you look at a fish allergy, it also says like cod. I can't remember what else I see if I asked, flounder, cod? Or when they talk about shellfish, they say lobster, shrimp, crab, am I wrong about that? People on the food code? That's meant to give you examples of what that allergen is.

Babekir, Amani: Probably I think wheat is just the wheat.

Devin Dutilly: What you had said is correct. The food code, the allergen definition, major food allergen definition, contains those examples behind it. Yes, that's correct.

Michelle Hill: What? Which means they're included as part of that allergy they're describing the allergy. What's under this umbrella of allergy?

Vinson, Scott: So you're saying because the nine major food allergens include wheat, that barley and rye should also be understood to be one of the nine major food allergens?

Michelle Hill: Absolutely. In fact, the way it is taught by most companies that train people for the CFPM is to learn what are the derivatives - what is this allergy? We can say dairy, but really you need to read the label for casein. So if you go back through and read the food code, it's gonna give you parts to include examples of what is included under that major allergen category, or within that category there's actually ...

Seymour, Jennifer: But that that really surprises me. I agreed that barley is a grass, but that not ... so it might be included in the category that are grasses, but to say that it's automatically excluded when wheat is excluded, that seems very suspicious to me.

Michelle Hill: I'm not wrong on this. So can you guys please speak to this, the people that know about this from the FDA, Devin perhaps?

Devin Dutilly: Yes. So, just to clarify the way that the major food allergens are defined in the food code aligns with the same way that they're aligned within the FD&C Act. I'll just go to it just so that I'm not misquoting anything here. So the major food allergens read, "Milk, egg, fish quantities such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster or shrimp, tree nuts such as almonds, pecans or walnuts, wheat, peanuts, and soybeans.

So it provides such as behind fish and it provides a such as behind crustacean shellfish it currently, as it's written, it does not provide such as behind wheat. That's the question.

Babekir, Amani: Yeah. So.

Michelle Hill: The framework we teach from includes descriptions like for the egg it would be yolk and then white because they're different protein structures. You can be allergic to one and not the other. Umm so interesting.

Vinson, Scott: Rye and barley are not wheat. But and I don't think it's their commonly understood to be wheat, it's probably an academic question for our purposes. So we should definitely mention in this comment that people who have been diagnosed with Celiac disease are intolerant to gluten and gluten is found in wheat, rye, barley and frequently also oats.

Babekir, Amani: So the main the main question here I think, and we have an agreement on it, is that we should mention gluten in our introduction of the document, as an example.

Moritz, Erin: Yes, I think at the very least, we need to say something about it. Because people are going to say well to this apply to gluten and personally, my opinion is that much of what, if not all, of what we've developed can be used for gluten. I'm not super familiar with all the processes that can happen in food establishments, so am definitely interested in hearing what other people think.

Vinson, Scott: I think we should list them, so that people in the restaurant, the food service workers, know they need to be aware that people who have Celiac or gluten intolerance or even gluten sensitivity need to watch out, not just for wheat but also barley and rye, oats, which may be present in the facility.

Michelle Hill: Have you ever seen it labeled that way? Scott, I'm just curious on a consumer label, have you ever seen it? Where they do, they just say wheat and wheat probably is present. Do they say wheat and parentheses?

Babekir, Amani: Yes.

Vinson, Scott: On boxes, on the consumer on the ingredient labels, yeah. You will frequently also see them in a restaurant or food service setting. It's gonna be less common - the consumer's not gonna see it, but the people working in the back of the house may see those ingredients listed on ingredient panels, in product packaging.

Michelle Hill: And it'll be listed as gluten or as wheat.

Vinson, Scott: They'll be listed as wheat, rye or barley. It won't be listed as gluten. That's very, very, very rare to actually see gluten in a product panel. Unless the product is actually gluten, I mean you will see gluten. You can buy gluten at the grocery store.

Seymour, Jennifer: Right, sometimes you'll see vital wheat gluten listed or something like that.

Michelle Hill: I was wondering how does the world treat Rye, barley that aren't wheat, do they list it as a wheat allergy? I mean, is the allergy the list for wheat or do they not list for barley? Is barley not considered? Do they ever call out barley?

Seymour, Jennifer: I would think yes.

Vinson, Scott: Barley's a separate grain. Barley is not considered wheat. It's a separate grain. So is rye.

Seymour, Jennifer: I think I have definitely seen a barley mushroom soup. And you know, that would not be labeled as a problem for a wheat allergy?

Vinson, Scott: That's correct.

Seymour, Jennifer: Something come like that? Yeah.

Babekir, Amani: OK, so I think, yeah, I think so. The introduction group needs to consider gluten on when they are working on their introduction, do we need to mention any cautious statement that is this document might not be sufficient to control gluten.

Seymour, Jennifer: I think so. Yeah. I think so. And that's where I think we were talking last time about including the link to the Gluten Intolerance Group, because just right away, I think of things like, you know, malt that's made from barley but people may not associate because it doesn't say barley or all those kinds of things, where if you really want to understand and make something gluten free you have to know a lot more about all these different, like what we're talking about, Emmer or and triticale and spelt and all these things that people would have to understand to make things gluten free that aren't necessarily. I mean it. Those last ones would be related for the wheat allergy, but I think both are good examples, or the fact that oats are often contaminated.

Seymour, Jennifer: All those things are worth having a link to somewhere else for understanding the issue of gluten.

Vinson, Scott: Yeah, but we shouldn't put links in this document, because I mean, they're probably gonna be printed out. So we should just list them out. It just put in the def in parentheses behind gluten and put all of the things that fall that contain gluten. All the grains that contain gluten, wheat, rye, barley, oats. Barley malt.

Moritz, Erin: And we direct them to the home page of good websites - I think the Gluten Intolerance Group - list out the name of the organization.

Seymour, Jennifer: I think the Gluten intolerance Group is the place to direct them, even if it's not a link, just direct them because they work so heavily in restaurants and helping restaurants to be appropriate for people.

Moritz, Erin: So even if it's printed out, we can say. Please go to gluten intolerance group at … and then list the website of their homepage.

Seymour, Jennifer: Yes.

Moritz, Erin: If they want to follow up on that, they'll at least have the home site web page, which hopefully will stay at least stay the same for a while.

Devin Dutilly: I think the intent of the comment was to provide some sort of disclaimer and including, if it says something, this is not intended to address this, but, “here you can get more resources” and so and there's a resource section at the bottom that we have so even if the links are printed off, you could put the actual live link so someone could type in the resource section at the bottom, so we could potentially put it in two areas, but that's just a thought, but the intent of that comment as Erin had mentioned, and Jennifer too, is to capture what is or is not and if it is, don't just say nothing's available. You know adding something like, the GiG might be a resource for someone who is looking for this - so there is something available.

Babekir, Amani:

Babekir, Amani: And that's good. Thank you. And I think we could move to the next one. This one is questioning the document, should it be framework or a toolkit?

And as per our charge is called framework. So do you have any other opinion on this comment?

Amber Potts: No, I keep it as framework.

Moritz, Erin: Yes, to me, a toolkit is a document where we would put a bunch of links to other sources. We do have a couple posters, but I think what we put together maybe is not like in the strictest definition of either one of those, but to me it's more, it has stayed more of a framework.

Babekir, Amani: OK. Thank you. The second one is about adding sections a limitations section to the document, so the user could understand where, how this document was developed; to frame any topic that might be forthcoming or emerging?

Amber Potts: Yeah, I like this. I think we should add at least where who developed this, why we developed it that way. People can learn about CFP and all kinds of things.

Babekir, Amani: OK.

Moritz, Erin: I don't understand why it's a limitation section.

Amber Potts: Yeah, I don't know if that's the right word. This is not regulated; you know enforceable code.

Michelle Hill: We wouldn't necessarily call it guidance either then, huh?

Amber Potts: Disclaimer, I don't know.

Babekir, Amani: No.

Moritz, Erin: Yeah, I think something towards the end may be detailing how it was developed. And then, if there's any disclaimers, like especially important disclaimers, we might want to have them at the beginning and in the section at the end.

Babekir, Amani: OK.

Moritz, Erin: That's what they were going for with limitations.

Babekir, Amani: OK. It's good. So let me see - what is - so this one. This one is talking again about a disclaimer and the language and disclaimer to let the readers know some of the documents could be generalized, so I think we addressed this one already. What do you think?

Amber Potts: Yes.

Babekir, Amani: This one is talking about temporary food events. Do you think we need to address that one, or is it out of the scope?

Amber Potts: But this is considered - what does that charge have about? What does ... they use alternate? What was the wording it used?

Babekir, Amani: Equal consideration.

Amber Potts: For alternate. What's it say?

Babekir, Amani: Yeah, alternate food sources such as food pantries, food bank, probably this is the one.

James O'Neal: Well, and I think if we're going to use the definition of food establishment from the FDA, I feel like … let me pull it back up. The definition of food establishment includes an operation that is conducted in a mobile, stationary, temporary or permanent facility or location. So I think that would fall under that.

Babekir, Amani: OK.

James O'Neal If we're going to utilize that definition, I think we would probably have to address it.

Babekir, Amani: So do you think we should address it under the equal consideration section or?

Amber Potts: Yeah, I think so. Although they need a lot more training because they don't, some people do this at temporary events. They don't do it for a living. You know what I mean? They just want to sell their whatever. I know, as someone with an allergy, I don't eat at Temporary events, so it's just not safe.

Babekir, Amani: OK. So this one talking about Major food allergy versus food allergies. We recommend changing this term, presumably food allergy. What do you think?

Amber Potts: What section is this coming from?

Babekir, Amani: This section is on the person in charge on probably a food allergy definition, food allergy.

Amber Potts: OK. Is this for the training section?

Babekir, Amani: For the training, yes, under …

Amber Potts: Yeah, we'll discuss that in our group and get back to everyone.

Babekir, Amani: The comment is to use through the whole document cross contact. That is one of the comments and also this about sanitizing, and equipment used for preparation, for preparing the customers allergy free meal. So. I'm not sure what it behind these comments, other than just to bring awareness.

Moritz, Erin: So are they saying that just washing and rinsing should be enough? I'm assuming like the soap would destabilize the proteins, maybe.

Devin Dutilly: I think the comment for sanitizing is not relevant because of the wash, rinse and sanitizing procedures in the in the food code that relates to microorganisms, so …

Moritz, Erin: Oh, yes, the definition of sanitizing is reducing microorganisms. OK, I get it.

Michelle Hill: Yes.

Devin Dutilly: So using the term for microorganisms, so sanitizing doesn't - you have the term is not defined towards removing or denaturing proteins, so.

Michelle Hill: Yes, and that would be an extraordinary chemical too, wouldn't it?

Babekir, Amani: Yes, but you still need for the proper cleaning. You still need to sanitize food contact.

Moritz, Erin: Yes, that's what I think. We should maybe leave it like that just because we don't want them thinking like they're still gonna have to properly sanitize it for microorganisms I would think, maybe they won't.

Babekir, Amani: That that is the proper procedure, yeah. To wash, rinse, sanitize.

Moritz, Erin: I get what the comment is getting at, but I don't necessarily know if removing sanitizer is the best approach.

Amber Potts: Is there science?

Vinson, Scott: But you don't sanitize between every customers meal preparation, you do it maybe once or twice a day, but it's not. It's not routinely done between each meal.

Babekir, Amani: Do you just wash and rinse and that's it? If you're gonna wash and rinse it, you're not …

Babekir, Amani: Yes, you probably need to do the third.

Moritz, Erin: Yes, it has to be with soap for sure.

Michelle Hill: The steps we teach as you guys have been saying are wash, rinse, sanitize, air dry.

Babekir, Amani: OK. So we're good keeping it.

Amber Potts: Yeah, I just have a question.

Vinson, Scott: This is one of those. So this is my group, our section in the Practices section. So we didn't know we would be addressing issues that so, so are we supposed to just remember our subgroup. Just remember that we've already addressed this at the full group level. So we don't need to discuss it when we have our subgroup call. Oh, OK. Got it.

Babekir, Amani: That's correct, yes. So I'm going to send out this document after we get done. And this one, we have just one. I think this does not use the allergen free terminology. We use it here, allergen free meal.

Devin Dutilly: I have to I have to jump off the call. Thank you very much. If you have any questions I would. This is just a just a personal recommendation, but if you are holding meetings and you think you would benefit from previous conversations of a federal partner being present, I would think that if you would like that please feel free to include all the federal partners on the on the meeting invite so that everybody is aware that they're occurring.

So if you need some input or something like that, feel free to include all the federal partners in the meeting. So at least somebody may be present on the meeting. So just to keep that in mind. So thank you very much. Again, thank you.

Babekir, Amani: That's great. Thank you, Devin.

Devin Dutilly: Thank you. Bye.

Babekir, Amani: Yeah, I think, yeah, I think we are over time and so that was the last one. We could keep it for you, Scott. So to discuss it to discuss it in your subgroup. <meeting adjourned>

Meeting Number 20	Meeting Date **09/01/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Previous Meeting Minutes	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Review changes by training, emergency and notification group

Template group with work on it

Two volunteers joint equal consideration group (get names from Michelle)

Issues will be worked on in the next meeting

Devin suggested issues to reform committee, update previous year notification and promote the current documents.

Amani suggested an issue for posting the framework in the CFP

Meeting Number 21	Meeting Date **09/29/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
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v.	Framework Points	Amani Babekir
vi.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: Michelle, would you like to take the roll call?

Michelle Hill: Certainly. [takes roll call of voting Committee Members]

Alrighty, we have eight, so I think that meets our quorum.

Babekir, Amani: Yes, thank you, Michelle.

Babekir, Amani: And just would like to remind you that the Conference for Food Protection, antitrust, this statement is active with this call. Just keep that in mind and we could get it started with our agenda items.

Babekir, Amani: First thing I want to share is the progress we made on the framework. I'll just give you an overview from the version which I have. Michelle and Ben, they are working on the format, and I will give them a chance to just give us a summary about what they are doing. I will share with you what we have done before we hand it to the format team. Can you see my screen?

Michelle Hill: Yes.

Babekir, Amani: What I've done here, I just combined together all the updated sections which I received from you. And we already reviewed it in our large meeting, so I just accepted all the changes and I kept some of the comments which need to be addressed by the template team.

We still have the introduction section we need to work on, and the template team will take care of that one. The training section. We have it here. All good. We have the handling section, food handling policy and practices, and it is all good here.

And we have also the notify customers check section, which is clean.

There are just notes for Michelle, and then to address some of the points, and adding the footnotes. The emergency response? We added here the updated version.

And, Wendy, since you are with us today, can I ask you a question before I jump to the next point in our agenda?

Bell, Wendy: Sure. I'll try my very best to answer.

Babekir, Amani: We were wondering about using existing pictures and the copyright around the pictures, … I sent out, I think, an e-mail about it, but we are still waiting for the response. I'm wondering if you could give us some insight about using the pictures in our documents and what is the copyright concerns that we need to address or any concerns about the copyright?

Bell, Wendy: I will figure this out with Vicki as she is who we present these questions to. So let me get a working e-mail and that way maybe we can get an answer before the meeting's over or we can definitely get one as soon as possible.

Babekir, Amani: That is great. Thank you very much, Wendy.

Bell, Wendy: OK. Thank you.

Babekir, Amani: So there's just one of the points that we need to clarify about the pictures. Other than that the section is ready. All good. And then I have we have the equal considerations section that Michelle is leading ...

Michelle Hill: Yes, and I'll have an update for you … its yet to come.

Babekir, Amani: OK, that's good. And then we have the definition section - and there is a couple of comments here and I think at one point we started discussing it … I wanted all of us to take an action while we are in the call and make the change on this section.

Ben Wagner: Amani?

Babekir, Amani: Any question before we address the comments on this section and get the update? Yes, Ben?

Ben Wagner: Michelle and I had worked on all the comments on the copy that you sent us for the framework, and we took those comments in the definition section and so we did make some changes based on those comments, that we thought would work for the group and we planned to have the group review and agree.

Babekir, Amani: That is fantastic. That is great, Ben. Do you think you covered all the comments here on the definition section, so I wouldn't need to worry about it?

Michelle Hill: Yes.

Ben Wagner: Correct.

Babekir, Amani: OK, that is great. And what about the definitions section? Also you will take care of that one, OK? I think that's all the updates; any questions before I turn it over to Ben and Michelle, if they want to add any extra information about the updated document.

Michelle Hill: Amani I'd like to share my screen if that would be OK with Ben. Is that OK with you? I think I have the most recent.

Ben Wagner: You do have the most recent copy.

Michelle Hill: OK.

Babekir, Amani: Yes, please go ahead.

Michelle Hill: OK. Thank you. Good. Alright, so the this is a dynamic table. It will update when we tell it to, so we won't have to worry about page numbers being right or wrong as the formatting changes. We did universal cleanup when it came to punctuation. Spacing of information on the page - we employed styles so that it's a predictable change when it does occur. So if you see something you don't like visually, let me know and it could be changed. We can now make one change through the style guide and have it update globally.

I've also removed any hyperlinking to the external world. Any linking that does occur or would occur as this gets published would be within the document itself.

Ben, thank you for doing this, dropped in all the definitions as per the definitions at the end of this document, they've been dropped in as footnotes, as agreed by committee.

We did things such as reorder the listing here because we looked at how it was actually listed officially within the Food Code, and so we've carried this convention throughout on how this gets listed so that it's always the same information appearing the same way.

We also made adjusted the title of the document to “Major Food Allergen Framework,” as that is the title, and we've carried that through to the Header for every page.

We've given a uniform look to the statement of purpose throughout - any time this appears, it'll look like this, where it's all cap and underlined.

Again, the flow here, the allergens are listed just as they appear in the same order here.

We did make sure we did correct leveling throughout so that all information appears at the correct level as part of an outline format. There's good continuity here visually on how things are appearing - visually clean things up.

Ben Wagner: Michelle, do you wanna take away the carriage return marking and all that?

Michelle Hill: Yep, I'm happy to do that. Thank you. I'm so used to seeing it that way. I don't even realize it. So thank you.

Pagination will change as I increase the font size as well. I went up to a 12-point font. We were at 11-point, and I printed it and it's really hard to read. It's a lot of information on the page. It put us up one more page, but I think we can play with spacing and keep it capped at 24 pages.

Umm, we did have a recommendation to make this a full sheet size sheet. So I wanna show you how it will look like when it goes to print for the person using this guidance.

This is our example. A lot of the icons did not carry through and so I went to just using regular keystrokes and we can talk about this if you guys don't agree. If this doesn't make sense, but if it's an X we've defined that as having the allergen present. If it's a lower-case M, it means it may contain the allergen depending on how it's been prepared. We also cleaned up the labeling on this table. It's called table one example, food allergen matrix used to say, food allergen table. All the stuff we've looked up all of it referred to as a matrix when it's laid out such as this.

I put a new graphic in here - the blueberry smoothie contained other ingredients and we just trimmed it down to what it might actually contain. This is the blank matrix, so this is Table 2, the template food allergen matrix. We've added this other four columns here called other components, and we've dropped in a footnote at the bottom that says a table such as this could be customized for gluten free and other food intolerances and sensitivities by utilizing the other components column, which is what these four are on the far right. So the idea here is that they could print this, have a clean copy and pencil it in. I did print it and it is easily used in this state, so I don't know about giving more space for that. I was able to legibly use it as a person would in the field.

Cleaning up some of this stuff, waiting for feedback on whether we're gonna keep these pictures of the auto injectors, and then we did drop in this table down here. We eliminated the little icon with the verbiage around they're being posters available because it was already listed here, so we just made it into a table and then we'll call the page number once the pagination has been set and all it really does is just tell you what the poster title is and it talks about how these are examples of posters that can be placed this section, the food allergy reaction, emergency Response Guide section is the only one that employed the use of that icon. So instead of having it at the beginning of the document calling out saying this would be used.

We figured that this would be a more efficient way to address that issue, and perhaps a clearer way. And so then we took direct language from the way these posters are named and made sure that's what we call them in the table. And then this is the equal considerations for other community food sources - FARE has a very nice guide available which we will be parsing information from for the correct language here, and then we'll call it out as a reference. There's quite a bit, so there's some nice guidance there, so I'll drop that in. We did clean up how this appears.

This is the definitions section - we decided to go with bold with the definition starting on the next line. The table was pushing out to too many pages, and we felt like this was more visually pleasing and kind of more of a traditional way of doing it.

So if you have feedback on that, that can be changed and, that's it. So hopefully I made sense.

Babekir, Amani: Do you have the reference section?

Michelle Hill: Yes. Oh, I wonder why that's not showing up. Ohh yeah, here it is. I'm sorry. I just had to go one more time. Yeah, I was just trying to figure that out right now. And I'm glad you brought that up because what we were wondering about is we've got the footnotes. Do we drop in another series of maybe superscript? That says, “here's our references”, or how do we wanna call it out?

Moritz, Erin: I thought that we took out all in-text references.

Babekir, Amani: So I'm wondering if we have the footnotes, do we need the references section at the end of the document?

Michelle Hill: All that's included in the footnotes at this point in time other than that table reference description - the footnotes are carrying the definitions of the words at their first appearance.

Babekir, Amani: So question to the committee, what do you think? Do we need to keep the reference section by the end of the document?

Moritz, Erin: Sorry, could you clarify?

Moritz, Erin: Are they? Are there references in the footnotes, or is it just the definitions in the footnotes?

Ben Wagner: So currently the footnotes only came from the original definitions table. The first time you see that word, that word or phrase, the definition is given in a footnote, none of the references are currently footnoted.

Babekir, Amani: Ah, I see. OK.

Michelle Hill: And maybe it's just because I was looking at it as a place that we were defining words, but obviously footnotes can be anything. So it would just be another footnote, if that's what you guys want to do. And that would eliminate the references section, potentially.

Although we do have the definition section still, even though they're referenced throughout.

Moritz, Erin: My personal preference would be to leave the reference section in. I feel like putting them in footnotes would just make it even messier with something that not everybody is going to be using.

Michelle Hill: The other thing to that point, Erin, after I printed this because I don't, I don't know how many people actually have printed this, but when you go to functionally print it, it is really nice to have that sheet, with just the references as part of a printout.

Babekir, Amani: That is good. I think we're gonna keep it as it is. Any comments from the team? Any suggestions? OK, so I think that's very good work, very nice work. Thanks to all the subgroup teams – you have done fantastic jobs just addressing all of the comments and updating your sections. So thank you very much and thank you Ben and Michelle for making it look very pretty, as it is right now, very good job.

Michelle Hill: Thank. Thank you, Madam Chair. I have run a spell check and it's a good thing I did because we had some misspelled words. And I also ran for whatever it's worth. I went through the process of reviewing it within word for readability and all of that 100% across the board for editing for whatever. It was really good scoring, easily read.

So yeah.

Babekir, Amani: That's good. What about, do we have any kind of template or format that we need to follow for the Conference of Food Protection when it comes to the guidelines?

Michelle Hill: That's a good question.

Bell, Wendy: This is gonna be posted on CFP website, correct.

Babekir, Amani: That's correct.

Bell, Wendy: So that is another Vicki question, because I know that the Food Defense Committee gone through some of those same issues, and I can try and look up what she said. But there are some stipulations to that, and I can definitely provide those to you.

Babekir, Amani: Thank you. Anything else before we go to our Issues? Thank you, Michelle.

Michelle Hill: Certainly. Thank you.

Babekir, Amani: That's good. So since we are good with our framework and we are within our timeline which will need to submit the framework by November 18, along with our Issues. We plan to work on the language until the end of October. So then we will have some time to put it in the right format and all of that.

So here just some of the points I wrote down just from our discussions from the comments, while we are working on the framework. Just wanting to refresh our discussion on this point. What do you think? What is the best way we could point to this framework in the food code? And I'm opening for discussion. If you raise your hand.

Michelle Hill: I was wondering if anybody from FDA could speak to that. I don't know who's on the call and looking here.

Michelle Hill: I don't see Devin on the call today.

Babekir, Amani: I think, yeah, I think Greg's maybe with us.

Abel, Greg A: We could put it in the as an annex right into the food code has a big annex section of resource materials. It could be proposed to be put in as a tool for those establishments wishing to create a food-allergen friendly environment, and here's the guidance to do so.

Babekir, Amani: OK.

Abel, Greg A: I think that's the most appropriate, it can be another direction. It could go is as is CFP supporting document to food allergens as well.

Babekir, Amani: And does it need to go in the food code?

Abel, Greg A: In the annex section, there's seven annexes for in some of the annexes, there's examples of the inspection form. There are examples of employee health policies that establishments could use to develop their own written policies. So and then there's chapters that talk about how to do a risk-based inspection, the public health reasons behind the provisions in the food code. And then there's an annex on references … there's one possibility to entertain - could it be another annex on food allergen management in retail establishments, and then if that doesn't go, it can be supported and recognized by the CFP on their website. I think there's an outdoor cooking guideline that committees have worked on over the years, and that's on the CFP website that people reference oftentimes. So we could go either direction and, in my knowledge, the big one would be to get the document into the Food Code as an Annex and then every time the Food Code is published it will be there.

Babekir, Amani: OK. Thank you.

Abel, Greg A: So two routes.

Moritz, Erin: I was also wondering if - Greg, you can certainly steer me in the correct direction here - but if there's anything in here, like any piece of it that might be worth requesting to put in the codified language, you know that would be strong enough to be held up.

Maybe it's, I know this might be the previous CFP, but something like requiring a list of ingredients used, or requiring maybe an emergency response plan, just like a small a small piece of what we put together that might be, you know, strong enough to put into the codified language. Does that ever happen in these kinds of situations, Greg?

Abel, Greg A: When these food allergen committees started forming, that was back in 2007. The first hurdle we got was to recognize that food allergens are real, and we made the person in charge to be knowledgeable on them, right? That was the first piece we got. I don't know the direction of where FDA is going with the last committee and some of the recommendations what was accepted? What's gonna be used? One thing, with putting food allergen management systems in the code as codified language, it would be difficult to enforce because a lot of inspectors aren't trained to recognize, like your example and learn about a list of ingredients. Provided you know, I think that could be a future endeavor, but to make sure that list is accurate, how do we enforce that right? And how do … who keeps track of that? But perhaps the idea of having the emergency response to an allergen event could be something that could be required, kind of like how we have written notification of a diarrheal and vomiting plan. You know, that's a requirement in the food code that all establishments have a way to rectify diarrhea and vomiting in the restaurant. Having an allergen response plan could be certainly something that could be taken from this document and suggested that that also be in a food establishment.

Moritz, Erin: And I think would be easier to enforce than something like an ingredient list.

Abel, Greg A: I've done this for The City of Minneapolis School District system, I think they have 80 schools - to develop an allergen free menu and my gosh, just on something that's simple as a school system that receives commodities. How difficult and time consuming it is to make sure that's accurate? So it's almost a whole new division of food safety, right?

Some manufacturers are some establishments and some states, like Minnesota for example, they keep, in the deli - if they have one - they keep a list of the ingredients that they use to make their Deli products. So if a consumer did ask, they can go to a binder or some kind of reference system and say, OK, we use this particular product, and this product contains these ingredients. So they could tease down any hidden Allergens, right? It's not a requirement, but some establishments do keep a list of ingredients voluntarily.

Moritz, Erin: So it does sound like, if we really wanted to take a small piece of this - something like requiring an emergency allergy plan - that would be one direction. My other question I have is, if this goes in, for example, as an Annex, could we still advertise it, you know, publish it through CFP?

Abel, Greg A: That's, you know, that's a good question. I don't know the answer for that - I can find out.

Babekir, Amani: OK.

Moritz, Erin: So I'm just wondering if it's like an either-or type situation or if we can do multiple steps.

Garvin, Amanda: Multiple.

Michelle Hill: Yes, I believe it's multiple as well.

Abel, Greg A: OK, I think you could advertise it and say, hey, this is where it's at. This is where it's published. It's published in the food Code Annex. It's published also at the CFP website.

I think it's a great tool, what's been created here. If those of you that have been around for a while, when FALCPA was passed in 2004 and became effective in 2006 , that public law said that FDA would work with CFP and develop a Food allergen guidance type manual, right. That was back in 2006. I was actually one of the authors of that manual, and we worked on it for two years, and it was kind of kind of doing the same thing that this committee is doing except this committee's work is a little more - we've learned a lot more about food allergens, a little more detail, there's more resources. I think it's easier to use. But FDA's document that was created in 2007, 2009, it never did pass our executive leadership, so I never did come out. We never did follow up with that public health law, so now the committee's kind of doing this work.

Babekir, Amani: Yes.

Abel, Greg A: I think it's great work.

Michelle Hill: So glad to hear that. Thank you, Greg.

Babekir, Amani: That's good. And to your point, Erin, about the previous committee works and any change to the food code they did - when we reviewed the previous work, we found in a couple of events that they did manage to add extra wording in the provision of the food code pertaining to allergens, so that's something. Also we could, besides creating the framework, change the food code. So you have the option now for the Annex, the CFP website and - do we want to add some of the nuggets inside the provisions of the Food Code? Amber, you suggested the emergency plan … anything else you think might be beneficial to addressing the whole profession there? What about the notification of the customer or …

Moritz, Erin: Yeah, that's kind of where my mind went next would be some sort of Notification requirements. Although I think that could get very messy if we really wanted to go down a rabbit hole with it.

Abel, Greg A: The notification one is very hard to do right. Remember, the city of Saint Paul, MN, one of the council members tried to pass a city law that he wanted all restaurants to declare and notify all food allergens that are possible in the menu. And at that time, food allergen people and groups came out to testify against it, because of the inaccuracy of it.

Who's gonna create the list when ingredients change? Especially right now you look at our food supply chain from a food manufacturing side - ingredients are changing left and right, left and right. Big companies can't get their main suppliers and they have to change micro ingredients a lot. So with that in mind, if something comes in, that's an allergen - who keeps track of all those menu details? And when you get into a retail environment, a restaurant, not a chain, that's everything's processed in a certain way, but more independently owned. We have different chefs making different creations. Here I mean, gosh, you know, having a notification is good, but on the other side, the case that notification was not accurate, and someone made their decision on that written notification and then had a reaction, right? So it's very difficult to enforce and to make sure it's accurate, if it becomes a food code provision in my opinion.

Babekir, Amani: Thank you.

Michelle Hill: Greg, I love what you just said and I'm thinking that maybe our opportunity to be part of the Food code language would be just around understanding how important a label is and accurately labeling things for allergen derivatives. I don't know if that's something that we can be very specific about, but as a consumer that's my biggest problem … is it correctly labeled … cause it's not.

Abel, Greg A: Yes, right. And people that live with this condition - if they have children and themselves, I mean, the first piece, the written notification, gives them a clue of what to eat, and start to ask questions. The next piece is to talk to the chef and find out how things are actually made in the kitchen or talk to the manager to get the assurance that your food definitely is going to be safe to eat.

Michelle Hill: Yes, I've lived it. I agree with you completely. Soy oil hides everywhere and my kid was so allergic to it, he would just projectile vomit. I'd be like, “you didn't tell me about the soy oil you used”.

Abel, Greg A: I have three celiac kids and I've been living with it for I don't know, 20 some years before FALCPA. In my spare time, I run a nonprofit and we have a booth at the State Fair of Minnesota, a gluten intolerance awareness booth and celiac disease, and we play the “Jeopardy” game to engage people, to come in, and it's surprising to me where we're at today. How much ignorance there is out there about even food allergens and gluten, cross contamination and such. Any education or awareness is great.

Vinson, Scott: A lot of times I've observed that people confuse gluten with glucose. So if you tell them that you're gluten intolerant, they think you can't have anything with sugar.

Babekir, Amani: So what about the training piece? Since we are talking here about awareness, I know in the food code there is some pieces about the training when it comes to allergens. If there is anything we want to add there …

Michelle Hill: To be more prescriptive in that regard, yes, I would love to know how to do that. Let's talk about that. I teach this stuff too and I would love to be able to say, look, you have to know this.

Abel, Greg A: Yeah, I think you know, in the certified food Manager courses that are accredited, there's an allergen chapter in those courses, right?

Michelle Hill: In the same place as physical contamination.

Babekir, Amani: So you think that probably will satisfy the detailed information about allergen training … we don't need to add anything extra?

Michelle Hill: How do you talk about knowing and understanding derivatives or how it appears in the food you're serving, because that's where I see people fall down anytime auditing for allergy. It's like going into the Bloomington School district here, which I'm working with right now for allergen control across their 17 schools. I'd love to talk to you, Greg, because this is the problem. It's a hairy beast. And so you have to assess your risk. You know, how many people are at risk and how are they at risk and then carrying that also to - because the schools have to keep not just the food safe, but the classrooms too. So my son is so allergic to soy that washable paint is soy based and he will break out in a rash any time he is exposed to it. So even understanding that allergens can be tactile, aero-inhaled and consumed, all of that's important! I don't know if that fits here, but ...

Babekir, Amani: I see. So I guess we need. To figure out if we want to stick this in the Annex and make changes or comments around addressing the framework in the Annex section or trying to figure out which pieces, we want to add to the actual Food Code.

Michelle Hill: Can we do both?

Babekir, Amani: So if you want to do both.

Let's figure out what nuggets we want to add there beside the emergency plan. We touch on the training - bring up the section of the food code that is addressing this training and look at it. Where do you think the emergency plan will go within the Food Code?

Michelle Hill: I like Greg's idea of having it be part of its own Annex or …

Babekir, Amani: Yes, but I mean, if we want to address it in the provision section of the Food Code - you want to add something?

Abel, Greg A: You would probably want to put it in Chapter 2. And I'm looking at it. OK, in Chapter 2 called 2-5 “Responding to contamination events”, and that's where the cleanup of vomiting and diarrhea events is located. So to me it seems like it would fit under Chapter 2-5 along with this “responding to food allergen events.”

Babekir, Amani: OK.

Abel, Greg A: Seems the most logical.

Moritz, Erin: And would we get any kind of push back? For considering an allergen, a contamination, do you think?

Abel, Greg A: Umm gosh, you know ...

Michelle Hill: We could call it a contaminant.

Abel, Greg A: Yeah, you know, it depends on who's looking at it, right? I mean, for 95% of the population, it's not right or whatever the statistic is. We could call it something else. “Responding to adverse … “ we could make a new chapter, “responding to ...”.

Moritz, Erin: How about we could call it something like, maybe based on the symptoms. For the medical result. Like for example, anaphylaxis.

Michelle Hill: We could say also that it was Food allergy - we could say it's a contamination event due to cross contact.

Moritz, Erin: Yes, I mean, I guess so for example, if somebody says, “don't make my meal with nuts” and nuts are in it, then it technically would be a contamination event ...

Michelle Hill: … due to allergen cross contact. I don't know why they have to be mutually exclusive. It's only because we think of that way ...

Moritz, Erin: This is me, putting on my little, tiny little regulator hat of what I might think if something like that came across … I think if that's worth pursuing, then yeah, let's do it.

Abel, Greg A: And then you would have to, if you pursue it through as CFP issue to add to a food code, then you'd have to be prepared to say, “well what should this Response plan include” - and it's in the document. And then what happens then is states will have to adopt it. And then that would mean all retail establishments would have to have an allergen response plan. So that means a booth at a State Fair would have to have one. That would mean a temporary food event for a car rally would have to have one, a restaurant, a grocery store Deli - which is fine. I mean, that is the scope of the food code.

Michelle Hill: I say yes.

Abel, Greg A: Yeah, it's kind of like the vomiting and diarrhea clean-up plan, right? We just want people to have some kind of a notion that you just don't go out with a mop and clean it up because if it is norovirus, I mean the person who's cleaning it up could spread it to the rest of the staff or other customers. So you want to take some types of precautions, even though it's something that's not going to, you know, take down a restaurant from operating, I mean, at least having that plan out there, and if we can get compliance of a certain percentage each year and increase that, then boom. You know, slowly get there with an educational piece, even though it's requirement.

Babekir, Amani: James … I see James’ hand.

James O’Neal: Yes - we're looking for somewhere to fit it ... could it fit … Chapter 2, section 103.11, which is a person in charge duties. I think it could possibly there as far as that the person in charge is knowledgeable about allergens and however, we wordsmith that, that could be a possibility.

Abel, Greg A: Yes, another good spot under subparagraph - that talks about employs properly trained, and food allergy awareness. So it could fit there too, and also say, “include an emergency response plan to an anaphylactic reaction.

Moritz, Erin: We just tack on ... trained in food allergen awareness and actions to take in response to a severe allergic reaction, or something like that ...

Abel, Greg A: Yeah, that would be easiest path. Thanks for that recommendation. Whoever gave that, I don't see you on my Teams list. Yeah.

Babekir, Amani: Thank you, James. Yes, Scott.

Vinson, Scott: I just want to clarify that this framework we've developed is just voluntary and not mandatory, is that right?

Babekir, Amani: That's correct.

Abel, Greg A: Yes.

Vinson, Scott: OK, the reason I ask is because some of this some of the discussion … go ahead ...

Moritz, Erin: But then whatever we decide to put in - any little bit into the food code - that little bit would become a requirement, but not the entire framework. That's my understanding, Greg. Is that correct?

Abel, Greg A: That's correct.

Moritz, Erin: OK.

Vinson, Scott: If it makes its way into the Food Code, which is a model code - then the States and local jurisdictions have to adopt it. The reason I ask is because we want to be careful that we don't Inject provisions into the food code that are controversial or could be construed by some state legislatures or agencies as too onerous, because that will discourage adoption of the food code. My organization has supported universal adoption of the most recent version of the food code across all jurisdictions, and we encourage all jurisdictions to update their food codes. But there is this movement afoot. We had a speaker from NEHA yesterday – they talked to my food safety task force members yesterday about this. This food freedom movement, which is causing some legislators in some states to reject the Food Code, and to not adopt it … and we don't want that to happen. So I want us to avoid a situation where we – especially with smaller establishments, which I don't represent, but they're not represented in these conversations – so somebody has to sort of bring up their interests. Do we keep this as a voluntary framework in that we don't try to shoehorn into the food code - subsets of this framework - to try to get it to be made mandatory. I have a feeling, I'm just getting an inkling from some of the earliest discussions, that some people on this call are trying to do that … that could backfire on us in the long term because some jurisdictions could then be less likely to adopt the food code. We don't want that to happen.

Babekir, Amani: Thank you. It's good.

Michelle Hill: But it's part of our charge, though. Correct, Amani - that's part of our charges, yeah?

Babekir, Amani: Yes. So what is happening here beside the framework - we wanna bring awareness about the framework, so it doesn't have to do anything about making it like a law to follow. And one of the things is to address it in the Annex of the Food Code, which is not kind of regulations there. The Annex is just kind of differences and more clarification to the provisions section of the food code. The other piece is to add, maybe three words on the provisions section of the food code. For example, the word of "emergency plan." We are gonna discuss that further, but just let's conclude what we are discussing here.

Chapter two. We say we're talking about the knowledge of the person in charge and maybe one of the pieces we say there, besides knowing the food allergy, also know the response plan if there is any event. So just maybe one sentence or two or three words. That's what we are discussing here and that's still under discussion and this is a good point to be aware of Scott. Amanda?

Vinson, Scott: So the response plan is one part of this framework document, and so what we're talking about is just including those provisions in this framework document, what to do when an allergen gets into a customer's meal, in that kind of a situation, putting that into the food code only.

Babekir, Amani: Yes. Erin?

Moritz, Erin: If we decide to go this route and essentially make something required, it's gonna have to be very basic for the exact reasons Scott just talked about, and it has to be doable too.

Babekir, Amani: Correct. Amanda, I wanna give you a chance before we end our call as I see, your hand.

Garvin, Amanda: You already said it Amani, but I wanted to highlight it again - is putting this in the Annex 2 "References", which I really think we should try for, is a really great idea and that is a way for us to put it in the food code. Look under Annex 2 - anything they have used to help with the food code is in here and some of the documents we've done through CFP are in here too. So not only putting it on our website, but definitely putting it in Annex 2 for sure. And I also do very much like the idea of having … I'm saying that the person in charge does have to be knowledgeable on allergens but not too in-depth, of course, but they should be knowledgeable. I think that's a great point, though, if we're gonna say they need to be knowledgeable, we might want to say how far do they actually be knowledgeable? Because I know that's something that an inspector could do very easily.

Abel, Greg A: Well, that part's in there - this demonstration knowledge on allergens.

Garvin, Amanda: It was in there.

Michelle Hill: Yes.

Abel, Greg A: It talks about the person in charge describing foods identified as major food allergens and the symptoms that major food allergens could cause to sensitive individuals.

Garvin, Amanda: To when we were saying that knowledge, but we were saying duties, Mm-hmm.

Abel, Greg A: Well, there's two parts - one is demonstration of knowledge and then the other piece talks about the duties, and the duties' part talks about that employees are. trained or have food allergy awareness, as duties require.

Garvin, Amanda: Yes, and I thought it was in there, but then, which one did we mention earlier? Somebody mentioned something earlier that I thought was excellent beyond there, OK.

Abel, Greg A: Duties, and I think Scott brings up a very good point when you start qualifying things, especially on food allergens like this. I'd be very careful if states are going to adopt this because I would give you example, North Dakota adopted the food code by reference and the legislators tagged on that they didn't want required - they didn't want the person in charge to have certified manager certification because they looked at the state of North Dakota and that was an added expense. So everything got passed except for that. So you know, putting something in on this nature and especially without health departments having the staff to enforce something like that.

Babekir, Amani: That's good.

Abel, Greg A: You know, might not get passed, so it it's. It's a delicate balance. There's one provision that's in the food code that hardly anybody knows about. It's an allergen control piece. And that piece is, and if you read the food code carefully, it says when you go from raw fish to another raw animal food protein, you have to stop, wash, clean and sanitize because of a fish allergen. So many people read right past that, and so many jurisdictions that do catch it say we're not enforcing it right now. They're not going to enforce allergen control as a mechanism in the code. This piece here I think is so robust with information sits in Annex 2 I think has its best shot of being part of the food safety culture of including food allergens.

Babekir, Amani: Yes. Thank you.

Moritz, Erin: But you said it's not either or.

Abel, Greg A: Say that again?

Moritz, Erin: So we could put this in the Annex and then take a little piece.

Abel, Greg A: You still can, yeah.

Moritz, Erin: And make codified ...

Babekir, Amani: Amber?

Abel, Greg A: If you decide to like maybe having a … Go ahead …

Amber Potts: I just wanna re-read our Charge for this specific topic. Just "recommend changes to the food code that support retail food establishments to operationalize Framework to prevent and control food allergic reactions." So maybe we can start next time with just seeing if we can vote on whether we want to actually put that in the code defined section or if we want to add that to the Annex or neither and just add it to the CFP website, but whatever we do should be supporting retail food establishments.

Babekir, Amani: And thank you, Amber, and thank you for the suggestion. Yes, I think in our next call that's gonna be our main objective – to vote on which option we wanna go for and focus on it, so I will just put down all the summary of the discussion we've done today and go from there. We don't have a lot of time you know to decide on this, just maybe two other calls to finalize this so we need to agree on our path moving forward. So thank you very much. It's great discussion. Thank you everyone and see you next in our next meeting.

Meeting Number	Meeting Date		Meeting Time
22	**10/13/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Framework Points	Amani Babekir
vi.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: Hi everyone, and thank you for joining us today. I don't see Michelle, so probably she will join us later. This meeting will now come to order, and I remind you that the conference for food protection antitrust statement is active during this call.

Babekir, Amani: I'm going to just go over the attendance. We have six voting members, so unless we have more people joining us, we wouldn't be able to vote. We can discuss things without voting. Then we could vote during a future meeting.

Babekir, Amani: First item on the agenda. I want to share with you the updated framework and really, its very good job being done here - from the subgroups and also from the template team – just making it a pretty, and very concise, document. I hope you get the chance to go over the Framework, so if you have any comments or any notes, feel free to share it in our meeting today because we don't have a lot of time remaining to keep working on this document. By the middle of next month we need to submit it for its first round of review by the Council. So we have just a couple of meetings to go over it. Feel free in between, if you have any comments, to send them our way.

There are couple of components here we need to discuss together as a group. I know I will start first here with the introduction section. We did add this section, which highlighted it in yellow to address the point about not restricting this Framework to just controlling for the Major Food Allergens, but all food allergens. But also there is a recommendation here to add a “limitation” section. As you can see on this comment - to address that this document is not covering all types of allergies. And maybe something needs to be also addressed in further work. What do you think? Do you think this part - which we added in the yellow – sufficient that this document is only focusing on the nine major allergens and there are other types of allergens, or you think we need more added language to the document? I will give you a couple of minutes to just go over the text we added and also hear the comments being addressed, by Devin here. If you could please admit people, if that is possible to do, and speak up because I can't see hands raised.

Vinson, Scott: So I see the parts you highlighted in yellow there. So you're asking us whether we approve of that sentence. That you highlighted in yellow, and whether we want that to be included in the document?

Babekir, Amani: Yeah. So.

Babekir, Amani: That section we all agreed on and we added it here in our meeting. What I'm trying to say is, “do you think that section is sufficient to address the comments here?” Or do we need to add anything further to the document?

Vinson, Scott: Oh, I see. Well, I like that sentence.

Ben Wagner: I feel like it's sufficient.

Babekir, Amani: Right. Thank you. Any other point or any other opinion? We good?

Dave Read: I think it looks good.

Babekir, Amani: OK. Thank you. There is this one about the limitation ...

Michelle Hill: Madam. Madam Chair, if I may, I jumped on. I'm here now. I apologize for my lateness.

Babekir, Amani: No problem. Thank you, Michelle. So we have this comment here. So, just going to give you a couple of minutes to go over it - it's about adding a section that is addressing the limitation of the document. Do we need to add this section?

Michelle Hill: Madam Chair, if I may, we did address this - we added language around this earlier in the document. OK. Oh, I see.

Babekir, Amani: Yeah, that is the one highlighted in yellow. So you think that is sufficient, are we good that is sufficient, or we need a separate section to address limitations?

Vinson, Scott: I think it's sufficient.

Babekir, Amani: So there is another one here also, and Ben wanted us to address it as a group. So before we go to the next comment, just I want to give you also an update about the image. I know we have questions about it, about the copyright. So the response we got from the Council is to keep the image in the document. We could blur the brand names here on the image, but also there is another option. We might need to delete the whole image, so this is still under discussion, but there are two options. We could blur the brand names, or we could do away with the whole images.

Michelle Hill: I'd be happy to blur the brand if that's how people wanna go. It's an easy fix for me.

Babekir, Amani: Thank you, Michelle.

Babekir, Amani: So this is about the equal consideration section. And Michelle, you might be able to respond to this one.

Michelle Hill: Yes. Thank you, Amani. This was put together with resources used from FARE and also USDA. I do have to drop in the references. I have notes around that to show where this information came from, but it was lifted directly from FDA and FARE and then just listed in a way that matched the document. I am totally open to input on whether it has to change or if it's acceptable. We just had to get something plugged in there that was from a reliable source.

Babekir, Amani: Thank you, Michelle. And do you think this comment from Devin, that it seems like this section is just hanging and we need to increase attention to the inclusion within the document.

Michelle Hill: Yeah, that's a good point, Madam Chair. I did notice that in the very beginning we addressed it in the first paragraph of our framework that we will have equal considerations for other Community food sources, and that wouldn't necessitate this section be here if you want to strike that language, that would be one way to go about it. We do talk about having a section that directly deals with this.

Babekir, Amani: Yes.

Ben Wagner: It was part of our charges, wasn't it?

Michelle Hill: It is indeed, yes.

Babekir, Amani: That is correct. So have we mentioned it in the introduction.

Vinson, Scott: Amani, are you asking whether we want to delete that entire section E?

Babekir, Amani: No, the comment we have resolved it, we don't need to do any action.

Vinson, Scott: Yes, I don't want to delete section E.

Babekir, Amani: No. OK. Then we have this comment here - the comment adding a footnote about food label formation being made available … have we addressed these one, Michelle in this section?

Michelle Hill: Yes, that is correct, we did adjust language for this.

Babekir, Amani: Is it under this section or where … ? Here are the comments ….

Michelle Hill: Oh yes, we recommended doing food label information made available in … And I think that's your bullet. “Allow consumers the opportunity to review original food packaging so they can read the labels, know the importance of reading every label every time, etc.” so maybe we don't need that.

Babekir, Amani: We don't need a note?

Michelle Hill: Well, we might though cause this section’s referring to specifically when you're feeding a large group of people. We might want to even have information posted. I know it doesn't say that, but that was the discussion around that item.

Babekir, Amani: So do we need to add any additional language to address this comment, or we are good to go? Going to give you some time …

Vinson, Scott: So we're specifically looking at bullet #2 under that sentence when offering foods to large groups.

Babekir, Amani: That's correct.

Vinson, Scott: Is that right? Bullet #2 is while most sections of this document aren't applicable to both food service venues etcetera. We're basically just telling the reader that they should have the staff of these facilities be mindful of allergens and how they're disclosed on food labels - that seems sufficient to me.

Babekir, Amani: OK, so we could resolve that one. And last one here. So there is recommendation, we have the definition of food intolerance/sensitivity, we have this definition, and the recommendation is to add more language. I don't know if you already added this. This is a way more detailed definition so are we good to add this definition instead of that one? Give you a minute to go over it.

Vinson, Scott: Just reading through the definition as a person who has celiac disease, I'm a little bit concerned that this proposed definition from FNS might seem to minimize the importance or severity of food intolerances. They say they're generally not life threatening. Over time, if a person who has celiac disease, for example, continues to consume gluten they may eventually get intestinal cancer, and so can be life threatening over time.

Michelle Hill: Absolutely. And I was considered with this definition. We talked through this quite a lot and it really is the case, I prefer the one that's listed there. But that's just me and it's for the same reason that Scott is bringing up.

Seymour, Jennifer: I guess the thing that I'm trying to understand here is celiac disease is an autoimmune disease. It's not a food intolerance.

Vinson, Scott: That's true. So.

Seymour, Jennifer: Right. So I guess you know maybe there is a need to possibly make that clear … I don't know if there's a way to but … You know, and that's where the difference between gluten intolerance and celiac disease, or important distinctions.

Vinson, Scott: Maybe we just sidestep the whole issue by not getting into the particulars because they may not be relevant for purposes of this document. To a reader, we just want to make sure that readers of this document, food workers, primarily food retail settings, are aware that they need to be careful about ingredients. Some people have allergies which could become immediately life threatening. Some people have food intolerances or perhaps other conditions which make ingestion of certain substances dangerous for them. I don't know that we need to get into the precise definitions and nuances involved because you're correct, Jennifer. The way that sentence reads now “Food intolerance/sensitivity and adverse reaction to a substance and food that does not involve the immune system” is not entirely correct, at least with regard to celiac disease, which is an autoimmune condition.

Babekir, Amani: And I agree with that point. I agree with you, Scott. Any additional thoughts? Or points?

Vinson, Scott: If we were to just omit the whole section, would that present problems?

Michelle Hill: We decided that it needed to be defined and it's a footnote.

Abel, Greg A: Why not just add celiac disease as an autoimmune - as another category? Food intolerances/sensitivities are celiac disease and/or autoimmune disorder.

Babekir, Amani: So do we add here to the language of the definition or here in the title?

Abel, Greg A: Wherever it makes sense, maybe I was thinking the title.

Michelle Hill: We need to look up where this is footnoted, where it first appears. Maybe that would help inform us of how we should change that.

Babekir, Amani: I think it was on the first page.

Michelle Hill: It's pretty early, yeah.

Babekir, Amani: Here you see food intolerance.

Michelle Hill: Yeah. So how is it used in the document? I wonder where it appears. Right here there … it says that I think it's probably earlier. Higher up, yeah.

Babekir, Amani: Yeah, it was on the 1st section.

Vinson, Scott: Yes, scroll up a little bit to footnote 11. Let's see how it's used in context.

Michelle Hill: There it is. It's at first bullet. No. Sorry. Amani, go down to the next page again, please, under ‘training’.

Vinson, Scott: There it is 1A.

Michelle Hill: Yes, 1A. So actually this is very important we get this right because we're telling them that these are the definitions that they need to know.

Babekir, Amani: Also here. Here we have intolerance and sensitivity.

Michelle Hill: So what's up higher too? That's probably where it should be footnoted, and it should look like the other one.

Babekir, Amani: Yeah. We could add - decide you know - the intolerance sensitivity and autoimmune disorders thing or specifically celiac disease, or any other disease.

Vinson, Scott: Because I'm not aware of any other autoimmune disorders that relate to food, maybe we just name celiac disease specifically. Does anyone else know if there are any others?

Michelle Hill: Yes, there's Crohn's disease, which can be ...

Vinson, Scott: Is that triggered by certain foods?

Michelle Hill: Absolutely. And so is colitis. Certain forms of colitis.

Thoma,Libby: Yeah, IBS.

Michelle Hill: Yep. or lymphocytic micro lymphocytic colitis, for sure - directly related. Because I have it, so I have that too. It sucks.

Vinson, Scott: Which I have it too, but I've never been told that it's triggered by any certain foods.

Michelle Hill: Ohh well.

Vinson, Scott: That's why I ask.

Michelle Hill: Interesting. We have different doctors.

Babekir, Amani: So on we talk a lot about autoimmune response I think or immune system response something like that on the definitions …

Michelle Hill: Wonder how FARE talks about it. Should I look that up real quick and see if we can find?

Babekir, Amani: Umm OK, try that.

Babekir, Amani: Here we cover it, because at the end of food allergic reaction, and how our immune system responds to the food? If it is part of disease or not, but it is an interaction between the immune system and the food. That should be sufficient. Because even Celiac disease that's how it's happens.

Michelle Hill: I have from the Cleveland Clinic a definition of “when you have a food intolerance, it means your digestive system has a hard time digesting and then in parentheses breaking down a food.”

Babekir, Amani: OK, so it does not involve the immune system. So we are good with that one. And the question is - the definition we put here for the food allergic right? “Food allergy,” he did say involves the immune system, wouldn't that cover also Celiac disease?

Michelle Hill: Yes.

Babekir, Amani: I think we are good here and we probably wouldn't need to add all of these details in this definition. Are we good with leaving the definition as it is for “food intolerance”?

Michelle Hill: Amani. Do you mind? I'd like to drop some stuff into the chat that I've just … you did too. OK, good, let's see ...

Vinson, Scott: I just put something in the chat that maybe we could consider putting in that first paragraph or I think it was near the top of the document. At the beginning, when we talk about the fact that this document technically only covers, you know, the nine major food allergens, but that readers should be aware that customers may have other issues involving ingestion of certain other foods.

Thoma,Libby: What if we said “to assist consumers with allergies food sensitivities? To autoimmune disorders? And intolerances? ...

Babekir, Amani: And do you think you can live with that? Could be added to the definition I just highlighted in yellow - like in addition to what we listed there, we added ‘audio immune disorders’.

Thoma,Libby: I think so.

Vinson, Scott: I would prefer that we name them specifically, the way I've done in my comment in the chat, because we need to remember our target audience, the reader. Most consumers are going to reference specifically the condition that they have. If they're talking to a food service worker preparing their meal, they're going to say, oh, I have Chron’s or I have IBS or something. They're not going to say, ‘I have an autoimmune disorder’. People don't talk that way in real life, so I would get specific with the name so that readers can be all on alert for those specific conditions.

Thoma,Libby: Yeah.

Michelle Hill: And of course, we'll cover all bases by saying and any other immune kind of thing, because there's a lot of stuff we don't know about as a collective group, yeah.

Thoma,Libby: I agree.

Michelle Hill: And everybody loves Wikipedia. I dropped theirs in, but it's kind of an interesting way to talk about it … “detrimental reaction, often delayed.”

Vinson, Scott: Yeah, looks good.

Babekir, Amani: OK. And shall you have added here the definition for the intolerance? Do you think that needs to be addressed here where we have the definition.

Babekir, Amani: We're good. On that one, keep it as it is.

Vinson, Scott: Frankly, I would get rid of it. Because of the issues discussed at the beginning of the document that we just went over. And this just muddies the waters. This formal definition, you know, at the end of the document kind of muddies the waters.

Babekir, Amani: I think we use it in different places here through the whole document so. Mm-hmm.

Michelle Hill: It was standardized to appear that way, yeah. I'm not against deleting the definition, but I think that's something our large group has to talk about and have.

Babekir, Amani: Yeah.

Michelle Hill: How does it … what are the consequences of not defining it? If there are any, I don't know.

Vinson, Scott: But we defined it at the at the front of the document.

Seymour, Jennifer: I think the section which we added here - we gave examples here, but we did not define what is the intolerance and sensitivity.

Michelle Hill: Yeah, think Scott got a really good point here. It's like, “if we don't treat it as being something really other than just that - by calling it out everywhere that it appears you know, maybe we don't treat it as a defined term. Is it cited on the next page … I forgot where …

Babekir, Amani: Yes. So besides here it's defined on the next page where we have “Training”, and it's being called out ... the definition of food allergy and also food intolerances.

Michelle Hill: Maybe we say “definitions of food allergy, cross contact and our understanding of food intolerance and sensitivity” ...

Babekir, Amani: And now my opinion, because that is going to take some work, to just remove the definition and make it just as a sentence. But “intolerance and sensitivity” is still gonna be a question. If I'm a reader, or so we are talking here about food allergy. What? What is the difference between food allergy and intolerance and sensitivity? Why is it being mentioned in three different ways?

Vinson, Scott: Yeah, this is tricky.

Michelle Hill: The way that FDA addresses it on their website is in the way that we have it.

Babekir, Amani: Yeah, they define it separately from food allergies, so I lean towards keeping the definition as it is. What? What do you think? Do you think this is good … and the other committee members?

Vinson, Scott: We can always punt and just let FDA decide what to do. They're going to be writing it ultimately anyway.

Babekir, Amani

Babekir, Amani: Yes. I'm going to delete this comment and leave it as it is. If you feel the opposite, let us know. We are gonna work on it through next week, so just tell us if you have an opposite opinion about it. We could proceed to the next discussion. Save it here. And this way we addressed everything on the document, and we will work on it to finalize it. I’ll work with Michelle to finalize it and it will be ready to be ... I will send it out to the Council, and we will send you a version.

Hopefully a week before we do that, so if you have any final revision or comments, you will get a chance to do so. I think that's it. Any other point before?

I switch into the second document. Any additional point before I move to the next topic. OK, let's move to the next one – it’s about our Issues, and hopefully you got the chance to see the document which I sent out before our meeting.

I listed the Issues which we thought about, we talked about, and I got the

Council II Chairs to help put it the best way to address the Issues, and how we could submit it to the Council. We're gonna all go over them one by one, making sure that's we are OK with each one of them. If we wanted to keep it as it is, or if we don't want to submit it.

The first one is to submit to the committee the final report and we're gonna need an Issue for that and just asking the Council to review and acknowledge the committee work, so this is the first. Are we good with the first issue?

Vinson, Scott: Yes.

Babekir, Amani: Any comments? OK. Thank you, Scott. Any other comments? We good? Second one, and this is one of the least options we could do for the sake of our framework is to get it posted and the CFP website. To do that, we need an Issue. So, we're gonna create an issue asking the Council to post this document to their website and we will specify the file type, such as a PDF file. Any comments about this Issue? Another point - we will ask them to remove the older version so to update the older version which has just the notification section from the previous committee, with this framework packet. Any comments or suggestion on this one?

Michelle Hill: Madam Chair, so the suggestion is that we would pull the current document from the website and then somehow merge it with what we currently have or check for commonality. And if we've missed something we add it in …. Or are we asking to replace that document specifically?

Babekir, Amani: The thing is because right now I think on the on the website there is one document which we use to generate our notification section.

Michelle Hill: Yes.

Babekir, Amani: That document is from the previous committee. So we worked on updating and enhancing all the content of that document in our Notification section. So the suggestion from the FDA is to ensure that the old version is being removed from the website. So it wouldn't be used by the food retail and instead they will use this updated version.

Michelle Hill: Thank you.

Babekir, Amani: Yes. Any other comments or suggestion? Are we good with this Issue?

Michelle Hill: I like it. I think it's good - necessary.

Babekir, Amani: OK. And then the third one, we talked about it in our previous meeting, is to ask the Council to re-form the allergic committee to address those Issues, which we could in address, or we listed as limitations to our document, in a new framework or a new guideline?

Michelle Hill: So we say we're going to continue or re-form the committee, and these are going to be the charges, so future work OK.

Babekir, Amani: Yes, it is not us, but we will ask. The Council is to re-form the committee, similar to what's done to our committee, because last year, last term, the allergen committee asked to re-form the committee and that's the reason we had this committee. We are hoping to do the same thing for the next term, ask for the allergen Committee to re-form because there are Issues on some points that need more clarification. Such as allergen cross contact and all of that in the food retail.

And this one is flexible. If you feel like there is an extra charge we need to add, we want, we need to remove the charges from here. We gonna have some time to review it probably in our next meeting to refine it and we will try to present it the Issue format set by the CFP. So we could work on it, but how do we feel about it? Do we feel we need to do that or not? We need to re-form the committee, or not?

Michelle Hill: I think we have to re-form the committee.

Babekir, Amani: Do you agree with that?

Vinson, Scott: I have a question.

Babekir, Amani: Yes?

Vinson, Scott: Are we using the word reform in this context? Reform like “RE dash form” or “reform”?

Babekir, Amani: Yes, it's re-form.

Michelle Hill: To reform to form again, maybe say yeah, yeah.

Vinson, Scott: To form again. OK, so re dash form OK.

Thoma,Libby: Would we have to go through the whole application process again as well?

Babekir, Amani: Umm, yeah. So if it's re-formed it could be stand-alone committee, and people have to apply and all of that. Similar to the way we've done it in our committee.

Thoma,Libby: OK. So we don't just get too re-up basically for this one.

Babekir, Amani: That's correct, yes.

Vinson, Scott: So we're being asked to reconstitute the committee.

Babekir, Amani: Ah, that's a neat term.

Michelle Hill: That or re-establish or form again, yeah.

Vinson, Scott: Reestablish. Yeah. OK.

Babekir, Amani: OK. So that's …

Michelle Hill: Amani, I think the confusion for this is that we should drop in a dash between the “re” and “form”, under Issue 3, just so it's clear what we're speaking about. Thank you.

Babekir, Amani: OK. But “reestablishes” means the same committee, or you referring to the same meaning we have here Scott?

Vinson, Scott: I think technically. Well, I'm not quite sure … Issue 3, was that part of our …

Charge from CFP? Technically, I think what they're asking us to do is to reconstitute the committee. Are we?

Michelle Hill: Or continue the work of continue the committee, yes

Babekir, Amani: I think they use some similar language in the previous term. You know the previous committee they use this kind of language, but we still could go back and see how it was done on the last term and I think there is a format. I'm not sure about the actual language. But Scott you asked about our charge.

Vinson, Scott: Right.

Babekir, Amani: Our charge is to create the framework and also suggest any changes to the Food Code. What I'm trying to say here is, do we want to ask … because there are things we have to ask the Council - like to approve and acknowledge our work.

And if we think there is a need for further work to be done to ask the Council to re-form a, you know, the committee. Or we could do nothing about it, and just ask to acknowledge and review our report.

Vinson, Scott: So, this committee that we're all serving on now, our job was to come up with a framework for the major food allergens. So with this Issue 3 here on the screen, we are then going to go back to CFP, ask them to reconstitute, recreate, reestablish the allergen committee again for next time and next time they're gonna be addressing these new issues, one of which is our Issue one. Figuring out what to do about the non-major food allergens because we've already addressed the major food allergens, am I getting this right?

Babekir, Amani: That's correct, yeah.

Vinson, Scott: OK. So in addition to #1, the non-major food allergen stuff, we're gonna ask this new allergen committee, which will be put together next time, to do these eight things. I'm not sure I understand. Why we are? Why this existing committee is being asked to address … where did this Issue 3 come from? What are these eight things? What was the genesis of the ….

Babekir, Amani: Sorry – can you hear we have a fire alarm in our building.

Vinson, Scott: Ohh.

Babekir, Amani: So I need to leave, and we could discuss this in our next meeting. But I have I have to leave the meeting.

Michelle Hill: So as Co chair, I guess we'll come back to it.

Vinson, Scott: Oh, I was gonna say, can she just leave it on? And maybe we'll …

Michelle Hill: Maybe she can. I think someone else actually started the meeting.

It's possible we might be able to continue it. David, did you start the meeting, Dave Read?

Dave Read: No, I did not

Michelle Hill: OK, I thought I saw that somewhere, but it hasn't died, I guess.

Vinson, Scott: Right. We're still going so ...

Dave Read: Ohh, well I might have, I might have been the first one to sign in …

Michelle Hill: I think that if you stick around.

Dave Read: It come it comes up on Microsoft Teams is where it comes in.

Michelle Hill: Sure. Yeah. I think that you're our host today.

Dave Read: Ohh wow, I had no idea.

Vinson, Scott: Well, we still have a Co-chair in Michelle, so we can continue, I think.

Michelle Hill: Wait, we could.

Dave Read: Yeah. In essence, I've been on a few CFP committees. So generally what happens is you decide if there are Issues that have come up that you wanna have a future allergen committee to consider. It doesn't mean the same group members are there. You reapply for membership in each conference. Generally they will keep most of the original members if they're interested again, and then they also add a few new members as well.

Vinson, Scott: Who came up with this list? This Issue #3 and the 8 items under it?

Michelle Hill: Through previous meetings. It's kind of like a laundry list or running list of what people have said over time and what we've discussed in previous meetings. It's completely flexible. That's why she had it displayed because it's up for debate, absolutely.

Vinson, Scott: Through previous meetings of what, this committee?

Michelle Hill: That's correct.

Vinson, Scott: Well, I think that's this is really the purview of the CFP. This isn't really our domain. They need to review the work product that we've come up with before they can decide what the next steps are.

Michelle Hill: This is just part of the flow. If we want to have an allergen committee to address anything that's existing moving forward, now is our chance to re-form it. So we need Issues to do that.

Michelle Hill: And so we can certainly strike stuff that doesn't make sense, or we don't think it's within reach. Yes.

Thoma,Libby: And see if we can add to that list as well.

Dave Read: Or delete.

Thoma,Libby: When would that work happen? When would we find out whether or not a 2023 Allergen committee has been formed and … whether or not we're going to be serving on it?

Michelle Hill: It happens during the biennial meeting. So in April, in Houston, when we all get together to do this work officially, that's when we'll submit our work for our first Issue saying we've completed the current work of this committee, so please accept our work. The second Issue is to update the documents on the CFP website and post this one. The third Issue concerns “do we need to continue this committee? If so, what Issues present themselves and this is what our entire committee is doing.

Courtney Halbrook: Yes.

Michelle Hill: Membership at that time, as it stands, would vote. Am I right on that Courtney, is that understanding correct?

Courtney Halbrook: Yeah, absolutely. It's just, excuse me, I was just about to try and … but you guys were doing such a great job of explaining it, but I think you nailed it. I think Dave nailed it. You've nailed it, Michelle. Typically, in the Council process at the meeting in April, your final report is submitted as you guys described, begging at the result of knowledge for separate Issues. They're requesting both. The document we posted and then the third Issue would be, to request that the committee be continued with these charges.

Sometimes the new charges stem from the previous charges that you didn't quite finish or complete, and you want to keep working on them, or over the course of working on those charges, you discovered other things. They're brought to the table for inspection, and other potential work, that the allergen committee could do. And so you're asking what to do with these charges? It's at the Council, so it's important that those charges are well written, and carefully prescribed, so it's very clear what the work will be and it's not too flexible.

You know, that's just the way – it is difficult for the body discuss if you don't have really good charges. And then the Council will review that. And we'll discuss and debate the need to continue the allergen committee and the Council will debate and vote whether or not the committee should continue.

That would be on the list of all the committees, including the conference, that people can sign up for. And if you want to continue your participation, you sign up. You don't, you don't. And there will hopefully be you Members that sign up to join. That's where we got, after all the signups are done. There is work to place all of those people. Everybody really gets their first choice, but it's how

many ... another 100 people sign up to be on the allergen committee, obviously we have limits people will serve. This is announced afterward. I don't know exactly when after. Fairly quickly you are notified what your committee you signed up for will work out.

Michelle Hill: Yeah. And this current biennium was really fast because we're working on a truncated schedule. So it'll be a little bit different, I think that by October … It's April … How does that work? When does the new biennium start then? Right away in April?

Courtney Halbrook: Yes.

Michelle Hill: After the biannual meeting, OK.

Courtney Halbrook: That starts pretty much right away, and then you'll have the full 2-year cycle to work on …

Michelle Hill: Well, that'll be nice.

Thoma,Libby: I was gonna say these last two years have flown by.

Courtney Halbrook: Yeah!

Michelle Hill: Yeah, it's only been, what, 18 months? Really? It was a year in September that we've been formed.

Courtney Halbrook: That's why it's really important to decide as a group. I said this already, but four should work. You guys have collectively agreed that you've done everything you were asked to do.

Vinson, Scott: Courtney, it's really hard to hear you. You're coming in and out and there's some background noise and so I have not caught what you've been saying during the last five minutes or so.

Courtney Halbrook: Technologized. Sorry, I think it's probably my microphone wasn't working great today.

Vinson, Scott: My impression of Issue 3 is that we're getting a little bit over our skis here. Whether or not to reconstitute the Allergen committee for the next CFP is really the purview of one of the councils.

Michelle Hill: It's council two.

Vinson, Scott: It seems like a breach of protocol for a committee, I mean we report to one of the Councils - Council II, in this case, we report to them - seems a little bit like we're trying to usurp their role and tell us what we want them to tell us to do next time. That feels like a breach of.

Michelle Hill: This is custom. It's customary.

Dave Read: Hey, that's often the way it's done. Yeah, it's often the way it's done is that a committee will come up with the Issues that weren't part of the charges that they think need to be addressed. And then you propose that the committee be reestablished. You list some thoughts on what those Issues are. And then the Executive Board will probably decide whether they're gonna do that or not, or if there's some other Issues that come up that they wanna add to the charges. And again just because it's reformed, you reapply if you want to participate in the next committee ... It's not an automatic that you continue on.

Courtney Halbrook: This is Courtney. Can you guys hear me better now?

Michelle Hill: Yes, ma'am.

Courtney Halbrook: It is customary for the Co-chair or the chair and vice chair of a committee to Identify future charges for that committee, if there are any. I don't feel like some of the specifics that you land on for the future charges you will need to be careful that you're not just creating a charge out of thin air to work on. There is a meaningful need for it to be part of the committee's work, and that would come from prior charges that you guys have worked on that have identified new and continuing work.

There could also be Issues that are submitted at Conference for Council to hear that pertain to allergens and the allergen related sections of the food code and that sort of thing. So Issues can come that way as well. Oftentimes, how committees are formed is because an issue was brought to council and it's deliberated and if there isn't quite a consensus on the issue or it needs a little more exploration, a committee is often formed and so it can go both ways. It’s definitely committee Chairs and vice chairs, along with the remainder of the committee, and voting and consensus, it is customary for you guys to identify future charges. Doesn't mean they're gonna go into effect. They will be reviewed by Council II and voted on by Council II and submitted to the State Delegates at the end of the Conference for voting. And that's how it all works. So, I wouldn't be too worried about that. Scott, you are following the protocol. It's just when you identify what you think the charges will be for the future that you have to be very specific and that they need to be meaningful.

Michelle Hill: Thank you so much for that, Courtney. I appreciate it.

Vinson, Scott: It's new to me. I've served on other committees, and we didn't operate this way. So this is new to me.

Courtney Halbrook: What I would do to help, and I can help you, Michelle, if you have trouble finding any … I would go back and look through some of the past Issues and you might have to go beyond just the last biennium. You might have to go to the one before

that to look for some Issues that were submitted to Council II that would give you an example of a committee seeking to extend their charges.

Michelle Hill: Yes, ma'am.

Courtney Halbrook: And you could see, you know, kind of how they wrote the Issue, how they worded it, what those charges looked like in comparison to previous charges, and, that might be helpful too. If you can identify a couple of those as examples to look at maybe, you guys can share that at your next meeting with the whole committee to talk through this a little further.

Michelle Hill: Yes, I like that idea quite a bit. Thank you. That's well advised. And we do have that information. It's not going to be a hard thing to put that together for everybody. That's something we did right in the beginning, when we first set our committee up, was to review the past so we could see the path forward where the hang ups might be. So absolutely, I think that's excellent. If there's anything further this … we're at-time now for this meeting, I guess. Does anybody else have anything they need to put forth or … ?

Courtney Halbrook: All good here.

Michelle Hill: OK. Well then, I will officially adjourn this meeting. Please be aware that we'll be sending out e-mail shortly here with requests of review from you all. So thank you so much for your time and have a good afternoon.

Meeting Number	Meeting Date		Meeting Time
23	**10/27/2022**		2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Issues points	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: Hi everyone. And this meeting will now come to order. We need to take the roll call Michelle; would you like to proceed with that?

Michelle Hill: I certainly would thank you, Miss Amani. [call the roll]

We have six voting Members present, three non-voting members present. I don't think that meets our quorum for voting purposes.

Babekir, Amani: OK, thank you, Michelle. So we don't have a major thing that's we need voting on today. So we just going to continue discussing our Issues. Hopefully you got the chance to look into the draft, which I sent out yesterday. But first I want just to give you an idea about what happened in the last committee, what issues they submitted and how they submitted. So to just get an idea the way they've been doing it in this committee. Before I do that just I would like to remind you about the Conference for Food Protection, antitrust statement and it is active. And thank you to Michelle because she dug into the previous issues and converted them into words to be easy to look at and she put together our draft for the issues we are planning to submit, so let me first share with you. Can you see my screen?

Ben Wagner: Yes.

Babekir, Amani: OK. Thank you. So as you can see in this one, the previous committee. The first thing they asked for is to acknowledge, you know the committee and their final report. And they thank the committee members and note that their work is complete. They ask for the re-creation of the allergen committee and that is the one which we were, you know, discussing in our last meeting and just back and forth about what is the best way we could do this.

So this how it's been done, it's just to ask for the re-creation of the committee and then we suggest Issues for this new committee. As you can see, we listed out the Issues we've been working on. It's starting from one, to two, to three. And then they have also another Issue that's they are asking the documents they developed to be posted in the website. And here is how they did it - it's just asking for the acceptance of the document by the CFP and authorizing the conference to make any necessary edits, and to post it on their website.

Another issue also they submitted is to make the change in the food code. And they have couple of issues under amend the food code. And they are giving more details here. So if we are thinking about making any changes into the provision section of the food

code we have to learn the language and where we need to put it and all of these details. So all their suggested changes - where in the language in the provisions section of the food code - so they provided all the language here.

OK, so that is just an idea about what happened in the last committee. Any questions before we proceed to our version which we drafted?

Michelle Hill: Amani, did you want me to share my version or the version that was sent out? Or are you going to do that?

Babekir, Amani: Can you see it on the screen?

Michelle Hill: Yes.

Babekir, Amani: So here the first one. We are asking to acknowledge here the committee final report and thanking the committee members, so we already agreed on our last meeting that we are OK with this section. Then here we are asking for the re-creation of the allergen committee to complete the following seven charts we listed. I'm going to open it now for discussion. What are your questions, suggestions, comments ... do you agree with this? Do we charge anything, we need to add? Just feel free to take the floor and just let us hear your voice.

Michelle Hill: Madam Chair, if I may, as putting this together, I just took the language, as was written in the draft document from our prior meetings. I'm curious about if item number 7 is correct. If anybody on the call is who asked for this, could you please speak up and tell me if this is right or correct it or whatever, and if not, we'll figure it out. But.

Babekir, Amani: Yeah, Michelle, this one was actually came out of the notification subgroup, which I was in charge.

Michelle Hill: OK.

Babekir, Amani: And Devin suggested that this is one of the points which is not very clear in our notification section and maybe needs more details of how we could provide the chef with more tools to identify allergens.

Michelle Hill: Alright, thank you for that clarity. If I may ask, who just arrived on the call, please, Welcome …

David Read: Well, this is Dave Reed. I was not able to get in through Microsoft Teams, so I ended up having to call in. Not sure if there's a new announcement there, if I missed it.

Michelle Hill: No, but you're welcome and glad you found a way. Thank you for being here. I'll mark you present.

Babekir, Amani: So David, now we are discussing the re-creation of the Allergen committee which we were discussing in our last meeting and just listing here all of the charges that we think might be worth looking at and discussing in the future committee, and all of this is from one to seven came out of our framework discussion, or just putting together the materials for all of the sections.

Amber Thompson: How long does the next allergen committee have to complete these charges, if we choose seven of those? What's the time frame? Is it two years?

Babekir, Amani: It is. It is 2 years but it is out of our hands because it's will be a new charge. It will be a new committee and they need to put their timeline on it, but the ideal time is 2 years.

Amber Thompson: OK.

Babekir, Amani: Any committee to finish their charge? Do you think that is too much or?

Amber Thompson: So we had we didn't have two years, right we had like …

Michelle Hill: A year? Yeah.

Amber Thompson: One year, right - less than a year. OK. Two years. No, this is fine. I think for one year. No, this but two years. Yeah.

Michelle Hill: And I think some of these will end up being that we direct other things to be done. It seems that we would have to ask for some kind of major study to be done around non-major food allergens, although I think that there's something really good posted at FDA right now on that specifically. Is that right? Does anybody know about that document? I'll hunt it down.

Babekir, Amani: Are we good with this points and with this section? OK, I think we are good with that one. So this is the first issue that we're going to submit. We're going to have another week also to look at it. So from now up to the end of next week, if you have any comments or any suggestion feel free to send it to us before we finalize the draft.

Michelle Hill: I just put into the chat a direct link to the FDA document. It's draft guidance on evaluating the public health importance of food allergens other than major food allergens. And it was what I was referring to just a moment ago.

Babekir, Amani: Thank you, Michelle. So this is the second issue here and this one is to publish the document on the CFP website, and giving more details about the title and giving the authorization to the conference to make any edits and to post it as a PDF format on the website. Any comments or change on this one? OK. So we are good with that one. And the third one is … the one which where we ask for this document to be included in Annex 2 of the Food Code. And I remember from our previous discussion's the recommendation we got from the Council and so we are going to ask for the document to be acknowledged in the Annex.

Michelle Hill: The way that this is written is that it would be in its full printed form, not just as a reference – it is actually a document that is present in its entirety within its own Annex is how this was framed. I don't know if that's right, but that's what I read.

Babekir, Amani: Remember in our last meeting, Greg said we need to identify the section where even in annex where we want to insert this.

Michelle Hill: Yeah. So there needs to be clarity here. I mean obviously we need to talk about this.

Babekir, Amani: Yes. But where do you think is the best place we could add it? Which section in the Annexes?

Amber Thompson: How many pages?

Michelle Hill: It's 22 pages.

Michelle Hill: As it's formatted right now. We could certainly reduce that. We wouldn't need a cover page, you know, and a table of contents, so what like 20 pages, 10 back-to-back.

Babekir, Amani: If you want to share the screen.

Moritz, Erin: '6 Steps to safety' from an emergency response plan that I think we just took that from.

Michelle Hill: Perhaps we suggest that it's just the language we keep and anything that refers to an outside published graphic, there's a direct reference as to how that can be found otherwise.

Babekir, Amani: Yeah.

Michelle Hill: I don't know how do they do that within the food code normally?

James O'Neal: So are we looking to where this would fit within the Annex? So I guess under what chapter is that what we're looking for?

Babekir, Amani: That is correct, yeah.

James O'Neal: OK, one section, let me pull it back up, a - Demonstration of knowledge, 2-102.11, Section 9. It describes foods identified as major food allergens and symptoms.

Eisner, Crystal: I think that sounds like a good area. We have not adopted the food code yet here in Harris County. Demonstration of knowledge does sound like it would be the best place.

Michelle Hill: So are you suggesting that it be addressed within the Annex that deals with demonstration of knowledge of a CFPM, or is it in the actual code that you're suggesting we would insert this under what the required education would be?

Eisner, Crystal: I think it would have to be under an Annex.

Michelle Hill: OK.

Eisner, Crystal: In my opinion.

Michelle Hill: Yeah, I think it has to be as well. So would it be the case that we would say in the demonstration of knowledge section, the 2-102.11 Section 9 – we would have a "please see Annex page, blah blah blah"?

Amber Thompson: So are we asking them to just take what we've created and put it in the Annex? So they're not going to do that. I mean, it's FDA who writes the food code, so it's going to have to go through like major revisions and all sorts of reviews and edits and I think the limited time. Looking at the food code, in Annex 3 public health reasons under food allergens person in charge, it talks about food allergies or increasing food safety is a Public health issue, goes on to talk about the "Why?". This came about in 2008, CFP passed an issue, but some parts of the Annexes gives a link to an FDA, another FDA web page. And so maybe we could house it on the FDA website.

Michelle Hill: That's an excellent idea.

Amber Thompson: For example, there's a link that says "food defense". So you click it and it takes you to the FDA food defense, you've got food, defense tools, plan builder. I don't know who wrote all these. So maybe that is an option. The FDA's website could link to CFP, which houses the Framework. That way it doesn't have to go through all the FDA approvals and all the Paper reduction act and all that kind of crazy stuff. Yes?

Michelle Hill: So are you suggesting, Amber, that it would be language that would appear in Annex 3 under L "Food allergens person in charge duties?" That would be a link out to CFP, where our document lives? OK. Sure.

Amber Thompson: Yes, if that's allowed. If not, then it would have to link to FDA, which would then link to CFP. I'm going to look through here and see if there's any other place I see a link that's not FDA and see if that's even in there, so.

Michelle Hill: OK, I think this is the right track.

Babekir, Amani: Yeah. So do I. Any additional thoughts on this?

Michelle Hill: One more thing, Amani, if you don't mind. Amber, was there a point in time where we discussed something about making an interactive, like an application does … ? Am I remembering that right?

Amber Thompson: Yes, it was going to be a Quick guide, right? A visual tool that had the major pieces of that framework in it. For those that maybe have a hard time reading where it's easier to just grab a booklet that has pictures and words, of course. But uh, more kind of shows them what to do instead of telling them what to do. , I'm looking through here. I do see outside links. I see a couple to ANSI, FSIS, Food marketing institute, restaurant.org. Here's a guidance on responding to food emergencies. We could have some kind of guidance on responding to food allergens or something like that, and they could house it here.

Michelle Hill: What is that again? In section … ?

Amber Thompson: Well, the guidance looks like they're located in Annex 2, which is the reference section.

Michelle Hill: Alright, thanks.

Amber Thompson: We could create a Food Allergen reference section in Annex 2.

Moritz, Erin: Would it be helpful if someone shared their screen?

Amber Thompson: Ohh yeah here.

Michelle Hill: You don't have a good imagination there, Erin.

Amber Thompson: I'm on one screen today, no. OK, so I'm in the food code.

Moritz, Erin: I mean, I could make stuff up, but.

Amber Thompson: See here references and then on four it's food defense guidance from farm to table. We could possibly add a 5. Major Food Allergen guidance or something like that. And then that way for future allergen committees, that's where they could house all the other guidance tools, tips, all that kind of stuff could be here, because if you go to this, Section 4 …

Michelle Hill: I wonder, I wonder if people would read this. I know I have been through this with a fine tooth comb before, it's just hard to remember what's there.

Amber Thompson: Oh yeah. I mean, you could read it and then reread it and find completely new stuff.

Michelle Hill: Yes.

Amber Thompson: It's like watching a really long movie and you watch it again. Like I don't remember that scene. Where did that scene come from?

Michelle Hill: Yeah. Or who's that character?

Amber Thompson: Right. They like their references, don't they?

Michelle Hill: I think other people have good ideas like we do! Chapter 4?

Amber Thompson: There you go. So if you go to this section, guidance on responding to food emergencies. And then we talk about CFP here and then it … Well, there was a section right here, "FDA publications". OK, you can click these links. Then you have USDA publications - so we could link … so there's some things from the National Restaurant Association, Food Marketing Institute , CDC, so we could possibly do what they've done for food defense, but for food allergies.

Babekir, Amani: Sounds like a good suggestion. Any comments on this one? And we probably need to define the language we going to put there.

Amber Thompson: Yeah, right.

Babekir, Amani: Uh, along with the link, yeah.

Amber Thompson: Right.

Michelle Hill: So is that something we can do over e-mail between people or as a committee or?

Babekir, Amani: Yeah.

Amber Thompson: Maybe if one or two people want to tackle the wording and then we all decide if we like it or not. And you can just possibly mimic what's already here, that it will be accepted more readily.

Michelle Hill: Amber, do you want to work on that with me and Amani?

Amber Thompson: Sure.

Michelle Hill: Anybody else want to be involved?

Michelle Hill: Don't mean to draft you, Amber, but you have good ideas.

Amber Thompson: It's OK.

Babekir, Amani: Any more volunteers? So I think, yeah, we could, we could work with you, Amber and let's say maybe early next week, we could work on this one and we could communicate by email to see your availability, to make just a very quick meeting, to put together the language. Does that sounds good, Amber?

Babekir, Amani: So, I think that we'll finalize our Issues. So we're going to have three Issues. One and two, just about addressing all the charges and the third one, the last charge ... our committee is asking to make a change in the food code, so these are the changes we would suggest. Any additional comments, suggestions? Do you think there is any further work we need to do or we are feeling good about it?

Michelle Hill: I should know this, but what's our next steps overall?

Babekir, Amani: Yeah. So about our next step, just we're going to, you know, put together the draft for the issues and also our framework draft. Then we're going to submit it to the Council in the middle of next month.

They will give it a review. And then hopefully they wouldn't send it back to us with a major change or anything. But we're going to have second round of review before we finalize.

Michelle Hill: Thank you.

Babekir, Amani: Amber, about the summarized document you're going to put together. I remember you said by the end of the year, like December. That is the rough timeline you give to us.

Amber Thompson: Yes.

Babekir, Amani: Probably, yeah, probably we need to submit it to the Council for review. Not sure if we have to do this by the middle of November or not, but I will keep you updated if it needs to be submitted by the mid of November. Would you be able to make it?

Amber Thompson: Uh, if with help, I can show you what I started working on it. Then I stopped. I was doing it through NEHAs Canva account. It's very easy to use. You just pop in information. I just grabbed a template and decided that was OK, so we can work on this then when we meet in Mid-December. If I can have someone help me with it, that should be fine

Babekir, Amani: OK, so probably Monday, Amber, we could meet and decide if we want to proceed working on it. I think it's better if we prepare it by the middle of November

Amber Thompson: Right.

Babekir, Amani: Any volunteers to help Amber with this document?

Michelle Hill: Amber, I'm always available too. I don't want to be volunteering for everything under the sun, though. Other people need to be involved too, but I'm certainly happy to help anyway I can.

Babekir, Amani: OK, that's good. So we have a good plan to do that, and finalize the language that we need on our third Issue.

Michelle Hill: Yes.

Babekir, Amani: And in our next meeting, we have bunch of meeting minutes we need to approve. We were a little bit behind on putting together our meeting notes. So we're going to spend some time, Michelle, to put it together and probably we're going to dedicate a lot of time in our next meeting on it and then we will decide what we are going to do about our future meetings - if we wanted to keep them on our calendars or if we want to make some changes on it, so we're going to decide on that later. Anything else? Any additional point before we conclude our meeting today? Thank you. [meeting adjourned]

Meeting Number 24	Meeting Date **11/10/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Issues points	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Babekir, Amani: So hi everyone. Thank you for attending the meeting today. And I'll just remind you about the Conference for Food Protection, Antitrust statement is active in this call. Now our meeting come to order and Michelle, would you like to take the attendance?

Michelle Hill: Sure. I'd be happy to. [calls the roll]

We have 6 voting Members present.

Babekir, Amani: OK, Thank you, Michelle. So we don't, we don't have critical things to vote on today, so hopefully we will be able to finalize the Issues we have in our agenda and in our whole committee work because probably this one might be our last meeting. But before we do that, let's first get an update about the summary, because in our last call, we thought about, getting Amber ready to proceed with creating that short document. But they discuss it together, with her team members, and they decided not to proceed with it. Michelle or Scott - do you want to give us update about this one? But I don't see Amber with us.

Michelle Hill: I'm happy to speak to it. The meeting consisted of myself, Scott and Amber. We had quite a discussion regarding how to proceed. The original discussion was seated around creating a small application that could be used to share allergen information that anybody with a smartphone which most people have these days, would be able to have it right there at their fingertips. We ran into conflict because who is sponsoring it? Is it a CFP application? Is it data from USDA, FSIS, who? Who owns it basically, and who condones it, who endorses it? It just got kind of hairy. So we decided that if that's a tool that people want later on, that they can certainly readdress doing that at maybe in the next committee.

Michelle Hill: Is that your take on it, too, Scott?

Vinson, Scott: Are we talking about the same meeting the one we had just the other day?

Michelle Hill: Yeah.

Vinson, Scott: When we talked about the development of a pocket guide?

Michelle Hill: Correct. Yeah, it originally started out with the discussion of it being electronic being built in Canva, and then we migrated over to the discussion regarding it being a pocket guide. Yes, that's correct.

Vinson, Scott: Yeah. So we identified …

Michelle Hill: Oh, that's right, we did, didn't we? We pulled out content.

Vinson, Scott: We - I think we had a pretty substantive discussion about the type of content that we thought would be most useful for the audiences who would be using the pocket guide, the Food service workers themselves. So we went through the entire 22-page framework document and identified the most relevant parts that we want the audience to look at and that would be sections B, 1 – 5 of the framework document, as well as C, 4. A, B and D, 1.

Michelle Hill: That's what I have in my notes too.

Vinson, Scott: And we discussed in particular figures by 5, on page 16, the importance of including those icons to talk about the symptoms that people demonstrate when they're having an allergy attack. Then also graphics of the types of reactions that children can have when they're having an allergic reaction. Then we talked about the format of a pocket guide. If it's in printed format, it could be on paper stock and be either in a sort of a trifold 6-sided document, or a front and back smaller card stock-size double-sided document.

But I think we all agree that the intended audience would be the Food service workers themselves.

Babekir, Amani: We don't have time to create the actual document or the digital version of other content.

Vinson, Scott: Yeah, we, simply were identifying the most relevant parts of the of the longer framework document that we thought the FDA should focus on for inclusion in a possible pocket guide or electronic version of a pocket guide, whichever direction they decided to go. But we wanted to at least identify the parts of our framework document that we thought should be included.

Babekir, Amani: OK.

Michelle Hill: Kind of like “mission critical: This stuff must be known”. That type of information. Didn’t we discuss having language put into the current framework? Maybe a paragraph that's just describes …. quickly, like if you wanted to have a shorter version, this is what it should absolutely have contained. Or was it that we were gonna just keep that in our notes to tell FDA? OK.

Vinson, Scott: I don't remember if a decision was made on that. Michelle, I think you said you were gonna talk to Amani about the best way to proceed on that.

Michelle Hill: Yeah, yeah, and I forgot. Oh we did OK. That's right.

Babekir, Amani: And yeah, and we discussed it. Yeah, we discussed it. Michelle. Yeah, we discussed it and we found out that we don't have enough time to include it in the actual framework because we have to be done with it next week by the next week. But they there is an option I think to have it as a supporting document.

Michelle Hill: So what she's talking about is that when we submit our Issues, we have the opportunity to submit anything we want in support of our argument for the Issue. And this could be a simple document that we write out that would be how to create - or most the most critical points - about allergen control or something like our framework. These aren't the right words, but to catch what I'm saying.

Babekir, Amani: Hmm, that's correct. So are we OK with that option? If there is any other suggestion or any objection of this option? So I think we could proceed with that one and just take what you concluded from your meeting, and just put it in a short document. That's it and include it as an attachment to the Issue.

Michelle Hill: OK.

Babekir, Amani: Then the second topic in our agenda are Issues which we're gonna submit to the Council and thank you to Michelle. She spent a lot of time trying to put it on the correct format and adding all the public health significance language. So I'm going to give her the floor to walk us through what she's done on our three Issues. So now we have three separate documents, each one consists of one Issue.

Michelle Hill: Correct. Thank you, Amani. This is a condensation of a lot of people's work. I just happened to be the one in-putting. So, if you have comments, questions, please. We're gonna have to make these choices today. We need to really figure this out.

What the language is and what we're doing. So this first Issue is the traditional first Issue, which is asking them to accept our final report which is like the quarterly reports that Amani and I have been required to file. And this one just shows the wrap up of the work.

Included with the final report will be the attachment of the meeting minutes, in addition to attendance records for each meeting. We will be circulating an e-mail shortly here that will have the Minutes attached and we will give you a couple few days to review and make comments, request changes, and then I think we're gonna have to probably do an e-mail vote or something like that to get them passed. We do need to have them passed and approved by next Friday as they're part of this. They're submitted along with the final report.

So this is Issue one in the allergen committee final report, and what we're asking them to consider for the next biennium is to is to accept our report, acknowledge it, and accept it, and thank the committee members for their completed work. And then re-creation

of the allergen committee to complete the following three charges. This terminology, “re-creation” is a part of the template, and it is necessary language that cannot be modified. That is the word they use. So there's a 20-page document published by CFP. It's available on their website. If anybody would like to look at it, it's well worth a read and it's called , “Issue Pre-Submission Guidance”. It is how to fill out the final report template. It walks you through step by step. It's an enormous amount of information. I was really surprised, but we did it right as far as I can tell. So these are, this is language we're gonna “use existing research and resources”. So item one of the next charges will be using existing research and resources to identify the non-major food allergens, and how to control for them and expand the major food allergen framework to include this information.

So we're basically asking the next committee to embellish on our framework, to cover when we can or how we are able to anything that's a non-major food allergen. Support guidance on how to control cross contact including receiving, storage preparation and service. Letter “B” is identifying, gather existing research and resources, to form an allergen control toolkit for all aspects of the flow of food. Things in a toolkit could be lists of derivatives on how an ingredient can be named on a label, an allergic component. It would be an example letter “C - identifying established tools to ensure implementation and compliance when notifying a consumer about food allergen”.

So this is how do we know that we've implemented, and we have compliance around notification, which was something that the 2018 and 2020 Biennium’s dealt with. And then #2 here “recommend changes to the food code that support retail food establishments to optimize operationalized framework to prevent and control food allergic reactions.” Again, this is standard language carried throughout the BIENNIUMS for this type of request. It's always the same language.

And then #3, “report back findings recommendations to the next biennial meeting of the CFP - again template language is required. I have no control over these things … What do you think about the charges, and should I proceed to public health significance or how do you wanna do that, Amani?

Babekir, Amani: Yeah, there any comments about this section? OK, sounds good.

Michelle Hill: I'm hoping people had a chance to read it before the meeting. This public health significance was data that we pulled together from different sources, and they're also cited here. So any of the references are where we pulled either quotation (and they’re footnoted). And again, this is a convention laid out by CFP on how you list this type of information when you're using a reference to support your public health significance statement. So this talks about it, focuses on the fact that cross-contact is a really big deal.

And that that's pretty much what we're looking for - cross-contact control in addition to more knowledge around non-major food allergens and how they impact things.

And hopefully you've been able to read the statements and have changes or input … it would be very welcome here. To be short, to the point, Amani and I worked the language together, but we are certainly open to changes ... just had to get something pulled together. Should I read out the public health significance statement?

Babekir, Amani: Let us give them time to read it.

Michelle Hill: I'll leave it up on the screen.

Babekir, Amani: Let us give it a couple of minutes for people. Comments? [waits two minutes] OK, I think that's enough time. Yeah, you can proceed.

Michelle Hill: OK. Umm at the recommended solution, I think we'll be getting good feedback from our

Council II co-chairs. What should be put here? I simply cut and pasted from the top portion, and then I read the whole big document about how to do things and it says you can't do that. So I'm hoping you'll give us some good feedback on how to review this language. But we're basically saying what our solution would be and it would be to re-form the committee and undertake the charges as we presented them. The attachments that go along with this document will have the final report that we will submit to the Executive Board for approval - again, that's next Friday.

And then attached to that, we'll have meeting minutes, meeting attendance, and then we'll also include these supporting attachments. These are meant to give background information to the Council when they're thinking about the current Issues that we're presenting here. So the two documents that we recommended as supporting attachments are “components of an effective allergen control plan.” It's a framework for food processors, which if you guys take a look at that, here's the link to FAARP out of U Nebraska. It's an excellent framework. It's well done, and it could be a good guideline for the future Committee, if they undertake and pursue these charges.

The second is the “draft guidance from FDA on the non-major food allergens. All they talk about - anybody can pull this document off the FDA website, and this will be very useful to the next committee as well if they need it so any impact or input on this would be welcome too always. Do you think there's other stuff that we could include that would support our argument for proceeding as we've recommended.

Babekir, Amani: I think also we could include the Summary document of the Framework.

Michelle Hill: OK. So regarding the summary document? Yes. Thank you. And we'll call it ... I don't know if this is what people want, I'm just typing ... we call it whatever you want. I'm just trying to work it on the fly.

Babekir, Amani: I think we could use our Framework title; we just will highlight that it is a summary.

Michelle Hill: Perfect. Thank you. Alright, so that's Issue one. I'm not hearing much about this. If you guys think of stuff after the meeting, please just e-mail us, if it strikes you later.

Here's Issue 2. This deals directly with the request to post the major allergen framework document to the CFP website. Again, specific language that's been dictated ,that we need to use around this issue, or as we propose this issue. So we've requested that this document entitled “Major Food Allergen framework”, and we're authorizing the CFP to make any necessary edits prior to posting the document. The edits would be things such as consistent format and non-technical content. Any changes cannot affect the actual meaning of the document.

The third was to prior to posting this document, we want it reviewed to remove any potential violations of the commercialism comity policy. We did remedy that a little bit ahead of time by blurring the brand names on the image of EAIs.

And Issue number 4 - we're going to remove the CFP-approved document “food allergy notification, a guidance for industry” for the simple fact that it's been incorporated into our framework document, and it's perhaps redundant at this point. So, that's the charge. Here's the public health significance. This is a long one … FARE - they have an awesome content.

Babekir, Amani: Michelle, I have Scott. Yes, Scott?

Vinson, Scott: I raised my hand prematurely. Go ahead, Michelle. I'll ask my question in a moment.

Michelle Hill: OK, all of this is footnoted. A lot of this data was taken from the FARE website itself. It just got reorganized a bit to be cobbled together in a way that makes more sense. We did draft some language, but I just would like people's input on this. All right. Thank you, Scott. That's all I'm gonna say about that.

Vinson, Scott: Yeah. So my question is, “Are we sure?” I see that most of this document’s Issue consists of our actual framework document. I just wanna make sure of that, because we had confusion on the call that the three of us had the other day about whether we were using the most updated version. Are we sure that this is the most updated version of the framework document? .

Michelle Hill: Yes, I have. Yes, we do have the most recent addition, absolutely.

Vinson, Scott: OK.

Michelle Hill: That's a good question. So if you - anybody wants me to make anything bigger so they can read it better, I can do that. I can try and get the “public health significance” on one screen, if people want to review that. Again, this is the committee’s words, so people need to have their input. You know, I'd really appreciate it actually. I've never submitted an Issue before ever to the conference, so this has been a big learning curve for me too. So, I'll stop messing with it so you can maybe read it.

Babekir, Amani: Going to give it a couple of minutes, so feel free to read it from the screen or you could pull up the document I just sent this morning.

Vinson, Scott: I looked at it earlier today and it looked fine to me. Are we voting to approve things today or do we not have a quorum or?

Babekir, Amani: Yes.

Michelle Hill: We don't have a quorum, but this technically – Amani and I – are responsible for filing these as the Co chairs, but we don't wanna just file stuff, we want everybody's opinion, so it doesn't necessarily have to get voted on, but we do need input and it's on a tight timeline at this point and that's why we're doing this, is that right Amani?

Babekir, Amani: Yeah. And I, Scott, we did vote on it in our previous calls.

Babekir, Amani: This is the bulk of the of the of the Issue, which is what we want the CFP to consider. We discussed it. We said that's what we're gonna ask - the whole document.

Vinson, Scott: Yeah. So you're just asking us if you filled out the paperwork properly and it looks fine to me.

Michelle Hill: Essentially that, and if there's any glaring omission or a statement that you don't agree with. Sometimes things get left out - more eyes are better than just mine and Amani’s. So we want you guys to know you're part of the team too. It's not just us generating this stuff - there should be consensus.

Michelle Hill: So this is Issue 2. Should I pull up Issue 3?

Babekir, Amani: Let's give it extra minute, just to go over it.

Michelle Hill: I'll try and center this so it's readable again.

Babekir, Amani: OK. [waits two minutes]

Babekir, Amani: Michelle, thank you. Can proceed to the third one?

Michelle Hill: So this third Issue, this was probably the hardest one. I think that we've worked on these charges for the next committee essentially. No, I'm wrong. Excuse me. Pardon me. This is not that. This is where we want to insert this into the food code. And actually what we're aiming for is the Annex … Annex 2, specifically. So the title of this document "major food allergen framework", we wanted to be included within Annex 2 of the Food code. So we're requesting that CFP send a letter asking FDA to add the document to Annex 2. And then we say the reference could be added in the following places within an Annex 2. And we give them 3 possibilities.

These are not in any order. They caution us, as we draft Issues, that we don't have multiple decisions within an Issue. It would be that these are suggestions and where it could go, but they're free to do what they'd like with where it gets inserted. So letter "A" deals with what we've listed here and is the actual page in the printed Food Code. The current one listed on FDA 2017 supplemental edition and then the PDF page that this content falls on, because they're different numbering conventions. So for clarity, we did include that we were thinking about going in as #5 in a list of things within references Section 2, and we would title it, "Food Allergens", maybe "Food Allergen Control", whatever …. And then we could house our major food allergen framework document there. And so then it's part of the of the Annex 2 section. And then because we have made a heading for "food allergen" information, we can keep adding content in that same spot. So it's kind of like building a little bit of a house for us in that way for the future. Letter "B", it's gonna be what we could do it within a list that's already there, and it would become item number 8 of that list. Or letter "C" - it would fall as letter "W" of another list. These are lists about how to train people and what's expected of them.

Babekir, Amani: Michelle.

Michelle Hill: Demonstration of knowledge and then the specific language would be CFP Council II Allergen Committee 2023, "major food allergen framework" - that's the document. And then we gonna provide the link to the CFP website where the document will be hosted and it must be the HTTP, the full link printed which makes sense. And then here's the public health significance again.

Babekir, Amani: You'd like to give it like a couple of minutes just for the people.

Michelle Hill: Sure. [a few minutes pass]

Babekir, Amani: Yes, David – are you speaking? We cannot hear you …

David Read: I'm sorry, I was on mute. I have a quick question on where it says "a reference could be added in the following places within next two ..." Are you considering one of those places or in each of those places?

Michelle Hill: No, you're right. That's a good catch. So we should say the reference could be added in one place.

David Read: One of the following places, OK.

Michelle Hill: Thank you. We did contemplate asking for our own Annex, but we think because there's already these - we fit well within the information already provided in these sections that it wouldn't, it didn't seem like it was a real complicated ask to insert this language.

Babekir, Amani: Yes.

Michelle Hill: In the Annex.

Vinson, Scott: So under Section 1 here, we are just providing FDA options of places to put the reference to the framework in the Annex, A, B and C are just options.

Michelle Hill: Correct.

Vinson, Scott: With that, they could consider …

Michelle Hill: We wanted to be specific around this because it has a better chance - as what we've been told - if we have very specific placement in mind.

Vinson, Scott: Yeah. Well, and that obviously required a lot of work on ...

Michelle Hill: Both of us. Yeah, we were busy.

Vinson, Scott: Someone spent time, probably yours, Michelle, and I just wanna recognize that work and you know, commend you both for a job well done.

Michelle Hill: Well, thank you. We had other people involved too, but thank you, yeah.

Babekir, Amani: Amber also was included, though. Yeah.

Michelle Hill: Now, thanks for that, Scott. Yeah, it's a lot to get your head around the CFP language stuff too. You gotta be right about that or it'll just come right back to you so had to be pretty decisive with wording.

Babekir, Amani: Do we have anyone from FDA today?

Michelle Hill: I thought I saw Greg - Greg, are you on the call?

Greg Abel: Yes, I joined via phone. I could not get on Teams.

Michelle Hill: That's what I thought. I saw a 612-area code and I thought "that might be Greg." Good.

Babekir, Amani: Do you have any comments about this one? Do you see those suggested areas?

Greg Abel: So I'm on the phone so I can't see. I'm sorry I could not log on video for some reason.

Babekir, Amani: No problem. So if you've got a chance, just look at Issue #3. See if you have any comments that would be great.

Greg Abel: Yeah, yes, that'll work … e-mail.

Babekir, Amani: Thank you. You could proceed, Michelle.

Michelle Hill: Thank you. This next section is the "public health significance". So we had to state our case as to why we'd wanna do these things. We lifted the language from the first part of the Food Code. It's actually the preamble that talks about what is the purpose of the code? I just didn't think we could say it any better than it had been said.

So the next statement here is of my creation and it's in addition … the FDA Food Code contains a series of Annexes which provide the backup information, Scientific data, references, rationale, etcetera, for the guidance guidelines in each chapter. If you want to further understand the why behind something in the food code, the annexes give you that information."

So here we point out, "Why would we even choose the annex?" And then we say here "by publishing the major food allergen framework within the Annex of the Food Code, FDA would be further clarifying its satisfaction of CFP Issue 2008-III-06, which has to do with allergen control and educating people around food allergens and promoting awareness. So, once included, as are part of an annex, additional framework documents could be listed, including any future CFP-published documents around allergy control and the prevention of cross contact. You think of any better way or different things to add there, let me know it this is good enough.

Babekir, Amani: Any comments, suggestions? OK, I think that's good.

Michelle Hill: I have nothing for attachments for this document. I don't know that we need attachments. Maybe we attach the actual printed pages with our language inserted into that area, of what we'd like so they know how we'd look depending on where they choose to put it. Other than that I can't think of anything else we could add, so open to ideas. Or maybe we leave it blank, I don't know.

Babekir, Amani: Yes, Christine.

Christine Sylvis: Hello. I was wondering, for the attachments. I think I've seen it before where you can cross reference the framework from the other Issue.

Michelle Hill: Yes, that's a good idea.

Christine Sylvis: So I think they'll be able to do that. And then I'm sorry it took me a few minutes to go through all the pages and the Food Code. So let me get back to the PDF or the Word document? So when we're asking … location on page 309 of the PDF.

Michelle Hill: Yes.

Christine Sylvis: We're asking for #5 entitled "Food allergen".

Michelle Hill: Yes, so instead of it just being four items, there would be 5 on that list.

Christine Sylvis: I've lost pages … now the very last thing in Annex 2, so it would be listed there as a #5, but then it would be #5 …. It would have to go at the end Annex 2 … I was looking at #4 where it says, "Food defense". So if we are doing that, we might need to say "#5 food allergens" and have an introductory statement about that and then have it listed as a reference publication. So actuality it would be listed as #5 on that page, but it would be inserted on page like 336. And we might, if we're going to do that, we might want to have "introduction" language prepared.

Michelle Hill: And so let me see if I'm understanding this correctly. Listing it as a fifth item on the list will necessitate that we actually have the framework published or is that not what you're asking?

Christine Sylvis: No, it could still be a reference.

Michelle Hill: OK.

Christine Sylvis: I'm just looking at #4 where it has the “food defense” guidance from farm to table, which is #4 on page. I think it was 309. I don't have enough screens. And then that is actually on page 333, where it's mentioned, and it has an introductory statement and then a list of reference publications.

Michelle Hill: Yes.

Christine Sylvis: So I think we would follow that same framework. Is that right, Greg?

Greg Abel: Yes.

Christine Sylvis: Is where it would go as #5, but the content would go under #4 which is on page 336.

Michelle Hill: While the PDF has its own pagination and then there's the printed number on the bottom of the page and what I'm having trouble with is that bottom number is not 306, maybe the printed number is 306 ...

Christine Sylvis: It's 336.

Michelle Hill: Yeah, here we go. 336. OK, now, now we're talking. Yes, yes. Right here. You got it. That's what you're saying. We need language around. Yes, yes.

Christine Sylvis: So if you scroll up just a little bit, you'll see where number four starts, right there. Ohh yes. So you would need a number five with the little introductory paragraph and then have the reference, as a link.

Michelle Hill: So the PDF is 389, and the code is page 333. I'm just writing this down, so I know where to start, and then we'll have a #5. So, d you think we should have language around that already prepared? I think you're right. Good. Thank you. I didn't even ... I can't believe we didn't even extrapolate out to that point. We should have done that because you know it's important, well, necessarily, where we could also drop in, any future guidance too if we get a #5 … this I really like.

Christine Sylvis: Yeah, I like that idea.

Michelle Hill: Yes, I like the fact that this is like a little house for it. I feel like it could really live here and make sense.

Babekir, Amani: And we could make that introduction a more generic introduction so be open to host other documents related to ...

Christine Sylvis: So yeah, it is when you're searching for the page number, it is 309 which is 253.

Michelle Hill: Thank you. There you go. Bless you.

Christine Sylvis: So it would be #5 there. At the very top. Would be food allergens or?

Michelle Hill: So it's page 309 of the PDF 253 of the code. OK. And that's why we when we run out the Issues, we've got very specific language. Well, this will require an introductory paragraph. Since we've got this up, maybe we should look at Page 320 as well, which was another place we thought maybe this could live. Under “management and personnel”, it would be number #8.

Babekir, Amani: Yes.

Michelle Hill: Chapter 2 ... Management personnel … demonstration. That's right, under “demonstration of knowledge”. OK. Yeah, it would be a #8. And it would just reference our document. I guess we could put it … I don’t wanna muddy the waters, but this is the other place ... I really like the other place better. And then we had a third place ... let's look at that real quick too, page 375. And this would be adding after “the bad bug book”. It'd be letter “W”.

Babekir, Amani: Yes.

Michelle Hill: So it's under supporting documents, and they're supporting documents to … this is the FDA list of guidance for reference - so it's a long, long list. So we'd be letter “W”.

Babekir, Amani: We have 12 minutes left. We could spend like 5 minutes just working on the language we wanna add as an introduction.

Michelle Hill: Yes. It's got to get done, so yes. All right, so I'm going to just start typing it here so that we can all see it and we'll figure out where it lands later.

Babekir, Amani: Just asking for volunteer. We just, we just need couple of sentences just to introduce whatever content is related to allergens. That might be referenced on that section.

Michelle Hill: Here we go …

Babekir, Amani: We're still looking for the section.

Michelle Hill: I am … I finally found it.

Babekir, Amani: OK.

Michelle Hill: So here's Section 4. So we'd be looking to write a similar paragraph like this, and then list our publications.

Babekir, Amani: So let's give it a minute. Yeah, let's give it a minute for the people just to look at that section and then we could articulate something related. Do you think people would say something similar like “the following summary of available resources around Allergy?”

Michelle Hill: I'm just going to start by cutting and pasting that statement. Keeping it simple sometimes is best.

Babekir, Amani: Christine, do you think that's enough?

Christine Sylvis: And I'm looking at the other four sections. They are very short. Just saying, “here's a list of resources” for the most part.

Michelle Hill: I'm really glad you brought this up ...

Christine Sylvis: I was looking for the other ones for some inspiration.

Michelle Hill: Yeah. I didn't even think about where it would actually, what that #5 meant. It's just too much. So I guess what we'd be saying here is that if we do list it as #5, we would say … “proposed language ...”

Christine Sylvis: Looking at, I was looking at writing some other Issues for a different committee. I think we would put that at the bottom in the recommended solution part, so the recommended solution there is a template for just adding it in with the underlying language.

Michelle Hill: Yeah, I saw that too.

Christine Sylvis: Language to be added.

Michelle Hill: We should do that. We should have it be like we exactly how we want it to appear. Like #5, blah, blah blah, OK. Yeah, that makes sense. OK. I saw that there is a template or guidance on how to write all that out appropriately.

Babekir, Amani: Any suggestions about the language? OK. And then we could work on the formatting. OK, we're gonna have up to Friday, we probably need to finalize everything by Wednesday afternoon, so if you have any comments, any suggestions, feel free to e-mail us by Wednesday, by next Wednesday afternoon.

Michelle Hill: November 16th. I think that I think that's reasonable.

Babekir, Amani: And also, as Michelle said, we're going to send out the minutes of all meetings we have. I think around 5 minutes from our previous meetings need approval.

Michelle Hill: Well, yeah, that's only 100 pages Amani.

Babekir, Amani: Yeah, we haven’t approved them. It's a little bit hectic to go over it because what we've done in most part of those most recent meeting is we use the transcript of the Teams – now it is word by word.

Michelle Hill: It's a good read, it's an interesting read.

Babekir, Amani: We’re going to need your approval. The other thing is we were gonna have four meetings, I think. Nothing left for meetings in November because we have Thanksgiving. And then we have, I think one or two meetings in December.

Yeah, we gonna receive the review because we're gonna send those documents to Courtney, and we're gonna receive feedback from them and we have up to December the 2nd to send it back to them. We will look have meeting in between, but if we need the Committee opinion on any update or change, if it is not like formatting on stuff like that, you might hear from us, we're gonna send you an e-mail and we need your response, if you want to make any change on the on our documents.

Michelle Hill: I was gonna say and just so you all know, we'll be very specific on our ask. And it would just be only for substantiative stuff that you know, content that matters kind of questions.

Babekir, Amani: Then for the meetings in January, there is 3 meetings in January. I'm just gonna keep them in the calendar in case we need them, but you're gonna see me, cancel them if we've done all the review and we submitted our documents, we don't have any standing Issues, I'm gonna cancel those. I want to close by just saying big “Thank you” to all of the committee members. It's great work. Very good job. It was my pleasure and my honor to work with all of you on the Committee.

Michelle Hill: I second that Amani, and I think we've had a very active group. I'm really glad that we were all able to treat this as a consensus forming process throughout and I found that we all dealt with each other with great respect, even though there might have been disagreement over content, so it has been my pleasure as well and I loved being your Co chair Amani. I really have enjoyed my time with you.

Babekir, Amani: Thank you, me too.

Babekir, Amani: Thank you. And I hope to see you at the Conference of Food Protection next year.

Michelle Hill: Yeah, that'd be nice, everybody. Alright.

Babekir, Amani: Thank you everyone.

Meeting Number 25	Meeting Date **12/05/2022**		Meeting Time 2:00 pm EST
Co-Chair; Meeting Chair Amani Babekir	Co-Chair Michelle Hill	Meeting Scribe Michelle Hill via Teams Transcript	Council II Chairs Wendy Bell/Courtney Halbrook
Advisory - FDA Greg Abel Advisory - CDC Erin Moritz Advisory - USDA Jennifer Green	Advisory – FDA Devin Dutilly Advisory – CDC Jenna Seymour		Advisory - FDA Mary Cartagena

AGENDA

i.	Meeting Call to Order	Amani Babekir
ii.	Roll Call	Michelle Hill
iii.	Scribe	Michelle Hill
iv.	CFP Antitrust Statement	Amani Babekir
v.	Issues points	Amani Babekir
vi.	Framework Points	Amani Babekir
vii.	Adjournment	Amani Babekir

MEETING MINUTES

Amani Babekir This meeting is called to order. We have asked you to meet with us today to finalize the four Issues we will be submitting to the CFP for consideration. Michelle could you please display the Issues for consideration?

Michelle Hill Yes, my pleasure.

Eisner, Crystal Is this the way it was brought it to us when we first got the charges?

Michelle Hill It may have been. It's been through a couple different rounds already with Courtney and Wendy, so I can't guarantee that this is the same language. We ended up re-working the Issues. It was three and then we were told to split Issue 01 into two separate Issues.

Babekir, Amani But the main language is the same to what we discussed in our meeting and we approved so you don't see very major changes here. The one that cross contact is being recommended by Devin Dutilly, I know he was not able to join us, but if you think there is more clarification we could add from your prospective.

Abel, Greg A When did Devin make that recommendation? Long time ago?

Babekir, Amani Yes - for this one, while we were working on our subgroups.

Abel, Greg A A long time ago. OK.

Babekir, Amani Uh, yeah. A long time ago. He suggested to have this charge for the future committee in order to address cross contact, so I guess we're trying to understand what do you think are the main concerns when it comes to cross contact from the FDAs perspective.

Abel, Greg A Well, probably more or less just advice on how to manage food allergens. And, I think to identify the non major food allergens and to be aware of cross contact scenarios, as there's so many of them.

Babekir, Amani So we include examples of ...

Abel, Greg A Uh, depending on, I mean could be shared equipment, shared oils, shared surfaces. It’s more … I don't know what Devin had in mind about controlling cross-contact.

Babekir, Amani Thank you. Yeah, it was actually.

Abel, Greg A But what do we have in our … what’s some of the … isn't some of that advice already in what the Committee has prepared?

Babekir, Amani So we have, yes that’s what we had - there's like one extra or something.

Michelle Hill Yes. However, this is kind of two requests in a way because it's asking it to identify the non-major food allergens and how to control for those, in addition to expanding that to be included in the framework.

Abel, Greg A What would that be? To me it'd be like, OK, so here are the major food allergens, the 9 coming up in 2023. And if you get a request by consumer that something else might be a food allergen to them, that chef for those food service workers could use some of the same knowledge for that particular allergen.

Babekir, Amani This correct, yeah. Crystal, I think I saw your hand up. I mean Christine.

Christine Sylvis Hi, this is Christine Sylvis. I had it up and I took it down. I was just confirming that A, B, and C relate only to non-major food allergens.

Babekir, Amani Yes … the thing is … this came up while we were working on our actual major food allergens which includes, you know, the nine major.

Babekir, Amani But things, yeah, but since in number one, we are talking here about non-major food allergy, and probably that includes expanding cross contact to include the non-major food allergens. We did touch on cross contact in our framework, but I guess we need extra more detailed information about it … it seems especially for receiving and storage, and preparation.

Michelle Hill Also, I'd like to point out that this is actually a huge ask. If you read #1 "using existing research and resource to identify the non-major food allergens and how to control for them", that's telling our next committee that they need to identify what the non-major food allergens are. Am I wrong in reading that?

Christine Sylvis That's definitely how it reads. So there are, of course, other countries that have additional allergens then eight or nine, but people can have allergens to all different types of food, so I'm just not really understanding what food establishments would be expected to do … control cross-contact just for the identified non-major food allergens or for any allergen that somebody might have. You would think that the process would be about the same as what they would do for the identified allergens.

Michelle Hill Except that they take big steps to control for the big nine and if they're not aware of an allergen present, it will cross-contact throughout the flow. You can't like, let's say, if somebody says I can't have.

Michelle Hill I don't know. I can't even fill the blank. I'm sorry.

Abel, Greg A Broccoli.

Michelle Hill Umm, thank you. Broccoli. Yeah and.

Michelle Hill So I think that's what drove this bus was, how do we control for the stuff that people tell to us after the fact? It's as simple as. "you can't eat that."

Abel, Greg A But I think it's just a matter, I think when I'm trying to go back to those comments back in June when this type of stuff came up. The framework worked on the 9 major food allergens, but making sure that people know that there are several other food allergens out there, like Christine mentioned, there's 163 plus possible foods that some people has been allergic to at one time or another. Maybe just raising awareness that there may be a request or a concern from a patron that they might be allergic to something else, that is not a major food allergen and the controls would be the same. And if there's no controls in place for them already, well, like Michelle said, "you best not eat that food."

Maybe it's a simple answer that "hey, these are the major food allergens defined by FALCPA, and these are non-major foods, but they still can be a problem for certain people.

Michelle Hill Yes.

Abel, Greg A Just to be aware.

Seymour, Jennifer So it does seem like they're probably like assuming the 163. We're not just going to list all of those various foods - I doubt that that would be helpful. It seems to me, from having experiences with people who have these problems with non-major allergens, that what they really need is staff and restaurants to really understand what is in their food, understand the names, the ingredients to be able … there's so many restaurants you walk in and they have such lacking information about allergens. I've a friend who has a severe dairy allergy and you go in and people say, oh, "well, you can't eat that cause eggs in it." They just don't understand food in some fundamental ways. And maybe it's more about that dealing with the other … those outside of these really controlled strictures is about just being able to have some basic understanding of what various foods are. Having some way for someone to look that up to be able to know what is in every food that they have if they need to. I mean that's becoming fairly common in chain restaurants where you walk in, you say something strange and they pull out a book and you know, have pages and pages of notes about what is in every food. I see that more and more often.

Babekir, Amani That is what I'm talking about …

Michelle Hill Me too. And I think that you've hit upon a very important part of this, as far as just everybody being better educated about derivation of ingredients and how they can be depicted on a label or, having good working knowledge of what's in the food that people are serving. Transparency.

Michelle Hill Maybe that's maybe when you just say …

Babekir, Amani What would you do?

Michelle Hill Something different than what we've said.

Babekir, Amani And then have that sort of be like just this …

Abel, Greg A But wouldn't it be? I think in the future, wouldn't it be nice to have a requirement that places keep a list of ingredients in a book right in a binder, so everything they have in stock would be a resource that you could look up the ingredients. This is the product ... this is what's in it, right?

Babekir, Amani Right.

Michelle Hill So an allergen matrix for all product on hand?

Abel, Greg A Yeah, I think in Minnesota there is one Deli chain where they do keep that matrix. A folder of "OK, they're getting this deli salad, but they have a garlic allergy, so let's look in this 3-ring binder of everything that goes into each salad.

Babekir, Amani So for the points A, B, and C, to make logic out of it is to make it related to the non-major food allergens. The points A, B, C, that are addressing the non-major food allergens, in which we said it is a limitation when it comes to our framework. We did not address the non-major food allergy. Do we agree with that … that A, B and C, are asking them to focus on the named major food allergen and address A, B, and C, and then we could add the recommendations which you just discussed, to add more clarification.

Michelle Hill So do we need to rephrase this or is it clear enough that we're speaking directly about this being our big goal? Maybe what we do is we say existing research and resources to identify non-major food allergens and how to control for them, period. And then a second part of the charge would be to include the request to update the framework. Maybe that makes it easier.

Babekir, Amani Yes.

Amber Thompson You could even just leave it like that and then put D as that. Is that what you meant? OK, sorry. Yeah.

Michelle Hill No, no, you got it. No, that was good ... I did not know where it was going so …. it's awesome. Thank you.

Babekir, Amani So do you want to add the extra points? That's Michelle and Jennifer, I think. Yes, Greg and Jennifer, they said about the awareness and all of these points under "A".

Michelle Hill I feel like by striking the word "the" from this main sentence, now we don't give a quantity to it, it's just to identify non-major food allergens versus all allergens. To me, "the" means "this is a definitive list."

Amber Thompson Yes, that's better.

Seymour, Jennifer Just one point that has come up … a weird allergen of someone that I know. You know right there preparation comes into it, but it looks like that word preparation is just In terms of cross-contact, but I think there also are some issues with preparation that might not go into ingredient lists. And what I mean by that is I know someone who can't eat vinegar, and vinegar is put in water sometimes to cook things. So it's this idea of even understanding preparation methods. I could easily see that not being on an ingredient list. Another one that has come up because of this allergen is that most chicken is brined in pickle juice, and people don't think about that and don't know that. And it doesn't seem again to be on the ingredient list or it's on the ingredient list as only "brine". People don't think of that as being vinegar, so I've encountered a lot of these weird things. It's about the way people do things to make cooking work better, but it doesn't really get considered as an ingredient to a lot of people.

Abel, Greg A Well, that would be education, right? Because it has to be excluded, right? If it's going to be packaged. Then, though, if it's a major food allergen, it has to be included on the label.

Seymour, Jennifer Right, right. It's just this is an example of one that isn't a major food allergen.

Abel, Greg A Right.

Seymour, Jennifer And I would be surprised if it's even listed in the 163 ... never encountered another person with that problem.

Abel, Greg A Don't hold the 163 as the magic number ... I just threw that out. I don't know if that's the actual ...

Michelle Hill No, it's in excess of 170.

Seymour, Jennifer Yes.

Abel, Greg A OK, I remember hearing 163 maybe 15 years ago, so ...

Michelle Hill Yeah, FAARP is a really good place to get that number.

Michelle Hill How about if we drop in here preparation, including knowledge of preparation methods? I don't know if that helps alleviate that issue.

Babekir, Amani So it should be a big issue. And when it comes to receiving, I think, Greg, you said something about the matrix or something, I can't recall it ...

Michelle Hill An allergen matrix?

Babekir, Amani Mm-hmm.

Michelle Hill When you are in the act of receiving large bulk food, sometimes you stack it wrong or you put it in the fridge and it spills or drips causing cross-contact.

Abel, Greg A During receiving, OK.

Michelle Hill Umm. Yes.

Michelle Hill "How to prepare" no, how about including using an allergen matrix or is that too prescriptive?

Abel, Greg A I think that's too prescriptive. We'd have to define what we mean by a matrix. I mean, a matrix could be a suggestion as a helpful hint, "right now, here's a way to manage … "

Michelle Hill How about including "during receiving"? Maybe that helps too … that's what we mean during the act of receiving.

Abel, Greg A Right - because once you receive it, now it becomes the storage.

Michelle Hill Yes. OK.

Babekir, Amani What about the storage? Do you need to define "Dry" and "Cold" storage or as you said …

Michelle Hill When I teach about storing, it implies any type of storage, whether it's hot or cold. But that's from my perspective as somebody teaching CFPMs … that's our audience.

Abel, Greg A Storage to me means anything regardless of temperature, right?

Michelle Hill Being held properly, is all we worry about, right?

Babekir, Amani I remember we wanted to add more clarification to them to make it very obvious.

Michelle Hill Yes.

Amber Thompson Receiving, storage, holding. We call it holding. Like you know, especially if it's like a salad bar. You don't want to drop peanuts in the, you know, cheese or whatever it is …

Michelle Hill Excellent.

Michelle Hill And that's a great example. When we set up a salad bar, it's always the allergen is in front so you don't drip, drip, drip from the back. This only helps if you know what the allergen is, so …

Babekir, Amani If we are good with this one, we could go to the next one.

Michelle Hill This is a huge ask … this is a very big ask.

Eisner, Crystal For #1, because anyone can be allergic to anything.

Babekir, Amani It's more. It's more for style, so we probably need to define what is the objective of this allergen control toolkit. So they will have a clear idea what is the purpose behind it.

Michelle Hill Yeah, maybe we should say the allergen control toolkit would include information or methods of food preparation ...

Amber Thompson More specific even, cover the major food allergens.

Michelle Hill Well, I think it would include both major and non-major allergens.

Babekir, Amani We might need to give an example of what is the toolkit we are talking about. Is it just a document? Is it checklist?

Amber Thompson Yeah, it could be …

Eisner, Crystal … Infograms …

Amber Thompson Yes, that's what I was thinking.

Michelle Hill And an allergen matrix …

Amber Thompson Yes … you could say, "For the purpose of ..." That way we know what for the purpose of.

I don't know how you would say this, but basically, that the food workers can easily identify … not identify, but easily ...

Amber Thompson

Michelle Hill … support which could …

Amber Thompson Digest this information or something like that.

Eisner, Crystal Identify, no.

Amber Thompson For ease of use for food service workers, or for ease of implementation, or something like that. Better understanding of controlling allergens.

Michelle Hill OK. Yeah, that's awesome. Makes me feel a lot better. What do you all think?

Amber Thompson Well, have an idea, but this will kind of change the format, but it may be more helpful overall … if we said ... "use the existing research and resources to expand upon the major food allergen framework, and is guidance on how to control non-major food allergen cross-contact. That way this allergen control toolkit is for both major and non-major food allergens.

Michelle Hill Yes.

Amber Thompson Because we really like that idea of a toolkit, but we just don't have time to put something like that together.

Michelle Hill Right. OK. Did I get this first part right … "to expand upon the major food allergen framework to include cross-contact"?

Amber Thompson Yes, to include A, B, C, then we don't need D. You could say "guidance on how to control non major food allergens."

Michelle Hill OK, run that by me again. I missed what you said.

Amber Thompson Yeah, "guidance on how to control non-major food allergen cross contact"

Michelle Hill Awesome.

Amber Thompson Would you consider Celiac part of the non-major food allergens?

Michelle Hill Umm, I would.

Amber Thompson How to control non-major food allergen and … ?

Abel, Greg A You think in the, you know, we kind of made a point to keep the guidance to just "allergens".

Amber Thompson OK.

Michelle Hill Because dealing with Celiac didn't change behavior was our rationale for that, right?

Amber Thompson Right, right. OK.

Babekir, Amani Along with you. OK, good.

Michelle Hill Just want to make sure we have the right reason for not expanding.

Abel, Greg A I think a lot of lot of celiac people just say "I have a wheat allergy". It's too hard to explain.

Babekir, Amani Yes, that's the case. And it seems we are almost out of our time. We can extend the meeting extra half an hour. So, if you are free please stay on the line, OK.

Babekir, Amani Thank you. So we could proceed.

Michelle Hill Are we all good with this revised number one statement?

Babekir, Amani Looks good to me.

Amber Thompson I don't need a comma there … Use existing research and resources to expand upon the major food allergen.

Michelle Hill Thank you.

Amber Thompson Framework to include.

Michelle Hill Awesome.

Amber Thompson Service, identify. Gather at some research.

Amber Thompson Yeah, I like the way … I like this.

Babekir, Amani Are we asking them to update the "major food allergen framework" document?

Michelle Hill I think we say that the first part, don't we here, "using existing research resources to expand upon" … you know, you're right, we don't talk about it actually improving the document.

Babekir, Amani We just ask them to update the document to make it ... part of our toolkit.

Amber Thompson Umm, no, I feel like the toolkit is for the food workers to understand allergen control.

Michelle Hill OK.

Amber Thompson Umm, not necessarily about notifying customers.

Michelle Hill Good point.

Amber Thompson I'm curious about compliance when notifying a consumer. Compliance implies that there's ordinance in place, so I don't know if there's codified language in the food code about notifying consumers. I know there's for labeling. But I don't know if that's expanded to restaurants.

Abel, Greg A There's nothing to notify consumers in the food code.

Amber Thompson OK, maybe we can change that word "compliance" to … Umm … "established tools to ensure …"

"Abel, Greg A How would you want to notify them? And if that's the case, what's the danger when you miss something? So I look at it from another point. As a note, I think it's great for large franchises that have controls in place that can list all the ingredients. But what if you have an independent? I mean, look how much trouble our …

Amber Thompson Umm.

Abel, Greg A As it is now, and if it's required to inform the consumer, they're going to say, "oh, no, this has nothing in it", but someone's going to forget something and then that person's going to have to suffer a reaction.

Amber Thompson Right, right.

Abel, Greg A You see the danger? I think that's dangerous. I would never trust it. Except for maybe a large chain that has the resources to actually have a standardized menu.

Amber Thompson Umm.

Abel, Greg A And look at all the times I messed up, with my even my home cooking, you know?

Amber Thompson Right.

Abel, Greg A So compliance we're "notifying the consumer about ..." but a compliance can indicate there is a regulation.

Amber Thompson Right.

Michelle Hill Yes … as well as a way to assess their ability to comply.

Abel, Greg A Yes.

Amber Thompson The allergen framework has a section about notifying consumers, right?

Michelle Hill It does, yes.

Abel, Greg A And how does it? Is it suggestion or how does? How is it suggested that they be notified?

Michelle Hill It's a whole section. Hang on I can bring that up.

Babekir, Amani And I think this one came up when we were working on the notification section.

Is to have those. tools, I think. And we said, B is a charge for the next committee.

Amber Thompson OK.

Michelle Hill So here's the framework on tools to notify. Here's menu item self-service. Here is the Allergen Matrix, menus, and signage …

Abel, Greg A OK, so in this situation we're just providing a toolkit if someone chooses to notify. These are some examples and how it can be done, right?

Michelle Hill Right.

Abel, Greg A Versus making it a requirement so.

Michelle Hill Correct.

Abel, Greg A You know, I think that's fine because it's the suggest it's toolkit. Hey, if you want to take the extra level, here's how you can notify your consumers.

Amber Thompson We could maybe say was meant for non-major food allergens. Maybe that's what this meant.

Babekir, Amani Yes.

Amber Thompson When notifying consumers about non-major food allergens.

Babekir, Amani Yes, as I recall, this came up when we were discussing, the notification section, so it wasn't part of the non-major food allergy.

Amber Thompson OK. I just don't like the word compliance. I think maybe if we can find a different word that would be fine.

Michelle Hill How about support? "Support tools to identify," "tools to support food workers when notifying customers about food allergens …"

Babekir, Amani To notify a consumer on how to ensure … that's compliance with this is standard operating procedure ….

Michelle Hill I see.

Babekir, Amani Maybe here, next to the tools, we say, "This includes standard operating procedures."

Michelle Hill Yep.

Amber Thompson Yeah, standardized menus or something like this. Full ingredient lists.

Babekir, Amani But I think also here on this one we want to have the restaurant make sure that their workers comply with whatever standard they have there to notify the customer.

Amber Thompson Right. They support and educate. Yeah, that's a hard one because it's really the restaurants, and that may be included in the framework under "training".

It's actually codified language that says, in the food code, that the person in charge is to ensure that food employees know about the major food allergens as it relates to their duties or something like that.

Michelle Hill Right.

Abel, Greg A Yeah, but that's not, I think, how that was written. It wasn't intended to make an allergen free entree safely.

Amber Thompson Right, right, right.

Abel, Greg A Yeah.

Babekir, Amani And I think to that piece, I remember when I walked into a restaurant and I ordered pizza, which is, you know, the gluten free one. And then they brought me the dish. I ate it and it wasn't the gluten free one.

Michelle Hill Oh my God.

Babekir, Amani So yeah, there is a missing piece here … how do you track ...

Amber Thompson Yeah, you. Yeah, right.

Abel, Greg A I think there's when you're working with humans, there's missing pieces everywhere. I remember Buffalo Wild Wings having a gluten free menu item on the menu and my son would order certain wing coating. Then the person at the different store said “well, you can't have this because it's has gluten in it” and my son says “well, it's advertised gluten free and we eat it up in the north location.” She said, “Yeah, it says that on the menu but our chef does it different, so there's gluten in it.”

Amber Thompson Yeah. Well, that's liability right there.

Babekir, Amani Yes!

Abel, Greg A Isn't that crazy? Even they're not conforming to their own standardized recipes?

Babekir, Amani Umm. Yeah. And maybe we need to help them establish some kind of standard to make sure if they have a gluten free thing on the menu it is actually gluten free.

Abel, Greg A Well, that's just that person not caring or understanding … just adapting the menu, the recipe to their own liking.

Michelle Hill And it even happens with school lunch. A lot actually. They want to add cheese to everything, so it is no longer dairy free … You need standardized recipes. You have to follow the recipe.

Amber Thompson Yeah, I'm curious if Buffalo Wild Wings corporate knew about that chef because that would be a fired chef, if that was my chef.

Abel, Greg A Yeah, exactly right.

Michelle Hill Me too. Me too. Yeah.

Amber Thompson That's ridiculous beyond all.

Abel, Greg A Mm-hmm.

Amber Thompson You can't choose what you how you want to prepare something. Open your own restaurant. The frustrates me.

Michelle Hill Especially when it's off menu like that. Yeah, that's not OK.

Amber Thompson That's a lack of education.

Babekir, Amani And maybe we need some kind of like a controlled checklist to ensure before you serve the dish, it is really gluten free, or whatever, as it's announced on the menu.

Abel, Greg A I think I think Scott came up with some language on one of the subcommittees about that exact thing, right?

Babekir, Amani Yes.

Abel, Greg A I thought we worked on something that I forget what Amber was at on the committee we were on. I forget all the committees and all their little pieces to the puzzle, but one of them was kind of having an assurance that the food that the food going out, there's a checks and balance and the food goes, goes out, that it is truly.

Amber Thompson Umm. Like a QA, right?

Abel, Greg A Yes.

Michelle Hill Like a final allergen plate check or something.

Amber Thompson Right.

Abel, Greg A We worked on that concept, yeah.

Michelle Hill I don't know if that's new concept and people are going to be like, what are you talking about. But I did drop that in.

Babekir, Amani Hmm.

Amber Thompson You could just put quality, QA person, or quality assurance person, then?

Michelle Hill Oh, there you go. Quality assurance.

Abel, Greg A But isn't what, but this is this A, B, C ,D and all relates to non-major food allergens not defined right?

Michelle Hill No, we define that. So now up here we start our charge with, we're going to “expand upon” and then we dropped in “non-major food allergen” under “Control for”. So all the rest of B, C and D - all apply too. Including major food. Am I wrong about that? You guys OK? Good. OK.

Amber Thompson Right, right, including the non.

Abel, Greg A But wasn't some of that stuff already developed this year? But we've talked about some of the stuff. So you're saying just review it and expand on it?

Michelle Hill Mm-hmm.

Abel, Greg A Just continue the work is what you're saying.

Babekir, Amani And I think to your point, some of these ideas have been touched on in the "Preparation" section, I think, but it's not too much, so it was probably one or two points about that.

Abel, Greg A Hey, did you guys know when FALCPA got passed in 2004, got implemented 2006? There was a charge in there, a part of the law, that FDA was supposed to work with the Conference for of Food Protection, to produce a food allergen control manual.

Amber Thompson Umm.

Abel, Greg A I worked on that from 2007, for couple several years. And it just never got past. We were going to submit it, but it never got past our executive leadership of FDA.

Michelle Hill Boy, that would be a valuable tool because that's something you could share with people.

Abel, Greg A Right? It was so disheartening not to have it be put out there. But no I can't share it. I don't even have it.

Michelle Hill OK.

Abel, Greg A I mean, it wasn't even passed, so it's not even a final document. But and I forget the reasons why it never … because what if FDA authored it … would someone take it as a standard of, you know, a certain level when it's was meant to be guidance not …

Michelle Hill Not the law.

Abel, Greg A Not the law, right. You know, it's like, "well, FDA says so" - it could have been some of that. There were seven of us that were working together. We talked everything - about these concepts here. Now, what, 10-1/2 years later, we're doing it again, but in a different format. I just think how far we could have been ahead in this country if we would have had that 10 years ago, 15 years ago.

Michelle Hill Well, Greg, you, and I both know that we've been spinning the same wheel, and that's why I write my food blogs too. I write "9allergens.com" where you can print out all the derivations for all nine major allergens as ingredients and how they might appear on a label because there's no other place to find that. I think that's something FDA should house, too. Tear sheets of their allergy section could be better, like "this is how it can appear on a label …" and list every instance.

Michelle Hill Like whoever thought sesame would be lurking in tomato products. But it is.

Abel, Greg A Oh my gosh, I never thought that really.

Michelle Hill It's in the base product. They add sesame in, as part of tomato paste, and it's not on the label as such, it is listed as "extracts, spices" because it is an antioxidant and it doesn't impart serious flavor. It happens when they cook tomatoes during the first cook, so it gets distributed to other purveyors with it as part of it the tomato product and it is not labeled for sesame. I wonder … I'd love to know somebody in the tomato world because I know people in the bun world and it split that world in half, you know, sesame, no sesame seed bun ...

Amber Thompson Ohh wow.

Michelle Hill Yeah.

Amber Thompson There's gonna be a lot of non-sesame buns soon.

Amber Thompson We're not wanting to support the Food service worker, we're wanting to support the person in charge who's in control of the food service workers job, of notifying the consumer, which is a very long sentence …

Amber Thompson Person in charge. When training, yeah, there we go. Training, I would say employees.

Michelle Hill Ohh OK well, if I say food workers that include people that don't get paid … like volunteers at food shelf?

Amber Thompson Oh, that's a good point.

Michelle Hill I had to go through and standardize the whole document, so it's in my head.

Abel, Greg A But we I guess in the food code, we call the "food employees."

Michelle Hill Oh, you do? OK.

Abel, Greg A Yeah.

Michelle Hill Even if they're not being paid.

Abel, Greg A Umm, Yeah.

Babekir, Amani So I have to jump to another meeting at 3 … so if we could finalize this and then just jump to the other to the other issue.

Michelle Hill OK , Let's go to Issue 3. This deals with how to amend the food code.

Amber Thompson OK.

Michelle Hill Umm, we have to pick a spot – as we offer three options listed and there can only be one.

Babekir, Amani Yeah. We suggested the three options, so have to pick one and then also and then give FDA the flexibility to pick wherever they want.

Michelle Hill And all of the discussions we had around this and this is just me talking. I love #1A.

Abel, Greg A Can you blow that up?

Michelle Hill Umm yeah.

Amber Thompson Letter “A.”

Michelle Hill Yes

Abel, Greg A Yes.

Amber Thompson Yes, I like this one too. Make it its own #5 dedicated section to everything we want to add, including all the future work. Sure.

Michelle Hill Yep. And then letters “B” and “C” are listed within Annex 2, just not is such a prominent spot.

Amber Thompson Yeah, yeah. I'm. I'm. I'm down with a there or 1A. Yeah.

Babekir, Amani Yep.

Michelle Hill How about everybody else? Anybody objecting to that? All right.

Babekir, Amani Yeah, I'm with you on that one.

Michelle Hill Good, that's done. And I won't even say “A”, I'll just say ...

Amber Thompson There we go.

Michelle Hill Yes. And I must cite this right, I'll make sure it's cited. There’s a big document on how to make things look right issued by CFP that I will check. OK, so that is done.

Babekir, Amani Remember to add “or a location where deemed appropriate by FDA.”

Michelle Hill Yeah, I have Courtney's e-mail saved in another file so … Amani, I'll make … I'll fly speck this ... I'll send it to you and then forward on ... OK, awesome.

Babekir, Amani Umm. Yes. And do we feel good about the one which we were working on?

Michelle Hill Should I bring it back up?

Abel, Greg A As far as food employee as defined in the food code, it means “an individual working with unpackaged food, equipment and utensils are food contact surfaces,” so the food code defines it as a “food employee.”

Michelle Hill OK. Thank you.

Michelle Hill Are we OK with this letter C?

Amber Thompson Training. Workers are notifying consumers about food allergens.

Amber Thompson I like it the way it's re-worded with training because we're supporting the training.

Michelle Hill Yes. OK. I don't want us to feel super rushed. I know its due today …

Amber Thompson No pressure.

Michelle Hill Uh-huh.

Babekir, Amani Good, good. That's great.

Michelle Hill We did it.

Amber Thompson Yes, looks good.

Babekir, Amani Thank you for joining and thank you for your input - it's really valuable.

Michelle Hill We could not have done it without you. Really appreciate everything.

Babekir, Amani This meeting is asjourned.

CFP - Council II - Allergen Committee **Meeting Attendance** **2022 Biennium**

Position	First	Last	1 11/12/21	2 11/23/21	3 12/09/21	4 01/06/22	5 01/20/22	6 02/03/22	7 02/17/22	8 03/03/22	9 03/17/22	10 03/31/22	11 04/14/22	12 04/28/22
C II Co-Chair	Joetta	DeFrancesco		1	1		1	1		1		1		
C II Co-Chair	Wendy	Bell												
C II Co-Chair	Courtney	Halbrook	1									1		
Co-Chair	Amani	Babekir	1	1	1	1	1	1	1	1	1	1	1	1
Co-Chair	Michelle	Hill	1	1	1	1	1	1	1			1	1	1
Voting	James	Baldwin	1	1	1	1	1	1		1				1
Voting	Anne	Dolhanyk	1	1	1	1			1	1				
Voting	Crystal	Eisner	1	1	1	1	1	1	1			1	1	1
Voting	Amanda	Garvin	1		1	1	1		1	1	1	1		
Voting	Vy	Goddard / Truong	1	1	1	1	1	1	1	1	1		1	
Voting	Darby	Greco	1	1	1				1					1
Voting	DeBrena	Hilton		1	1									
Voting	Cassandra	Mitchell	1	1	1	1	1	1	1		1	1	1	
Voting	James	Oneal	1	1	1	1	1	1	1	1	1	1	1	1
Voting	Amber	Potts - Thompson		1	1	1	1	1		1	1	1		
Voting	David	Read	1	1	1	1	1	1	1	1	1	1	1	1
Voting	Libby	Thoma	1	1	1	1	1	1	1	1	1	1	1	
Voting	Scott	Vinson	1	1	1	1	1	1		1		1	1	
Voting	Steven	von Bodungen	1		1	1	1	1	1	1	1			
Voting	Ben	Wagner	1	1	1	1		1	1		1		1	1
		Invited Total Voting:	17	17	17	17	17	17	17	17	17	17	17	17
			15	15	17	15	13	13	13	11	10	10	10	8
		Required for Quorum:	10	10	10	10	10	10	10	10	10	10	10	10
Advisor	Greg	Abel		1	1	1		1		1	1	1		
Advisor	Mary	Cartagena	1	1	1		1	1						
Advisor	Devin	Dutilly								1	1	1	1	1
Advisor	*Jennifer*	*Green*		*1*		*1*		*1*		*1*			*1*	*1*
Advisor	Erin	Moritz	1	1	1		1	1		1	1	1		1
Advisor	Beth	Wittry	1											
Advisor	Jenna	Seymour			1	1	1	1		1	1	1	1	1
At Large	Susan	Algeo	1	1	1	1					1			
At Large	Janice	Brady		1										
At Large	Nicole	Lapore	1		1	1	1	1		1	1			1
At Large	Tom	Larsen*												
At Large	Susan	Leaverton	1											
At Large	Christina	Meinhardt	1	1		1		1		1				1
At Large	Aubrey	Noller	1	1	1	1		1		1	1	1	1	
At Large	Christine	Sylvis	1	1	1	1	1	1		1		1		1
		Invited Total:	14	14	14	14	14	14	14	14	14	14	14	14
			9	9	8	8	5	9	0	9	7	6	4	7

CFP - Council II - Allergen Committee **Meeting Attendance** **2022 Biennium**

Position	First	Last	13 05/12/22	14 06/09/22	15 06/23/22	16 07/07/22	17 08/04/22	18 08/18/22	19 09/01/22	20 09/29/22	21 10/27/22	22 11/10/22	23 12/05/22
C II Co-Chair	Joetta	DeFrancesco									0		0
C II Co-Chair	Wendy	Bell	1			1		1		1			0
C II Co-Chair	Courtney	Halbrook		1								1	0
Co-Chair	Amani	Babekir	1	1	1	1	1	1	1	1	1	1	1
Co-Chair	Michelle	Hill	1	1		1	1	1	1	1	1	1	1
Voting	James	Baldwin		1	1						0	0	
Voting	Anne	Dolhanyk									0	0	
Voting	Crystal	Eisner			1	1	1	1	1		1	0	1
Voting	Amanda	Garvin	1		1	1				1	0	0	
Voting	Vy	Goddard / Truong	1		1						0	0	
Voting	Darby	Greco									0	0	
Voting	DeBrena	Hilton									0	0	
Voting	Cassandra	Mitchell									0	0	
Voting	James	Oneal	1	1	1	1	1	1	1	1	1	1	
Voting	Amber	Potts - Thompson	1	1	1	1	1	1	1	1	1	0	1
Voting	David	Read	1	1	1	1	1	1	1	1	1	1	
Voting	Libby	Thoma		1		1	1		1		0	1	
Voting	Scott	Vinson		1	1	1	1	1	1	1	0	1	1
Voting	Steven	von Bodungen									0	0	
Voting	Ben	Wagner	1	1	1	1				1	1	1	
		Invited Total Voting:	17	17	17	17	17	17	17	17	17	17	
			8	9	10	10	8	7	8	8	7	7	
		Required for Quorum:	10	10	10	10	10	10	10	10	10	10	
Advisor	Greg	Abel		1	1	1	1		1				1
Advisor	Mary	Cartagena											
Advisor	Devin	Dutilly	1		1	1	1	1	1				
Advisor	*Jennifer*	*Green*	*1*	*1*	*1*	*1*	*1*		*1*				*1*
Advisor	Erin	Moritz		1		1	1	1	1		1		
Advisor	Beth	Wittry											
Advisor	Jenna	Seymour	1			1	1	1	1		1		1
At Large	Susan	Algeo	1	1	1	1	1		1				
At Large	Janice	Brady			1								
At Large	Nicole	Lapore		1	1	1							
At Large	Tom	Larsen*											
At Large	Susan	Leaverton											
At Large	Christina	Meinhardt						1			1		
At Large	Aubrey	Noller	1	1									
At Large	Christine	Sylvis					1	1	1			1	1
		Invited Total:	14	14	14	14	14	14	14	14	14	14	
			5	6	6	7	7	5	7	0	3	1	

Major Food Allergen Framework

Conference for Food Protection
2023 Biennium
Council II: Allergen Committee
Publication Date: _____

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Contents

Introduction

PURPOSE This document is to serve as a voluntary operational framework for FOOD ALLERGY[1] prevention and control of the MAJOR FOOD ALLERGENS[2] (as defined below) using existing research and other evidence-based materials for FOOD ESTABLISHMENTS[3] and OTHER COMMUNITY FOOD SOURCES[4]. Readers should be aware, however, that people may have other allergies beyond the major food allergens, and food establishments may employ the same practices outlined in this document to assist CONSUMERS[5] with allergies, FOOD INTOLERANCE/SENSITIVITY[6] beyond those listed herein.

Readers should be aware that consumers may have other food allergies, intolerances, or sensitivities (such as celiac disease, Crohn's disease, IBS/IBD, and others) which, although not technically allergies, are triggered by ingestion of particular foods.

SCOPE This document covers food allergy training of FOOD HANDLERS[7]; food handling policies and practices; consumer notification tools for food allergens; a food allergy reaction and emergency response guide; and equal consideration for other community food sources.

BACKGROUND A food allergy happens when a person's immune system overreacts to a food protein. Approximately thirty million people in the U.S. have food allergies, leading to 200,000 emergency department visits per year. FOOD ALLERGIC REACTIONS[8] vary in severity, from mildly itchy skin and lip swelling to severe, life-threatening symptoms (ANAPHYLAXIS[9]) and death. In the United States, 51% of adults and 42% of children with food allergies have experienced a severe reaction.

1 "Food allergy" means the reaction of the body's immune system to certain proteins in food. Reactions can vary in severity from mild symptoms involving hives and lip swelling to severe, life-threatening symptoms, called anaphylaxis, which may involve shock and fatal respiratory problems.

2 "Major Food Allergen" mean the allergens in foods that cause over 90% of allergic reactions: milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.

3 "Food establishment" means an operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

4 "Other community food sources" means food sources that are made available to the public on a need basis, e.g., food bank, food shelf, food pantry.

5 "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale

6 An adverse reaction to a substance in food that does not involve the immune system, e.g., the inability to process or breakdown a certain food such as the milk sugar lactose which can lead to discomfort or have ill effects.

7 "Food handler" means a person who handles food utensils or who prepares, processes, or serves food or beverages for people other than members of their immediate household.

8 "Food allergic reaction" means an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. The immune response can be severe and life-threatening.

9 "Anaphylaxis" means a life-threatening allergic reaction due to over-release of certain chemicals in the body resulting in shock when a person with an allergy is exposed to an allergen. Allergies to food, insect stings, medications, and latex, are most frequently associated with this type of severe response, and may include skin symptoms or swollen lips, difficulty breathing, reduced blood pressure, and gastrointestinal symptoms.

The **Major Food Allergens** that cause over 90% of all allergic reactions in people are these types of food:

- Milk
- Eggs
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans
- Sesame[10]

This guide includes example procedures, considerations, and resources that a food establishment can use to respond when someone notifies the food establishment about a food allergy or reports an allergic reaction. It also provides a framework for providing consumers accurate information about food ingredients so they can make informed decisions when ordering.

Although comprehensive, this guide might not provide everything that needs to be considered for a food allergy reaction and emergency response plan. It might also contain materials that are not relevant to every food establishment, so please consider internal procedures or standard operating procedures when using this material.

10 Sesame has been added to the list of Major Food Allergens via the FASTER Act of 2021, effective January 1, 2023.

A. Training

PURPOSE This is a framework to educate food handlers about (1) the Major Food Allergens – milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame; and (2) other allergy and intolerance issues they may encounter.

Duties in food establishment (intensity of training increases with responsibility)

1. PIC - Person in Charge (PIC)[11]

Training should include

a) Definitions for food allergy, food intolerance/sensitivity, and CROSS-CONTACT[12].
b) List of the symptoms of a food allergic reaction, including anaphylaxis.
c) List of the Major Food Allergens in FDA's Food Code.
d) Dangers of food allergens and how to prevent cross-contact.
e) Using proper cleaning methods, such as wash, rinse, and sanitize, to prevent cross-contact.
f) How and when to communicate with consumers and staff about food allergens.
g) Special considerations related to food allergens for workstations and SELF-SERVICE[13] areas.
h) How to handle food allergy requests.
i) How to deal with food allergy emergencies.
j) Proper food preparation for guests with food allergies.
k) How to read a food LABEL[14] and understand the importance of food labels.
l) Personal hygiene practices to prevent cross-contact.
m) How to receive and store foods that contain Major Food Allergens to prevent cross-contact.

2. Front of house; wait staff, hostess/host, to-go personnel

Training should include

a) Definitions for food allergy, food intolerance/sensitivity, and cross-contact.
b) List of the symptoms of a food allergic reaction, including anaphylaxis.
c) List of the Major Food Allergens in FDA's Food Code.
d) How to handle food allergy requests.
e) How to deal with food allergy emergencies.

3. Back of house; Food handler *(as defined in FDA's Food Code)*

Training should include

a) List of the Major Food Allergens in FDA's Food Code.
b) Dangers of food allergens and how to prevent cross-contact.
c) Cleaning and personal hygiene practices to prevent cross-contact.
d) In-depth knowledge of MENU[15] items and preparation as it relates to assigned duties.
e) Proper food preparation for consumers with food allergies.
f) How to read a food label and understand the importance of food labels.

11 "Person in Charge (PIC)" means the person present at a food establishment who is responsible for the operation at the time of inspection.

12 "Cross-contact" means the unintentional transfer of an allergen from a food or food-contact surface containing an allergen to a food or food-contact surface that does not contain the allergen.

13 "Self-service" means areas where a food handler is not present to serve a consumer and the consumer is responsible for serving themselves. Examples: buffets, salad bars, sushi bars, or display cases.

14 "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and any word, statement, or other information that appears on the outside container or wrapper of the retail package.

15 "Menu" means all written and verbal lists of foods prepared and offered in a food establishment.

4. Understanding Labels

a) Manufacturers of PACKAGED FOOD[16] products that contain a Major Food Allergen are required by law to list that allergen on the product label – including if they are, or are a component of, a flavor, color, incidental additive, or spice (i.e., sesame paste).
b) There are several ways the allergen can be listed, so CONSUMERS[17] must read product labels carefully.
   i. The allergen may be listed in a 'Contains' statement.
   ii. If the product does not have a 'Contains' statement, consumers should review the entire ingredient list.
   iii. A 'may contain' or 'produced in a facility' marking is a voluntary, separate allergen advisory statement when there is a chance that a food allergen could be present. Anything labeled in this manner should be considered to have an allergen present.
c) Common allergens can have other names. For example, caseinates (in all forms), and whey (in all forms) are all milk proteins.
d) Although the same allergen can be present in multiple ingredients, its "food source name" (for example, milk), or common or usual name, must appear in the ingredient list just once to comply with LABELING[18] requirements.

SUPPLY CHAIN CONSIDERATIONS Manufacturers change their ingredients and production methods continually and without warning; it is especially important to read the ingredient label, and ingredient statement, for the presence of major food allergens with each shipment. Contact the manufacturer in advance if you have questions about food allergens that may be in a product.

e) Major food allergen labeling information can be found within:
   - FDA's "21 CFR 101", https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101
   - USDA's "Allergens – Voluntary Labeling Statements," https://www.fsis.usda.gov/guidelines/2013-0010
   - USDA's **"**FSIS Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling," https://www.fsis.usda.gov/sites/default/files/import/Allergens-Ingredients.pdf

16 "Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food handler, upon consumer request.

17 "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

18 "Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

B. Food-Handling Policies & Practices to Help Consumers with Food Allergies

PURPOSE Example policies and practices are provided here that will reduce the risk of a consumer being exposed to a food allergen.

With food allergens, it is **very important** to avoid having **even small amounts** of an ingredient to which a consumer is allergic come into contact with their food, utensils, tableware, and packaging. The unintentional transfer of an allergen from a food or food-contact surface containing an allergen to a food or food-contact surface that does not contain the allergen is called **cross-contact**. Sometimes it is obvious when an allergy-causing ingredient has gotten into a food through cross-contact because the ingredient can be easily seen, but other times it is not obvious, and great care should be taken to avoid these situations.

Following these guidelines, which apply to **all food handlers** who come into contact with food, beverages, and any food preparation surface, can help consumers with allergies avoid potentially life-threatening allergic reactions.

Train relevant staff in the following procedures

1. Food & Ingredient Storage

a) **Label** and segregate unpackaged foods containing one or more of the Major Food Allergens away from each other, and store separately from other foods and ingredients. *Make sure to read ingredient labels to check for the presence of allergens before labeling and segregating.
b) Spills of any of the Major Food Allergens should be cleaned up immediately, following the usual cleaning procedures used in the food establishment. If any Major Food Allergen accidentally comes into contact with other food ingredients that do not contain that allergen, these ingredients should be excluded from use.

2. Self-Service Items

a) For food items that were made on site, **label** the food items, or place **signs** next to the food items, that clearly identify the presence of one or more of the Major Food Allergens, or keep ingredient lists on site that identify the presence of one or more of the Major Food Allergens.
b) Labels and signage should be in both English and Spanish, and/or other languages appropriate to either the establishment, or the geographic area.

3. Taking a Food Order

a) When a consumer informs staff they have a food allergy, intolerance, or sensitivity, immediately **notify** the Person in Charge (PIC) or designated person (manager, chef, or key employees).
b) Help the consumer **identify** menu items that contain ingredients to which they are allergic and offer suggestions for alternative menu items.
c) If no alternative menu options are available, politely **inform** the consumer.
d) If it is possible to **modify** a menu item so that it does not include ingredients the consumer must avoid, inform the consumer, and ask if the modification would suit their needs.
e) **Verify** with the food handler that the proposed menu item modification is possible, feasible, and can be done safely for the consumer.
f) Make a **note** on the consumer's order that they have a food allergy/intolerance/sensitivity and which ingredients they must avoid so that other food handlers are aware.

4. Preparing a Food Order

a) Thoroughly clean all areas and equipment that will be used for preparing the allergic consumer's meal, even if those areas had already been cleaned for normal use.
b) Wash hands thoroughly before preparing the allergic consumer's meal. In some situations it may be necessary to change apron/chef coat, if previously soiled with potential allergens.
c) Use dedicated equipment or physically separate products to prevent cross-contact.

i. Use color-coded or specially marked supplies, uniforms, equipment, and utensils designated for preparing allergen-free meals.
ii. Avoid using the same cooking medium (e.g., oil or water) and surface (e.g., grill, prep table) when handling ingredients with and without allergens.

d) Use ingredients that do not contain the allergen(s) to which the consumer is allergic. Check ingredient labels for packaged foods.
e) Prepare food in a manner that eliminates cross-contact. All preparation, including garnishes, should be done by only one food handler who is dedicated to ensuring the meal is allergen-free, and who is not preparing other consumers' meals at the same time.

i. **If a mistake is made**, and an ingredient to which the consumer is allergic is accidentally included in the meal, it is **not sufficient** to simply remove the offending ingredient, because cross-contact will have occurred. In case this happens, **re-make** the consumer's meal.
ii. Wash your hands with soap and water before continuing preparation to avoid potential, or additional, cross-contact.

f) Cover the meal with a clean lid to prevent cross-contact and mark the meal as "allergy" so other staff are aware.
g) Notify the PIC, or designated food handler once the allergen-free meal is prepared and ready for service.
h) Wash, rinse, and store special equipment for allergen-free meals to be ready for next use.
i) Wash your hands with soap and water before touching anything else if you have handled a food allergen.

5. Delivering a Food Order

a) Verify with the food handler who prepared the meal that it does not contain the allergen specified by the consumer.
b) Ensure no cross-contact with other meals occurs during transport of the meal to the consumer.
c) Use a separate meal tray to deliver the meal.
d) VERIFY with the consumer that the meal meets their needs.
e) Discard the meal and offer to re-make it for the consumer if the meal contains ingredients to which the consumer is allergic. **Notify** the PIC. **Review** procedures and **retrain** the food handler(s) who prepared and handled the meal on these procedures **before** allowing them to re-make the consumer's meal.

C. Tools to Notify Consumers about Major Food Allergens

PURPOSE The purpose of this guidance is to provide examples of how to give consumers accurate information about food ingredients that are, or that contain, Major Food Allergens so they can make informed decisions when ordering. Giving incorrect or incomplete information can put consumers at risk for allergic reactions.

Consumers with food allergies depend on accurate allergen information when deciding what to eat. It is most effective to tell the consumer both verbally and in writing (e.g., on labels and menus) about the presence of food allergens and the risks of cross-contact.

1. Food Allergens in Menu Items & Self-Served Food[19] Items

a) Review your menu and source ingredients.
b) Use a table (see "Figure 1: Example Food Allergen Matrix" below), listing each menu item and noting the presence of major food allergens including all ingredients such as egg washes, sauces, garnishes, etc. Remember, a food might have more than one allergen.
c) Print "Figure 2. Allergen Matrix – Major Food Allergens Present in Menu Items" (following page) and use it for staff and consumers.
d) Assign a person in charge to regularly, at least once a year, review the food allergen table and update it as needed to verify the ingredients have not changed. Review and update when ingredients, suppliers or processes have changed, and/or a new item has been added to the menu. Consider off-menu items, seasonal and specialty items.
e) Have accessible the full list of ingredients for menu items for consumers with allergies or intolerances beyond the top nine. Consumers may be allergic to ingredients beyond the Major Food Allergens, like gluten. Understanding the full list of ingredients may help you better assist these consumers.

2. Create a Food Allergen Matrix *(based upon your current menu items)*

Figure 1. Example Food Allergen Matrix

Food Items*		Major Food Allergens								
		Egg	Fish	Milk	Peanut	Sesame	Shellfish	Soybean	Tree Nut	Wheat
Breads or Breaded	Bagels	X		X		m		m		
	Gluten Free biscuit	X		X				m	m	
	Sourdough bread									
	Croutons	X		m		m			m	
	Onion rings	X		X						
	Chicken nuggets	X						m		
	Mac and cheese	X		X						
Cheese	American			X						
	Provolone			X						
	Cheddar			X						
	Peanut oil in fryer				X			X		
Lettuce Salad	no Dressing									
	with Dressing	X		X				X		

"X" Contains this allergen.

"m" May contain this allergen or is processed in a facility with this allergen.

19 "Self-served food" means Restaurant-type food that is available at a salad bar, hot food bar, buffet line, cafeteria line, or similar self-service facility, and is served by the consumers themselves. Self-service food also includes self-service beverages, such as drinks dispensed from a soda fountain and coffee available on a self-service basis

Figure 2. Allergen Matrix[20]

Major Food Allergens Present in Menu Items

Food Items *	Major Food Allergens									Other Components			
	Egg	Fish	Milk	Peanut	Sesame	Shellfish	Soybean	TreeNut	Wheat				

"X" Contains this allergen.
"m" May contain this allergen or is processed in a facility with this allergen.
** Include off-menu items, seasonal and specialty items.*

Created on:_____ Reviewed on:_____ Next review:_____

20 A table such as this could be customized for gluten-free and other food intolerances and sensitivities by utilizing the “Other Components” column.

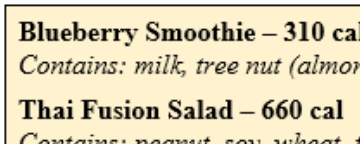
3. Menus & Signage

Design and update existing menus (including those for online ordering, catering, specials, and take-out) to ensure names and descriptions of **all** food items include Major Food Allergens present in each food. For example:

a) Have signage to notify consumers and food handlers an allergen menu exists.
b) Next to each menu item, include text to specify allergens (e.g., *Contains egg, milk*).
c) Use images (or "icons") of food allergens next to menu items where they are present. Include a key so consumers know what the icons represent. Links to websites with pre-made icons are included below.

Figure 3. Examples of notifications

Example 1: In-menu allergen notification.



Example 2: Allergen icons.

4. Talk with Consumers

a) Encourage staff to **ask consumers** about any food allergies they might have.
b) **Provide a list** of menu items and their ingredients for food handlers and consumers as a reference.
c) **Appoint at least one trained food handler per shift** to respond to consumer requests and questions about food allergens.

5. Other Ways to Inform Consumers

a) **Static clings** on display cases provide Major Food Allergen information in consumer view. **Tags or tents** next to food items also work well.
b) **Counter cards, table-talkers, or signs** at the point-of-sale or pick-up to inform consumers.
c) Consider **placing a sign in a prominent location**, when contact with a Major Food Allergen is possible or unavoidable (e.g., French fries prepared in the same fryer as breaded [wheat-containing] items).
d) **Websites** where you can find graphics and other icons for food allergens include:

i. International Association for Food Protection (IAFP) Food Allergen Icons
https://www.foodprotection.org/resources/food-allergen-icons/
ii. StateFoodSafety Allergen Icons
https://drive.google.com/drive/folders/1z_Ie5yxvWq5vFLnWnR7FeIXZDQePhygI?usp=sharing
iii. Erudus Food Allergy Icons
https://erudus.com/standardised-food-allergy-icons/

D. Food Allergy Reaction & Emergency Response Guide

PURPOSE This section is to serve as a resource for food establishments when writing a food allergy reaction and emergency response plan. This guide includes example procedures, considerations, and resources that a food establishment can use to respond when someone reports an allergic reaction. Although this section was written specifically for food allergies, some parts are applicable to reactions caused by other exposures, such as bee stings. Example informational posters are included for you to use within your food establishment.

1. What an allergic reaction may look like

Allergies are complex and allergic reactions can vary from person to person.

Allergic reactions can present in many ways. Food allergic reactions vary in severity, from mildly itchy skin and lip swelling to severe, life-threatening symptoms (anaphylaxis) and death. Some signs and symptoms only affect one part of the body (for example, hives around the mouth). Some signs and symptoms mean that multiple areas of the body are affected (for example, dizziness).

Even within the same person, reactions can differ from food-to-food and day-to-day. For example, a person might experience itching around the mouth after eating an almond, but they could have difficulty breathing and require emergency care after eating a peanut. Even reactions to the same food on different eating occasions can cause different symptoms in the same person.

Different people, including children, experience different symptoms too. For example, not everyone experiences nausea or diarrhea during a reaction. Likewise, it is possible to have a severe life-threatening reaction (anaphylaxis) without any skin symptoms, such as a rash or hives.

2. Allergic reactions in children and adolescents

Children can experience serious food allergic reactions, with an alarming number of fatal anaphylactic reactions occurring during adolescence. Milk, egg, wheat, and soy allergies are more common in childhood than adulthood.

Children can have difficulty communicating what they are experiencing during a reaction. Some children put their hands in their mouths or scratch at their tongues. Their voices may change (for example, becoming hoarse or squeaky), and they might slur their words.

3. If someone reports an allergic reaction

These are **examples** of potential actions to take when a person reports an allergic reaction. Procedures may differ depending on the severity of the reaction. Food establishments should evaluate their need for internal procedures or additional steps. based on corporate policies or other circumstances.

*** When in doubt, call 911 ***

a) Clearly direct one person to dial 911 and report an allergic reaction.
b) Follow the directions of emergency services personnel and the food establishment's food allergy emergency response plan.

4. Epinephrine auto-injectors

a) What is an auto-injector?
EPINEPHRINE AUTO-INJECTORS[21] are medical devices for injecting a measured dose of epinephrine directly into a person experiencing an allergic reaction. The devices are designed to be given through clothing. Multiple brands of auto-injectors are available in the United States, and other countries, and may look slightly different. In the U.S., you cannot buy an epinephrine auto-injector unless you have a prescription from a health care provider. Food establishments will not be able to stock an auto-injector for general use.
Epinephrine auto-injectors have specific directions for use printed directly on the device. **Always follow the instructions printed on the auto-injector**. Always call emergency services when an auto-injector needs to be administered, as a relapse is possible.

b) Here are some example images of what an epinephrine auto-injector might look like; not all auto-injectors will look like these.

Figure 4. Examples of Epinephrine auto-injectors (EAIs)

5. Additional considerations for the food establishment

The following questions and scenarios may be used to develop a detailed food allergy reaction and emergency response plan and/or can be used as a practice drill. Not all questions and scenarios will apply to a food establishment and some food establishments might have additional questions to consider.

a) What ingredient information will be provided to a consumer if they ask? Will this information be written or verbal?

i. If a person experiences a reaction, their first question will be if the allergen was present in any of the food(s) they ate.

b) The exact numbers to dial to reach emergency services should be clearly posted by all telephones.

i. Is there an additional number to dial or extra step to get an outside line?

c) Each person should be aware of any role they play during an emergency. You may consider who will:

i. Be the primary person in charge and ensure each person is performing their duties.

21 A device for injecting oneself with a single, preloaded dose of a drug. The device typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body.

ii. Call emergency services and relay information.
iii. Direct and meet emergency medical services? Are there clear instructions available on how to find the food establishment?
iv. Interact with and physically assist the consumer, if necessary.
v. Keep the area around the person experiencing the reaction clear.

d) Will the food establishment keep any allergy-specific supplies (for example, antihistamines or itch creams) on hand? If yes, when will they be used?

REMINDER Epinephrine is the only medication that can treat a severe allergic reaction and must be prescribed by a health care provider.

e) Will staff have permission to search a person's belongings for an epinephrine auto-injector if they are unable to assist?
f) Can staff administer epinephrine auto-injectors? If yes, which people have permission?
g) Is there an automated external defibrillator ("AED") available? If yes, are staff trained to use it?
h) What are the procedures if the person experiencing a reaction does not want to call an ambulance? If the person leaves before the ambulance arrives, who will pay for any charges incurred?
i) Is there a debriefing and/or reporting requirement after the incident? If yes, include those steps in the allergic reaction response plan.
j) Modify the response plan, as necessary, to better prepare for future incidents.

6. Examples of Posters *(that can be placed within your food establishment to support food allergy preparedness and emergencies)*

E. Equal Consideration for Other Community Food Sources

Other community food sources provide healthy, nutritious food to those in need. For individuals with food allergies, it can be difficult to find safe foods. People with food allergies may need additional support and it is important to consider the food sources' ability to do the following:

- Have at least one well-trained person that is available to speak with those who have allergy concerns. It is important to identify foods that do not contain *at least* the Major Food Allergens so appropriate suggestions can be made.
- Allow consumers the opportunity to review original food packaging so they can read the labels. Know the importance of reading every label, every time, as ingredients can change without warning.
- Make sure staff understand the dangers of cross-contact and how to avoid it. Find out what procedures are in place to avoid cross-contact in the storage and/or preparation of food, if it is being prepared on site, so it can be shared readily.
- If food is cooked and/or served on the premises, be sure workers knows how to recognize the signs and symptoms of anaphylaxis and what the protocols are for a food-allergic emergency.

When offering foods/meals to large groups, encourage preparation of meals that are free of the Major Food Allergens.

- If foods or meals with food allergens are served, provide materials (e.g., signage, labels, tags, tents) in prominent and visible locations to inform consumers.
- While most sections of this document are applicable to both food service venues as well as other community food sources, special attention should be paid to the understanding of how allergens are listed on food labels and the availability of food label information.

Food Sources During an Emergency and Disaster Preparedness

Whether an earthquake, hurricane or wildfire, natural disasters, in addition to man-made ones, can happen at any time, often with little notice. Establish procedures for accessing allergen-friendly foods during an emergency. A crisis is never a time to experiment with a new food or product.

Fig

Food Allergy Reactions

Nine Major Food Allergens

- Milk
- Eggs
- Fish
- Shellfish
- Tree nuts
- Peanuts
- Wheat
- Soybeans
- Sesame

Symptoms of a Severe Allergic Reaction

LUNG
Short of breath, wheezing, repetitive cough

HEART
Pale, blue, faint, weak pulse, dizzy

THROAT
Tight, hoarse, trouble breathing/ swallowing

MOUTH
Significant swelling of the tongue and/or lips

SKIN
Many hives over body, widespread redness

GUT
Repetitive vomiting, severe diarrhea

OTHER
Feeling something bad is about to happen, anxiety, confusion

OR A COMBINATION
of symptoms from different body areas.

FOR **MILD SYMPTOMS** FROM **MORE THAN ONE** SYSTEM AREA, GIVE EPINEPHRINE.

If someone is having a SEVERE ALLERGIC REACTION…

INJECT EPINEPHRINE IMMEDIATELY

Follow the instructions on the device.

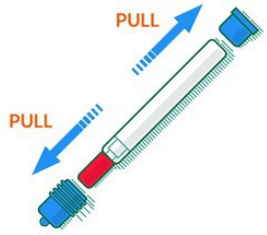
CALL 911

Tell them the individual is having an allergic reaction.

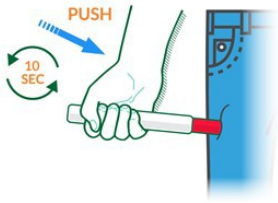
LAY them down.

If breathing is difficult or they are vomiting, let them sit up or lie on their side.

STEP 1. Prepare the epinephrine auto injector for injection by following the instructions on the device.



STEP 2. Administer the injection by firmly push the needle into the leg until a click is heard or felt. Hold the device there.



Written allergic reaction response plan is can be found here: _____

Adapted from Michigan Department of Agriculture and Rural Development, Michigan Restaurant Association, https://www.foodallergy.org/living-food-allergies/food-allergy-essentials/food-allergy-anaphylaxis-emergency-care-plan, and https://www.fda.gov/food/food-labeling-nutrition/food-allergies

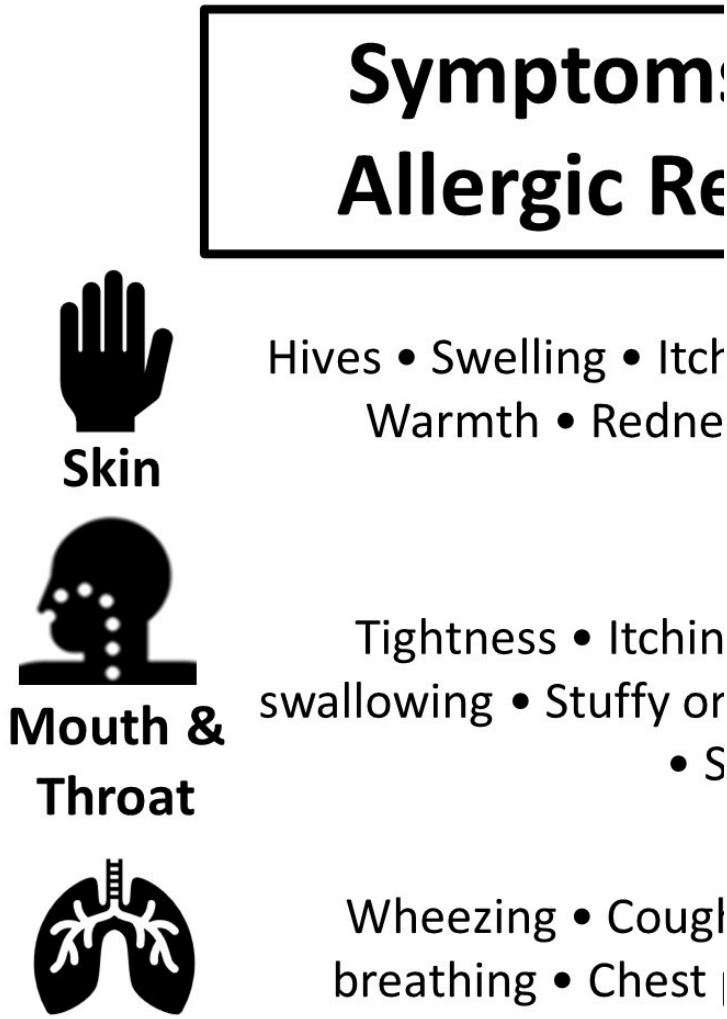


Figure 6. Symptoms of an Allergic Reaction

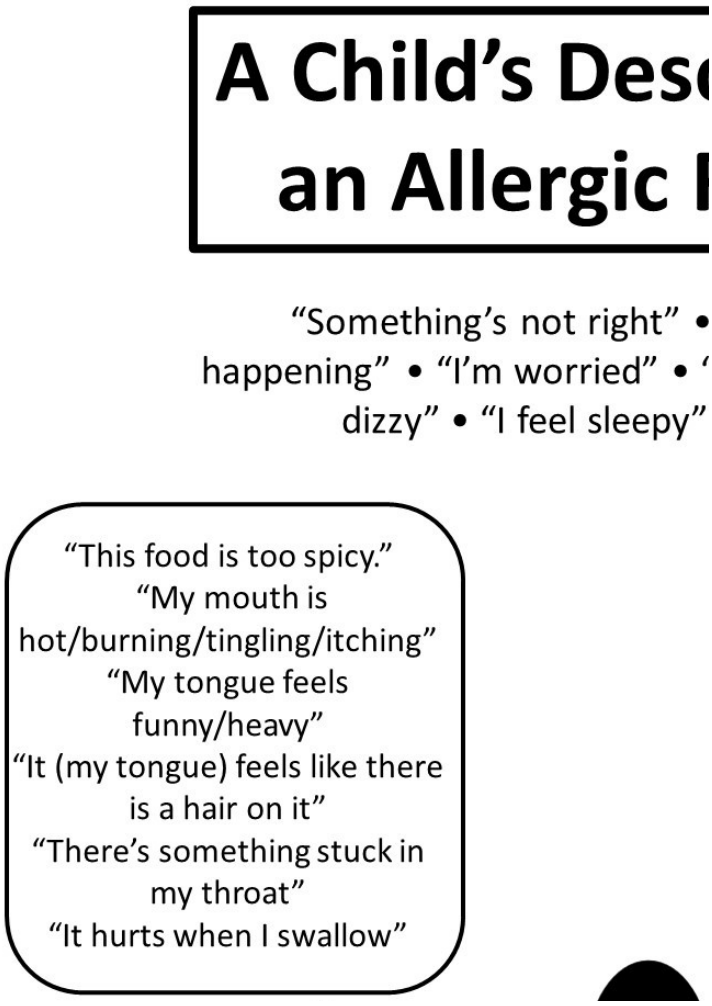


Figure 7. A Child's Description of an Allergic Reaction

Figure 8. Food Allergy Aware - Six that save lives

FOOD ALLERGY AWARE

SIX THAT SAVE LIVES

1

The Symptoms

Signs of a serious food allergy reaction – known as anaphylaxis – are 2 or more of the following after eating a suspect food:

- Hives, itching and/or skin redness
- Swelling of the tongue, lips or throat
- Breathing difficulty, wheezing or coughing
- Stomach cramps or vomiting or diarrhea
- Feeling faint / drop in blood pressure (If only this 1 symptom, it is still anaphylaxis.)

2

In Anaphylaxis: Use the auto-injector right away. Call 911 and report a food allergy emergency.

Epinephrine shots are given via the auto-injector to the outer thigh muscle. This is considered a very safe drug. Antihistamines are acceptable as secondary medication only. They won't halt anaphylaxis. Allergists say: err on the side of using the auto-injector.

3

Time is of the Essence

In studies of those who have died of anaphylaxis, they did not receive an epinephrine injection, or they got it too late, after a reaction had progressed. In anaphylaxis, prompt use of the shot is always essential.

4

Go to the Hospita

A person who had an eme epinephrine shot must be to hospital for observation. transport, IF symptoms ha improved within 10 to 15 n a second auto-injection s be given.

5

Reclining is Best

During the ambulance r the person having the se reaction should be lying d with the legs raised (this im blood flow). NIAID guidel recommend the patient re oxygen and IV fluid.

6

Don't Go It Alone

No person should be exp to be fully responsible fo administration of an epine auto-injector. Assistance anaphylaxis is crucia

From allergicliving.com. Based on guidelines from NIAID and the Canadian Society of Allergy and Clinical Immunology.

Definitions

Anaphylaxis
A life-threatening allergic reaction due to over-release of certain chemicals in the body resulting in shock when a person with an allergy is exposed to an allergen. Allergies to food, insect stings, medications, and latex, are most frequently associated with this type of severe response, and may include skin symptoms or swollen lips, difficulty breathing, reduced blood pressure, and gastrointestinal symptoms.

Consumer
A person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

Cross-contact
The unintentional transfer of an allergen from a food or food-contact surface to a food or food-contact surface that does not contain the allergen.

Epinephrine auto-injector
A device for injecting oneself with a single, preloaded dose of a drug. The device typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body.

Food allergic reaction
An adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. The immune response can be severe and life-threatening.

Food allergy
The reaction of the body's immune system to certain proteins in food. Reactions can vary in severity from mild symptoms involving hives and lip swelling to severe, life-threatening symptoms, called anaphylaxis, which may involve shock and fatal respiratory problems.

Food establishment
An operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

Food handler
A person who handles food utensils or who prepares, processes, or serves food or beverages for people other than members of his or her immediate household.

Food intolerance/sensitivity
An adverse reaction to a substance in food that does not involve the immune system, e.g., the inability to process or breakdown a certain food such as the milk sugar lactose which can lead to discomfort or have ill effects.

Label
A display of written, printed, or graphic matter upon the immediate container of any article; and any word, statement, or other information that appears on the outside container or wrapper of the retail package.

Labeling
All labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

Major Food Allergen
The allergens in foods that cause over 90% of allergic reactions: milk, egg, fish (such as bass, flounder, or cod), Crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, sesame, and soybeans.

Menu
All written and verbal lists of foods prepared and offered to consumers.

Other community food sources
Food sources that are made available to the public on a need basis, e.g., food bank, food shelf, food pantry.

Packaged food
"Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. (2) "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food handler, upon consumer request.

Person in Charge (PIC)
The person present at a food establishment who is responsible for the operation at the time of inspection.

Self-served food
Restaurant-type food that is available at a salad bar, hot food bar, buffet line, cafeteria line, or similar self-service facility, and is served by the consumers themselves. Self-service food also includes self-service beverages, such as drinks dispensed from a soda fountain and coffee available on a self-service basis.

Self-service
Areas where a food handler is not present to serve a consumer and the consumer is responsible for serving themselves, such as at a buffet, salad bar, sushi bar, or display case.

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FARE/Child: How a Child Might Describe a Reaction | Food Allergy Research & Education
https://www.foodallergy.org/resources/how-child-might-describe-reaction
SNHD: HACCP-Based SOPs (southernnevadahealthdistrict.org)
https://www.southernnevadahealthdistrict.org/download/FERL-Resources/SOP-ALLERGY-TRAINING-AND-RESPONSE-20190102.pdf
Significant portions of this guidance were informed by materials developed by the Southern Nevada Health District.
https://www.southernnevadahealthdistrict.org/permits-and-regulations/food-establishment-resource-library/food-allergy-awareness-materials/
FARE: Navigating Food Assistance Programs with Food Allergies
https://www.foodallergy.org/resources/food-banks-and-soup-kitchens
FDA: Have Food Allergies? Read the Label
https://www.fda.gov/consumers/consumer-updates/have-food-allergies-read-label

Train relevant staff in the following procedures:

1. Food & Ingredient Storage

a) Label and segregate unpackaged foods containing one or more of the Major Food Allergens away from each other, and store separately from other foods and ingredients. *Make sure to read ingredient labels to check for the presence of allergens before labeling and segregating.

b) Spills of any of the Major Food Allergens should be cleaned up immediately, following the usual cleaning procedures used in the food establishment. If any Major Food Allergen accidentally comes into contact with other food ingredients that do not contain that allergen, these ingredients should be excluded from use.

2. Self-Service Items

a) For food items that were made on site, label the food items, or place signs next to the food items, that clearly identify the presence of one or more of the Major Food Allergens, or keep ingredient lists on site that identify the presence of one or more of the Major Food Allergens.

b) Labels and signage should be in both English and Spanish, and/or other languages appropriate to either the establishment, or the geographic area.

3. Taking a Food Order

a) Encourage staff to ask consumers about any food allergies they might have.

b) When a consumer informs staff they have a food allergy, intolerance, or sensitivity, immediately notify the Person in Charge (PIC) or designated person (manager, chef, or key employees).

c) Provide a list of menu items and their ingredients for food handlers and consumers as a reference.

d) Help the consumer identify menu items that contain ingredients to which they are allergic and offer suggestions for alternative menu items.

e) If no alternative menu options are available, politely inform the consumer.

f) If it is possible to modify a menu item so that it does not include ingredients the consumer must avoid, inform the consumer, and ask if the modification would suit their needs.

g) Verify with the food handler that the proposed menu item modification is possible, feasible, and can be done safely for the consumer.

h) Make a note on the consumer's order that they have a food allergy/intolerance/sensitivity and which ingredients they must avoid so that other food handlers are aware.

4. Preparing a Food Order

a) Thoroughly clean all areas and equipment that will be used for preparing the allergic consumer's meal, even if those areas had already been cleaned for normal use.

b) Wash hands thoroughly before preparing the allergic consumer's meal. It is necessary to change apron/chef coat, if previously soiled with potential allergens.

c) Use dedicated equipment or physically separate products to prevent cross-contact.

   i. Use color-coded or specially marked supplies, uniforms, equipment, and utensils designated for preparing allergen-free meals.

   ii. Avoid using the same cooking medium (e.g., oil or water) and surface (e.g., grill, prep table) when handling ingredients with and without allergens.

d) Use ingredients that do not contain the allergen(s) to which the consumer is allergic. Check ingredient labels for packaged foods.

e) Prepare food in a manner that eliminates cross-contact. All preparation, including garnishes, should be done by only one food handler who is dedicated to ensuring the meal is allergen-free, and who is not preparing other consumers' meals at the same time.

   i. If a mistake is made, and an ingredient to which the consumer is allergic is accidentally included in the meal, it is not sufficient to simply remove the offending ingredient, because cross-contact will have occurred. In case this happens, re-make the consumer's meal.

   ii. Wash your hands with soap and water before continuing preparation to avoid potential, or additional, cross-contact.

f) Cover the meal with a clean lid to prevent cross-contact and mark the meal as "allergy" so other staff are aware.

g) Notify the PIC, or designated food handler once the allergen-free meal is prepared and ready for service.

h) Wash, rinse, and store special equipment for allergen-free meals to be ready for next use.

i) Wash your hands with soap and water before touching anything else if you have handled a food allergen.

5. Delivering a Food Order

a) Verify with the food handler who prepared the meal that it does not contain the allergen specified by the consumer.

b) Ensure no cross-contact with other meals occurs during transport of the meal to the consumer.

c) Use a separate meal tray to deliver the meal.

d) VERIFY with the consumer that the meal meets their needs.

e) Discard the meal and offer to re-make it for the consumer if the meal contains ingredients to which the consumer is allergic. Notify the PIC. Review procedures and retrain the food handler(s) who prepared and handled the meal on these procedures before allowing them to re-make the consumer's meal.

6. If someone reports an allergic reaction

*** When in doubt, call 911 ***

a) Clearly direct one person to dial 911 and report an allergic reaction.

b) Follow the directions of emergency services personnel and the food establishment's food allergy emergency response plan.