Issue: 2023 I-001

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: 2020-1-004; new or additional information has been included or attached.

Title:

Report - CFP-ISSC JSC Issue #1

Issue you would like the Conference to consider:

The CFP-ISSC Joint Shellfish Committee seeks acknowledgement of the committee's report, with thanks to the members of the committee for their work.

Public Health Significance:

The previous CFP Shellfish Committee identified the lack of shellstock tag and shellstock illness investigation resources available for state and local retail food inspectors and retail food establishments. Delays in investigating a foodborne disease outbreak can occur when shellstock tags are not properly maintained as required by the FDA Food Code. Retail food establishments must understand the importance of shellstock tags and have adequate best practice documents on how to properly maintain shellstock tags to protect public health. Timely investigation of *Vibrio parahaemolyticus* (Vp) cases by State and local health officials are often impeded by unsuccessful efforts to determine product source. Incidences of Vp illnesses associated with molluscan shellfish consumption have increased and continue to be a significant challenge to health authorities. A toolkit for state and local inspectors can assist in gathering the needed data during an investigation, prevent illnesses, and could increase the accuracy of growing area closures.

Recommended Solution: The Conference recommends...:

- 1. Acknowledgment of the CFP-ISSC Joint Shellfish Committee Final Report.
- 2. Thank the committee members for their diligent work on the development of a significant number of best practices and guidance documents to further the joint effort between retail food establishments and regulators to protect public health.
- 3. Disband the committee; all assigned charges have been completed.

Submitter Information 1:

Name: Barry Parsons Organization: Cenza, Inc

Address: 25 Swinehart Road City/State/Zip: Gilbertsville, PA 19525

Telephone: 717-419-5103

E-mail: barry@cenzasmart.com

Submitter Information 2:

Name: Joe Graham

Organization: Washington State Department of Health

Address: PO Box 47824 City/State/Zip: Olympia, WA 98504

Telephone: 360-338-2717

E-mail: Joe.graham@doh.wa.gov

Content Documents:

- "CFP-ISSC Joint Shellfish Committee Final Report"
- "CFP- SSC Shellfish Committee Roster"
- "i. Shellstock Tag Procedures English (see attached PDF)"
- "ii. Shellstock Tag Procedures Spanish (see attached PDF)"
- "iii. Shellstock Tag Procedures Infographic (see attached PDF)"
- "iv. Shellstock Tags English (see attached PDF)"
- "v. Shellstock Tags Spanish (see attached PDF)"
- "vi. Anatomy of Shellstock Tags (see attached PDF)"
- "vii. Molluscan Shellfish The Basics (see attached PDF)"
- "viii. Shellfish Code Language Table (see attached PDF)"
- "ix. Molluscan Shellfish Environmental Investigation Field Worksheet"
- "x. Molluscan Shellfish Investigation Field Checklist (see attached PDF)"

Supporting Attachments:

- "i. Alaska shellfish retail guide 1"
- "i. Alaska shellfish retail guide 2"
- "ii. Assess AMC Shellfish"
- "iii. Hawaii retail shellfish requirements"
- "iv. Molluscan Shellfish"
- "v. Molluscan Shellfish Handling"
- "vi. Record Keeping"
- "vii. Retail Shellfish Requirements"
- "viii. Shellfish at Retail 5 08"

Issue: 2023 I-002

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: 2020-1-004; new or additional information has been included or attached.

Title:

CFP-ISSC JSC #2 Approve and Post Guidance and Best Practices Documents

Issue you would like the Conference to consider:

- 1. Guidance documents to assist regulators during shellstock foodborne illness outbreak investigations
- 2. Best Practice documents for retail food establishments on the importance and correct process for maintaining shellstock tags.

Public Health Significance:

The previous CFP Shellfish Committee identified the lack of shellstock tag and shellstock illness investigation resources available for state and local retail food inspectors and retail food establishments. Delays in the investigation of a foodborne disease outbreak can occur when shellstock tags are not properly maintained as required by the FDA Food Code. Retail food establishments must understand the importance of shellstock tags and have adequate training on maintaining shellstock tags to protect public health. There is a need for inclusive materials due to the diversity of the population. Having the documents in Spanish and also having a infographic is important so these tools can reach the diverse retail workforce. Timely investigation of *Vibrio parahaemolyticus* (Vp) cases by State and local health officials are impeded by unsuccessful efforts to determine product source. The incidence of Vp illness associated with molluscan shellfish consumption is on the rise and continues to be a significant challenge to health authorities. A toolkit for state and local inspectors can assist in gathering the needed data during an investigation, prevent illnesses, and could increase the accuracy of growing area closures.

Recommended Solution: The Conference recommends...:

1. Approval of the five retail food establishment best practice documents in English and Spanish

- a. Shellstock Tag Procedures English (see attached PDF)
- b. Shellstock Tag Procedures Spanish (see attached PDF)
- c. Shellstock Tag Procedures Infographic (see attached PDF)
- d. Shellstock Tags English (see attached PDF)
- e. Shellstock Tags Spanish (see attached PDF
- 2. Approval of the five guidance documents for state and local food safety inspectors.
- f. Anatomy of Shellstock Tags (see attached PDF)
- g. Molluscan Shellfish the Basics (see attached PDF)
- h. Shellfish Code Language Table (see attached PDF)
- i. Molluscan Shellfish Environmental Investigation Field Worksheet (see attached Word document)
- j. Molluscan Shellfish Investigation Field Checklist (see attached PDF)
- 3. Post the approved guidance documents on the CFP website.

Submitter Information 1:

Name: Barry Parsons Organization: Cenza, Inc

Address: 25 Swinehart Road City/State/Zip: Gilbertsville, PA 19525

Telephone: 717-419-5103

E-mail: barry@cenzasmart.com

Submitter Information 2:

Name: Joe Graham

Organization: Washington State Department of Health

Address: PO Box 47824

City/State/Zip: Olympia, WA 98504

Telephone: 360-338-2717

E-mail: Joe.graham@doh.wa.gov

Content Documents:

- "a. Shellstock Tag Procedures English (see attached PDF)"
- "b. Shellstock Tag Procedures Spanish (see attached PDF)"
- "c. Shellstock Tag Procedure Infographic (see attached PDF)"
- "d. Shellstock Tags English (see attached PDF)"
- "e. Shellstock Tags Spanish (see attached PDF)"
- "f. Anatomy of Shellstock Tags (see attached PDF)"
- "g. Molluscan Shellfish the Basics (see attached PDF"
- "h. Shellfish Code Language Table (see attached PDF"
- "i. Molluscan Shellfish Environmental Investigation Field Worksheet (see att"
- "j. Molluscan Shellfish Investigation Field Checklist (see attached PDF)"

Supporting Attachments:

- "a. Alaska shellfish retail guide 1"
- "a. Alaska shellfish retail guide 2"
- "b. Assess AMC Shellfish"
- "c. Hawaii_retail shellfish requirements"
- "d. Molluscan Shellfish"
- "e. Molluscan Shellfish Handling"
- "f. Record Keeping"
- "g. Retail Shellfish Requirements"
- "h. Shellfish at Retail 5_08"

Issue: 2023 I-003

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action					
Delegate Action:	Accepted	 _Rejected	- 					
All information above the line	e is for conference use only.							
Issue History:								
This is a brand new Is	This is a brand new Issue.							
Title:								

Issue you would like the Conference to consider:

Gloves Used as a Single-Use Disposable Utensil

Disposable gloves are defined as a utensil in the 2022 FDA Food Code (3-304.11). Currently, there is no specific provision within the FDA Food Code that covers hand washing and using a disposable glove as a single-use utensil, similar to a tong or spatula. When a glove is used as a single-use disposable utensil, and no contamination of the hand has occurred, there should be no need to wash hands after glove removal or between changes.

Public Health Significance:

Hand washing is a critical activity to ensure against cross-contamination. The FDA Food Code indicates there are specific times when hands must be washed (2-301.14). The various rules within the FDA Food Code are focused on potential contamination events while there is an opportunity to include interpretation for when contamination does not occur, such as when using a disposable glove in a single-use situation, similar to a tong or spatula. Rather than adding an additional hand wash step that would not occur if any other utensil was used, the glove(s) should be allowed to be removed and/or changed without a hand wash procedure in instances where contamination of the hand has not occurred.

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA requesting that the most current edition of the *Food Code Annex 7, Guide 3-B, 8. Hands clean and properly washed*, be amended as follows: IN/OUT

This item should be marked IN or OUT of compliance. This item is marked IN compliance only when employees are observed using proper handwashing techniques at appropriate times and places. Hands are not required to be washed between each change of gloves, if it is observed that there was no change in the task being performed and no activities which

could potentially result in cross contamination. <u>Also, hands are not required to be washed</u> after or between glove changes if gloves are used as a single-use disposable utensil and no activities resulting in hand contamination were observed.

Submitter Information 1:

Name: Patrick Guzzle

Organization: National Restaurant Association Address: 6751 Forum Drive, STE 220

City/State/Zip: Orlando, FL 32821 Telephone: 208-515-8688

E-mail: pguzzle@restaurant.org

Submitter Information 2:

Name: Kate Piche

Organization: National Restaurant Association Address: 233 S Wacker Drive Ste 3600

City/State/Zip: Chicago, IL 60606

Telephone: 3124856925

E-mail: kpiche@restaurant.org

Issue: 2023 I-004

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended		No Action	
Delegate Action:	Accepted		_ Rejected		-	
All information above the line	e is for conference use	only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
Amend Food Code 2-	301.14 – Allow [Donning	of Loose-Fitting	Gloves	}	

Issue you would like the Conference to consider:

Amend 2-301.14 to allow glove use without washing hands under some circumstances.

Public Health Significance:

Gloves are an important tool in food service to prevent bare hand contact with ready-to-eat foods and also to protect hands from sources of contamination, thus reducing the amount of handwashing that needs to occur. Many food establishments use loose-fitting gloves as a utensil to handle food items like raw meat and do not follow 2-301.14(H), which requires a hand wash prior to donning gloves.

While the Food Code does specify that gloves can be a utensil (see the definition of "utensil" in the code) it further does not specify when gloves should no longer be treated as gloves. According to 2-301.14(H), hands must be washed before gloves are donned to initiate food preparation. If gloves/utensils are still considered gloves, then the procedures in place in many restaurants are not allowed since they generally do not include a hand washing step prior to donning the glove. Furthermore, if the process includes the use of double-gloving (traditional gloves under loose-fitting gloves), this process is not allowed at all since gloved hands cannot be washed prior to placing the loose-fitting glove over the primary glove.

Many state and local agencies have allowed this process and see the use of loose-fitting gloves as a utensil through a variance or some other pathway. The FDA has stated that they do not see this practice as disallowed based on the current language of the Food Code. Industry has expressed frustration as multiple regulatory jurisdictions have interpreted the Food Code to say that this is not an allowed process.

This issue seeks to codify what industry wants to do and many regulators (including the FDA) have allowed in some capacity.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the most current edition of the Food Code be amended as follows:

2-301.14 When to Wash.

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES^P and:

- (A) After touching bare human body parts other than clean hands and clean, exposed portions of arms; P
- (B) After using the toilet room; P
- (C) After caring for or handling SERVICE ANIMALS or aquatic animals as specified in \P 2-403.11(B); P
- (D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using TOBACCO PRODUCTS, eating, or drinking; P
- (E) After handling soiled EQUIPMENT or UTENSILS; P
- (F) During FOOD preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; P
- (G) When switching between working with raw FOOD and working with READY-TO-EAT FOOD: P
- (H) Except as specified in ¶ (J) of this section, Before donning gloves to initiate a task that involves working with FOOD; P and
- (I) After engaging in other activities that contaminate the hands. P
- (J) Loose-fitting gloves may be placed over hands/gloved hands as long as the following criteria are met:
- (1) The gloves are donned using a hands-free process such as using a glove holder/dispenser that allows hands/gloved hands to be inserted into the loose-fitting gloves without hand/gloved hand contact with the outside of the loose-fitting glove; and
- (2) After use, the loose-fitting gloves are removed using a method that does not contaminate the hands/gloved hands such as shaking the loose-fitting gloves off directly into a trash receptacle.

Submitter Information 1:

Name: Matthew Brandt

Organization: Colorado Department of Public Health & Environment

Address: 4300 Cherry Creek Dr SouthA-2

City/State/Zip: Denver, CO 80246 Telephone: 720-550-0322

E-mail: matthew.brandt@state.co.us

Submitter Information 2:

Name: Jason Horn

Organization: In-N-Out Burger

Address: 13502 Hamburger Lane City/State/Zip: Baldwin Park, CA 91706

Telephone: 626-813-5326 E-mail: jhorn@innout.com

Issue: 2023 I-005

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 Is	sue.		
Title:			

Add cross contact definition & codified/Annex language within the Food Code

Issue you would like the Conference to consider:

Unintended allergen presence due to allergen cross-contact at food establishments presents a risk to consumers with food allergies. Currently, the FDA Food Code does not define allergen cross-contact nor does it address management of allergen cross-contact within food establishments. This issue recommends that "allergen cross-contact" be defined within the Food Code as well as the addition of codified language addressing control of unintended allergen presence.

Public Health Significance:

Labeling of major food allergens (MFAs) within a food establishment is a major step towards protecting consumers with food allergies by helping them make informed choices based on the labeling information about the intentional addition of MFAs in foods. However, MFA labeling alone does not address all the needed protections. Another source of MFAs within food establishments is unintended allergen presence due to cross-contact that may occur because of the very nature of the small spaces and the high throughput of orders with different allergen profiles being prepared using shared cooking utensils and common food contact surfaces. Addressing allergen cross-contact to reduce the incidences of unintended allergen presence can help achieve the overall goal of safe food for consumers with food allergies.

Food allergies and other types of food hypersensitivities affect millions of Americans and their families with estimates of food allergies in US consumers reported to be as high as 8% in children and 10.8% in adults (Gupta et al., 2011; Gupta et al., 2019). National consumer survey data from the Food Allergy Research & Education (FARE), found that 50% or more of consumers report one or more allergic reactions per year and, of unintentional exposures resulting in reactions, 24% were reported to occur due to crosscontact. Cross-contact also appeared as the most common reason for unintentional exposure to food allergens (Fierstein et al., 2021). A survey conducted by FARE in 2021,

found that restaurants are the second most common location, following home, for food allergy reactions. Another study found similar data where after one's home, restaurants are the second most common location for food allergic reactions (Oriel et al., 2021).

Analysis of food product recall data has shown that allergen cross-contact presents an opportunity for allergens to be present in food products if proper controls are not instituted (Gendel et al., 2013; Sharma et al., 2022). While research has shown that certain model Food Code cleaning procedures are effective at removing allergenic compounds (Bedford et al., 2020) it remains important that the risk of cross-contact be addressed to employ effective cleaning procedures for allergen management within the food establishment.

It has been acknowledged that requirements to control allergen cross-contact in food establishments is a gap in the existing Food Code. Unintentional allergens being present in foods can be mitigated through control measures (Boyd et al., 2018). For the retail industry, taking steps to control allergen cross-contact can be challenging, but taking these steps are important in reducing the risk of allergenic proteins being present unintentionally. Allergen cross-contact control measures should be risk-based and implemented using scientific principles. To reduce the risk to the consumer from unintended allergen presence due to cross contact, special consideration should be placed on the following: (1) the storage and preparation areas provide adequate space and flow, (2) appropriate food preparation and service procedures are followed when foods are prepared for a consumer with a food allergy, and (3) employees are properly trained on food allergen management within the food establishment including employee hygiene and the impact of allergen cross-contact on the risk to a consumer that has a food allergy.

A plethora of information exists to educate stakeholders on allergen cross-contact. Refer to Supporting Document entitled, "Attachment 1 - Summary of FDA Allergen Cross Contact References" to obtain list of resources. Although this information exists, the FDA Food Code lacks explicit recognition of allergen cross-contact to minimize the potential risks associated with allergen cross-contact within a food establishment. The FDA Food Code currently requires labeling of MFAs for packaged food and written consumer notification for unpackaged foods. By addressing allergen cross-contact in the FDA Food Code, regulatory authorities, industry partners, and consumers will formally recognize the risks from allergen cross-contact and take steps to actively manage allergen cross-contact within the food establishment. Labeling of MFAs in packaged food, providing written consumer notification of MFAs in unpackaged food coupled with a plan to address allergen cross-contact provide greater assurance to consumers that MFAs are being addressed within the food establishment.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that:

- 1. FDA define the term 'allergen cross-contact' in the Food Code to address the unintentional incorporation of major food allergens into food.
- FDA incorporate codified language in the Food Code addressing a Food
 Establishment having a plan in place to address unintended allergen presence in
 food due to allergen cross-contact.

Submitter Information 1:

Name: Glenda R Lewis

Organization: U.S. Food and Drug Administration

Address: 5001 Campus Drive City/State/Zip: College Park, MD 20740

Telephone: 240-402-2150

E-mail: glenda.lewis@fda.hhs.gov

Submitter Information 2:

Name: Devin Dutilly

Organization: U.S. Food and Drug Administration

Address: 5001 Campus Drive City/State/Zip: College Park, MD 20740

Telephone: 301-348-1980

E-mail: devin.dutilly@fda.hhs.gov

Supporting Attachments:

- "Attachment 1 Summary of FDA Allergen Cross Contact References"
- "Bedford et al 2020"
- "Boden et al 2005"
- "Boyd pre-print research paper"
- "Gendel and Zhu 2013"
- "Gupta et al 2011"
- "Gupta et al 2019"
- "Attachment 8-Allergen cross contact reference Sharma et al2022 IAFP Poster"

Issue: 2023 I-006

Council Recommendation:	Accepted as Submitted		Accepted as Amended	No Action	
recommendation.	Odbillitted		_/\lineriaea	 _ 140 / (011011	
Delegate Action:	Accepted		_ Rejected	 _	
All information above the line	e is for conference use	e only.			
Issue History:					
This is a brand new Is	ssue.				
Title:					
Regulating use of "ma	ay contain" type	advisory	labels		

Issue you would like the Conference to consider:

A proposed definition to establish appropriate limits and definitions for use of the terms "may contain" and "made in a facility that processes" allergens.

Public Health Significance:

Food allergies are affecting more people every day. It is vital that people with allergies know what is in the products they consume so that they do not have a life-threatening reaction.

The Food Allergy Safety, Treatment, Education, and Research Act of 2021 or the FASTER Act of 2021 act which mandates the labeling of sesame as a declared allergen has led to unintended consequences. Companies that never had sesame in their products are deliberately adding sesame to comply with the change in the law rather than engaging in good manufacturing practices. This has led to consumers with sesame allergy to have far fewer choices in bakery products and restaurants where they can eat. The FDA has publicly acknowledged that this is happening and that the practice is not upholding the spirit of the law.

A proposal that may help the issue without causing too much disruption to industry would be for the FDA to establish a legal definition for disclosing cross-contact, like "made in a facility" or "main contain." That way, companies that have sesame products and fear cross contamination can clearly disclose the cross-contact and the consumer can then decide whether they feel safe taking the risk of purchasing the product. This would kill two birds with one stone because there has long been confusion in the allergy community about the significance of these cautionary phrases which are currently unregulated.

Recommended Solution: The Conference recommends...:

sending a letter to the FDA requesting the agency to establish a legal definition for disclosing cross-contact for the presence of food allergens. Such definition should clearly explain the limits and ramifications of terms like "may contain" or "made in a facility that also processes" perhaps using threshold amounts that would trigger the use of the warnings.

Submitter Information:

Name: Laurel Francoeur
Organization: Francoeur Law Office
Address: 63 Shore RoadSuite 24
City/State/Zip: Winchester, MA 01890

Telephone: 781 705 2552

E-mail: laurel@francoeurlaw.com

Issue: 2023 I-007

Council Recommendation:	Accepted as Submitted		Accepted as Amended	No	o Action	
Delegate Action:	Accepted		Rejected			
All information above the line	•	e only.	_ 110,000.00			
Issue History:						
This is a brand new Is	ssue.					
Title:						
Bread bakers adding	sesame flour to	recipe ra	ather than "may	contain."		

Issue you would like the Conference to consider:

I would like the conference to consider a way to induce bread bakers to stop making breads more dangerous by adding sesame flour to their recipes. Perhaps by changing the requirements of a "may contain" statement to be more protective of the manufacturers yet still alerting consumers of the possible presence of sesame. Many sesame allergic people have safely eaten many breads for years that had possible cross contact with sesame seeds. The seeds are less allergenic than the flour that is now being added. Eating bread anywhere outside the home has become much more dangerous and nearly impossible for sesame allergic people. It was much safer and easier before the FASTER Act went into effect.

Public Health Significance:

The public health consequences of bread makers adding sesame four is massive. Many previously safe places are now dangerous. Caregivers of small children, and many parents themselves, may not know of the additional risks of their previously safe spots. Accidental ingestion risks for sesame allergic people have increased tremendously.

Recommended Solution: The Conference recommends...:

Working with the stakeholders to find a solution or maybe labeling language that protects consumers, but does not compel the bakers to add the allergen to previous recipes that did not contain sesame. There has to be a better solution than adding a dangerous and potent form of the allergen to recipes rather than to have an appropriate label. Maybe also consider an incentive for eliminating sesame since it isn't a critical ingredient in many of these products. It does not offer additional nutritional value and is only ornamental for most breads.

Submitter Information:

Name: Malinda Hain

Organization: self

Address: 530 Metro Station City/State/Zip: Apex, NC 27502 Telephone: 9123081289

E-mail: malindahain@me.com

Issue: 2023 I-008

Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	
Delegate Action:	Accepted		_ Rejected		_	
All information above the line	is for conference us	e only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
Sesame Update To S	ection 403(w)(1) of the F	D&C Act (21 U	.S.C. 34	3(w)(1))	

Issue you would like the Conference to consider:

I would like the Conference to consider advocating to update the Food, Drug, and Cosmetic Act (FD&C) to authorize food manufacturers to label products with an advisory warning of cross contamination of sesame, in order to prevent food manufacturers from adding sesame flour to their bread as a substitute for compliance with the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act.

Public Health Significance:

The FASTER Act, which was enacted to "protect" those with sesame allergies by identifying sesame as the 9th "major food allergen" has backfired and resulted in bakeries adding a small amount of sesame flour to bread - not to enhance flavor - but solely to identify sesame as an ingredient, due to their perceived inability to comply with Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)). The current law requires that food manufacturers label for the 9 major food allergens. If an allergen is not an ingredient in the food, the manufacturer is prohibited from listing it as an ingredient. In addition, good manufacturing practices are required for food allergen preventative controls. Due to the financial burden of "good manufacturing practices," for decades, it has been an accepted practice for companies to label a product with an advisory warning, such as "made in a facility with ____" or "may contain __" or "made on shared lines with ____", in order to warn of the potential cross contamination of an allergen, without adding that allergen as an ingredient to the food. When the FASTER Act was passed, rather than rely upon this accepted practice, food manufacturers (and in particular bakeries), have become fearful that an advisory warning is insufficient to comply with the FD&C Act. As such, these manufacturers are adding a small amount of sesame flour to their bread for the sole purpose of declaring an allergen. As a consequence of this decision, it has become nearly impossible for a sesame allergic person to find safe bread to eat. Of note, sesame is a unique allergy. Many with sesame allergies are not affected by cross contamination of seeds, due to the fact that the protein that causes a reaction is located inside the seed. The

waxy coating of the seed acts as a barrier. Although some people may be sensitive to cross contamination, there are many people who have safely been able to consume bread made in a facility with sesame seeds without any issue. However, it is unlikely that someone with an active sesame allergy can consume sesame flour baked into the bread. People with sesame allergies are no longer able to safely eat hamburgers, hot dogs, pizza, and rolls due to sesame flour being added to these foods to avoid compliance with good manufacturing standards. Children with sesame allergies who rely upon hot lunch programs are now struggling to find safe foods to eat. Restaurants such as Wendy's, Chikfli-a, Culver's, Olive Garden and Maggiano's are being impacted by their bread suppliers adding sesame to their bread. Of concern, this change is not well known or advertised to the public, and many restaurant managers are not being educated about these changes. As such, those with sesame allergies are at an extremely high risk of an accidental reaction, due to the fact that reliable restaurants where they safely ate weeks ago may no longer be safe for them. It is not a question of if, but a question of when someone will get sick and possibly die from eating a burger at Wendy's because they did not know that sesame flour was added to the bread. Unlike sesame seeds, the small percentage of flour being added is not visible or noticeable; however, also unlike sesame seeds (which are less potent due to how they are digested), a small amount of sesame flour could be deathly.

Recommended Solution: The Conference recommends...:

A preferable law, which would benefit both bakeries and those with sesame allergies, would allow for bakeries to label their packages with an advisory warning to clearly indicate whether 1) Sesame seeds and/or flour is the facility; and 2) Sesame seeds and/or flour is used on a shared line. With this information, a person with sesame allergies can make an informed decision about whether the potential cross contamination is a risk based upon their sensitivity to the allergen. In addition, bakeries will not need to add a small percentage of sesame flour to otherwise sesame-free bread. Of note, people with sesame allergies who can tolerate cross contamination have been safely eating bread from bakeries that use sesame seeds without issue. Adding sesame flour to bread is NOT the answer to protect those with sesame allergies. Rather, truth in labeling and allowing for advisory warnings is the answer to protect those with sesame allergies. It is necessary to update the FD&C Act and codify the permissive use of advisory labels. Although advisory labels have been an accepted practice with respect to other allergens, it is clear that food manufacturers (and in particular bakeries) are not comfortable relying on this practice with respect to sesame seeds. Rather, they need the security and protection of a statute to prevent the fear of litigation. Notice of a risk of cross contamination would prevent litigation. It would be at the consumer's risk to consume food with such a warning. As noted above, those with sesame allergies should be trusted to make their own informed decisions about their health when provided with accurate information about the potential for cross contamination in a facility. However, adding sesame flour directly to bread takes that right away. This is overt discrimination. It is despicable to add a small amount of an allergen to food solely to exclude a class of people. There is a better way. An update to the FD&C Act with respect to advisory warnings is long overdue.

Submitter Information:

Name: Jamie Waynee

Organization: None

Address: 1175 studio In

City/State/Zip: riverwoods, IL 60015-1916

Telephone: 3123883933

E-mail: jamieheather23@yahoo.com

Content Documents:

• "FARE responds to companies intentionally adding sesame"

• "Bread Suppliers Adding Sesame"

Supporting Attachments:

• "Tough New Labeling Law For Sesame Prompts Companies To Add It"

Issue: 2023 I-009

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 Is	ssue.				
Title:					

Issue you would like the Conference to consider:

The Food Allergy Safety, Treatment, Education, and Research (FASTER) Act was a positive change for the allergy community, bringing sesame labeling in line with other top allergens. Unintended consequences of this change have included companies adding small amounts of sesame to their products, rendering them unsafe for those with sesame allergies, which impacts products available for retail sale and those supplied to restaurants.

Companies adding sesame to products previously safe for sesame-allergic

The purpose of the change in the law was to increase safety for those who are sesame-allergic. However, in response to the changes in the law requiring sesame labeling, manufacturers, including members of major baking organizations, have opted, in some cases, to add sesame flour to products. This action impacts restaurants and retail sales downstream, as once-safe products now pose a life-threatening risk for those with sesame allergies. Some people have multiple allergies, so choices are already limited, and this change has caused great upheaval in the sesame allergy community.

Public Health Significance:

More than a million people in the United States are allergic to sesame, or approximately 0.49% of the population. Many of these individuals have co-morbid allergies and other allergic diseases, such as asthma.

A balanced diet requires the ability to safely eat whole grains in the form of bread, tortillas, crackers, and other products. Severely limiting safe options is not only inconvenient, but it can have harmful effects on health.

Recommended Solution: The Conference recommends...:

We recommend that restaurants and retail organizations that sell bread and related products to consumers communicate with manufacturers that the strategy of adding risk to foods to mitigate risks to avoid the requirements for cross-contact mitigation is **not**

acceptable in a country where approximately 6% of the population has food allergies. Negotiations with major baking companies to introduce sesame-free lines of common products such as bread loaves, hot dog and hamburger buns, crackers, breadcrumbs, etc. should be prioritized. In the short-term, risk communication about product changes should be amplified to avoid potentially fatal outcomes.

Submitter Information:

Name: Josie Howard-Ruben
Organization: Rush University
Address: 1408 S Clifton Ave
City/State/Zip: Park Ridge, IL 60068

Telephone: 8472088284

E-mail: josiehowardruben@gmail.com

Issue: 2023 I-010

Council Recommendation:	Accepted as Submitted		Accepted as Amended	 No Action	
Delegate Action:	Accepted _		Rejected		
All information above the line	is for conference use on	ly.			
Issue History: This is a brand new Iss	sue.				

Labeling under Food Allergy Safety, Treatment, Education & Research Act

Issue you would like the Conference to consider:

Title:

The Food Allergy Safety, Treatment, Education and Research Act ("FASTER Act") added sesame to the list of major food allergens which manufacturers are required to declare on product labels. The intent of the law was to make food safer for consumers with food allergies, as sesame was frequently included in categories such as "spices" or "natural flavors." As a parent of a child who manages a sesame allergy, we celebrated this news, and looked forward to January 2023. Manufacturers had 18+ months to comply with the new labeling laws. Rather than taking the steps needed to segregate sesame, and apply safe manufacturing practices, nearly every company who manufactures ANY product with sesame has instead opted to ADD small amounts of sesame to their products so that they can declare it on the label. It appears they are interpreting the FASTER Act to mean they must guarantee there is no cross contamination with sesame, and they have declared that impossible to comply with. Because the FASTER Act does not include permission or guidance on the issue of when a product is run on the same line, or produced in the same facility with sesame, they felt it was "safer" for food allergy consumers if they added the allergen and declared it as an ingredient on the label. The list of companies who have taken this approach is not short. Previously some companies chose to label for sesame consumers with sesame allergy had several options of bread and hamburger buns to choose from in their local grocery stores, and generally could eat out at a number of places without issue. "Go to" restaurants were places where they did not use sesame seeded buns. As a consumer, I could choose to accept the risk that bread products may have been cross contaminated with a product containing a sesame seed, knowing that whole seeds cannot be digested and are unlikely to cause a reaction. None of these items are now safe, and that choice has been taken away from my family, and others with sesame allergies. By choosing to add sesame flour to all bread products as their way to "comply" with the FASTER Act, the following is a short list of products that we have identified and can no longer use in our home: most fast food restaurants (nearly all buns now contain sesame flour), many chain restaurants (addition of sesame flour to bread and pizza has increased

risk of cross contamination), nearly every sliced bread, hamburger and hot dog bun supplied to restaurants now contains sesame flour, plain and cinnamon raisin bagels now contain sesame flour, many pizza places have now added sesame flour. The list goes on and on. This has created a tremendous danger to consumers with sesame allergies, as products they have used for years are now changing recipes. A collection of articles was recently published by the Food Allergy Research & Education ("FARE") summarizing these challenges and is available at

http://www.foodallergy.org/resources/fare-response-companies-intentionally-adding-sesame-flour-faster-act-goes-effect

Public Health Significance:

330 million people in the US have been diagnosed with a sesame allergy. It's the 9th most common allergen, and has been the most difficult to navigate. Restaurants will now be under increased challenges to try to accommodate their allergic clientele, and the risks of cross contamination have significantly INCREASED because the number of products containing this allergen has increased so significantly. Children who eat in school cafeterias will no longer be able to eat the things they used to eat, and are not likely to know of changes in the laws, or company practices. Food servers have not been properly educated. In the times we have eaten out since January 2023, I have educated 75% of the servers on the new changes - none were aware of the new law, and had no idea so much sesame was in their kitchen. I have read about 3 food allergy deaths since December 2022 in the US. Children should not be put at risk because companies have cut corners and chosen to work around the legal requirements put in place to keep them safe.

If companies and restaurant establishments have the obligation to segregate allergens and train employees, but could simply label that a product is "made on a shared line with products containing [insert allergen]" that would give consumers the option to decide whether to eat that product or not. If a product was labeled "made in a facility with [insert allergen] but made on dedicated [insert allergen] free line" that would provide enough information to food allergy families to be able to make an educated decision. Currently any "may contain" or "made in a facility with" or similar label is voluntary, the absence of such a warning does not mean the product is safe to consume, and consumers are simply left guessing as to whether products are safe or not.

Recommended Solution: The Conference recommends...:

Amend the FASTER Act and the Food Code to standardize labeling options for food allergens in addition to existing good manufacturing practices. Include standard definitions for labeling cross contamination that will inform consumers and allow them to make their own choices about what is safe for their families. This would render the absence of such a label meaningful, allowing food allergic consumers the ability to make meaningful decisions for their health and safety. Include strict penalties for changing recipes to intentionally add any of the top 9 allergens to existing recipes for the purpose of being able to declare it as an ingredient.

Submitter Information:

Name: Jennifer Gonzalez

Organization: None

Address: 839 Pinecrest Ave SE City/State/Zip: Grand Rapids, MI 49506

Telephone: 248-904-0560

E-mail: jeng49506@gmail.com

Issue: 2023 I-011

Council Recommendation:	Accepted as Submitted	Accepted as	No Action					
Delegate Action:	Accepted	Rejected	_					
All information above the line	is for conference use only.							
Issue History:								
This is a brand new Is	This is a brand new Issue.							
Title:								

Issue you would like the Conference to consider:

Manufacturers have begun to add sesame to protect from legal action.

The conference needs to address the current problem around food labeling and the manufacturers ability to change formulations to include allergens as a way to circumvent liability.

Public Health Significance:

As of the change in labeling requirements to include a "contains" statement for sesame ingredients, manufacturers have begun to put trace amounts of sesame into products that had not before contained sesame. This is in an attempt to alleviate any possible legal responsibility in the event a person allergic to sesame consumed their product and sustained damages. It is a legal loophole which allows these companies to change their formulations for the sole purpose of covering themselves from liability. This creates further hardships for anyone who has to deal with a sesame allergy. It may be legal at this point, but it is not the right thing for these companies to be allowed to do. It has far reaching consequences for people who already have a limited ability to purchase and consume products safe for them.

This has caused extreme hardships for those with a food allergy to sesame . For example, it is now incredibly difficult to find a safe bread if you are a person with a food allergy to sesame. Prior to the change in labeling requirements, I was able to find multiple bread products which did not label for sesame, and were therefore "safe". Of those breads, none are now safe- because they have ADDED sesame in trace amounts to their formulation. How is this allowed? They didn't change their recipes for any other reason except to protect themselves.

For those families that have to navigate the world around food allergies this has created an unintended hardship. The purpose of labeling for sesame was to ensure those with a sesame allergy were properly informed so they could make safe choices and protect themselves and those they love from a potential fatal reaction. However, the way in which the law has been allowed to be implemented has caused even greater hardship.

It is imperative that we are able to have proper labeling for the top 9 allergens, while not having companies add allergens into food to prevent lawsuits. It's unfair, it's unsafe and it needs to be addressed.

Recommended Solution: The Conference recommends...:

Lawmakers must create a prescription for changing labeling while not allowing manufacturers to change formulations to evade potential liability.

Submitter Information:

Name: Michelle Smith

Organization: Parent of a food allergy child for 19 years

Address: 22 Kentnor Street
City/State/Zip: Metuchen, NJ 08840
Telephone: (732)330-0997

E-mail: chellismith@hotmail.com

Issue: 2023 I-012

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended		No Action	
Delegate Action:	Accepted		_ Rejected		_	
All information above the line	e is for conference us	e only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
Establish written proc	edures for mana	aging foo	d allergy event	3		

Issue you would like the Conference to consider:

Food establishments should have written procedures that clearly state if and how food employees should respond to patrons having allergic reactions and severe allergic reactions resulting in anaphylaxis. Explicit guidance should be specified for, but not limited to: who is qualified to intervene during an allergic reaction event; whether a food establishment does or does not stock epinephrine injectors, antihistamines, and/or corticosteroids; and when food employees should seek medical help. The 2022 Food Code does not require written procedures for managing food allergy events.

Public Health Significance:

Approximately 10% of adults in the United States have food allergies, and retail food establishments are a frequent location of food allergy events (Gupta 2016, Radke 2017). A 2017 publication from the CDC's Environmental Health Specialist's Network (EHS-Net) reported that managers and staff were not confident in their establishment's ability to effectively respond to an emergency event arising from a food allergen exposure. Among 2,822 individuals included in the Food Allergy Research & Education registry were surveyed and over 50% of respondents who experienced a reaction at retail had informed restaurant staff of the allergy, over 25% of respondents also reported that allergens had been declared on the menu, and 14% occurred when allergens were declared on the menu and establishment staff were informed (Oriel 2020). While recent changes to the Food Code have improved requirements for informing consumers of common allergens, as well as food handler training for food allergens, responding to food allergy event is not addressed.

Currently, the person in charge (PIC) is required to demonstrate knowledge by "Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction" in section 2-102.11(C)(9). In section 2-103.11 (O) the PIC is required to ensure that: "EMPLOYEES are properly trained in FOOD safety, including FOOD allergy awareness, as

it relates to their assigned duties. FOOD allergy awareness includes describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction." Additionally, sections 3-602.11 (B)(5) and 3-602.12 (C) require labeling for major food allergens. However, the 2022 Food Code does not require any form of written plan or procedures for responding to an allergy event.

A written plan for responding to food allergy events can help food establishments to manage liability and designate appropriate individuals to respond, if appropriate. All food employees should feel confident about whether they should or should not intervene during a food allergy event, and if intervention is necessary, what intervention entails.

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA requesting the following to be added to 2-501 Responding to Contamination Events of the most recent edition of the Food Code

<u>2-502.11 Responding to Food Allergy Events.</u>

A FOOD ESTABLISHMENT shall have written procedures for EMPLOYEES to follow when responding to an allergic reaction, and severe allergic reactions resulting in anaphylaxis, experienced in the FOOD ESTABLISHMENT.

Submitter Information 1:

Name: Allison Howell

Organization: The Ohio State University/ Center for Foodborne Illness Research and

Prevention

Address: Parker Food Science and Technology Building2015 Fyffe Road

City/State/Zip: Columbus, OH 43210

Telephone: 419-305-5615

E-mail: howell.497@osu.edu

Submitter Information 2:

Name: Nicole Arnold

Organization: The Ohio State University/ Ohio State University Extension

Address: 381 Campbell Hall1787 Neil Avenue

City/State/Zip: Columbus, OH 43210

Telephone: 614-247-6109

E-mail: arnold.1363@osu.edu

Supporting Attachments:

- "Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff"
- "Characteristics of Food Allergic Reactions in the United States"

Issue: 2023 I-013

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 Is	ssue.						
Title:							
PSC14 Re-create Pla	n Review Committ	tee					

Issue you would like the Conference to consider:

Through their committee process, the Conference for Food Protection developed the Plan Review for Food Establishment 2016 guidance. Since the guidance was based on an earlier edition of the FDA Food Code (2013), it is recommended that the Plan Review Committee be re-created to update the document for conformance with the FDA 2022 Food Code and present findings at the 2025 CFP Biennial Meeting.

Public Health Significance:

Plan Review lays the foundation for an operation to be in long term compliance with the FDA Food Code. Jurisdictions conducting plan review benefit from technical guidance that is based on the most current edition of the FDA Food Code. A Conference for Food Protection document fosters consistency and standardization across jurisdictions for the plan review process.

Recommended Solution: The Conference recommends...:

Re-creation of the Conference for Food Protection Plan Review Committee with the following charges:

- 1. Review and update the 2016 Plan Review for Food Establishment guidance
- 2. Consider the inclusion of food safety management system components into the guidance document
- 3. Present an updated document for approval at the 2025 biennial meeting

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Catherine Feeney

Organization: CFP PSC - Rhode Island Department of Health

Address: 3 Capitol Hill Room 203 City/State/Zip: Providence, RI 02908

Telephone: 4012227717

E-mail: catherine.feeney@health.ri.gov

Supporting Attachments:

• "PSC Issue #14 list of supporting attachments"

Issue: 2023 I-014

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 Is	ssue.						
Title:							
Re-Establish Plan Re	view Committee	;					

Issue you would like the Conference to consider:

Plan Review Committee be re-established to review and update the Food Establishment Plan Review Manual and present their findings at the 2025 CFP Biennial Meeting. The current manual was last updated to be consistent with the FDA 2013 Food Code.

Public Health Significance:

The plan review process aims to prevent foodborne illness by verifying the installation and design of a sanitary facility. The process further includes menu review, food preparation, and food flow.

Recommended Solution: The Conference recommends...:

that the Plan Review Committee be re-established with the following recommendations:

- 1. update the Food Establishment Plan Review Manual, including Appendices, in accordance with the FDA 2022 Food Code, and
- 2. report back the committee's findings at the 2025 Biennial Meeting.

Submitter Information 1:

Name: Vasanthi Hofer

Organization: Maricopa County Environmental Services Department

Address: 301 W Jefferson StreetSuite 170

City/State/Zip: Phoenix, AZ 85003

Telephone: 6025066986

E-mail: Vasanthi.Hofer@maricopa.gov

Submitter Information 2:

Name: Bryan Hare

Organization: Maricopa County Environmental Services Department

Address: 301 W Jefferson StreetSuite 170

City/State/Zip: Phoenix, AZ 85003

Telephone: 6025066971

E-mail: Bryan.Hare@maricopa.gov

Issue: 2023 I-015

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: 2014 I-003; new or additional information has been included or attached.

Title:

Re-create the Plan Review Committee (PRC)

Issue you would like the Conference to consider:

The PRC was not re-created following the 2016 CFP Biennial meeting. Since this time, many trends have gained popularity in the food service industry, including shared kitchens, multi-concept ghost kitchens, etc. In addition, two new FDA Food Codes have been published since 2016. No updates to the four guidance documents produced by the PRC have been made during this time. The Conference should recreate the PRC to review and revise, if needed, all previously published PRC guidance documents available on the CFP website in light of the 2022 Food Code and popular industry practices.

Public Health Significance:

The PRC's work has historically provided recommendations to promote public health and prevent environmental health related illnesses through proper planning of food establishment construction. Previous guidance documents provided by this committee may be out of compliance with the current FDA Food Code and may fail to address recent trends and practices within the food service industry.

Recommended Solution: The Conference recommends...:

The PRC be recreated following the 2023 CFP Biennial meeting with the following charges:

- 1) Review and revise the following documents as needed to address changes in the latest version of the FDA Food Code, as well as latest and popular industry trends.
- a) Plan Review for Food Establishments 2016
- b) Recommended Guidance for Permanent Outdoor Cooking at Permanent Food Establishment 2014
- c) Recommended Guidance for Mobile Food Establishments 2014

- d) Temporary Food Establishments 2011
- 2) Determine if there are other guidance documents that should be developed to address newer technologies and begin the process of developing these resources.
- 3) Report back to the next biennial meeting of the Conference for Food Protection

Submitter Information:

Name: Michelle Haynes

Organization: Florida Department of Business and Professional Regulation

Address: 2601 Blair Stone Rd City/State/Zip: Tallahassee, FL 32399

Telephone: 850.717.1292

E-mail: michelle.haynes@myfloridalicense.com

Issue: 2023 I-016

Council	Accepted as	Accepted as				
Recommendation:	Submitted	Amended	No Action	_		
Delegate Action:	Accepted	Rejected				
All information above the line is for conference use only.						
Issue History:						
This is a brand new Is	ssue.					
Title:						
Re-creation of the Ha	nd Hygiene committ	ee				

Issue you would like the Conference to consider:

Foodservice and food processing operators spend considerable time and money training food handling staff to wash their hands, but there is no definition or standard for a clean hand. The Food Code includes definitions for a handwashing sink and a cleaning procedure for washing hands [2-301.12], but there is no standard for a clean hand. Finally, there is only one written process for cleaning hands. Further, given the potential for unintentional or intentional contamination of potable water (e.g., from flooding, aging infrastructure), alternative handwashing or hand cleansing methods are necessary.

Public Health Significance:

Per the CDC's website, washing hands with soap and water could reduce diarrheal deaths by up to 50%; if everyone washed their hands, approximately 1M lives would be saved (https://www.cdc.gov/hygiene/fast-facts.html). Handwashing is one of 4 preventive measures CDC lists for prevention of foodborne illness. Current recommendations require a 20 second handwash, which is a challenge for food service operators who, it has been suggested, should wash their hands 29 times per hour (Strobehn et al. 2008). A study of street food vendors found employees were not able to take the time to wash their hands when they had a large number of orders to prepare because of time pressure (Green et al, 2005). The Union of Concerned Scientists article <u>Troubled Waters</u> (Persad et.al, 2020), outlines the challenges with California's water system. Drought, flooding, and an aging infrastructure is putting stress on the water supply, leading to potential shortages, and risk for contamination. There is no reason to believe California is the only state experiencing such issues. Handwashing data from 436,125 foodservice inspections conducted between January 1, 2017 and December 31, 2019 indicate 15% of inspections found noncompliance for handwashing sinks (i.e., people could not wash their hands according to the written process) and 13% found non-compliance with handwashing requirements.

Recommended Solution: The Conference recommends...:

The re-creation of a Hand Hygiene Committee with the following charges:

- 1. Define what is a clean hand, e.g. a two-log bacterial load reduction on the hands.
- 2. Identify more than one method for effective hand washing when:
 - o Potable water is available, and
 - When potable water is not available.
- 3. Report the Committee's findings and recommendations at the next Biennial Meeting.

Submitter Information 1:

Name: Janet Buffer

Organization: Center for Foodborne Illness Research and Prevention

Address: 213 Parker Hall2015 Fyffe Road

City/State/Zip: Columbus, OH 43210

Telephone: (614)599-4541 E-mail: buffer.3@osu.edu

Submitter Information 2:

Name: Jim Mann

Organization: Handwashing for Life Address: 1216 Flamingo Parkway City/State/Zip: Libertyville, IL 43210

Telephone: 847-918-0254

E-mail: jmann@handwashingforlife.com

Supporting Attachments:

- "References"
- "Factors Impacting Food Workers' & Managers' Safe Food Preparation Practices"
- "Hand Washing Frequencies and Procedures Used in Retail Food Service"

Issue: 2023 I-017

Council Recommendation:	Accepted as Submitted		Accepted as _Amended	 No Action	
Delegate Action:	Accepted		_ Rejected	_	
All information above the line	e is for conference use	only.			
Issue History: This is a brand new Is	ssue.				
Title:					

Issue you would like the Conference to consider:

Amend 3-301.11(E)(6) to specify that double handwashing means washing hands twice whenever a hand wash is required and that nail brushes must be used every time hands are washed.

Amend Food Code 3-301.11 - Double Handwashing and Nail Brush Usage

Public Health Significance:

Bare hand contact with ready-to-eat foods is disallowed by the Food Code because of the potential for transmission of fecal-oral route pathogens by asymptomatic food employees. The Food Code allows food establishments to engage in bare hand contact under certain circumstances as long as two or more "control measures" are in place; two of the control measures specifically listed in the Food Code are "double handwashing" and "nail brushes." The Food Code does not provide any specific information about those control measures. Operators have interpreted this section of the Food Code to imply that double handwashing means washing hands inside the restroom and then again when returning to the kitchen (see attachments) and that nail brushes can be used occasionally instead of every time hands are washed.

In regards to the double hand washing issue, we have found several online sources, both from industry and regulatory, that defines "double handwashing" as washing hands in the restroom and then again in the kitchen. Further clarification would address the conflict between this interpretation and the guidance from the FDA.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the most current edition of the Food Code be amended as follows:

3-301.11 Preventing Contamination from Hands

- (E) FOOD EMPLOYEES not serving a HIGHLY SUSCEPTIBLE POPULATION may contact exposed, READY-TO-EAT FOOD with their bare hand if:
- (6) Documentation that FOOD EMPLOYEES contacting READY-TO-EAT FOOD with bare hands use two or more of the following control measures to provide additional safeguards to HAZARDS associated with bare hand contact:
- (a) Double handwashing,
- (i) For the purposes of this section, double handwashing means washing hands twice whenever required to do so as specified under § 2-301.14.
- (b) Nail brushes used every time hands are washed,
- (c) A hand antiseptic after handwashing as specified under § 2-301.16,
- (d) Incentive programs such as paid sick leave that assist or encourage FOOD EMPLOYEES not to work when they are ill, or
- (e) Other control measures approved by the REGULATORY AUTHORITY; and

Submitter Information:

Name: Matthew Brandt

Organization: Colorado Department of Public Health and Environment

Address: 4300 Cherry Creek Dr SouthA-2

City/State/Zip: Denver, CO 80246

Telephone: 7205500322

E-mail: matthew.brandt@state.co.us

Supporting Attachments:

- "California Double Handwashing"
- "West Virginia Double Handwashing"
- "ResPro Double Handwashing"
- "State Food Safety_Double Handwashing"

Issue: 2023 I-018

Council	Accepted as	Accepted as		
Recommendation:	Submitted _	Amended	No Action	
Delegate Action:	Accepted _	Rejected		
All information above the line	e is for conference use onl	y.		
Issue History:				
This is a brand new Is	ssue.			
Title:				
Chemical Sanitizing to	est strips Expiration	Date		

Issue you would like the Conference to consider:

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration. Concentration of the SANITIZING solution shall be accurately determined using a test kit or other device according to manufacturer instructions. Language should be added regarding expired test strips.

Public Health Significance:

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

These strips ensure that the right dilutions have been done & proper strengths of sanitizing/disinfection chemicals will work as needed.

According to manufacturer guidelines, expired tests strips may no longer be accurate in assessing the concentration or pH of the sanitizer and therefore, would no longer hold up as an accurate test to take enforcement on.

Some operators and inspectors may not realize that their test strips expire and could be checking their concentrations with expired strips that may not be giving an accurate reading, producing a potential health risk by being under or over the accepted limit. This false reading could cause someone to not be sanitizing at a high enough concentration which would be an issue, or they could be over sanitizing which would also lead to a potential health risk.

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA requesting that Section 4-501.116 be modified as follows (new language is underlined)

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

- 1. Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device.
- 2. <u>Sanitizing test kit shall be used according to manufacture instructions and date marking limitations.</u>

Submitter Information 1:

Name: Michael Otzelberger

Organization: WI DATCP

Address: 2811 Agriculture Drive City/State/Zip: Madison, WI 53708

Telephone: 16087330410

E-mail: michael.otzelberger@wisconsin.gov

Submitter Information 2:

Name: Lindy Wiedmeyer

Organization: City of Racine Public Health Dept

Address: 730 Washington Ave City/State/Zip: Racine, WI 53403 Telephone: 262-636-9567

E-mail: Lindy.wiedmeyer@cityofracine.org

Issue: 2023 I-019

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: 2020-I-015; the recommended solution has been revised.

Title:

Report - Foodborne Illness Investigation Committee

Issue you would like the Conference to consider:

The Foodborne Illness Investigation Committee seeks acknowledgement of the committee's final report, with thanks to the members of the committee for their work.

Public Health Significance:

Every year in the United States there are millions of cases of foodborne illness and a majority of these cases are attributable to food establishments (Jones & Angulo, 2006). Investigation of these reports of illness is of paramount importance to a) stop additional people from being exposed and becoming ill; b) understand the system failure within a food establishment that led people to become ill; and c) identify a source of contaminated food that may have entered the food establishment. In addition, quickly identifying the source of outbreaks through purchase records is crucial to identify the specific product so that public health advisories can warn consumers to avoid certain implicated products instead of broad categories (such as Romaine, tomatoes, or papayas). Such advisories have an enormous economic impact on the food sector and retail food establishments. Solving outbreaks quickly using consumer purchase records also reduces the number of people that may become ill and subsequent industry liability. Some regulatory authorities have been denied access to consumer food product purchase information, and clarification that the Food Code provides authority to access these records will reduce illnesses and associated economic impacts.

The Food Code appendix 2's supporting documents reference the Voluntary National Retail Food Program Standards (VNRFPS) along with the Council to Improve Foodborne Outbreak Response's Guidelines for Foodborne Outbreak Response. Both documents include the need for investigating foodborne illness outbreaks and having the ability to trace food back to its source.

Jones, T. F., & Angulo, F. J. (2006). Eating in Restaurants: A Risk Factor for Foodborne Disease? *Clinical Infectious Disease*, *43*, 1324-1328. doi:1058-4838/2006/4310-0017

Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., . . . Griffin, P. M. (2011). Foodborne illness acquired in the United States--major pathogens. *Emerg Infect Dis*, *17*(1), 7-15. doi:10.3201/eid1701.091101p1

Recommended Solution: The Conference recommends...:

- 1. Acknowledgement of the Foodborne Illness Investigation Final Report.
- 2. Thanking the Committee members for their work.
- 3. Disbanding the committee since all charges have been met.
- 4. Posting a PDF of the Committee developed "Food Establishment Consumer Purchase Best Practices" guidance document for CFP branding under Conference-Developed Guides and Documents on the CFP website.

Submitter Information 1:

Name: Catherine Feeney

Organization: Rhode Island Department of Health

Address: 3 Capitol Hill Room 203 City/State/Zip: Providence, RI 02908

Telephone: 4015800893

E-mail: catherine.feeney@health.ri.gov

Submitter Information 2:

Name: Robert Brown

Organization: Whole Foods Market
Address: 550 Bowie Street
City/State/Zip: Austin, TX 78703
Telephone: 512-944-7405

E-mail: Robert.Brown@wholefoods.com

Content Documents:

- "Final Report Foodborne Illness Investigation Committee"
- "Food Establishment Best Practices for Providing Consumer Purchase Informati"
- "Foodborne Illness Investigation Committee Roster"

Supporting Attachments:

"SHOPPER HISTORY Best Practices for Use during Foodborne Illness Investigati"

Issue: 2023 I-020

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: 2020-I-015; the recommended solution has been revised.

Title:

FBIIC2-Interpret if 2022 FDA Food Code Provides Investigation Authority

Issue you would like the Conference to consider:

The Committee would like for the U.S. Food and Drug Administration (FDA) to provide a Food Code interpretation to inform regulatory authorities that Food Code Section 8-304.11(H) coupled with Section 8-402.11 provides sufficient authority for the regulatory authority to investigate and obtain information, including records, that are needed as part of the foodborne illness investigation from food establishments.

Food Code section 8-402.11 states that:

After the REGULATORY AUTHORITY presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the PERSON IN CHARGE shall allow the REGULATORY AUTHORITY to determine if the FOOD ESTABLISHMENT is in compliance with this Code by allowing access to the establishment, allowing inspection, and providing information and records specified in this Code and to which the REGULATORY AUTHORITY is entitled according to LAW, during the FOOD ESTABLISHMENT'S hours of operation and other reasonable times.

Food Code section 8-304.11(H) states that the permit holder shall:

Comply with directives of the REGULATORY AUTHORITY including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the REGULATORY AUTHORITY in regard to the PERMIT HOLDER'S FOOD ESTABLISHMENT or in response to community emergencies:

Public Health Significance:

Every year in the United States there are millions of cases of foodborne illness (Scallan et al., 2011), and a majority of these cases are attributable to food establishments (Jones & Angulo, 2006). Investigation of these reports of illness is of paramount importance to a) stop additional people from being exposed and becoming ill; b) understand the system

failure within a food establishment that led people to become ill; and c) identify a source of contaminated food that may have entered the food establishment.

The Food Code explicitly gives regulators authority to conduct inspections. Authority to access the facility, conduct the inspection, and enforce the Food Code is clear throughout Chapter 8 - Compliance and Enforcement. However, there is no direct reference to foodborne illness investigations which are more focused on obtaining information, including traceback records, and customer purchase history needed to investigate and quickly identify the source of the outbreak and to ensure that control measures are in place to prevent additional illnesses. In addition to public health, the economic impact and industry liability can be mitigated when the source of a foodborne illness outbreak is quickly identified.

The Food Code Annex 2's supporting documents reference the Voluntary National Retail Food Program Standards (VNRFPS) along with the Council to Improve Foodborne Outbreak Response's Guidelines for Foodborne Outbreak Response. Both documents include the need for investigating foodborne illness outbreaks.

Despite not including investigations specifically in the Food Code, an FDA interpretation is needed to determine if that authority is implied.

Jones, T. F., & Angulo, F. J. (2006). Eating in Restaurants: A Risk Factor for Foodborne Disease? *Clinical Infectious Disease*, *43*, 1324-1328. doi:1058-4838/2006/4310-0017

Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., . . . Griffin, P. M. (2011). Foodborne illness acquired in the United States--major pathogens. *Emerg Infect Dis*, *17*(1), 7-15. doi:10.3201/eid1701.091101p1

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting an interpretation of the Food Code clarifying that Section 8-304.11(H) coupled with Section 8-402.11 and other relevant sections provide sufficient authority for a regulatory authority to conduct a foodborne illness investigation and obtain access to needed information.

Submitter Information 1:

Name: Catherine Feeney

Organization: Rhode Island Department of Health

Address: 3 Capitol Hill Room 203 City/State/Zip: Providence, RI 02908

Telephone: 4015800893

E-mail: catherine.feeney@health.ri.gov

Submitter Information 2:

Name: Robert Brown

Organization: Whole Foods Market Address: 550 Bowie Street City/State/Zip: Austin, TX 78703

Telephone: 5129447405

E-mail: Robert.Brown@wholefoods.com

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.

Issue: 2023 I-021

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: 2020-I-015; the recommended solution has been revised.

Title:

FBIIC3-Amend 2022 FDA Food Code to Provide Access for FBI Investigation

Issue you would like the Conference to consider:

The Committee would like for the U.S. Food and Drug Administration (FDA) to add language to provide the regulatory and/or health authority access to investigate reports of foodborne illness.

Currently, the Food Code does not provide access for regulatory/health authorities to gather information in a food establishment for a foodborne illness investigation. It contains language to assess information on code compliance (what is currently occurring) and plan review (what will occur in the future) but lacks language to assess and gather historical information such as processing record review, product traceback, purchase history, etc. (which is the primary focus of a foodborne illness investigation).

Furthermore, Standard 5 of the FDA Voluntary National Retail Food Program Standards (VNRFPS) assesses whether a regulatory program has developed policies to investigate foodborne illness. These policies implicitly rely on States' public health authorities for preventing disease transmission. Language permitting access in the Food Code will ensure that all jurisdictions that adopt the Food Code will have the same baseline authority to investigate foodborne illness.

Public Health Significance:

Every year in the United States there are millions of cases of foodborne illness (Scallan et al., 2011), and a majority of these cases are attributable to food establishments (Jones & Angulo, 2006). Investigation of these reports of illness is of paramount importance to a) stop additional people from being exposed and becoming ill; b) understand the system failure within a food establishment that led people to become ill; and c) identify a source of contaminated food that may have entered the food establishment.

The Food Code Annex 2's supporting documents reference the Voluntary National Retail Food Program Standards along with the Council to Improve Foodborne Outbreak

Response's Guidelines for Foodborne Outbreak Response. Both documents include the need for investigating foodborne illness outbreaks.

Conducting investigations into how people became sick is an integral part of a food safety program. By understanding the system failures that resulted in a foodborne outbreak, practices can be changed to prevent the failure from happening in the future. Because of the investigation's importance, FDA includes this subject matter in VNRFPS Standard 2 under the epidemiology construct and International Food Protection Training Institute (IFPTI) includes this as a foundational element for the basic competency level. Additionally, the important nature of this work has led to the development of additional advanced courses (e.g., FDA ER324 Epi-Ready for Response Teams, and CDC's Environmental Assessment Training Series).

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that Chapter 8 of the most current published version of the Food Code be amended to include:

The REGULATORY AUTHORITY shall act when it has reasonable cause to believe that a FOOD ESTABLISHMENT may be associated with a foodborne illness investigation; by assessing all relevant facilities, EQUIPMENT, FOOD, personnel, and available records.

Submitter Information 1:

Name: Catherine Feeney

Organization: Rhode Island Department of Health

Address: 3 Capitol Hill Room 203 City/State/Zip: Providence, RI 02908

Telephone: 4015800893

E-mail: catherine.feeney@health.ri.gov

Submitter Information 2:

Name: Robert Brown

Organization: Whole Foods Market Address: 550 Bowie Street City/State/Zip: Austin, TX 78703 Telephone: 5129447405

E-mail: Robert.Brown@wholefoods.com

Issue: 2023 I-022

Council Recommendation:	Accepted as Submitted	Accepted as _Amended	 No Action	
Delegate Action:	Accepted	_ Rejected	_	
All information above the line	e is for conference use only.			
Issue History: This is a brand new Is	ssue.			
Title:				

Issue you would like the Conference to consider:

We propose amending Food Code 3-501.14 to include an option to cool time and temperature control for safety (TCS) foods at a depth of 2 inches or less, uncovered, and refrigerated, without time and temperature monitoring.

Amend Food Code to allow cooling without time and temperature monitoring.

Hot foods should be cooled rapidly to minimize pathogen growth and prevent outbreaks. Unfortunately, rapid cooling is often difficult for restaurants to accomplish and for inspectors to verify. The Food Code requirements for achieving proper cooling rely on frequent monitoring of time and temperatures. This monitoring is not always feasible for restaurant operators because of the time required to adequately monitor the cooling process.

The Food Code outlines methods that can promote rapid cooling of TCS foods but does not specify how to apply the methods to various situations or whether some methods are more effective than others. Inspectors and operators are left to evaluate every method, or combination of methods, to determine which meet the time requirement. We recommend that operators and inspectors be allowed to also focus on specified cooling methods that are known to facilitate guick and proper cooling without additional time monitoring.

The recommended solution is intended to reduce the complexities of monitoring cooling time/temperature parameters by offering a safe, simple, and clear alternative: foods can be cooled uncovered, in a refrigerated environment at a depth of 2 inches or less, with no additional time and temperature monitoring required.

Public Health Significance:

Our proposed option of refrigerated cooling at an uncovered depth of 2 inches or less, provides a clear cooling standard for operators. This option is also beneficial to inspectors, as it is easy to verify during an inspection and easy to train new operators on safe cooling methods. Ultimately, this option will potentially reduce operating costs for food establishments and reduce time dedication for operators and inspection staff while providing a more reliable way to reduce foodborne illness.

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling hot foods too slowly is one of the most common pathogen growth factors contributing to restaurant-related outbreaks (Gould *et al.*, 2013).

The FDA Food Code contains specific time and temperature parameters recommended to achieve proper cooling and suggests methods that can promote rapid cooling. Even with these guidelines restaurants continue to struggle with proper cooling (Hedeen & Smith, 2020; Wittry *et. al,* 2022). An FDA study assessing the occurrence of foodborne illness risk factors in retail settings found that cooling was out of compliance in 72% (196) of the full-service restaurants where cooling was observed (U.S. FDA, "Report on the occurrence", 2018)

Washington State has already adopted this alternative cooling option (in place for 17 years) and it is strongly preferred by operators within the state. Seattle-King County Health Department conducted a risk factor study in 2016, which included 2115 restaurants, and found that 75% of operators reported using the 2-inch cooling option to cool hot foods. Only 12% of operators reported using time and temperature monitoring as outlined by the FDA food code (unpublished data, Seattle-King County Health Department). Since 2-inch cooling without time-temperature monitoring was implemented, no foodborne outbreaks have been associated with this cooling method.

The cooling standard in Washington shows that providing an option to cool at a depth of 2 inches or less, ventilated, and refrigerated provides a solution that is consistently safe and that restaurant operators have adopted enthusiastically.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting 3-501.14 of the current Food Code be amended as specified below:

- 3-501.14 Cooling.
- (A) Except as specified under (B) of this section, Cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled:
- (1) Within 2 hours from 57°C (135°F) to 21°C (70°F); P and
- (2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less. P
- (B) As an alternative to the cooling provisions of subsection A of this section, FOODS that are being continuously cooled must be cooled in a shallow layer of two inches or less, uncovered, in cooling or cold holding EQUIPMENT maintaining an ambient temperature of 5°C (41°F) or less.
- (<u>BC</u>) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled within 4 hours to 5°C (41°F) or less if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna. ^P
- (Θ) Except as specified under \P (Θ) of this section, a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in \P 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less. P

(ĐE) Raw EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less. P

Submitter Information 1:

Name: Nicole Hedeen

Organization: Minnesota Department of Health

Address: 625 Robert St. N City/State/Zip: St. Paul, MN 55155

Telephone: 651.201.4075

E-mail: nicole.hedeen@state.mn.us

Submitter Information 2:

Name: Susan Shelton

Organization: Washington State Department of Health

Address: 111 Israel Rd. SE City/State/Zip: Tumwater, WA 98501

Telephone: 509.212.1206

E-mail: susan.shelton@doh.wa.gov

Supporting Attachments:

- "Summary of Issue to Amend 3-501-14"
- "Supplemental Materials"
- "Supporting Publications"
- "National Restaurant Association Letter of Support"
- "Taco Time Letter of Support"

Issue: 2023 I-023

Council Recommendation:	Accepted as Submitted		Accepted as Amended	 No Action	
Delegate Action:	Accepted		Rejected	-	
All information above the line	is for conference use or	nly.			
Issue History: This is a brand new Is	ssue.				
Title:					

Issue you would like the Conference to consider:

A recommendation is being made to include alternate cooking time/temperature combinations as found in USDA FSIS Appendix A as acceptable cooking parameters for 3-502.12 (D)(2)(b).

Amend Food Code to Update Final Cook Temps for Sous Vide under 3-502.12

Public Health Significance:

Sous vide is translated to under vacuum from French. This type of cooking uses heat stable pouches to cook foods in a controlled environment. Some of the benefits of sous vide cooking are that the food cooks in its juices, enhancing flavor, and the consistent temperature provides an environment where food does not become overcooked. The food safety aspects of the low temperature, long processing time used in sous vide have been studied, and temperatures below the final cook temperatures provided in the FDA Food Code 3-401.11(A)(3) have been researched. One study titled *Effect of Time and Temperature on Physicochemical and Microbiological Properties of Sous Vide Chicken Breast Fillets* found that the optimum time/temperature combination for cooking chicken using sous vide is 60°C for 60 minutes.

FDA Food Code has made allowances for some reduced oxygen packaging (ROP) to be done without requiring a variance, as stated in 3-502.12. This section of the code allows for food establishments to use a HACCP Plan only for some ROP methods without applying for a variance, since the validation science is well-known. However, 3-502.12 (D)(2)(b) requires that food cooked using sous vide methods must reach final cook temperatures that are provided in 3-401.11(A)-(C). Most retail food establishments that cook using sous vide want to use alternate cooking time/temperatures, so this requirement makes it impractical for establishments to use 3-502.12 to ROP without a variance.

USDA FSIS has written a guidance document that is used to evaluate the production of ready-to-eat foods with respect to salmonella and other pathogens. This document, titled "FSIS Cooking Guideline for Meat and Poultry Products (Appendix A)" has been well

researched in terms of the science behind the pathogen destruction parameters. In this document, there are many additional time/temperature combinations that result in the equivalent destruction of pathogens as the FDA Food Code 3-401.11 parameters. Although relative humidity is included in this document, relative humidity would not be a factor specifically for sous vide cooking, as the food is being cooked in the package. Since the science behind the parameters in this document is widely accepted, cooking sous vide using these parameters does not need additional validation. Therefore, a HACCP Plan for a sous vide product cooked using these parameters should not require a variance.

There is current precedent for inclusion of the FSIS Appendix A in the FDA Food Code. FDA Food Code Section 3-401.11(B) provides some time/temperature combinations acceptable for cooking of whole meat roasts. This does not apply to the current issue however, since poultry products are not included. Providing uniform guidance for cooking across the agencies would increase industry confidence and promote consistency among regulators.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting that the most recent version of the FDA Food Code, Section 3-502.12(D)(2)(b), be amended to include the "FSIS Cooking Guideline for Meat and Poultry Products" as acceptable final cooking parameters for reduced oxygen packaging without a variance.

Submitter Information:

Name: Veronica Bryant

Organization: NC DHHS

Address: 1632 Mail Service Center

City/State/Zip: Raleigh, NC 27699 Telephone: 919-218-6943

E-mail: veronica.bryant@dhhs.nc.gov

Supporting Attachments:

• "Effect of Time and Temperature on Physicochemical Properties of Chicken"

Issue: 2023 I-024

Council Recommendation:	Accepted as Submitted	Accept Amend		_ No Action _		
Delegate Action:	Accepted	Rejecte	ed	_		
All information above the line is for conference use only.						
Issue History:						
This is a brand new Issue.						
Title: Amend Food Code - S	Strike "leaking a	utomatic fire sori	nkler heads"			

Issue you would like the Conference to consider:

The National Fire Sprinkler Association (NFSA) requests that the wording "leaking automatic fire sprinkler heads" be removed from Pages 66, 111 and 127 in the US FDA 2022 Food Code. This language should be stricken as US fire, building, and property maintenance codes address this matter and are enforced by other code officials and authorities having jurisdiction (AHJ) through nationally adopted model codes and standards. These codes and standards are developed through a full, open, consensus-based process. Language to be changed is here:

FDA 2022 Food Code

Page 66 3-305.12 Food Storage, Prohibited Areas (G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed.

Page 111 4-401.11 Equipment.... (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed.

Page 127 4-903.12 Prohibitions. (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed.

Public Health Significance:

The FDA Food Code language "leaking automatic fire sprinkler heads" should be stricken from the 2022 Food Code as fire sprinklers are now regulated by available, enforceable, and most pertinent fire protection codes and standards that address leaking sprinklers and all other fire sprinkler equipment. The specific code and standard references are here: IFC (International Fire Code), Section 903.5 (from 2000 to the current 2021 edition) requires the inspection, testing and maintenance of fire sprinklers to be per NFPA 25.

Since 2000, commercial buildings in the United States have been designed, built, maintained, and inspected under the International Building Code (IBC) and the International Fire Code (IFC). These codes and referenced standards require leaking fire

sprinkler heads or any leaking fire protection equipment, including piping, to be repaired immediately. These same codes have shifted the inspection, and enforcement of building fire protection maintenance through more direct local and legally required mechanisms - usually fire department/fire marshals.

ICC free code viewer: https://codes.iccsafe.org

NFPA (National Fire Protection Association) 1 Fire Code, Section 13.3.3.4.1.1.1 (from the 1997 to 2021 edition) requires the inspection, testing and maintenance of fire sprinklers to be per NFPA 25.

NFPA (National Fire Protection Association) 25, Section 5.2 (beginning in the 2002 Version), first requires leaking fire sprinkler heads, as well as other leaking equipment, piping, etc. to be replaced.

NFPA (National Fire Protection Association) free code viewer: www.nfpa.org/1 and www.nfpa.org/101

History

The 1986 Conference for Food Protection first developed food safety regulatory rules in 1986 and the processes for all US states to adopt these rules. Conversely, National Building and Fire Protection regulatory rules (by the ICC - International Code Council and NFPA - National Fire Protection Association) were also developed and adopted in the mid-90s and early 2000s. The Conference for Food Protection initially regulated fire protection maintenance concerns around food areas because there was not a nationally accepted building and fire code in prior to the 1990's. Today, several codes and standards require leaking fire sprinklers to be replaced and there is no reason for fire protection to be addressed by the food code.

Today, and since 2000, all editions of the US model construction code, i.e., the IBC, IFC, IPMC (International Property Maintenance Code), NFPA 1 Fire Code, and the NFPA 101 Life Safety Code all reference specific inspection, testing, and maintenance standards (like NFPA 25, the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems) for all existing buildings and occupancies. This referenced and enforced standard requires leaking sprinklers to be replaced immediately by the building owner through licensed contractors and enforced by local code officials and authorities having jurisdiction (AHJ).

Recommended Solution: The Conference recommends...:

A letter be sent to the FDA requesting the current Food Code be amended as follows: 3-305.12 Food Storage, Prohibited Areas.

FOOD may not be stored:

- (A) In locker rooms;
- (B) In toilet rooms;
- (C) In dressing rooms;
- (D) In garbage rooms;
- (E) In mechanical rooms;

- (F) Under sewer lines that are not shielded to intercept potential drips;
- (G) Under leaking water lines, including leaking automatic fire sprinklerheads, or under lines on which water has condensed;
- (H) Under open stairwells; or
- (I) Under other sources of contamination
- 4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.
- (A) Except as specified in ¶ (B) of this section, EQUIPMENT, a cabinet used for the storage of FOOD, or a cabinet that is used to store cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be located:
- (1) In locker rooms;
- (2) In toilet rooms;
- (3) In garbage rooms;
- (4) In mechanical rooms;
- (5) Under sewer lines that are not shielded to intercept potential drips;
- (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
- (7) Under open stairwells; or
- (8) Under other sources of contamination.
- 4-903.12 Prohibitions.
- (A) Except as specified in ¶ (B) of this section, cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be stored:
- (1) In locker rooms;
- (2) In toilet rooms;
- (3) In garbage rooms;
- (4) In mechanical rooms;
- (5) Under sewer lines that are not shielded to intercept potential drips;
- (6) Under leaking water lines including leaking automatic fire sprinklerheads or under lines on which water has condensed:
- (7) Under open stairwells; or
- (8) Under other sources of contamination.

Submitter Information 1:

Name: Cindy Giedraitis

Organization: National Fire Sprinkler Association

Address: PO Box 10403

City/State/Zip: College Station, TX 77842

Telephone: 979-324-8934 E-mail: cindy@nfsa.org

Submitter Information 2:

Name: Jeffrey Hugo

Organization: National Fire Sprinkler Associatoin

Address: 1088 West Borton road City/State/Zip: Essexville, MI 48732

Telephone: 845-519-5963 E-mail: hugo@nfsa.org

Supporting Attachments:

• "All 3 IFC and NFPA Code References for FDA Food Code"

Issue: 2023 I-025

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 Is	ssue.				
Title:					

Amend Food Code to include procedures for clean-up of vomit and diarrhea

Issue you would like the Conference to consider:

The clean-up of vomiting and diarrheal events, as stated in the 2022 FDA Food Code, does not specify what exactly is required for a proper response. Due to vague language in the 2022 FDA Food Code, regulatory agencies have deferred to the 2022 FDA Food Code 2-501.11 Annex 3 Public Health Reasons, which lists what a food establishment should "consider" (11 bullet points) when developing a written plan, in order to minimize the spread, exposure, and contamination. The word "consider" leads to confusion, a lack of understanding, and inconsistencies of what is actually required (at a bare minimum) among industry and regulatory agencies.

Public Health Significance:

"According to the CDC, Norovirus is the leading cause of foodborne disease outbreaks in the United States." (2022 FDA Food Code 2-501.11 Annex 3- Public Health Reasons/Administrative Guidelines)

"When an employee, customer, or other individual vomits or has a diarrheal event in a food establishment, there is a real potential for the spread of harmful pathogens in the establishment. Putting the proper response into action in a timely manner can help reduce the likelihood that food may become contaminated and that others may become ill as a result of the accident." (2022 FDA Food Code 2-501.11 Annex 3-Public Health Reasons/Administrative Guidelines)

A timely response cannot occur without having the following in a written plan and onsite:

- EPA registered disinfection products sufficient to inactivate norovirus
- Personal Protective Equipment (PPE)
- Cleaning and disinfecting equipment
- Procedures for cleaning, sanitizing, and disinfecting

Procedures for containment and removal

"Effective clean-up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact surfaces and disinfecting countertops and floors, such as certain quaternary ammonium compounds, may not be effective against Norovirus. It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration." (2022 FDA Food Code 2-501.11 Annex 3- Public Health Reasons)

"Additionally, exposed food employees are also at risk of contracting Norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers." (2022 FDA Food Code 2-501.11 Annex 3-Public Health Reasons)

"Once such an episode has occurred, timely effective clean-up is imperative. Key to achieving an appropriate, timely response by food employees is the availability and access to a written plan upon which to refer to for reference." (2022 FDA Food Code 2-501.11 Annex 3- Public Health Reasons)

The recommended language was developed to provide guidance to assist the operator and regulators when a vomiting and/or diarrheal event occurs. Adding clarifying language and specific requirements to the FDA Food Code will:

- Create consistency in requirements among industry and regulatory agencies.
- Better support regulatory agencies in the enforcement of requirements.
- Allow for a proper response in a timely manner due to having specific supplies onsite.
- Minimize the spread, exposure, and contamination due to adding the following supplies to the requirements: EPA registered disinfection products sufficient to inactivate norovirus, PPE, and cleaning and disinfecting equipment.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting Section 2-501.11 of the most current edition of the Food Code be amended as follows:

2-501.11 Clean-up of Vomiting and Diarrheal Events.

A FOOD ESTABLISHMENT shall have procedures for EMPLOYEES to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the FOOD ESTABLISHMENT. The procedures shall address the specific actions EMPLOYEES must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter and shall include the following:

(A) Availability of effective disinfectants, such as EPA registered disinfection products sufficient to inactivate norovirus, personal protective EQUIPMENT, and other cleaning and disinfecting EQUIPMENT and appurtenances intended for response and their proper use. ^{Pf}

- (B) Procedures for cleaning, sanitizing, and disinfection of surfaces and cleaning and disinfecting EQUIPMENT that may have become contaminated. Pf
- (C) Procedures for containment and removal of any discharges, cleaning and disinfecting EQUIPMENT, and food that may have been exposed. Pf

Submitter Information 1:

Name: Katie Matulis

Organization: Wisconsin Department of Agriculture

Address: 2922 N. Palmer Street City/State/Zip: Milwaukee, WI 53212

Telephone: 414-369-9047

E-mail: katie.matulis@wisconsin.gov

Submitter Information 2:

Name: Carrie Pohjola

Organization: Wisconsin Department of Agriculture

Address: 2922 N. Palmer Street City/State/Zip: Milwaukee, WI 53212

Telephone: 715-579-9487

E-mail: carrie.pohjola@wisconsin.gov

Issue: 2023 I-026

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:							
Add off-site warewashing facilities for multiuse articles to Food Code							

Issue you would like the Conference to consider:

The language in the Food Code does not provide adequate guidance surrounding off-site cleaning of multiuse utensils, tableware, take-home food containers and take-out beverage containers (multiuse articles). While some jurisdictions approve variances (see supporting attachments) for the use of off-site warewashing facilities for multiuse articles, the Food Code does not explicitly address or allow this, creating a confusing patchwork of regulations amid increasing public concern over single-use articles.

Public Health Significance:

While the Conference for Food Protection is currently creating a definition for consumerowned reusable containers and the appropriate handling of Time/Temperature Control for Safety Foods when sold in reusable containers (Safe Use of Reusable Container Committee (Issue 2020-I-024)), not all consumers will want to bring their own container. Food handling regulations must accommodate the need for off-site warewashing and associated transportation of multiuse articles to reduce waste and excess packaging. Reducing uncertainty in the language of the regulation encourages nonhazardous time/temperature controlled practices that are safe, convenient and sensitive to the beliefs and desires of many consumers.

Updates to the Food Code will have benefits for state regulatory agencies who rely on federal synthesis of these pertinent issues. Significant time and resources can be saved with the adoption of guidance that is clear and uniformly enforceable, removing the need for individual local variances. Consensus on off-site warewashing standards and associated transportation for multiuse articles is critical for agencies and industry, along with public health and environment.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting Part(s) 3-3, 4-4, 4-6, 4-7, 4-9 and/or Annex 3 (whichever portions FDA deems appropriate) of the most current edition of the Food Code be amended (using applicable language developed by FDA) to clarify how to safely use off-site warewashing facilities for multiuse utensils, tableware, take-home food container and take-out beverage container cleaning.

Submitter Information 1:

Name: Kelley Dennings

Organization: Center for Biological Diversity
Address: 1411 K Street NWSte 1300
City/State/Zip: Washington, DC 20005

Telephone: 919-355-8102

E-mail: kdennings@biologicaldiversity.org

Submitter Information 2:

Name: Heather Trim

Organization: Zero Waste Washington Address: 816 2nd AveSte 200 City/State/Zip: Seattle, WA 98104

Telephone: 206-441-1791

E-mail: heather@zerowastewashington.org

Supporting Attachments:

- "ME Refilling Returnables Policy 2021, Page 2, Section II "Variance""
- "Plymouth MA Mitigating Use of Plastics 2019, Page 1, Bullet 2"
- "CA Bring Your Own Container Act vendor fact sheet 2019, Page 1 "rent""
- "Philly Zero Waste Guide Food Establishments 2021, Page 4"
- "WA State Retail Food Code, 2022, page 38, Section 03348, (2b)"

Issue: 2023 I-027

Council Recommendation:	Accepted as Submitted		Accepted as Amended	No Action		
Delegate Action:	Accepted		_ Rejected			
All information above the line	e is for conference use	e only.				
Issue History:						
This is a brand new Issue.						
Title: Amend Food Code – Packaging Requirements for Vended TCS Foods						

Issue you would like the Conference to consider:

Amend 3-305.13 to allow for Time/Temperature Control for Safety foods dispensed from vending machines to be packaged within the vending machine.

Public Health Significance:

Complex vending machines have become more commonplace throughout the United States. Vending machines, which traditionally have been used to dispense pre-packaged, non-TCS foods, now have the capability to cook and package TCS foods entirely within the machine. These machines, which meet other Food Code requirements, like section 4-204.111 requiring automatic temperature-triggered lockouts, are often equipped with self-cleaning systems, which can clean and sanitize food-contact surfaces between products. Furthermore, these machines have the capability to safely store food packaging and package food in a sanitary manner.

Certification bodies already certify machines that vend time/temperature control for safety foods into packaging that is stored within the vending machine. Harmonizing the requirements between the Food Code and certification bodies will help remove undue confusion for equipment developers, certifiers, and regulators. Furthermore, adopting additional language addressing how foods are packaged within a vending machine will help bring parity between regulations and current vending technology.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting Section 3-305.13 and Annex 3 of the current Food Code be amended as follows:

3-305.13 Vended Time/Temperature Control for Safety Food, Original Container.

(A) Except as specified in ¶(B) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD dispensed through a VENDING MACHINE shall be in the PACKAGE in

which it was placed at the FOOD ESTABLISHMENT or FOOD PROCESSING PLANT at which it was prepared.

(B) FOODS that are to be PACKAGED within the VENDING MACHINE must be held, PACKAGED, and dispensed in a sanitary manner.

Annex 3. Public Health Reasons/Administrative Guideline

3-305.13 Vended Time/Temperature Control for Safety Food, Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended time/temperature control for safety food allows microbes that may be present an opportunity to contaminate the food. Therefore, it is critical that holding, packaging, and dispensing of food within a vending machine be performed in a safe and hygienic manner. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, time/temperature control for safety foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

Submitter Information 1:

Name: **Christopher Rupert** Organization: **Compass North America** 2400 Yorkmont Road Address: City/State/Zip: Charlotte, NC 28217 Telephone: (704) 315-3422

E-mail: christopher.rupert@compass-usa.com

Submitter Information 2:

Christine Summers Name:

Organization: Canteen

Address: 2400 Yorkmont Road Charlotte, NC 28217 City/State/Zip: Telephone: (425) 281-6397

E-mail: christine.summers@compass-usa.com

Issue: 2023 I-028

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 Is	ssue.							
Title:								

Issue you would like the Conference to consider:

Creation of a Committee - E-Commerce Best Practices

During COVID, grocery stores saw a drastic spike in how consumers obtained their foods. Stores in Wisconsin reported 5 years of growth in 6 months' time as well as E-Commerce sales increasing 4 times greater than normal. Stores were not equipped for shopping the increase in orders and did not have storage areas to hold shopped items while they were in the queue for pick up. Since then, E-Commerce shopping has become a routine way of feeding families. Concerns regarding E-Commerce shopping have arisen including cross contamination of raw proteins bagged with ready to eat foods, TCS foods not properly held refrigerated or frozen, surface characteristics in storage areas and equipment concerns. Questions have also arisen on who is the responsible party for the purchased items that have not been yet picked up by the consumer.

Public Health Significance:

The creation of guidance on how to address food safety requirements for E-Commerce would provide benefits for both regulators and industry. It would detail how to safely handle foods as well as construction requirements for areas used for holding shopped items. It will also benefit industry in providing training when employees are shopping for items as well as what to do with foods that might not be picked up by the consumer and responsible parties during the process.

Recommended Solution: The Conference recommends...:

that an E-Commerce Committee be created and charged with the following:

- 1. Identify best practices and existing guidance that pertain to E-Commerce shopping at retail.
- 2. Develop a comprehensive guidance document for retail food establishments with best practices specific to E-Commerce shopping to ensure general Food Code

recommendations are followed. These recommendations would include proper handling during the shopping process to ensure adequate temperature control and cross contamination, construction and equipment requirements for areas where shopped products are held, procedures to address items that were shopped but not picked up by the consumer and any other concerns that may arise during guidance development.

- 3. Determine appropriate mechanisms for distributing the committee's work.
- 4. Report the committee's findings and recommendations at the next Biennial Meeting.

Submitter Information 1:

Name: Katie Matulis Organization: WI DATCP

Address: 2811 Agriculture DrivePO Box 8911

City/State/Zip: Madison, WI 53708-8911

Telephone: 414-369-9047

E-mail: Katie.Matulis@wisconsin.gov

Submitter Information 2:

Name: Carrie Pohjola Organization: WI DATCP

Address: 2811 Agriculture DrivePO Box 8911

City/State/Zip: Madison, WI 53708-8911

Telephone: 715-579-9487

E-mail: Carrie.Pohjola@Wisconsin.gov

Issue: 2023 I-029

Council	Accepted as	Accepted as		
Recommendation:	Submitted	Amended	No Action	_
Delegate Action:	Accepted	Rejected		
All information above the line	e is for conference use only	<u>′. </u>		
Issue History:				
This is a brand new Is	ssue.			
Title:				
Amend the Food Cod	le, Section 8-401.10			

Issue you would like the Conference to consider:

Under section 8-401.10, Establishing Inspection Interval allows for less frequent inspections. Adapt a new subparagraph in italics under paragraph B to say that the regulatory authority can increase the interval between inspections if the food establishment has a third-party inspection program. This will allow the use of inspections performed by a third party in combination with regulatory inspections to meet the required FDA Food Code regulatory quota for number of inspections. This subsection should be voluntary for industry and regulatory with an option to opt out of the program if either party is not satisfied. The regulatory agency has final approval of the third-party program submitted and can request any changes, updates, or edits as needed. This will allow increased inspection interval for regulatory agencies and support food safety programs under fiscal constraints.

Public Health Significance:

Third-party inspections at retail and manufacturing facilities are already an established part of food safety management systems. This allows an opportunity to further establish a food safety partnership between industry and regulatory. For regulators challenged by funding issues and staffing, this would alleviate the financial constraints and allow them to focus on high risk establishments and other areas of public health work. Industry has proven that they have "self-policing" in place by the provision of internal programs where third-party certified food safety auditors can provide technical expertise and knowledge across a wide range of different food businesses. The impact to industry for such a program would allow participation in the regulatory process and provide an opportunity for a partnership approach to food safety which could benefit and meet future needs.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA requesting the following:

1)Under 8-401.10 Establishing Inspection Interval, provide sub-section under paragraph B -

"Regulatory authority can increase the interval between inspections if the food establishment has an approved third-party audit system in place."

2)The conference recommends to establish a process whereby the food establishment receives a third-party food safety inspection at least every 6 months under a program approved by the regulatory authority. The establishment is contacted at least once every 6 months by telephone or other means by the regulatory authority to ensure that the establishment manager and the third-party inspection program have not changed.

Submitter Information:

Name: Caroline Friel Organization: Wawa Inc

Address: 260 W Baltimore Pike City/State/Zip: Media, PA 19063 Telephone: 6103226708

E-mail: caroline.friel@wawa.com

Content Documents:

"Food Safety News"

"Food Safety Capacity Assessment"

"Differences Between Official Inspections and Third Party Audits"

"The Role of Auditing, Food Safety and Quality"

Supporting Attachments:

"The Integrity of Private Third Party Food Compliance Monitoring"

Issue: 2023 I-030

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 Is	ssue.						
Title:							
Creation of a Food Tr	aceability Rule (Committe	ee				

Issue you would like the Conference to consider:

A Food Traceability Rule Committee be created, composed of members from all constituencies of the CFP. The Committee will be charged with:

- 1. Identifying best practices and existing guidance documents that relate to traceability of foods on the Food Traceability List (FTL).
- 2. Developing a guidance document(s) for food establishments that includes best practices for requirements for records for foods on the FTL.
- 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 include requirements as specified in the Food Traceability Rule as they relate to retail food establishments (RFE).
- 4. 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 2 (References, Part 3-Supporting Documents) be amended by adding references to the new Food Traceability Rule as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website. Include Food Traceability in Annex 3 (Public Health Reasons/Administrative Guidelines).
- 5. Reporting the committee's findings and recommendations to the next Biennial Meeting of the Conference for Food Protection

Public Health Significance:

The final rule is a key component of FDA's New Era of Smarter Food Safety Blueprint and implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA).

Recommended Solution: The Conference recommends...:

Creation of a Food Traceability Rule Committee to report findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

Submitter Information 1:

Name: Mario Seminara

Organization: Food Safety Works LLC Address: 13021 W Warren Ave Lakewood, CO 80228

Telephone: 720-681-1615

E-mail: mario@foodsafetyworksllc.com

Submitter Information 2:

Name: W Lynn Hodges

Organization: HACCP Consulting Group LLC

Address: 664 Brookhaven Ct. City/State/Zip: Waxahachie, TX 75165

Telephone: 972-268-5243

E-mail: wlh@hodges-hacg.com

Issue: 2023 I-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 Is	ssue.						
Title:	, FDA						
Clarify 7-204.12 (D) to separate EPA and FDA jurisdictions							

Issue you would like the Conference to consider:

We request that a modification of 7-204.12 (D) be made to clarify EPA and FDA regulatory authority

Public Health Significance:

The benefits of a produce wash to control pathogenic microorganisms on the surface of produce and in the wash/crisping water compared to water treatment alone is well established in literature and EPA stamped pesticide labels.

The Environmental Protection Agency (EPA) recognizes the complexity of produce washes by stating, "The most complex area [of regulation] involves the use of antimicrobials in or on food" (EPA Pesticide Registration Manual Chapter 18). Currently, the Food and Drug Administration (FDA) has primary jurisdiction of antimicrobials used in or on processed fruits and vegetables, whereas the EPA has primary jurisdiction on antimicrobials for preand/or post-harvest crops, and use of antimicrobials by consumers on raw agricultural commodities.

Under these conditions, produce washes can be used on processed fruits and vegetables under FDA authority without needing to comply with 40 CFR 156. At the moment, 7-204.12 states the produce wash must meet FDA and EPA criteria, which is not true. This may inadvertently force food establishments to opt for more expensive or higher concentrated products to wash their processed fruits and vegetables.

Recommended Solution: The Conference recommends...:

 A letter be sent to the FDA requesting that section 7-204.12 (D) of the most current edition of the Food Code be amended as follows (added language underlined and italicized) 1. 7-204.14 (D) - Meet the requirements in 40 CFR 156 Labeling Requirements for Pesticide and Devices <u>if the product is intended for use on raw agricultural commodities or to control microorganism in the wash/crisping water</u>

Submitter Information 1:

Name: David Buckley
Organization: Diversey, Inc.
Address: 1300 Altura Road
City/State/Zip: Fort Mill, SC 29708

Telephone: 8034872058

E-mail: david.buckley@diversey.com

Submitter Information 2:

Name: Laurie Hale
Organization: Diversey, Inc.
Address: 1300 Altura Road
City/State/Zip: Fort Mill, SC 29708

Telephone: 2482259321

E-mail: Laurie.Hale@diversey.com

Council Accepted as Accepted as Recommendation: Submitted _____ Amended _____ No Action _____

Delegate Action: Accepted _____ Rejected _____ Rejected _____ All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Reducing Cross Contamination Risk from Use of Reusable Wiping Cloths

Issue you would like the Conference to consider:

The use of reusable cloth wiping towels for quick cleanup of food spills on non-food contact surfaces is a common practice in food establishments. However, it remains one of the most frequently encountered Food Code violations due to failure of one the many steps required to ensure this practice doesn't become a risk to guests and patrons of food establishments. Such steps include:

- Ensuring wiping cloths are held in a sanitizer solution at the appropriate concentration required for efficacy to prevent growth of microorganisms on the cloth itself.
- Ensuring wiping cloths are held in a sanitizer solution free from soil, as soils can negatively impact the concentration of the active ingredient in the sanitizer solution.
- Ensuring individual wiping cloths are not used for practices which could promote cross contamination (e.g., use of the same cloth for wiping raw and ready-to-eat food spills)

As noted below, failure of one or more of these steps may lead to microbial contamination of the sanitizer solution, the wiping cloth, or both, which may lead to cross contamination within a food establishment. We are asking The Conference to consider supporting an amendment to The FDA Food Code which would include code language restricting use of these reusable wiping cloths to non-food-contact surfaces only, mimicking language that already appears within the Annex.

Public Health Significance:

Research has shown reusable wiping cloths to be a potentially risky practice for spread of pathogens within food establishments. A summary of research on the topic appears below.

A study in 2006 reported the findings of a bacterial survey of 37 dishcloths and 10 tabletops from bars and restaurants in New York, California, and Arizona (1). The authors detected

coliforms in 89.2% of cloths (mean bacterial count: 7.6×10^5 CFU/cloth) and *Escherichia coli* in 54.1% of cloths (mean bacterial count: 1.9×10^3 CFU/cloth). The authors also noted that cleaning tables with in-use dishcloths resulted in a significant increase in both bacterial and coliform counts, as compared to be fore cleaning. Finally, the authors found a variety of bacteria, including *Listeria innocua* in 24.3% (n = 9) of all dishcloth samples. While *Listeria innocua* is not itself a foodborne pathogen, its presence is sometimes used as an indicator organism for *Listeria monocytogenes*.

A 2020 study evaluated the potential for various food allergens (peanut, milk, and egg) to spread to multiple consecutive surfaces using a variety of methods, including the use of reusable terry cloths (2). It was found that allergen transfer was minimized when terry cloths were stored in appropriate solutions of sanitizer in between use, suggesting the potential for an increased chance of allergen cross contamination if sanitizer levels become inadequate.

Several studies have also demonstrated the potential for reusable wiping cloths to spread bacteria and viruses between surfaces. A 2020 study using large tabletops and reusable terry cloths held in sanitizer solutions found that both bacteria (*E. coli, Listeria innocua*) and virus (MS2 bacteriophage) were readily transferred to multiple consecutive surfaces in the absence of sanitizing solution, illustrating the importance of an appropriate concentration of sanitizer for minimizing cross contamination. Similar to these results, a 2012 study demonstrated the potential for damp terry cloths to readily transfer MS2 bacteriophage and Feline Calicivirus to clean surfaces (4).

Given that reusable wiping cloths can become a risk for bacterial and viral cross contamination within a food establishment, especially when sanitizer concentrations fall to levels inadequate for surface sanitization, the addition of language in the FDA Food Code emphasizing that these reusable wiping cloths are not considered an appropriate cleaning step for food contact surfaces may potentially help reduce the risk of foodborne illness outbreaks associated with cross contamination. This also would align code language more closely to that of the Annex, which states that the use of a reusable wet wiping cloth "does not constitute cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code".

References:

- 1. Yepiz-Gomez, M. & Bright, Kelly. (2006). Identity and Numbers of Bacteria Present on Tabletops and in Dishcloths Used to Wipe Down Tabletops in Public Restaurants and Bars. Food Protection Trends. 26. 786-792.
- Bedford, B., Liggans, G., Williams, L., & Jackson, L. (2020). Allergen Removal and Transfer with Wiping and Cleaning Methods Used in Retail and Food Service Establishments. Journal of Food Protection, 83(7), 1248-1260.
- 3. Goulter, R. M., Clayton, J. S., Moore, R. G., Bradshaw, J. M., Frye, J. W., Puntch, E. J., & Jaykus, L. A. (2020). Characterizing Microbial Cross-Contamination on Large Surfaces Using a Traditional "Cloth and Bucket" Disinfection Method. Food Protection Trends, 40(6), 392-401.
- 4. Gibson, K. E., Crandall, P. G., & Ricke, S. C. (2012). Removal and transfer of viruses on food contact surfaces by cleaning cloths. Applied and environmental microbiology, 78(9), 3037-3044.

Recommended Solution: The Conference recommends...:

Recommended Solution:

A letter be sent to FDA requesting to amend FDA Food Code 3-304.14 (Wiping Cloths, Use Limitation) as follows:

- 3-304.14 Wiping Cloths, Use Limitation.
- (A) Cloths in-use for wiping FOOD spills from TABLEWARE and carry-out containers that occur as FOOD is being served shall be:
- (1) Maintained dry; and
- (2) Used for no other purpose.
- (B) Cloths in-use for wiping counters and other EQUIPMENT surfaces shall be:
- (1) Held between uses in a chemical sanitizer solution at a concentration meeting the <u>criteria specified</u> under § 4-501.114; and
- (2) Laundered daily as specified under ¶ 4-802.11(D).
- (C) Use of dry and wet wiping cloths do not constitute an appropriate method for cleaning and SANITIZATION of FOOD CONTACT SURFACES where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code
- (D) Cloths in-use for wiping surfaces in contact with raw animal FOODS shall be kept separate from cloths used for other purposes.
- (E) Dry wiping cloths and the chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be free of FOOD debris and visible soil.
- (F) Containers of chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES.
- (G) SINGLE-USE disposable sanitizer wipes shall be used in accordance with EPA approved manufacturer's label use instructions.

Submitter Information 1:

Name: Chip Manuel, Ph.D. Organization: GOJO Industries

Address: One GOJO PlazaSuite 500

City/State/Zip: Akron, OH 44311 Telephone: (330) 255-6000

E-mail: ManuelC@GOJO.Com

Submitter Information 2:

Name: James W. Arbogast, Ph.D.

Organization: GOJO Industries

Address: One GOJO PlazaSuite 500

City/State/Zip: Akron, OH 44311

Telephone: (330) 255-6000

E-mail: ArbogasJ@GOJO.Com

Supporting Attachments:

- "Identity and Numbers of Bacteria Present on Tabletops and in Dishcloths Use"
- "Allergen Removal and Transfer with Wiping and Cleaning Methods"
- "Characterizing Microbial Cross-Contamination on Large Surfaces"
- "Removal and transfer of viruses on food contact surfaces"

Issue: 2023 II-001

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended		_ No Action	
Delegate Action:	Accepted		_ Rejected		_	
All information above the line	e is for conference us	e only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
Report - Food Protect	tion Manager Ce	ertificatio	n Committee (F	PMCC)		

Issue you would like the Conference to consider:

Acknowledging the Food Protection Manager Certification Committee (FPMCC) final report with attachments and extending thanks to the Committee members for their work.

Public Health Significance:

The credentialing process for *Certified Food Protection Managers* assists in the protection and promotion of food safety by carefully determining the competencies necessary to prevent foodborne illness, unbiased education and training for acquisition of competencies necessary to maintain food safety, and fair assessment practices to ensure that individuals have achieved mastery of these competencies.

Recommended Solution: The Conference recommends...:

acknowledgement of the 2021 - 2022 Food Protection Manager Certification Committee (FPMCC) Final Report and thanking the committee members for their work.

The Conference further recommends the continuation of the following charge (from Issue #: 2020 II-001) assigned to the Food Protection Manager Certification Committee (FPMCC), a standing committee, for the 2023-2024 biennium:

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 Standard for Accreditation for Food Protection Manager Certification programs and the accreditation process are administered in a fair and responsible manner.

Submitter Information:

Name: Susan Quam

Organization: Wisconsin Restaurant Association

Address: 2801 Fish Hatchery Road

City/State/Zip: Madison, WI 53713

Telephone: 6082162875

E-mail: squam@wirestaurant.org

Content Documents:

- "2021-22 FPMCC Final Report"
- "2021-22 FPMCC Final Roster"
- "2023 CFP FPMCC Bylaws with Proposed Changes"
- "2023 CFP Standard for Accreditation of FPM with Proposed Changes"

Supporting Attachments:

• "2021-22 FPMCC Minutes"

Issue: 2023 II-002

Council Recommendation:	Accepted as Submitted		Accepted as Amended	 No Action	
Delegate Action:	Accepted		Rejected		
All information above the line	is for conference use o	only.			
Issue History: This is a brand new Is	sue.				
Title:					

Issue you would like the Conference to consider:

FPMCC 2 Proposed Changes to the FPMCC Committee Bylaws

Approval of the revisions to the Food Protection Manager Certification Committee Bylaws. All revisions are contained within the revised document: "2022 CFP FPMCC Bylaws with Proposed Changes". Strike-through font indicates content being removed and underline

indicates content added.

Public Health Significance:

The credentialing process for Certified Food Protection Managers assists in the protection and promotion of food safety by carefully determining the competencies necessary to prevent food-borne illness, unbiased education and training for acquisition of competencies necessary to maintain food safety, and fair assessment practices to ensure that individuals have achieved mastery of these competencies. The Bylaws which govern the Food Protection Manager Certification Committee ensure a standardized approach to management of this credential.

Recommended Solution: The Conference recommends...:

- approval of the revised Food Protection Manager Certification Committee Bylaws (attached to Issue titled: FPMCC Final Report; attachment title: 2022 CFP FPMCC Bylaws with Proposed Changes);
- 2. authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
- 3. that the revised Bylaws be posted on the CFP website in PDF format.

Submitter Information:

Name: Susan Quam

Organization: Wisconsin Restaurant Association

Address: 2801 Fish Hatchery Road

City/State/Zip: Madison, WI 53713

Telephone: 6082162875

E-mail: squam@wirestaurant.org

Issue: 2023 II-003

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:

FPMCC 3 Proposed Changes to the CFP Standard for Accredited FPM Cert. Pgrms

Issue you would like the Conference to consider:

Approval of revisions to the Standard for Accreditation of Food Protection Manager Certification Programs.

Public Health Significance:

The credentialing process for *Certified Food Protection Managers* assists in the protection and promotion of food safety by carefully determining the competencies necessary to prevent foodborne illness, unbiased education and training for acquisition of competencies necessary to maintain food safety, and fair assessment practices to ensure that individuals have achieved mastery of these competencies.

Recommended Solution: The Conference recommends...:

- 1. approval of the revised Standard for Accreditation of Food Protection Manager Certification Programs (attached to Issue titled: FPMCC Final Report; attachment title: 2023 CFP Standard for Accreditation of FPM with Proposed Changes);
- 2. authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
- 3. that the revised Bylaws be posted on the CFP website in PDF format.

Submitter Information:

Name: Susan Quam

Organization: Wisconsin Restaurant Association

Address: 2801 Fish Hatchery Road

City/State/Zip: Madison, WI 53713

6082162875 Telephone:

E-mail: squam@wirestaurant.org

Issue: 2023 II-004

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: 2020 II-004; new or additional information has been included or attached.

Title:

FPMCC 4 Response to Issue 2020 II-004

Issue you would like the Conference to consider:

At the 2020 Biennial Meeting, the Food Protection Manager Certification Committee was charged 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. After deliberation, the FPMCC is recommending no change in the frequency of the required certification examination time period from the current maximum of five years.

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 impacts included:

- 1. The Standard currently allows Certification Providers to issue certifications for less than five years if the Provider chooses to.
- 2. Certification Providers must justify to the Accreditation Body that its recertification period is developed using criteria based on changes in regulatory requirements, ongoing changes in technology, information from stakeholders and interested bodies, and other changes associated with scheme requirements.
- 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 food establishment owners/operators.

- 4. Insufficient evidence exists that more frequent Food Manager Certification renewals would lead to fewer food borne illness outbreaks or improved public health outcomes.
- 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, decreasing the recertification timeframe to four years may not add a
 tangible benefit.

Recommended Solution: The Conference recommends...:

No change to the frequency of required Food Protection Manager certification examination validity from the current maximum of five years.

Submitter Information:

Name: Susan Quam

Organization: Wisconsin Restaurant Association

Address: 2801 Fish Hatchery Road

City/State/Zip: Madison, WI 53713

Telephone: 6082162875

E-mail: squam@wirestaurant.org

Issue: 2023 II-005

Council Recommendation:	Accepted as Submitted		Accepted as Amended		_ No Action _	
Delegate Action:	Accepted		– Rejected			
All information above the line	e is for conference use	e only.	_ ,		_	
Issue History:						
This is a brand new Is	ssue.					
Title:						
Report-Constitution B	sylaws and Proce	edures C	Committee (CBF	PC)		

Issue you would like the Conference to consider:

Acknowledgement of the work completed by the Constitution, Bylaws and Procedures Committee for the 2021-2023 Biennium.

At the 2020 (rescheduled to 2021) Biennial Meeting the CBPC was charged with the following:

- 1. Issue # 2020 II-006
- 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
- This language needs to be incorporated into the constitution
- 2. Issue #2020 II-010 Representation from the Constitution and ByLaws Committee on the Local Regulatory Representation Committee

In addition the Executive Board charged the CBPC with the following actions.

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

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

Public Health Significance:

The Constitution, Bylaws and Procedure Committee shall submit recommendations to improve the Conference administrative functions through proposals to amend the Constitution and Bylaws.

The CFP Constitution is our foundational document; and therefore needs to be unassailable.

Recommended Solution: The Conference recommends...:

Acknowledgement of the 2021-2023 Constitution Bylaws and Procedures Committee Final Report and thanking the committee members for their hard work.

Submitter Information 1:

Name: Sean Paul Dunleavy
Organization: Food Safe T Systems
Address: 6200 Cherry Ridge Dr
City/State/Zip: Howell, MI 48855

Telephone: 5178617991

E-mail: sdunleavy67@gmail.com

Submitter Information 2:

Name: Davene Sarrocco-Smith Organization: Emeritus / Public Health

Address: 215 Scotland Dr. City/State/Zip: Dallas, GA 30157 Telephone: 440-476-2429

E-mail: davenesarrocco@yahoo.com

Content Documents:

- "CBPC Report"
- "Roster"

Supporting Attachments:

"Governing Policy Document"

Issue: 2023 II-006

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above the line	e is for conference us	e only.	
Issue History: This is a brand new Is	ssue.		
Title:			
CBPC #2: CBPC Dut	ies; Constitution	Article XVI	

Issue you would like the Conference to consider:

Acceptance of the Draft of the revised version of the Conference for Food Protection Constitution Bylaws 2021 Article XVI Duties and Responsibilities of Committees Section 3

Public Health Significance:

Issue 2020 - II-006 charged the CBPC with recurring review of governing documents to ensure CFP's documents remain consistent with changes made by Assembly or by Board actions. The list of governing documents in recurring order are attached to the Constitution, Bylaws, and Procedures Report, for reference.

Recommended Solution: The Conference recommends...:

the Constitution and Bylaws, approved 2021, be updated to include the following language changes in

Article XVI Duties and Responsibilities of Committees

Section 3. The Constitution and Bylaws/Procedures Committee shall submit recommendations to

improve Conference administrative functions through proposals to amend the Constitution and

Bylaws. The committee shall review proposed memorandums of understanding and ensure consistency among governing documents. such as the Constitution and Bylaws, the CFP Biennial

Meeting/Procedures document, and other governing documents.

Subsection 1. The governing documents be reviewed on a recurrent basis with at least one document or set of documents per biennium cycle. Such review shall occur in succession from one biennium to the next and prioritized in the manner below, unless directed by the Board to accomplish the Conference objectives:

- a. CFP Constitution and Bylaws
- b. CFP Biennial Meeting/Procedures document
- c. Position descriptions
- d. Governing policy documents.

Subsection 2. The Committee shall report all recommendations to the Board prior to Council II deliberation and shall follow the direction of the Board.

Note: language to be removed indicated by strikethrough, new language added is underlined.

Submitter Information 1:

Name: Sean Paul Dunleavy
Organization: Food Safe T Systems
Address: 6200 Cherry Ridge Dr
City/State/Zip: Howell, MI 48855

Telephone: 5178617991

E-mail: sdunleavy67@gmail.com

Submitter Information 2:

Name: Davene Sarrocco-Smith Organization: Emeritus / Public Health

Address: 215 Scotland Dr. City/State/Zip: Dallas, GA 30157 Telephone: 440-476-2429

E-mail: davenesarrocco@yahoo.com

Issue: 2023 II-007

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended	No Action
Delegate Action:	Accepted		_ Rejected	
All information above the line	e is for conference us	e only.		
Issue History:				
This is a brand new Is	ssue.			
Title: CBPC #3: Federal Pa	ortners and Com	mittee M	embership Artic	de XV

Issue you would like the Conference to consider:

Acceptance of the draft of the revised version of the Conference for Food Protection Constitution Article XV

Public Health Significance:

Clarification on Federal Agency participation and membership as consultants and alternates for CFP Committee work.

Federal Agency participation in committee work is vital to the mission of CFP

Recommended Solution: The Conference recommends...:

Amending the Conference for Food Protection Constitution and Bylaws 2021 as follows:

Article XV Committees

Section 1. CFP members in good standing may express interest to serve on a committee by forwarding their name to the Executive Assistant following the CFP Biennial Meeting. This list will be used in creation of committee rosters. All appointments to Committees shall be made to provide a balance in representation of the stake holders in the particular matter under consideration.

Subsection 2. Each Federal agency participants (FDA, USDA, CDC) may appoint a consultant and an alternate for each committee. The consultant and alternate participates in committee discussions but does not vote. An alternate may act in the appointed consultant's place if the consultant is unable to attend. Consultants may or may not be CFP members to serve on a committee but shall be members to attend Biennial meetings. Only one person per Federal agency participant who is a non-CFP member per Council Committee is permitted.

(Note: language to be deleted is in strikethrough and new language is underlined)

Submitter Information 1:

Name: Sean Paul Dunleavy
Organization: Food Safe T Systems
Address: 6200 Cherry Ridge Dr
City/State/Zip: Howell, MI 48855

Telephone: 5178617991

E-mail: sdunleavy67@gmail.com

Submitter Information 2:

Name: Davene Sarrocco-Smith

Organization: Emeritus

Address: ***

City/State/Zip: Dallas, GA 30132

Telephone: 888888888

E-mail: davenesarrocco@yahoo.com

Issue: 2023 II-008

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended	 No Action	
Delegate Action:	Accepted		_ Rejected	_	
All information above the line	s is for conference use	only.			
Issue History:					
This is a brand new Is	ssue.				
Title:					
CBPC #4: Membersh	ip; Constitution A	Articles I	II, IV, XVIII		

Issue you would like the Conference to consider:

Acceptance of the revised version of the Conference for Food Protection Constitution and Bylaws 2021 Articles III, IV, and XVIII regarding Membership and Registration.

Public Health Significance:

As CFP moves to a new Registration and Membership Database management system, updated language in regards to membership as part of the biennial meeting registration or paid as a dues only membership is needed. For consistency additional changes in Articles IV and XVIII were also made.

Membership as both dues only and as part of registration are vital to the continuation of the work of CFP, including Committee, Council and Board eligibility.

Recommended Solution: The Conference recommends...:

amending the Conference for Food Protection Constitution and Bylaws 2021 as follows:

Article III Registration and Membership Membership and Registration

Section 1. Membership

<u>Subsection 1.</u> Persons who are interested in promoting the objective <u>of CFP as described</u> in Article I may become members of the Conference by applying to the Executive Treasure, using forms provided, and paying the membership fee established by the Board under Article VI, Section 12.

(Note: Previous Section 5 moved to new Subsection 2)

Section 5 Subsection 2. Membership in the Conference is classified into constituencies that are representative of the key stakeholder groups which support the objectives of Article 1 and facilitate the requirements of Article IV. The Conference constituencies are defined as follows:

Subsection 1 <u>a.</u> The Regulatory constituency is comprised of those officers, agents, or authorized representatives having authority over the regulation of food establishments, production, processing, vending, distribution, or have oversight for prevention of foodborne illness in accordance with rules and/or laws in their respective Governmental jurisdiction. Sub-categories of this constituency include:

- 1. <u>i.</u> Local Regulator: Government employee or agent representing a territorial division of local government with responsibility for regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness.
- 2. <u>ii.</u> State Regulator: Government employee or agent representing a territorial division of state government with responsibility for regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness.
- iii. Federal Regulator: Government employee or agent representing a program or agency of the Federal Government with responsibility for regulation of food establishments, production, processing, vending, or distribution, or has oversight or other regulatory authority for prevention of foodborne illness or control of pathogens causing foodborne illness.
- 4. <u>iv</u>. District/Territory Regulator: Government employee or agent representing District of Columbia or one of the six U.S. territories with responsibility for regulation of food establishments, production, processing, vending, or distribution, or has oversight for prevention of foodborne illness.

Subsection 2. <u>b.</u> The Industry constituency is comprised of those employees, agents, or executives representing business entities that operate food establishment, production, processing, vending, or distribution, or providers of an industry related service to such food operations, or representatives of a professional organization or trade association that promotes, supports, or markets to/for the food industry or its related services. Subcategories of this constituency include:

- i. Food Service Industry: Employees, agents, or executives representing business entities that operate food service establishments. Examples include, but are not limited to, restaurants of all sizes/types/styles of service, caterers, military food service, institutional and other health care food service, schools and university food service, common carrier food service (planes, trains, etc.), corporate food service operations, and Government food service.
- ii. Retail Food Industry: Employees, agents, or executives representing business entities that operate retail food establishments. Examples include, but are not limited to, grocery stores, supermarkets, convenience stores, retail pharmacies, produce markets, roadside stands, department stores, warehouse sales clubs, seafood markets, retail bakeries, military base PX/groceries, liquor stores, and retail food associations.
- 3. <u>iii.</u> Processing Food Industry: Employees, agents, or executives representing business entities that manufacture, process, package, or label food items for wholesale sale. Examples include, but are not limited to, commercial food manufacturing, canning, packaging, commercial bakeries, commercial meat slaughter and processing, packing houses and distribution centers, farming and

- agricultural processing and packing operations, ice processing, packing plants, and food processing trade associations.
- 4. <u>iv.</u> Vending and Distribution Food Industry: Employees, agents, or executives representing business entities that own and/or operate food companies that vend or distribute food either wholesale or retail. Examples include, but are not limited to, coffee and food vending service companies, service companies, commissaries, food supply chain operators, wholesale distributors, shipping lines, brokers, equipment manufacturers, and suppliers of products and services to operating service companies, and food vending and distribution trade associations.
- 5. v. Food Industry Support: Employees, agents, or executives representing business entities that provide direct or support services to food service establishments, retail food establishments, processing food operations, vending and distribution food operations, or regulatory agencies. Examples include, but are not limited to, professional organizations, food protection support trade associations, pest control companies, auditing firms, standards associations, consultants, cleaning and sanitation management operations, training and/or testing companies or services, equipment and supply operations, software and technology, dieticians or dietary managers, and media and legal representatives.

Subsection 3. c. The Academia constituency is comprised of academic professionals employed by a college or university involved in education or research involving food sciences, food operations, or food safety. Examples include, but are not limited to, professors, adjunct instructors, researchers, teaching assistants, and extension agents.

Subsection 4. <u>d.</u> The Consumer constituency is comprised of employees, agents, or executives representing consumer advocacy organizations supporting food safety, food wholesomeness, allergen awareness, food policy matters and food standards and guidelines.

Subsection 5. e. The Emeritus constituency is comprised of persons retired or honorably discharged from full-time work and no longer receiving compensation for work related to the Conference's mission. This constituency is designed for those professionals who, prior to retirement, were members of any Conference stakeholder group in good standing of the Conference for Food Protection for at least three biennial cycles (6 years). Previous membership does not have to be in contiguous biennial cycles. An Emeritus member may participate as an attendee/observer in all usual Conference functions such as attending the CFP Biennial Meeting, including workshops, Council deliberations, Assembly of Delegates, and social functions. Emeritus members may serve as a member of a Council Committee, as a Council Committee Chair, and participate and vote in constituency caucus meetings. The Board may elect to assign an Emeritus member to participate in other Conference related activities.

Subsection 6. <u>f.</u> The Student constituency is comprised of any student enrolled in a two year, four-year, or graduate program in a college or university involving food sciences, food operations, or food safety. A student member may participate as an attendee/observer in all usual Conference functions such as attending the <u>CFP</u> Biennial Meeting, including workshops, Council deliberations, Assembly of Delegates, and social functions. Student members may serve as a member of a Council Committee. The Board may elect to assign a student member to participate in other Conference related activities.

<u>Subsection 3</u> Persons with a current membership are entitled to be on the membership list, apply to be considered for a Council member or Council alternate position, apply to participate on committees, and receive communications of other Conference matters determined by the Board to be of interest to all members of the Conference. The requirements to serve in official CFP capacities, are described under Article IV. Membership renewal may be paid with CFP Biennial Meeting registration or by a dues-only membership.

Section 2. Any members interested in promoting the objective in Article I may attend the CFP Biennial Meetings by registering their name, address, and the constituency they represent with the Executive Treasure, using forms provided, and paying the registration-fee established by the Board under Article VI, Section 12. Persons may apply for membership and registration at the same time.

Section 3. Persons paying the Conference membership fee through the Executive Treasurer's office, or by paid registration at the CFP Biennial Meetings, are members of the Conference and are entitled to be on an official list to receive copies of the CFP Biennial Meeting proceedings and other Conference matters determined by the Board to be of interest to all members of the Conference.

Section 4. Conference membership begins at the time of payment of the membership fee. Membership paid as part of the CFP Biennial Meeting registration begins on the first day of one CFP Biennial Meeting and ends the day prior to the next CFP Biennial Meeting.

Section 2. Membership Combined with Registration

Subsection 1. Membership included with the CFP Biennial Meeting registration begins at the time of payment, continues through the CFP Biennial Meeting covered by the registration, and expires on the day prior to the Opening Session of the subsequent CFP Biennial Meeting.

<u>Subsection 2. Current membership is not required to register for a CFP Biennial Meeting.</u>
<u>Section 3. Dues-Only Membership</u>

Subsection 1. A dues-only membership is available to persons who do not attend a CFP Biennial Meeting, and begins at the time of payment and expires on the day prior to the Opening Session for the next CFP Biennial Meeting. A dues-only membership is usually paid after the Closing Session of a CFP Biennial Meeting. Dues-only membership will not exceed the two (2) years between CFP Biennial Meetings.

Article IV Composition of Organizational Components and Eligibility Requirements for Service in Official Capacities

Section 1. The Assembly shall consist of persons attending the Conference meeting and qualified as voting delegates under Article XVII, Section 3 and 4.

Section 2. To be eligible to serve on the Board, Councils, Committees, or as Issue Chair or Program Chair; individuals must be current members of the Conference. and must be inattendance at the CFP Biennial Meeting at which they are appointed or elected or shall have attended the CFP Biennial Meeting immediately preceding the one at which they are appointed or elected.

Article XVIII Rules of the CFP Biennial Meeting

Section 1. The current version of the "CFP Biennial Meeting/Conference Procedures" document contains the rules of the Biennial meeting.

Section 2. CFP Biennial meeting participation is registration is open to all interested individuals. who choose to become members and attend. Individuals may serve as appointed or elected members on the Board, Councils, and committees, or as a participating registered member.

(Note: Language to be deleted is in strikethrough and language to be added is underlined)

Submitter Information 1:

Name: Sean Paul Dunleavy
Organization: Food Safe T Systems
Address: 6200 Cherry Ridge Dr
City/State/Zip: Howell, MI 48855

Telephone: 5178617991

E-mail: sdunleavy67@gmail.com

Submitter Information 2:

Name: Davene Sarrocco-Smith Organization: Emeritus / Public Health

Address: 215 Scotland Dr. City/State/Zip: Dallas, GA 30157 Telephone: 440-476-2429

E-mail: davenesarrocco@yahoo.com

Issue: 2023 II-009

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended	 No Action	
Delegate Action:	Accepted		_ Rejected	 _	
All information above the line	e is for conference use	only.			
Issue History:					
This is a brand new Is	ssue.				
Title:					
PSC1 Program Stand	dards Committee	Report			

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Program Standards Committee seeks Council II's acknowledgment of the committee's final report and thank the committee members for their work and dedication during the 2020-2023 biennium.

Public Health Significance:

The Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) were developed to serve as a guide for regulatory retail food program managers in the design, management, and execution of a retail food program with the public health outcome of reducing foodborne illness risk factors. The Program Standards Committee is a standing committee reporting to the CFP Executive Board. The Committee provides ongoing input to the FDA on issues that arise with the Retail Program Standards. The Committee serves the Conference by indirectly assisting Retail Program Standards enrollees in making progress towards meeting the Retail Program Standards. The Committee continues to work with the FDA internal Program Standards working group and the FDA Clearinghouse Workgroup to clarify and address questions about the Retail Program Standards.

Recommended Solution: The Conference recommends...:

- 1. Acknowledgment of the 2020-2023 Program Standards Committee Final Report; and
- 2. Thanking the Committee members for their work and dedication during the 2020-2023 biennium.

The Conference further recommends the Program Standards Committee, a CFP standing committee, be charged with the following during the 2023-2025 biennium:

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; and
- 3. Maintain the "Crosswalk Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training.

Submitter Information 1:

Name: Angela Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Kenesha Williamson

Organization: CFP PSC - Publix Super Markets Inc

Address: 1936 George Jenkins BlvdCQA

City/State/Zip: Lakeland, FL 33815 Telephone: 863-688-1188 ext. 32472

E-mail: kenesha.williamson@publix.com

Content Documents:

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

Supporting Attachments:

- "PSC Subcommittee 1 Final Report"
- "PSC Subcommittee 2 Final Report"

- "PSC Subcommittee 3 Final Report"
- "PSC Subcommittee 4 Final Report"
- "PSC 1 Final Report Charge 2 supporting attachment"
- "RPSS Post Event Data Part1"
- "RPSS Post Event Data Part2"
- "RPSS Post Event Data Part3"
- "RPSS Post Event Data Part4"
- "PSC2 2022 Program Standards Standard 1 Regulatory Foundation"
- "PSC2 CFP Issue 2020 II-031"
- "PSC3 & PSC5 2022 Program Standard 2 Appendix B-1"
- "PSC 4, PSC13 & PSC17 2022 Program Standards 2 Trained Regulatory Staff"
- "PSC5 Course Descriptions and Objectives FDA38 FDA39"
- "PSC5 AFDO Risk-based Inspection Methods in Retail FD218"
- "PSC6 & PSC13 National Curriculum Standard"
- "PSC7 2022 Program Standards 3 Inspection Program Based on HACCP Principles"
- "PSC7 RPS 2022 Standard 3 Self-Assessment and Verification Audit form"
- "PSC8 RPS Standard 2 Trained Staff Instructions and Worksheet for a V.A."
- "PSC 8 RPS Standard 6 Compliance Enforcement Inst and Worksheet for a VA"
- "PSC 9 & PSC17 Standard 5 FBI and Food Defense Preparedness and Response"
- "PSC9 2022 Program Standards Definitions"
- "PSC12 2022 Program Standards 8 Program Support and Resources"
- "PSC12 Issue 2020 II-017 Packet"
- "PSC13 IFSS Framework Basic Advanced Feb 2021 Color Chart tab"
- "PSC13 IFSS Framework Basic Advanced Feb 2021 Descriptors tab"
- "PSC13 IFSS Framework Basic Advanced Feb 2021 first tab"
- "PSC14 & PSC15 Plan Review for Food Establishments Guide 2016"
- "PSC15 Annex 3 Ch. 8 Comp & Enf Const Insp and Approval 8-201.12 & 8-203.10"
- "PSC18 www.foodprotect.org Crosswalk Screenshot"
- "PSC19 Issue 2020 II-033"

Issue: 2023 II-010

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:

PSC3 Tracking Versions of Standard 2 Appendix B-1

Issue you would like the Conference to consider:

Add a version number and/or date to Appendix B-1 to identify when new or revised courses are added to the Standard for auditing purposes.

Public Health Significance:

Appendix B-1 is updated on the FDA Website in real time. Adding a version number and/or revision date to Appendix B-1, as existing training courses are updated and new courses become incorporated, will clarify which required courses should appear in FSIO training records for auditing purposes.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that a version number and/or revision date footnote be added to Appendix B-1 as existing training courses are updated and new courses become available.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Dave Read
Organization: CFP PSC - IFPTI
Address: 2861 2nd Street North

City/State/Zip: North St. Paul, MN 55109

Telephone: 651-485-8905

E-mail: davidread2861@gmail.com

Supporting Attachments:

"PSC Issue #3 list of supporting attachments"

Issue: 2023 II-011

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action				
Delegate Action:	Accepted	Rejected					
All information above the line is for conference use only.							
Icous History							

Issue History:

This is a brand new Issue.

Title:

PSC4 Change Re-standardization Frequency for staff not standardizing others

Issue you would like the Conference to consider:

The current frequency of re-standardization should change from three years to five years for inspection staff who do not standardize others.

Public Health Significance:

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 the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 2. Therefore, the change in frequency for re-standardization will lighten the burden for meeting VNRFRPS Standard 2, which involves performing four joint inspections with a "training standard" every three years. For standardization officers, the existing restandardization frequency of every three years should be maintained.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the frequency of re-standardization be changed 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.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Evelin Pollock

Organization: CFP PSC - Harris County Public Health

Address: 2221 West Loop South City/State/Zip: Houstin, TX 77027

Telephone: 7132746452

E-mail: evelin.pollock@phs.hctx.net

Supporting Attachments:

"PSC Issue #4 list of supporting attachments"

Council Accepted as Accepted as Recommendation: Submitted Amended No Action

Delegate Action: Accepted Rejected

Issue: 2023 II-012

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

PSC5 Add FD218 to Standard 2 Post Curriculum

Issue you would like the Conference to consider:

Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Program Standard 2, Trained Regulatory Staff Appendix B-1, Coursework for Food Safety Inspection Officers (FSIO) would be improved by the inclusion of FD218, Risk Based Inspection Methods.

Public Health Significance:

VNRFRPS Standard 2 explains that regulatory staff shall have the knowledge, skills, and ability to adequately perform their required duties. 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 to conducting inspections.

The prerequisites for FD218 are Communication Skills for Regulators (CC8011W), FDA Food Code (FD112), and Food Microbiological Control Series (MIC01 through MIC15). Most of which are part of the Standard 2 "pre" curriculum which a food safety inspection officer (FSIO) must complete prior to conducting independent inspections. Annex 5 of the FDA Code specifically covers risk-based inspection methodology. However, not all jurisdictions use the FDA Food Code as their regulatory foundation and may not require their staff to review Annex 5 of the FDA Code.

FD218 is also more accessible now than in the past. The course would have typically been taken at the point an inspector had already been in the field for around two years. Now, the inspectors can access this course a lot more readily because it is offered monthly as an instructor-led virtual course. Given the time frame for Standard 2 curriculum is now 24 months, completion of FD218 in the "post" curriculum is achievable.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting addition of FD218 Risk-Based Inspection Methods to Standard 2 "post" curriculum to be completed prior to standardization and within 24 months of hire or assignment to the regulatory retail food program.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Kenesha Williamson

Organization: CFP PSC - Publix Super Markets Inc Address: 1936 George Jenkins BlvdCQA

City/State/Zip: Lakeland, FL 33815

Telephone: 863-688-1188 ext. 32472

E-mail: kenesha.williamson@publix.com

Supporting Attachments:

"PSC Issue #5 list of supporting attachments"

Issue: 2023 II-013

Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	
Delegate Action:	Accepted		Rejected		_	
All information above the line	e is for conference us	e only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
Update the Standard	2 Curriculum to	include F	ood Safety Cu	lture		

Issue you would like the Conference to consider:

Food safety culture is a concept that should be part of the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 2 to ensure retail food program inspection staff can recognize and progress positive food safety practices in retail food establishments.

Public Health Significance:

Food safety culture is a concept necessary for retail food program inspection staff that should be instilled at the beginning of the training process. The addition of food safety culture training to the Standard 2 curriculum will promote awareness of this concept during retail food field inspections to be used to educate and guide retail food establishments to improve the food safety practices led by organizational culture.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that as part of Standard 2, in the "Description of Requirement" section under Step 1: Pre-Inspection Curriculum, add item 5. Food Safety Culture to the list of curriculum areas.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the Food Safety Inspection Officer (FSIO) must satisfactorily complete training in prerequisite 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;
- 4. Communication Skills;
- 5. Food Safety Culture

Submitter Information 1:

Name: Deanna E Copeland

Organization: Association of Food & Drug Officials Address: 155 W. Market Street, 3rd Floor

City/State/Zip: York, PA 17401 Telephone: 713-480-2354

E-mail: dcopeland@afdo.org

Submitter Information 2:

Name: Angela Montalbano

Organization: NYS Dept. of Agriculture and Markets

Address: 250 Veterans Memorial Hwy.

City/State/Zip: Hauppauge, NY 11788

Telephone: 347-203-6508

E-mail: Angela.montalbano@agriculture.ny.gov

Issue: 2023 II-014

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 Is	ssue.					
Title:						
PSC6 Reference Nati	ional Curriculum	Standa	d in VNRFRPS	Standa	rd 2	

Issue you would like the Conference to consider:

Adding language to VNRFRPS Standard 2 that references the FDA's National Curriculum Standard as a blueprint for Food Safety Inspection Officer training.

Public Health Significance:

The requirement summary for VNRFRPS Standard 2 states "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 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. The NCS also provides behavioral anchors (performance indicators) that serve to clarify the competencies and can be used for assessment purposes. Taken together, the competencies and behavioral anchors form "blueprints" that can be used to: develop new courses/training; update existing courses/training; evaluate courses/training for equivalency; and assess individual performance.

The NCS was developed through facilitated sessions with subject matter experts from FDA as well as state and local food safety protection agencies. The NCS is a living document that pertains to regulatory food protection professionals at various stages of their careers: Basic, Advanced, Expert (Specialist), and Leadership (Executive Administration).

At the Basic Level, the regulatory professional would begin with the Gen Eds followed by the Food Foundations topic or content areas prior to specializing in a specific program area, whether it be retail food, manufactured food, animal food, or unprocessed food.

Within the retail component of the NCS, topic or content areas addressed at the Basic Level include Regulatory Foundations for Retail Food Safety, Risk Based Inspections, Non-

Traditional Food Operations, Specialized Processing Methods. At the Advanced Level, topic or content areas include Plan Review and Special Processes.

The attached draft of 2022 Retail Food Program Standard 2 contains proposed language for consideration. Also attached is the current NCS with the Retail Food Framework component.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that language be added to VNRFRPS Standard 2 page 2-2 to include the NCS as a blueprint for FSIO training as follows (new language is underlined):

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.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Dave Read

Organization: CFP PSC - IFPTI
Address: 2861 2nd Street North
City/State/Zip: North St. Paul, MN 55109

Telephone: 6514858905

E-mail: davidread2861@gmail.com

Content Documents:

• "PSC Issue #6 list of content documents"

Supporting Attachments:

• "PSC Issue #6 list of supporting attachments"

Council Accepted as Accepted as Recommendation: Submitted 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:

PSC13 Add NCS Exam Option to Standard 2

Issue you would like the Conference to consider:

Adding an additional option for a written examination for Food Safety Inspection Officers (FSIOs) under Step 1 Pre-Inspection Curriculum Option 2 to allow a food protection certification examination based on the FDA's National Curriculum Standard (NCS). The written examination would be developed using methods that are psychometrically valid and reliable.

Public Health Significance:

The addition of another written examination provides more flexibility and access for FSIOs to demonstrate a basic level of food safety knowledge under Option 2 after completion of the pre-inspection curriculum. The FDA has been building the NCS since 2011, through five-year cooperative agreements with nonprofit food protection organizations. The NCS outlines the competencies needed by FSIOs for successful job performance. The NCS has been developed by subject matter experts representing local, state, and Federal regulatory jurisdictions. A significant number of online training courses have been developed using the competencies established in the NCS. Many FSIOs have already taken NCS training courses through the FDA Learning Management System.

The Partnership for Food Protection (PFP), sponsored by the FDA, Training and Credentialing Committee provides support for the implementation of the NCS including forming the NCS Review Cycle Subcommittee to review the competencies developed in the NCS.

Written exams are being developed based on the competencies outlined in the Basic Level of the NCS which includes the GenEds, Food Foundations, Retail Food, and Manufactured Food. A written exam for the GenEds is in the final stages of implementation and the others are in the pilot testing phase and are expected to be available in 2023.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that a fifth written examination option be added to VNRFRPS Standard 2, Step 1 Pre-Inspection Curriculum Option 2 stating: on page 2-3 under Option 2 Successful passing of one of the five written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge. Adding language on page 2-4 for an additional written examination as follows:

"5. A food protection certification examination based on the National Curriculum Standard that is developed using methods that are psychometrically valid and reliable".

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Dave Read Organization: CFP PSC - IFPTI

Address: 2861 2nd Street North
City/State/Zip: North St. Paul, MN 55109

Telephone: 6514858905

E-mail: davidread2861@gmail.com

Content Documents:

"PSC Issue #13 list of content documents"

Supporting Attachments:

• "PSC Issue #13 list of supporting attachments"

Issue: 2023 II-016

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 Iss	sue.			

Title:

Verification Audit guidelines for Standard 2 with regards to Appendix B-1

Issue you would like the Conference to consider:

With regular maintenance and updates anticipated for Appendix B-1: Curriculum for Retail Food Safety Inspection Officers, there are no directions or guidelines for determining whether compliance with the Standard would or would not be achieved ONLY if all qualified personnel met the requirements of the most current version of Appendix B-1.

Public Health Significance:

Appendix B-1 is a significant resource for FSIOs and is used as a check-list for both self-assessment with compliance to Standard 2 and for verification audits of the same compliance. FDA has noted that Appendix B-1 will be updated on a frequency necessary to keep it a living, current document. While this effort is to be applauded, it has the potential of being unnecessarily disruptive and confusing with regards to understanding whether a jurisdiction and/or FSIO is in compliance with Standard 2. If the jurisdiction or individual was in compliance with an earlier version, are they still in compliance if a new version is released, and for how long? Conformance with Standard 2 should not be up to individual interpretation of the requirements of the elements of the Standard.

Recommended Solution: The Conference recommends...:

The assignment of developing the self-audit and verification auditor guidelines that would allow an objective review of a jurisdiction's compliance with Standard 2 with consideration of different versions of Appendix B-1. Recommendation that this be assigned to the Program Standards Committee, to work with FDA to develop recommended guidelines and standards on how to use Appendix B-1 with Standard 2 to determine compliance of staff training with newer and older versions of Appendix B-1.

Submitter Information:

Name: Rance Baker

Organization: NEHA

Address: 720 S Colorado Blvd. Ste. 105A

City/State/Zip: Denver, CO 80246

Telephone: 3038022131 E-mail: rbaker@neha.org

Issue: 2023 II-017

Council Recommendation:	Accepted as Submitted	Accepted as _ Amended	 No Action	
Delegate Action:	Accepted	_ Rejected		
All information above the line	e is for conference use only.			
Issue History: This is a brand new Is	ssue.			
Title:				

Issue you would like the Conference to consider:

The Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard 2: Trained Regulatory Staff requires that all staff conducting retail food inspections are trained and standardized in risk categories 3 and 4, as defined in the 2017 Food Code Annex 5, Table 1. This requirement does not allow for a food safety inspection officer (FSIO) to be trained and standardized in only lower risk categories. A training plan allowing for FSIOs to be trained in conducting inspections of lower risk categories is needed to meet staffing and community needs.

Creation of a sub-committee - Standard 2 non-high risk inspection training

Public Health Significance:

High-risk retail food inspections, which include complex food preparation, highly susceptible populations, and/or specialized processes, require a higher level of competency. This requires devotion of significant time and resources to complete proper training and standardization. Not all FSIOs need to inspect high-risk facilities as part of their daily duties. A geographical inspection area could have multiple FSIOs, each with different training and experience levels. Many FSIOs are generalists or cross trained in other environmental health disciplines and may be conducting inspections of facilities that also have separate, non-high risk retail facilities such as packaged food stores, storage facilities, farm stands or stores, vending machines, or a small low-risk café attached to the current inspection site. Cross-trained individuals could complete multiple types of inspections, removing the need for a revisit to the same site by more highly trained FSIO, thereby saving time and resources. This would allow non-high risk FSIOs to complete more inspections and encourage more cross-training among generalist inspectors. Those that are trained and standardized on high-risk facilities would be able to focus more time on higher risk facilities, deferring lower risk facilities to sufficiently trained FSIOs operating within their skill sets.

To meet the needs of regulatory authority programs with limited resources, a layered training plan is critical, providing both the necessary and sufficient level of training and practical field experience for each type of inspection to be conducted. Both classroom education time and field training can be tailored for maximum efficiency for the activities within each inspection area. This allows for those human and financial resources to be utilized effectively. It also allows for a gradual development of skill sets for incoming staff and a measured approach, which permits training time to be spread out over the course of a work year. This will ensure that inspection frequency mandates are being met while increasing staff development opportunities. This has specific and measurable benefits to both the regulatory authority and the FSIO.

Many regulatory jurisdictions participate in both VNRFRPS and Manufactured Food Regulatory Program Standards (MFRPS). The MFRPS program, Standard 2-Training Program allows for a layered approach, utilizing a variety of FSIOs conducting inspections at different risk levels, including inspections that are low-risk only. The current MFRPS require a written training plan that ensures all FSIOs receive training required to adequately perform their work assignments. The training plan includes course curriculums, which provide for basic and advanced food inspection training, as well as continuing education opportunities.

The coursework and field training requirements for MFRPS are broken down into three categories, including FSIOs who will only inspect non-high risk food warehouses, FSIOs who will inspect general manufactured food firms, and FSIOs with advanced skill sets who will inspect specific types of specialized processes and/or preventive control inspections. There are specific coursework and training requirements laid out for each level of FSIO within the MFRPS program. Advanced Manufactured inspections including specialized and preventive control inspections require more coursework, field training, and audits before conducting independent inspections. Identifying the training and auditing requirements for non-high risk and high-risk retail food inspections would ensure the development, utilization, standardization, and documentation of proper skill sets for each risk category. Assigning risk levels to facilities and verifying risk levels pre-inspection ensures the FSIO is conducting an inspection within their trained skill set. Allowing non-high risk trained FSIOs for retail food inspections as well will allow for unification of and alignment between the requirements of both VNRFRPS and MFRPS, Standard 2.

A clearinghouse workgroup question has already been developed to address risk category 1 establishments under standard 2, question 16. Field Training for a Food Safety Inspection Officer (FSIO). The workgroup concluded that "if staff members were only trained in risk category 1 establishments, they may be ill equipped to deal with menu changes, process changes, and equipment changes that result in a more complex operation. FSIOs need exposure to a variety of different food establishments to be able to determine if the food establishment is properly categorized, determine the compliance status of Risk Factors and Good Retail Practices (GRPs), determine appropriate immediate corrective action if needed, and promote active managerial control over the risk factors using various strategies. These actions require highly trained, competent professionals." However, training a FSIO in risk level assessment and conducting that assessment prior to starting the inspection, in addition to using previous inspection history, prevents the inspector from conducting an inspection that is beyond their skill level. The risk level of a retail facility should already be identified from inspection history prior to conducting the

inspection. Retail Program Standards already addresses risk assessment in standard 2 and standard 4. In standard 2, the CFP training plan verifies that a trainee reviewed an establishment file for documentation indicating the assigned risk category. Standard 4 quality assurance plan element 3 verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. The FSIO must inform the supervisor when the establishment is not in the proper risk category or when the required frequency is not met. If for some reason, a higher risk level is discovered after the start of the inspection, the inspection should stop until a further trained inspector is available. The same circumstances can happen in manufacturing inspections under MFRPS in which a specialized or preventive control inspection is needed. These circumstances should be rare and any major changes to a facility's menu, equipment, or risk level should be presented to the jurisdiction prior to change. Regardless, the training components of a non-high risk FSIO should still include all listed components of Standard 2 training requirements so that they are highly competent in the risk level in which they have been trained.

Recommended Solution: The Conference recommends...:

A sub-committee of the Program Standards Committee be created to develop a training and standardization plan in VNRFRPS, Standard 2 for FSIOs conducting only non-high-risk inspections, similar to MFRPS, Standard 2 training requirements.

The sub-committee will be charged with:

- 1. Defining a unified system of risk categories, similar to MFRPS, Standard 2, which can be utilized by all organizations operating within VNRFRPS, Standard 2.
- 2. Identifying appropriate coursework required for each risk level of required inspections.
- 3. Developing any coursework needed that is not currently available.
- 4. Creating a feasible timeline for FSIOs to achieve both intellectual and practical skill sets.
- Adapting documentation and auditing requirements to ensure skill sets are gained and retained.
- 6. Designing a pathway for FSIOs to escalate to the next level of standardization within the identified system of risk levels.
- 7. Report back to the next biennial meeting of the Conference for Food Protection.

Submitter Information:

Name: Heather Sanders

Organization: Pennsylvania Department of Agriculture

Address: 2301 N Cameron St City/State/Zip: Harrisburg, PA 17110

Telephone: 7178362115

E-mail: HESANDERS@PA.GOV

Supporting Attachments:

- "MFRPS Standards 2"
- "Retail Program Standard 2"
- "Retail Program Standard 4"

Issue: 2023 II-018

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above the line	e is for conference use only.			
Issue History: This is a brand new Is	ssue.			
Title:				

PSC7 Std 3 Requirements and Self-Assessment & Verification Audit Form Edits

3 Requirements document and the Self-Assessment and Verification Audit form.

Issue you would like the Conference to consider:

Correcting the order of the terms "Validation" and "Verification" in the VNRFRPS Standard

Public Health Significance:

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.

When creating a HACCP plan, especially for Special Processes at Retail, the process must include concepts and actions that are proven (validated) by a process authority. Once the plan is put into action, Monitoring and Corrective Actions are checked and signed off (Verified) by the person in charge.

When a HACCP plan has been sent to a regulatory authority to be approved to meet a regulatory requirement, the plan is "Validated" by the responsible regulatory authority as being a sound and safe plan. Once the plan has been put into action, a regulatory authority would then do a site visit to "Verify" that the approved plan is being followed.

In the VNRFRPS Standard 3 - Self-Assessment and Verification Audit form, the sixth step refers to the Verification and Validation of the HACCP Plan Policy. The terminology currently used reverses the actual process of approval.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting to modify the VNRFRPS Standard 3 Requirements and Self-Assessment and Verification Audit Form at each use of the terms "Validation and

Verification" by reversing the terminology for "Validation" and "Verification" to reduce confusion and reinforce the correct usage of the terms "Validation" and "Verification".

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Rance Baker Organization: CFP PSC - NEHA

Address: 720 S Colorado Blvd, Ste 105A

City/State/Zip: Denver, CO 80209

Telephone: 3038022131 E-mail: rbaker@neha.org

Content Documents:

"PSC Issue #7 list of content documents"

Supporting Attachments:

• "PSC Issue #7 list of supporting attachments"

Issue: 2023 II-019

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: 2018 II-18 and 2020 II-023; the recommended solution has been revised.

Title:

PSC15 Incorporation of Plan Review into VNRFRPS Standard 3

Issue you would like the Conference to consider:

An outcome of the 2020 Biennial Conference for Food Protection (Issue #2020 II-023) was to continue the work of the Plan Review Committee using the previous committee's Preliminary Plan Review Proposal document as a starting point. Specifically, the charges were:

- 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 (VNRFRPS).
- 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.

Public Health Significance:

Plan Review lays the foundation for an operation to be in long term compliance with the FDA Food Code. The facility design, food safety management system, standard operating procedures, and HACCP plans when required should be reviewed and modified as needed prior to operation for the control of the foodborne illness risk factors and prevention of foodborne illness. During the plan review process, the regulatory agency or its designee works in tandem with the food facility operator to set the stage for success in achieving Food Code conformance and developing a food safety culture. A food safety management system needs to be developed preoperationally, prior to the opening inspection and establishment approval. It is recommended that such procedures be written and include information on the following:

- How transmission of foodborne illness is prevented.
- Plans to procure food from approved sources.

- How food is handled to prevent contamination and control risk factors.
- Plans for training staff.
- Procedures for cleaning and sanitizing.

Whether done by the agency or an external partner, plan review gives the regulatory authority a unique opportunity to proactively ensure the safe operation of food services and retail food operations.

Recommended Solution: The Conference recommends...:

incorporating plan review into Standard 3 - Inspection Program based on HACCP Principles.

1. Add a new element seven (7) to Standard 3 - Inspection Program based on HACCP Principles to include:

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 jurisdiction should conduct the review of the plans with the establishments food safety management system in mind. This would include a discussion with the operator to determine what procedures, training and monitoring will be done in the establishment to address foodborne illness risk factors.

2. Add language to Standard 3 under Description of Requirement.

Recommended language is:

- 7. 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 AUTHORITY discusses the establishments food safety management system as part of the plan review process. (See definition in Note 2) 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
- 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 between the agencies and the process for plan review is documented.

- 3. Add language to Standard 3 under Description of Requirement Documentation. Recommended language is:
- 7. Documentation of the food establishment construction plan, and equipment specification review process that includes:
- 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) 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
- h) Documentation of all plan reviews conducted (approval, conditional, denial) or if plan review is conducted externally, documentation of the process (policy, contract, MOU).
- 4. Add Note 1 to reference the Plan Review for Food Establishment guidance.
- 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/.
- 5. Add Note 2 to define Food Safety Management System.

<u>Food Safety Management System refers to a specific set of actions (e.g., procedures, training, and monitoring)</u> 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.

6. Add language to the Self-Assessment and Verification Audit Form - Standard 3 by adding #7.

Recommended language is:

7. 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 AUTHORITY 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.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Catherine Feeney

Organization: CFP PSC - Rhode Island Department of Health

Address: 3 Capitol Hill Room 203 City/State/Zip: Providence, RI 02908

Telephone: 4012227717

E-mail: catherine.feeney@health.ri.gov

Content Documents:

"PSC Issue #15 list of content documents"

Supporting Attachments:

"PSC Issue #15 list of supporting attachments"

Issue: 2023 II-020

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above the line	e is for conference use only.		
Issue History: This is a brand new Is	ssue.		
Title:			

Amend VNRFRPS Standard 3, Inspection Program Based On HACCP Principles

Issue you would like the Conference to consider:

Allow jurisdictions to adopt alternative written and implemented policies in relation to the assessment of active managerial control and out-of-compliance foodborne illness risk factor violations.

Public Health Significance:

The Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) requires, regardless of the overall assessment of the facility, follow-up activities on all out-of-compliance foodborne illness risk factors and core violations. A reply to a clearing house question clarifies that all priority, priority foundation and core violations should show correction as defined in the food code under sections 8-406.11. "Core violations do not require an immediate on-site correction but follow up should be performed." (see clearing house reply - attachment 1)

Violation compliance rates have remained steady under the current compliance model in the food code. To show compliance with Standard 3, follow-up activities are required for all violations based on clarifying documentation identified from the clearing house. This is very restrictive to regulatory agencies that are looking at alternative methods of enforcement with limited time and resources.

Regulatory programs that are striving to move the needle by developing alternative enforcement systems of assessment while striving to comply with the program standards are restricted to a method of 100% violation return-to-compliance. Operators with strong food safety management systems that incur a few outstanding violations are pulling regulatory program time and resources away from the facilities that are truly struggling and that need regulators' time and attention. There are situations where appropriate corrective actions cannot occur at the time of the inspection but have a very low risk to the public's health. Under the current model, regulators are required to gather documentation of

conformance or a written schedule of compliance for risk factors and low risk core violations.

Because of the nuances in the Standard, regulators are unable to implement alternative compliance assessment models and maintain compliance with the Standard. Facilities that have demonstrated a strong foundation of active managerial control are also required to show resolution of all violations. It is not appropriate to require corrective action and follow-up activities for every situation where core items, and even in some cases risk-factors, are out of compliance but have little to no impact on public health.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the relevant portion of Standard 3 of the most recent VNRFRPS be amended to allow additional latitude for compliance (language to be added is underlined; language to be deleted is in strikethrough format):

Under "Description of Requirement" add asterisks behind 4. c) and the following footnote at the bottom to read:

4. c) Follow-up activities ****

****Note: jurisdictions using a system that measures the overall compliance of an inspection and the overall active managerial control of an establishment may have a system in which follow-up activities are not required for all violations if:

- 1. The system is based on the risk of violations,
- 2. The program has a system that assesses the establishments overall management of food safety risks,
- 3. The system has criteria in which follow-up activities are required at establishments that do not demonstrate active management of risks.

"Standard 3: Inspection Program Based on HACCP Principles Instructions for Completing the Program Self-Assessment and Verification Audit Form" In the description of how to use the form, modify section 4. c) to read:

- 4. Corrective Action Policy
- c. The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations- or a written and implemented policy that:
 - 1. Is based on the risk of violations.
 - 2. Assesses establishments overall management of risks, and
 - 3. <u>follow-up activities are required at establishments that do not demonstrate the active management of risks.</u>

In the audit form, modify Criteria 4 Written and Implemented Corrective Action Policy to read:

- c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations- or a written and implemented policy that:
 - 1. Is based on the risk of violations,
 - 2. Assesses establishments overall management of risks, and

3. <u>follow-up activities are required at establishments that do not demonstrate the active management of risks.</u>

Attachments:

Submitter Information:

Name: Robert Warwick

Organization: Colorado Dept. of Public Health & Environment

Address: Retail Food Workgroup Lead4300 Cherry Creek South Dr

City/State/Zip: Denver, CO 80246-1523

Telephone: 720.550.0242

E-mail: Robert.Warwick@state.co.us

Supporting Attachments:

• "Clearing House Question STND 3 Response"

Issue: 2023 II-021

Council Recommendation:	Accepted as Submitted		Accepted as Amended	 No Action	
Delegate Action:	Accepted		Rejected		
All information above the line	is for conference use o	only.			
Issue History: This is a brand new Is	sue.				
Title:					

Issue you would like the Conference to consider:

Creation of a committee: specialized processes in program standards

Incorporation of more specific criteria related to special processes into the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS). The contents of the written policies on variance requests, verification and validation of HACCP plans should be identified in Standard 3 - Inspections based on HACCP Principles. A training plan for staff who conduct verification inspections of approved plans should be identified in Standard 2 - Trained Regulatory Staff.

Public Health Significance:

Currently, Standard 2 - Trained Regulatory Staff includes training and standardization for knowledge of HACCP principles but does not require any training or assessment specific to knowledge of specialized processes at retail. FSIOs in some jurisdictions are both validating the variance and/or HACCP plan in addition to conducting field verification inspections. Specialized processes review, approval, and field validation activities require more knowledge and training than traditional HACCP training currently prescribed in Standard 2. Retail Food facilities conducting specialized processes are expected to have knowledge and training for these higher risk processes and the same should be expected from regulatory agencies reviewing and inspecting the same plans. Courses like FD312, Specialized Processes at Retail, are very helpful but are not required and also are not intended to be repeated should changes to the requirements based on science, or the Food Code occur. Continuing education options should be available and incorporated into Standard 2, such as the FD312 online, self-paced prerequisite courses. Options for online, self-paced courses, as well as validation of knowledge for both variance and HACCP review and field verification purposes should be included in the requirements of Standard 2.

Currently, Standard 3 - Inspection Based on HACCP Principles requires a policy for addressing variance requests related to risk factors and interventions as well as a policy for verification and validation of HACCP plans required by the Food Code. The standard does

not prescribe what a quality policy should include, such as what defines a qualified individual for both reviewing a variance and/or HACCP plan and for conducting field verification, what should be included in the variance and/or HACCP validation, the process for approving or denying submissions, frequency of verification audits, etc. Without more specific policy requirements, specialized process review and field verification audits will vary greatly in quality in every jurisdiction. Policies may range from specialized process teams with academia support to jurisdictions with minimal education, training, and/or academia support. Defining what a regulatory specialized process policy and program should include would create consistency among training and implementation of these higher risk processes.

Manufactured Foods Regulatory Program Standards (MFRPS) specifies inspector training specific to each specialized process before an inspector can conduct specialized process inspections. Advanced food inspection training topics for MFRPS include acidified foods, low-acid foods, Seafood HACCP, trace-back investigations, foodborne illness investigations, and Preventive Controls for Human Food. MFRPS Standard 2 only allows FSIOs who have been trained and audited on specific specialized processes to conduct related inspections. MFRPS Standard 3: Inspection program indicates that the inspector is responsible for the review of the manufactured food firm's documents such as schedule process, HACCP plans, process controls, food safety plans, monitoring, verification and deviation or corrective action records. An inspector cannot review these plans until they are trained on each specialized process.

To create and maintain consistency between both manufactured food and retail food regulatory inspection programs which have specialized process programs, it would be beneficial to incorporate training and qualifications requirements into the VNRFRPS similar to those found in the MFRPS.

Recommended Solution: The Conference recommends...:

A subcommittee of the Program Standards Committee be created to identify recommendations for incorporating training specific to specialized processes in the Voluntary National Retail Food Regulatory Standards. The committee should consider:

- The inclusion of training specific to specialized processes in Standard 2 for inspectors conducting validation and verification of variances and HACCP plans including:
 - 1. Pre- and/or Post-Inspection curriculum
 - 2. Initial Field Training and Experience
 - 3. Field Standardization
 - 4. Continuing Education
 - 5. Qualifications for inspectors conducting validation and verification for variances and HACCP Plans.
- 2. Requirements for the Variance Request Policy and Verification and Validation of HACCP Plan Policy required by Standard 3.
- 3. The committee should report its findings and recommendations to the 2025 Biennial Meeting of the Conference for Food Protection.

Submitter Information:

Name: Heather Sanders

Organization: Pennsylvania Department of Agriculture

Address: 2301 N Cameron St City/State/Zip: Harrisburg, PA 17110

Telephone: 7178362115

E-mail: HESANDERS@PA.GOV

Supporting Attachments:

- "MFRPS Standards 2"
- "MFRPS Standards 3"
- "Retail Program Standard 2"
- "Retail Program Standard 2 coursework"

Issue: 2023 II-022

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended		No Action		
Delegate Action:	Accepted		_ Rejected		_		
All information above the line	All information above the line is for conference use only.						
Issue History:							
This is a brand new Is	ssue.						
Title:							
Report - Employee Fo	ood Safety Train	ing Com	mittee (EFSTC)			

Issue you would like the Conference to consider:

Acknowledging the Employee Food Safety Training Committee (EFSTC) final report with attachments and recognize by extending our sincerest gratitude and appreciation to the Committee members for their commitment and hard work.

Public Health Significance:

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 Training Committee (EFSTC) updated and addressed food employee knowledge, skills, and abilities (KSA) 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.

Recommended Solution: The Conference recommends...:

acknowledgement of the 2021 - 2023 Employee Food Safety Training Committee (EFSTC) Final Report.

The Conference gratefully appreciates and thanks all Committee Members for their work during the 2021 - 2023 biennium. In addition, special acknowledgement is given to previous Employee Food Safety Training Committee Members from the 2014 - 2016 biennium and 2018 - 2020 biennium for their expertise and commitment to public health.

The Conference further recommends disbanding the Employee Food Safety Training Committee (EFSTC) because the committee successfully updated the CFP "Employee Food Safety Training Guidance Document".

Submitter Information:

Name: Tara Paster Cammarata

Organization: CENZA, Inc. FKA Paster Training, Inc.

Address: 25 Swinehart Road City/State/Zip: Gilbertsville, PA 19525

Telephone: 4844318240

E-mail: Tara@CenzaSmart.com

Content Documents:

"EFST Committee Final Report"

"Employee Food Safety Guidance Document (2017 FDA Food Code)"

Supporting Attachments:

- "A 10.08.2021 EFST Report"
- "B 03.30.2022 EFST Report"
- "C 09.11.2022 EFST Report"
- "D EFST Committee Roster"

Issue: 2023 II-023

Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	
Delegate Action:	Accepted		Rejected		_	
All information above the line	e is for conference use	only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
EFSTC2 Publish Emp	oloyee Food Safe	ety Train	ing Guidance (2	2017 FD	A Food Code	∋)

Issue you would like the Conference to consider:

The Employee Food Safety Training Committee 2 (EFSTC2) recommends publishing the "Employee Food Safety Training Guidance Document (2017 FDA Food Code)" on the CFP website.

Public Health Significance:

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 Training Committee 2 (EFSTC2) updated and addressed food employee knowledge, skills, and abilities (KSA) in the following seven areas:

- 1. Foundations of Food Safety
- 2. Employee Health Outcomes
- 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 to ultimately strengthen the global food supply and protecting public health.

Recommended Solution: The Conference recommends...:

publishing the "Employee Food Safety Training Guidance Document (2017 FDA Food Code)" on the CFP website.

Submitter Information:

Name: Tara Cammarata

Organization: Cenza, Inc.

Address: 25 Swinehart Road City/State/Zip: Gilbertsville, PA 19525

Telephone: (484) 431-8240

E-mail: Tara@CenzaSmart.com

Content Documents:

• "Employee Food Safety Training Guidance Document (2017 FDA Food Code)"

Issue: 2023 II-024

No Action

Delegate Action:	Accepted	Rejected	
All information above the li	ne is for conference i	use only	

Accepted as

Amended

Issue History:

Recommendation:

Council

This issue was submitted for consideration at a previous biennial meeting, see issue: 2020-II-010; new or additional information has been included or attached.

Title:

Local Regulatory Voting Representation

Issue you would like the Conference to consider:

Accepted as

Submitted

- Acknowledge the Committee report and thank the Committee members for their time.
- Acknowledge that the Committee did examine the current By-laws, including an
 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.
- 4. Acknowledge that the Committee did include representation from the Constitution and By-laws 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 from the Constitution and Bylaws Committee.

Disband the Committee as all charges from Issue 2020-II-010 have been completed.

Public Health Significance:

Foodborne illness in the United States is a major cause of personal distress, preventable illness and death and avoidable economic burden. Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., ... & Griffin, P. M. (2011). Foodborne illness acquired in the United States-major pathogens. Emerging infectious diseases, 17(1), 7.

- Current USDA ERS data estimates the annual cost of foodborne illness for the 15 leading foodborne pathogens, in terms of pain and suffering, reduced productivity, and medical costs to be 17.5 billion dollars. USDA ERS Cost Estimates of Foodborne Illnesses, 2023 https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx
- The Food and Drug Administration (FDA) endeavors to assist approximately 75 state and territorial agencies; however, more than 3,000 local health? departments assume primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry.

Recommended Solution: The Conference recommends...:

Acknowledgement of the 2021-2023 Local Regulatory Voting Representation Committee thanking the committee for their time and disbanding the committee as all charges from Issue 2020-II-10 have been completed.

Submitter Information:

Name: Joetta DeFrancesco

Organization: National Environmental Health Association Address: 410 Georgetown Drive410 Georgetown Dr

City/State/Zip: Tallahassee, FL 32305

Telephone: 2394052211

E-mail: JDeFrancesco@NEHA.org

Content Documents:

- "Local Regulatory Voting Representation Final Report"
- "Local Regulatory Voting Representation Roster"

Supporting Attachments:

- "Local Regulatory Voting Representation Minutes 22-II-10"
- "Local Regulatory Voting Representation Survey 22-II-10"
- "Local Regulatory Voting Representation Survey 22-II-10"

Issue: 2023 II-025

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 Is	SUP		
Trillo lo a braria riow lo	odo.		
Title:			

Issue you would like the Conference to consider:

PSC8 Create Standard 4 Verification Audit Instructions

VNRFRPS Standard 4, Uniform Inspection Program, does not contain specific verification audit instructions. Other VNRFRPS Standards that require file reviews and calculations during the audit process, such as VNRFRPS Standard 2, Trained Regulatory Staff and VNRFRPS Standard 6, Compliance and Enforcement, contain "INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT".

Public Health Significance:

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 quidance 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.

VNRFRPS Standard 2 verification audit instructions include how to determine the number of employee training records to review, obtain random numbers, select employee training records to review, verify documentation of the completion of the standard training criteria, and make a determination based on the results of the audit. Standard 2 also provides a Verification Audit Worksheet.

VNRFRPS Standard 6 verification audit instructions include the number of files to select for the verification audit, when supplemental sampling is required, and the rate of agreement

with the self-assessment to meet the Standard. Standard 6 also provides a Verification Audit Worksheet.

Detailed verification audit instructions to guide the auditor, such as those in VNRFRPS Standards 2 and 6, will help ensure equality during the audit process regardless of the size of the jurisdiction.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting instructions for conducting a verification audit on Standard 4, Uniform Inspection Program, be developed.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Christine Sylvis

Organization: CFP PSC - Southern Nevada Health District

Address: 280 S. Decatur Blvd City/State/Zip: Las Vegas, NV 89127

Telephone: 7027590507 E-mail: sylvis@snhd.org

Supporting Attachments:

"PSC Issue #8 list of supporting attachments"

Issue: 2023 II-026

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above the line	e is for conference use o	only.	
Issue History:			
This is a brand new Is	ssue.		
Title:			
PSC9 Edits to Standa	ard 5 and Definition	ns	

Issue you would like the Conference to consider:

Editing VNRFRPS Standard 5 and the Program Standards Definitions document to correct errors and achieve consistency with the other Standards.

Public Health Significance:

Standard 5 requires the regulatory program to have an established system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination. Removing the excessive asterisks, reformatting key terms within the Standard, and expanding on their definitions will make the document less confusing. Using small caps font format to indicate defined terms is already established in the FDA Food Code and implemented in Standard 9.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting to approve the proposed edits to VNRFRPS Standard 5 and the Program Standards Definitions document as described below.

- Remove the footnote from Standard 5 page 5-5 and all corresponding asterisks.
- 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.
 - "12) Foodborne Disease Outbreak The occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. <u>Foodborne</u> <u>Disease Outbreaks include both Suspect Foodborne Outbreaks and</u> <u>Confirmed Foodborne Disease Outbreaks."</u>
- 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.

"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."

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Matthew Brandt

Organization: CFP PSC - Colorado Dept. of Public Health & Env.

Address: 4300 Cherry Creek Drive South

City/State/Zip: Denver, CO 80246

Telephone: 7205500322

E-mail: matthew.brandt@state.co.us

Content Documents:

"PSC Issue #9 list of content documents"

Supporting Attachments:

"PSC Issue #9 list of supporting attachments"

Issue: 2023 II-027

Council Recommendation:	Accepted as Submitted	Accepted as	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: 2020 II-033; the recommended solution has been revised.

Title:

PSC16 Development of a Roadmap for the requirements in VNRFRPS Standard 5

Issue you would like the Conference to consider:

The Program Standards Committee recommends continuation of Issue 2020 II-033 to develop a roadmap for the requirements of VNRFRPS Standard 5. A roadmap was identified as being 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.

Public Health Significance:

The FDA Voluntary National Retail Food Regulatory Program Standards (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 2020 II-033. The subcommittee comprised of regulators, industry and federal partners determined that Standard 5 was vital in providing procedures, communications and rapid response to food borne illness complaints and outbreaks. Standard 5 is very robust and serves as a crucial step in providing an adequate response to foodborne illness outbreaks. A review of the FDA Program Standards Enrolled Jurisdictions indicated that less than 10% of enrollees meet Standard 5. The subcommittee determined that breaking down the steps would be an approach beneficial to enrolled jurisdictions, particularly smaller jurisdictions with limited resources. The subcommittee began by developing a roadmap explaining the requirements and, in some cases, providing examples and templates of required documentation.

Recommended Solution: The Conference recommends...:

The Program Standards committee continue to work on finalizing the roadmap. Part of the Roadmap would include tools and templates, such as the Data Collection Template. Due to the nature of VNRFRPS Standard 5, it is also recommended that the subcommittee formed to work on this issue be made up of a majority of regulators who have experience and understanding of Standard 5.

1. Charges:

- 1. Finalize a Roadmap to assist jurisdictions in understanding the necessary requirements.
- 2. Review Standard 5 and make recommendations or amendments for improvements to the Standard
- 3. Report back committee findings and recommendations to the next Biennial Meeting
- 2. Acknowledgement of the Draft Roadmap for Standard 5 document to be utilized as a starting point for the 2023-2025 Program Standards Committee work on this issue.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Elizabeth Nutt
Organization: CFP PSC - AFDO

Address: 155 W. Market Street3rd Floor

City/State/Zip: York, PA 17401 Telephone: 9182711420 E-mail: enutt@afdo.org

Content Documents:

"PSC Issue #16 list of content documents"

Issue: 2023 II-028

Council Recommendation:	Accepted as Submitted		accepted as amended		No Action					
Delegate Action:	Accepted	R	Rejected							
All information above the line is for conference use only.										
Issue History:										
This is a brand new Issue.										
Title:										

Issue you would like the Conference to consider:

Adding notations to Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 2, Step 5: Continuing Education and Training and incorporated into the note following the Description of Requirement and immediately before Outcome sections.

PSC17 Referencing Crosswalk – Requirements for Foodborne Illness Training

Public Health Significance:

The Program Standards Committee is charged with maintaining the Crosswalk - Requirements for Foodborne Illness Training Program as a resource for foodborne illness training content baseline.

Whereas FDA has recognized that the ultimate goal of all retail food regulatory programs is to reduce or eliminate the occurrence of illnesses and deaths from food produced at the retail level, as currently presented the Crosswalk is not referenced as a resource tool within the VNRFRPS. The Committee endorses the Crosswalk as a reference tool that will benefit programs who are considering implementing foodborne illness training programs.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting incorporation of the "Crosswalk - Requirements for Foodborne Illness Training Programs" as a content reference for foodborne illness training resources within Standard 2 and Standard 5 of the VNRFRPS.

Adding language to Standard 2 on page 8 for an additional activity as follows:

"6. Foodborne illness training referenced in the Crosswalk Requirements for Foodborne Illness Training Programs - Standard 5."

and

Adding language to Standard 5 on page 4-5 as an additional note as follows:

"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)"

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: DeBrena Hilton

Organization: CFP PSC - Tulsa Health Department

Address: 5051 S. 129th East Avenue

City/State/Zip: Tulsa, OK 74134 Telephone: 9185954302

E-mail: dhilton@tulsa-health.org

Content Documents:

"PSC Issue #17 list of content documents"

Supporting Attachments:

"PSC Issue #17 list of supporting attachments"

Issue: 2023 II-029

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:

PSC18 Requirements for Foodborne Illness Training Program Crosswalk Content

Issue you would like the Conference to consider:

Creating a user-friendly Crosswalk tool experience and adding resource tools to the CFP website alongside the Crosswalk Requirements for Foodborne Illness Training Programs - Standard 5 so that those using listed resources can find them quickly.

Public Health Significance:

The Program Standards Committee is charged with maintaining the Crosswalk - Requirements for Foodborne Illness Training Program as a resource for foodborne illness training content baseline. However, the Crosswalk that was created to identify essential foodborne disease outbreak training educational content references documents that are hard to find on the internet.

Recommended Solution: The Conference recommends...:

that the Crosswalk references provided on the CFP website be updated by CFP to include only the most recent version to eliminate confusion. The conference also recommends that a letter be sent to FDA, NEHA and CDC requesting that the resource documents and programs listed within the "Crosswalk - Requirements for Foodborne Illness Training Programs Based on Standard 5" be provided to CFP. It is further recommended that CFP attach these reference documents and programs to the Conference-Developed Guides and Documents along with the Crosswalk Requirements for Foodborne Illness Training Programs - Standard 5 on the CFP website to make them more accessible.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: DeBrena Hilton

Organization: CFP PSC - Tulsa Health Department

Address: 5051 S. 129th East Avenue

City/State/Zip: Tulsa, OK 74134

Telephone: 9185954302

E-mail: dhilton@tulsa-health.org

Supporting Attachments:

"PSC Issue #18 list of supporting attachments"

Issue: 2023 II-030

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: 2020 II-033; the recommended solution has been revised.

Title:

PSC19 Continuation of Issue # 2020 II-033

Issue you would like the Conference to consider:

The Program Standards Committee (PSC) recommends continuation of Issue # 2020 II-033 Charges 3, 4 & 5 to consider inclusion of specific components and revisions of Standard 5 of the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).

Public Health Significance:

The review of VNRFRPS Standard 5 Foodborne Illness and Food Defense Preparedness should be conducted to ensure the most current and important items related to illnesses investigation are included in Standard 5. The PSC was unable to complete these charges and feels that this work should be continued in the next biennium.

Recommended Solution: The Conference recommends...:

that the Program Standards Committee be charged with continuing the work from Issue 2020 II-033 Charges 3, 4 and 5 in the next biennium. The following charges should be assigned to the PSC:

- 1. Review the "Description of Requirements" to ensure the requirements provide program flexibility and include items generally part of a retail food program.
- 2. 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.
- 3. 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 in VNRFRPS Standard 5.

4. Present any revisions to VNRFRPS Standard 5 based on these reviews to the 2025 CFP biennial meeting.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: DeBrena Hilton

Organization: CFP PSC - Tulsa Health Department

Address: 5051 S. 129th East Avenue

City/State/Zip: Tulsa, OK 74134 Telephone: 9185954302

E-mail: dhilton@tulsa-health.org

Supporting Attachments:

"PSC Issue #19 list of supporting attachments"

Issue: 2023 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: PSC10 Standard 6 Es	stablishment File	e Worksh	eet Form 3A			

Issue you would like the Conference to consider:

An additional Compliance and Enforcement Establishment File Worksheet based on FDA Food Code Form 3-A to be included in VNRFRPS Standard 6, Compliance and Enforcement resources.

Public Health Significance:

VNRFRPS 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.

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 Form 3-A represent foodborne illness risk factors and public health interventions. Risk factors are food preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks and include: Food from Unsafe Sources, Improper Holding Temperatures, Inadequate Cooking, Contaminated Equipment, and Poor Personal Hygiene. Public health interventions are strategies that can be developed with retail and food service operators to reduce the occurrence of foodborne illness and protect consumer health and include: Demonstration of Knowledge, Employee Health Controls, Controlling Hands as a Vehicle of Contamination, Time and Temperature Parameters for Controlling Pathogens, and the Consumer Advisory.

VNRFRPS Standard 6 includes a Compliance and Enforcement Establishment File Worksheet based on the risk factors and interventions. 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.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting creation of an additional VNRFRPS Standard 6 Establishment File Worksheet based on the FDA Food Code Form 3-A, Food Establishment Inspection Report, to be included in VNRFRPS Standard 6, Compliance and Enforcement resources.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Matthew Brandt

Organization: CFP PSC - Colorado Dept. of Public Health & Env.

Address: 4300 Cherry Creek Drive South

City/State/Zip: Denver, CO 80246

Telephone: 7205500322

E-mail: matthew.brandt@state.co.us

Content Documents:

"PSC Issue #10 list of content documents"

Issue: 2023 II-032

Council Accepted as Accepted as Recommendation: Submitted 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:

PSC11 Draft Standard 6 Standardized Key Crosswalk to the 2017 FDA Food Code

Issue you would like the Conference to consider:

Update the VNRFRPS Standard 6 - Standardized Key Crosswalk to the 2017 FDA Food Code and remove mention of the former document title "Quick Reference Applicable Food Code Risk Factor Provisions".

Public Health Significance:

The current version of VNRFRPS Standard 6 contains a Standardized Key Crosswalk to the 2017 FDA Food Code also known as the Quick Reference Applicable Food Code Risk Factor Provisions. The online version of the Retail Program Standards lists this document as the Quick Reference Applicable Food Code Risk Factor Provisions. The downloadable version of the Retail Program Standards (Voluntary National Retail Food Regulatory Program Standards Compiled) lists this document in the table of contents as Standard 6: Standardized Key Crosswalk to the 2017 FDA Food Code, but when downloaded the file name is "Quick Reference Applicable Food Code Risk Factor Provisions". 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 VNRFRPS 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.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the VNRFRPS Standard 6 - Standardized Key Crosswalk to the 2017 FDA Food Code be updated 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" as the file name and website link to the document on the Voluntary National Retail Food Regulatory Program Standards landing page.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Christine Sylvis

Organization: CFP PSC - Southern Nevada Health District

Address: 280 S. Decatur Blvd City/State/Zip: Las Vegas, NV 89127

Telephone: 7027590507 E-mail: sylvis@snhd.org

Content Documents:

"PSC Issue #11 list of content documents"

Issue: 2023 II-033

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:						
Amend VNRFRPS Standard 6, Compliance And Enforcement						

Issue you would like the Conference to consider:

Allow jurisdictions that have adopted alternative inspection programs and enforcement methods to apply those methodologies in determining Standard 6 compliance.

Public Health Significance:

While conducting audits, Standard 6 often fails to capture compliance and enforcement activities used by a jurisdiction to achieve compliance.

Many of the enforcement activities that are listed in the Standard: warning letters, reinspection, citations, fines, permit suspension, hearings, active managerial assessments are never evaluated to ensure they were used appropriately, and consequently the current assessment process defined in Standard 3 and confirmed in Standard 6 often ends with a facility that has had one or more priority or priority foundation violations that were corrected on site at time of inspection on the start point inspection. As a result, a facility satisfies the compliance enforcement process but the Standards may fail to recognize the tools that jurisdictions use to gain compliance with the regulations.

Standard 6 focuses on a demonstrable follow-up for each violation noted during an inspection. There are many violations that have little to no impact on public health that may not need further action by the regulatory authority or the facility until the time of the next inspection (consumer advisories, missing ceiling tiles, cracked floor tiles). This contradicts the intent of Standard 3, which is to model a regulatory program based on HACCP principles and HACCP-focused, risk-based processes. Inspections are based on the type of operation and their inherent food safety risks where the inspection frequency is assigned and regulatory resources are utilized based on the food operations with the greatest risk. However, when it comes to follow-up activities on out-of-compliance violations, the standards only provide one option for compliance, documentation of resolution for all violations.

The description for Standard 6 includes the following statement: "Compliance and enforcement options may vary depending on state and local law", however the current standard does not afford any such options or variability to states and/or local jurisdictions that are attempting alternative methods of facility assessment and violation compliance. The current goal of the Standard is to have facilities achieve 100 percent documented compliance with the regulations for all violations. This approach severely limits states/local programs from developing alternative methods of enforcement.

The instructions for conducting a verification audit of a program on page 6-27 states: "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." Yet the guide for conducting a verification audit and the reply received from the clearinghouse (attachment #1) clearly does not allow for this type of latitude.

Our suggestion: Allow for alternative means to demonstrate a compliance and enforcement process that does not rely solely on the documented resolution of every violation. Currently, multiple standards (such as Standard 2 and 8) offer alternative ways to achieve conformance, Standard 6 should allow for the same opportunity.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the relevant portion of Standard 6 of the most recent VNRFRPS be amended as specified below.

Standard 6 Compliance and Enforcement, Second paragraph under "Description of Requirement" (page 6-2) and elements be amended as follows:

The program must demonstrate <u>compliance with procedures defined by their jurisdiction</u> <u>which places eredible follow-up for each violation noted during an inspection, with particular emphasis being placed</u> on risk factors that most often contribute to foodborne illness and Food Code interventions intended to prevent foodborne illness. The resolution of out-of-compliance risk factors and/or Food Code interventions <u>or action taken based on the defined procedures established by the jurisdiction must be documented in each establishment record.</u> The essential program elements required to meet this standard are:

- 1. A written step-by-step procedure that describes how compliance and enforcement tools are to be used to achieve compliance.
- Inspection report form(s) that records and quantifies the compliance status of risk factors and interventions (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
- 3. Documentation on the establishment inspection report form or in the establishment file using the statistical method for file selection in the Supplement to Standard 6, Appendix F, where at least 80 percent of sampled establishments meet the following conditions:
- a) The inspection and enforcement staff takes compliance and enforcement action according to the procedure (i.e., the staff follow the step-by-step compliance and enforcement procedures when violations occur), and

- b) When applicable based on the jurisdictions adopted policies and procedures, Rresolution was successfully achieved for all out-of-control risk factors or interventions that were recorded on the selected routine inspection.
- "Standard 6 Compliance and Enforcement Instructions for Completing the Program Self-Assessment and Verification Audit Form" Criteria 2. Assessment of Effectiveness (page 6-8) be amended as follows:
- b) The jurisdiction has written documentation verifying that at least 80% of the sampled files follow the agency's step-by-step compliance and enforcement procedures and actions, <u>if applicable</u>, were taken to resolve out-of-compliance risk factors recorded on the selected routine inspection in accordance with the Standard criteria.

"Standard 6 - Compliance and Enforcement Instructions and Worksheet for Conducting a Self-Assessment" be amended as follows:

STEP 3 - Assess the Effectiveness of the Compliance & Enforcement Program (page 6-11)

Each jurisdiction shall measure the effectiveness of their compliance and enforcement program to determine if the jurisdiction has satisfactorily resolved FBI Risk Factor and Public Health Intervention violations. The results of the review will be used to assess the success of the compliance and enforcement program. The following process are methods that jurisdictions can use for Option 1 (all files reviewed) or for Options 2-3 (randomly selected establishment files or routine inspections).

(page 6-13)

Completion of these three items requires a complete review of the selected establishment file. To facilitate the documentation of the file review, the self-assessor may complete the table provided at the bottom of the Establishment File Worksheet. The summary table provides a method for defining the acronyms and notations used on the worksheet to describe the type of compliance and enforcement action taken. The self-assessor must review all the documentation in the establishment file from the "start-point" inspection forward to the current date to determine if the jurisdiction's written procedure was followed.-follow-up action was taken and documented for each risk factor and public health intervention that was out of compliance on the "start-point" inspection.

The self-assessor must place an "X" in the "File Meets the Standard 6 Criteria" box if:

 The completed Worksheet shows at least one follow-up action in each columnwhere a foodborne illness risk factor or public health intervention violation was marked on the

"start-point" inspection; and

The jurisdiction's written procedure was followed.

The self-assessor must place an "X" in the "File Does NOT Meet the Standard 6 Criteria box." if:

- The completed Worksheet shows that one or more of the "start-point" violations do not have at least one follow-up activity; or
- The jurisdiction's written procedure was not followed for one or more follow-up activities.

"Standard 6 - Compliance and Enforcement Instructions and Worksheet for Conducting a Verification Audit" be amended as follows:

(page 6-27) 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.

(page 6-30) Part III - Verify Self-Assessment findings for each selected establishment file

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, vVerify 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.

Submitter Information:

Name: Robert Warwick

Organization: Colorado Dept. of Public Health & Environment

Address: Retail Food Workgroup Lead4300 Cherry Creek South Dr

City/State/Zip: Denver, CO 80246-1523

Telephone: 7205500242

E-mail: Robert.Warwick@state.co.us

Supporting Attachments:

"Clearing House Question STND 6 final"

Issue: 2023 II-034

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:						
PSC12 Defining Standard 8 Verification Audit Parameters						

Issue you would like the Conference to consider:

The 2022 addition to VNRFRPS Standard 8 lacks the definition and metrics that would allow verification audits of the Standard to be fully objective and defensible.

Public Health Significance:

Updated language in VNRFRPS 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.

For this option, the guide language is vague: "A HD can use their own method they feel is appropriate for them to demonstrate adequate staffing levels." This language could cause confusion for a verification auditor as to whether the jurisdiction was able to demonstrate adequate staffing levels. This could cause subjective and not fully defensible results from the auditor.

There is a need for clear language and parameters for the auditor to work within.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting them to develop a self-audit and verification auditor worksheet that would allow the objective review of a jurisdiction's staffing level to determine compliance with VNRFRPS Standard 8 when using the third option listed in the Standard for evaluating adequate staffing level.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC - Minnesota Dept of Health

Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 6512015634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Rance Baker Organization: CFP PSC - NEHA

Address: 720 S Colorado Blvd, Ste 105A

City/State/Zip: Denver, CO 80209

Telephone: 3037569090 E-mail: rbaker@neha.org

Supporting Attachments:

• "PSC Issue #12 list of supporting attachments"

Issue: 2023 II-035

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: 2018 II-018; new or additional information has been included or attached.

Title:

Standard 8 Staffing Level Criteria

Issue you would like the Conference to consider:

The current assessment tool for Standard 8 Staffing Level Criteria located on the CFP website is not the correct workbook intended to be used. The final workbook should replace the draft version on the CFP website to be able to use this tool to its full capacity as intended in Issue: 2020 II-018.

Public Health Significance:

The current Standard 8 assessment tool on the CFP website resources contains a draft tab that has caused confusion amongst its users and distorts the staff level outcomes. It is important that the correct assessment tool is provided on the CFP website resources so staffing level criteria can be determined by the method approved at the 2021 CFP Biennial Conference in Issue: 2020 II-018.

Recommended Solution: The Conference recommends...:

The Conference recommends that the correct workbook for Standard 8 Staffing Level Criteria titled "Alternative S8 Workbook Model_3_4 Risk Code_2022(1)" replace the workbook titled "Standard-8-re-evaluation-of-stafing-alternative-conformance-workbook-04-19-2022-1 (1)" uploaded in the CFP website.

Submitter Information 1:

Name: Evelin Pollock

Organization: HarrisCounty Public Health Address: 2221 West Loop South City/State/Zip: Houston, TX 77027

Telephone: 713-248-5691

E-mail: Evelin.pollock@phs.hctx.net

Submitter Information 2:

Name: Deanna Copeland

Organization: Association of Food & Drug Officials Address: 155 W. Market Street, 3rd Floor

City/State/Zip: York, PA 17401 Telephone: 713-480-2354

E-mail: dcopeland@afdo.org

Content Documents:

• "Alternative S8 Workbook Model_3_4 Risk Codes"

Supporting Attachments:

• "PSC Issue #2 New assessment tool for Standard 8 Staffing Level Criteria"

Issue: 2023 II-036

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: 2020 II-031; the recommended solution has been revised.

Title:

PSC2 Assign 2020 II-031 to CFP Program Standards Committee

Issue you would like the Conference to consider:

Regarding 2020-II-031, consensus was reached on drafting an Issue to assign this issue to the CFP Program Standards Committee (PSC). In order to garner more input and support from all stakeholders for potential changes to Standard 1 - Regulatory Foundation, the PSC can then continue working on the issue originally submitted by AFDO at the 2020 biennial meeting. This issue needs further review within the committee process.

Public Health Significance:

Due to the vagueness of only meeting 80% of the provisions in the FDA Food Code, many Priority and Priority Foundation requirements may be missing from jurisdictions across the country. Missing Priority and Priority Foundation items will lead to a significant increase in out-of-control foodborne illness risk factors in those jurisdictions that do not fully meet all the provisions in the FDA Food Code.

Recommended Solution: The Conference recommends...:

That Issue 2020-II-031 be assigned to the CFP Program Standards Committee with the following charges:

- Conduct a comprehensive review of all the factors regarding VNRFRPS Standard 1

 Regulatory Foundation and assessment of the 80% code provision requirement to meet the Standard.
- 2. Provide recommendations to the 2025 CFP biennial meeting.

Submitter Information 1:

Name: Angie Wheeler

Organization: CFP PSC Chair - Minnesota Department of Health

Address: 625 Robert Street NorthPO Box 64975

City/State/Zip: Saint Paul, MN 55164-0975

Telephone: 651-201-5634

E-mail: angie.wheeler@state.mn.us

Submitter Information 2:

Name: Mike Touhey

Organization: CFP PSC - Washoe County Health District

Address: 1001 E 9th Street City/State/Zip: Reno, NV 89512 Telephone: 775-433-8996

E-mail: mtouhey@washoecounty.gov

Supporting Attachments:

• "PSC Issue #2 list of supporting attachments"

Issue: 2023 II-037

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 Is	ssue.					
Title:						

Issue you would like the Conference to consider:

Retail Program Standards Verification Auditor Criteria

The establishment of Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) verification auditor criteria is to ensure the required verification audit is completed with quality and integrity to confirm the accuracy of a self-assessment. These criteria should be defined by FDA with stakeholder input and included in the 2026 VNRFRPS Administrative Procedures.

This Issue is being submitted well in advance of implementation to allow for proper notice and awareness to jurisdictions who will need to identify an auditor (that meets the new criteria), and for new auditors who will need to become fully qualified when the new criteria are in place.

Public Health Significance:

The VNRFRPS provide a successful model of continuous improvement for state, local, tribal, and territorial retail food protection programs. VNRFRPS Self-Assessment accuracy is verified by the audit, and there is an expectation that auditors have an understanding of the current VNRFRPS and conduct audits with consistency and uniformity. Under the 2022 Administrative Procedures to the VNRFRPS, the sole requirement for an auditor is that the person cannot have responsibility for the day-to-day operations of the jurisdiction requesting the audit.

FDA recognizes that auditors may originate from different segments of the food safety community including regulators, industry representatives or independent companies with varying experience with both conducting audits and working with the VNRFRPS. This can lead to inconsistencies among audits and open audits up to questions of validity.

In order to perform a competent audit of a VNRFRPS self-assessment, auditors must have access to the most current and updated VNRFRPS materials and have a basic

understanding of the audit process. To ensure the utmost integrity of the audit, it is critically important that auditor criteria be defined and included in the Administrative Procedures to the VNRFRPS. The criteria must establish a minimum level of knowledge and comprehension for those conducting audits, but also be achievable and accessible to the diverse pool of auditors from various regulatory and non-regulatory organizations.

During the next two years, FDA will complete a job task analysis (JTA) on the role of the VNRFRPS auditor in collaboration with our state, local, tribal, and territorial retail verification partners. The JTA will identify gaps in the current VNRFRPS training content and allow FDA to establish training more targeted to verification auditors. FDA will work to develop and enhance training, including updating existing Self-Assessment and Verification Audit workshops to address the identified needs of Verification auditors. FDA will use this information to establish initial and on-going maintenance criteria for verification auditors that will meet the needs of auditors to maximize access and ensure a level of quality and integrity in verification audits.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA asking that FDA define qualifications for a Retail Program Standards Auditor, to include attending an FDA-developed Verification Audit workshop and on-going maintenance requirements, and that this change be included in the 2026 VNRFRPS Administrative Procedures.

FDA would report back to the Conference in the 2025 Biennium the status of the verification auditor criteria development.

Submitter Information 1:

Name: Glenda R. Lewis

Organization: US Food and Drug Administration

Address: 5001 Campus Drive City/State/Zip: College Park, MD 20740

Telephone: 240-402-2150

E-mail: glenda.lewis@fda.hhs.gov

Submitter Information 2:

Name: Robert Sudler

Organization: US Food and Drug Administration

Address: 5001 Campus Drive City/State/Zip: College Park, MD 20740

Telephone: 240-402--1943

E-mail: robert.sudler@fda.hhs.gov

Issue: 2023 II-038

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: 2020 11-009; new or additional information has been included or attached.

Title:

Report – Food Defense Committee (FDC)

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) FDC seeks Council II's acknowledgment of the committee's final report and to thank the committee members for their work.

Public Health Significance:

Food defense, protecting food from intentional adulteration, is an important concept for the entire farm-to-table system, including food establishments (as defined in Model Food Code). As food establishment operators and regulators continue to look at risk factor data and supporting a food safety system approach, the need to protect consumers and retailers from potential food adulteration incidents is paramount. Current food defense resources found in the FDA Food Code are not sufficient to meet the needs of food establishments. There are about 3 pages of reference materials in Annex 2, Section 4 (pages 333-336) of the most current published version of the FDA Model Food Code. Many of these references are difficult to find because of broken/outdated links. Additionally, several of the resources are not designed for food establishments. In addition, Food Defense is not adequately defined or addressed in the FDA Model Food Code. Food Defense is an important topic because there have been several intentional adulteration events related to food establishments in the United States and other countries. Examples include:

- 1984 Rajneeshee attack on 10 salad bars in Oregon (750 illnesses)
- 2002-2003 Nicotine poisoning of retail meats in Michigan (100 illnesses)
- 2009 Pesticide poisonings of salsa at a restaurant in Kansas (40 illnesses)
- 2016 Intentional contamination of RTE food at local grocery stores in Michigan (No illnesses)
- 2017 Intentional contamination of RTE food at restaurants in South Lake Tahoe in California (4 illnesses)

- 2018 Intentional tampering and contamination of food at multiple retail stores in Arizona (No illnesses)
- 2021 Intentional contamination of processed meat and microwaveable products at local stores in London (No illnesses)

The 2021 Biennial Meeting reestablished the FDC to evaluate ways to improve Food Defense awareness for both operators and regulators in food establishments. The committee discussed efforts to protect food from acts of intentional adulteration or tampering. Working with FDA and USDA FSIS, the Committee is providing an updated list of current food defense references to be included in Annex 2, Section 4 of the FDA Model Food Code. We recommend an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments, an addition to 2-103.11 requiring that a Person in Charge ensure awareness of food defense, and a definition for Food Defense. The Committee worked closely with the FDA Food Defense and Emergency Coordination staff in CFSAN.

including their participation in our committee meetings to discuss our charges. The 2021 - 2023 FDC has completed its charges.

Recommended Solution: The Conference recommends...:

Acknowledgement of the 2021- 2023 Food Defense Committee Final Report, thanking the committee members for the completed work, and disbanding the committee because all assigned charges have been completed.

Submitter Information 1:

Name: Albert Espinoza, R.S.

Organization: H-E-B

Address: 646 S. Flores

City/State/Zip: San Antonio, TX 78204

Telephone: 210-884-5783

E-mail: Espinoza.albert@HEB.com

Submitter Information 2:

Name: Jennifer M Bonsky

Organization: Michigan Department of Agriculture and Rural Development

Address: P.O. Box 30017 City/State/Zip: Lansing, MI 48933 Telephone: 15176140149

E-mail: bonskyj@michigan.gov

Content Documents:

- "Food Defense Committee Final Report CFP Executive Board"
- "Food Defense Employee Orientation"

Supporting Attachments:

"Food Defense roster 2120-2023 3 21 2022"

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.

Issue: 2023 II-039

Council Recommendation:	Accepted as Submitted	Accepted as _Amended		No Action	
Delegate Action:	Accepted	_ Rejected		_	
All information above the line	All information above the line is for conference use only.				
Issue History: This is a brand new Is	ssue.				
Title:					

FDC Issue 2–Amend 2022 FDA Food Code to add food defense rule under 2-102

Issue you would like the Conference to consider:

The committee voted YES, it is appropriate and recommends an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments. The committee also voted to propose two additional recommendations as appropriate:

ADD - 2-102.11 (C) (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.

The committee also voted to propose these two additional recommendations as appropriate:

ADD - FOOD DEFENSE Definition:

1-201.10 "FOOD DEFENSE" is the effort to protect food from acts of intentional ADULTERATION.

ADD - 2-103.11 (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.

Public Health Significance:

Food establishment personnel play a key role in protecting food from someone intent on adulterating or tampering with the food to either cause illness or death on a large scale. These proposed updates to the 2022 FDA model Food Code describe steps that managers and persons in charge should take to promote employee awareness and report any suspicion of food adulteration or product tampering. It is not intended to require that all food employees attend a formal training or pass a test that is part of an accredited program.

In addition, Food Defense is not adequately defined or addressed in the 2022 FDA Model Food Code. Food Defense is an important topic because there have been several

intentional adulteration events related to food establishments in the United States and other countries. Examples include:

- 1984 Rajneeshee attack on 10 salad bars in Oregon (750 illnesses)
- 2002-2003 Nicotine poisoning of retail meats in Michigan (100 illnesses)
- 2009 Pesticide poisonings of salsa at a restaurant in Kansas (40 illnesses)
- 2016 Intentional contamination of RTE food at local grocery stores in Michigan (No illnesses)
- 2017 Intentional contamination of RTE food at restaurants in South Lake Tahoe in California (4 illnesses)
- 2018 Intentional tampering and contamination of food at multiple retail stores in Arizona (No illnesses)
- 2021 Intentional contamination of processed meat and microwaveable products at local stores in London (No illnesses)

Recommended Solution: The Conference recommends...:

A letter be sent to the FDA requesting that the most current edition of the Food Code be amended as follows (new language is underlined):

2-102.11 (C) (18) Explaining steps that are taken to prevent intentional adulteration by CONSUMERS, EMPLOYEES, or other persons including monitoring operations, ingredients, supplies, and finished products for unusual or suspicious activities, and similar food defense activities.

2-103.11 (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.

1-201.10 (B) <u>"Food Defense"</u> is the effort to protect food from acts of intentional adulteration.

Submitter Information 1:

Name: Albert Espinoza, R.S.

Organization: H-E-B

Address: 646 S. Flores

City/State/Zip: San Antonio, TX 78204

Telephone: 2108845783

E-mail: Espinoza.albert@HEB.com

Submitter Information 2:

Name: Jennifer M Bonsky

Organization: Michigan Department of Agriculture and Rural Development

Address: P.O. Box 30017 City/State/Zip: Lansing, MI 48933 Telephone: 15176140149

E-mail: bonskyj@michigan.gov

or a commercial proprietary process.

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name

Issue: 2023 II-040

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 Is	ssue.							
Title:								

Issue you would like the Conference to consider:

Working with FDA and USDA FSIS, the FDC is providing current food defense references to be included in Annex 2, Section 4 of the 2022 FDA model Food Code.

FDC Issue 3 – Amend FDA Food Code, Annex 2, Sect. 4 Food Defense references

Public Health Significance:

The current food defense references in Annex 2, Section 4 of the FDA model Food Code are outdated and do not provide current guidance by FDA, USDA FSIS, industry trade associations and other agencies. The proposed annex information provides links to FDA, USDA FSIS, industry trade associations and other agencies for current usable guidance for food defense guidance in food establishments. Food defense is an increasing food safety issue. Restaurant and retail food service managers need to be aware of food defense issues; know steps that their facility can take to prevent intentional contamination; and monitor operations, ingredients, supplies, and finished products for unusual or suspicious activities; and similar food defense activities.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that the 2022 Food Code be amended to include updated references to Annex 2, Section 4, Food Defense Guidance from Farm to Table as follows (the entire Annex 2, Section 4 will be replaced with the updated, underlined language below):

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all-inclusive. It contains links to websites and describes publications from federal agencies (primarily FDA, CDC, and USDA) and industry groups with information of interest for regulators, industry, and consumers. Responsibility for updating the web pages lies with

the listed organization and those listed are up to date as of the printing of the current Food Code.

U.S. Food and Drug Administration:

The FDA has developed food defense tools, resources, and regulation and guidance documents to help food establishments and food facilities prevent, prepare for, respond to, and recover from acts of intentional adulteration of the food supply.

<u>These resources can be found by visiting Food Defense | FDA (www.fda.gov/food/food-defense) website or by searching U.S. Food and Drug Administration (fda.gov) on the FDA website includes:</u>

- Guidance for Industry: Food Security Preventive Measures Guidance for Retail Food Stores and Food Service Establishments: This guidance is designed as an aid to operators of retail food stores and food service establishments (for example, bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fundraisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for home-bound persons, mobile food carts, restaurants, and vending machine operators). This guidance identifies the kinds of preventive measures they may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions.
- Food Defense 101 Front-line Employee Training: The web-based course provides front-line employees with simple procedures to protect the food supply against an intentional attack.
- Food Defense Plan Builder: This is a user-friendly tool designed to help owners and
 operators of a food facility in the development of a food defense plan that is specific
 to their facility. The plan builder is designed for food manufacturers and processors
 but can also be used by retail and foodservice operators to develop food defense
 plans.
- Food Related Emergency Exercise Bundle (FREE-B): Exercise scenarios based on both intentional and unintentional food contamination events. FREE-B assists government regulatory and public health agencies in assessing the readiness of their entity to respond to a food contamination event. The FREE-B is designed to allow for multiple jurisdictions and organizations (medical community, private sector, law enforcement, first responder communities) to 'play' with the host agency, or, quite simply, for an individual agency to test their own plans, protocols, and procedures independently.
- Food Defense Mitigation Strategies Database (FDMSD): Online database designed
 to help owners and operators of a food facility with identifying mitigation strategies to
 protect the food against intentional adulteration. The FDMSD includes mitigation
 strategies for some common points, steps, and procedures that are often found at
 food facilities.
- <u>"See Something, Say Something" Poster: FDA collaborated with partner agencies in the Food and Agriculture Sector Council to develop a poster for food facilities and food establishments to raise awareness of the indicators of terrorism and terrorism-</u>

related crime, as well as the importance of reporting suspicious activity to state and local law enforcement.

Other FDA Resources:

- <u>To report an emergency involving food, drugs, medical devices, dietary supplements, or cosmetics, call 1-866-300-4374 or 1-301-796-8240.</u>
- <u>To report a problem with FDA-regulated products by phone: Call 1-888-INFO-FDA (1-888-463-6332) or Consumer Complaint Coordinators | FDA.</u>
- <u>Use the MedWatch Online Voluntary Reporting Form (fda.gov) to report adverse</u> events with human food and medical products.
- <u>Use the Safety Reporting Portal (hhs.gov) online form to report problems with pet food, dietary supplements, and tobacco products. This form also accepts mandatory reports, such as Reportable Food Registry for Industry.</u>

U.S. Department of Agriculture

USDA Food Safety and Inspection Service (FSIS) promotes food defense by encouraging establishments to voluntarily adopt a functional food defense plan; implement food defense practices (including inside, outside, and personnel security measures); and conduct training and exercises to ensure preparedness. (Note: resources may be found by searching Home | Food Safety and Inspection Service (usda.gov) for keywords Food Defense, Security, and other similar keywords or visiting Food Defense | Food Safety and Inspection Service (usda.gov)).

Food Defense | Food Safety and Inspection Service (usda.gov): This site discusses a comprehensive approach that addresses food safety, food defense, and food security considerations improves resilience and protects public health.

- Food Defense for In-Commerce Firms: Provides resources and information on food safety and food defense for in-commerce firms.
- Food Defense Guidelines for the transportation and Distribution of Meat, Poultry and Processed Egg Products: The FSIS Food Defense Guidelines for the Transportation and Distribution of Meat, Poultry, and Processed Egg Products is designed to assist those handling food products during transportation and storage. These guidelines provide a list of defense measures that can be taken to prevent intentional contamination of meat, poultry, and processed egg products during loading, unloading, transportation, and in-transit storage.

<u>USDA Food and Nutrition Resources (FNS) for Schools:</u>

- A Biosecurity Checklist School Foodservice Programs | Missouri Department of Elementary and Secondary Education (mo.gov): <u>USDA FNS has prepared a</u> <u>Biosecurity Checklist for School Foodservice Programs for developing a biosecurity</u> <u>management plan. Its purpose is to help protect the health of the children and adults</u> <u>in the school by strengthening the safety of the foodservice operation.</u>
- Emergency_readiness_plan_a_guide_for_the_school_foodservice_operation.pdf (hhs.gov): Emergency Readiness Plan: Forms for the School Foodservice Operation includes several prototype forms to assist foodservice professionals when writing an emergency readiness plan.

Responding_Food_Recall_FNS_05302014.pdf (azureedge.us): Provides an overview of the recall process for USDA foods with a focus on school meals programs. Particular attention is given to the roles of various entities in communicating information to ensure that recalls are handled in a timely and effective manner.

Other USDA Resources:

• USDA Meat & Poultry Hotline: 1-888-MPHotline (1-888-674-6854).

Industry Publications:

A variety of resource are available from industry groups. (Note: these documents may also be found by searching for keywords Food Defense, Security, and other similar keywords):

- National Restaurant Association | National Restaurant Association: provides access to security information and guidelines targeted specifically the restaurant industry.
- FMI | The Food Industry Association: provides access to security information and guidelines targeted specifically to food retailers.
- FMI | Voice of The Food Industry Blog: provides access to information.
- Conference-Developed Guides and Documents | Conference for Food Protection:
 Provides guidance documents related to retail food safety.

Guidance on Responding to Food Emergencies

- Environmental Health Services Program Home | EHS | CDC: This site provides free tools and guidance, training, and research for environmental health practitioners and programs serving states, tribes, localities, and territories.
- Information on Specific Types of Emergencies| Emergency Preparedness and Response (cdc.gov): Provides resources for preparedness and response to specific types of emergencies.
- Conference for Food Protection: <u>Provides resources</u>, <u>specifically emergency action</u>
 <u>plan information</u>: <u>Emergency Action Plan for Retail Food Establishments</u> |
 <u>Conference of Food Protection</u>)

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all-inclusive. It contains links to publications from federal regulatory agencies (primarily-FDA, CDC, and USDA) and industry groups with information of interest to regulators, industry, and consumers. Responsibility for updating the web pages lies with the listed-organization and those listed are up to date as of the printing of the 2005 Food Code. FDA Publications:

These guidance documents identify the kinds of preventive measures that food establishment and food processing operators may take to minimize risks to food undertheir control, from tampering or other malicious, criminal, or terrorist actions:

Retail Food Stores and Food Service Establishments: Food Security

Preventive Measures Guidance at

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm082751.htm

• Food Producers, Processors, and Transporters: Food Security Preventive

Measures Guidance at

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083075.htm

Annex 2 - References

333

- Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid
 Milk Processors Food Security Preventive Measures Guidance at
 http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083049.htm.
- Importers and Filers: Food Security Preventive Measures Guidance at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm078978.htm.
- The Bioterrorism Act of 2002 at: http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm.
 USDA Publications:
- Food Safety and Inspection Service (FSIS) Security Guidelines for Food Processors at

FSIS Guidelines "Keep America's Food Safe" at

https://www.fsis.usda.gov/wps/wcm/connect/457116c6-dccb-494a-a419 62d07d4123a4/PHVv2Homeland_Food_SecuritySecurity_Guide.pdf?MOD=AJPERES

https://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-and-emergencyresponse/preparation-and-prevention/guidance-documents/security-guidelines/keepamericas-food-safe-

This guidance is designed to assist transporters, warehouses, distributors, retailers, and restaurants with enhancing their security programs to further protect the food supply from contamination due to criminal or terrorist acts.

• FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products at:

https://www.fsis.usda.gov/shared/PDF/Transportation_Security_Guidelines.pdf
This guidance contains recommendations to ensure the security of food productsthrough all phases of the distribution process.

Annex 2 - References

Annex 2 - References

335

Additional information on FSIS food security guidance publications is available over the Internet at http://www.fsis.usda.gov.

Industry Publications:

- National Restaurant Association. Information for restaurants can be found on the National Restaurant Association's web page at http://www.restaurant.org.
- Food Marketing Institute (FMI) Security Information and Resources web pageat http://www.fmi.org/foodsafety/ provides access to security information and guidelines targeted specifically to food retailers.

Guidance on Responding to Food Emergencies:

- Centers for Disease Control and Prevention (CDC) Emergency Preparedness and Response information can be found at https://www.cdc.gov/nceh/ehs/etp/food.htm.
- USDA Food and Nutrition Service food emergency publication, Responding to a Food Recall at https://www.fns.usda.gov/responding-food-recall-proceduresrecalls-usda-foods-
- FDA's Office of Emergency Operations at 301-443-1240 for FDA regulated products and FSIS Technical Service Center at 1-800-233-3935 for USDA regulated products.
- Conference for Food Protection (CFP) Emergency Action Plan for Retail Food Establishments, 2nd Editon can be found at http://www.foodprotect.org/.
 Food Defense and Emergency Guidance of Interest to Schools:
- A Biosecurity Checklist for School Foodservice: Developing a Biosecurity
 Management Plan

The document is from the USDA - Food and Nutrition Service and provides information for school food service managers. It can be found at https://dese.mo.gov/sites/default/files/BiosecurityRevisedChecklist.pdf. The exact-link to the checklist is http://foodbiosecurity.nfsmi.org/FSManager.php.

- USDA Food and Nutrition Service food emergency publication, Emergency-Readiness Plan: A Guide for the School Foodservice Operation at:
 http://www.nfsmi.org/documentlibraryfiles/PDF/20080207044955.pdf

 Defense Guidance of Interest to Consumers:
- Food Safety and Security: What Consumers Need to Know, at-

http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/getanswers/food-safety-fact-sheets/emergency-preparedness/food-safety-and-securitywhat-consumers-need-to-know.

• Food Tampering: An Extra Ounce of Caution, at

http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079137.htm

Submitter Information 1:

Name: Albert Espinoza, R.S.

Organization: H-E-B

Address: 646 S. Flores

City/State/Zip: San Antonio, TX 78204

Telephone: 2108845783

E-mail: Espinoza.albert@HEB.com

Submitter Information 2:

Name: Jennifer M Bonsky

Organization: Michigan Department of Agriculture and Rural Development

Address: P.O. Box 30017 City/State/Zip: Lansing, MI 48933 Telephone: 15176140149

E-mail: bonskyj@michigan.gov

Issue: 2023 II-041

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:

FDC Issue 4 – Approval and Posting of Food Defense Guidance Document

Issue you would like the Conference to consider:

As a part of our work to promote Food Defense in food establishments, the Food Defense Committee (FDC) developed a guidance document outlining best practices to provide a safe environment, being vigilant to prevent acts of adulteration or product tampering. Consider approval of the guidance document to be posted on the CFP website for conference-developed guides and documents.

Public Health Significance:

Food establishments can utilize this guidance document to promote employee awareness. Having a written simple guidance checklist with important steps may prevent major illness incidence and promote public health.

Recommended Solution: The Conference recommends...:

That the Food Defense Guidance Document attached to issue 1, be approved, and posted to the CFP website as a usable Word document and authorize the Conference to make any necessary edits prior to posting to assure consistency of format and non-technical content: edits will not affect the technical content of the document.

Submitter Information 1:

Albert Espinoza, R.S. Name:

Organization: H-E-B

Address: 646 S. Flores

City/State/Zip: San Antonio, TX 78204

Telephone: 2108845783

E-mail: Espinoza.albert@HEB.com

Submitter Information 2:

Name: Jennifer M Bonsky

Organization: Michigan Department of Agriculture and Rural Development

Address: P.O. Box 30017 City/State/Zip: Lansing, MI 48933 Telephone: 15176140149

E-mail: bonskyj@michigan.gov

Supporting Attachments:

"Food Defense Guidance Document"

Issue: 2023 II-042

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 Is	ssue.						
Title:	Management S	vstem (FSMS) Committ	00				

Issue you would like the Conference to consider:

The Food Safety Management System (FSMS) Committee asks the Conference to acknowledge their final report and thank the committee members for their efforts and hard work.

Public Health Significance:

At the 2020/2021 Biennial Meeting of the Conference for Food Protection, the Food Safety Management System (FSMS) Committee was created and charged (Issue: 2020-II-030) to work with stakeholders such as, but not limited to, the Retail Food Safety Regulatory Association Collaborative to identify recommendations for developing and implementing documented, Hazard Analysis Critical Control Point (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 identified barriers to the universal voluntary development and implementation of documented FSMSs consistent with Annex 4 of the Food Code, solutions for overcoming the identified barriers; and provided recommendations for how to promote the solutions.

The committee also conducted a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs in a future edition of the Food Code taking into consideration the hurdles/challenges involved in such a requirement. We also considered how a requirement to proactively control foodborne illness risk factor occurrence might best be incorporated while recognizing the diversity within the retail and food service industries.

The committee developed recommendations on next steps to promote awareness and education for the universal development and implementation of documented FSMSs consistent with Annex 4.

Recommended Solution: The Conference recommends...:

acknowledgement of the committee's Final Report and thanking the committee members for their work.

Submitter Information 1:

Name: Christine Sylvis

Organization: Southern Nevada Health District

Address: P.O. Box 3902

City/State/Zip: Las Vegas, NV 89017

Telephone: 17027590507 E-mail: sylvis@snhd.org

Submitter Information 2:

Name: Mandy Sedlak

Organization: Ecolab

Address: 1601 West Diehl Road City/State/Zip: Naperville, IL 60563

Telephone: 612-271-4935

E-mail: Mandy.sedlak@ecolab.com

Content Documents:

- "2021-2023 FSMS Committee Roster"
- "2021-2023 FSMS Committee Final Report"
- "FSMS Findings Report"

Supporting Attachments:

- "2021-2023 FSMS Committee Meeting Minutes"
- "2021-2023 FSMS Committee Attendance Log"

Issue: 2023 II-043

Council Recommendation:	Accepted as Submitted	Accepted as	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:						

Issue you would like the Conference to consider:

Amend the most current edition of the FDA Food Code to include Active Managerial Control (AMC) and Food Safety Management Systems (FSMSs) in the definitions in Chapter 1 and incorporate AMC and FSMS into the duties of the person in charge in § 2-103.11.

FSMS #2 Amend Food Code – Define Active Managerial Control and FSMS

Public Health Significance:

In order to make a positive impact on foodborne illness, retail and food service operators must achieve active managerial control of the risk factors contributing to foodborne illness.

As described in Annex 4, active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their businesses to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

The concept of AMC is already contained in the Food Code under the duties of the person in charge in § 2-103.1, but the term is not defined or used in Chapters 1-8, and only used in the annex, preface and the table of contents. The term "active managerial control" is cited 110 times in the Food Code including the annexes.

The FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-service Restaurants, 2013-2014 (FDA 2018) support the concept that operators of retail food establishments must be proactive and implement food safety management systems that will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors. By reducing the occurrence of foodborne illness risk factors, foodborne illnesses can also be reduced.

FSMSs play an important role in controlling hazards in retail operations by incorporating a specific set of actions (e.g., procedures, training, and monitoring) to help achieve active

managerial control of foodborne illness risk factors. The term AMC 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. Ultimately, responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems.

The 2017 FDA Food Code annexes reference "food safety management system" 53 times. Annex 4 supports/recommends the development and implementation of FSMSs and the elements of an effective food safety management system are described. However, the term FSMS is not defined or used in Chapters 1-8.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the most current edition of the Food Code be amended as follows:

- Section 2-103.11 Person in Charge be amended as follows (language to be removed is marked with strikethrough and language added is marked with underline format):
 - 2-103.11 Person in Charge. The PERSON IN CHARGE shall ensure that maintain active managerial control by ensuring:
- The voluntary use of food safety management systems be incorporated into the duties of the person in charge in §2-103.11 Person in Charge.
- 3. The definition of active managerial control be added to §1-201.10 Statement of Application and Listing of Terms.
 - The definition may be taken from Annex 4 which states "Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors."
- 4. The definition of Food Safety Management Systems be added to §1-201.10 Statement of Application and Listing of Terms.
 - The Food Code does not contain a definition of food safety management systems. While working on the charges of Issue 2020-II-030, the CFP Food Safety Management System Committee composed a definition of food safety management systems. This definition is proposed: "Food safety management systems refer 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."

Submitter Information 1:

Name: Christine Sylvis

Organization: Southern Nevada Health District

Address: P.O. Box 3902

City/State/Zip: Las Vegas, NV 89017

Telephone: 702-759-0507 E-mail: sylvis@snhd.org

Submitter Information 2:

Name: Mandy Sedlak

Organization: Ecolab

Address: 1601 West Diehl Road City/State/Zip: Naperville, IL 60563

Telephone: 612-271-4935

E-mail: Mandy.sedlak@ecolab.com

Supporting Attachments:

"FDA Report on the Occurrence of Foodborne Illness Risk Factors- Restaurants"

Issue: 2023 II-044

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted _	Rejected	
All information above the line	e is for conference use onl	ly.	
Issue History:			
This is a brand new Is	ssue.		
Title:			
FSMS #3 Re-create F	SMS Committee		

Issue you would like the Conference to consider:

The Food Safety Management System (FSMS) Committee be reestablished to continue 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.

Public Health Significance:

FSMSs are an important concept that needs further development to educate regulators and industry on the topic, increase awareness on the benefits of FSMSs, develop tools and resources for establishments to implement FSMSs, and the incorporation of FSMSs into future editions of the Food Code.

Recommended Solution: The Conference recommends...:

The Food Safety Management System (FSMS) Committee be reestablished with the following charges:

- 1. Collaborate with the Retail Food Safety Regulatory Association Collaborative to create resources for establishments to develop FSMSs.
 - a. Toolbox may include instructions how to create a SOP, draft SOP templates, job aids, case studies, etc. The committee should consider reviewing the "Guidance for School Food Authorities: Developing a School Food Safety Program Based on the Process Approach to HACCP Principles."
 - b. Review the CDC EHS-Net project on employee health and consider collaborating to build on the results to further expand a framework to address employee health FSMSs.
- 2. Review 2021-2023 FSMS Committee Committee Charges Report and identify specific items to develop remedies.

- 3. Develop recommendations on next steps to promote universal development and implementation of documented FSMSs to be included in a future edition of the Food Code.
 - a. Conduct a gap analysis of Food Code § 2-103.11 to identify opportunities to incorporate FSMSs into the duties of the person in charge.
- 4. Collaborate with the Retail Food Safety Regulatory Association Collaborative to conduct a cost/benefit analysis of implemented FSMSs.
- Report the committee's findings and recommendations at the next Biennial Meeting of the Conference for Food Protection. Surender

Submitter Information 1:

Name: Christine Sylvis

Organization: Southern Nevada Health District

Address: P.O. Box 3902

City/State/Zip: Las Vegas, NV 89017

Telephone: 702-759-0507 E-mail: sylvis@snhd.org

Submitter Information 2:

Name: Mandy Sedlak

Organization: Ecolab

Address: 1601 West Diehl Road City/State/Zip: Naperville, IL 60563

Telephone: 612-271-4935

E-mail: Mandy.sedlak@ecolab.com

Issue: 2023 II-045

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended		No Action	
Delegate Action:	Accepted		_ Rejected		_	
All information above the line	e is for conference use	only.				
Issue History:						
This is a brand new Issue.						
Title:						
FSMS #4 – Create FSMS Committee as Standing Committee						

Issue you would like the Conference to consider:

Convert the current Food Safety Management System (FSMS) Council Committee to a new Standing Committee and add duties and charges to the Constitution and Bylaws for the FSMS Committee.

The 2021 CFP Meeting established the FSMS Committee. During the process of completing their charges, the committee identified much more work needed in this initiative. They foresee future endeavors in harmonizing person in charge responsibilities in the FDA Food Code to include the implementation of FSMS, providing additional resources for establishments to develop written FSMSs, and aid in development of a foundation to build a positive food safety culture.

Public Health Significance:

The FDA Food Code emphasizes the need for risk-based preventive controls and daily active managerial control (AMC) of the risk factors contributing to foodborne illness in food establishments. AMC is "the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors". AMC involves the proactive identification and prevention of food safety hazards through a continuous system of monitoring and verification procedures for performing critical operational steps in a food preparation process. Two strategies supporting AMC efforts in food establishments have received growing attention: The presence of a Certified Food Protection Manager (CFPM) and the implementation of FSMSs.

Inadequate FSMSs are thought to contribute to the worldwide burden of foodborne disease (Luning et al., 2008). For example, HACCP has been shown to have positive effects on food safety, but the poor implementation of HACCP has been described as a precursor to foodborne outbreaks (Cormier, 2007; Luning et al., 2009; Ropkins and Beck, 2000).

The 2013-2024 FDA Retail Food Risk Factor Study examines the occurrence of foodborne illness risk factors, food safety practices, and behaviors in food establishments. In the 2013-2014 Restaurant Data Collection study, the agency investigated the relationship between FSMSs, CFPM, and the occurrence of foodborne illness risk factors from 2013 to 2014. FSMSs were the strongest predictor of data items being out-of-compliance in both fast food and full-service restaurants. The average number of out-of-compliance data items was greatly reduced when there was a well-developed FSMS in place. This was true for both fast food restaurants and full-service restaurants. On average, restaurants with well-developed FSMSs had less than half as many risk factors and food safety practices that were out-of-compliance than restaurants with non-existent FSMSs.

Following the October 2010 release of the FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998-2008), the FDA launched its Retail Food Safety Initiative which further emphasized the need for industry to establish food safety management systems and actively monitor compliance with those systems to reduce the occurrence of risk factors in retail operations.

In recognition of the importance of FSMSs in managing food safety hazards, the USDA has required all public schools to have a food safety plan based on process HACCP principles since 2005. Schools that do not meet this mandate are in jeopardy of losing their federal funds. The FDA collaborated with USDA on the development of the food safety plan model.

Despite over 20 years of promotion of voluntary FSMSs, widespread adoption of the Food Code across the U.S., and other ongoing food safety prevention efforts at the retail level, foodborne illness from retail establishments continues to be a substantial public health burden that must be addressed in novel ways.

The 2021-2023 FSMS Committee completed the charges of identifying barriers to the universal voluntary development and implementation of documented FSMSs. The Committee identified solutions for overcoming the barriers, conducted a pros/cons assessment of including a requirement for food establishments to develop and implement FSMSs in a future edition of the Food Code, and developed recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4. The FSMS Committee should work with the Retail Food Safety Regulatory Association Collaborative and other identified stakeholders. A Standing Committee will allow for charges to be assigned as they are identified without the recreation of the committee each biennium. Future assignments to the FSMS Standing Committee may include:

- reviewing the findings of the 2021-2023 FSMS Committee to identify specific items to develop remedies for
- creating resources to aid retail food establishments in developing FSMSs
- reviewing the CDC EHS-Net project on employee health and consider collaborating to address the employee health component in FSMSs, and
- conducting a cost/benefit analysis of implemented FSMSs.

Recommended Solution: The Conference recommends...:

1.) Amend the CFP Constitution and Bylaws 2021, Article XV Committees, Section 2 to include a new Food Safety Management System Committee (new language is underlined):

Article XV Committees

Section 2. The following Standing Committees shall be established:

- Issue Committee
- Program Committee
- Constitution and Bylaws/Procedures Committee
- Resolutions Committee
- Audit Committee
- Food Protection Manager Certification Committee (FPMCC)
- Program Standards Committee
- Finance Committee
- Nominating Committee
- Strategic Planning Committee (SPC)
- Publications Committee
- Food Safety Management System (FSMS)
- 2.) Amend the CFP Constitution and Bylaws 2021, Article XVI Duties and Responsibilities of Committees to include a new Section 12 which describes the purpose of the Food Safety Management System Committee and the current Sections 12 and 13 be renumbered to accommodate the change (new language is underlined):

Section 12. The Food Safety Management System Committee shall report to the Board and shall have the objective of incorporating Food Safety Management Systems into everyday activities of retail food establishments and provide ongoing development of resources to assist the food safety community in achieving active managerial control of foodborne illness risk factors.

Submitter Information 1:

Name: Christine Sylvis

Organization: Southern Nevada Health District

Address: P.O. Box 3902

City/State/Zip: Las Vegas, NV 89017

Telephone: 702-759-0507 E-mail: sylvis@snhd.org

Submitter Information 2:

Name: Mandy Sedlak

Organization: Ecolab

Address: 1601 West Diehl Road City/State/Zip: Naperville, IL 60563

Telephone: 612-271-4935

E-mail: Mandy.sedlak@ecolab.com

Supporting Attachments:

• "Reference for FSMS #4 – Create FSMS Committee as Standing Committee"

Issue: 2023 II-046

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:						
Report - Digital Food Safety System Committee (DFSSC)						

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Digital Food Safety System Committee seeks Council II's acknowledgment of the committee's final report and expression of thanks to the committee members for their work

Public Health Significance:

The Digital Food Safety System Committee was established at the 2020 CFP Biennial Meeting (Issue 2020-II-021). The committee was charged to identify existing best practices, guidance documents, and research related to the use of digital food safety management systems including digital temperature monitoring equipment. This information has been reviewed and compiled by the committee members into a guidance document titled Draft General Best Practice Guidelines for Digital Food Safety Management Systems (DFSMS). This guidance document has been created for use and/or reference for industry and regulatory authorities to provide general knowledge and awareness around technology as use of these systems continues to increase in the retail food industry. The committee also reviewed, discussed, and has provided recommendations around appropriate methods to share the committee's work which completes the final charge of the committee.

Recommended Solution: The Conference recommends...:

- 1. Acknowledgement of the Digital Food Safety System Committee Final Report.
- 2. Thank the voting members, at large non-voting members, federal consultants and observers for their dedication and hard work.
- 3. Disband the committee; all assigned charges have been completed.

Submitter Information 1:

Name: Eric Moore

Organization: Testo North America
Address: 2 West Market StSuite 5
City/State/Zip: West Chester, PA 19060

Telephone: 215.806.4717 E-mail: emoore@testo.com

Submitter Information 2:

Name: Ben Chapman

Organization: North Carolina State University

Address: North Carolina State UniversityCampus Box 7606

City/State/Zip: Raleigh, NC 27695

Telephone: 919.515.8099

E-mail: bjchapma@ncsu.edu

Content Documents:

- "Digital Food Safety System Committee Final Report"
- "Digital Food Safety System Committee Member Roster"
- "General Best Practice Guidelines for Digital Food Safety Management"

Supporting Attachments:

- "Original CFP Issue 2020 II 021"
- "DFSSC Meeting Minutes"
- "DFSSC Definitions"
- "Computerized Systems in Food Processing FDA"
- "SubCommittee Draft DFSS Best Practices Doc"

Issue: 2023 II-047

Council Recommendation:	Accepted as Submitted	Accepted as _ Amended	 No Action	
Delegate Action:	Accepted	_ Rejected		
All information above the line	e is for conference use only.			
Issue History: This is a brand new Is	ssue.			
Title:				

Issue you would like the Conference to consider:

DFSSC 2 - Approve and Post General Best Practice Guidelines

The Conference for Food Protection (CFP) Digital Food Safety System Committee seeks Council II's

approval of the General Best Practice Guidelines for Digital Food Safety Management Systems and posting of the document to the CFP website.

Public Health Significance:

The Digital Food Safety System Committee was established at the 2020 CFP Biennial Meeting (Issue 2020-II-021). The committee was charged to identify existing best practice, guidance documents, and research related to the use of digital food safety management systems including digital temperature monitoring equipment. This information has been reviewed and compiled by the committee members to establish a guidance document, General Best Practice Guidelines for Digital Food Safety Management Systems, intended for use and/or reference by industry and regulatory authorities as the adoption of technology platforms continues to increase in the retail food industry.

Recommended Solution: The Conference recommends...:

- Approval of the committee generated draft guidance document entitled "DRAFT General Best Practice Guidelines for Digital Food Safety Management Systems" (See document attached to Issue titled: Report - Digital Food Safety System Committee (DFSSC)).
- 2. Posting of the guidance document on the CFP website in a downloadable format with functional hyperlinks; and
- Authorizing the Conference to make any additional edits prior to posting the document to assure consistency of format and non-technical content; edits will not affect the technical content of the document.

Submitter Information 1:

Name: Eric Moore

Organization: Testo North America
Address: 2 West Market StSuite 5
City/State/Zip: West Chester, PA 19060

Telephone: 215.806.4717

E-mail: emoore@testo.com

Submitter Information 2:

Name: Ben Chapman

Organization: North Carolina State University

Address: North Carolina State UniversityCampus Box 7606

City/State/Zip: Raleigh, NC 27695

Telephone: 919.515.8099

E-mail: bjchapma@ncsu.edu

Issue: 2023 II-048

Council Recommendation:	Accepted as Submitted	Accepted as Amended		No Action	
Delegate Action:	Accepted	Rejected		_	
All information above the line	e is for conference use only.				
Issue History: This is a brand new Issue.					
Title:					

DFSSC 3 - Amend Food Code Annexes to Include Reference to Guidance Document

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Digital Food Safety System Committee requests Annexes 2 and 4 (or the location deemed appropriate by the FDA) of the FDA Food Code be amended to include/reference the document titled "General Best Practice Guidelines for Digital Food Safety Management Systems". The Committee recognizes that FDA may implement this solution in a different manner than what is written here and supports this action.

Public Health Significance:

The 2020 biennial meeting established the formation of the Digital Food Safety System Committee to identify existing best practice, guidance documents, and research related to the use of digital food safety management systems including digital temperature monitoring equipment. The committee was also charged with 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. This information has been reviewed and compiled by the committee members to establish a guidance document, General Best Practice Guidelines for Digital Food Safety Management Systems, intended for use and/or reference by industry and regulatory authorities as the adoption of technology platforms continues to increase in the retail food industry.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that the current version of the FDA Model Food Code Annex 4 - Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors, and Annex 2 - References, 3. Supporting Documents be amended by including a reference to the "General Best Practice Guidelines for Digital Food Safety Management Systems" (document is attached to Issue titled: Report - Digital Food Safety System Committee (DFSSC)).

Submitter Information 1:

Name: Eric Moore

Organization: Testo North America
Address: 2 West Market StSuite 5
City/State/Zip: West Chester, PA 19060

Telephone: 215.806.4717

E-mail: emoore@testo.com

Submitter Information 2:

Name: Ben Chapman

Organization: North Carolina State University

Address: North Carolina State UniversityCampus Box 7606

City/State/Zip: Raleigh, NC 27695

Telephone: 919.515.8099

E-mail: bjchapma@ncsu.edu

Issue: 2023 II-049

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: 2020-II-011; new or additional information has been included or attached.

Title:

Report – Allergen Committee

Issue you would like the Conference to consider:

Acknowledgement of the 2021 - 2023 Allergen Committee Final Report and thanking the committee members for the completed work.

Public Health Significance:

Food allergies and sensitivities impact at least 3% of the human population. Researchers estimate that 32 million Americans have food allergies, including 5.6 million children under age 18 - that is roughly two children in every classroom. 1, 2, 3

Studies published in 2018 and 2019 estimate the number of Americans of all ages who have convincing symptoms of allergy to specific foods: shellfish(8.2 million), milk (6.1 million), peanut (6.1 million), tree nuts (3.9 million), egg (2.6 million) fin fish (2.6 million), wheat (2.4 million), soy (1.9 million), sesame (0.7 million).^{1,4}

Managing allergen exposure is the only reliable method of reducing the incidence of life-threatening allergic reactions. There must be clear communication between the consumer and the food worker to control for allergens in the flow of food. It was recognized by the previous Allergen Committee that a framework be developed to provide useful training and educational materials to foods workers, management, and the public.

References

- 1. Gupta RS, Warren CM, Smith BM, Jiang J, Blumenstock JA, Davis MM, Schleimer RP, Nadeau KC. Prevalence and Severity of Food Allergies Among US Adults. JAMA Network Open 2019; 2(1):e185630.doi:10.1001/jamanetworkopen.2018.5630.
- 2. United States Census Bureau Quick Facts (2015 and 2016 estimates).
- 3. Gupta RS, Warren CM, Smith BM, Blumenstock JA, Jiang J, Davis MM, Nadeau KC. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. Pediatrics 2018; 142(6):e20181235.

4. Warren CM, Chadha AS, Sicherer SH, Jiang J, Gupta RS. Prevalence and Severity of Sesame Allergy in the United States. JAMA Network Open 2019; 2(8):e199144. doi:10.1001/jamanetworkopen.2019.9144.

Recommended Solution: The Conference recommends...:

Acknowledgement of the 2021 - 2023 Allergen Committee (AC) Report, and thanks the committee members for the completed work.

Submitter Information 1:

Name: Amani Babekir, Co-chair

Organization: Ecolab

Address: 8300 Capital Drive City/State/Zip: Greensboro, NC 27409

Telephone: 336-931-2139

E-mail: amani.babekir@ecolab.com

Submitter Information 2:

Name: Michelle Hill, Co-chair Organization: Allergen Free Cooking 9122 Princeton Court City/State/Zip: Woodbury, MN 55125

Telephone: 612-701-4004

E-mail: michelle@allergenfreecook.com

Content Documents:

- "Allergen Committee (AC) Final Report to the Executive Board"
- "Allergen Committee Member Roster"
- "Major Food Allergen Framework"
- "SUMMARY Major Food Allergen Framework"

Supporting Attachments:

- "Allergen Committee Meeting Minutes"
- "Allergen Committee Meeting Attendance"

Issue: 2023 II-050

Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	
Delegate Action:	Accepted _		Rejected			
All information above the line	is for conference use only	y.				
Issue History: This is a brand new Issue.						

Title:

Allergen Committee 2 Publish "Major Food Allergen Framework" and SUMMARY

Issue you would like the Conference to consider:

The "Major Food Allergen Framework" is meant to be a useful tool for food employees to understand and control for the Major Food Allergens in food intended for consumers, and we request that this document, and its Summary, be posted on CFPs website, making it accessible.

Public Health Significance:

Food allergies are experienced by approximately 32 million people in the United States each year, 1, 2, 3 with more than 170 foods being reported to cause these reactions. 4 Every three minutes, a food allergy reaction sends someone to the emergency room. 5

It is estimated that the Major Food Allergens have the greatest impact on the US population, with millions reporting convincing symptoms of allergic reactions to shellfish (8.2 million), milk (6.1 million), peanut (6.1 million), tree nuts (3.9 million), egg (2.6 million), fin fish (2.6 million), wheat (2.4 million), soy (1.9 million), sesame (0.7 million).

The most common food allergies in children are to peanut, milk, shellfish, and tree nut; where as the most common food allergies experienced in adults are to shellfish, milk, peanut, and tree nut.⁷

Reports suggest that most fatal food allergy reactions are triggered by food consumed outside the home, 8, 9, 10 with ingestion of an allergen the concern for severe reactions. 11, 12

Avoiding allergens requires careful reading of labels and stringent cleaning procedures, as even trace amounts of a food allergen can cause a reaction. ^{13, 14, 15, 16} In the US, advisory/precautionary labeling is voluntary. The terms do not reflect specific risks, and random product testing has found allergen levels ranging from undetectable to amounts that can cause allergic reactions. ¹⁷ Given this uncertainty in the marketplace, it is important to understand how to control for the nine Major Food Allergens as defined by the 2022 Food Code.

References

- 1. Gupta RS, Warren CM, Smith BM, Jiang J, Blumenstock JA, Davis MM, Schleimer RP, Nadeau KC. Prevalence and Severity of Food Allergies Among US Adults. JAMA Network Open 2019; 2(1):e185630.doi:10.1001/jamanetworkopen.2018.5630.
- 2. United States Census Bureau Quick Facts (2015 and 2016 estimates).
- 3. Gupta RS, Warren CM, Smith BM, Blumenstock JA, Jiang J, Davis MM, Nadeau KC. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. Pediatrics 2018; 142(6):e20181235.
- 4. NIAID-Sponsored Expert Panel. Guidelines for the diagnosis and management of food allergy in the United States: Report of the NIAID-sponsored expert panel. J Allergy Clin Immunol. 2010; 126(6):S1- 58.
- 5. Clark S, Espinola J, Rudders SA, Banerji, A, Camargo CA. Frequency of US emergency department visits
- 6. Warren CM, Chadha AS, Sicherer SH, Jiang J, Gupta RS. Prevalence and Severity of Sesame Allergy in the United States. JAMA Network Open 2019; 2(8):e199144. doi:10.1001/jamanetworkopen.2019.9144.
- 7. Kamdar TA, Peterson S, Lau CH, Saltoun CA, Gupta RS, & Bryce PJ. Prevalence and characteristics of adult-onset food allergy. J Allergy Clin Immunol Pract. 2015; 3(1):114-115.e1.
- 8. Bock SA, Muñoz-Furlong A, Sampson HA. Further fatalities caused by anaphylactic reactions to food, 2001-2006. J Allergy Clin Immunol. 2007; 119(4):1016-1018.
- 9. Bock SA, Muñoz-Furlong A, Sampson HA. Fatalities due to anaphylactic reactions to foods. J Allergy Clin Immunol. 2001; 107(1):191-193.
- 10. Sampson HA, Mendelson L, Rosen J. Fatal and near-fatal anaphylactic reactions to food in children and adolescents. N Engl J Med.1992; 327(6):380-384.
- 11. Greenhawt MJ, McMorris MS, Furlong TJ. Self-reported allergic reactions to peanut and tree nuts on commercial airlines. J Allergy Clin Immunol. 2009; 124(3):598-599.
- 12. Comstock SS, DeMera R, Vega L, Boren EJ, Deanne S, Haapanen LA, Teuber SS. Allergic reactions to peanuts, tree nuts, and seeds aboard commercial airliners. Ann Allergy Asthma Immunol. 2008; 101:51-56.
- 13. Yunginger JW, Gauerke MB, Jones RT, Dahlberg MJE, Ackerman SJ. Use of radioimmunoassay to determine the nature, quantity and source of allergenic contamination of sunflower butter. J Food Prot. 1983; 46:625-628.
- 14. Jones R, Squillace D, Yunginger J. Anaphylaxis in a milk-allergic child after ingestion of milk contaminated kosher-pareve-labeled "dairy-free" dessert. Ann Allergy. 1992; 68:223-227.
- 15. Hourihane J, Kilbrun S, Nordlee J, et al. An evaluation of the sensitivity of subjects with peanut allergy to very low doses of peanut: a randomized, double-blind, placebo-controlled food challenge study. J Allergy Clin Immunol. 1997; 100:596-600.
- 16. Ford LS, Taylor SL, Pacenza R, Niemann LM, Lambrecht DM, Sicherer SH. Food allergen advisory labeling and product contamination with egg, milk, and peanut. J Allergy Clin Immunol. 2010; 126(2):384-385.

17. Ford LS, Taylor SL, Pacenza R, Niemann LM, Lambrecht DM, Sicherer SH. Food allergen advisory labeling and product contamination with egg, milk, and peanut. J Allergy Clin Immunol. 2010; 126(2):384-385.

Recommended Solution: The Conference recommends...:

1. Acceptance of the committee-generated document entitled, "Major Food Allergen Framework" (attached as content to this Issue);

and

2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP website to assure consistency of format and non-technical content; edits will not affect the technical content of the document:

and

- 3. Prior to posting the final document on the CFP website in PDF format, it will be reviewed to remove any potential violations of the CFP Commercialism and Comity Policy;
- and

4. Removal of the CFP-approved document, "Food Allergy Notifications: A Guidance for Industry," from the CFP website as it is now addressed within the document, "Major Food Allergen Framework."

Submitter Information 1:

Name: Amani Babekir, Co-chair

Organization: Ecolab

Address: 8300 Capital Drive City/State/Zip: Greensboro, NC 27409

Telephone: 336-931-2139

E-mail: amani.babekir@ecolab.com

Submitter Information 2:

Name: Michelle Hill

Organization: Allergen Free Cooking Address: 9122 Princeton Court City/State/Zip: Woodbury, MN 55125

Telephone: 612-701-4004

E-mail: michelle@allergenfreecook.com

Content Documents:

- "Major Food Allergen Framework"
- "Summary Major Food Allergen Framework"

Issue: 2023 II-051

Council Recommendation:	Accepted as Submitted		Accepted as _Amended	No Action	
Delegate Action:	Accepted		_ Rejected	 _	
All information above the line	e is for conference use	e only.			
Issue History: This is a brand new Is	ssue.				
Title·					

Issue you would like the Conference to consider:

The document, "Major Food Allergen Framework" contains critical guidance and information about food allergens and was developed to provide support to both food service workers and consumers. Annex 2 of the FDA Model Food Code, entitled "References", provides information in support of provisions throughout the Code, and is the location where Food Allergens could be housed. By adding to the existing list, item "5. Food Allergens", a predictable space within Annex 2 is created where guidance and resources can now be listed and into the future.

Allergen Committee 3 Amend Annex 2 "References" Section of the Food Code.

Public Health Significance:

The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service.

This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. Alternatives that offer an equivalent level of public health protection to ensure that food at retail and foodservice is safe are recognized in this model."¹

In addition, the FDA Code contains a series of annexes which provide the backup information (scientific data, references, or rational, etc.) for the guidelines in each chapter. If one wishes to further understand the reasoning behind the Food Code, the Annexes provide that information.

By publishing the "Major Food Allergen Framework" within the Annex of the Food Code, FDA will be further clarifying its satisfaction of the CFP Issue 2008-III-06, which deals with educating people around food allergens and promoting food allergy awareness.² Once

included as, or part of, an Annex, additional framework documents could be listed, including any future CFP-published documents around allergen control and the prevention of cross-contact.

References

- (1) FDA Food Code, page i (PDF page 3)
- (2) FDA Food Code, page 350 351 (PDF pages 406 407)

Recommended Solution: The Conference recommends...:

1. A letter be sent to FDA requesting that Annex 2 "References", or other location where deemed appropriate by FDA, of the most current edition of the Food Code be amended as follows:

FDA Food Code, page 290 (PDF page 323)

Insert "<u>5. Food Allergens</u>" and dedicate this section to food allergen references including the "Major Food Allergen Framework" with the direct link to the CFP website where the document is housed.

Possible introductory paragraph, "5. The following is a summary of available resources on Food Allergens that is of interest to the retail and food service community. This listing is provided below and is not all inclusive. Responsibility for updating the web pages lies with the listed organization."

Submitter Information 1:

Name: Amani Babekir, Co-chair

Organization: Ecolab

Address: 8300 Capital Drive City/State/Zip: Greensboro, NC 27409

Telephone: 336-931-2139

E-mail: amani.babekir@ecolab.com

Submitter Information 2:

Name: Michelle Hill, Co-chair Organization: Allergen Free Cooking Address: 9122 Princeton Court City/State/Zip: Woodbury, MN 55125

Telephone: 612-701-4004

E-mail: michelle@allergenfreecook.com

Issue: 2023 II-052

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:

Allergen Committee 4 Re-create the Allergen Committee

Issue you would like the Conference to consider:

Re-creation of the Allergen Committee would allow the expansion of the document "Major Food Allergen Framework" to provide further guidance around cross-contact, allergen control, tools, and information pertaining to non-major food allergens.

Public Health Significance:

Dealing with food allergies can be overwhelming for a consumer as well as a food worker. The effects of a food-induced allergic reaction range from bothersome to potentially deadly. There is no cure, so anyone with a food allergy must vigilantly avoid the foods that trigger a reaction.¹ This places pressure on food workers to understand allergenic ingredients and how they appear in products, including non-major food allergens. It also makes it crucial that messaging around cross-contact be aimed at both the food worker *and* the consumer².

A "framework" is defined as, "a set of principles, ideas, etc. that you use when you are forming your decisions and judgments." Cross-contact describes the inadvertent introduction of an allergen into a product that would not intentionally contain that allergen as an ingredient.

While most cross-contact can be avoided through control of the environment during food production and preparation, only cross-contact by Major Food Allergens is currently addressed, so guidance falls short of comprehensive cross-contact control for food allergens.

In an effort to reduce the incidence of food allergic reactions, including those provoked by non-Major Food Allergens, the development of a comprehensive framework around allergen control within Retail Food operations is necessary. Clear, concise, uniform messaging around cross-contact⁴, what it is and how to avoid it, is essential to this framework.

References

- 1. Retrieved November 9, 2022, from, https://www.health.harvard.edu/healthbeat/6-tips-formanaging-food-allergies/
- 2. Article "CUSTOMER JOURNEYS: How to Keep Customers Connected and Coming Back" retrieved November 9, 2022, from https://www.salesforce.com/products/marketing-cloud/best-practices/customer-journeys/
- 3. Definition retrieved November 9, 2022, from https://www.macmillandictionary.com/us/dictionary/american/framework
- 4. Article "Avoiding Cross-Contamination and Cross-Contact in Commercial Kitchens" retrieved November 9, 2022, from https://modernrestaurantmanagement.com/avoiding-cross-contamination-and-cross-contact-in-commercial-kitchens/

Recommended Solution: The Conference recommends...:

Re-creation of the Allergen Committee with the following charges:

- 1. Using existing research and resources to expand upon the "Major Food Allergen Framework" to include:
- a. Guidance on how to control non-major food allergen cross-contact, including during receiving, storage, holding, preparation (including knowledge of preparation methods), and service.
- b. Identify and gather existing research and resources to form an "Allergen Control Toolkit", (which could include checklists, infographics, allergen matrix for all products, etc.) that can be used by food workers to better understand allergen control.
- c. Identify and establish tools (such as SOPs, standardized menus, ingredient lists, quality assurance, etc.) to support the PIC when training food workers around notifying a Consumer about food allergens.
- d. Update the document "Major Food Allergen Framework" to include the gathered information from steps a c.
- 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.

Submitter Information 1:

Name: Amani Babekir, Co-chair

Organization: Ecolab

Address: 8300 Capital Drive City/State/Zip: Greensboro, NC 27409

Telephone: 336-931-2139

E-mail: amani.babekir@ecolab.com

Submitter Information 2:

Name: Michelle Hill, Co-chair Organization: Allergen Free Cooking 9122 Princeton Court

City/State/Zip: Telephone: E-mail: Woodbury, MN 55125

612-701-4004

michelle@allergenfreecook.com

Issue: 2023 II-053

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted _	Rejected	
All information above the line	e is for conference use only	/.	
Issue History:			
This is a brand new Is	ssue.		
Title:			
Create a CFP Techno	ology Solutions Stan	ding Committee	

Issue you would like the Conference to consider:

This Issue proposes creating a new Standing Committee and adding duties and charges to the Constitution and Bylaws for a CFP Technology Solutions Standing Committee.

In April 2019, the CFP Strategic Planning Committee proposed to the Board the creation of a new Standing Committee to work under the general charge to:

- Define the known channels of communication (Website/Email/Mobile App/Social), their architecture and function for the membership.
- Define the functions for engagement at the Biennial meeting and Ongoing Sustainment Biennial Meeting (App/Website/Social Media: Virtual Conference/Council Tracking or "Blogs"/Navigator).
- Sustaining/Ongoing:
 - Member-Facing (Mobile App/Social Media/Website Revision: News/Reports/Virtual Roundtables/Multiformat Info Sharing/Forums)
 - Volunteer-Facing (App/Website: Volunteer Portal/Volunteer Committee Forums or "workrooms")
- Define "user needs" (Member Biennial Meeting/Member Ongoing/Volunteer Ongoing)

In September 2020, the Board established an ad hoc Digital Engagement Committee to investigate options for managing membership services and services related to biennial meetings; committee charges included:

- 1. Work with Conference leadership to identify membership services and services related to Biennial Meetings that are: a. Provided through the current contract with Eventbrite; and b. Needed in addition to the services provided by Eventbrite to best serve CFP members.
- 2. Conduct research for potential replacement vendors.

- 3. Obtain cost estimates for the most viable vendor packages; and
- 4. Report recommendations back at the April 2021 Board meeting.

An ad hoc Digital Engagement Committee was reappointed by the Board for the 2021-2023 biennium with the following charges:

- 1. Ensure CFP's biennial meeting app (e.g., Attendify) is ready for next biennial meeting. The app must meet or exceed the features/functionality of the last meeting.
- 2. Explore and make recommendation to board for "people resources" needed to sustain CFP's digital/technology strategy (e.g., Wild Apricot database admin, social media admin, digital/technology committee).
- 3. Explore CFP needs and pros/cons of making the Ad Hoc Digital Engagement Committee a standing committee and make recommendation to board prior to next CFP meeting.
- 4. Compile prioritized list of future website needs/improvements (functionality, aesthetics, content, etc.) and requirements, which can be used to gather bids for website redesign services.
- 5. Identify video conference and document storage/sharing solution needs and requirements, identify potential solutions, explore costs, and make recommendation to the board.

During completion of the 2021-2023 charges (above), the committee identified ongoing work activity needed to enhance CFP technology solutions and simplify and encourage member engagement. The ad hoc committee foresees work beyond the 2023-2025 biennium with charges that include but are not limited to identifying, vetting, and recommending:

- 1. document sharing and collaboration solutions,
- 2. website redesign/optimization,
- 3. process optimization,
- 4. social media and communication solutions,
- 5. ongoing technology solution support.

In fulfillment of charge #3 for the 2021-2023 biennium, the CFP Board has approved the submittal of this Issue to convert the ad hoc Digital Engagement Committee to a new Standing Committee.

The purpose of a standing Digital Engagement and Technology Solutions committee will be to engage and bring value to CFP membership by identifying, researching, and recommending digital/technology solutions. In determining our recommended charges, the current ad hoc committee does <u>not</u> believe hybrid or virtual biennial meeting solution sourcing or IT problem solving should be a function of this committee because the biennial meeting requires specialized event planning focus, and troubleshooting requires IT skill capabilities beyond those of a typical CFP volunteer.

Public Health Significance:

The mission and operational work of the Conference for Food Protection is dependent upon the engagement of its members, volunteers (board/committees/councils), and partner organizations. Prior membership surveys have identified opportunities for CFP to better leverage technology to remove member engagement barriers including locating information, streamlining staff and volunteer time commitments, optimizing communication, and sharing strategic and operational decisions across committees, etc. Modern engagement and technology solutions will better attract and enable next generations of CFP members to engage more easily to continue CFP's public health focused mission and operations.

Recommended Solution: The Conference recommends...:

1.) Amend the CFP Constitution and Bylaws 2021, Article XV Committees, Section 2 to include a new bullet for the Digital Engagement and Technology Solutions Committee (new language is underlined):

Article XV Committees

Section 2. The following Standing Committees shall be established:

- Issue Committee
- Program Committee
- Constitution and Bylaws/Procedures Committee
- Resolutions Committee
- Audit Committee
- Food Protection Manager Certification Committee (FPMCC)
- Program Standards Committee
- Finance Committee
- Nominating Committee
- Strategic Planning Committee (SPC)
- Publications Committee
- Digital Engagement and Technology Solutions Committee (DETS)
- 2.) Amend the CFP Constitution and Bylaws 2021, Article XVI Duties and Responsibilities of Committees, to insert a new Section 12 which describes the duties of the Digital Engagement and Technology Solutions Committee, and the current Sections 12 and 13 be renumbered to accommodate the change (new language is underlined).

Section 12. The Digital Engagement and Technology Solutions Committee shall report to the Board and shall have the objective of identifying, vetting, and recommending digital engagement and technology solutions which brings value to membership, encourages engagement with CFP, and improves internal processes. This committee will also work with the Board to identify and prioritize digital technology activities for each biennium.

The Conference also recommends the Digital Engagement and Technology Solutions Committee be charged during the 2023-2025 biennium to identify, vet, and recommend to the CFP Board:

- 1) document sharing and collaboration solutions,
- 2) website redesign/optimization,
- 3) social media and communication solutions.

Submitter Information 1:

Name: Vanessa Bussiere

Organization: Aspire Food Safety Solutions LLC

Address: Tacoma, WA 98422 City/State/Zip: Tacoma, WA 98422

Telephone: 253-334-5181

E-mail: vanessa@aspirefoodsafety.com

Submitter Information 2:

Name: Chirag Bhatt

Organization: HS Gov Tech Solutions Inc.

Address: Houston, TX

City/State/Zip: Houston, TX 77002

Telephone: 281-684-6883

E-mail: Chirag.Bhatt@hsgovtech.com

Issue: 2023 III-001

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: 2020-III-015; new or additional information has been included or attached.

Title:

Report - Eval of Intended Use Hazards During Retail Meat Grinding Committee

Issue you would like the Conference to consider:

The Evaluation of Intended Use Hazards During Retail Meat Grinding Committee (IUMGC) requests acknowledgement of their final report and thanking the committee members for their efforts and hard work.

Public Health Significance:

STECs are hazards that are reasonably likely to occur in raw beef products and in 2011, USDA FSIS declared raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, contaminated with Shiga toxin-producing *Escherichia coli* (STEC) O26, O45, O103, O111, O121, or O145 adulterated (76 FR 58157; Sep. 20, 2011). A previously published CFP document, "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" (2014), was developed to provide food safety guidelines for grinding raw beef at retail. In addition, in 2015, USDA FSIS published a final rule requiring recordkeeping at retail establishments for raw beef grinding operations, "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" (80 FR 79231; Dec 21, 2015), to facilitate identification of product during foodborne illness investigations.

In continued outreach to the food industry in 2021, USDA FSIS published "Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" emphasizing the importance of considering the intended use of intact and non-intact beef products. USDA FSIS and other issues submitted to CFP in 2020 (August 2021 Conference) requested that the 2014 CFP guidance be updated with additional information on the importance of considering the intended use of beef products prior to grinding to reduce the risk of contamination of STECs in beef ground at retail and the importance of sharing this information.

In order to increase awareness of known hazards as well as to educate retailers with raw beef grinding operations, a committee was formed to evaluate the 2014 CFP document and provide updated guidance based on recordkeeping requirements finalized in 2015 and guidance released in 2021.

Recommended Solution: The Conference recommends...:

- 1. Acknowledgement of the Intended Use Hazards During Retail Meat Grinding Committee Report.
- 2. Thanking the committee members for their work.
- 3. Disbanding the Committee, all assigned charges have been completed.

Submitter Information 1:

Name: Hilary Thesmar

Organization: FMI

Address: 2345 Crystal DriveSuite 800

City/State/Zip: Arlington, VA 22043

Telephone: 2024949016

E-mail: hthesmar@fmi.org

Submitter Information 2:

Name: Ellen Shumaker

Organization: NCSU

Address: 4101 Beryl Road, 220E City/State/Zip: Raleigh, NC 27695 Telephone: 919-515-9842

E-mail: Ellen shumaker@ncsu.edu

Content Documents:

- "Intended Use Hazards During Retail Meat Grinding Committee Final Report"
- "Committee Member Roster"
- "Evaluation of Intended Use Hazards During Retail Meat Grinding Guidance"
- "Evaluation of Intended Use Hazards During Retail Meat Grinding Guidance"

Issue: 2023 III-002

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: 2020 III-015; new or additional information has been included or attached.

Title:

IUMGC 2 – Approval of Guidance Document

Issue you would like the Conference to consider:

Approval of the Evaluation of Intended Use Hazards During Retail Meat Grinding Committee's guidance document entitled "Evaluation of Intended Use Hazards During Retail Meat Grinding" and posting of the guidance document on the CFP website in PDF format.

Public Health Significance:

STECs are hazards that are reasonably likely to occur in raw beef products and in 2011, USDA FSIS declared raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, contaminated with Shiga toxin-producing *Escherichia coli* (STEC) O26, O45, O103, O111, O121, or O145 adulterated (76 FR 58157; Sep. 20, 2011). A previously published CFP document, "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" (2014), was developed to provide food safety guidelines for grinding raw beef at retail. In addition, in 2015, USDA FSIS published a final rule requiring recordkeeping at retail establishments for raw beef grinding operations, "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" (80 FR 79231; Dec 21, 2015), to facilitate identification of product during foodborne illness investigations.

In continued outreach to the food industry in 2021, USDA FSIS published "Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" emphasizing the importance of considering the intended use of intact and non-intact beef products. USDA FSIS and other issues submitted to CFP in 2020 (August 2021 Conference) requested that the 2014 CFP guidance be updated with additional information on the importance of considering the intended use of beef products prior to grinding to reduce the risk of contamination of STECs in beef ground at retail and the importance of sharing this information.

In order to increase awareness of known hazards as well as to educate retailers with raw beef grinding operations, a committee was formed to evaluate the 2014 CFP document and provide updated guidance based on recordkeeping requirements finalized in 2015 and guidance released in 2021.

Recommended Solution: The Conference recommends...:

- Approval of the committee generated guidance document entitled "Evaluation of Intended Use Hazards during Retail Meat Grinding" (attached as a content document to the Issue titled: Report - Eval of Intended Use Hazards During Retail Meat Grinding Committee); and
- 2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
- 3. Posting the final document on the CFP website in PDF format.

Submitter Information 1:

Name: Hilary Thesmar

Organization: FMI

Address: 2345 Crystal DrSuite 800 City/State/Zip: Arlington, VA 22043

Telephone: 2024949016

E-mail: hthesmar@fmi.org

Submitter Information 2:

Name: Ellen Shumaker

Organization: NCSU

Address: 4101 Beryl Road, 220E City/State/Zip: Raleigh, NC 27695

Telephone: 919-515-9842

E-mail: ellen shumaker@ncsu.edu

Issue: 2023 III-003

Council Recommendation:	Accepted as Submitted	Accepted as	_ 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: 2020-III-015; new or additional information has been included or attached.

Title:

IUMGC 3 - Amend Food Code

Issue you would like the Conference to consider:

Inclusion of the committee generated guidance document entitled, "Evaluation of Intended Use Hazards During Retail Meat Grinding" in the most current version of the FDA Model Food Code Annex 2 (Annex 2 References section K).

Public Health Significance:

STECs are hazards that are reasonably likely to occur in raw beef products and in 2011, USDA FSIS declared raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, contaminated with Shiga toxin-producing *Escherichia coli* (STEC) O26, O45, O103, O111, O121, or O145 adulterated (76 FR 58157; Sep. 20, 2011). A previously published CFP document, "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" (2014), was developed to provide food safety guidelines for grinding raw beef at retail. In addition, in 2015, USDA FSIS published a final rule requiring recordkeeping at retail establishments for raw beef grinding operations, "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" (80 FR 79231; Dec 21, 2015), to facilitate identification of product during foodborne illness investigations.

In continued outreach to the food industry in 2021, USDA FSIS published "Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" emphasizing the importance of considering the intended use of intact and non-intact beef products. USDA FSIS and other issues submitted to CFP in 2020 (August 2021 Conference) requested that the 2014 CFP guidance be updated with additional information on the importance of considering the intended use of beef products prior to grinding to reduce the risk of contamination of STECs in beef ground at retail and the importance of sharing this information.

In order to increase awareness of known hazards as well as to educate retailers with raw beef grinding operations, a committee was formed to evaluate the 2014 CFP document and provide updated guidance based on recordkeeping requirements finalized in 2015 and guidance released in 2021.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that the most recent edition of the Food Code be amended to include a reference to the guidance document "Evaluation of Intended Use Hazards During Retail Meat Grinding" (attached as a content document to the Issue titled: Report - Eval of Intended Use Hazards During Retail Meat Grinding Committee) in Annex 2. References, 3. Supporting Documents, K. Requirements and Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information.

Submitter Information 1:

Name: Hilary Thesmar

Organization: FMI

Address: 2345 Crystal DrSuite 800 City/State/Zip: Arlington, VA 22043

Telephone: 2024949016 E-mail: hthesmar@fmi.org

Submitter Information 2:

Name: Ellen Shumaker

Organization: NCSU

Address: 4101 Beryl Road, 220E City/State/Zip: Raleigh, NC 27695

Telephone: 9195159842

E-mail: ellen shumaker@ncsu.edu

Issue: 2023 III-004

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: 2020-III-017; new or additional information has been included or attached.

Title:

Report – Retail Sushi HACCP Standardization Committee (RSHSC)

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee requests acknowledgement of their final report and thanking the committee members for their efforts and hard work.

Public Health Significance:

Retail sushi establishments prepare sushi products using many different methods of preparation, and for the rice portion of the sushi products, often use acidification methods to render rice, a TCS food, as non-TCS. This preparation method is used throughout the country, and the interpretation of the requirements of a HACCP Plan can vary. There are many retail sushi establishments that operate in different jurisdictions, and standardization of these requirements and interpretations is needed to help ease the burden of variance and HACCP requirements on industry partners. Additionally, guidance and other resources can be created to provide a better understanding of retail sushi preparation, and HACCP/variance requirements for both operators and regulators nationwide.

Recommended Solution: The Conference recommends...:

- Acknowledgement of the attached Retail Sushi HACCP Standardization Committee Report.
- 2. Thanking the committee members for their work.
- 3. The Committee be disbanded; all assigned charges have been completed.

Submitter Information 1:

Name: Veronica Bryant Organization: RSHSC Chair

Address: 1632 Mail Service Center

City/State/Zip: Raleigh, NC 27699 Telephone: 919-218-6943

E-mail: veronica.bryant@dhhs.nc.gov

Submitter Information 2:

Name: Rupesh Modi

Organization: RSHSC Vice Chair Address: 11949 Steele Creek Rd City/State/Zip: Charlotte, NC 28273

Telephone: 704-926-2293

E-mail: rmodi@hisshosushi.com

Content Documents:

- "Committee Final Report"
- "Committee Member Roster"
- "Guidance Document for Retail Sushi HACCP Standardization"
- "Review of National Requirements for HACCP/Variance for Acidification of Ric"

Issue: 2023 III-005

Council	Accepted as		Accepted as		
Recommendation:	Submitted		_ Amended	 No Action	
Delegate Action:	Accepted		_ Rejected	 <u>_</u>	
All information above the line	e is for conference us	e only.			
Issue History:					
This is a brand new Is	ssue.				
Title:					
RSHSC 2 – Approval	of Guidance Do	cument			

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee requests acceptance of the guidance document titled "Guidance Document for Retail Sushi HACCP Standardization" and inclusion of the guidance document on the CFP website in pdf form.

Public Health Significance:

To meet the charges given to the Retail Sushi HACCP Standardization Committee, a guidance document was developed to provide uniform guidance on HACCP plan and Variance requirements for retail sushi preparation.

This guidance document was created to provide standardized information for regulators and industry members for sushi variance and HACCP plans. The document provides the background information related to sushi, standardized parameters for critical control points and critical limits, and examples of operating procedures, food flow diagrams, and hazard analysis. The intent of the guide is to provide parameters and examples for sushi HACCP plans so that the variance and HACCP plan approval can be more uniform across jurisdictions. There are retail sushi establishments that operate in many different jurisdictions, and standardization of the HACCP and variance requirements and interpretations is needed to help ease the burden of the requirements on industry partners.

Recommended Solution: The Conference recommends...:

 Acceptance of the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization" (attached as a content document to Issue titled: Report - Retail Sushi HACCP Standardization Committee (RSHSC) 1); and

- 2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
- 3. Posting the final document on the CFP website in PDF format

Submitter Information 1:

Name: Veronica Bryant Organization: RSHSC Chair

Address: 1632 Mail Service Center

City/State/Zip: Raleigh, NC 27699 Telephone: 919-218-6943

E-mail: veronica.bryant@dhhs.nc.gov

Submitter Information 2:

Name: Rupesh Modi
Organization: RSHSC Vice Chair
Address: 11949 Steele Creek Rd
City/State/Zip: Charlotte, NC 28273

Telephone: 704-926-2293

E-mail: rmodi@hisshosushi.com

Issue: 2023 III-006

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 Is	sue.				
Title:					

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee requests inclusion of the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization", in the FDA Model Food Code Annex.

RSHSC 3 – Amend Food Code Annexes to Reference Approved Document

Public Health Significance:

To promote uniform review and approval of sushi acidification variance and HACCP plans, the Retail Sushi HACCP Standardization Committee created a guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization." Providing this tool will assist regulatory and industry partners in achieving more uniform review of sushi variance and HACCP plans. Since the FDA Food Code Annex is often the initial resource that is accessed by both regulators and operators for additional information on retail food processes, including a reference to this document will help promote this guidance as a resource.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that the most recent edition of the Food Code Annex be amended to include a reference to the document entitled "Guidance Document for Retail Sushi HACCP Standardization" (attached as a content document to Issue titled: Report - Retail Sushi HACCP Standardization Committee (RSHSC) 1) in a section determined to be appropriate by the FDA. Suggestions for location of the document reference are Annex 2 - Supporting Documents or Annex 3 - Section 3-502.11.

Submitter Information 1:

Name: Veronica Bryant
Organization: RSHSC Chair
Address: 5605 Six Forks Rd

City/State/Zip: Raleigh, NC 27699

Telephone: 9192186943

E-mail: veronica.bryant@dhhs.nc.gov

Submitter Information 2:

Name: Rupesh Modi

Organization: RSHSC Vice Chair Address: 11949 Steele Creek Rd City/State/Zip: Charlotte, NC 28273

Telephone: 704-926-2293

E-mail: rmodi@hisshosushi.com

Issue: 2023 III-007

Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action
Delegate Action:	Accepted		Rejected		-
All information above the line	is for conference use of	only.			
Issue History: This is a brand new Is	sue.				
Title: RSHSC 4 – Review a	nd Streamlining o	of Retail	Sushi HACCP	Process	5

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee would like for FDA to investigate implementing a standardized process for review and approval of HACCP plans from chain food establishments operating in multi-state jurisdictions.

Public Health Significance:

Retail sushi establishments prepare sushi products using many different methods of preparation, and often use acidification methods to render rice, a TCS food, as non-TCS. This preparation method is used throughout the country, and the interpretation of the requirements of a HACCP Plan for acidification or any other specialized processing method found in FDA Food Code Section 3-502.11 can vary. There are many retail establishments that operate in multiple jurisdictions, and standardization of these requirements and interpretations is needed to help ease the burden of variance and HACCP requirements on industry partners. Having each individual jurisdiction with individual procedures and approval guidelines does not make the acidified food or any other food prepared with a specialized processing method any safer, but it does provide obstacles to operators submitting plans for approval.

Although the FDA Food Code states in 3-502.11 that HACCP Plans are required for rendering a food non-TCS, there are no specific parameters outlined for what is needed in the HACCP Plan. Section 8-201.14 provides basic information about the contents of a HACCP Plan but does not provide enough detail to ensure that all jurisdictions are requiring the same information for HACCP Plans and variances to be approved. For example, since it is not explicitly stated that the critical limit for acidification is typically below 4.2, there are multiple values required by jurisdictions across the country as was found during the review and completion of RSRHCS Charge #1. When a chain food establishment prepares a HACCP plan for submission, individual jurisdictions often impose their own requirements. The result is chain establishments submitting and maintaining

multiple, sometimes dozens, of different plans to satisfy the individual jurisdictions. This does not provide a benefit to public health but does create a burden for operators and regulatory jurisdictions, where time and money is spent on these individualized plans.

The Committee is asking that FDA do a review of how HACCP plans are submitted, and what parameters are used for approval. Using this information, FDA can provide improvements to streamline the process. Ideally, this would come in the form of a committee or task force made up of multiple subject matter experts from regulatory, industry and academic partners to provide review of chain HACCP plans. If a group of experts agree that a HACCP plan meets food safety requirements, then individual jurisdictions may more readily accept the plans as submitted to their individual jurisdictions. This will not only be a huge assistance to the operators that are submitting the plans, but also will assist local and state jurisdictions by saving time and resources involved in HACCP plan review.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting that FDA identify a panel of experts that can review HACCP Plans for chain establishments operating in multiple jurisdictions and provide a validation and approval of the HACCP Plan, and that FDA issue a written interpretation encouraging regulatory authorities to accept the HACCP Plans as approved by the panel, in an effort to standardize HACCP Plan review.

Submitter Information 1:

Name: Veronica Bryant Organization: RSHSC Chair

Address: 1632 Mail Service Center

City/State/Zip: Raleigh, NC 27699 Telephone: 919-218-6943

E-mail: veronica.bryant@dhhs.nc.gov

Submitter Information 2:

Name: Rupesh Modi
Organization: RSHSC Vice Chair
Address: 11949 Steele Creek Rd
City/State/Zip: Charlotte, NC 28273

Telephone: 704-926-2293

E-mail: rmodi@hisshosushi.com

Issue: 2023 III-008

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended		No Action	
Delegate Action:	Accepted		_ Rejected		_	
All information above the line	e is for conference use	e only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
RSHSC 5 – Including	Rice Acidification	n Paran	neters in Food (Code		

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee would like for the FDA to update the FDA Food Code to include the specific parameters for rice acidification.

Public Health Significance:

Retail sushi establishments prepare sushi products using many different methods of preparation, and often use acidification methods to render rice, a TCS food, as non-TCS. Although the FDA Food Code states in 3-502.11 that HACCP Plans are required for rendering a food non-TCS, there are no specific parameters outlined for what is needed in the HACCP Plan. Section 8-201.14 provides basic information about the contents of a HACCP Plan but does not provide enough detail to ensure that all jurisdictions are using the same approach for HACCP Plans and variances and requiring the same information to be approved. For example, since it is not explicitly stated that the critical limit for acidification is typically below 4.2, there are multiple values required by jurisdictions across the country as was found during the review and completion of RSRHCS Charge #1.

Rice acidification is a relatively simple process that only requires a single Critical Control Point. Rice acidifies quickly and is easy to prepare for pH measurement. Rice acidification is likely the most common HACCP plan reviewed in local and state jurisdictions. If the specific parameters such as the critical limit, monitoring procedure, and corrective actions were included in the Food Code, it would ease a burden on regulators and operators, saving time in the submission, review, and approval.

There is already precedent for including parameters for HACCP Plans for individual procedures in the Food Code. Section 3-502.12 provides parameters to follow for reduced oxygen packaging. In addition, there are several states, such as Ohio, that already include this in their individual state code. The Committee is requesting a similar section be added for rice acidification.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the most recent version of the Food Code be amended to include specific requirements to follow for rice acidification, including critical control point, critical limit, and corrective action parameters consistent with the parameters in the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization" (attached as a content document to Issue titled: Report - Retail Sushi HACCP Standardization Committee).

Submitter Information 1:

Name: Veronica Bryant
Organization: RSHSC Chair
Address: 5605 Six Forks Rd
City/State/Zip: Raleigh, NC 27699

Telephone: 9192186943

E-mail: veronica.bryant@dhhs.nc.gov

Submitter Information 2:

Name: Rupesh Modi
Organization: RSHSC Vice Chair
Address: 11949 Steele Creek Rd
City/State/Zip: Charlotte, NC 28273

Telephone: 704-926-2293

E-mail: rmodi@hisshosushi.com

Issue: 2023 III-009

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended		No Action	
Delegate Action:	Accepted		_ Rejected		_	
All information above the line	e is for conference use	only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
Report – Safe Use of	Reusable Conta	iners Co	ommittee (SUR	CC)		

Issue you would like the Conference to consider:

The Safe Use of Reusable Containers Committee requests acknowledging their final report and thanking the committee members for their efforts and hard work.

Public Health Significance:

The growing concern of the environmental impact of single use food containers in the retail service industry has led to an increase in wanting to use personal containers or reuse containers offered in the retail food setting. The committee was formed during the 2021 CFP Biennial (rescheduled from 2020) based on issues that were submitted to explore scenarios, review literature and current documentation on the subject, develop guidance on the safe use of reusable containers and finally propose possible food code language. The committee's final report contains developed guidance to assist the operator and regulators on situations where the reuse of containers can be done safely.

Recommended Solution: The Conference recommends...:

- 1. Acknowledgement of the Safe Use of Reusable Containers Committee Report.
- 2. Thanking the committee members for their work.
- 3. The Committee be disbanded; all assigned charges have been completed...

Submitter Information 1:

Name: Carrie Pohjola Organization: SURCC Co-Chair

Address: 2811 Agriculture DrivePO Box 8911

City/State/Zip: Madison, WI 53708-8911

Telephone: 715-579-9487

E-mail: Carrie.Pohjola@wisconsin.gov

Submitter Information 2:

Name: Dagny Tucker Organization: SURCC Co-Chair

Address: PO Box 925

City/State/Zip: Lyons, CO 80540 Telephone: 303-915-3079

E-mail: dagny@threadcountcreative.com

Content Documents:

- "SURCC Final Report"
- "Committee Roster"
- "Guidance Document for Safe Use of Reusable Containers"

Supporting Attachments:

- "Meeting Summations"
- "Scenario Matrix"

Issue: 2023 III-010

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended	 No Action	
Delegate Action:	Accepted		_ Rejected	_	
All information above the line	e is for conference use	only.			
Issue History:					
This is a brand new Is	ssue.				
Title:					
SURCC 2 – Approval	and Posting of (Guidanc	e Document		

Issue you would like the Conference to consider:

Approval of the Safe Use of Reusable Containers Committee guidance document entitled "Guidance Document for Safe Use of Reusable Containers" and posting of the guidance document on the CFP website in a downloadable PDF format.

Public Health Significance:

At the 2021 Biennial meeting Issue 2020 I-024 (combined with 2020 I-022 and 2020 I-023) was transferred to Council III. Council III charged the Safe Use of Reusable Containers Committee with clarifying scenarios related to reusable containers within the scope of regulation. It also charged the committee to identify and analyze the scientific and other literature related to consumer-owned containers at retail. And finally, to draft guidance around scenarios identified in the issue.

The guidance document provides food safety best practices for the reuse of containers in the retail setting. It includes the current allowance for the reuse of containers as well as container construction and condition requirements. Five contamination-free filling methods at retail are addressed, with examples of each method. Third-party reuse providers are addressed with an example standard operating procedures provided. Finally, a list of resources is provided in the guidance document which includes current jurisdiction language where this is allowed, current reuse examples, scientific articles related to reusable containers and guidance for reusable containers.

Recommended Solution: The Conference recommends...:

 Approval of the committee generated draft guidance document entitled "Guidance Document for the Safe Reuse of Containers". (See document attached to Issue titled: Report - Safe Use of Reusable Containers Committee (SURCC))

- 2. Posting the guidance document on the CFP website in a down-loadable PDF format; and
- 3. Authorizing the Conference to make any necessary edits prior to posting the document to assure consistency of format and non-technical content; edits will not affect the technical content of the document.

Submitter Information 1:

Name: Carrie Pohjola Organization: SURCC Co-Chair

Address: 2811 Agriculture DrivePO Box 8911

City/State/Zip: Madison, WI 53708-8911

Telephone: 715-579-9487

E-mail: Carrie.Pohjola@wisconsin.gov

Submitter Information 2:

Name: Dagny Tucker
Organization: SURCC Co-Chair
Address: PO Box 925

City/State/Zip: Lyons, CO 80540 Telephone: 303-915-3079

E-mail: dagny@threadcountcreative.com

Issue: 2023 III-011

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above the line	e is for conference us	e only.	
Issue History:			
This is a brand new Is	ssue.		
Title: SURCC 3 – Amend F	ood Code to Inc	lude Reusable Containe	er Definition

Issue you would like the Conference to consider:

The Food Code be amended to define the term Reusable Container.

Public Health Significance:

At the 2021 Biennial meeting Issue 2020 I-024 (combined with 2020 I-022 and 2020 I-023) was transferred to Council III. Council III charged the Safe Use of Reusable Containers Committee with clarifying scenarios related to reusable containers within the scope of regulation. It also charged the committee to identify and analyze the scientific and other literature related to consumer-owned containers at retail. And finally, to draft guidance around scenarios identified in the Issue.

The committee requests the approval of amended food code language that will define the new term Reusable Container and be supported by the guidance document developed by the committee and presented in SURCC 2 - Approval and Posting of Guidance Document.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting paragraph 1-201.10(B) in the current Food Code be amended as follows:

Reusable Container.

A product or primary packaging to hold food that is used repeatedly, refilled, or returned for multiple uses and conforms to characteristics of sanitary construction as defined in Parts 4-1 and 4-2 of the Food Code.

Submitter Information 1:

Name: Carrie Pohjola Organization: SURCC Co-Chair

Address: 2811 Agriculture DrivePO Box 8911

City/State/Zip: Madison, WI 53708-8911

Telephone: 715-579-9487

E-mail: Carrie.Pohjola@wisconsin.gov

Submitter Information 2:

Name: Dagny Tucker Organization: SURCC Co-Chair

Address: PO Box 925 City/State/Zip: Lyons, CO 80540 Telephone: 303-915-3079

E-mail: dagny@threadcountcreative.com

Issue: 2023 III-012

Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	
Delegate Action:	Accepted		_ Rejected		_	
All information above the line	e is for conference us	e only.				
Issue History:						
This is a brand new Is	ssue.					
Title:						
SURCC 4 – Amend F	ood Code Lang	uage to i	nclude Reuse d	of Contai	iners	

Issue you would like the Conference to consider:

Amend food code language to allow for the reuse of containers in a retail facility.

Public Health Significance:

At the 2021 Biennial meeting Issue 2020 I-024 (combined with 2020 I-022 and 2020 I-023) was transferred to Council III. Council III charged the Safe Use of Reusable Containers Committee with clarifying scenarios related to reusable containers within the scope of regulation. It also charged the committee to identify and analyze the scientific and other literature related to consumer-owned containers at retail. And finally, to draft guidance around scenarios identified in the issue.

The committee requests the approval of amended food code language that will include the new term Reusable Container which will be supported by the guidance document developed by the committee and presented in the Issue titled: SURCC 2 - Approval and Posting of Guidance Document.

The guidance document provides food safety best practices for the reuse of containers in the retail setting. It includes the current allowance for the reuse of containers as well container construction and condition requirements. Five contamination-free filling methods at retail are addressed with examples of each method. Third-party reuse providers are addressed; an example standard operating procedure is provided. Finally, a list of resources is provided in the guidance document which includes current jurisdiction language where this is allowed, current reuse examples, scientific articles related to reusable containers and guidance for reusable containers.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting Section 3-304.17 of the current Food Code be amended as follows:

- 3-304.17 Refilling Returnables Refilling REUSABLE CONTAINERS.
- (A) Except as specified in ¶¶ (B) (E) of this section, empty containers returned to a FOOD ESTABLISHMENT for cleaning and refilling with FOOD shall be cleaned and refilled in a regulated FOOD PROCESSING PLANT.^P
- (A) A REUSABLE CONTAINER shall be designed and constructed for reuse in accordance with the

requirements specified under Part 4-1 and 4-2.

- (B) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with FOOD if the FOOD container is:
- (B) Only REUSABLE CONTAINERS returned to a FOOD ESTABLISHMENT may be refilled with READY-TO-EAT
- or TIME/TEMPERATURE CONTROL FOR SAFETY FOODS either by a FOOD EMPLOYEE or the CONSUMER, except as specified in ¶¶ (1)-(2) of this section.
- (1) Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 and 4-2:^P
- (1) A CONSUMER-owned container not specifically designed for reuse may be refilled by the
- same CONSUMER with a non-TIME/TEMPERATURE CONTROL FOR SAFETY FOOD or BEVERAGE in a contamination-free transfer process.
- (2) One that was initially provided by the FOOD ESTABLISHMENT to the CONSUMER, either empty or filled with FOOD by the FOOD ESTABLISHMENT, for the purpose of being returned for reuse:
- (2) CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE

machine or system.

- (3) Returned to the FOOD ESTABLISHMENT by the CONSUMER after use;
- (4) Subject to the following steps before being refilled with FOOD:
- (a) Cleaned as specified under Part 4-6 of this Code,
- (b) Sanitized as specified under Part 4-7 of this Code; P and
- (c) Visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified under Part 4-1 and 4-2.
- (C) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with BEVERAGE if:
- (1) The BEVERAGE is not a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD:
- (2) The design of the container and of the rinsing EQUIPMENT and the nature of the BEVERAGE, when considered together, allow effective cleaning at home or in the FOOD ESTABLISHMENT:

- (3) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;
- (4) The CONSUMER-owned container returned to the FOOD ESTABLISHMENT for refilling is refilled for sale or service only to the same CONSUMER; and
- (5) The container is refilled by:
- (a) An EMPLOYEE of the FOOD ESTABLISHMENT, or
- (b) The owner of the container if the BEVERAGE system includes a contamination-free transfer process as specified under ¶¶ 4-204.13(A), (B), and (D) that cannot be bypassed by the container owner.
- (C) Establishment or third-party reuse service provider owned, managed, or provided REUSABLE CONTAINERS

returned to a FOOD ESTABLISHMENT for refilling with FOOD shall be cleaned as specified under Part 4-6 and

sanitized as specified under Part 4-7 of this Code prior to refilling.

- (D) CONSUMER-owned, personal take-out BEVERAGE containers, such as thermally insulated bottles, nonspill coffee cups, and promotional BEVERAGE glasses, may be refilled by EMPLOYEES or the CONSUMER if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D).
- (D) REUSABLE CONTAINERs returned to a FOOD ESTABLISHMENT for refilling by a FOOD EMPLOYEE
- or the CONSUMER must be refilled in a contamination-free transfer process such that:
- (1) Any CONSUMER-owned container is isolated from FOOD-CONTACT SURFACES or such surfaces shall be cleaned as specified under Part 4-6 and sanitized as specified under Part 4-7 of this Code by a FOOD EMPLOYEE after each filling.
- (E) CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE or system.

Submitter Information 1:

Name: Carrie Pohjola
Organization: SURCC Co-Cihair

Address: 2811 Agriculture DrivePO Box 8911

City/State/Zip: Madison, WI 53708-8911

Telephone: 715-579-9487

E-mail: Carrie.Pohjola@Wisconsin.gov

Submitter Information 2:

Name: Dagny Tucker
Organization: SURCC Co-Chair
Address: PO Box 925
City/State/Zip: Lyons, CO 80540

Telephone: E-mail: 303-915-3079

dagny@threadcountcreative.com

Issue: 2023 III-013

Council	Accepted as	Accepted as	
Recommendation:	Submitted _	Amended	No Action
Delegate Action:	Accepted _	Rejected	
All information above the line	e is for conference use only	/.	
Issue History:			
This is a brand new Is	ssue.		
Title:			
Report - Disinfectant	Committee (DC)		

Issue you would like the Conference to consider:

The Disinfectant Committee requests acknowledgement of their final report, thanking the committee members for their hard work, and that the committee be disbanded.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogen outbreak occurs, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but are not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

- 1) Disinfectants that require a rinse step prior to resuming regular operations; and
- 2) Disinfectants that do not require a post-rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, do not require a rinse step prior to further use due to their conformity to 40 CFR 180 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to <u>disinfect food-contact equipment and utensils</u> can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address the use of disinfectants in food establishments along with a guidance document to provide detailed information on disinfectants and how they should be used would alleviate confusion and potential misuse of disinfectants in such settings.

This Issue submission does <u>not</u> include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

- 1. Acknowledgement of the Disinfectant Committee Report.
- 2. Thanking the members of the Committee for their work.
- 3. The Committee be disbanded; all assigned charges have been completed.

Submitter Information 1:

Name: Dale Grinstead

Organization: Mountain Top Microbiology

Address: 230 Shadow Creek Ln City/State/Zip: Highlands, NC 28741-7029

Telephone: 2626310719

E-mail: dale.grinstead626@gmail.com

Submitter Information 2:

Name: Anna Starobin

Organization: Food Safety/Antimicrobials Consulting, LLC

Address: 201 Kemp Rd. West City/State/Zip: Greensboro, NC 27410

Telephone: 336-558-5359

E-mail: anna.starobin718@gmail.com

Content Documents:

- "Final report"
- "Committee roster"
- "Guidance for the Safe and Proper Use of Sanitizers and Disinfectants in Foo"

Issue: 2023 III-014

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended	 No Action	
Delegate Action:	Accepted		_ Rejected	 _	
All information above the line	e is for conference use	e only.			
Issue History:					
This is a brand new Is	ssue.				
Title:					
DC 2 - Approval and I	Posting of Guida	ance Doc	cument		

Issue you would like the Conference to consider:

The Disinfectant Committee requests approval of the guidance document and that it be posted to the CFP website.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogens outbreaks occur, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

- 1) Disinfectants that require a rinse step prior to resuming regular operations; and
- 2) Disinfectants that do not require a post-rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, does not require a rinse step prior to further use due to their conformity to 40 CFR 180.940 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to <u>disinfect food-contact equipment and utensils</u> can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address the use of disinfectants in food establishments, along with a guidance document to provide detailed information on disinfectants and how they should be used, would alleviate confusion and potential misuse of disinfectants in such settings.

This Issue submission does <u>not</u> include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

- 1. Approving the "Guidance for the Safe and Proper Use of Sanitizers and Disinfectants in Food Establishments" guidance document (attached as a content document to the Issue titled: Report Disinfectant Committee (DC)).
- 2. The guidance document be posted to the CFP website; and
- 3. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP website to assure consistency of format and non-technical content; edits will not affect the technical content of the document.

Submitter Information 1:

Name: Dale Grinstead

Organization: Mountain Top Microbiology Address: 230 Shadow Creek Ln City/State/Zip: Highlands, NC 28741-7029

Telephone: 2626310719

E-mail: dale.grinstead626@gmail.com

Submitter Information 2:

Name: Anna Starobin

Organization: Food Safety/Antimicrobials Consulting, LLC

Address: 201 Kemp Rd. West City/State/Zip: Greensboro, NC 27410

Telephone: 3365585359

E-mail: anna.starobin718@gmail.com

Issue: 2023 III-015

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended	 _ No Action	
Delegate Action:	Accepted		_ Rejected	 _	
All information above the line	e is for conference us	e only.			
Issue History:					
This is a brand new Is	ssue.				
Title:					
DC 3 - Amend Food (Code to Address	Use of I	Disinfectants		

Issue you would like the Conference to consider:

The Disinfectant Committee feels that several changes to the Food Code are needed to address the use of disinfectants. This issue details those recommended changes.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogens outbreaks occur, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

- 1) Disinfectants that require a rinse step prior to resuming regular operations; and
- 2) Disinfectants that do not require a post-rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, does not require a rinse step prior to further use due to their conformity to 40 CFR 180.940 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to <u>disinfect food-contact equipment and utensils</u> can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address the use of disinfectants in food establishments, along with a guidance document to provide detailed information on disinfectants and how they should be used, would alleviate confusion and potential misuse of disinfectants in such settings.

This Issue submission does <u>not</u> include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the most recent edition of the Food Code be amended as follows:

- 1-201.10 Statement of Application and Listing of Terms.
- (B) Terms Defined. As used in this Code, each of the terms listed in \P 1-201.10(B) shall have the meaning stated below.

"Disinfection" means the application of a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi, or viruses, but not necessarily bacterial spores on cleaned food-contact or other hard, non-porous surfaces.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 5 categories:

- (1) Cleaners and, SANITIZERS, and disinfectants, which include cleaning and, SANITIZING agents, <u>DISINFECTION agents</u> and agents such as caustics, acids, drying agents, polishes, and other chemicals;
- (2) Pesticides, except SANITIZERS <u>and disinfectants</u>, which include substances such as insecticides and rodenticides:

Renumber the current Food Code Sections 4-8 and 4-9 to 4-9 and 4-10, respectively to accommodate the following:

4-8 DISINFECTION OF EQUIPMENT AND UTENSILS

<u>Subparts</u>

4-801 Objective

4-802 Frequency

4-803 Methods

Objective

4-801.10 Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.

EQUIPMENT, FOOD-CONTACT SURFACES, non-FOOD-CONTACT SURFACES, and

UTENSILS shall be disinfected when pathogens of concern are not controlled by available sanitizers.

<u>Frequency</u>

4-802.11 Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils. EQUIPMENT, FOOD-CONTACT SURFACES, non-FOOD-CONTACT SURFACES, and UTENSILS, shall be disinfected:

- (A) If contaminated with vomitus, fecal matter, blood, or any other bodily fluid.
- (B) During an outbreak caused by microorganisms not controlled by sanitizers.
- (C) When a greater level of microbial control is required.
- (D) When instructed by REGULATORY AUTHORITY.

Methods

4-803.11 Chemical.

- (A) FOOD-CONTACT SURFACES and non-FOOD-CONTACT SURFACES shall be disinfected in accordance with EPA-registered label use instructions. Pf
- (B) Disinfectants applied to a FOOD-CONTACT SURFACE shall be rinsed with potable water, unless otherwise specified on the EPA-registered label use instructions.
- 7-102.11 Common Name.

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners and, SANITIZERS, and disinfectants taken from bulk supplies shall be clearly and individually identified with the common name of the material. Pf

4-302.14 Sanitizing and Disinfecting Solutions, Testing Devices.

A test kit or other device that accurately measures the concentration in MG/L of SANITIZING or disinfecting solutions shall be provided Pf

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer or Disinfectant Concentration.

Concentration of the SANITIZING <u>or disinfecting</u> solution shall be accurately determined by using a test kit or other device. Pf

Annex 3. Public Health Reasons/Administrative Guidelines

4-302.14 Sanitizing and Disinfecting Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing <u>and disinfecting</u> solutions are required for 2 reasons:

- 1. The use of chemical sanitizers <u>and disinfectants</u> requires minimum concentrations of the sanitizer <u>or disinfectant</u> during the <u>sanitization or disinfection</u> final rinse step to ensure sanitization <u>and disinfection</u>; and
- 2. Too much sanitizer or disinfectant in the final rinse water step could be toxic.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer <u>or Disinfectant</u> Concentration.

The effectiveness of chemical sanitizers <u>or disinfectants</u> is determined primarily by the concentration and pH of the sanitizer <u>or disinfectant</u> solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer <u>or disinfectant</u> solution.

Objective

4-801.10. Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.

Food establishments must be able to control microorganisms that pose a risk to employees and patrons to protect public health within their establishment. Since sanitizers only reduce, as opposed to eliminate, the number of microorganisms on a surface and do not control all types of microorganisms, i.e., bacteria, fungi, viruses, and spores, a disinfectant with an appropriate EPA-registered efficacy claim may be required.

Several examples of situations when a higher level of antimicrobial efficacy and/or a broader range of microorganisms maybe required are listed below:

- Clean-up of bodily fluid spills
- Microorganism of concern is not listed on the product label, (i.e., viruses, biofilm, fungus)
- A higher level of antimicrobial efficacy is desired
- When required to by a regulatory authority

<u>Frequency</u>

4-802.11 Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.

Frequency of disinfection varies depending on circumstances at the time of disinfection. During normal, routine conditions, surfaces should be disinfected at least daily. High-touch surfaces (e.g., door handles, dispensers, restroom surfaces) should be disinfected at least daily when the facility is open. During outbreaks surfaces should be disinfected at the frequency recommended by public health officials. Surfaces should also be disinfected immediately after a bodily fluid event.

<u>Methods</u>

4-803.11 Chemical.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Submitter Information 1:

Name: Dale Grinstead

Organization: Mountain Top Microbiology Address: 230 Shadow Creek Ln City/State/Zip: Highlands, NC 28741-7029

Telephone: 2626310719

E-mail: dale.grinstead626@gmail.com

Submitter Information 2:

Name: Anna Starobin

Organization: Food Safety/Antimicrobials Consulting, LLC

Address: 201 Kemp Rd. West City/State/Zip: Greensboro, NC 27410

Telephone: 3365585359

E-mail: anna.starobin718@gmail.com

Issue: 2023 III-016

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:						
DC 4 - Amend Food Code Annex on Hand Antiseptics						

Issue you would like the Conference to consider:

The Disinfectant Committee feels that several changes to the Food Code are needed to address the use of disinfectants. This Issue details those recommended changes.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogens outbreaks occur, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

- 1) Disinfectants that require a rinse step prior to resuming regular operations; and
- 2) Disinfectants that do not require a post-rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, does not require a rinse step prior to further use due to their conformity to 40 CFR 180.940 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to <u>disinfect food-contact</u> <u>equipment and utensils</u> can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address correct some of the language around the use of hand antiseptics that is in the annex will alleviate confusion and potential misuse of disinfectants in food establishments.

This Issue submission does <u>not</u> include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the current Model Food Code be amended as follows:

Annex 3. Public Health Reasons/Administrative Guidelines

2-301.16 Hand Antiseptics

Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement. However, removing Reducing microorganisms from human skin is a totally different process than sanitizing surfaces and sterilization of human skin is nearly impossible to achieve without

damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms <u>on hands</u> than the 5-log reduction required for "sanitization." Therefore, the effect achieved from using antimicrobial hand agents <u>(often called "hand sanitizers")</u> is not consistent with the definition of "sanitization" in the Food Code.

Submitter Information 1:

Name: Dale Grinstead

Organization: Mountain Top Microbiology Address: 230 Shadow Creek Ln City/State/Zip: Highlands, NC 28741-7029

Telephone: 2626310719

E-mail: dale.grinstead626@gmail.com

Submitter Information 2:

Name: Anna Starobin

Organization: Food Safety/Antimicrobials Consulting, LLC

Address: 201 Kemp Rd. West City/State/Zip: Greensboro, NC 27410

Telephone: 3365585359

E-mail: anna.starobin718@gmail.com

Issue: 2023 III-017

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 Is	ssue.					
Title:						

DC 5 - Amend Food Code Annex - Use of Disinfectants During Clean-up of V&D

Issue you would like the Conference to consider:

The Disinfectant Committee feels that several changes to the Food Code are needed to address the use of disinfectants. This Issue details those recommended changes, which includes rearranging the bullet points in Annex 3, 2-501.11, paragraph 9 to make sure that the steps listed reflect the order of actions covered by the plan.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogens outbreaks occur, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control

bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

- 1) Disinfectants that require a rinse step prior to resuming regular operations; and
- 2) Disinfectants that do not require a post rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, do not require a rinse step prior to further use due to their conformity to 40 CFR 180.940 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to <u>disinfect food-contact equipment and utensils</u> can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

A specific situation when use of disinfectants in food establishments is appropriate is during clean-up following a vomiting or diarrheal event. Updates to the Food Code to address the use of disinfectants during body fluid clean-up along with a guidance document to provide detailed information on disinfectants and how they should be used would alleviate confusion and potential misuse of disinfectants in such settings.

This Issue submission does <u>not</u> include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the current Model Food Code be amended as follows:

Annex 3. Public Health Reasons/Administrative Guidelines

2-501.11 Clean-up of Vomiting and Diarrheal Events.

paragraph 6

Effective clean_up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact surfaces and-disinfecting countertops and floors, such as certain quaternary ammonium-compounds, non-food contact surfaces may not be effective against some viruses such as Norovirus. It is therefore important that food establishments have procedures for the-cleaning and disinfection of vomitus and/or diarrheal contamination events that include address, among other items, the use of proper disinfectants at the proper concentration. EPA-registered disinfectants against the microorganisms of concern.

paragraph 9

When developing a written plan that addresses the need for the cleaning and disinfection of a vomitus and/or diarrheal contamination event, a food establishment should consider:

- The procedures for containment and removal of any discharges, including airborne particulates; The conditions under which the plan will be implemented;
- The availability of effective disinfectants, such as EPA registered disinfection
 products sufficient to inactivate norovirus, personal protective equipment, and other
 cleaning and disinfecting appurtenances tools intended for response and their
 proper use; The procedure for cleaning, sanitizing, and, as necessary, the
 disinfection of any surfaces that may have become contaminated;
- The circumstances under which a food employee is to wear personal protective
 equipment for cleaning and disinfecting of a contaminated area; The procedures for
 the evaluation and disposal of any food that may have been exposed to discharges;
- Notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area; The availability of effective disinfectants, such as EPA registered disinfection products sufficient to inactivate norovirus, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and their proper use;
- The procedures for minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage;
- The segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated; Procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter;
- The procedures for containment and removal of any discharges, including airborne particulates; The circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;
- The procedure for cleaning, sanitizing, and disinfecting of any surfaces that may have become contaminated; Notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;

- The procedures for the evaluation and disposal of any food that may have been exposed to discharges; The segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;
- Procedures for the disposal and/or cleaning and disinfection of tools and equipment
 used to clean up vomitus or fecal matter; and Minimizing risk of disease transmission
 through the exclusion and restriction of ill employees as specified in §2-201.12 of the
 Food Code:
- The procedures for minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in §2-201.12 of the Food Code; Minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and
- The conditions under which the plan will be implemented.

Submitter Information 1:

Name: Dale Grinstead

Organization: Mountain Top Microbiology Address: 230 Shadow Creek Ln City/State/Zip: Highlands, NC 28741-7029

Telephone: 2626310719

E-mail: dale.grinstead626@gmail.com

Submitter Information 2:

Name: Anna Starobin

Organization: Food Safety/Antimicrobials Consulting, LLC

Address: 201 Kemp Rd. West City/State/Zip: Greensboro, NC 27410

Telephone: 3365585359

E-mail: anna.starobin718@gmail.com

Issue: 2023 III-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 is a brand new Is	ssue.		
Title: Commercial Space Tr	avel and Food S	afety	

Issue you would like the Conference to consider:

Creation of a Commercial Space Food Safety Committee

Public Health Significance:

Space missions as defined by space station, lunar mission(s), asteroid mission(s), Mars mission(s) and or other off-Earth missions require food safety for astronauts. Private space missions (commercial flying) are increasing but there are no defined criteria for food safety for these private missions.

This topic is an Issue because we have no evidence that the food is being held to standard. We know that food for Government program astronauts must meet high standards, we don't know if commercial space food must meet those same standards.

Not all food is created equal and not all food can go into space. The commercialization of flights cross that barrier affecting both food that travels into space and is consumed during or after the event.

Various newspaper articles depict commercial space travel food consumption, cold pizza and lamb. See attached PDF documents for reference: Daily Breeze Article, Axiom Article, 2 Million Dollar Bacon Sando article, and Kimchi Article New York Times. It should also be noted that foods like kimchi and a bacon sandwich, were specially developed to fly in space. This took years of research and millions of dollars to achieve. NASA currently has 250 food items that have been approved for space travel; the question still lies within, for commercial space travel, there are no known standards that would protect consumed food - Was it cooled correctly, held at a safe temperature, transported safely, stored correctly, served correctly, disposed of properly/off gassing/crumbs?

In addition, the after travel/space port celebrations: there may be the desire to celebrate with an after-flight toast. Such situations also create circumstances where short duration weightlessness is experienced. If a person experiences nausea, vomiting, and/or diarrhea,

it may not be known if these symptoms are due to weightlessness or a foodborne illness event. There should be standards in place to provide protection for the individuals experiencing the post-flight celebration where alcoholic beverages and food are involved.

Because commercial space companies are already seeking food provisions for their missions, it is important to address commercial space food safety. And to investigate whether or not regulations and policy should be found needed in the protection of people participating in commercial space program missions.

NASA currently has standards which include four areas of food safety: packaging/containerization, facility design, cleaning, and food engineering/testing; however these standards do not apply to commercial space travel. Since NASA guidelines do not address commercial space travel food safety, this gap needs to be addressed.

Recommended Solution: The Conference recommends...:

That a special committee be formed to explore commercial space food safety. This should be done in order to have a more robust conversation about this Issue. The Committee should be charged with:

- 1. Research and investigate current standards for food safety for commercial space travel;
- 2. Recommending to the FDA that it considers adding commercial space food providers as part of the definition for FOOD ESABLISHMENT;
- 3. Drafting standards for food safety and commercial space travel that meet or exceed NASA standards for food safety;
- 4. Standards should address food handling practices, holding temperatures, cooling parameters, sanitary storage of food, and other associated requirements;
- 5. Review and update standards as research informs additional needs; and
- 6. Report back to the Conference in 2025 with recommendations.

Submitter Information:

Name: David Wilson

Organization: David Wilson Space Food Research Center

Address: 121 W. Hillgrove #35 City/State/Zip: LaGrange, IL 60525

Telephone: 7085820022

E-mail: spacefoodie@outlook.com

Supporting Attachments:

- "Daily Breeze Article"
- "Axiom Article"
- "2 Million Dollar Bacon Sando Article"
- "Kimchi Article New York Times"

Issue: 2023 III-019

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:							
Create a Committee - Sea Moss and Sea Moss Gel Committee							

Issue you would like the Conference to consider:

Create a sea moss and sea moss gel committee to identify the hazards most likely associated with sea moss and the production and storage of sea moss gel, determine if specific predetermined controls can be applied to mitigate the identified hazards when producing and storing sea moss gel in a retail food establishment, and develop a guidance document for the production and storage of sea moss gel (if the Committee's findings support such) for use by retail food establishment operators and regulators.

Public Health Significance:

Sea moss gel poses an inherent *Clostridium botulinum* risk due to the very nature of the product; in addition, the product is often packaged or stored in a state that reduces the oxygen transfer rate.

Sea moss gel is a relatively new product that has become a fast-growing healthy eating trend. The most common sea mosses used to make sea moss gel seem to be Genus Gracilaria and *Chondrus Crispus*, based upon social media searches. The dry sea moss is rehydrated in water and then blended with water to create a gel. Fruit juice and/or herbs are often added in the process to create flavored or infused sea moss gel. The gel is sold as is or added to foods such as smoothies and other beverages, ice cream, custards, broth, etc. In some cases, the sea moss gel and/or products containing sea moss gel are packaged in mason jars or similar containers that could produce a reduced oxygen environment. Sea moss gel gummies are also produced in a similar fashion. Sea moss gel products are being produced in and sold from manufacturing facilities, retail food establishments as well as unregulated, home kitchens. A large variety of sea moss gel products can be found on online ordering sites/platforms.

There is little historical data or guidance available due to the newness of the product. Many state and local regulatory agencies across the country have struggled to identify how best to classify sea moss gel, with some treating sea moss gel as a dietary supplement and

others treating it as a food. Best practices and/or requirements, including a HACCP plan and variance, have been established by some state and local regulatory agencies to address the production of sea moss gel within retail food establishments (see attachment titled "Sea Moss & Sea Moss Gel Guidance" as an example). At least one state has issued a consumer warning for products containing sea moss gel due to the concern of underprocessing of a food offered for sale without licensing or inspection (see attachment titled "Consumer Advisory - MDARD Urges Consumers to Dispose of Sea Moss Lemonade").

FDA Retail Food Specialists have provided the following two answers when regulatory agencies have inquired about sea moss gel.

Answer #1

"Sea moss is a type of seaweed that is a sea vegetable also known as carrageenan gum, since carrageenan is one of the components of sea moss. When mixed with water and emulsified, sea moss will become a thick substance due to its carrageenan element. This thick substance is often used in food products as a stabilizer, emulsifier, or thickener.

According to sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is considered a Food Additive that is subject to review, unless the use of the substance is already deemed as a GRAS (generally recognized as safe) substance. 21CFR172.620 lists carrageenan as an approved food additive when used according to the conditions described in this section https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.620 Keep in mind, it is an approved food additive only when derived from the members of the families Gigartinaceae and Solieriaceae of the class Rodophyceae (red seaweed) including, Chondrus crispus, Chondrus ocellatus, Eucheuma cottonii, Eucheuma spinosum, Gigartina acicularis, Gigartina pistillata, Gigartina radula and Gigartina stellata.

Additionally, 21CFR182.7255

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=182.7255 lists chondrus extract as a GRAS substance when used as a stabilizer. And Fucoidan concentrate from *Fucus vesiculosus* (a brown seaweed also known as Bladderwrack, Black Tang, or Rockweed) has also been deemed a GRAS substance when used as an ingredient in baked goods (bread, cake, noodles), soups, snack foods, imitation dairy products, and seasonings and flavors at use levels up to 30 milligrams per serving https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=661

Regarding your question whether FDA would classify sea moss gel as a food additive, you must evaluate if the sea moss gel products you are assessing for use in retail establishments fall within the above-mentioned approved food additive or GRAS notices. This would include knowing the species of seaweed the gel was made from and whether any other ingredients were added to the final product. Regarding classification as a dietary supplement, sea moss gel does not fit the definition of a dietary supplement (ingredients such as vitamins, minerals, herbs, amino acids, and enzymes) https://www.fda.gov/food/dietary-supplements/dietary-supplement-products-ingredients and therefore should not be classified as such when added to food products at the retail establishment."

Answer #2:

"...our branch did have a discussion about sea moss. I don't know if the specifics exactly match what you've run into, but we had some discussions on Chondrus crispus (common

name for Irish sea moss). The overall message is that the sea moss doesn't have authorized use as a food or color additive - hence it needs a GRAS conclusion, prior sanction, or other exemption under section 201(s) of the FD&C Act for use of C. crispus in food. FDA is not aware of any of these alternative means of compliance with section 201(s) for this product. The firms might have publicly available safety evidence to support its use to be concluded as GRAS without prior notice to FDA. Ultimately, food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

For the sea moss to be considered a food itself, we have had some internal discussions about sourcing and how it really should be regulated. The Center has not commented and more federal guidance is being worked on... hopefully. You could say this is a plant product, but then it comes from the ocean! Produce? Seafood? Again, more will have to be discussed on that one and we are waiting to hear back ourselves.

Also, if the ingredient imparts color to food, they may meet the statutory definition of "color additive" found in section 201(t)(1) the FD&C Act. Color additives are subject to premarket approval by FDA and require a listing in title 21 CFR providing for such use before they can be lawfully used in products marketed in the U.S. Currently, there is no listing in 21 CFR authorizing use of a C. crispus ingredient as a color additive in beverages. If an ingredient imparts color to the food (and that is the intended use, to color a food) and there is evidence to support the safe use of the ingredients as a color additive in beverages, authorization for use as a color additive can be sought through filing of a color additive petition. More information about color additives and color additive petitions here à https://www.fda.gov/industry/color-additives.

Lastly, regarding these smoothie additions - there's always a chance that some health claims might be made given the type of commercial market smoothies exist within. See this site that has a plethora of FDA FAQs on authorized health claims for food/supplements: https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard. The concern is usually that claims might be made about some of these ingredients treating a medical condition or being some sort of cure for an ailment without scientific evidence."

Sourcing of raw sea moss with which to make sea moss gel is a potential concern due to natural toxins in the harvest area, contaminated waters, heavy metals, etc. (see attachment titled "The Identification of Potential Food Safety Hazards in Seaweed"). The production and storage of sea moss gel may involve increased food safety risks (including *Clostridium botulinum*) that require strict controls to produce a safe product.

Recommended Solution: The Conference recommends...:

A sea moss and sea moss gel committee be created with the following charges:

- 1. Review current regulations related to sea moss and sea moss gel.
- 2. Review available scientific literature regarding the production and storage of sea moss gel.
- 3. Identify the hazards most likely associated with sea moss and the production and storage of sea moss gel.

- 4. Determine if specific predetermined controls can be applied to mitigate the identified hazards when producing and storing sea moss gel in a retail food establishment and, if so, identify the specific control measures necessary.
- 5. Identify state and local regulatory agencies that have established best practices, guidance and/or requirements for the production of sea moss gel in retail food establishments and review their materials.
- 6. Develop a guidance document (if the Committee's findings support such) for posting on the CFP website to be used by retail food establishment operators and regulators for the production and storage of sea moss gel within a retail food establishment.
- 7. Determine if the production of sea moss gel within a retail food establishment should be considered a specialized processing method and, if so, whether it should be added to section 3-502.11 in the FDA Food Code, a separate section be created in the FDA Food Code, or not be specified in the FDA Food Code.
- 8. Consider other changes and/or additions to the FDA Food Code that may be relevant to the classification, identification, production, control, labeling, etc. of sea moss gel.
- 9. Report the Committee's findings and recommendations at the next Biennial Meeting.

Submitter Information:

Name: Cynthia Walker

Organization: Steritech

Address: 5810 N Cherokee Ave City/State/Zip: Tampa, FL 33604 813.516.1742

E-mail: cynthia.walker@steritech.com

Supporting Attachments:

- "Sea Moss & Sea Moss Gel Guidance"
- "Consumer Advisory MDARD Urges Consumers to Dispose of Sea Moss Lemonade"
- "The Identification of Potential Food Safety Hazards in Seaweed"

Issue: 2023 III-020

Council Recommendation:	Accepted as Submitted		Accepted as Amended	No Action
Delegate Action:	Accepted		Rejected	
All information above the line	is for conference use o	only.		
Issue History: This is a brand new Is	sue.			
Title:				

Issue you would like the Conference to consider:

Creating a committee to be charged with reviewing available scientific data and recommending uniform standards on food safety, compliance and enforcement of retail cold brew coffee for inclusion in the Food Code.

Create a Committee - Retail Cold Brew Coffee Safety & Compliance Committee

Public Health Significance:

The Food Code currently does not have any standards specific to retail cold brew coffee. Retailers must determine what food safety and compliance standards to follow, and state and local health inspectors are left uncertain about what standards to adopt and enforce against. This situation has created a patchwork of enforcement interpretation and inconsistent standard adoption across the retail industry. Retail operators need uniformly applied standards to protect the health and safety of cold brew coffee consumers.

Due to very limited published research on cold brew food safety that is available in the public domain, the National Coffee Association (NCA) has initiated a comprehensive cold brew challenge study with a leading third-party, accredited laboratory and intentionally designed the experiment to answer health inspectors' questions. The research findings can help inform the creation of a food code standard and provide supporting evidence that cold brew coffee is not a time/temperature control for safety food (TCS) and whether cold brew stored in airtight packaging for > 48 hours such as a stainless-steel keg should be considered Reduced Oxygen Packaging (ROP). We anticipate study results to be available in a white paper in June 2023. Please see supporting attachments for further details.

Recommended Solution: The Conference recommends...:

a Retail Cold Brew Coffee Safety & Compliance Committee be created and charged with the following:

- 1. Consider the need for having uniform standards on retail cold brew coffee food safety for consistent enforcement across all U.S. health department and retail food safety jurisdictions.
- 2. Identify and review available food safety literature and challenge study data on retail cold brew coffee.
- 3. Propose language on retail cold brew coffee food safety for inclusion in the Food Code.
- 4. Report the Committee's findings back at the next biennial meeting.

Submitter Information 1:

Name: Mark E. Corey

Organization: National Coffee Association USA, Inc.

Address: 45 BroadwaySuite 1140 City/State/Zip: New York, NY 10006

Telephone: 6469244034

E-mail: mcorey@ncausa.org

Submitter Information 2:

Name: William Murray

Organization: National Coffee Association USA, Inc.

Address: 45 BroadwaySuite 1140 City/State/Zip: New York, NY 10006

Telephone: 2127664007

E-mail: wmmurray@ncausa.org

Supporting Attachments:

• "NCA Support Letter Research 01 23 2023"

Issue: 2023 III-021

Council Recommendation:	Accepted as Submitted		Accepted as _ Amended		No Action		
Delegate Action:	Accepted		_ Rejected		_		
All information above the line	e is for conference use	e only.					
Issue History:							
This is a brand new Issue.							
Title:							
Creation of a Commit	tee to Define He	at-Treat	ed				

Issue you would like the Conference to consider:

A recommendation is being made to create a Committee to evaluate the science of and construct parameters for heat treatment as it relates to the definition of a TCS food to allow for a more consistent interpretation of foods that are considered TCS.

Public Health Significance:

Heat treatment of food products can have various impacts on microorganism growth, from increasing the likelihood of growth through water absorption for plant foods to the destruction of competitive or pathogenic microflora. Due to the complex nature of the effects of heat treatment on the safety of food products, the use of the term "heat-treated" without further definition leads to confusion regarding when the term is applicable.

The definition of TCS foods in Paragraph 1-201.10(B) includes both plant and animal foods that are heat-treated. When heat is intentionally applied to a food product from a heating element, the categorization of heat treatment seems simple; however, at retail there are many examples of indirect heating through air or liquid that put into question the applicability of the term "heat-treated". For example, drying herbs in a dehydrator is considered heat treatment, but whether the term applies to herbs dried in warm parts of the kitchen or via sun-drying is up for interpretation. When pickling, hot brine is often added to plant foods to maximize acid penetration, but there is currently no guidance on whether this is considered a heat-treated plant food. Additionally, without a standard definition, it is unclear if the temperature of the brine, or any other heat treatment temperature, impacts whether the food is considered heat treated and therefore TCS.

In 2001, the Institute of Food Technologists (IFT) prepared a new framework for what we now refer to as TCS foods, which can be found in Chapter VIII of "Evaluation and Definition of Potentially Hazardous Foods". As part of this framework, there are two tables which offer pH and water activity values to further aid in determining if a food is non-TCS, with Table A having more lenient values due to being applicable to foods where vegetative cells

have been destroyed¹. Although the framework prepared by the IFT explains the rationale of having two tables to account for products that are "heat treated to destroy vegetative cells", the document does not provide a definition as to what is considered adequate heat treatment for all types of food products. Instructions for determining which table to use do exist in the Food Code Annex 3 Paragraph 1-201.10(B), where TCS foods are discussed; however, these instructions reference Section 3-401.11, which does not contain final cook temperatures for many foods where table A is applied, such as plant foods. The absence of a definition for "heat treated to destroy vegetative cells" as it relates to Table A causes confusion for determining which table is applicable as well as determining critical limits to set for special processes. Examples of where confusion has been seen at retail are pickled vegetables, products that have been heated and cooled before packaging, and meat and dairy alternative products.

The ambiguity that exists due to the lack of these definitions is causing inconsistent interpretation of foods that are considered TCS, which is potentially leading to temperature abuse of foods that microbiologically pose a threat to public health. This committee formation recommendation is being made to provide clarity of what constitutes "heat-treated" and "heat-treated to destroy vegetative cells" to provide a more robust, microbiologically accurate picture of what foods require time and temperature control that will not be compromised due to differing interpretations.

References

1. Institute of Food Technologists (IFT) Report, Evaluation and Definition of Potentially Hazardous Foods, Food and Drug Administration Contract No. 223-98-2333, Task Order No. 4, December 31, 2001.

https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-PotentiallyHazardous-Foods.pdf

Recommended Solution: The Conference recommends...:

That a committee be created to complete the following charges and report the committee's findings at the next biennial meeting.

The resulting Committee will be charged with:

- 1. Identifying and evaluating risk-based literature that aids in defining a temperature threshold for what is considered heat treatment for all types of foods.
- 2. Developing a definition for "heat-treated" that will adequately convey the risk and will clarify which processes seen at retail result in a food product being TCS. As part of this definition, it is recommended to also clarify the meaning of "heat-treated to destroy vegetative cells" as it appears in Table A in Paragraph 1-201.10(B) to also include an additional temperature for plant foods that do not have a final cook temperature in Section 3-401.11.
- 3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to the FDA recommending the most recent version of the FDA Food Code to include the newly formed definition for "heat-treated" as referenced in Paragraph 1-201.10(B) where Time and Temperature Control for Safety Foods is defined and "heat-treated to destroy vegetative cells" as referenced in Table A of this definition.

4. Report the committee's findings and recommendations at the next biennial meeting.

Submitter Information 1:

Name: Mary Yavelak

Organization: NC State University

Address: 4101 Beryl RoadSuite 220

City/State/Zip: Raleigh, NC 27607 Telephone: 919-867-7909

E-mail: mkyavela@ncsu.edu

Submitter Information 2:

Name: Veronica Bryant

Organization: NC DHHS

Address: 5605 Six Forks Rd City/State/Zip: Raleigh, NC 27699 Telephone: 919-218-6943

E-mail: Veronica.bryant@dhhs.nc.gov

Supporting Attachments:

"Evaluation and Definition of Potentially Hazardous Foods - Chapter V111"

Issue: 2023 III-022

Council Recommendation:	Accepted as Submitted		Accepted as _Amended	 No Action	
Delegate Action:	Accepted		_ Rejected	_	
All information above the line	e is for conference use	e only.			
Issue History:					
This is a brand new Is	ssue.				
Title:					
Creation of a Commit	tee: Rehydrated	Foods			

Issue you would like the Conference to consider:

A recommendation is being made to create a committee to evaluate the food preparation practices related to rehydrated foods and provide food safety guidance and recommendations

Public Health Significance:

There has been an increase in popularity of dehydrated foods in recent years. As food costs are rising, food operators are looking for ways to extend the shelf life on products and use products in different and more cost-effective ways. Several states have seen an increase in freeze drying requests for variances. There have been multiple states with sea moss gel being created, and the process is not adequately addressed in the Food Code, even with an increased risk of *C. botulinum*. The process of dehydrating the food has been considered a specialized process requiring a HACCP Plan and a variance, but there has been little information provided on the process of rehydrating foods.

When looking at the definition of a Time/Temperature Control for Safety (TCS) as stated in the 2022 FDA Food Code Section 1-201.10(B), it is difficult to determine whether rehydrated foods meet this definition. Examples of rehydrated foods include potato flakes, beans, vegetables noodles, etc., As one specific example: when plant foods such as peppers or mushrooms are rehydrated, they are often placed in room temperature water, which means they are not considered a heat-treated plant food during rehydration. The resulting rehydrated food would be similar in pH and water activity to the original vegetable prior to being dehydrated, which is not considered a TCS food. Even if the pH and water activities are similar, the food safety risks of the rehydrated vegetable may be very different than the original raw vegetable product due to changes that occur in the cell structures during processing. However, based on current 2022 FDA Food Code definitions of a TCS food per 1-201.10(B), neither have any time or temperature controls in place.

There may be food safety considerations for the temperature of the dehydration process, rehydration liquid, length of time of rehydration, and storage after rehydration. A review of potential risks associated with these products is needed, as this information is not easily accessible for industry or regulatory partners. Additionally, without Food Code parameters in place, guidance for handling of these products is needed.

Recommended Solution: The Conference recommends...:

that a committee be created to evaluate the preparation of rehydrated foods at retail, the food safety hazards, and the guidance related to controlling these hazards.

Charges for this committee would include:

- 1. Reviewing of the literature available on rehydration of food practices at retail
- 2. Analyzing of food safety hazards likely to occur during rehydration process and after during storage
- 3. Providing guidance on controlling hazards, in a guidance document or another format
- 4. Identifying the recommended methods to disseminate the committee's findings
- 5. Reporting the committee's findings at the next CFP Biennial Conference

Submitter Information:

Name: Veronica Bryant

Organization: NC DHHS

Address: 5605 Six Forks Rd City/State/Zip: Raleigh, NC 27699 Telephone: 919-218-6943

E-mail: veronica.bryant@dhhs.nc.gov

Issue: 2023 III-023

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:							
Revise definition of Reduced Oxygen Packaging specific to packaging type							

Issue you would like the Conference to consider:

The current definition of Reduced Oxygen Packaging (ROP) Cook-Chill Packaging does not include packaging such as film covered trays that are sealed.

Public Health Significance:

The current definition of Reduced Oxygen Packaging (ROP) Cook-Chill Packaging does not include packaging such as film covered trays that are sealed. The FDA identifies that time and temperature control for safety (TCS) food that is heated just prior to packaging in a bag or a film sealed on trays results in a process that aligns with the Food Code definition of ROP (Attachment #1).

There are operations that are packaging hot TCS food in trays with a plastic film. Cooking food drives off oxygen from the food thereby lowering the oxygen level in that food. After the bag or tray with film is sealed, the oxygen level in the headspace and the oxygen level in the hot TCS food will equilibrate. This results in a package with an oxygen level below what is normally found in the atmosphere resulting in a process that aligns with the Food Code definition of ROP.

The definition for cook chill does not recognize the use of a film sealing process on a tray as ROP. Updating the code will allow for it to better align with the FDA guidance.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the definition of the term "Reduced Oxygen-Packaging" under 1-201.10 (B) in the current Food Code be amended as follows:

Reduced Oxygen Packaging.

(2) "Reduced oxygen packaging" includes:

(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable bags PACKAGING (such as a bag or film on trays) that are is then sealed or crimped closed. The bagged-PACKAGED FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

Submitter Information:

Name: Robert Warwick, REHS

Organization: CO Dept. Public Health & Env. - Retail Food Unit

Address: 4300 Cherry Creek Dr. South

City/State/Zip: Denver, CO 80246

Telephone: 720-550-0242

E-mail: robert.warwick@state.co.us

Supporting Attachments:

"Heat sealing without a vacuum v03"

Issue: 2023 III-024

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 Is	ssue.						
Title:							
Amend ¶3-501.13(E)	thawing of froze	n ROP fi	sh				

Issue you would like the Conference to consider:

Since the incorporation of paragraph 3-501.13(E) in the 2013 Food Code, there is confusion on how to thaw reduced oxygen packaged fish. There have also been different interpretations of what is meant by removing frozen fish from the reduced oxygen environment. The intent of the Food Code is for reduced oxygen packaged fish to be completely removed from the reduced oxygen packaging, so that the reduced oxygen environment is removed. There was never an intent to just place holes or slits in the reduced oxygen packaging (ROP) to remove it from that environment. Placing holes or slits in the ROP may not ensure that the hazard of *Clostridium botulinum* growth and toxin formation will be eliminated. This is due to uncertainties in the amount of oxygen transmission allowed by holes and slits of unknown size and number that would be needed to revert the reduced oxygen packaging environment to an oxygen content to a level normally found in the atmosphere (approximately 21% at sea level) which would render the packaging no longer ROP. Thus, completely removing the fish from the ROP ensures that the reduced oxygen environment is removed, and the hazard of *C. botulinum* growth and toxin formation is removed.

Public Health Significance:

Fish Retailers should be aware that when a manufacturer processes fish and fishery products, they are required to have and implement a written HACCP plan that controls reasonably likely to occur hazards under 21 CFR Parts 123 and 1240, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (the Seafood HACCP Rule). The hazard of *Clostridium botulinum* growth and toxin formation becomes reasonably likely to occur when fish is placed in reduced oxygen packaging (ROP).

C. botulinum is a pathogen that grows in reduced oxygen environments with little to no oxygen (e.g., ROP) and consists of two groups, proteolytics and nonproteolytics. Proteolytics grow at a minimum temperature of 50°F and can be controlled by refrigeration.

However, nonproteolytics, common in fish, grow at a minimum of 38°F. Nonproteolytics are not adequately controlled by refrigeration alone. Temperature abuse during distribution and subsequent processing including thawing, can occur in addition to improper refrigeration storage between 40-50°F at the consumer level. While nonproteolytics grow slowly at 37.9-41°F and take seven days to exceed maximum cumulative time and temperature exposure limits for growth and toxin formation, when temperatures are at 42-50°F, nonproteolytics can grow and produce toxin within two days. Additionally, if the temperature is increased to 51-70°F, growth and toxin formation can occur in 11 hours and only 6 hours when temperatures are above 70°F. Exceeding cumulative time and temperature exposure limits can render the product unsafe due to the potential formation of botulinum toxin, the most toxic substance known.

FDA's Fish and Fishery Products Hazards and Control Guidance, June 2022, Chapter 13, recommends processing controls for *C. botulinum* in frozen and refrigerated fish. Controls can be either freezing with proper labeling, refrigeration with the use of time temperature indicators (TTIs) or refrigeration in combination with a barrier such as product formulation to achieve a target water phase salt, water activity, or pH. The additional barrier to refrigeration is intended to control for the hazard of nonproteolytic growth and toxin formation during cumulative time and temperature exposures from packaging of the finished product throughout distribution until removal from ROP. Completely removing the fish from ROP removes the reduced oxygen environment and the hazard of *C. botulinum* growth and toxin formation.

Freezing with proper labeling as a control strategy for frozen product is intended to prevent exposure of the product to conditions conducive to the production of toxin by nonproteolytic strains of *C. botulinum* in ROP.

If freezing and proper labeling was chosen by the manufacturer as the control for nonproteolytic strains of *C. botulinum*, then each individual package of the ROP fish should be labeled to be kept frozen until used and thawed under refrigeration immediately before use (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use."). Alternatively, labeling with instructions to keep the product frozen until used and to remove packaging before thawing instead of instructions to thaw under refrigeration immediately before use, may also be used. If this type of labeling is not present on each individual frozen ROP package unit, it may or may not be acceptable to store under refrigeration, depending in part on whether there is a barrier such as pH or water activity to growth of *C botulinum* in addition to refrigeration.

As an added safeguard to prevent the possibility of *C. botulinum* toxin formation, the Food Code requires that any frozen ROP fish that does not have a barrier to growth of *C. botulinum* in addition to refrigeration be completely removed from the reduced oxygen environment or package prior to thawing. This is to discourage the practice of thawing frozen ROP fish and holding it at 41°F or less for a prolonged time and/or selling it as a refrigerated product in ROP.

Recommended Solution: The Conference recommends...:

the FDA Food Code be amended to read:

3-501.13 Thawing.

Except as specified in \P (D) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be thawed:

- (E) REDUCED OXYGEN PACKAGED FISH that bears a label indicating that it is to be kept frozen until time of use shall be <u>completely</u> removed from the reduced oxygen environment <u>and packaging</u>:
- (1) Prior to its thawing under refrigeration as specified in ¶(A) of this section; or
- (2) Prior to, or Immediately upon completion of, its thawing using procedures specified in ¶
- (B) of this section.

Submitter Information 1:

Name: Glenda R. Lewis

Organization: U.S. Food and Drug Administration

Address: 5001 Campus Drive City/State/Zip: College Park, MD 20740

Telephone: 240-402-2150

E-mail: glenda.lewis@fda.hhs.gov

Submitter Information 2:

Name: Veronica Moore

Organization: U.S. Food and Drug Administration

Address: 5001 Campus Drive City/State/Zip: College Park, MD 20740

Telephone: 240-402-1409

E-mail: veronica.moore@fda.hhs.gov

Issue: 2023 III-025

Council Recommendation:	Accepted as Submitted	Accepted as Amended			No Action		
Delegate Action:	Accepted		_ _Rejected		-		
All information above the line	e is for conference use	e only.					
Issue History:							
This is a brand new Issue.							
Title:							
Amend Food Code to Clarify Fish Thawing Requirements in 3-501.13(E)							

Issue you would like the Conference to consider:

A recommendation is being made to clarify the requirement for frozen fish to be removed from the reduced oxygen environment before thawing as required in FDA Food Code 3-501.13(E).

Public Health Significance:

The FDA Food Code requires fish to be removed from the reduced oxygen environment before thawing in Section 3-501.13(E). This requirement exists due to the risk of *Clostridium botulinum* type E spores present in marine environments. These spores can germinate and produce toxin at refrigeration temperatures in anaerobic environments. FDA Fish and Fisheries Products Hazards and Controls Guidance Appendix 4 states that for *C. botulinum* type E and non-proteolytic types B and F the maximum storage time to ensure there is no germination, growth, and toxin formation is seven days between 37.9°F and 41°F (3.3°C - 5°C).

The "Fish and Fisheries Products Hazards and Controls Guidance" lists freezing as a control for *C. botulinum* in Chapter 13. When freezing is used as the only control, it must remain frozen before, during, and after packaging. Section 3-501.13(E) states "REDUCED OXYGEN PACKAGED FISH that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment prior to thawing..." "Removed from the reduced oxygen environment" is not specifically defined but is interpreted in the field to mean that once oxygen has been introduced into the package, it has been removed from the environment. Therefore, puncturing, slitting, or opening the packaging has been observed as compliance with this Section of the Code.

There are some specific food safety reasons why the practice of opening the package but not removing the product while thawing has been used by operators. While thawing, there is some liquid that collects around the fish products. Leaving the fish in the bag allows for

better protection from cross contamination. Additionally, the product remains covered if it is in an opened package. This also protects from potential contamination.

There have been multiple interpretations heard throughout the country on the meaning of "removed from the reduced oxygen environment" which has led to confusion among industry and regulators. A consistent interpretation that is based on risk is needed. If introducing oxygen by puncturing or opening the package removes the *C. botulinum* risk, then this interpretation assists industry partners with other food safety risks and should be formally issued for consistency and clarity.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the most recent version of the FDA Food Code Section 3-501.13(E) be amended within the Code Section to clarify the statement "removed from the reduced oxygen environment," with this clarification to allow the package to be opened without the product being removed as long as no additional *C. botulinum* risk exists.

Submitter Information:

Name: Veronica Bryant

Organization: NC DHHS

Address: 5605 Six Forks Rd City/State/Zip: Raleigh, NC 27699 Telephone: 919-218-6943

E-mail: veronica.bryant@dhhs.nc.gov

Supporting Attachments:

"Fish and Fisheries Products Hazards and Controls Guidance"

Issue: 2023 III-026

Council Recommendation:	Accepted as Submitted	Accepted as	No Action					
Delegate Action:	Accepted	Rejected						
All information above the line	All information above the line is for conference use only.							
Issue History:								
This is a brand new Issue.								
Title:								

Issue you would like the Conference to consider:

Add new defined term "Impermeable" to clarify cook-chill processes

The current definition of Reduced Oxygen Packaging (ROP) includes the term "Impermeable". This is not a defined term in the code. The FDA suggest that packaging hot food with breathable packaging would not be considered ROP as defined in the Food Code. This is supported by the FDA who has stated that for seafood, packaging that has an oxygen transmission rate (OTR) of 10,000 cc/m2/24 hours at 24°C, or higher (often referred to as 10K OTR and occasionally printed on the packaging) is considered oxygen permeable and not ROP and could be grounds for a variance.

The lack of a definition for impermeable in the food code allows for the use of any packaging (bag or film sealed on a tray) that can be demonstrated by the industry to show any oxygen transfer rate to be used and not be considered an ROP process. As long as there is any level of permeability demonstrated by the manufacturer, then the process would not be considered ROP; if the transfer rate is too slow then spoilage may not occur and C. botulinum risks may increase.

Impermeable is also used to define bandages and wound covers in the Food Code. To make "impermeable" a defined term in relation to the ROP process, it is recommended to change the term from "impermeable" in these sections to "waterproof". This change aligns with the terminology used by bandage manufacturers and the food service industry.

Public Health Significance:

There are operators who are packaging time and temperature control for safety (TCS) food using ROP methods in breathable plastic bags or with a breathable plastic film over trays. Breathable packaging may be designed to provide oxygen levels that will allow spoilage organisms to grow and spoil food before it becomes hazardous from C. botulinum or L. monocytogenes. Defining the required level of permeability for the packaging ensures that spoilage will occur before C. botulinum or L. monocytogenes have an impact on the product.

Impermeable is not currently defined and changing 7-202.12(B)(2) to a different terminology would allow impermeable to be defined as it relates to ROP.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the current Food Code be amended as follows: 1-201.10(B)

Impermeable.

- (1) "Impermeable" means packaging with an oxygen transmission rate such as 10,000 cc/m2/24 hours at 24°C, or lower for raw FISH which will not provide a sufficient exchange of oxygen to allow naturally occurring aerobic spoilage organisms on the product to grow and spoil the product before C. botulinum toxin is produced under moderate temperature abuse.
- (2) "Impermeable" does not include packaging with an oxygen transmission rate of 10,000 cc/m2/24 hours at 24°C or higher that is used for only raw FISH.

Reduced Oxygen Packaging.

- (2) "Reduced oxygen packaging" includes:
- (c) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring FOOD, and impermeable-IMPERMEABLE PACKAGING material;
- (d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable IMPERMEABLE bags that are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or
- (e) Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an <u>impermeable-IMPERMEABLE</u> bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

2-201.11(A)

Reportable symptoms

- (1) Has any of the following symptoms:
- (e) A lesion containing pus such as a boil or infected wound that is open or draining and is:
- (i) On the hands or wrists, *unless* an *impermeable*-waterproof cover such as a finger cot or stall protects the lesion and a SINGLE-USE glove is worn over the *impermeable*-waterproof cover. P
- (ii) On exposed portions of the arms, *unless the lesion is protected by an impermeable waterproof cover*, or

2-201.13(I)

Uncovered infected wound or pustular boil - removing restriction

- (I) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(I) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:
- (1) An impermeable waterproof cover such as a finger cot or stall and a single-use <u>SINGLE-USE</u> glove over the impermeable waterproof cover if the infected wound or pustular boil is on the hand, finger, or wrist; P
- (2) An impermeable waterproof cover on the arm if the infected wound or pustular boil is on the arm: or

7-202.12 Conditions of Use.

POISONOUS OR TOXIC MATERIALS shall be:

- (B) Applied so that:
- (2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and this is achieved by: P
- (b) Covering the items with impermeable-waterproof covers, P or

Annex 3. Public Health Reasons/Administrative Guidelines

2-201.11 Responsibilities of the Person in Charge, Food Employees, and Conditional Employees.

Reporting Symptoms:

paragraph 4

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing *Staphylococcus aureus* into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but an impermeable waterproof bandage is not considered necessary for food safety purposes.

Annex 6: Food Processing Criteria

- 2. Reduced Oxygen Packaging
- (B) Definitions
- (1) Cook-chill packaging, in which cooked food is hot filled into impermeable IMPERMEABLE bags and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.
- (2) Controlled Atmosphere Packaging (CAP) in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable-IMPERMEABLE packaging material.

(4) Sous Vide, in which raw or partially cooked food is placed in a hermetically sealed, impermeable-IMPERMEABLE bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

Submitter Information:

Name: Robert Warwick, REHS

Organization: CO Dept. Public Health & Env. - Retail Food Unit

Address: 4300 Cherry Creek Dr. S, A-2

City/State/Zip: Denver, CO 80246 Telephone: 720-550-0242

E-mail: robert.warwick@state.co.us

Supporting Attachments:

"Heat sealing without a vacuum v03"

- "Vacuum packaging and oxygen transfer rate of packaging material"
- "Controlling the Hazard of Clostridium botulinum Growth and Toxin Formation"
- "Technical Assistance Network Response to your Case 299700_ Food Code"
- "Technical Assistance Network Response to your Case 301854_ Food Code"

Issue: 2023 III-027

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: Amend Food Code to	Include Definition	on of "Preservation"					

Issue you would like the Conference to consider:

The FDA 2022 Model Food Code should provide a definition for the term "preservation" as used in 3-502.11(A) and (C). As a starting point for development of that definition, we would like to propose the language in the recommended solution.

Public Health Significance:

When using "preservation" as the criteria to determine whether a variance and an approved Hazard Analysis - Critical Control Points (HACCP) plan are to be required, the intended meaning of the term needs to be clearly provided. Without clarification, both retail operators and regulators will arrive at their own interpretations. Those conclusions may conflict, deviating from FDA's intended meaning and potentially leading to public health risk resulting from misinterpretation. Searching the 2022 Food Code and previous versions, and the FDA and USDA websites, yields no official definition, and searching numerous Extension Service websites also yields no clearly stated definition. There is need for consistency in application of HACCP and variance requirements across jurisdictions, and clear statements of essential definitions are critical to establishing that needed consistency.

The lack of an official definition leads to increased regulatory burden in addressing processes submitted for approval as preservation, which in fact are often not preservation processes in the way they are used. Common examples include cold pickling of non-Time temperature Control for Safety (non-TCS) foods, and preparation of gravlax, ceviche or similar products. In turn this also creates an unnecessary burden on retail operators when they are requested to apply for a variance that is not necessary. A greater concern exists in that actual preservation processes are often found being conducted at retail without approval. This appears to be due in part to the lack of an official definition for inspector training purposes, as well as the lack of said definition provided as education to the retail food industry.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the current Food Code be amended as follows:

1-201.10 Statement of Application and Listing of Terms.

(B) Terms Defined. As used in this Code, each of the term listed in \P 1-201.10(B) shall have the meaning stated below.

"Preservation" means formulating, processing and/or packaging a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD in a manner which extends shelf life of the refrigerated READY-TO-EAT FOOD product beyond seven days as allowed under 3-501.17, or which renders the final product a non-TIME/TEMPERATURE CONTROL FOR SAFETY FOOD.

Submitter Information 1:

Name: Jonathan Wheeler

Organization: SC Department of Health and Environmental Control

Address: 2600 Bull Street City/State/Zip: Columbia, SC 29201

Telephone: 803-896-0535

E-mail: wheelejd@dhec.sc.gov

Submitter Information 2:

Name: Sandra Craig

Organization: SC Department of Health and Environmental Control

Address: 2600 Bull Street City/State/Zip: Columbia, SC 29201

Telephone: 8038960640

E-mail: craigsd@dhec.sc.gov

Issue: 2023 III-028

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: 2020 Council III Issue 031; new or additional information has been included or attached.

Title:

Amend Food Code - Delete 4-101.12 Cast Iron, Use Limitations

Issue you would like the Conference to consider:

Amend Food Code Section 4-101.12 (Cast Iron, Use Limitation) to allow cast iron to be used for utensils or food-contact surfaces of equipment whether or not the surface is heated or used for cooking.

Public Health Significance:

Food Code Annex 3 Section 4-101.12 states that "...the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean." The attached reports conducted by 3rd party laboratories has concluded that microorganisms can be removed from cast iron cookware with similar effectiveness of food grade stainless steel and both plastic and glass tableware.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the current Food Code be amended as follows:

4-101.12 Cast Iron, Use Limitation. (A) Except as specified in ¶¶ (B) and (C) of this section, cast iron may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.

- (B) Cast iron may be used as a surface for cooking.
- (C) Cast iron may be used in UTENSILS for serving FOOD if the UTENSILS are used only as part of an uninterrupted process from cooking through service.

Annex 3 4-101.12 Cast Iron, Use Limitation. Equipment and utensils constructed of cast iron meet the requirement of durability as intended in section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces the

residues in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.

Submitter Information:

Name: David Fletcher
Organization: Lodge Cast Iron
Address: 204 E. 5th Street

City/State/Zip: South Pittsburg, TN 37419 Telephone: 4238377181 ext. 168

E-mail: dfletcher@lodgecastiron.com

Supporting Attachments:

- "Cleaning Effectiveness of Cast Iron Pans and Glass and Plastic Plates..."
- "Microorganism Recovery Equivalence from Cast Iron and Food Grade..."

Issue: 2023 III-029

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above the line	is for conference use c	only.	
Issue History: This is a brand new Is	sue.		
Title: Modification of the Def	finition of TCS Fo	oods	

Issue you would like the Conference to consider:

Modification of the definition of Time/Temperature Control for Safety (TCS) foods

Public Health Significance:

The current definition of TCS foods includes only a limited number of cut plant foods. The published literature provides ample evidence that this list could be expanded, and additional publication will likely continue to expand this list. The literature shows that if avocado, cucumbers, zucchini squash, dragon fruit, banana, starfruit, mango, pineapple, guava, or wax apple are cut/diced/peeled/comminuted they will permit significant growth of *Listeria*, pathogenic *E. coli*, and/or *Salmonella* at ambient temperatures. The ability of pathogens to grow on these cut fruits and vegetables (and likely many more) highlight the need to modify the definition of TCS by removing the incomplete list of plant foods and simplifying the code to include all cut fruits and vegetables.

A supporting document is attached (TCS Foods 2022 Food Code Locations) to highlight where the term TCS food occurs throughout the Food Code.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the definition of Time/Temperature Control for Safety (TCS) Food under 1-201.10(B) of the current Food Code be amended as follows:

Time/Temperature Control for Safety Food (formerly "potentially hazardous food (PHF)).

- (1) "Time/temperature control for safety food" means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
- (2) "Time/temperature control for safety food" includes:

(a) An animal FOOD that is raw or heat-treated; a plant FOOD that is <u>raw and cut/diced/peeled/comminuted or</u> heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

Submitter Information 1:

Name: Ellen Shumaker

Organization: North Carolina State University

Address: 4101 BERYL RD City/State/Zip: Raleigh, NC 27695

Telephone: 9195159842

E-mail: ellen_shumaker@ncsu.edu

Submitter Information 2:

Name: Don Schaffner
Organization: Rutgers University
Address: 65 Dudley Rd

City/State/Zip: New Brunswick, NJ 08901

Telephone: (848) 932-5411

E-mail: don.schaffner@rutgers.edu

Supporting Attachments:

- "Literature Review- Microbial Growth in Cut Fruits and Vegetables"
- "TCS Foods 2022 Food Code Locations"

Issue: 2023 III-030

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 Is	sue.					
Title:						

Issue you would like the Conference to consider:

We would like for the U.S. Food and Drug Administration (FDA) to add other validated laboratory methods in addition to culture for reinstating an excluded or restricted food worker.

Amend Food Code – Add Laboratory Methods for Reinstating III Food Workers

Currently, the Food Code specifies the use of a culture-based method for removal of an exclusion or restriction of a food handler infected with shigellosis, salmonellosis, and Shiga toxin-producing E. coli disease. Culture-based method are still used but are being replaced by culture independent diagnostic tests (CIDTs) such as molecular or enzyme-based methods which do not produce an isolate. We are asking the conference to consider broadening the criteria for readmission of a food handler to include this new generation of diagnostic tests.

Additional support for the adoption of this issue has been received from the National Restaurant Association (see supporting attachment). Patrick Guzzle, Vice President, Food Science with the National Restaurant Association has expressed support for this issue as it will allow for additional tools for excluded or restricted employees to return to work safely and more quickly.

Public Health Significance:

The use of CIDTs in clinical practice continues to increase. FoodNet, a collaboration between CDC, FDA, USDA-FSIS, and 10 state health departments that conducts active population-based surveillance has seen a marked increase in the use of CIDTS since 2012. Access to culture (which is currently the only testing option allowed by the Food Code) is expected to become increasingly limited, making compliance with this Food Code requirement challenging.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the most recent Food Code be amended as follows:

2-201.13 Removal, Adjustment, or retention of Exclusions and Restrictions.

Shigella spp. Diagnosis - Removing Exclusion or Restriction

- (E) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(2) or (E)(1) or who was RESTRICTED under Subparagraph 2-201.12(E)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and of the following conditions is met:
- (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Shigella* spp. infection based on test results showing-2 consecutive negative stool specimen cultures test results from a validated laboratory test that is acceptable to the REGULATORY AUTHORITY obtained from stool specimens that are taken:
- (a) Not earlier than 48 hours after discontinuance of antibiotics, P and
- (b) At least 24 hours apart; P

STEC diagnosis - removing exclusions or restriction

- (F) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraph 2-201.12(A)(2) or (F)(1) or who was RESTRICTED under Subparagraph 2-201.12(F)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:
- (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of an infection from SHIGA TOXIN-PRODUCING ESCHERICHIA COLI based on test results that show-2 consecutive negative-stool-specimen cultures test results from a validated laboratory test that is acceptable to the REGULATORY AUTHORITY obtained from stool specimens that are taken:
- (a) Not earlier than 48 hours after discontinuance of antibiotics; and
- (b) At least 24 hours apart; P

Nontyphoidal Salmonella - removing exclusion or restriction

- (G) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(2) or who was RESTRICTED as specified under ¶ 2-201.12(G) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:
- (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a Salmonella (nontyphoidal) infection based on test results showing-2 consecutive negative-stool specimen cultures test results from a validated laboratory test that is acceptable to the REGULATORY AUTHORITY obtained from stool specimens that are taken;
- (a) Not earlier than 48 hours after discontinuance of antibiotics, P and
- (b) At least 24 hours apart; P

Submitter Information 1:

Name: Robert Warwick, REHS

Organization: Colorado Dept. of Public Health & Environment

Address: Retail Food Work Group Lead4300 Cherry Creek South Dr

City/State/Zip: Denver, CO 80246-1523

Telephone: 720.550.0242

E-mail: robert.warwick@state.co.us

Submitter Information 2:

Name: Rachel Jervis, MPH

Organization: Colorado Dept. of Public Health & Environment

Address: Foodborne, Enteric Diseases Program Manager4300 Cherry Creek

South Dr

City/State/Zip: Denver, CO 80246-1523

Telephone: 720.257.9388

E-mail: rachel.jervis@state.co.us

Supporting Attachments:

"National Restaurant Association Food Safety Compliance Team_support"

Issue: 2023 III-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 Is	sue.					
Title:						

Amend Food Code - Considerations for Bulk Refillable Hand Soap Dispensers

Issue you would like the Conference to consider:

Bulk refillable soap dispensers can become highly contaminated with bacteria and can harbor bacterial biofilms. Remediation of contaminated dispensers to remove the contamination is extremely difficult, and research has shown that contaminated bulk soap dispensers can transfer bacterial contaminants to hands leading to an ineffective handwash. Disease outbreaks have been linked contaminated bulk soap dispensers in healthcare settings. Hand hygiene guidance issued by the Centers for Disease Control and Prevention notes that use of refillable soap dispensers can become contaminated with bacteria if they are "topped off", and several recent studies have identified foodborne pathogens in soap and dispenser samples obtained from food establishment restrooms.

We ask The Conference to support an issue to amend the FDA Food Code by including additional considerations for establishments that choose to use these dispensers, to help prevent these dispensers from becoming contaminated with pathogenic bacteria that may lead to an outbreak.

Public Health Significance:

There are least two recently published peer-reviewed research studies which report the detection of foodborne pathogens in bulk soap.

A 2018 study describes the collection of 296 bulk soap samples from food establishments (e.g., grocery, sit down restaurants, fast food restaurants, and convenience stores) across the United States (1). Samples were screened for total heterotrophic viable bacteria, *Pseudomonas*. coliforms and *Escherichia coli*, and *Salmonella*. The researchers found:

 Bulk soap samples were contaminated with detectable levels of bacteria around 15% of the time, and when contaminated, contained very high levels of bacteria (>7.0 log₁₀ colony forming units [CFU]/mL).

- One sample contained Shigella sonnei, the bacteria responsible for most Shigellosis
 cases in the developed world. Shigellosis is characterized by severe diarrhea and
 can be caused by less than 100 bacterial cells of Shigella species.
- A variety of opportunistic pathogens were identified in the samples, including Klebsiella pneumoniae, Serratia marcescens, Enterobacter species, and Pseudomonas species, which may pose a risk to certain individuals (e.g., immunocompromised individuals).

Researchers in Iran published a study in 2020 where they collected of 643 bulk soap and bulk soap dispenser samples from public restrooms in Iran (2). The samples were screened for a variety of bacteria using selective plating and biochemical confirmation methods. There were several key findings from this study:

- Dispensers and liquid soap samples were contaminated with bacteria 97.8% and 16.8% of the time, respectively.
- Shigella species were identified in 17 (2.6%) of liquid soap samples.
- Bulk dispensers had a variety of bacteria identified, including Staphylococcus aureus (n=38 [6.0%]), Salmonella species (n=10 [1.6%]), Escherichia coli (n=187 [29.0%]), and Shigella species (n=12 [1.9%]).

Research has shown that contaminated bulk soap can transfer the bacterial contaminants to the hands of individuals who used the soap in handwashing (3). A 2011 study identified naturally contaminated soap dispensers in an elementary school system, and then had student and staff volunteers wash their hands using the contaminated dispensers. Gramnegative bacteria on the hands of students and staff increased by 1.42 \log_{10} CFU per hand (26-fold) after washing with soap from contaminated bulk-soap-refillable dispensers. The same study found that washing with soap from dispensers with sealed refills significantly (0.30 \log_{10}) reduced bacteria on hands.

If not properly maintained, use of bulk soap dispensers for handwashing has demonstrated risks. Foodborne and opportunistic pathogens have been isolated from bulk soap and bulk soap dispenser samples (1, 2). Contaminated bulk soap has been shown to transfer the contaminants to the hands of individuals (3) and contaminated dispensers are extremely difficult to remediate (4). Outbreaks attributed to contaminated bulk soap dispensers have been identified in healthcare settings (5) which has led to hand hygiene guidance by the CDC recommending against topping off of these dispensers (6). We propose this food safety risk should be addressed through amendment of the 2022 FDA Food Code.

References:

- Schaffner, D. W., Jensen, D., Gerba, C. P., Shumaker, D., & Arbogast, J. W. (2018). Influence of Soap Characteristics and Food Service Facility Type on the Degree of Bacterial Contamination of Open, Refillable Bulk Soaps. J Food Prot. 81(2), 218-225.
- Matini E, Shayeghi F, Vaghar ME, Nematian J, Hosseini SS, Mojri N, Taherabadi NT, Hakimi R, Ahmadi N, Badkoubeh N, Esmaeili H, Akhlaghi M, Vaseghnia H. A survey of public restrooms microbial contamination in Tehran city, capital of Iran, during 2019. J Family Med Prim Care. 2020 Jun 30;9(6):3131-3135.

- 3. Zapka, C. A., Campbell, E. J., Maxwell, S. L., Gerba, C. P., Dolan, M. J., Arbogast, J. W., & Macinga, D. R. (2011). Bacterial hand contamination and transfer after use of contaminated bulk-soap-refillable dispensers. Appl Env Micro. *77*(9)
- 4. Lorenz LA, Ramsay BD, Goeres DM, Fields MW, Zapka CA, Macinga DR. Evaluation and remediation of bulk soap dispensers for biofilm. Biofouling. 2012;28(1):99-109.
- 5. Buffet-Bataillon S, Rabier V, Bétrémieux P, Beuchée A, Bauer M, Pladys P, Le Gall E, Cormier M, Jolivet-Gougeon A. Outbreak of Serratia marcescens in a neonatal intensive care unit: contaminated unmedicated liquid soap and risk factors. J Hosp Infect. 2009 May;72(1):17-22.
- 6. Boyce, J. M., and D. Pittet. 2002. Guideline for hand hygiene in health-care settings. Morbid. Mortal. Week. Rep. 51:1-56.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the amendment of The FDA Food Code section 6-301.11 (Handwashing Cleanser, Availability) as follows:

- 6-301.11 Handwashing Cleanser, Availability.
- (A) Each HANDWASHING SINK or group of 2 adjacent HANDWASHING SINKS shall be provided with a supply of hand cleaning liquid, powder, or bar soap. Pf
- (B) If a hand cleaning liquid is used, its associated dispenser must be free from filth, visible debris, or any other sign of gross contamination.
- (C) If a handwashing cleanser is dispensed from a receptacle that is designed to be refillable with an open reservoir and an accompanying lid, the receptacle must:
 - 1. Be of durable construction;
 - 2. Contain an interior constructed with a SMOOTH, EASILY CLEANABLE surface:
 - 3. Be cleaned and sanitized as frequently as necessary to protect against contamination with microorganisms of public health concern.
 - 4. <u>Be resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.</u>

Submitter Information 1:

Name: Chip Manuel
Organization: GOJO Industries
Address: 1 Gojo Plz Suite 500
City/State/Zip: Akron, OH 44311
Telephone: (330) 255-6000
E-mail: ManuelC@gojo.com

Submitter Information 2:

Name: James W. Arbogast Organization: GOJO Industries Address: 1 Gojo Plz Suite 500 City/State/Zip: Akron, OH 44311 Telephone: 330-255-6000

E-mail: ArbogasJ@gojo.com

Supporting Attachments:

- "Influence of Soap Characteristics and Food Service Facility Type"
- "A survey of public restrooms microbial contamination in Tehran city"
- "Bacterial hand contamination and transfer after use of contaminated bulk"
- "Evaluation and remediation of bulk soap dispensers for biofilm"
- "Outbreak of Serratia marcescens"
- "Guideline for hand hygiene in health-care settings"

Issue: 2023 III-032

Council Recommendation:	Accepted as Submitted	Accepted aAmended	s 	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:							

Issue you would like the Conference to consider:

Adding aqueous ozone as an approved sanitizer in section 4-501.114 of the FDA Food Code.

Amend Food Code - Add Aqueous Ozone as an Approved Sanitizer in 4-501.114

Public Health Significance:

There is long history of use of ozone as a disinfectant in food and beverage processing.

- The application of ozone to disinfect bottled water was approved as Generally Recognized As Safe (GRAS) in 1982;
- The application of ozone for direct contact on foods was approved as GRAS by the U.S. Food and Drug Administration (FDA) in June 2001 under the FDA Final Rule 21 CFR Part 173.336.

(Source: Ozone Processing of Foods and Beverages - IFT.org)

The FDA Food Code makes an allowance for alternative sanitizers but has specific requirements that places the burden on the permit holder to demonstrate efficacy. (Section 4-501.114)

- (D) If another solution of a chemical specified under ¶¶ (A) (C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANTIZATION and the use of the solution shall be APPROVED;
- (E) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions; and
- (F) If a chemical SANITIZER is generated by a device located on-site at the FOOD ESTABLISHMENT it shall be used as specified in (A) - (D) of this section and shall be produced by a device that:

- (1) Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),
- (2) Complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements,
- (3) Displays the EPA device manufacturing facility registration number on the device, and
- (4) Is operated and maintained in accordance with manufacturer's instructions

The California Retail Food Code expressly allows the use of aqueous ozone as a sanitizer in retail food establishments.

- 114099.6. Manual sanitization shall be accomplished in the final sanitizing rinse by one of the following:
- (4) Contact with a solution of ozone that meets the requirements of Section 180.940 of Title 40 of the Code of Federal Regulations and that is generated by a device located onsite at the food facility that meets all of the following requirements:
- (A) Complies with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seg.).
- (B) Complies with federal device requirements as specified in Section 152.500 of Title 40 of the Code of Federal Regulations, and federal labeling requirements as specified in Section 156.10 of Title 40 of the Code of Federal Regulations.
- (C) Displays the United States Environmental Protection Agency device manufacturing facility registration number on the device.
- (D) Is operated and maintained in accordance with the manufacturer's instructions and manufactured using good manufacturing practices as specified in Part 110 of Title 21 of the Code of Federal Regulations.

Further, the California Department of Public Health has establishment a variance process for an ozone generating equipment that has "demonstrated through challenge studies, the efficacy of the solution produced by its equipment; however, it does not meet the requirements of Title 40 of the Code of Federal Regulations 180.940 as required by Section 114099.6(b)(4) of the" California Retail Food Code.

 Alternate Sanitizer Variance Application for Oxidus* Aqueous Ozone Disinfection System

*Preferred terminology is Aqueous Ozone without use of the word Oxidus

In general, the best practice for determining the appropriate CT value for an aqueous suspension of ozone in a food production environment is to maintain the ozone concentration at as high a value as possible that will ensure the atmospheric ozone concentration will not exceed the OSHA standard for the workplace of 0.1 ppm over an 8 hour work shift. Decades of experience have proven that an aqueous ozone concentration of 1.5 - 2.1 ppm at the faucet is quite appropriate for this purpose. The appropriate contact time will vary depending upon the specific pathogens of concern and the organic products and work surfaces to be disinfected. For many bacteria of concern in food production, if the pathogens are suspended in water, a continuous average aqueous ozone concentration of

approximately 0.04 ppm is sufficient to provide instantaneous 5-log kills, so an ozone concentration of 1.5 - 2.1 ppm would be far more than sufficient.

If the pathogens are attached to a product or work surface, longer contact times will be required depending upon the complexity of the surfaces and the pathogens involved. In this regard, agitation provided by the likes of flume operation or using one's hands to disturb the product surface during rinsing will decrease the amount of time necessary for appropriate disinfection. Also, if there is a large organic load being disinfected in a deep sink, such as several heads of lettuce, freshly ozonated water must be continuously added to the sink, as such an organic load in ozonated water will rapidly reduce the ozone concentration.

Adding ozone as an approved sanitizer in the FDA Food Code will:

- Provide retail food establishments an additional approved method for sanitizing food contact surfaces; and
- Reduce the administrative burden of permit holders to demonstrate the efficacy of this sanitizing method.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the current Food Code be amended as follows:

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

(D) An ozone solution shall:

- 1. Have a concentration at 0.3-2.1 ppm as measured by ORP meter (Oxidation-Reduction Potential) with reading between 695-925 mv or using ozone colorimetric test kit. Exposure time may vary from 30 seconds to up to 5 minutes.
- 2. <u>Meets the requirements of Section 180.940 of Title 40 of the Code of Federal Regulations;</u>
- 3. Meet the requirements specified under (G) of this section if the ozone solution is generated by a device located onsite at the food facility that meets all of the following requirements
- (D)(E) If another solution of a chemical specified under $\P\P$ (A) (C)(D) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITIZATION and the use of the solution shall be APPROVED; P
- (E)(F) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions. P and
- (F)(G) If a chemical SANITIZER is generated by a device located on-site at the FOOD ESTABLISHMENT it shall be used as specified in $\P\P$ (A) (D)(E) of this section and shall be produced by a device that:
- (1) Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), P
- (2) Complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements, $^{\rm P}$

- (3) Displays the EPA device manufacturing facility registration number on the device, Pf and
- (4) Is operated and maintained in accordance with manufacturer's instructions Pf.

Submitter Information 1:

Name: Patrick Guzzle

Organization: National Restaurant Association Address: 6751 Forum Drive, STE 220

City/State/Zip: Orlando, FL 32821

Telephone: 2085158688

E-mail: pguzzle@restaurant.org

Submitter Information 2:

Name: Kate Piche

Organization: National Restaurant Association Address: 233 S Wacker Drive Ste 3600

City/State/Zip: Chicago, IL 60606

Telephone: 3124856925

E-mail: kpiche@restaurant.org

Supporting Attachments:

- "Ozone Data for CFP 2023"
- "Efficacy of Ozonated Water against Various Food-Related Microorganisms"