

FDA Report

Conference for Food Protection Executive Board Meeting
April 22, 2015 Boise ID

Kevin Smith
FDA/CFSAN/ Office of Food Safety

Organization and Personnel

- Since the last CFP Board Meeting...
 - New Director of CFSAN – Dr. Susan Maine
 - Reorganization in CFSAN/Office of Food Safety - New/Modified Divisions and Staffs
 - Retail Food Protection Staff
 - Division for Produce Safety
 - Division of Plant Products and Beverages
 - Division of Dairy, Egg and Meat Products
 - Division of Seafood Safety
 - New Personnel on Retail Food Policy Team

Organization and Personnel

Office of Regulatory Affairs

- Significant Realignment has been proposed
 - New District Structure based on Product Areas, including Food and Feed
 - Regional Office restructure
 - Planned for FY2017
- Retirements
 - Central Region- Virginia Connelly and John Powell

Supplement to the 2013 Food Code

- Planned Release – May 2015
- Constituent Update will be issued
- Posted as .pdf on www.fda.gov/foodcode
- Not likely to be available in hard copy
- Considering flagging items that have been modified in the full 2013 Food Code .pdf file

Key Changes in the Supplement to the 2013 Food Code

- Duties of the Person in Charge
- Contents of a HACCP Plan
- Equipment and Utensil Cleaning Agent, Availability
- Public Posting of Inspection Results
- Emergency Action Plan for Retail Food Establishments
- Salmonella as a Reportable Illness
- Competency of an Inspector

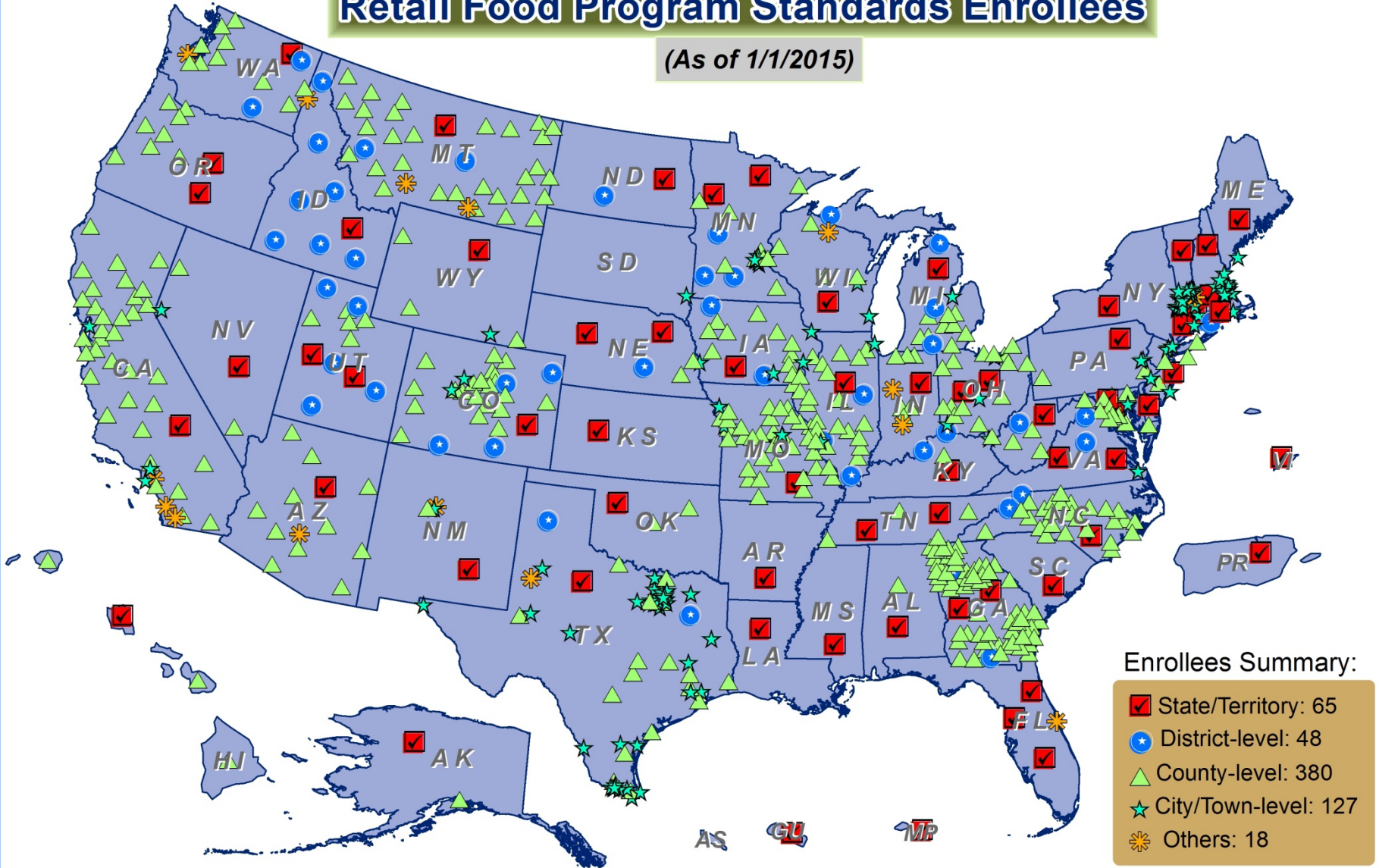
CFP related issues not addressed in Supplement to 2013 Food Code

- Exclusion of employees-Sore Throat with Fever
- Imminent Health Hazard – Actions required by operator
- Use of- Time as Public Health Control Foods starting at room temperature
- Display whole raw fish and crustacean shellfish
- Minimum temperature for Microwave Steam Cooking of Seafood
- Designating certain cheeses non-TCS foods

A. Further Develop a National Integrated Food Safety System through the Adoption of the Voluntary Retail Food Program Standard	FY 2013 Quarter 4	FY 2014 Quarter 4	FY 2014 increase/ decrease	FY 2015 Quarter 1
1. Number of state, local and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards	563	623	60	638
2. Annual increase in the number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards and have a current* and completed self assessment (SA).	272 (since	280	8	352
3. Annual increase in the number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards that have a current and completed self assessment and are meeting 3 or more Program Standards.	92 (since 1	106	14	107

Retail Food Program Standards Enrollees

(As of 1/1/2015)





Retail Food Program Standards Enrollments

STATE	#State Agency	#County Agency	#District Agency	#City/Town Agency	#Other Agency	#Total enrolled	% population by State
Alabama	1	1	0	0	0	2	13.78
Alaska	1	1	0	0	0	2	100
Arizona	1	11	0	0	1	13	93.93
Arkansas*	1	0	0	0	0	1	100
California	1	34	0	3	3	41	89.86
Colorado	1	21	4(13 counties)	2	0	28	93.06
Connecticut	2	0	3(2 cities, 16 towns)	2	2	9	10.11
Delaware*	1	0	0	0	0	1	100
District of Columbia*	1	0	0	0	1	2	100
Florida*	3	0	0	0	1	4	100
Georgia	2	68	2(5 counties)	0	0	72	73.68
Hawaii	1	3	0	0	0	4	100
Idaho	1	0	7(44 counties)	0	1	9	100
Illinois	1	19	3(10 counties, 2 cities, 2 towns)	1	0	24	15.41
Indiana	1	6	0	0	2	9	26.12
Iowa	1	13	2(14 counties)	4	0	20	100
Kansas*	1	0	0	0	0	1	100
Kentucky	1	1	2(13 counties)	0	0	4	33.41
Louisiana*	1	0	0	0	0	1	100
Maine	1	0	0	1	0	2	4.99
Maryland	1	7	0	1	0	9	56.97
Massachusetts	1	0	0	39	1	41	20.93
Michigan	1	9	4(15 counties)	1	0	15	38.94
Minnesota	2	9	3(8 counties)	6	0	20	49.58
Mississippi*	1	0	0	0	0	1	100
Missouri	1	33	0	6	0	40	80.06
Montana	1	30	2(9 counties)	0	2	35	79.00
Nebraska	2	2	1(3 counties)	0	0	5	100
Nevada	1	2	0	1	0	4	89.91
New Hampshire	1	0	0	2	0	3	65.17
New Jersey	1	2	0	5	0	8	17.89
New Mexico	1	1	0	1	1	4	58.68
New York	1	2	0	0	0	3	14.62
North Carolina	1	27	2(6 counties)	0	0	30	55.16
North Dakota	1	0	1(5 counties)	0	0	2	6.58
Ohio	2	15	0	4	0	21	43.21
Oklahoma	1	2	0	0	0	3	100
Oregon	2	8	0	0	0	10	63.06
Pennsylvania	1	2	0	3	0	6	29.46
Rhode Island*	1	0	0	0	0	1	100
South Carolina*	1	0	0	0	0	1	100
South Dakota**	0	0	0	1	0	1	18.90
Tennessee	2	4	0	0	0	6	36.61
Texas	1	17	2(8 counties, 2 cities)	40	1	61	78.69
Utah	2	5	5(20 counties)	0	0	12	97.26
Vermont*	1	0	0	0	0	1	100
Virginia	2	4	2(10 counties, 2 cities)	1	0	9	28.67
Washington	1	10	2(5 counties)	0	1	14	77.09
West Virginia	1	4	1(9 counties, 1 city)	0	0	6	24.78
Wisconsin	1	4	0	2	1	8	16.23
Wyoming	1	3	0	1	0	5	33.29

*: only state-agency enrolled; **: no state-agency enrolled.

Level of 638 Enrolled-agency: State—61; Territory—4 (Guam, Northern Mariana Islands, Puerto Rico, Virgin Islands); County—380; District—48 (197 counties, 9 cities, 18 towns); City—92; Town—35; Tribe—9; Univ.—6; Park—1; NASA—1; Community—1.

99.74% (1 States without state-level agency enrolled) of the U.S. population that reside in a state in which one or more of the eligible state-level agencies with a retail food regulatory program has enrolled in the Voluntary National Retail Food Regulatory Program Standards.

60.15% of the U. S. population that reside in a locality (city, county, parish, etc.) in which the eligible local-level agency with a retail food regulatory program has enrolled in the Voluntary National Retail Food Regulatory Program Standards*.

* -populations (such as: *Arkansas, Delaware, District of Columbia, Florida, Kansas, Louisiana, Mississippi, Rhode Island, South Carolina, Vermont*) in jurisdictions where no local-level retail food regulatory program exists will be included in this figure if the prevailing state-level agency has enrolled.

Then & Now: Investment in Retail Program Standards

	FY2009	FY2012	FY2013	FY2014	FY2015
<i>Retail Cooperative Agreements (total)</i>	\$250K	\$3.24M	\$3.20M	\$3.31M	\$6.66M
“Retail Program Standards” Cooperative Agreements	N/A	\$2.6M	\$2.4M	\$2.4M	\$3.9M
Cooperative Agreement with AFDO	N/A	N/A	\$600K	\$670K	\$2.42M
Cooperative Agreement with NACCHO	N/A	\$145K	\$202K	\$240K	\$340K
“Micro Purchase” Funds*	\$250K	\$500K	N/A	N/A	N/A

* Cooperative Agreement with AFDO replaced “micro purchase” funds

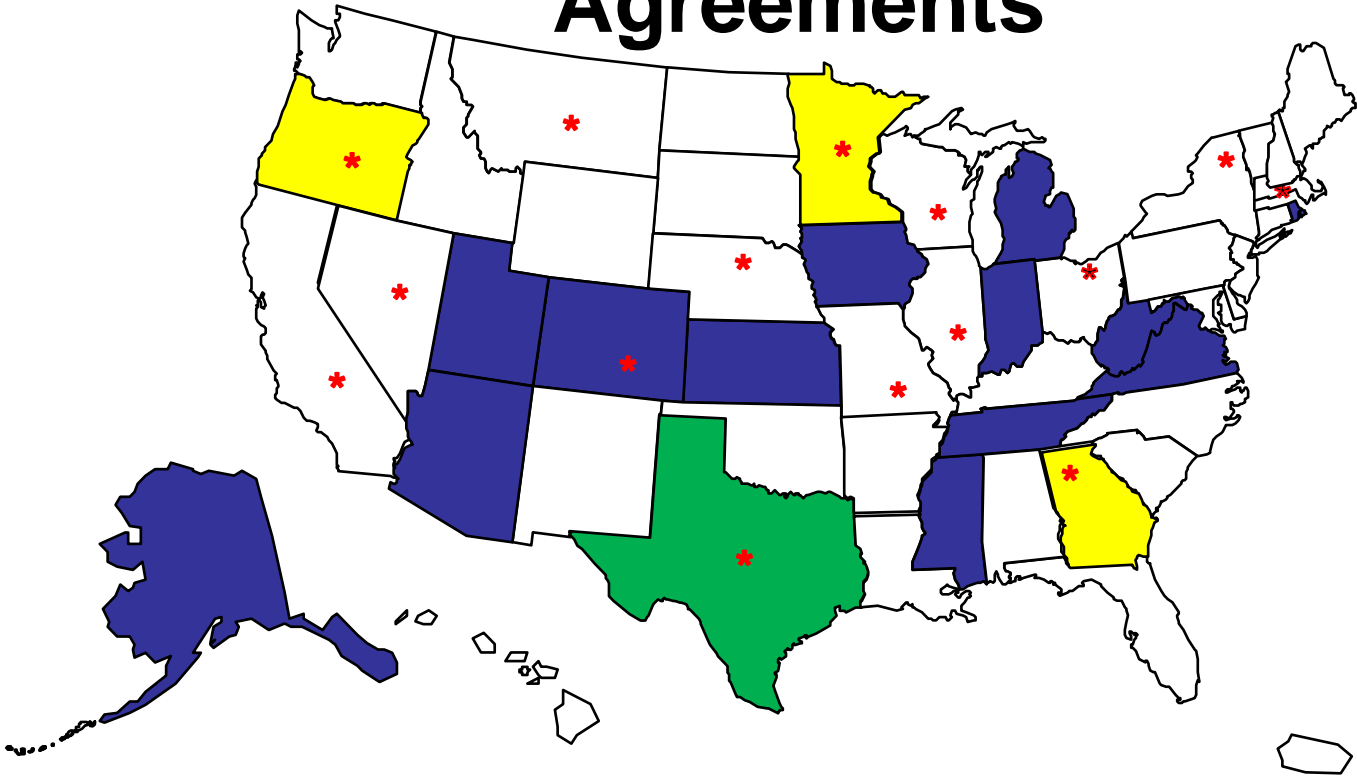
“Retail Program Standards” Cooperative Agreements

- Established in 2012
- Direct funding to state, local, territorial, and tribal retail food regulatory programs
- Up to \$70,000 per year
 - Most are multiyear (up to 5 years)
- Program Goals

“Retail Program Standards” Cooperative Agreements – Funding

2012	2013 & 2014	2015
<ul style="list-style-type: none">• \$2.6M• 38 awards<ul style="list-style-type: none">– 34 five-year awards– 1 three-year award– 3 one-year awards	<ul style="list-style-type: none">• \$2.4M• 35 jurisdictions continue with their projects• 3 jurisdictions who requested one-year awards completed their projects	<ul style="list-style-type: none">• \$3.9M• 35 jurisdictions continue with their projects• RFA will issue soon to expand this program by an additional ~22 awardees

Agreements



Yellow: State Department, Department of Agriculture, Health and Human Services that have **1-yr award**.

Green: State Department, Department of Agriculture, Health and Human Services that have **3-yr awards**.

Blue: State Department, Department of Agriculture, Health and Human Services that have **5-yr awards**.

Red Star: Local (County and City) Health Department

“Retail Program Standards” Cooperative Agreements Outcomes

- Formal employee training programs
- Learning management systems to track training and standardizations
- Standardized inspection programs based on HACCP principles
- Electronic inspection reporting systems
- Electronic complaint and foodborne illness tracking systems
- Compliance and enforcement programs
- Risk factor studies
- Outreach and training activities to assist industry with achieving active managerial control

Cooperative Agreement with AFDO

- Established in 2013
- Managed by AFDO
 - FDA/AFDO Joint Advisory Group (JAG) provides oversight
- Simple application and reporting process
- Apply online at AFDO's Retail Program Standards Website at:
<http://afdo.org/retailstandards>

Cooperative Agreement with AFDO

- Category 1 – Small Projects
 - Up to \$3,000
- Category 2 – Moderate Projects
 - \$10,000-\$20,000
- Category 3 – Training
 - Up to \$2,000

Cooperative Agreement with AFDO – Program Requirements

Jurisdictions:

- Can apply for up to one grant in each category; total of 3 per calendar year
- Should coordinate internally to ensure the maximum number of applications is not exceeded
- Submit all required information on applications via online portal - www.afdo.org/retailstandards

AFDO Applications & Awards Analysis

Number of Applications (Years 1 and 2)	#	% of Total	Amount Requested	% of Total
Category 1 (Small Projects)	288	45.6%	\$757,214	23.8%
Category 2 (Moderate Projects)	111	17.6%	\$1,996,681	62.7%
Category 3 (Training)	233	36.9%	\$432,294	13.6%
Total Number of Applications	632	100.0%	\$3,186,189	100.0%

Number of Awards (Years 1 and 2)	#	% of Total	Amount Awarded	% of Total
Category 1	175	52.4%	\$457,740	47.1%
Category 2	15	4.5%	\$249,353	25.6%
Category 3	144	43.1%	\$265,363	27.3%
Total Number of Awards	334	100.0%	\$972,455.67	100.0%

Manufactured Food Regulatory Program Standards (MFRPS)

Manufactured Food Regulatory Program Standards

September 2013



The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and has been assigned OMB control number 0910-0601.

To request a copy of the standards go to:

http://www.fda.gov/ora/fed_state/default.htm

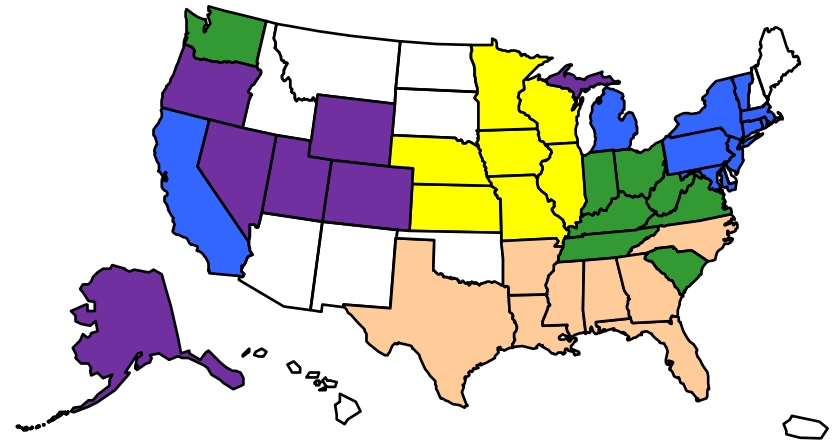
U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

OMB Control No. 0910-0601
Expiration Date: 09-30-2016

- Uniform foundation for the design and management of state programs responsible for regulating food manufacturers
- Institute a comprehensive quality assurance & standardization program

Building a Stronger MFRPS Community

- 40 programs in 39 States
 - Increased from 28 programs in 2010 to 40 programs in 2013
 - FoodSHIELD: Workgroup & Quarterly Webinar
 - MFRP Alliance
 - 4th Annual MFRPS Training March 9-12, 2015
 - Strengthen: Community, Collaboration, Resources, and Program Advancement
- 
- A map of the United States with states colored to represent program distribution. Green: Washington. Purple: Oregon, California, Nevada, Idaho, Utah, Arizona, New Mexico, Texas, Alaska. Blue: California. Yellow: Wyoming, Colorado, Kansas, Oklahoma, Missouri, Arkansas, Louisiana, Mississippi, Alabama, Georgia, Florida, South Carolina, North Carolina, Virginia, West Virginia, Maryland, Delaware, Pennsylvania, New Jersey, New York, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire, Maine, New Brunswick, Nova Scotia, Prince Edward Island, New Brunswick, Nova Scotia, Prince Edward Island, New Brunswick, Nova Scotia, Prince Edward Island. White: Montana, North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, Texas, Louisiana, Mississippi, Alabama, Georgia, Florida, South Carolina, North Carolina, Virginia, West Virginia, Maryland, Delaware, Pennsylvania, New Jersey, New York, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire, Maine, New Brunswick, Nova Scotia, Prince Edward Island, New Brunswick, Nova Scotia, Prince Edward Island, New Brunswick, Nova Scotia, Prince Edward Island.

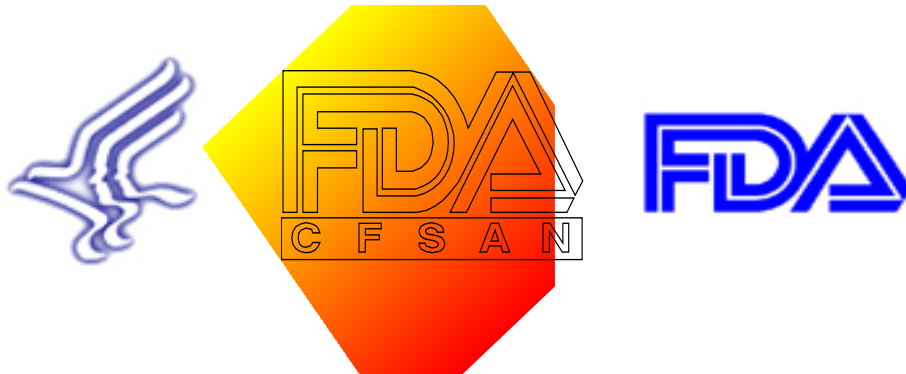


Animal Feed Regulatory Program Standards



- National Standards for feed inspection programs
- Joint project of the FDA and Association of American Feed Control Officials (AAFCO)
- Committee established in 2011 to develop Standards
- Draft document completed in 2012
- Final document released in 2014
- 13 State Programs Enrolled (obligated)

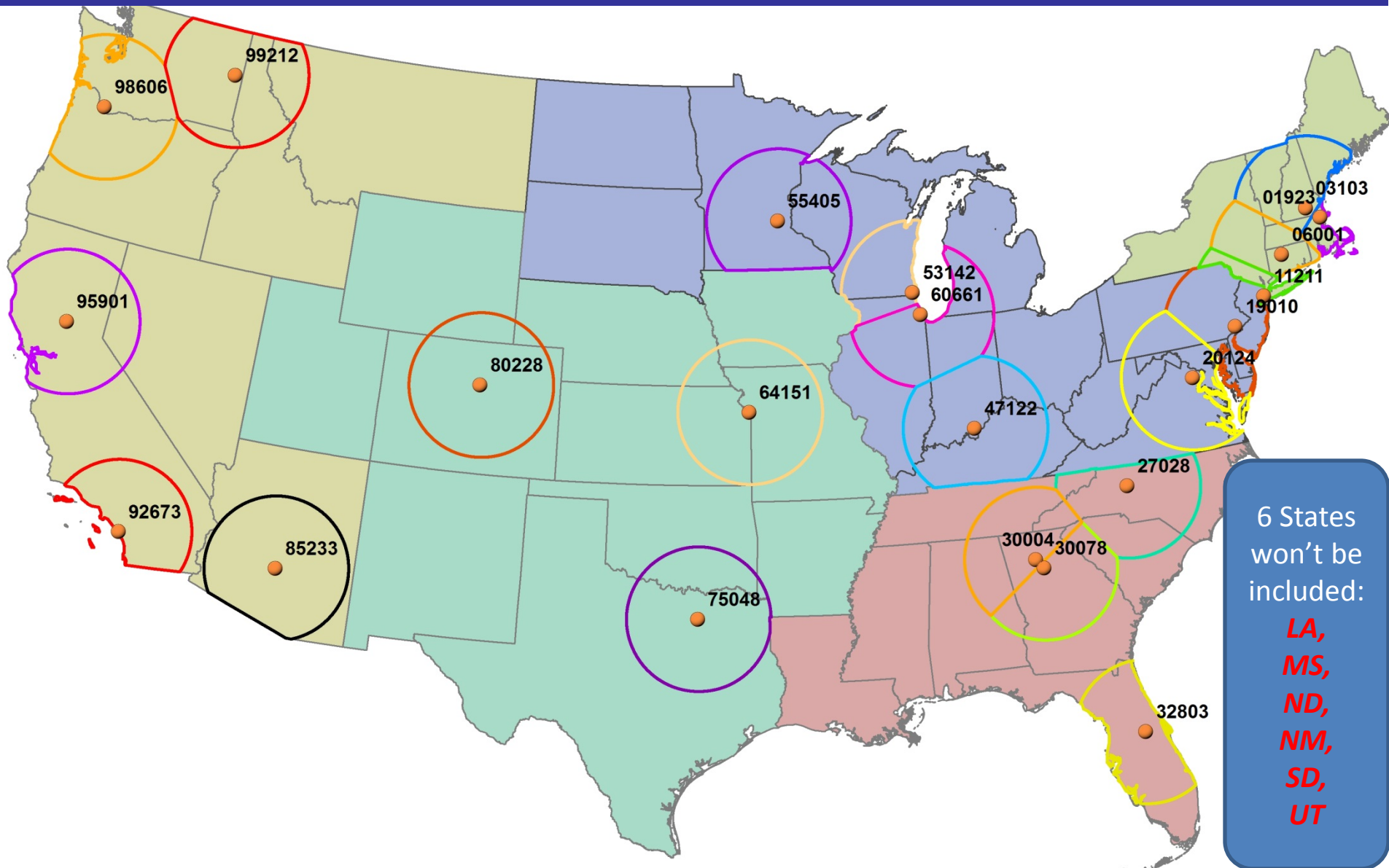
FDA Foodborne Illness Risk Factor Study Update



FDA Foodborne Illness Risk Factor Study

- **October 2014** - Completed the data collection in fast food and full service restaurants (835 total)
- **Currently** analyzing data from the restaurant data collection
- **October 2015** - release of a Restaurant Risk Factor Study Report
- **October 2015** – Begin 15-month data collection (thru Dec. 2016) in Health Care (Hospitals; Long-Term Care); Schools (K-12); and Retail Food Stores (Focus on Deli Areas, plus produce and seafood)

150 mile around 22 specialists home zip center (restricted by FDA region definitions)



Data Analysis

- Focus of 10 Primary Data Items
 - Handwashing, NBHC
 - Cross-Contamination, Cleaning and Sanitizing
 - Cold and Hot Holding, Date Marking, Cooling
 - Cooking, Reheating for Hot Holding
- Correlations between Risk Factor Control and:
 - Nature of the Operation, Chain/Independent
 - FS Management Systems – Procedures, Training & Monitoring
 - Manager Certification

Healthy People 2020 Objectives

Fast-Food (Obj. No.)	Full Service (Obj. No.)	Increase the proportion of restaurants where:
FS-6.1	FS-6.6	Employees practice proper handwashing
FS-6.2	FS-6.7	No contact of bare hands with ready-to-eat (RTE) foods
FS-6.3	FS-6.8	Food contact surfaces are cleaned and sanitized
FS-6.4	FS-6.9	Foods requiring refrigeration are held at the proper temperature
FS-6.5	FS-6.10	Foods displayed or stored hot are held at the proper temperature

FDA Foodborne Illness Risk Factor Study

- FDA working with the *National Center for Food Protection and Defense* on . . .
 - Web-based platform on FoodSHIELD for a risk factor study database that can be used and accessed by State/local/tribal organizations to store and maintained data from their own studies.
 - Summer 2015 - Target date for having the database system operational and available for use

FDA-NACCHO Cooperative Agreement

FDA/CFSAN/OFS/Retail Food Policy Team

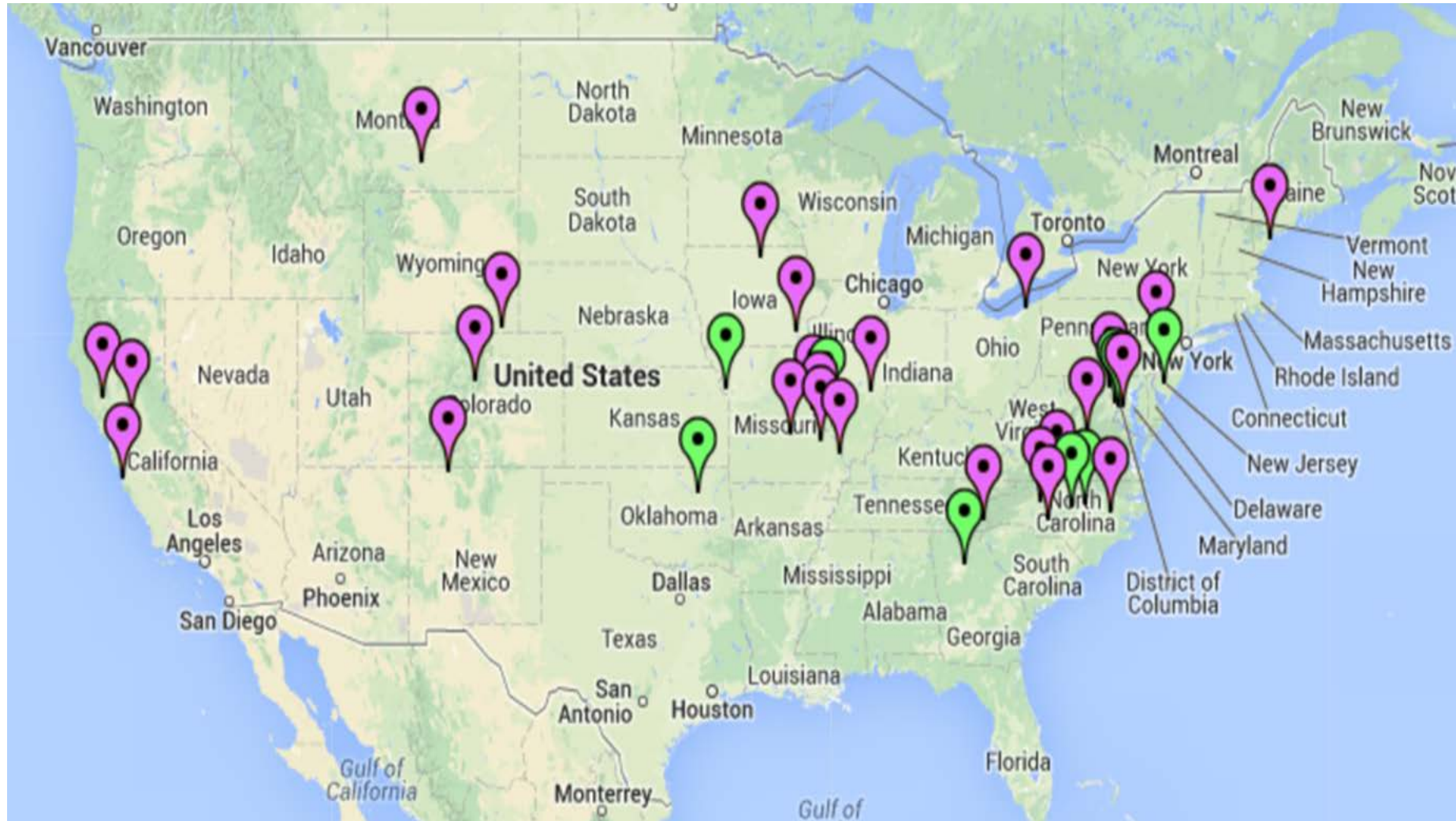
Four Specific Aims

- **Aim 1** - Increase local health departments awareness of food safety regulation tools, resources & practices
- **Aim 2** - Strengthen local health department involvement in food safety regulation (establish a peer mentorship program)
- **Aim 3** - Improve FDA, NACCHO and local health departments knowledge of the connection between the FDA Voluntary Retail Food Regulatory Program Standards and public health accreditation as guided by the Public Health Accreditation Board (PHAB)
- **Aim 4** - Improve NACCHO's and FDA's understanding of the effectiveness of food inspection grading and scoring systems

Local Health Dept. Mentorship Program

- Mentor-Mentee Program (Highlights)
 - Cohort 1 (2012): 3 Mentors and 6 Mentees
 - Cohort 2 (2013): 5 Mentors and 10 Mentees
 - Cohort 3 (2014): 5 Mentors and 13 Mentees
- Mentor-Mentee Program
 - Cohort 4 (2015): 7 Mentors and 18 Mentees

NACCHO Mentorship Program



Aim #2

Food Establishment Inspection Scoring and Grading Systems

- Survey of LHDs to better understand prevalence of food establishment inspection scoring and grading systems nationally
 - Perceived impact of scoring and grading on food safety practices
 - Methods that jurisdictions use to communicate inspection results to the public

Report available at bookstore on www.NACCHO.org

Food Establishment Inspection Scoring and Grading Systems

- Completing initial case studies on LHD experience with scoring and grading systems - Kern County, CA and Southern NV Health District – reports will issue in coming weeks
- 6 additional jurisdictions being considered for the case studies
- Interviews with the regulatory authority, political body, and the restaurant industry

Other Activities with NACCHO Cooperative Agreement

- Crosswalk between requirements for Public Health Agency Accreditation and FDA Retail Program Standards
- Sharing Sessions(Webinars) on Program Standards
- 9-State Roundtable Meeting on the use of Program Standards in supporting State-Local Delegation Agreements (June 2015)

Menu Labeling Final Rule

Covered Establishments

- Establishments are covered that are:
 - **Restaurants or similar retail food establishments**
 - Retail establishment that offers for sale “restaurant type food”
 - **Part of a chain with 20 or more locations**
 - Fixed locations
 - **Doing business under the same name**
 - Name presented to the public or the name of the parent entity if no name is presented to the public, (e.g., concession stand); this includes slight variations of the name, for example, due to location, region, or size.
 - **Offering for sale substantially the same menu items**
 - A significant proportion of menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components even if the name of item varies (e.g. “Bay View Crab Cake” and “Ocean View Crab Cake”)

Examples of Facilities That Are Covered

- Restaurants - quick service and sit-down
- Grocery and convenience stores
- Food take-out facilities and pizza delivery services
- Entertainment venues (e.g. movie theaters, amusement parks)
- Cafeterias
- Coffee shops
- Superstores
- Some managed food service operations

Foods That Are Covered

- **Standard menu items**
 - Restaurant type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display
- **Combination meals**
 - Standard menu item that consists of more than one food item; may be represented on the menu or menu board in narrative form, numerically, or pictorially
 - May include a variable menu item or be a variable menu item
- **Variable menu items**
 - Standard menu item that comes in different flavors, varieties, or combinations and is listed as a single menu item

Displaying Calories on Menus and Menu Boards

- Calories for each standard menu item listed on a menu/menu board must be displayed adjacent to the name or price of the menu item in a type size no smaller than that of the name or price of the menu item whichever is smaller, with certain color and contrast requirements
- For menu items that come in different flavors or varieties that are listed as a single item, calorie declarations where there are only two options available must be presented with a slash between the two calorie declarations (e.g., "150/250 calories") or as a range (e.g., "150-300 calories") if there are three or more options

Succinct Statement

To enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards

“2,000 calories a day is used for general nutrition advice, but calorie needs vary”

- Must appear on the bottom of each page of a multi-page menu and the bottom of a menu board, above, below or beside the Statement of Availability.
- Optional statements are permitted on children’s menus and menu boards

Written Nutrition Information

- The statement “Additional nutrition information available upon request” is required on menus and menu boards
- For menus it is required on the first page of the menu with menu items listed either above, below or beside the Succinct Statement
- For menu boards it must appear on the bottom of the menu board either above, below, or beside the Succinct Statement
- Written nutrition information must include the macronutrients that are currently required in the Nutrition Facts label on packaged foods

Written Nutrition Information

Written Nutrition Information can be in the form of:

- Posters
- Tray liners
- Counter cards
- Signs
- Handouts
- Booklets,
- Computer/kiosk

Preemption

- State or locality may establish nutrition labeling requirements identical to Federal requirements. State or local jurisdiction would then enforce its own requirements
- Establishments not covered (e.g. chains with less than 20 establishments) may be subject to regulation by states unless they voluntarily register to be covered with FDA
- States/localities can petition the agency to be exempt from the requirements. FDA has already received a petition from the City of Philadelphia to be exempt from preemption

Effective Date

- One year effective date
 - December 2015
- Balances the industry's need for additional time with the public health need for this information

Next Steps

- Development of guidance for the industry
- Completion of enforcement strategy
- Stakeholder outreach

Contact Information

felicia.billingslea@fda.hhs.gov

Mailboxes to submit questions on menu labeling and vending machine labeling –

CalorieLabeling@fda.hhs.gov

FDA Food Safety Modernization Act (FSMA)

FSMA Overview

- **Phase 1: Set standards**
 - Develop regulations, guidance, protocols for new administrative enforcement tools
- **Phase 2: Implement standards**
 - Design strategies to implement standards
 - Fully develop and implement the standards
- **Phase 3: Monitor, evaluate, refresh**
- **Engagement along the way**

FSMA Operational Strategy

- **Provides a foundation for fully developing and implementing FSMA standards**
 - **Regulations, guidance, protocols**
- **Captures in broad, high-level terms our current thinking on strategy and guiding principles for the implementation of FSMA standards.**
- **View at fda.gov/fsma**

Phase 1: Standard Setting

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	Jan 16, 2013	Aug 30, 2015
Preventive Controls (Animal Food)*	Oct 29, 2013	Aug 30, 2015
Produce Safety*	Jan 16, 2013	Oct 31, 2015
Foreign Supplier Verification Program*	Jul 29, 2013	Oct 31, 2015
Third Party Accreditation	Jul 29, 2013	Oct 31, 2015
Sanitary Transport	Feb 5, 2014	Mar 31, 2016
Intentional Adulteration	Dec 24, 2013	May 31, 2016

**Supplemental proposals published September 2014*

Compliance Dates by Business Size





Rule	2014 Dec 15	2015		2016	2017	2018	2019	2020	2021
		Aug 30	Oct 31						
Produce Safety	Suppl. Prop.	Final		Large	Large	Water	Water		
				Small	Small	Small	Water	Water	
				Small	Small	Small	Small	Water	Water
Preventive Controls Human	Suppl. Prop.	Final	Large						
					Small				
					Small	Small			
Preventive Controls Animal	Suppl. Prop.	Final	Large						
					Small	Small			
					Small	Small			
FSVP*	Suppl. Prop.	Final		Large					
						Small			
						Small	Small		

 Suppl. Prop.
  Final
  Large
  Small
  V. Small
  Water

*importer compliance date is the later of: 1) 18 months after publication of the final rule or 2) 6 months after the foreign supplier must comply with PC or Produce Safety final rules, if applicable

Compliance Dates by Business Size

Rule	2015	2016		2017	2018	2019
	Oct 31	Mar 31	May 31			
Intentional Adulteration						
Sanitary Transport						
3 rd Party Cert.						

 Final
  Large
  Small
  V. Small

Questions



FDA/CFSAN/Office of Food Safety

Retail Food Protection Staff

Email: kevin.smith@fda.hhs.gov

Website: <http://www.fda.gov/RetailFoodProtection>

submitted by Kevin Smith at previous EB meeting and assigned to the Issue Committee
EB asked to provide any suggested edits or comments.... IC will report back in August with final draft

For consideration by the Conference for Food Protection Executive Board - August 27, 2014

1. Board should consider establishing a standard set of "Reason" Statements to be provided when a Recommendation of "No Action" is put forward by a CFP Council. Such standard statements should be general in nature to recognize that the Council is made up of numerous individuals who reasons for not voting to accept the issue "as submitted" or "as amended" may be diverse and varied.
2. The following should be considered as general statements that capture why the recommended solution submitted with the issue was not accepted by the Council:
 - a. **The Council did not attain majority support for a Recommended Solution that it deems appropriate for consideration by the Assembly of Delegates** should this also include a "why"?
 - b. **The Council believes the issue and/or the associated recommended solution is better addressed in an alternate issue that has been submitted to the Conference**
 - c. **The Council believes the issue is outside the purview of the Conference**
3. Under this format, it is likely that the Reason outlined in item a will be the most common reason provided. If the Board believes there may be situations in which the Assembly may benefit from more detail, a supplemental statement could be added when applicable, as follows:

Optional supplement to selection a.:

Council believes the issue and/or recommended solution warrants additional research or consideration and anticipates that related issues will be considered at a future CFP Meeting

Respectfully submitted to the Board by Kevin Smith

suggestions / comments from EB:

- Council III - science may be the basis for decision (e.g., science does not support the recommendation)
- Should final recommendations be revisited on final day if too many "no actions" are taken?
- When "code" already addresses the question... MUST include the specific code section
- include an "other" option
- are these to be a "requirement"? do we need to submit an Issue requiring this... or will this be an EB decision to implement the statements as a guidance document?