

FDA Report to the Executive Board of the Conference for Food Protection

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Personnel News

After 8 years as the Director of CFSAN's Retail Food and Cooperative Programs Coordination Staff, Kevin Smith recently assumed a new position in CFSAN's Office of Food Safety where he will serve as a Senior Advisor for Food Safety. Kevin will advise senior leadership on food safety policy and provide technical support to FDA, other government agencies, and industry personnel on a range of food safety issues. In addition to other projects, he looks forward to providing advice and support to FDA's retail food protection efforts, which has been the primary focus of his 14 years at FDA. Kevin's email and phone number remains unchanged.

Effective July 25, 2015, Ms. Glenda Lewis was selected from among many qualified candidates to assume the position of Director of the Retail Food Protection Staff. Glenda has been working in the Retail Program at CFSAN for almost 20 years, including the past 14 as a Team Leader. In addition to assuming the leadership role in the CFSAN retail food safety efforts, Glenda will also be responsible for oversight of CFSAN's role in the Interstate Travel Program, which regulates food safety and environmental support services for foodservice operations on interstate passenger conveyances including planes, trains and ships. Glenda's promotion creates a vacancy in the Team Leader position. Mr. Girvin Liggans has been named Acting Team Leader of the Retail Food Policy Team in CFSAN until that position is filled through a detail announcement preceding a vacancy announcement to fill the position permanently.

Other important personnel updates impacting the Retail Food Program include the recent and planned retirements of two Retail Specialists in the Office of Regulatory Affairs. After 41 years at FDA, Ray Duffill a Retail Food Specialist in the Northeast Region retired on Aug 3, 2015. In October 2015, Larry Edwards a Retail Food Specialist in the Central Region will retire after a long and distinguished career at FDA and the US Public Health Service, a great deal of which focused on Retail Food Safety. Both of these gentlemen will be missed. As reported in April, the State Cooperative Program Director for Retail and Milk in the Central Region, Virginia Connelly retired. There is currently a job announcement open, but at this time it is restricted to current employees of ORA. There are no specific updates from what was reported in April to the Board regarding the broader ORA realignment that will impact the reporting structure for ORA personnel in the Cooperative Programs. In addition, at this time Ms. Barbara Cassens continues to serve as the Acting Director for ORA's Office of Partnerships. There have also been a series of details for individuals serving Deputy Director in Office of Partnerships. Ms. Laurie Farmer, Director of State Cooperative Programs in the Southeast Region is currently serving in that detail. Others who recently served in that detail include Mr. Alan Tart and CAPT Wendy Fanaselle.

Supplement to the 2013 Food Code

On July 2, 2014 FDA issued a Constituent Update announcing the publication of Supplement to the 2013 Food Code. That Update can be viewed at:

<http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm453530.htm>

An overview of the changes made in the Supplement was provided to the CFP Executive Board at the April 2015 Meeting. In brief, the Supplement modifies the 2013 Food Code to:

- Expand the duties of the Person in Charge in a food establishment to include overseeing the routine monitoring of food temperatures during hot and cold holding.
- Expand and clarify the type of information that should be included when a Hazard Analysis and Critical Control Point Plan is required by a regulatory authority.
- Emphasize that cleaning and sanitizing agents should be provided and available for use during all hours of operation.
- Clarify the difference between Typhoid Fever and nontyphoidal *Salmonellosis* with regard to the reporting of illness and the exclusion and restriction of ill food employees.
- Suggest that regulatory authorities ensure that inspection staff has access to the necessary training and continuing education.

FDA continues to examine other recommendations for FDA made at the 2014 Biennial Meeting of the Conference for Food Protection. Postings related some of those items that did not require a change to the Food Code, should appear on FDA's Food Code Reference System in the coming weeks. Discussions are ongoing regarding other recommendations, including the recommendation from Council III regarding the criteria used to determine if certain cheeses are appropriate for storage and display outside of temperature control. FDA understands that the originators may submit an issue for the 2016 CFP that significantly modifies the recommended solution made in the 2014 Issue.

FDA will provide a status report on all 2014 CFP recommendations made to FDA in a letter that can be shared with the CFP membership no later than October 2015.

Email Alerts for Retail Food Protection Information

FDA has established a free email alert service allows subscribers to receive updated Retail Food Protection information as it becomes available. Among other things, this will include word of new guidance documents, new postings to the Food Code Reference System, and quarterly updates to the Listing of Jurisdictions Enrolled in Voluntary National Retail Food Regulatory Program Standards. To subscribe, valid email address is required. Email will be used to deliver the type of information requested according to the subscriber preferences. CFP members are encouraged to subscribe by visiting the following website:

https://public.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_426 Please sign up and share this link with your stakeholders!

Retail Program Standards

In the coming days, FDA will issue a Constituent Update announcing the availability of the 2015 edition of the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). The Retail Program Standards serve as a guide for promoting continuous improvement among retail food regulatory programs administered by state, local, tribal, and territorial agencies. FDA works closely with stakeholders through the Conference for Food Protection to periodically review and update the Retail Program Standards.

The 2015 edition of the Retail Program Standards incorporates the following changes:

- An updated [*Standard 1: Self-Assessment Worksheet for Part I*](#). This worksheet provides a step-by-step process that regulatory programs can use to see how their regulatory foundation differs from the 2013 FDA Food Code.
- An updated [*Standard 1: Self-Assessment Worksheet for Part II*](#). This worksheet provides a step-by-step process that regulatory programs can use to see how their regulatory foundation differs from the 2013 FDA Food Code;
- An updated [*Standard 6: Self-Assessment Instructions and Worksheet*](#). This document provides a step-by-step process that regulatory programs can use to evaluate the consistency and effectiveness of their compliance and enforcement activities.
- The addition of a [*Standard 6: Verification Audit Instructions and Worksheet*](#). This document provides a step-by-step process that an independent auditor can use to review the findings from a jurisdiction's self-assessment of their compliance and enforcement activities.

FDA has made significant enhancements to the Program Standards Website on the fda.gov. The Standards themselves, supporting information and tools, and the listing of enrolled jurisdiction can all be accessed at a new shortcut: www.fda.gov/retailprogramstandards. The website includes a breakdown of the numbers of enrollees from each of

Number of Enrolled Jurisdictions

- As of 7/1/2015, there are 658 jurisdictions enrolled in the Retail Program Standards. This includes 61 State-level agencies (from all but 1 State) and 4 territories. The other 600+ enrollees come from local health departments (county, city, township, and district), tribal organizations, universities and federal agencies. Enrollment has increased by over 100 jurisdictions over the past three years.
- Over 62% of the U.S. population lives in a locality where the agency primarily responsible for retail food protection is enrolled in the retail program Standards.

Enrolled Jurisdictions with a Current Self-Assessment

- As of 9/30/2012, 40% of enrolled jurisdictions had a current self-assessment (219 / 547 enrolled jurisdictions). As of 7/1/2015, 55% of enrolled jurisdictions had a current self-assessment (357 / 658 enrolled jurisdictions). This represents a 63% increase in the total number of jurisdictions with a current self-assessment since 2012.

Enrolled Jurisdictions with a Current Self-Assessment that Meet 3 or More Standards

- As of 7/1/2015, 17% of enrolled jurisdictions had a current self-assessment and met 3 or more Standards (112 / 658 enrolled jurisdictions). As of 9/30/2012, 13% of enrolled jurisdictions had a current self-assessment and met 3 or more Standards (92 / 563 enrolled jurisdictions). This constitutes a 22% increase in the total number of jurisdictions that had a current self-assessment AND met three or more Standards.

Enrolled Jurisdictions with a Current Self-Assessment that Meet 5 or More Standards

- As of 7/1/2015, 6% of enrolled jurisdictions had a current self-assessment and met 3 or more Standards (38 / 658 enrolled jurisdictions). As of 9/30/2012, only 3% of enrolled jurisdictions had a current self-assessment and met 5 or more Standards (18 / 547 enrolled jurisdictions).

Opportunities to Improve Program Standards Implementation

Retail Program Standards Mentorship Program

A Program Standards Mentorship Program administered by National Association of County and City Health Officials (NACCHO) under a cooperative agreement with FDA continues to be well received by the participating local health departments (LHD). The 4th Cohort is just wrapping up its work. As reported previously, Cohort 4 had 25 total participating LHDs (7 mentors and 18 mentees). All participants came together at a face to face meeting to share information about progress each LHD made through the mentorship program. The response from all participants has been overwhelmingly positive. More information about the mentorship program is available at <http://www.naccho.org/topics/environmental/foodsafety/retail/>

A 5th Cohort of mentors and mentees will be selected to participate in FY16. The application process will begin in October 2015, with selections made no later than December 2015. Funding will be available. Past participants awards have typically been about \$10,000. All LHDs

State and Local Interaction

On June 4 and 5, 2015 NACCHO and FDA also hosted a meeting with Retail Food Safety Program leaders from Departments of Health or Agriculture in 9 States on how the Retail Program Standards are used with regard to delegation agreements that the State agencies have with LHDs in their states. Robust discussion and valuable sharing centered on the following questions:

The purpose of the meeting was to learn:

- To date, what role have the Program Standards played in relationship between State-level agencies and the local agencies that have been delegated authority for the licensing and inspection of retail/foodservice establishments?
- How can FDA and other organizations best assist State agencies interested in using the Retail Program Standards as a tool for interacting with and fostering continuous improvement among local agencies?

- How can FDA facilitate more capacity building and widespread implementation of the Retail Program Standards amongst local retail food regulatory programs that are delegated authority by State agencies?

FDA staff representing the various components of the NRFT also participated as did NACCHO personnel who are active in the FDA-NACCHO Cooperative agreement. State Participants: Lisa Staley (Maryland), Michael Moore (Massachusetts), Steven Diaz (Minnesota), Patrick Guzzle (Idaho), Becky Krzyzanowski (Michigan), Tracey Weeks (Connecticut), Therese Pilonetti (Colorado), Blanca Caballero (Arizona), Melissa Ham (North Carolina).

FDA is considering ways to best position the Retail Program Standards to enhance the manner in which State and locals engage one another and promote mutual progress toward achieving the objectives of the Program Standards. The Conference for Food Protection may be able to play an important role in exploring the opportunities.

Retail Program Standards Cooperative Agreements

In June 2015, FDA announced the availability of cooperative agreements to be awarded under limited competition to state, local, tribal and territorial retail food regulatory programs. The intended outcome of these cooperative agreements is to advance efforts for a nationally integrated food safety system through the conformance with and advancement of the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). The Retail Program Standards apply to operation and management of a retail food regulatory program that is focused on the reduction of risk factors known to contribute to foodborne illness and the promotion of industry action to achieve active managerial control of these risk factors. FDA/ORA intends to fund up to \$1,495,000 for fiscal year 2015 in support of this grant program. It is estimated that up to 22 awards may be made, not to exceed \$70,000 in total costs (direct plus indirect), per award. FDA will be awarding Cooperative Agreements directly to State, local and territorial retail programs in amounts up to \$70,000 year for up to 5 years. The application period closed on July 15, 2015.

Retail Program Standards Grants

After 2 successful years, Year 3 of the FDA-funded, AFDO-administered Retail Program Standards Grants is almost upon us. Applications can be submitted starting on **Tuesday, September 1, 2015 and applications are accepted through Friday, October 9**, the program provides funds for the completion of projects and training to enhance conformance with the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). Grant funding is open to state, local, territorial, and tribal regulatory retail food programs that have enrolled in the Retail Program Standards. Applicants to this program can expect a simple application process, up-front funding when required by the project, and simple reporting requirements. Because of the success of this program in Years 1 & 2 and the progress jurisdictions made in increasing their conformance with the standards, total funding for this program is expected to increase significantly for Year 3, from approximately \$500K per year in Years 1 & 2, to \$1.5 million or more in Year 3. Consequently, we expect the number of awards to increase. Awards are available for:

- **Small Projects** up to \$3,000, for jurisdictions to complete a self-assessment of all nine Standards, small projects related to meeting one or more Standards, or a verification audit;

- **Moderate Projects**, \$10,000-\$20,000, for more ambitious projects that further conformance with the Retail Program Standards (computer software systems, risk factor studies, development of a written compliance program, training events, etc.); and
- **Training** up to \$3,000, for jurisdiction staff to meet the requirements of Standard 2 (Step 1 & 3 Curriculum or CEU maintenance) or to attend FDA Regional Seminars to maintain FDA Standardization.

For more information visit Retail Food Safety Grants Website at <http://afdo.org/retailstandards>.

FDA Retail Risk Factor Study

In October 2014, FDA completed its data collection in fast food and full service restaurants (835 total). We are in the process of analyzing data from the restaurant data collection and will release a Restaurant Risk Factor Study Report by the end 2015. In addition to the full report, FDA will also issue informative fact sheets and user friendly materials that will help the public understand the findings without reading a very lengthy report. We also intend to explore publishing articles in peer review journals that focus on certain elements of the study. FDA would welcome opportunity to share key findings and results of the Restaurant Risk Factor Study at the Sunday AM session of the 2016 CFP Biennial meeting.

In October 2015, FDA will begin 15-month data collection (thru Dec. 2016) in randomly selected Health Care (roughly 400 Hospitals and Long-Term Care facilities); Schools (roughly 400 schools K-12); and Retail Food Stores (roughly 400 retail stores that have a Deli, plus produce and seafood). The data collection form will be almost identical to the Restaurant Data Collection Form. As with the restaurant study, FDA Retail Specialists will be the data collectors and will reach out to the state or local regulatory authority having jurisdiction to gather information about their program and to facilitate access to the establishments. Also, as with the Restaurant Study, our data collection will go beyond simply observing compliance with the Food Code and will also do a limited assessment of the food safety management systems that may be present and will collect more information about the operation itself, such as whether the facility is part of multi-unit chain, the level activity at the time of the visit and policies and practices regarding certified food protection managers. The reports for these three sectors would be targeted for early 2017 (roughly 1 year after completion of the data collection).

Regional Food Protection Seminars

CFP members and all interested in Food Safety are encouraged to attend the annual Food Protection Seminars held in each of the five FDA regions. Much of the agendas for these seminars address topics that are important to the mission and activities of the Conference for Food Protection

Northeast Region Seminar

Dates: August 19-21, 2015

Location: Troy, NY

Primary FDA Regional Contact: Mary Leong, (718) 662-5536, Mary.Leong@fda.hhs.gov

Central Region Seminar

Dates: August 11-14, 2015

Location: Richmond, VA

Primary FDA Regional Contact: Larry Edwards, (703) 538-2176 ext. 110,

Lawrence.Edwards@fda.hhs.gov

Southeast Region Seminar

Dates: December, 2015

Location: Baton Rouge, Louisiana

Primary FDA Regional Contact: Chris Smith, (404) 253-1264, Chris.Smith@fda.hhs.gov

Southwest Region Seminar

Dates: September 15-18, 2015

Location: Breckenridge, CO

Primary FDA Regional Contact: Mario Seminara, (303)236-3026, Mario.Seminara@fda.hhs.gov

Pacific Region Seminar

Dates: September 22-24, 2015

Location: Helena, MT

Primary FDA Regional Contact: Brad Tufto, (509) 353-2554, Brad.Tufto@fda.hhs.gov

Menu Labeling

On July 10, FDA announced in the Federal Register an Extension of the Compliance Date for **Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments**. In response to requests for an extension and for further clarification of the rule's requirements, FDA established a new compliance date is December 1, 2016. On July 9, FDA published a Constituent Update that included a statement from Michael Taylor that explains the reasons for the extension in more detail and indicates that FDA plans to issue a draft guidance document that provides answers to some of the more frequently asked and crosscutting questions that the agency has received to further assist covered establishments in complying with the rule. The CU is available at:

<http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm453529.htm>

Preparing for FSMA Implementation

CFSAN's Office of Food Safety has been restructured to accommodate significant growth associated with the implementation of FSMA regulations, especially the Preventative Controls (Human Food) and Produce Safety that will publish in final form later this year.

The deadlines for the publishing the seven FSAM Rules and the Compliance Dates by business size were included in the April 2015 FDA Report to the CFP Executive Board. As a reminder, FDA must submit final rules to the Federal Register by the following dates:

- Preventive Controls for Human Food: August 30, 2015;
- Preventive Controls for Animal Food: August 30, 2015
- Produce Safety: October 31, 2015;
- Foreign Supplier Verification Programs: October 31, 2015;
- Accreditation of Third Party Auditors: October 31, 2015
- Sanitary Transport of Food and Feed: March 31, 2016; and
- Intentional Adulteration: May 31, 2016

Board members and interested CFP members are encouraged to learn more about three Alliances that have been formed to assist regulated firms in preventing foodborne illness and improve understanding and comply with regulations including those established under FSMA. Similar alliances have been established in the past to assist in implementation of the rules Seafood HACCP and Juice HACCP.

Food Safety Preventive Controls Alliance

The U.S. Food and Drug Administration in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH), a nationally-recognized leader in food safety, created the [Food Safety Preventive Controls Alliance \(FSPCA\)](#) to develop training courses and technical information on preventing contamination for both human and animal food during production. The technical information being developed by the Alliance will help industry—particularly small- and medium-size companies—comply with the new preventive controls rules for human and animal food mandated by the FDA Food Safety Modernization Act (FSMA).

The FDA-funded Alliance, initiated in September 2011, is composed of members from the FDA, state regulatory agencies, the food industry, and academia.

Among other things the Alliance is developing a standardized hazard analysis and preventive controls training course and distance education modules for food industry and regulatory personnel and will establish a technical assistance network who will provide technical assistance to the food industry, especially for small- and medium-sized businesses, to enhance food safety and compliance with the new preventive controls rules for human and animal food.

Produce Safety Alliance

FDA and the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) established the Produce Safety Alliance to provide produce farmers, along with other groups, the information they need to ensure the safety of fresh produce for consumers. The Produce Safety Alliance is providing fundamental, on-farm food safety knowledge and will assist farmers with the information that they will need to comply with FDA's produce safety regulation. It is housed at Cornell University through a USDA Agricultural Marketing Service grant funded cooperatively by both USDA and FDA. Cornell's national Good Agricultural Practices (GAPs) program has been a leader in the development of education outreach materials on GAPs and in dissemination of food safety knowledge to the agricultural community. For more information, visit the [Produce Safety Alliance's page](#) .

Sprout Safety Alliance

FDA has also supported the establishment of a Sprout Safety Alliance in cooperation with the Institute for Food Safety and Health, Illinois Institute of Technology to conduct education and outreach to promote the safe production of fresh sprouts. FDA is launching this specific initiative in light of a number of outbreaks that have been attributed to sprouts, and because specific requirements for sprouts are included in the proposed rule on produce safety. The Alliance will develop and identify new and existing educational materials to help industry, particularly small companies, grow safe sprouts. Also, this effort will help prepare sprout farms to comply with the proposed produce safety rule. [Read more on the Sprout Alliance.](#)

Submitted to the CFP Executive Board by Kevin Smith, August 12, 2015.