

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

**August 22-23, 2017 – Greensboro, North Carolina**

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### **Update on the Status of 2016 CFP Meeting Recommendations**

In correspondence to the Conference for Food Protection dated August 8, 2016, FDA concurred with the recommendations stemming from Issue 2016-I-023. FDA believes it is important to ensure that food establishments know and understand the importance of the shellstock tags and maintenance of them for traceback purposes in an outbreak situation. However, after further discussion, internally and with the Interstate Shellfish Sanitation Conference (ISSC) Executive Director, Ken Moore, FDA does not believe changing the risk designation in paragraph 3-203.12 (A) of the Food Code would solve the many issues involving foodborne illness traceback associated with raw molluscan shellfish. It has become apparent through our discussions that the ISSC requested action that the CFP Accepted as Submitted and recommended to FDA, to change the Food Code in paragraph 3-203.12(A) from a Priority Foundation Item (Pf) to a Priority Item (P), will not achieve the desired public health outcome of improving traceback and is inconsistent with how Priority designations are assigned to provisions in the Food Code. Provisions contained in the Food Code are presented as being in one of three categories: PRIORITY ITEM (i.e. a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard); PRIORITY FOUNDATION ITEM (i.e., a provision in this Code whose application supports, facilitates or enables one or more Priority Items); and, CORE ITEM (i.e., a provision in this Code that is not designated as a Priority Item or a Priority Foundation Item and that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.)

For reference, the Food Code specifies in section 3-203.12:

3-203.12 Shellstock, Maintaining Identification.

(A) Except as specified under Subparagraph (C) (2) of this section, SHELLSTOCK tags or labels shall remain attached to the container in which the SHELLSTOCK are received until the container is empty.<sup>Pf</sup>

(B) The date when the last SHELLSTOCK from the container is sold or served shall be recorded on the tag or label.<sup>Pf</sup>

(C) The identity of the source of SHELLSTOCK that are sold or served shall be maintained by retaining SHELLSTOCK tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under ¶ B of this section, by:<sup>Pf</sup>

1) Using an APPROVED record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under ¶ B of this section;<sup>Pf</sup> and

(2) If SHELLSTOCK are removed from its tagged or labeled container:

(a) Preserving source identification by using a record keeping system as specified under Subparagraph (C)(1) of this section,<sup>Pf</sup> and

(b) Ensuring that SHELLSTOCK from one tagged or labeled container are not COMMINGLED with SHELLSTOCK from another container with different CERTIFICATION NUMBERS; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the CONSUMER.<sup>Pf</sup>

FDA requests that the CFP support FDA not addressing the first recommendation resulting from Issue 2016-I-023 (for a change in the Food Code at this time) but continue to support and move forward with the second recommendation of Issue 2016-I-023 that reads, “2) The FDA begin discussions with the ISSC and Conference for Food Protection to identify steps that can be taken to enhance implementation and enforcement of shellfish record keeping at retail establishments.” As part of these discussions between FDA, ISSC, and CFP, consideration could also be given to the potential and appropriateness of Food Code changes that may enhance foodborne illness traceback efforts.

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### **FDA Agency Programmatic Updates**

#### **ORA Restructuring**

On May 15, 2017 FDA’s Office of Regulatory Affairs (ORA) underwent restructuring as a part of the e Agency’s Program Alignment. ORA houses all the Field Specialist, the Office of Partnerships and the Office of Training Education and Development (DHRD renamed to OTED and elevated in the organization).

The biggest change for Retail in this restructuring is the establishment of the Office of State Cooperative Programs. This moves the reporting structure of 5 FDA Regions to one Headquarters office. Laurie Farmer is the Acting OSCP Director and is here as my guest for the meeting. The ORA management for Retail is now specific to this one program, so ORA managers in the program will have more involvement as they will have the time to focus in one area. Previously the Directors of State Cooperative Programs could have up to 4 programs reporting to them in a specific territory.

The good news is the change is all internal. The field Specialist maintained their same state assignments and work with CFSAN for national retail food policy development and CFP engagement will continue through the great working relationship between CFSAN and all the ORA components.

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### **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 23 – 25, 2017

Location: South Burlington, Vermont

Primary FDA Contact: Al Pistorio, 781-587-7427, [alfred.pistorio@fda.hhs.gov](mailto:alfred.pistorio@fda.hhs.gov)

#### **Southwest Region Seminar**

Dates: September 18-21, 2017

Location: Kansas City, MO

Primary FDA Contact: Cindy Kunkel, 913-752-2401, [Cynthia.kunkel@fda.hhs.gov](mailto:Cynthia.kunkel@fda.hhs.gov)

#### **Central Region Seminar**

Dates: September 19 – 21, 2017

Location: Minneapolis, MN

Primary FDA Contact: Greg Abel, 612-758-7199, [greg.abel@fda.hhs.gov](mailto:greg.abel@fda.hhs.gov)

[2017 FDA Regional Retail Food Safety Seminar & NEHA Region 4 Conference](#)

#### **Pacific Region Seminar**

Dates: September 26-28, 2017

Location: Spokane, Washington

Primary FDA Contact: Kathryn Kennedy, 503-671-9711 X 16, [Kathryn.Kennedy@fda.hhs.gov](mailto:Kathryn.Kennedy@fda.hhs.gov)

#### **Southeast Region Seminar**

Dates: October 17 – 19, 2017

Location: Wilmington, NC

Primary FDA Contact: Donna Wanucha, 678-616-5600, [donna.wanucha@fda.hhs.gov](mailto:donna.wanucha@fda.hhs.gov)

**2017 Food Code**

Work continues on the development of the 2017 Food Code and we are anticipating a release by end of calendar year 2017 with a web release initially and printing taking longer. We have had to adjust the Joint Agency Introduction Letter with the changing of Agency leads as late as the end of July and including signatures of the current Agency leads. Communications Outreach will be through a Constituent Update.

The **Food Code Reference System** may be accessed at: <http://www.accessdata.fda.gov/scripts/fcrs/>

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

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**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.

Enhancements to the Program Standards Website on the [fda.gov](http://fda.gov) continue to highlight the Standards themselves, supporting information and tools, and the listing of enrolled jurisdictions. These can all be accessed at the shortcut: [www.fda.gov/retailprogramstandards](http://www.fda.gov/retailprogramstandards). The website includes a breakdown of the numbers of enrollees from each of the jurisdiction types.

### Number of Enrolled Jurisdictions

- As of 6/30/17, there are 775 jurisdictions enrolled in the Retail Program Standards. This includes **61 State-level agencies** (from all but 1 State) and **5 Territories** (American Samoa, Guam, Northern Mariana Islands, Puerto Rico, Virgin Islands); **453 County-level agencies**; **68 District-level agencies** (each agency oversees 2 or more jurisdictions)(256 counties, 21 cities, 44 towns, 6 villages); **111 City**; **51 Town**; and **26 enrollees are other type agencies (Tribe--11; Univ.--9; Park--1; Federal Agency--3; Community--1; Village—1)**. Enrollment has steadily increased over the past few years, from 547 enrolled as of 9/30/2012 to the current 775 enrollees.
- **99.74%** (1 State 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.
- Nearly 68% (67.78%) of the U.S. population lives in a locality (city, county, parish, etc.) in which the local-level agency primarily responsible for retail food protection is enrolled in the retail program Standards.

### Enrolled Jurisdictions with a Current Self-Assessment

- As of 6/30/2017, 53.8% of enrolled jurisdictions had a current self-assessment (417/775 enrolled jurisdictions). As of 9/30/2012, 40% of enrolled jurisdictions had a current self-assessment (219/547 enrolled jurisdictions).

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

- As of 6/30/2017, 20% of enrolled jurisdictions had a current\* and completed self-assessment and met 3 or more Standards (153/775 enrolled jurisdictions). As of 9/30/2012, 13% of enrolled jurisdictions had a current self-assessment and met 3 or more Standards (69/547 enrolled jurisdictions).

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

- As of 6/30/2017, 6% of enrolled jurisdictions had a current\* self-assessment and met 5 or more Standards (48/775 enrolled jurisdictions) with an increase of 7 jurisdictions since 9/30/2016. 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).

### Enrolled Jurisdictions with a Current Self-Assessment that Meet 6 or More Standards

- As of 6/30/2017, 2.8% of enrolled jurisdictions had a current\* self-assessment and met 6 or more Standards (22/775 enrolled jurisdictions).

\*The “current” means that enrollee has at least one activity (such as completed a period of SA, achieved meeting Program Standards, have done verification audit) in recent 5 years (For FY17Q3, it is from 7/1/2012 to 6/30/2017).

For jurisdictions seeking to conform to the Retail Program Standards at this time, use the 2015 version of the Standards found at:

<https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm>

### **2017 Retail Program Standards**

The Federal Register 60-day notice comment period for public comment on draft versions of the 2017 Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) closed on May 19, 2017. To date, FDA has received and responded to two comments to the 60-day notice. The subsequent 30-day notice published July 18, 2017 and its comment period is still open as of the writing of this report and closes on August 18, 2017. The 2015 version of the Voluntary National Retail Food Regulatory Program Standards expiration date for the forms and collection has been extended to 8/31/17. We will continue to update you as we can.

### **Opportunities to Improve Program Standards Implementation**

#### **Retail Program Standards Mentorship Program**

The Retail Program Standards Mentorship Program (administered by National Association of County and City Health Officials (NACCHO) under a cooperative agreement with FDA) will continue for 2017-2018. Funding has been used to conduct several research projects and administer the mentorship program. Since 2012, FDA has invested over \$1.4 million in the Mentorship Program which has provided 124 awards to retail food regulatory programs. The response from all participants in the Mentorship Program has been overwhelmingly positive. More information about the mentorship program is available at <http://www.naccho.org/topics/environmental/foodsafety/retail/>

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### **2017 Retail Program Standards Grant Program**

FDA and the Association of Food and Drug Officials (AFDO) announced the successful completion of the application period for the 2017 AFDO-administered Retail Program Standards Grant Program. The program provides funds for the completion of projects and training to enhance conformance with Retail Program Standards.

Each year, grant funding is open to State, local, territorial, and tribal regulatory retail food programs that have enrolled in the Retail Program Standards. Project categories for the 2017 funding year include:

- **177 awarded 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, a verification audit or audits, or custom projects that increase a jurisdiction's conformance with the standards;
- **54 awarded 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.);
- **182 awarded 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; and
- **20 awarded Food Protection Task Force Support Projects** up to \$3,000 per award. The goal of this category is to advance conformance with the Retail Program Standards by supporting attendance at Food Protection Task Force activities (or similar Food Advisory Board/Council activities, whether Task Force/Board/Council is supported by an FDA grant or not).

Approximately \$2 Million in funding was available for this granting year. For more information visit Retail Food Safety Grants Website at <http://afdo.org/retailstandards>.

The 2018 AFDO-administered Retail Program Standards Grant Program Portal will open on September 4, 2017. Enrolled programs can apply for grant funding through [10/2/2017](#)

The Advancing Conformance with the Voluntary National Retail Food Regulatory Program Standards Cooperative Agreement Cohort 3 funding opportunity posted March 31, 2017 and closed on May 31, 2017. The link is: <https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-17-007.html>

The Funding Opportunity Announcement (FOA) Number is RFA-FD-17-007 and the FOA Purpose is to achieve the intended outcome of this FOA which is to advance efforts for a nationally integrated food safety system by assisting retail food regulatory programs in achieving conformance with the Retail Program Standards. These cooperative agreements are intended to assist regulatory food retail programs in developing, implementing, and improving the infrastructure necessary to support conformance with the Retail Program Standards. FDA/ORI intends to fund up to \$2,300,000, for fiscal year

2017 in support of this grant program. It is anticipated that up to 33 awards will be made, not to exceed \$70,000 in total costs (direct plus indirect), per award.

All applications received for this funding opportunity have been reviewed and approvals finalized. Notice of awards should be issued before the end of August 2017. 28 cooperative agreements will be awarded.

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### **FDA Retail Risk Factor Study**

The status remains the same as previously reported in the April 2017 FDA report to the CFP Board and as shown below.

#### **FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-service Restaurants, 2013-2014**

FDA has analyzed the data from the restaurant data collection in 2013-2014 and the FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-service Restaurants, 2013-2014 is under senior manager review. Outreach is planned via Constituent Update and Social media. In addition to the full report, FDA will also issue informative fact sheets that will help the public understand key findings in an easier format.

The 2<sup>nd</sup> data collection period for restaurants is scheduled from October 1, 2017 to September 30, 2018.

#### **Retail Food Store, Health Care and School Data Collection**

In December 2016, FDA completed its 15-month data collection (October 2015 thru Dec. 2016) in randomly selected Health Care (Hospitals and Long-Term Care facilities); Schools (schools K-12); and Retail Food Stores (retail stores that have a Deli, plus produce and seafood). As with the restaurant study, FDA Retail Food Specialists were the data collectors and reached 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, the data collection goes beyond simply observations of food safety practices, it included a limited assessment of food safety management systems that may be present and collected 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 report for these three sectors is targeted for roughly 1-2 years after completion of the data collection.

Respectfully submitted to the CFP Executive Board by Glenda R. Lewis, CFSAN, on August 22-23, 2017.