



**U.S. Food and Drug Administration**  
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# **FDA Report**

## **Conference for Food Protection**

### **Boise, Idaho**

### **April 16, 2016**

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**Director, Office of Food Safety**  
**Center for Food Safety and Applied Nutrition**  
**Food and Drug Administration**



# Overview

- **Recent Staff Changes at FDA**
- **Food Safety Modernization Act**
  - Phase 2 Implementation & Technical Assistance Network
  - Sanitary Food Transportation Act Update
- **Guidance and Regulatory Updates**
  - Acrylamide Guidance for Industry
  - Menu Labeling
- **Retail Program Standards**
- **FDA-Submitted Issues to 2016 CFP**



# Recent Staff Changes at FDA

- New Commissioner of Food and Drugs is Robert M. Califf, M.D.
- Mike Taylor, Deputy Commissioner for Foods and Veterinary Medicine will leave FDA and Dr. Steve Ostroff will replace him
- **ORA OP** – Barbara Cassens, Director of Office of Partnerships (OP) and Alan Tart, Deputy Director of OP
- **CFSAN** - Dr. Susan Mayne, Director of CFSAN
- Dr. Mickey Parrish, CFSAN's Acting Senior Science Advisor
- Kevin Smith, new Senior Advisor in CFSAN/Office of Food Safety (OFS)
- Glenda Lewis, new Director, Retail Food Protection Staff, CFSAN/OFS



# FSMA Implementation

## *“A Continuum”*

- **Phase 1: Set Standards**  
Develop regulations, guidance, policy
  
- **Phase 2: Design Strategies to Promote and Oversee Industry Compliance**  
Identify performance metrics to measure success



# Phase 1: Standard Setting

Regulation	Proposal	Final
Preventive Controls (Human Food)*	Jan 16, 2013	Sept 17, 2015 <sup>◇</sup>
Preventive Controls (Animal Food)*	Oct 29, 2013	Sept 17, 2015 <sup>◇</sup>
Produce Safety*	Jan 16, 2013	Nov 27, 2015 <sup>◇</sup>
Foreign Supplier Verification Program*	Jul 29, 2013	Nov 27, 2015 <sup>◇</sup>
Third Party Accreditation	Jul 29, 2013	Nov 27, 2015 <sup>◇</sup>
Sanitary Transport	Feb 5, 2014	Mar 31, 2016
Intentional Adulteration	Dec 24, 2013	May 31, 2016

*\*Supplemental proposals published September 2014*

5 <sup>◇</sup>*Final rule publication date*



# Technical Assistance Network

- Launched on September 10, 2015
  - Provide technical assistance to industry, regulators and other stakeholders
  - Address questions related to FSMA rules, programs, and implementation
- Submitting Questions
  - Submit inquiries via the web form or by mail
  - To submit a question about FSMA visit [www.fda.gov/fsma](http://www.fda.gov/fsma) and go to “Contact us”



# Who is Covered by the Sanitary Food Transportation Act?

- The final rule applies to shippers, receivers, loaders, and carriers who transport food in the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce.



# Waivers

- The Agency may waive the requirements of the rule if it determines that the waiver will not result in transportation of food under conditions that would be unsafe to humans or animals.
  - Prior to the compliance date, the Agency intends to publish waivers in the Federal Register, as announced in the proposed rule.





# Waivers

- Agency intends to publish waivers for food establishments, e.g., retail stores, restaurants, and home grocery delivery, holding valid permits, when acting as receivers, shippers, or carriers delivering food to consumers
  - FDA acknowledges that controls already exist under the Retail Food Program, with state, territorial, tribal and local enforcement, and FDA oversight.



# FSMA Funding Opportunity

- State regulatory agencies have a better understanding and knowledge of the specific growing and harvesting practices and have long standing relationships with produce growers
- Implementation of the produce rule is dependent on partnerships between FDA and states
- To support that partnership, FDA announced the availability of funding opportunity to solicit applications for cooperative agreements with state regulatory agencies to help plan for and develop infrastructure needed to implement the produce rule

<http://www.fda.gov/food/newsevents/constituentupdates/ucm491281.htm>



# FSMA Funding Opportunity

- \$19 million in FY16 grant \$\$ available for States to Support Implementation of the FSMA Produce Rule
- Available to states to conduct outreach, education, compliance and enforcement of the produce safety rule.
- Funding will continue for five years subject to availability of funding from Congress.



# Acrylamide

- Background
- November 2013: Draft Guidance for Industry: Acrylamide in Foods.
- March 2016: Final Guidance
  - Provides information to help growers, manufacturers and food service operators reduce acrylamide levels in certain foods
- Next steps



# FDA New Menu and Menu Board Food Labeling Regulations

Section 4205 of the Patient Protection and Affordable Care Act  
Amends certain nutrition labeling provisions of the Federal  
Food, Drug and Cosmetic Act

Mailbox to submit questions on menu labeling

[CalorieLabeling@fda.hhs.gov](mailto:CalorieLabeling@fda.hhs.gov)



## What does section 4205 require for Restaurants and Similar Retail Food Establishments?

- Disclose calorie information on menus and menu boards for standard menu items
- Post a succinct statement concerning suggested daily caloric intake on menus and menu boards
- Disclose calorie information on signs adjacent to foods on display and self-service foods that are standard menu items
- Provide written nutrition information upon consumer request
- Post on menus and menu boards a statement that written nutrition information is available upon request



# Menu Labeling Regulations

- Covers menu and vending machine labeling
- Proposed rule issued on April 6, 2011
  - Over 900 comments received
- Final rule issued on December 1, 2014 with effective date of December 1, 2015



# Extension of Compliance Date for Menu Labeling

- Industry, trade, and other associations, including the grocery industry, asked for an additional year to comply with the menu labeling final rule
- FDA agreed to additional time to allow the agency to provide further clarifying guidance to help facilitate efficient compliance across all covered establishments to come into compliance with the rule
- On July 9, 2015, FDA extended the compliance date for menu labeling to December 1, 2016
- December 2015, the 2016 Omnibus Bill extended the compliance date to one year following the publication of final guidance





## **Draft Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From Home Foods – Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)**

- On FDA.gov at:  
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm461934.htm>
- Issued September 11, 2015
- 45 day comment period closed on November 2, 2015



# Retail Program Standards

## Where are we now (as of FY16 Q2)?

- ✓ **699** enrolled jurisdictions representing **63%** of the population in the United States

In the previous 39 months, we have seen:

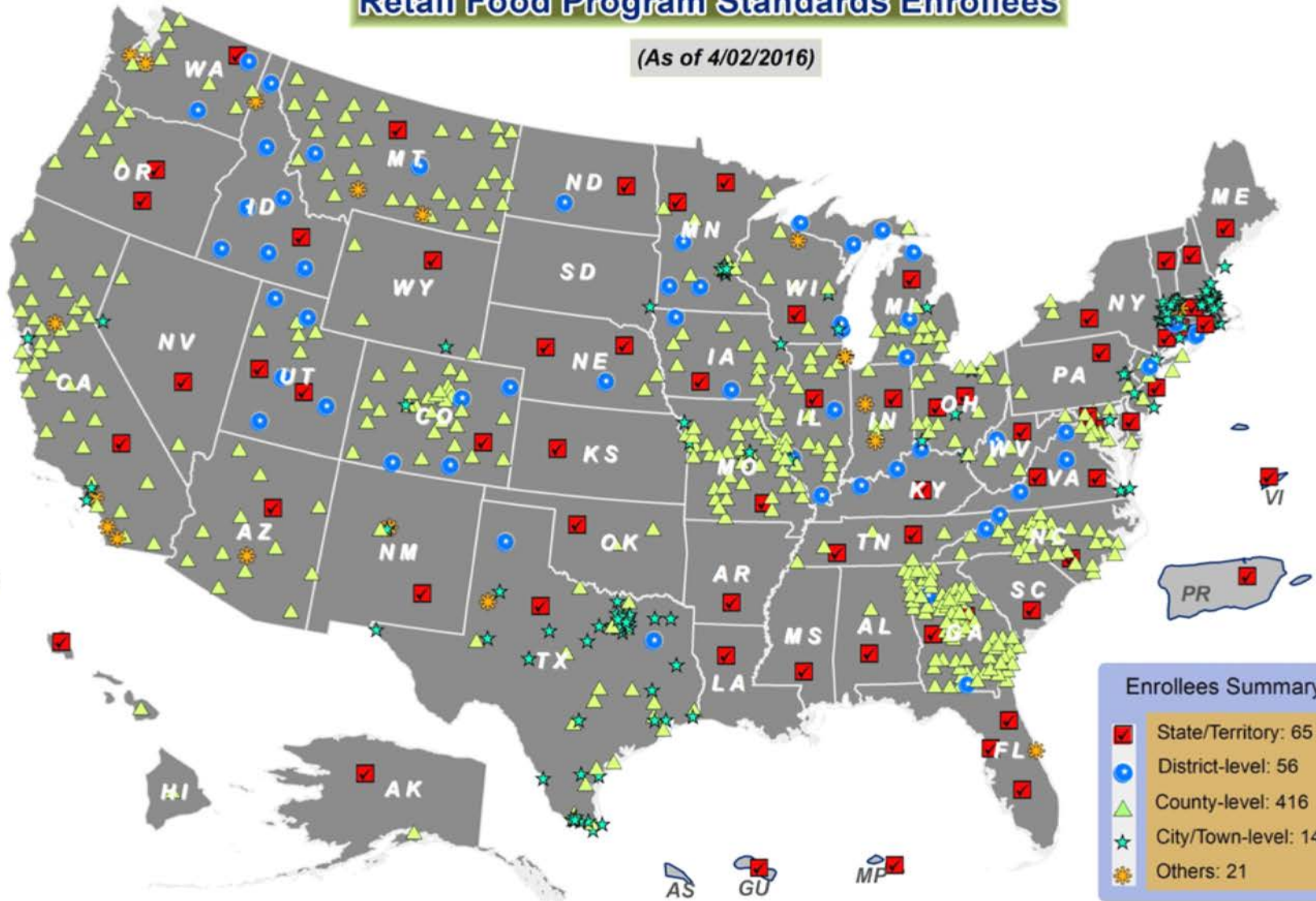
- ✓ **68%** increase in jurisdictions with a current self-assessment
- ✓ **91%** increase in jurisdictions with a current self-assessment that meet 3 or more Standards

## Enrollment Breakdown

- ✓ State/Territory: 65 (9%)
- ✓ District-level: 56 (8%)
- ✓ County-Level: 415 (60%)
- ✓ City/Town-level: 142 (20%)
- ✓ Others: 21 (3%)

## Retail Food Program Standards Enrollees

(As of 4/02/2016)



### Enrollees Summary:

- State/Territory: 65
- District-level: 56
- ▲ County-level: 416
- ★ City/Town-level: 142
- ☀ Others: 21



# Retail Program Standards Funding

- FDA provides **funding to enrolled retail food regulatory programs through the following three mechanisms:**
  - **ORA/OP - Multi-year, direct Cooperative Agreements**
  - **ORA/OP - Single-year grants**, awarded through a Retail Association Cooperative Agreement
  - **CFSAN/OFS - Single-year contracts**, awarded through the Mentorship Program, a component of a Cooperative Agreement with NACCHO to strengthen and promote the role of local health departments in retail food safety regulation



# FDA-Submitted Issues for 2016 CFP

1. Employee Health Interventions – Reducing Norovirus
2. Use of pre-formulated sanitizing solutions
3. Amendments to Program Standards No. 4 – Uniform Inspection Program (Part 1)
4. Amendments to Program Standards No. 4 – Uniform Inspection Program (Part 2)
5. Amendments to Program Standards No. 9 – Program Assessment



Thank you

