



# **FSMA: Where We've Been and Where We're Going**

**2014 ASTA Regulatory /  
Legislative Workshop  
October 15, 2014**

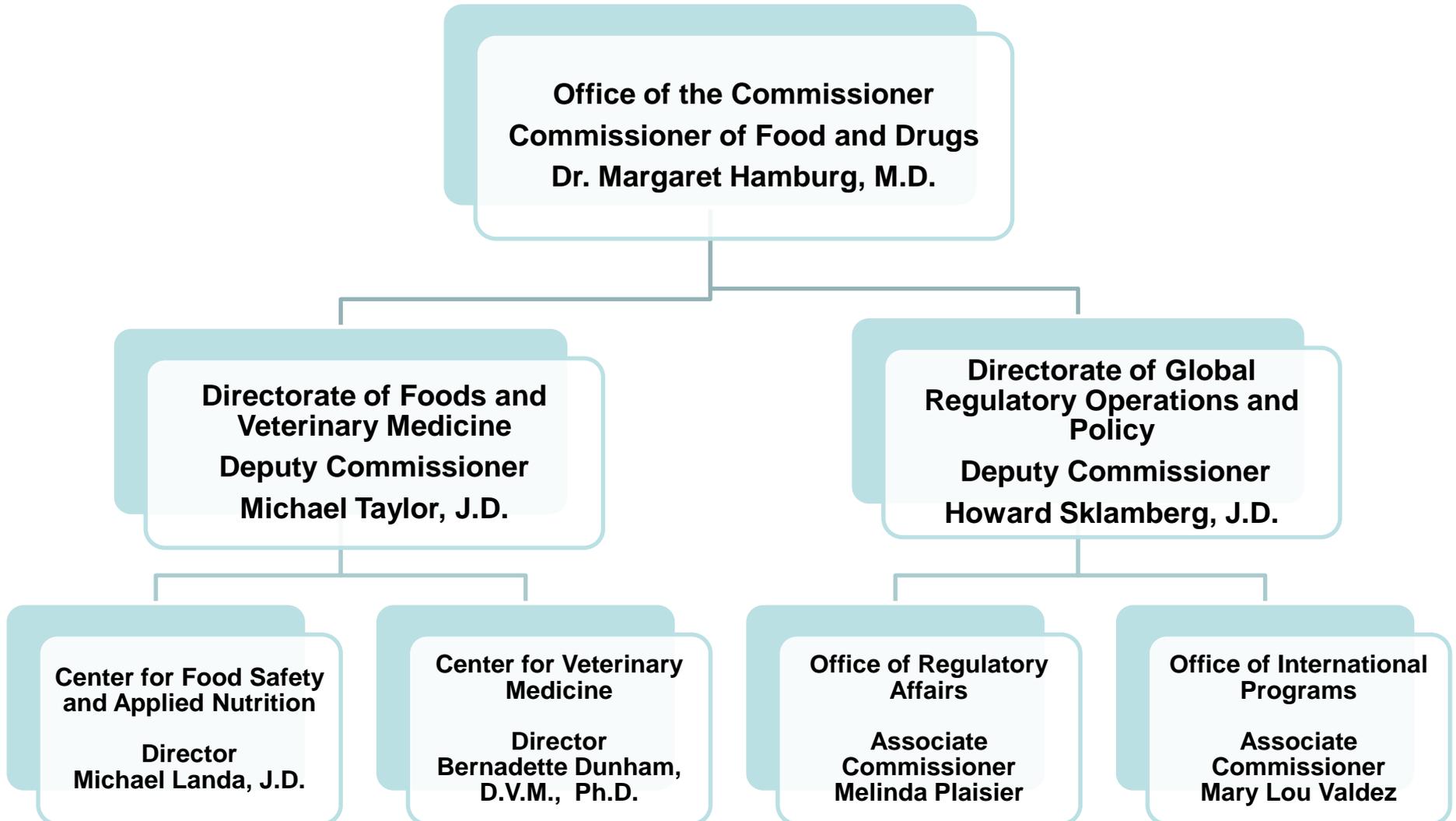
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# Presentation Overview

- FSMA implementation as a continuum
- 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
- Stakeholder engagement throughout the process

# Collaboration within FDA Food / Feed Program

## *Spans Two Directorates and Four Offices/Centers*





# Phase 1: FSMA Standard Setting





# Phase 1: FSMA Standard Setting

- Six core teams were formed in January 2011 to focus on FSMA deliverables
  - Preventive Standards
  - Inspection and Compliance
  - Imports
  - Federal/State Integration
  - Fees
  - Reports and Studies
- Teams are developing regulations, guidance, and protocols for new administrative tools

# Phase I: Standard Setting

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

*\*Supplemental proposals for some sections – Sept 2014*



# Phase 1: Other Accomplishments

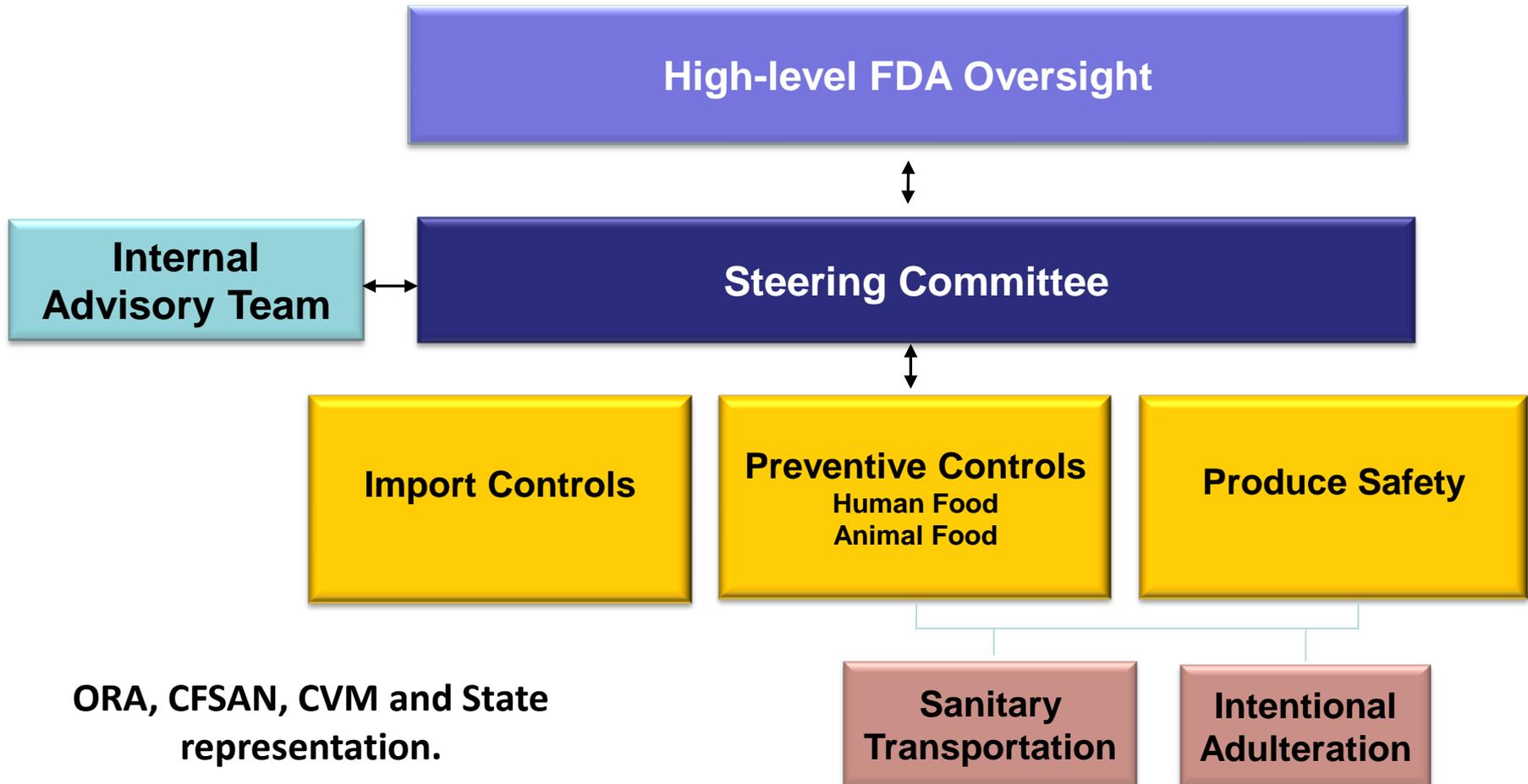
- Administrative enforcement tools
  - Administrative detention, mandatory recall, suspension of registration
- Registration – biennial registration
- Manner of inspection
  - Component inspections, intelligent questionnaires



# Transition to Phase 2: Implementation

- Teams continue rulemaking, guidance and other policy work until completed
- Concurrently, workgroups:
  - Implement the final rules, programs established through guidance and other policy
  - Design specific strategies, capacity building, training and operation plans needed to implement FSMA
- Steering Committee oversees 3 workgroups:
  - Preventive Controls in Food and Feed Facilities
  - Produce Safety Standards
  - Import Oversight

# Operations and Policy Working Together



# Phase 2: Implement the Standards

- What is changing?
  - FDA will operate differently
  - FDA will educate before and while it regulates
  - Company's food safety culture will guide FDA's approach

**FDA will continue to engage partners,  
encourage transparency**



# How FDA Will Operate Differently

- FDA will speak with one voice
- Inspection, compliance functions specialized
- Investigators and subject matter experts work together to drive correction of problems
- Invest in regulator training to promote consistent inspections, decision making

# Preventive Controls Plan for Training Food Safety Staff

- Regulatory training will need to be developed for all food safety staff, *e.g., investigators, state inspectors, supervisors, compliance officers, SMEs*
- Regulatory Training will include:
  1. Technical Knowledge
  2. Inspection/Audit Skills and Knowledge
  3. Behavior and Systems Thinking (soft skills – communications and critical thinking, *e.g., problem solving, root cause analysis*)
- Leverage existing training from within and from industry





# How FDA Will Operate Differently (cont.)

- Robust data integration, analysis and information sharing
- Public health metrics
- Work closely with government counterparts and other food safety system stakeholders



# Educate Before and While We Regulate

- Facilitate industry implementation of modern, preventive practices through:
  - Commodity and sector-specific guidance
  - Education, outreach and technical assistance
  - Regulatory incentives for compliance



# Company's Food Safety Culture Guides FDA Approach

- Targeted, risk-based inspection models
- Wider range of inspection, sampling, testing and data collection activities
- Improve risk-based work planning through targeted data collection and more timely data analysis and program evaluation



# 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](http://fda.gov/fsma)

# Phase 2: Workgroups Charge

- Develop a framework and multi-year implementation plan for ensuring compliance with regulations:
  - Training for regulators
  - Data collection, analysis, updated IT
  - Performance goals and metrics
  - Inspections, compliance and enforcement
  - Education, outreach and technical assistance for industry
    - Alliances



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

- Background
  - FDA recognized the need to assist the regulated industry to comply with FDA's PC regulations
  - FSPCA is modeled after the Seafood HACCP Alliance
  - Established as part of the Institute for Food Safety and Health; initial funding provided September, 2011
  - FDA collaboration with industry, regulatory, academia and researchers to develop a core curriculum and educational materials

# Alliance's Primary Goals

- Develop standardized training program
- Develop a variety of training modules and delivery mechanisms, including “train-the-trainer” for food industry and regulatory personnel
- Help develop guidance information
- Create a technical assistance network for small- and medium-sized food companies

**The process is challenging, since the final rule provisions have not been established**

# Curriculum Content & Progress

Peer review complete 😊 or pending 😊, awaiting regulation 😞, needs work 😞

Introduction to Preventive Controls	😊	Allergen Control Plan	😊
Prerequisite Programs and GMPs	😊	Process Control Plan	😊
Food Safety Hazards	😊	Verification / Validation	😊
Preliminary Steps	😊	Record-keeping	😊
Food Safety Plan Overview	😊	Recall Plan	😊
Hazard Analysis and Preventive Control Determination	😊	Regulation Overview	😞
Supplier Verification	😞	Implementation and Resources	😞
Sanitation Control Plan	😊	Food Safety Plan Example	😊

# Curriculum Trial Run ("Shakedown")

- First time materials were presented – May 28-30, 2014
- Invitees from academia, government and industry with experience in developing and delivering food safety courses
- Objectives:
  1. Make sure that the content is right
  2. Obtain suggestions for reorganization if it is needed
  3. Solicit input on exercises – when and how long
  4. Determine the need for additional instructors' notes, manual, slides
  5. Estimate timing
- Revised curriculum based on "Shakedown" feedback
- The FSPCA curriculum will not be finished until AFTER the final rule is published



# Operational Strategy Appendix



# Import Oversight

- Develop skills, capacity, and processes to:
  - Audit Foreign Supplier Verification Program and accredited third-party certifiers;
  - Conduct comparability assessments
- Implement Voluntary Qualified Importer Program and other measures to expedite entries for good performers
- Reconfigure current import screening and field exam activities for oversight of all import activities

# Preventive Controls

- Build on FDA's experience with seafood and juice HACCP
- Place more emphasis on data collection and analysis
  - Assess compliance of individual firms through range of inspection and sampling techniques
  - Use data to guide risk-based inspection priority, frequency, depth and approach
- Efficiently screen firms for food safety performance, evaluate food safety culture



# Preventive Controls

## *New Compliance and Enforcement Strategy*

- During inspections, seek compliance
  - Encourage firms to correct violations on their own
  - Increase the incentive for compliance
- If compliance is not achieved, use enforcement tools
  - Deficiency letters at district level
  - Administrative enforcement tools
  - Judicial enforcement tools



# Stakeholder Engagement



# Stakeholder Engagement

- Transparency Remains a Priority
- Next Phase: Inclusive/Coalition Approach
  - Engage stakeholders to help determine reasonable and practical ways to implement provisions and concepts before rules become final.
- Future: Partnerships/Collaboration Key
  - Establish mechanisms, including working with multiple partners, to foster industry understanding of final rules/guidance and encourage firms to comply and initiate any corrections on their own.



# More Information Available

- Web site: <http://www.fda.gov/fsma>
- Subscription feature available
- Send questions to [FSMA@fda.hhs.gov](mailto:FSMA@fda.hhs.gov)

The screenshot shows the FDA website header with the U.S. Department of Health & Human Services logo and the FDA logo. The main navigation bar includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, and Cosmetics. The 'Food' section is highlighted, and the breadcrumb trail reads: Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA). The main content area features a sidebar with 'Guidance & Regulation' and 'Food Safety Modernization Act (FSMA)' sections. The main article title is 'Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)' with the subtitle 'Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards' and the date 'May 2, 2014'.

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A to Z Index | Follow FDA

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## Food

Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA)

**Guidance & Regulation**

Food Safety Modernization Act (FSMA)

The Law, Rules & Guidance

### Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)

Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards

May 2, 2014



# Questions?