



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

## **Collaborative Food Safety Forum**

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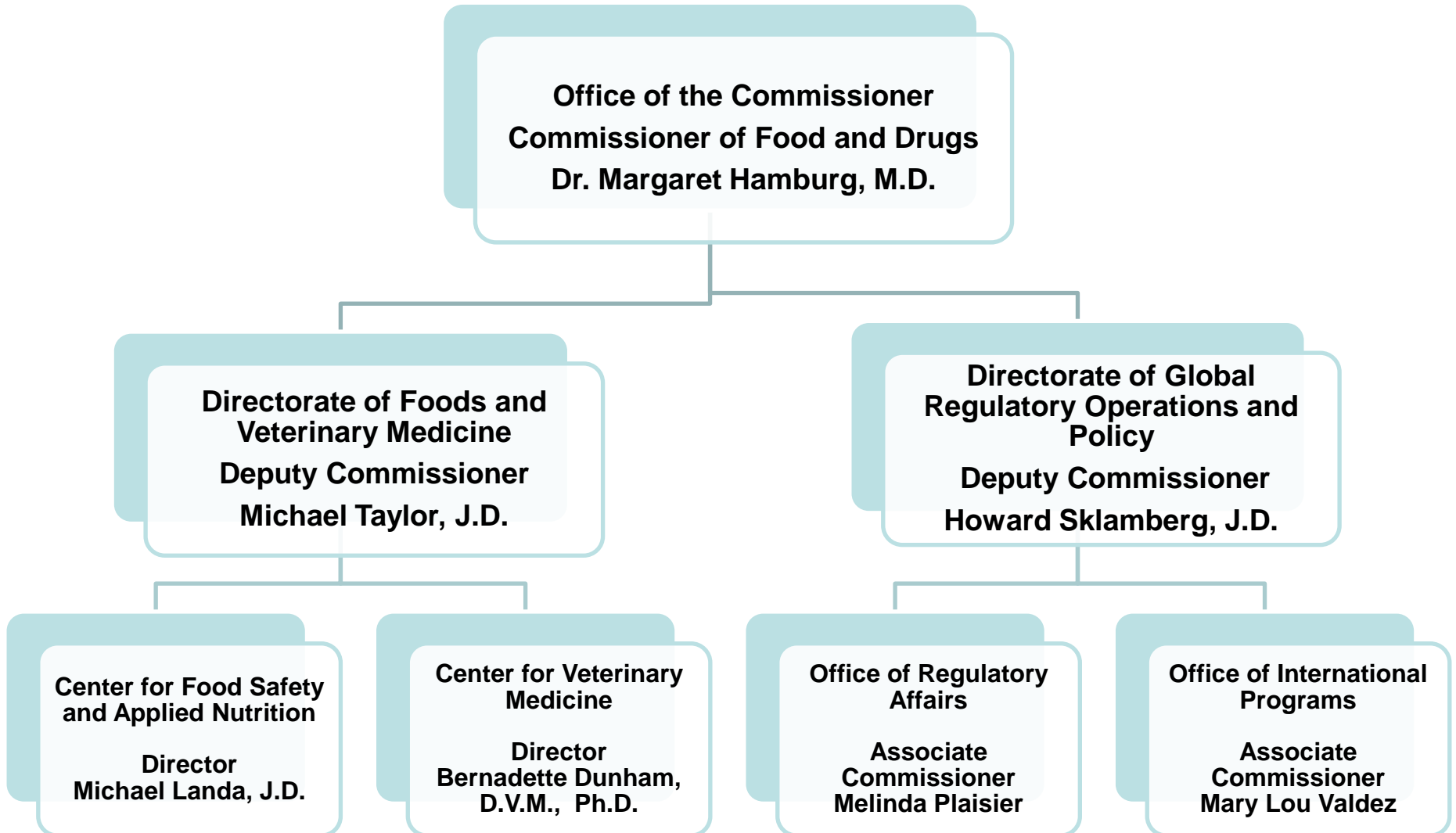
**June 18, 2014**

# Presentation Overview

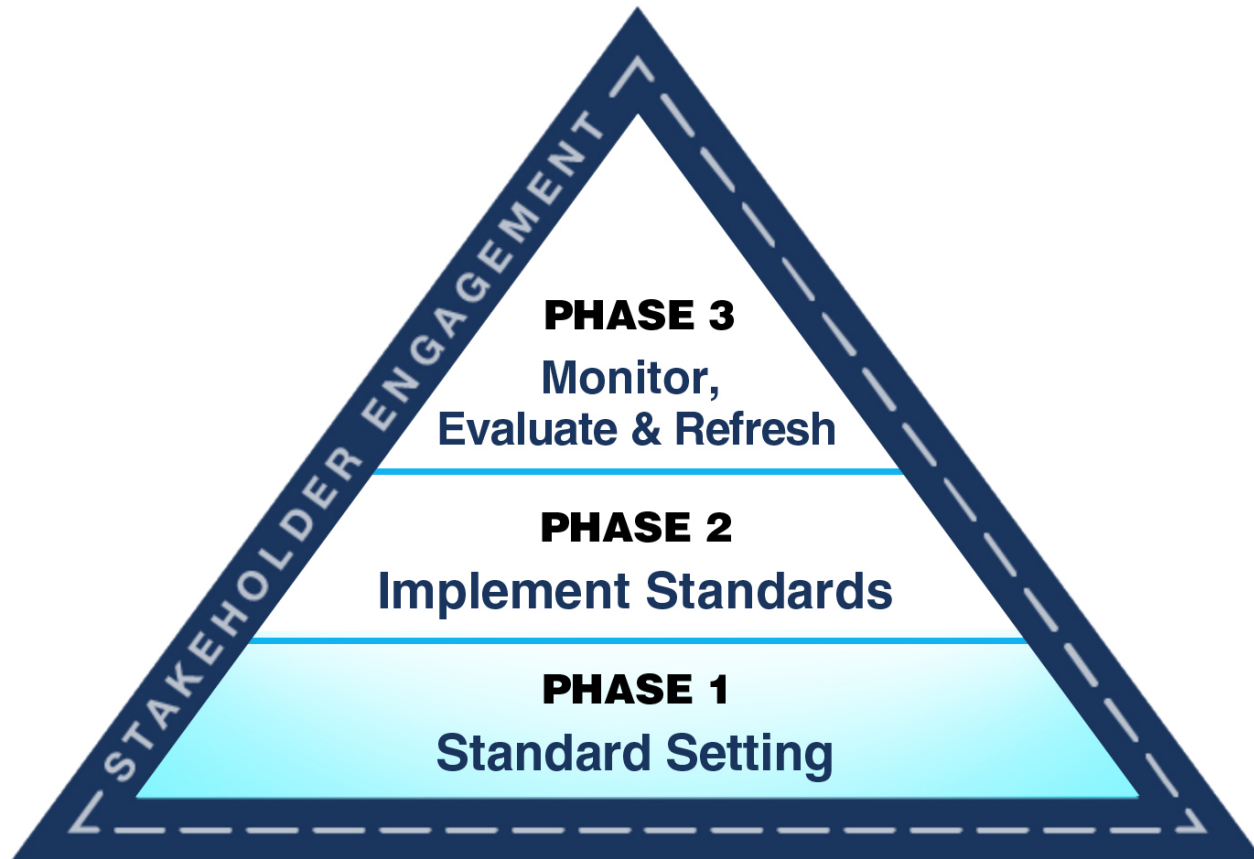
- FSMA implementation as a continuum
- Phase 1: Set standards
  - Develop regulations, guidance, protocols for new administrative enforcement tools
- Phase 2: Implement standards
  - Establish programs and strategies to promote and oversee compliance
- Phase 3: Monitor, evaluate, refresh
- Stakeholder engagement throughout the process

# Collaboration within FDA Food / Feed Program

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



# FSMA Implementation



**FDA FOOD SAFETY**  
MODERNIZATION ACT



# 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 – summer 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
  - Develop 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



# Phase 2: Implementation of Standards



# Phase 2: Implement the Standards

- What is changing?
  - FDA will operate differently
  - FDA will educate before it regulates and along the way
  - 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
- Invest in regulator training to promote consistent inspections, decision making
- Investigators and subject matter experts work together to drive correction of problems

# 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

# Education Before Regulation and Along the Way

- Facilitate industry implementation of modern, preventive practices with FDA's new toolkit, which includes:
  - 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

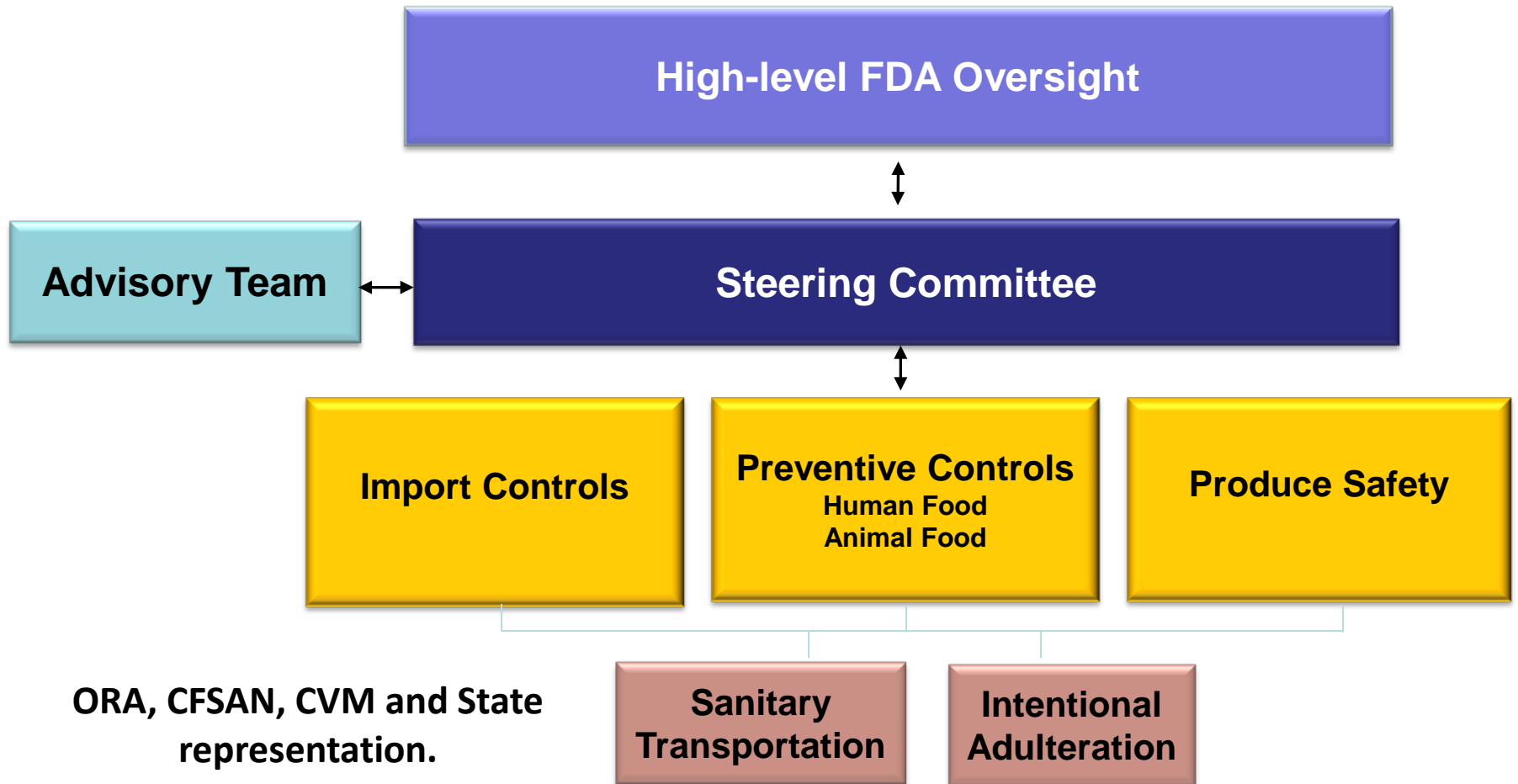
- Provides a foundation for implementing FSMA standards
  - Regulations, guidance, protocols
- Captures in broad, high-level terms our current thinking on strategy and guiding principles for the implementation of FSMA standards.
- View at [fda.gov/fsma](http://fda.gov/fsma)



# Phase 2: Workgroups Charge

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

# Operations and Policy Working Together





# How the Operational Strategy Applies to Each Rule



# Produce Safety

- Educate before regulating and along the way
  - Technical assistance
- Consider work performed by public-private parties to drive food safety in determining FDA activities
- Create and deploy cadre of specialized produce safety experts for on-farm activities
- Encourage industry to comply and make corrections on its own
  - Use of enforcement tools if action is not forthcoming

# 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 a variety of 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 active, showing a breadcrumb trail: Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA). A sidebar menu under 'Guidance & Regulation' lists 'Food Safety Modernization Act (FSMA)' and 'The Law, Rules & Guidance'. The main content area features the title 'Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)' and the subtitle 'Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards', dated May 2, 2014.



# Questions?

***Thank you for your attention!***