

FSMA Operational Strategy - How FDA Will Implement the New Regulations

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FSMA Operational Strategy

How FDA will Implement the New Regulations

United Fresh 2014 Meeting

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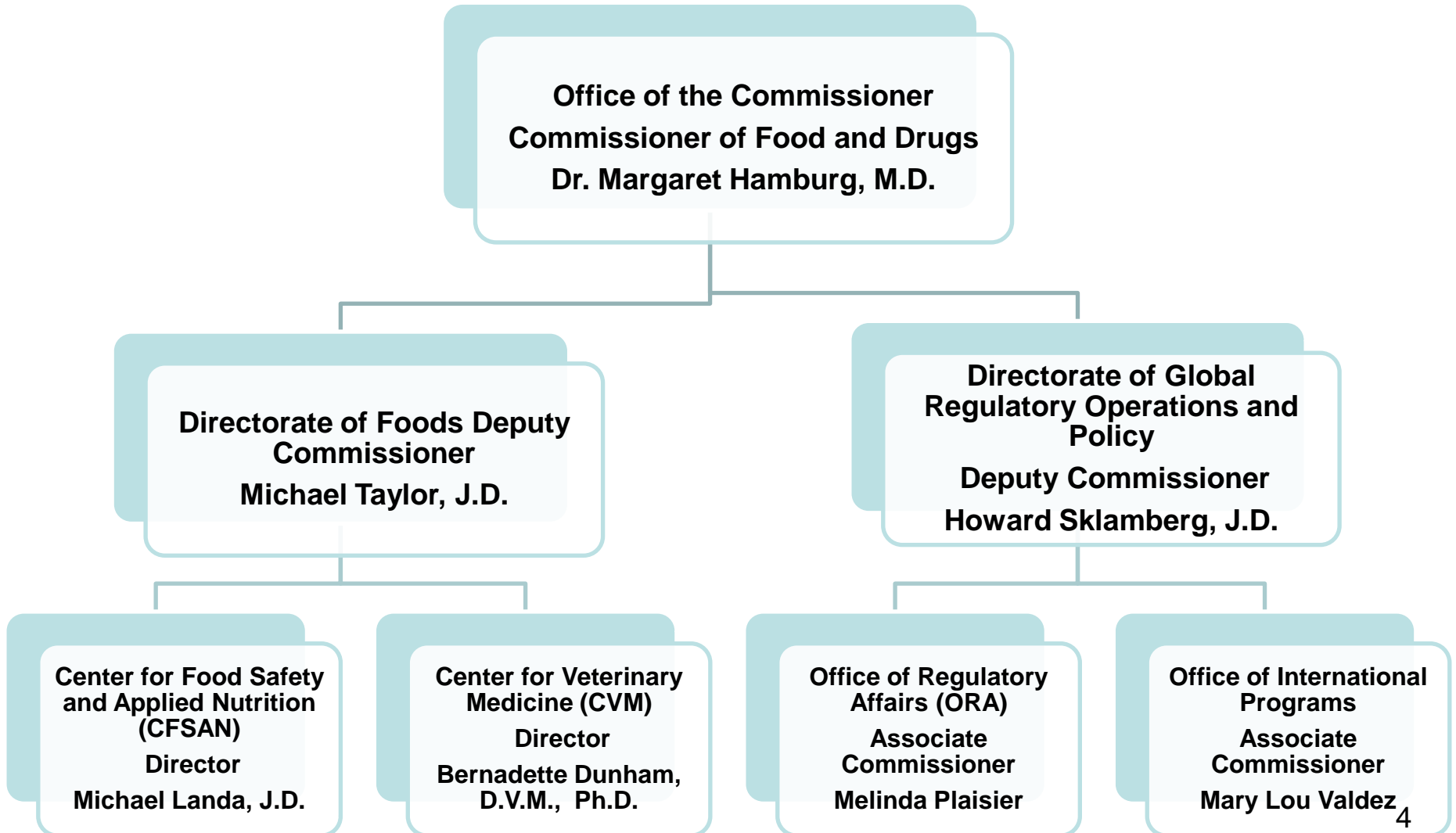
June 11, 2014

Presentation Overview

- **Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)**
 - **Intersection with FDA Program Alignment**
- **Status: FDA FSMA Implementation**
 - **FSMA Implementation Teams (FIT)**
 - **FSMA Operations Team (FOT)**
- **Stakeholder Engagement**

Enterprise-wide Collaboration within FDA Food / Feed Program

Spans Two Directorates and Four Offices/Centers



Overview: Operational Strategy for Implementing The FDA Food Safety Modernization Act



FDA's FSMA Operational Strategy Document

- **Provides a foundation for creating an operational strategy that supports the reduction of preventable foodborne illness**
- **Outlines the drivers of change in FDA's approach to food safety oversight**
- **Guides the next phase of FSMA implementation which reflects the Agency's current thinking on implementation**
- **Dovetails with the FDA Commissioner's Program Alignment initiative**

FDA's Program Alignment Effort

- In February 2014, FDA's Commissioner of Food and Drugs, Margaret A. Hamburg issued a memorandum announcing a core set of operational changes recommended by the Program Alignment Group <http://www.fda.gov/AboutFDA/CentersOffices/>
- The Commissioner charged the group to develop plans to improve the efficiency, effectiveness, and timeliness of the Agency's regulatory and compliance activities including:
 - Commodity-Based and Vertically-Integrated Regulatory Program
 - Specialization/Training
 - Agency Work Planning
 - Compliance Policy and Enforcement Strategy
 - Imports
 - Laboratory Optimization
 - Streamlining

FDA's Program Alignment Effort

- **Organize activities around distinct commodity-based and vertically-integrated regulatory programs, *e.g., food and feeds***
- **Streamline business processes and decision making and structure changes in the organization, *e.g., streamline interactions between ORA and Center experts***
- **Specialize FDA's inspection and compliance functions to adapt and effectively oversee rapid technical advancements with FDA's regulated industries and demands of new legislation**

**FDA's Program Alignment will support
FSMA Implementation**

FDA's Program Alignment Effort

Goal: Improve communications and collaboration and to clarify roles, responsibilities and decision rights across all Agency components

Scope: Office of Regulatory Affairs and all Centers

Timing: Action plans finalized by October 1, 2014 with implementation in subsequent fiscal years

Future of Food Safety with FSMA

Advancing Public Health

Fostering consistent industry understanding & implementation of standards

Promoting widespread voluntary industry compliance

Strengthening FDA's leadership role in science & innovation

Leveraging & Collaboration

Establishing a global food safety network

Integrating data & sharing information amongst & between public & private partners

Enhancing operational partnerships with States and other government counterparts

Strategic and Risk-Based Industry Oversight

Expanding workforce skills through training & real-time technical support for frontline to promote consistent inspections & decision making

Expanding oversight tool kit to promote and verify compliance

Developing explicit enforcement strategies including use of new administrative tools

Improving risk-based work planning through enhanced, systematic data collection, sharing, and evaluation

Establishing public health metrics

Operational Strategy Document - Appendix

Provides the guiding principles for how the operational strategy can be implemented with respect to:

- **Preventive Controls in Food and Feed Facilities**
- **Produce Safety Standards**
- **Import Oversight**

Operational Strategy Document - Appendix

Preventive Controls in Food and Feed Facilities

General

- Build on FDA’s experience in implementing seafood and juice HACCP
- Change how we inspect by seeking voluntary compliance first
- Put more emphasis on data analysis and targeted risk factors

Operational Strategy Document - Appendix

Preventive Controls in Food and Feed Facilities

Inspection and Surveillance

- **Efficiently screening firms for food safety performance**
 - To guide risk-based inspection priority, frequency, depth

- **Providing firms incentives for compliance**
 - Enhanced presence in high-risk firms and products
 - Reduced scrutiny of firms with proven track record

- **Assessing the compliance of individual firms**
 - Through range of inspection and sampling techniques

Operational Strategy Document - Appendix

Preventive Controls in Food and Feed Facilities

Inspection and Surveillance

- **Making in-depth assessments of individual firms when needed**
 - To increase the incentive for compliance; determine the need for compliance or enforcement actions
- **Collecting data to inform understanding and analysis**
 - Of sector-wide hazards, practices, and deficiencies
- **Collecting data on compliance rates**
 - To evaluate program performance and plan future efforts

Operational Strategy Document - Appendix

Preventive Controls in Food and Feed Facilities

Enforcement

- **Voluntary Compliance**
 - Voluntary correction of problems including recalls at the facility level
 - Voluntary correction at District level through deficiency letters
- **When Voluntary Compliance Cannot be Achieved**
 - Administrative Enforcement Tools
 - Judicial Enforcement Tools

Operational Strategy Document - Appendix

Produce Safety Standards

- **Deploying a cadre of produce safety experts**
- **Actively supporting education and technical assistance for growers**
- **Supporting public and private parties involved in audits and other accountability functions**
- **Conducting targeted on-farm surveys and inspections**
 - Gaining voluntary industry compliance first; using administrative compliance and enforcement actions when necessary to protect public health
- **Responding to produce outbreaks ; in-depth environmental assessments to identify contributing factors**

Operational Strategy Document - Appendix

Import Oversight

- **Developing the skills, capacity, and processes to audit foreign supplier verification programs and hold importers accountable**
- **Reconfiguring current import screening and field exam activities to complement oversight of FSMA's foreign supplier verification requirement**
- **Implementing the voluntary qualified importer program and other measures to expedite entries for good performers**

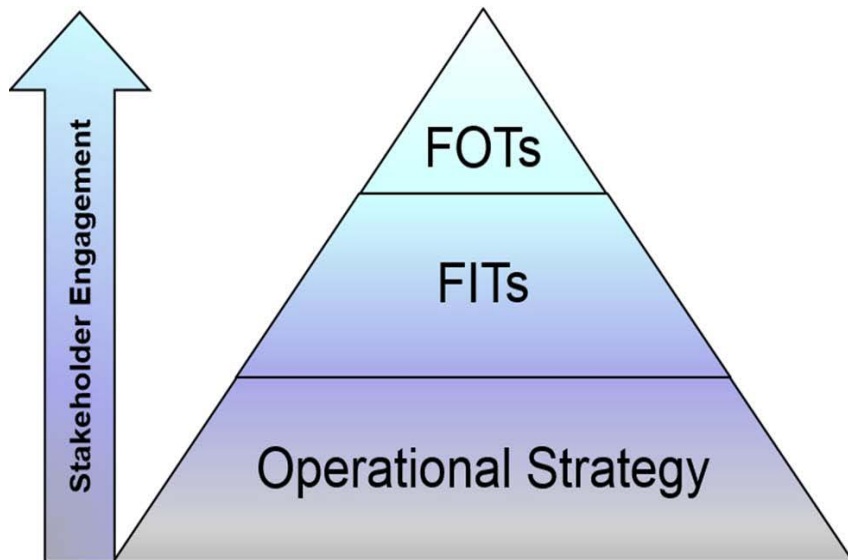
Operational Strategy Document Appendix

Import Oversight

- **Developing the skills, capacity, and processes to audit accrediting bodies and accredited third-party certifiers**
- **Developing the skills, capacity, and processes to conduct comparability assessments of foreign government regulatory systems**
- **Building data integration and analysis systems and harnessing all available sources of relevant information**

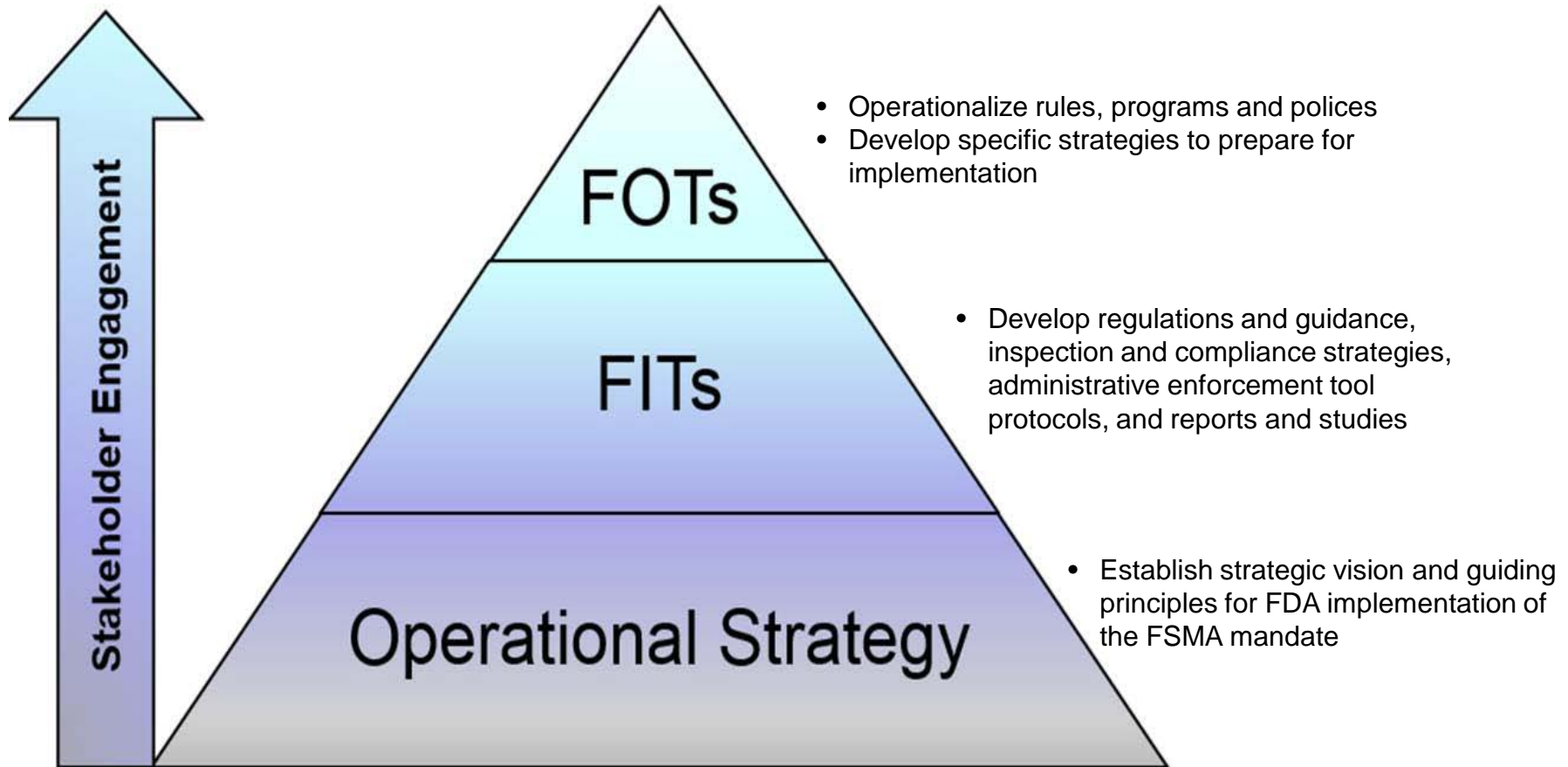
Status: FDA FSMA Implementation

FSMA Implementation Teams (FIT) FSMA Operations Team (FOT)



Operational Strategy, FITs, and FOTs

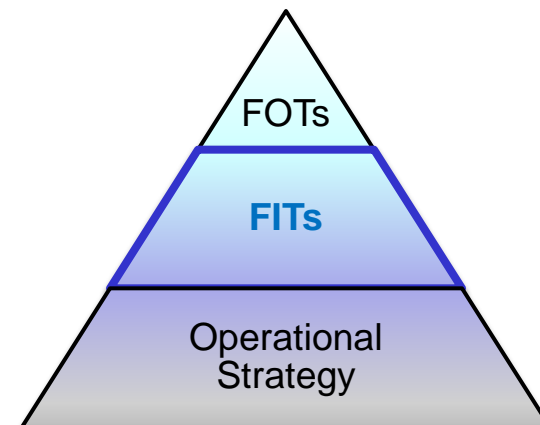
How They Fit Together



Continuous communication/
engagement with Internal and
external stakeholders

FSMA Implementation

- **FDA is in the midst of the rulemaking and guidance development process**
- **FSMA implementation teams (FIT) have already developed many ideas for how FDA can better oversee the food industry, strengthen the global food safety system, and enhance public health**



Implementation Executive Committee

Strategic Communications
& Outreach Team

Prevention Standards

Produce Safety Regulation

Produce Safety Guidance

Preventive Controls Regulation

Preventive Controls Guidance

Safe Food Transport

Food Defense

Contaminants

Inspection & Compliance

Mandatory Recall / Recall Communications

Administrative Enforcement Tools

Registration

Tracing

RFR Improvements

Imports

Importer Verification & VQIP

Import Certification

Accredited Third-Party Certification

Lab Accreditation & Integrated Consortium / FERN

International Capacity Building

Comparability

Federal/State Integration

Operational Partnership

Capacity Building

Training

Fees

Inspection & Auditor Fees

Reports & Studies

Reports to Congress / Studies

Six FSMA Implementation Teams (FITs)



Preventive Standards FIT Team Accomplishments

Proposed Rule	Date Published
Preventive Controls (Human Food)*	Jan 2013
Produce Safety*	Jan 2013
Preventive Controls (Animal Food)*	Oct 2013
Intentional Adulteration	Dec 2013
Sanitary Transport of Food and Feed	Feb 2013

**Re-proposals of some sections - summer 2014*

Import FIT Accomplishments

Proposed Rule	Date Published
Foreign Supplier Verification Program*	July 2013
Accredited Third Party Certification	July 2013

**Re-proposal of some sections - summer 2014*

International Capacity Building

- Published report: **Feb 2013**

Systems Recognition

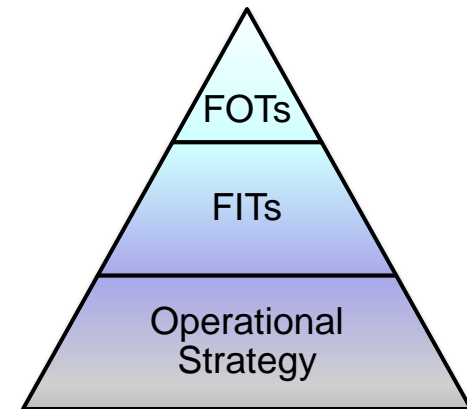
- Pilots in New Zealand and Canada

Inspection & Compliance FIT Team Accomplishments

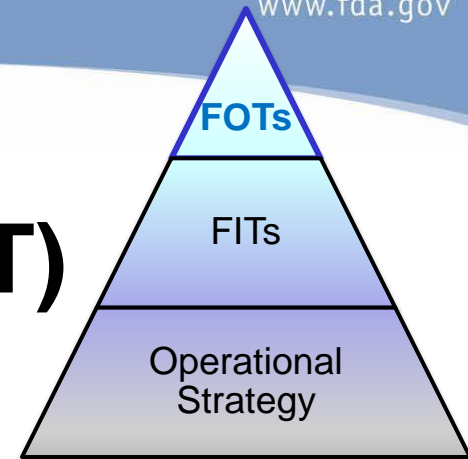
- **Administrative Enforcement Tools**
 - Administrative Detention, Mandatory Recall, Suspension of Registration
- **Registration**
 - Biennial Registration
- **Frequency of Inspection**
 - Meeting FSMA Frequencies
- **Manner of Inspection**
 - Component Inspections, Intelligent Questionnaires
- **Tracing**
 - IFT Report on Pilot Studies, Designating High Risk Foods

FSMA Implementation Transitioning to Next Phase

- **FSMA Implementation Teams (FITs) continue until rulemaking, guidance, and other policy work is completed**
- **Any operations related work or work that has been completed that can inform decisions relative to FSMA related-operations is being transferred from the FITs to the FSMA Operations Team (FOT)**



FSMA Operations Team (FOT)



In January 2013, a Steering Committee was launched to oversee three workgroups charged to:

- Operationalize the final rules, programs established through guidance, and other policy
- Develop specific strategies, capacity building, training and operation plans needed to implement FSMA



**FSMA Operations
Team (FOT)
Organizational Chart**



**Three FOT Work Groups:
ORA, CFSAN, CVM and State
representation.**



FSMA Operations Team Workgroups Charge

Develop a multi-year implementation plan for assuring compliance with the regulations including:

- **Education, outreach & technical assistance**
- **Inspections, compliance & enforcement**
- **Training**
- **Data collection**
- **Performance goals and metrics**
- **FSMA related IT**



Internal and External Stakeholder Engagement



Stakeholder Engagement

- **Transparency Remains a Priority**
- **Next Phase of FSMA Implementation: Inclusive/Coalition Approach**
 - Engage with external public/private sector and internal stakeholders to elicit input to inform the development of post final rule implementation strategies, determine reasonable / practical ways to implement standards
- **Future: Partnerships/Collaboration Key**
 - Establish mechanisms that include working with multiple partners to foster industry understanding of final rules/guidance, and to facilitate high rates of voluntary industry compliance



Per Consent Decree

Regulation	Date for Final Rule
Preventive Controls (Human Food)	08/30/2015
Preventive Controls (Animal Food)	08/30/2015
Produce Safety	10/31/2015
Foreign Supplier Verification Program	10/31/2015
Third Party Accreditation	10/31/2015
Sanitary Transport of Food and Feed	03/31/2016
Intentional Adulteration	05/31/2016

More Information Available

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

The screenshot shows the top portion of the FDA website. At the top left is the U.S. Department of Health & Human Services logo. The main header features the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". To the right of the header is a search bar with a "SEARCH" button. Below the header is a navigation bar with buttons for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products.

Food

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

Guidance & Regulation

- ▶ **Food Safety Modernization Act (FSMA)**
- The Law, Rules & Guidance
- How to Comment on FSMA
- Fact Sheets & Presentations
- Frequently Asked Questions
- Speeches, Videos, & Webinars

FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

Stay connected with FSMA E-mail Updates!

Spotlight

- Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)
- Questions and Answers for Brewers/Distillers on the FSMA Proposed Rule for

Most Popular

- Information by Topic
- Full Text of the Law
- Public Meetings
- Presentations
- Rules and Guidance for Industry



Questions?

Thank you for your attention!

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