FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

FDA

AMERICAN SPICE TRADE ASSOCIATION REGULATORY WORKSHOP

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FSMA Phase 1:
7 Foundational Rules

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

***Supplemental proposals published September 2014*

Compliance Dates

- First compliance dates:
  - PC Human & modernized CGMPs – September 2016
  - Animal CGMPs – September 2016
  - Produce Safety: Sprouts – January 2017
  - Sanitary Transportation – April 2017
  - Foreign Supplier Verification – May 2017
  - PC Animal – September 2017
  - Produce Safety (other than sprouts) – January 2018
  - Intentional Adulteration – July 2019
- Phased in by size of business

Enforcement Discretion

- FDA issued several guidance documents granting enforcement discretion for:
  - Facilities that would be farms except for certain factors
  - Written assurance requirements in the FSVP, PC Human, PC Animal, and Produce rules
  - Animal PC requirements for certain human by-products use as animal food
  - FSVP requirements for importers of food contact substances
  - FSVP requirements for importers of grain Raw Agricultural Commodities
  - Certain supply chain requirements for co-manufacturers
  - FSVP requirements for importers of live animals that must be slaughtered and processed at establishments regulated by USDA and subject to HACCP requirements

FSMA Phase 2: Key Implementation Principles

- Move food system from reaction to prevention
- High rates of compliance critical to success
- Educate before and while regulating
- Facilitate consistent decision making by regulators
- Domestic and import parity
- Risk-based approach to inspection and work planning
- Critical role of partnerships
- Meaningful metrics

FSMA Phase 2: Implementation Plan

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

Industry Education, Outreach, and Technical Assistance

- Key Implementation Principle: Facilitate industry compliance with prevention-oriented standards through guidance; developing tools/resources for education, outreach, and technical assistance
  - Website
  - Guidance Documents
  - Alliances
  - Technical Assistance Networks

Regulator Technical Assistance and Training

- Key Implementation Principle: Invest in regulator training/continuing education, on-going calibration of regulators to promote consistent inspections and decision making
  - FSMA Rule Readiness: Industry Best Practices
  - Alliance Courses with Industry
  - Regulator Specific Training
  - Technical Assistance Network/Resources

Program Alignment: Essential to FSMA Implementation

- District office and laboratory realignments
  - Food districts; medical product districts; import districts
- Inspection and compliance staff trained as specialists by product area.
  - Field investigators will be teaming with HQ SMEs (horizontal integration)
    - Real time collaboration during inspections
    - Improved consistency in our inspection approach
- FY 2015-2016: Planning years
- FY 2017: Transition year
- FY 2018: Operational

Key Preventive Controls for Human Foods (PCHF) Guidance Documents

- Hazard Analysis and Preventive Controls: initial chapters draft published 8/16
  - Chapter 6: Use of Heat Treatments – draft published 8/17
  - Chapter 15: Supply Chain – draft published 1/18
- "Solely engaged" guidance – draft published 10/17
- Listeria in RTE (Ready to Eat) Food: draft published 1/17
- Classification of Activities for Farms and Facilities: draft published 8/16
- Small Entity Compliance Guide: published 10/16
- Planned: Hazard Analysis – additional chapters; Food Allergens, Classification of RTE and non-RTE

PCHF Inspections

- Two field assignments
  - Modernized cGMP + PC lite
  - Full PC
- FY 17 accomplishments:
  - Modernized cGMP: 720 inspections
  - Full PC: 165
- FY 18:
  - Modernized cGMPs: For all firms within compliance date
  - 500 full PC inspections planned (400 domestic, 100 foreign)
    - 4 States are doing PC inspections

Key Foreign Supplier Verification Programs (FSVP) Guidance Documents

- Compliance Guide: draft Published 1/18
- Small Entity Compliance Guide: published 1/18
- Recognition of Acceptable UFI: published 3/17
- Compliance with UFI: published 5/17
- Considerations for Determining Whether A Measure Provides the Same Level of Public Health Protection: draft published 1/18 (also relevant to PC and Produce rules)

FSVP Industry Training - Alliance

- Food Safety Preventive Controls Alliance (FSPCA)
  - Curriculum to train importers subject to the FSVP rule
  - Released updated version 1.1
- Modules for the Preventive Controls and Produce Safety Curricula

FSVP Inspection Program

- Initiated June 2017
- Preannounced
- Evaluating compliance with the FSVP requirements
- Consistent with PC inspections for supply chain provisions

FDA's Accredited Third-Party Certification Program

- Establishes a voluntary, fee-based program for the recognition of accreditation bodies that accredit third-party auditors to conduct food safety audits and, where appropriate, to issue certifications of foreign facilities and the foods for humans and animals they produce.
- These certificates can be used for 2 purposes:
  1. Voluntary Qualified Importer Program
  2. Import Certification
- Not required for FSVP and PC rules
- "Third-Party Audits and FSMA" Fact Sheet: https://www.fda.gov/food/guidanceregulation/fsma/ucm543296.htm

FDA's Accredited Third-Party Program

FDA

FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality.

Accreditation Bodies

Accreditation bodies would in turn accredit qualified third-party auditors.

Third-Party Auditors or Certification Bodies

Third-party auditors/certification bodies would audit and issue certifications for foreign facilities and foods.

Foreign Facility

Foreign facilities may choose to be audited by an accredited auditor/certification body.

FDA's Accredited Third-Party Certification Program

- Recognized four ABs – since 1/18
- ANSI accredited the first certification body – 8/18
- Public Registry of Recognized Accreditation Bodies
- Public Registry of Accredited Third-Party Certification Bodies
- FY19 User Fee Notice - 8/18

Voluntary Qualified Importer Program (VQIP)

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Participation is limited to importers who meet all eligibility criteria, including offering food from a facility certified under FDA's Accredited Third-Party Certification Program.
- Portal opened October 2018 for FY20 benefit year
- User fee notice will publish in August 2019
  - 2015 estimate of annual fee was $16,400
- Benefits to begin October 2019

Benefits of VQIP

- Expedited entry into the U.S.
- Examination and/or sampling generally limited to "for cause" situations
- Any sampling or examination done at location chosen by the importer
- Expedited laboratory analysis, if sampled
- VQIP Importers Help Desk
- FDA will post approved VQIP importers, if desired

Intentional Adulteration

- Initial compliance date 7/19
- Continued stakeholder engagement
- Developing industry training through FSPCA
- Two-phase inspectional approach
  - Quick-Check
  - Full inspection

Recalls

- Mandatory Recall Authority
- SCORE Team

FDA's Imported Food Safety Toolkit

Ensuring safe food is offered for import

- Foreign inspections, facilities and farms
- Foreign Supplier Verification Programs
- Third-Party Certification – FDA's Accredited TPCP, Reliable audits
- Voluntary Qualified Importer Program
- Partnerships and collaborations, e.g. Systems Recognition
- Outreach, education, training, capacity building

Interdicting unsafe food at the port of entry

- Facility registration, prior notice, screening and entry review processes
- Examination, sampling, detention
- Import alerts, certification

Responding to unsafe food that has entered the market

- Outbreak response
- Recalls

What is Systems Recognition?

- A tool for regulatory cooperation and partnership
- Systems recognition describes whether a country's food safety system provides a similar, though not necessarily identical, system of protections; and the food safety authority provides similar oversight and monitoring resulting in comparable food safety outcomes.

How does Systems Recognition Differ From Equivalence?

- Systems recognition is an assessment of an overall food safety system and is not required to access to the U.S. market for FDA-regulated foods.
- Equivalence determinations are: an obligation under the WTO-SPS Agreement; can be accepted for a specific measure or measures related to a certain product or category of products, or on a system-wide basis; and are a market access tool.
- Equivalence can be one-way. Unlike equivalence, systems recognition is intended to be a two-way partnership.

How Does Systems Recognition Benefit FDA?

- Systems recognition allows us to:
  - Allocate our resources, including inspectional and port of entry resources, in a more risk-based manner
  - Identify those partners we can rely on for follow-up
  - Offers the prospect of sharing data and information to enhance food safety activities

Food Safety Systems Recognized Countries

- New Zealand – 2012
- Canada – 2016
- Australia - 2017

Leveraging Public-Private Partnerships for Food Safety

- Private assurance programs - a cornerstone of food safety in the business to business relationship
- Public sector can benefit from leveraging existing best practices in the food safety industry
  - Assessing alignment between private assurance programs and public food safety requirements
  - Determining reliability of food safety audits conducted by competent auditors

FDA's Nutrition Innovation Strategy

- Modernizing Claims
- Modernizing Ingredient Labels
- Modernizing Standards of Identity
- Implementing the Nutrition Facts Label and Menu Labeling
- Reducing Sodium


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