Human PC Final

Final Rule for Preventive Controls for Human Food

ASTA, October 14, 2015

http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

Human PC Final

Background

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

- Originally proposed: January 16, 2013
- Supplemental proposal: September 29, 2014
- Public comments: More than 8,000 for the original proposal; more than 1,300 for the supplemental proposal
- Final rule: published September 17, 2015

Who is Covered by PCHF?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
  - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply

Updated Current Good Manufacturing Practices

- Protection against allergen cross-contact
- Certain provisions containing recommendations have been deleted
- Previously nonbinding provisions, such as education and training, are now binding.

Qualifications of Individuals

- Must have the education/ training/ experience necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties
- Must receive training in the principles of food hygiene and food safety, as appropriate to the food, the facility and the individual's assigned duties

Food Safety Plan

- Hazard analysis
- Preventive controls
- Supply-chain program
- Recall plan
- Procedures for monitoring
- Corrective action procedures
- Verification procedures

Food Safety Plan – Hazard Analysis

- Hazard identification must consider known or reasonably foreseeable biological, chemical and physical hazards.
  - These could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain.
- Hazard evaluation must consider severity of illness/injury and probability of occurrence in absence of preventive controls

Food Safety Plan – Preventive Controls

- Measures required to ensure that hazards are significantly minimized or prevented. These include:
  - Process controls
  - Food allergen controls
  - Sanitation controls
  - Supply-chain controls
  - Recall plan

Food Safety Plan – Preventive Controls

- Include controls at critical control points (CCPs), if any, and controls other than those at CCPs that are appropriate for food safety
- Not required when hazard is controlled by another entity later in the distribution chain
  - Disclose that food is for further processing
  - Obtain assurances hazard will be controlled

Assurances Regarding PCs

- Must include:
  - Name, date, signature
  - The specific assurance required
  - Acknowledgement that the facility that provides the assurance assumes legal responsibility to act consistent with the assurance and document actions taken to satisfy the assurance
  - Provision regarding termination

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Food Safety Plan - Monitoring

- Facility must have written procedures, including the frequency they are to be performed, for monitoring the preventive controls (as appropriate to the nature of the preventive control)
- Monitoring must be documented in records subject to verification.

Food Safety Plan – Corrective Actions and Corrections

- Facility must have written procedures for steps to be taken when preventive controls are not properly implemented
  - Identify and correct a problem
  - Reduce likelihood of occurrence
  - Evaluate food for safety
  - Prevent adulterated food from entering commerce

Food Safety Plan - Verification

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- Includes (as appropriate to the facility, food and nature of the preventive control):
  - Validation of preventive controls
  - Verification of monitoring and corrective actions
  - Calibration of process monitoring and verification instruments
  - Product testing, environmental monitoring
  - Records review

Reanalysis of Food Safety Plan

- At least every three years
- Whenever there is a significant change that creates the potential for a new hazard or a significant increase in one previously identified
- When there is new information about potential hazards associated with a food
- When a preventive control is ineffective

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PC Qualified Individual

- A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

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Responsibilities of a PC QI

- Preparation of the food safety plan
- Validation of preventive controls
- Review of records
- Reanalysis

Facilities Storing Unexposed Packaged Food

- Exempt from the requirements for hazard analysis and risk-based preventive controls
- Modified requirements apply if the food requires time/temperature control for safety
  - Monitoring, corrective actions, and verification for temperature controls

"Solely Engaged in Storage"

- Holding – Storage of food
- Includes incidental activities
  - activities performed for the safe or effective storage of that food (e.g., fumigating)
  - activities performed as a practical necessity for the distribution of that food (e.g., breaking down pallets)

Supply-Chain Program

- Manufacturing/processing facilities must have a risk-based supply-chain program to ensure control of hazards in raw materials and other ingredients when the control is applied before receipt (“supply-chain applied control”).

Supplier

- The establishment that manufactures/ processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

Supply-Chain Program

- Use approved suppliers
- Determine appropriate supplier verification activities
- Conduct and document supplier verification activities
- When applicable, verify a supply-chain-applied control applied by an entity other than the facility's supplier or obtain documentation of verification by another entity

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Supplier Verification Activities

- Onsite audits
- Sampling and testing
- Review of relevant food safety records
- Other as appropriate

Activity and frequency based on nature of hazard, where it is controlled and supplier performance.

Onsite Audits

- Annual audits are the appropriate verification activity for hazards that may cause serious adverse health consequences/death
- Other verification activities or less frequent auditing may provide adequate assurance that hazards are controlled.

Onsite Audits

- Must be performed by a qualified auditor
  - Government employee
  - Third-party (e.g., agent of a certification body)
  - Employee of receiving facility
  - Another entity in the supply chain
- Inspection may substitute for audit in certain cases

Qualified Facilities

- Very small businesses are qualified facilities exempt from the requirements for hazard analysis and risk-based preventive controls (but have some modified requirements).
  - Average less than $1M per year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale

Modified Requirements for a Qualified Facility

- Attestation the facility is a qualified facility; AND
- Attestation that hazards have been identified and that preventive controls have been implemented and are being monitored; OR
- Attestation facility is in compliance with an applicable non-Federal food safety law

Compliance Dates for Businesses

- *Very small businesses* (less than $1 million in annual food sales): Three years
- Businesses subject to the Pasteurized Milk Ordinance: Three years
- *Small businesses* (a business with fewer than 500 full-time equivalent employees): Two years
- *All other businesses*: One year
- Separate compliance dates for supply-chain program

Planned Guidances

- Hazard analysis and preventive controls
- Environmental monitoring
- Food allergen controls
- Validation of process controls
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

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For More Information

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- To contact FDA about FSMA and find the new online form for submitting questions: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

ASTA Regulatory Workshop

Foreign Supplier Verification Program

October 14, 2015

Sharon Lindan Mayl, JD
Senior Advisor for Policy
Office of Foods and Veterinary Medicine
Food and Drug Administration

http://www.fda.gov/fsma

FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW

Background

Challenges Presented by Globalization

- Increasing volume of imported products
- Greater complexity in imported products
- More foreign facilities supplying the U.S.
- Greater complexity in supply chains
- Imports coming from countries with less sophisticated regulatory systems
- Greater opportunities for economic fraud
- Food security concerns

Traditional Import Paradigm

- Border focused
- Virtually all of the information used to assess admissibility came from the import data submitted to CBP.
- FDA made a decision about the compliance status of the product at the time of entry with limited time, resources, and information.

Paradigm Shift

- The border can no longer be our primary line of defense. It should only serve as a final checkpoint on other controls.
- FSMA creates a multilayered safety net.
  - Role of manufacturer
  - Role of importers
  - Role of third parties
  - Role of foreign regulatory bodies
  - Role of FDA

FSMA Import Provisions

- Sec. 201. Inspection Frequency
- Sec. 301. Foreign Supplier Verification Program (FSVP)
- Sec. 302. Voluntary Qualified Importer Program (VQIP)
- Sec. 303. Certification for Food Imports
- Sec. 304. Prior Notice of Imported Food Shipments
- Sec. 305. Capacity Building
- Sec. 306. Inspection of Foreign Food Facilities
- Sec. 307. Accreditation of Third-Party Auditors
- Sec. 308. Foreign Offices of the FDA
- Sec. 309. Smuggled Food
- Sec. 404. Compliance with International Agreements

FSVP Proposed Rule

FSVP Key Principles

- Importers would be responsible for ensuring that the food they bring into the U.S. meets FDA safety standards.
- The requirements will provide flexibility based on the risk of the food.
- Under FSMA section 404, requirements must be consistent with WTO, other agreements.

Who Is Covered by FSVP?

- All importers must establish and follow an FSVP, unless otherwise exempted.
- U.S. importer is the person who has purchased the food offered for import.
  - If there is no U.S. owner at the time of entry, the importer is the U.S. consignee.
  - If no U.S. owner or consignee at time of entry, the importer is the U.S. agent/representative of the foreign owner/consignee.

Who Is Exempt from FSVP?

- Importers of juice and seafood whose suppliers are in compliance with the HACCP program (part 120 or 123)
- Small quantities of food imported for research and evaluation purposes
- Food imported for personal consumption
- Facilities subject to FDA's low acid canned food requirements (microbiological hazards only)
- Alcoholic beverages
- Food that is trans-shipped or that is imported for future export and not consumed or distributed in the U.S.

FSVP Proposed Rule

- Importers would generally be required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies.
  - Most requirements must be done by a qualified individual
- In general, importers would need to provide:
  - Hazard Analysis
  - Risk evaluation
  - Supplier verification activities
  - Complaints, investigations, and corrective actions (if necessary)
  - Periodic reassessment of the FSVP (every 3 years)
  - Importer identification at entry
  - Recordkeeping

Hazard Analysis

- Must be written
- Identify any “known or reasonably foreseeable hazards” are “significant”
  - “Significant hazard” is one that a knowledgeable person would, based on a hazard analysis, establish controls to significantly minimize or prevent the hazard in the food and components to manage those controls
- Hazards can be:
  - Microbiological, chemical/radiological, or physical
  - Naturally occurring, unintentional, intentionally introduce for economic gain

Evaluation of Risk

- Takes a holistic approach
- In addition to hazard analysis, importer would be required to consider supplier-related risks in determining appropriate supplier verification activities
- Importer would be required to promptly reevaluate risks when it becomes aware of new information about risks

Supplier Verification Activities

- Importer would need to establish and follow written procedures to ensure use of suppliers approved on the basis of the risk evaluation
- When necessary and appropriate, importer may use unapproved supplier if importer subjects the food to adequate verification activities

Supplier Verification Activities

- Importer to determine appropriate verification activities (and frequency) based on risk evaluation
- Possible verification activities:
  - Onsite audit
  - Sampling and testing
  - Review of food safety records (e.g., food safety plans, deficiencies, corrective actions)
  - Other appropriate activities
- When there is a serious hazard controlled by foreign supplier, importer would need to obtain an annual onsite audit unless it determined that other activities and/or less frequent auditing are appropriate

Modified FSVP Requirements

- Importation of a dietary supplement or dietary supplement component
- Importation of food by very small importer or from very small foreign supplier
- Importation of food from a foreign supplier in good compliance standing with a food safety system FDA has officially recognized as comparable to U.S. system

Importers in Compliance with PC Supplier Program Provisions

- Importers in compliance with PC supplier program provisions would be deemed in compliance with most FSVP requirements
  - To avoid redundant regulations on importers who also are receiving facilities that import raw materials or other ingredients
- If importer's customer is in compliance with PC supplier program provisions, importer would annually obtain written assurance of compliance

Status of FSVP

Final Rule: October 31, 2015

Proposed Compliance Dates:

- Generally 18 months (1.5 years)

OR

- 6 months after the foreign supplier is required to comply with preventive controls or produce safety regulations

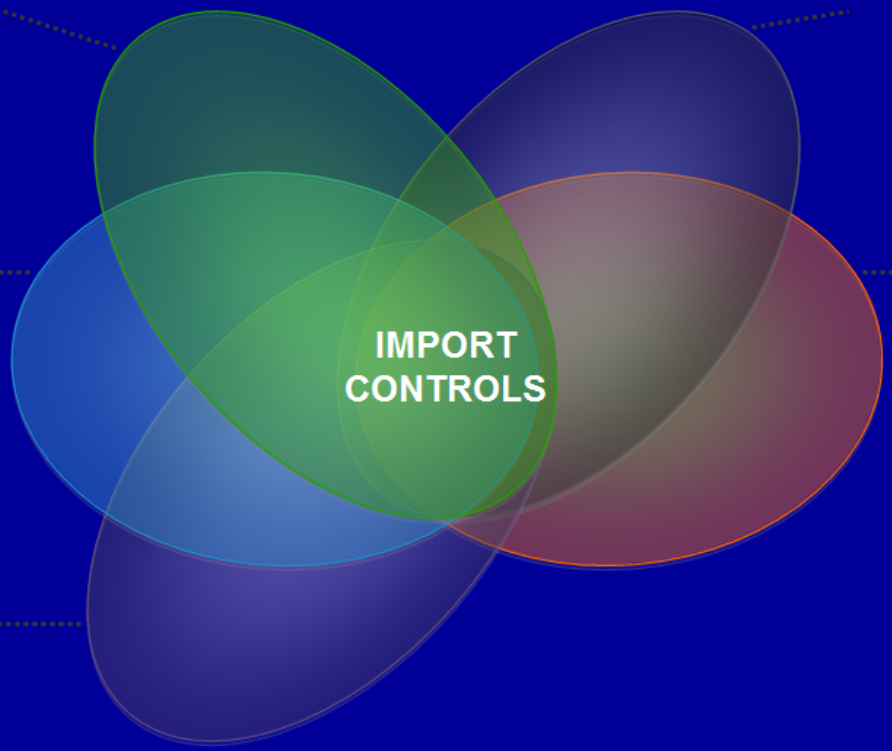
Phase II FSVP Implementation

Programs Under Import Controls Phase II Workgroup

VQIP
Sec. 302: Allows for expedited review and entry; facility certification required (Sec. 806 of FD&C Act)

Accredited Third Party
Sec. 307: Accreditation of Third-Party Auditors / Certification Bodies to conduct food safety audits and to issue certifications (Sec. 808 of FD&C Act)

Import Certification
Sec. 303: Certification for high-risk food imports (Sec. 801(q) of FD&C Act)



Lab Accreditation
Sec. 202: Provides for recognition of laboratory accreditation bodies (Sec. 422 of FD&C Act)

FSVP
Sec. 301: Requires importers to develop, maintain and follow an FSVP for each food imported, unless an exemption applies (Sec. 805 of FD&C Act)

***Systems Recognition**

Critical Operational Considerations

- Industry/stakeholder education, outreach, and technical assistance
- Regulator training and technical support
- IT, integration of domestic and import systems
- FDA work planning/staffing to help ensure industry compliance, e.g., inspections, audits, sample collections and import program data integration to target resources
- International trade context
- Requested $25.5 M in FY16 for modernized import system

Questions

- For more information, visit our website: http://www.fda.gov/fsma

FSMA Implementation Update

ASTA Regulatory Workshop
October 14, 2015

Kathy Gombas
Senior Advisor, Office of Food Safety
FDA/Center for Food Safety and Applied Nutrition

Presentation Overview

- FSMA Implementation Guiding Principles
- Industry Training / Technical Assistance
- Regulator Training / Technical Assistance
- Inspection / Compliance Approaches

Driving Change and Guiding FSMA Implementation

- FDA's Program Alignment Initiative
- FDA's FSMA Operational Strategy

FDA Program Alignment Initiative

February 2014 FDA Commissioner's Memo

- Vertically Integrated, Commodity Specific Programs
- Specialization of Inspection / Compliance Staff, Regulatory Labs
- Clear, Current, Consistently Applied Technical / Operational Policy
- Clear Roles, Responsibilities, Streamlined Decision Making
- Risk Based Allocation of Program Resources
- Agreed Upon Performance/Public Health Metrics

FDA's FSMA Operational Strategy

May 2014 Strategy and Guiding Principles

How FDA will Operate Differently

- 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

General FSMA Implementation Guiding Principles

Industry Education, Outreach and Technical Assistance

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

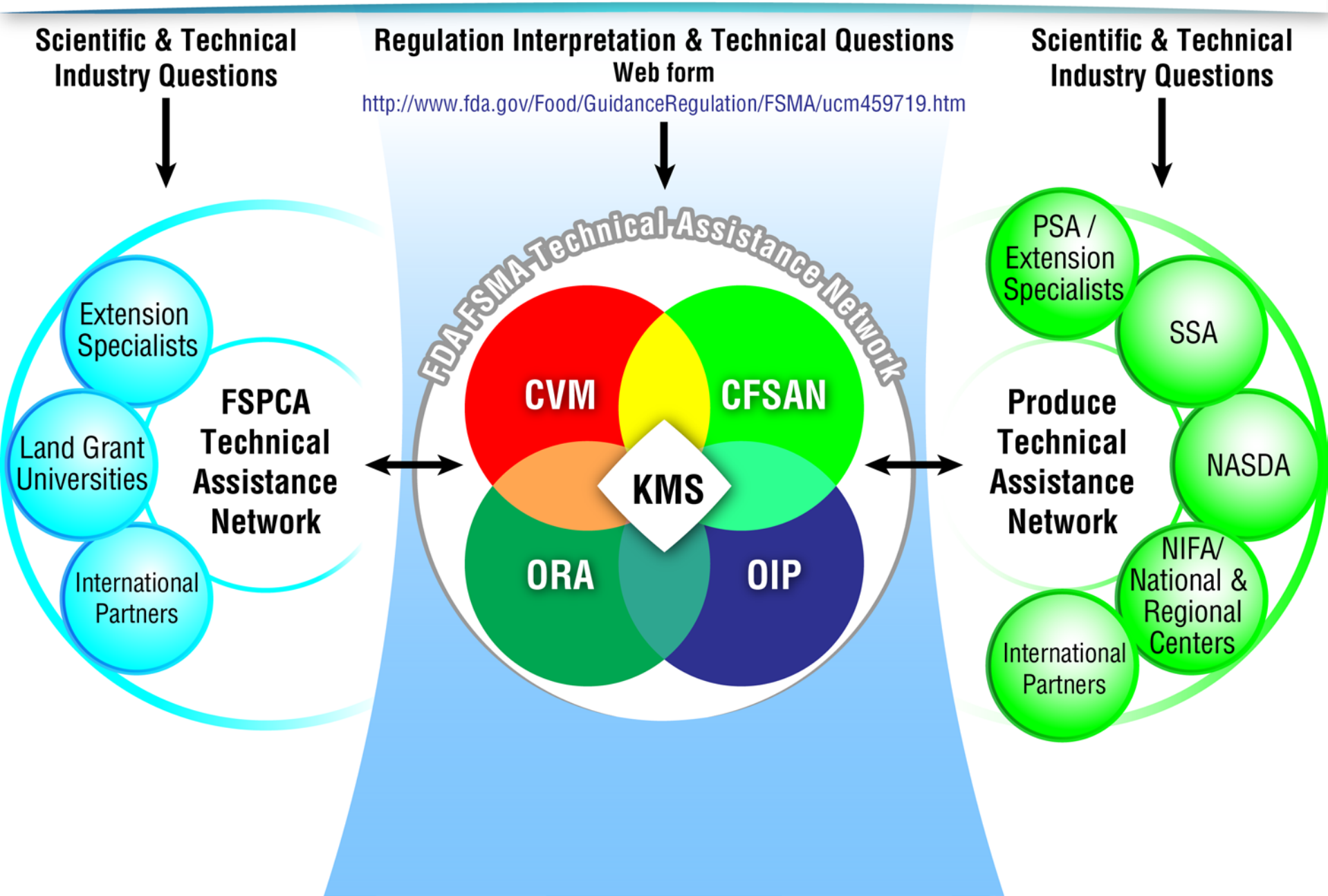
Technical Assistance Networks

- Establish within FDA a consolidated FSMA Technical Assistance Network to provide central, consistent sources of outreach and technical assistance

- Leverage existing internal infrastructure, business processes and IT systems (Knowledge Management System)

- Leverage external resources, e.g. Alliances, Extension Specialists, Universities, International Partners

FSMA Technical Assistance Networks



FDA Technical Assistance Network

- Launched FDA FSMA Technical Assistance Network on September 10, 2015

- For questions go to http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

Food Safety Modernization Act (FSMA)
The Law, Rules & Guidance
How to Comment on FSMA
Fact Sheets & Presentations
Frequently Asked Questions
FDA Actions to Date
Archive

How to Contact FDA About FSMA

You may contact FDA about FSMA by submitting an inquiry form.

The modified form is designed to facilitate questions that are specific to FSMA and its implementation. Your use of the forr will provide the FSMA Technical Assistance Network with the information needed to give accurate and timely responses and to improve our customer service. We hope you find our online form useful in identifying the specific nature of your inquiry and we remain open to suggestions about improving the form to meet your needs.

Submit Inquiry

You may also mail your question to the address below:

Food and Drug Administration
5100 Paint Branch Pkwy
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

NOTE: For Food Safety Preventive Controls Alliance Training questions, please direct inquiries to fspca@iit.edu.

Food and Cosmetics Information Center (FCIC) Inquiry Form
(FDA form # 3907)

* = Required Information

I am a member of this category * --None--

Email *

Country * --None--

Zip Code *

Is your inquiry specific to the Food Safety Modernization Act requirements * Yes ☐ No ☐

Inquiry (650 character limit) *

4 q 8 v s f

Enter the code above here *

The Food and Drug Administration's (FDA), Food and Cosmetic Information Center (FCIC) will respond to your web inquiry as soon as possible. However, response times may vary, due to public health priorities and the high volume of inquiries we receive. We strive to provide the public with accurate and current information, which at times requires extensive research. Please be assured that we will respond as soon as possible. Thank you for your patience and for contacting FDA's FCIC.

Submit

U.S. Department of Health and Human Services

U.S. Food and Drug Administration

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(FDA form # 3907)

* = Required Information

I am a member of this category *

Email *

Country *

Zip Code *

Is your inquiry specific to the Food Safety Modernization Act requirements *

Inquiry (650 character limit) *

--None--
--None--
Academia
Consumer
Media
Medical
Industry/Business
Other Government Official – Domestic
Other Government Official - International
Regulator – Compliance Staff
Regulator – FDA Investigator
Regulator – State Inspector
N/A

4 q 8 v s f

Enter the code above here *

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* = Required Information

I am a member of this category * --None--

Email *

Country * --None--

Zip Code *

Is your inquiry specific to the Food Safety Modernization Act requirements * Yes ☑ No ☐

FSMA Topics * --None--

- --None--
- Other
- Preventive Controls-Animal Food
- Preventive Controls-Human Food

Inquiry (650 character limit) *

4 q 8 v s f

Enter the code above here *

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(FDA form # 3907)

* = Required Information

I am a member of this category * --None--

Email *

Country * --None--

Zip Code *

Is your inquiry specific to the Food Safety Modernization Act requirements * Yes ☐ No ☑

Product * --None--

Product Type *

Inquiry (650 character limit) *

- --None--
- Cosmetic
- Dietary Supplement
- Food

4 q 8 v s f

Enter the code above here *

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Inquiry (650 character limit) *

4 q 8 v s f

Enter the code above here *

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Submit

Web Form Auto Response

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC) has received your inquiry. Your inquiry has been assigned **case number 00055396.** Please retain this case number and reference it in future correspondence regarding this inquiry.

We will respond to your inquiry as soon as possible. However, response times may vary, due to public health priorities and the high volume of inquiries we receive.

We strive to provide the public with accurate and current information, which at times requires extensive research. Please be assured that we will respond as soon as possible.

Industry Training & Technical Assistance

Plans include

- Collaborating with the Food Safety Preventive Controls Alliance to establish training and technical assistance
  - Domestic technical assistance through extension community
  - Collaborating with the Alliance on capacity building through its International Subcommittee (International Partners)
- Working with regulatory counterparts and multinational organizations
- Developing and disseminating outreach, education, and technical materials

General FSMA Implementation Guiding Principles

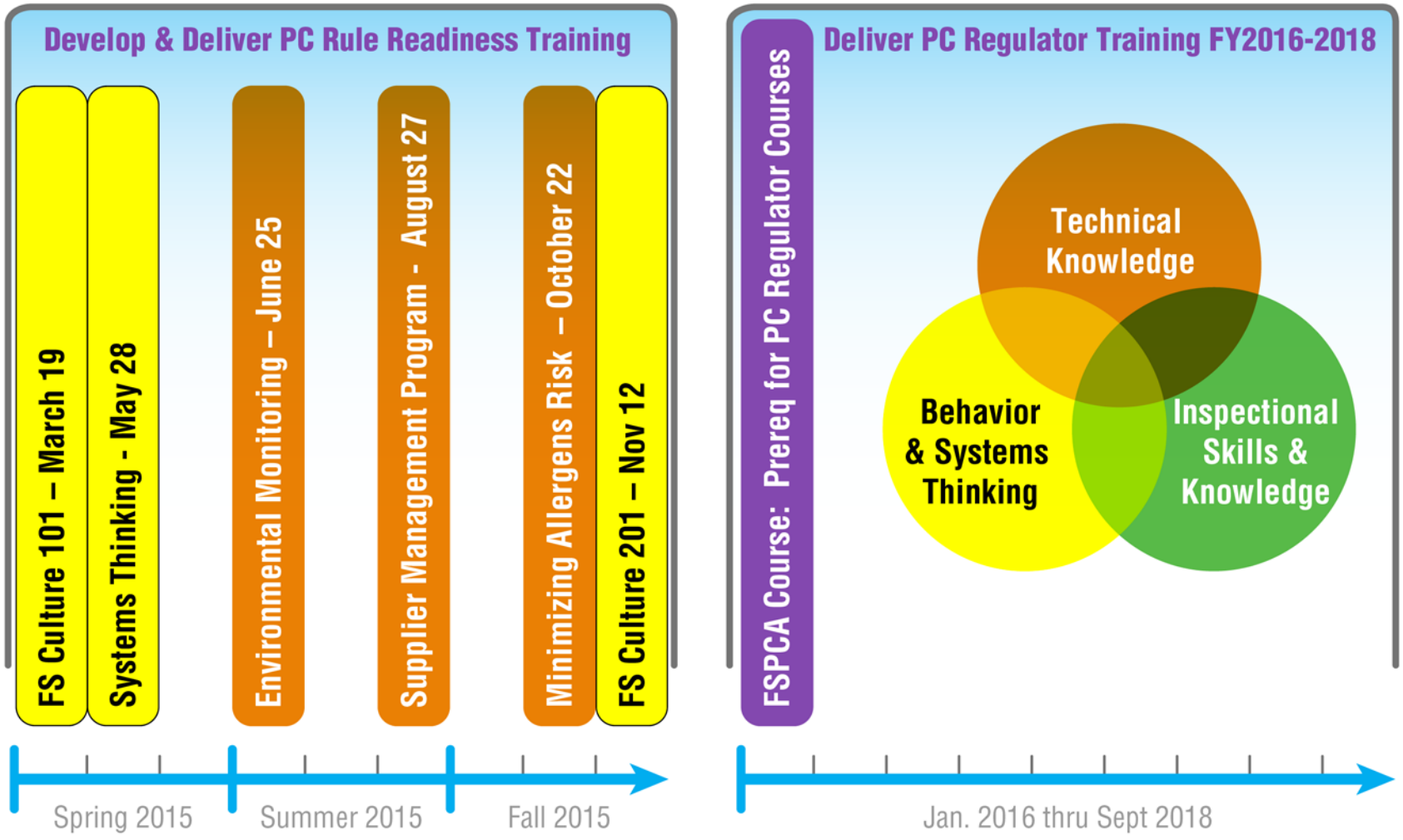
Regulator Education, Outreach and Technical Assistance

- **Invest in regulator training/continuing education, on-going calibration of regulators to promote consistent inspections and decision making**

Regulator Training

- **FDA/State regulators will attend Alliance training with industry**
- **Regulators will also attend regulator-specific training**
- **Regulator training will include:**
  - **Technical Knowledge**
  - **Inspection Skills and Knowledge**
  - **Behavior and Systems Thinking**

PC Training Plan: FY15 PC Rule Readiness Plan & FY 15-18 PC Regulator Plan



PC Rule Readiness TRAINING

2015 Sessions

- *Food Safety Culture 101 – March 19*
- *Systems Thinking – May 28*
- *Environmental Monitoring* - June 25
- *Supplier Management Program*- August 27
- *Minimizing Allergens Risk* - October 22
- *Food Safety Culture 201* – November 12

Events for sharing industry best practices & FDA perspectives

Development and Delivery Model

Objective: To develop and deliver PC Regulator & Train-the-Trainers (TTT) curricula
Curricula Developers, TTT, and Instructor Cadre will include experts from ORA/CFSAN/CVM/States
FSMA Training Workgroup established Selection Criteria for Curricula Developers, TTTs and Instructors

Curricula Development → **Delivery**

Curricula Developers

- Design & Develop PC Regulator Curriculum
- Design & Develop TTT curriculum

Train-the-Trainers (TTT)

- Receive:
  - Instructor Skills Course
  - FSPCA Course (knowledge)
- Deliver PC Regulator & TTT curricula to Instructor Cadre
- Provide support & mentoring to Instructor Cadre
- Provide technical assistance to Industry, Instructor Cadre, and Food & Feed Safety Staff

Instructor Cadre

- Receive:
  - Instructor Skills Course
  - FSPCA Course (knowledge)
  - FDA PC Regulator & TTT Course
- Deliver PC Regulator curriculum to Food & Feed Safety Staff (phased approach FY16-18)
- Provide support & mentoring to Food & Feed Safety Staff
- Provide technical assistance to Food & Feed Safety Staff

Food and Feed Safety Staff*

- Receive:
  - FSPCA course (prerequisite)
  - PC Regulator Training
- Conduct PC Inspections
  Phased in over 3 years:
  - Large Firms FY 2017
  - Small Firms FY 2018
  - Very Small Firms FY 2019

** Includes FDA investigators, supervisors/managers, compliance officers, Subject Matter Experts, Technical Experts, and state inspectors*

Technical Assistance for Regulators

- **Internal technical network** to provide consistent sources of technical assistance
  - Infrastructure – Field Staff through Subject Matter Experts
  - Knowledge Management System

- **Resource Library**

Facility Information and Resources

- Firm History
  - Compliance Actions
  - Sampling Results
  - RFRs
  - Recalls
  - Consumer Complaints
- Resources
  - IOM
  - CPGs
  - Hazards and Controls
  - Special Instructions / Assignments
  - Guidance Documents
  - Links for Training Videos
  - FACT Sheets
  - Fresh Cut Processing
  - Nut Roasting
  - Pasteurization
  - List of SME's

Name	Email Address	Phone #	Expertise
Wayne Rockford	*Wayne.Rockford@fda.hhs.gov*	*240-402-0000*	*Fresh Cut Produce*
Joseph Walsh	*Joseph.Walsh@fda.hhs.gov*	*240-402-1000*	*Nut Processing*

General FSMA Implementation Guiding Principles

Regulatory Inspections

Goal: Gain Industry Compliance

Not a "One Size Fits All Approach"

- Wider range of inspection, sampling, testing and data collection activities
- Consider firm's food safety culture, compliance history, work of public-private third parties to establish frequency/scope of inspections

General FSMA Implementation Guiding Principles

Regulatory Inspections (cont.)

Systems Based Inspections, Not "Observation Focused"

- Noncompliance viewed in context of firm's food safety system/programs, public health risk/impact; identification of system failures
- Review of self identified non-conformances and firm's actions
- Recognize firms for finding/fixing problems: continuous improvement

Interactive, Cooperative Inspections

- Open, constructive dialogue with firm employees during inspections
- Investigators and Center subject matter experts work together to gain firm compliance/corrective actions

General FSMA Implementation Guiding Principles

Compliance/Regulatory Strategies

Encourage Industry to Comply and Make Corrections on its Own

- Timely, adequate corrective actions to areas of noncompliance
- Swift enforcement when corrective actions are not forthcoming

General FSMA Implementation Guiding Principles

Compliance/Regulatory Strategies (cont.)

Recognition that Not all Observations are Equal Relative to Risk and Potential for Public Health Impact

- Deviations categorized as critical, major, minor; linked to public health outcomes

Regulatory strategy that is dynamic

- Different violations trigger different regulatory response
- Different industry timeframes for corrective action
- Different timeframes for FDA or state verification

Questions?