



FSMA Implementation Update

**State Communication Internal Dialogue for
Human Food
11/10/2015**

**Priya Rathnam
Center for Food Safety and Applied Nutrition**



Introduction

- Preventive Controls (PC) Human Food Background
- Inspection Approach
- Regulatory Strategy
- Regulator Training
- Information Technology (IT)/Observation Corrective Action Report (OCAR)
- Technical Assistance

FSMA Implementation

“A Continuum”

- **Phase 1: Set Standards**
 - **Develop regulations, guidance, policy**
- **Phase 2: Design Strategies to Promote and Oversee Industry Compliance**
 - **Identify performance metrics to measure success**
- **Phase 3: Implement, Monitor, Evaluate, Refresh**
 - **Transition strategies and performance metrics from design to operational, evaluate success**

Phase 1: Standard Setting

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	Jan 16, 2013	Aug 30, 2015 Sept 17, 2015 [◇]
Preventive Controls (Animal Food)*	Oct 29, 2013	Aug 30, 2015 Sept 17, 2015 [◇]
Produce Safety*	Jan 16, 2013	Oct 31, 2015
Foreign Supplier Verification Program*	Jul 29, 2013	Oct 31, 2015
Third Party Accreditation	Jul 29, 2013	Oct 31, 2015
Sanitary Transport	Feb 5, 2014	Mar 31, 2016
Intentional Adulteration	Dec 24, 2013	May 31, 2016

**Supplemental proposals published September 2014*

◇ Final rule publication date

Preventive Control Rules

Key Areas Addressed

- **Establish Current Good Manufacturing Practices for animal food**
- **Hazard Analysis and Risk-Based Preventive Controls**
 - **Each facility is required to implement a written food safety plan that focuses on preventing hazards in animal foods**
- **Revised Definition of a ‘Farm’**



PC Rule for Human Food Businesses Compliance Dates

Table 53.--Compliance Dates for the Requirements of Part 117 Other than the Requirements for a Supply-Chain Program (Subpart G)

Size of Business	Compliance Date
Qualified facility (including very small business) as defined in § 117.3	September 17, 2018, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016
Small business as defined in § 117.3	September 18, 2017
Businesses subject to the Pasteurized Milk Ordinance	September 17, 2018
All other businesses	September 19, 2016

Small Business – business with fewer than 500 full-time equivalent employees

Very Small Business – less than \$1M per year in sales of human sales

PC Rule for Human Food

Compliance Dates

Supply-Chain Program

Separate compliance dates have been established for the supply-chain program provisions to accommodate compliance dates for suppliers of different sizes and subject to different rules (e.g., Produce Safety Standards).

Planned Guidance

PC Rule for Human Food Facilities

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



Key Implementation Principles

Accountability / Stakeholder Engagement

- **Work closely with industry, government agencies, academia, and other key stakeholders/partners**
- **Recognize the role of the marketplace in influencing and expanding industry compliance with FSMA rules, i.e., leverage with private/public third party audit system**
- **Develop meaningful public health/performance metrics to measure success**

Inspection Approach

- No “one size fits all” approach
- Systems based; not observation focused
- Large firm structure may lend itself to evaluating:
 - Adequacy of overarching food safety programs relative to the Food Safety Plan that are developed and managed at the corporate level
 - Implementation of the Food Safety Plan at the facility level
- Two-tier feasibility study (Human Food)

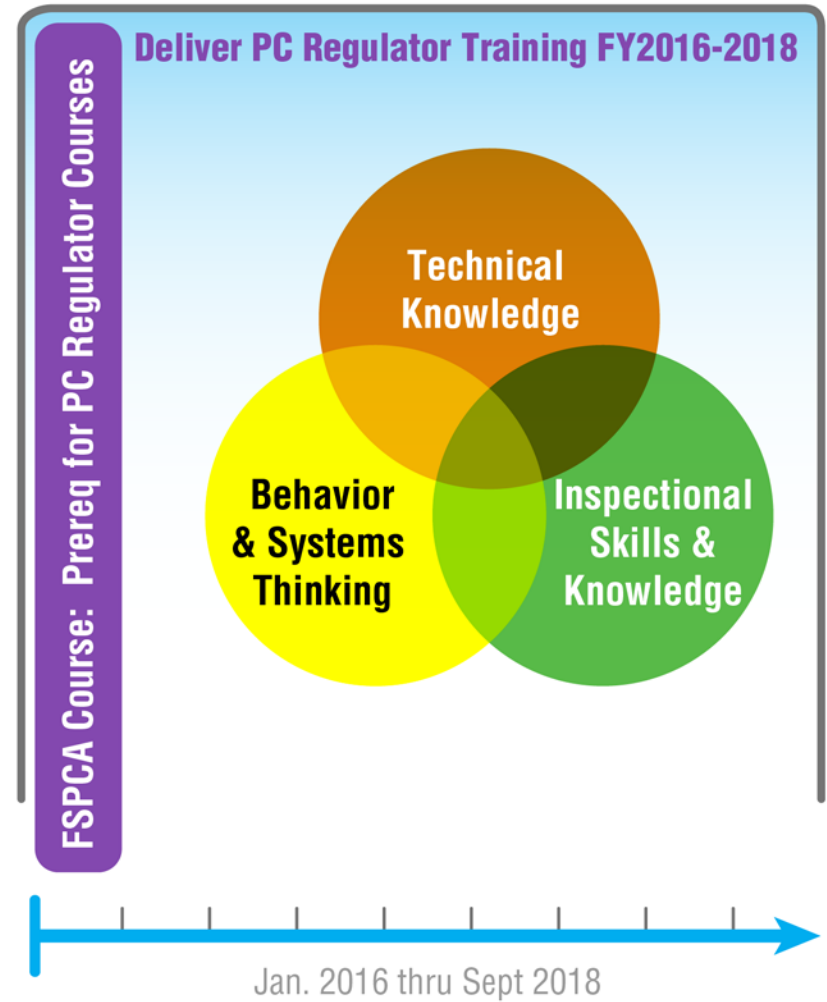
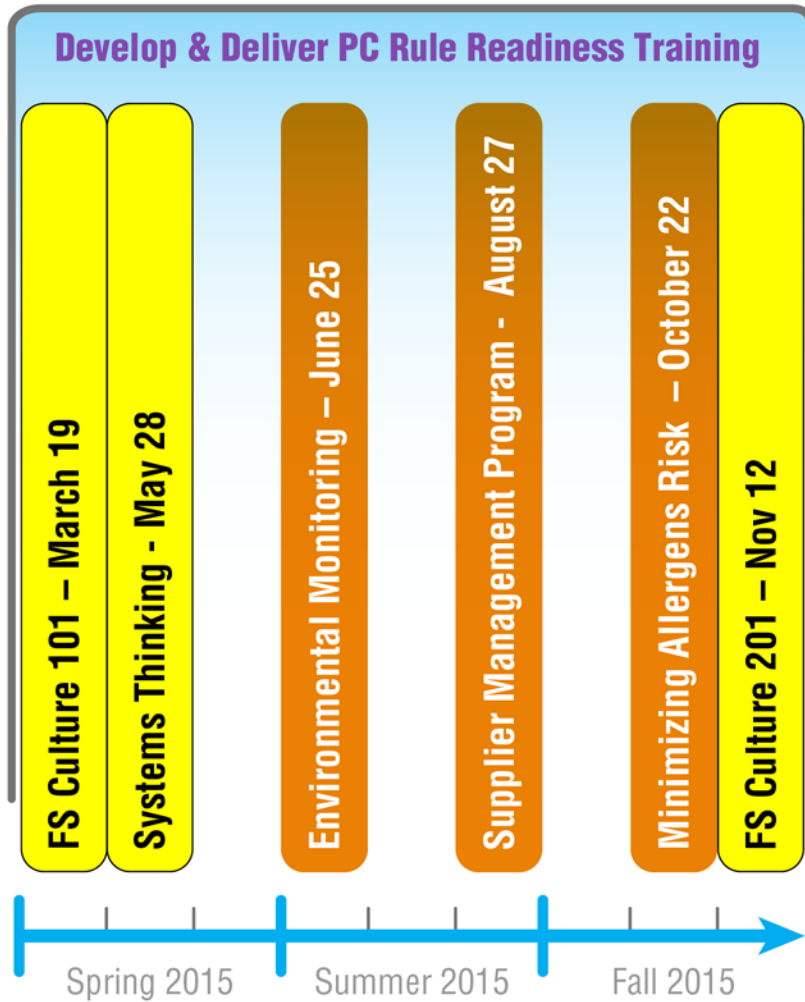
PC Rules: **Regulatory Strategy**

- **Rethinking what goes on an FDA483, how a FDA483 is written, whether certain noncompliance issues, if corrected during the inspection, need to be cited on the FDA483**
- **Rank violations according to public health outcome**
 - **Minor, major, critical to inform the classification (NAI, VAI, OAI), follow-up verification activities and timing for these activities, workplanning**

Regulatory Training

- FDA/State regulators will attend Food Safety Preventive Controls 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



Behavior & Systems Thinking
 Technical Knowledge
 FSPCA Training
 Inspection Skills & Knowledge

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

IT and OCAR

OCAR =

Observation Corrective Action Report

- One stop - inspection preparation, reporting, and compliance follow-up reporting platform
- Report = structured data
- State and Industry Portal

Technical Assistance

- Establish an FDA FSMA Technical Assistance Network to provide central, consistent sources of outreach and technical assistance for industry & regulators
 - Part 1: FSMA Rule Interpretation Questions
 - Part 2: Food Safety Regulatory Community

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

FDA Technical Assistance Network

Part 1

- Launched FDA's FSMA Technical Assistance Network on September 10, 2015
 - Provide technical assistance to industry, regulators, academia, and consumers regarding FSMA
 - Address questions related to FSMA rules, programs, and implementation

- Collaborate with external technical resources, e.g. Alliances, Extension Specialists, Universities, International Partners

FDA Technical Assistance Network

Part 1

- FDA At-a-Glance - “How to Submit a Question”
- Submit inquiries via the web form or by mail
- To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)

FDA Technical Assistance Network

- Questions will be tracked and trended using the Knowledge Management System
- Repeat questions will be addressed in FAQs or guidance documents posted on www.fda.gov/fsma
- Future efforts will include a Public Knowledge Base

FSMA Information for FDA and States

For the latest information about FSMA and our internal implementation efforts:

FDA Commissioned Officials: <https://www.foodshield.org/>

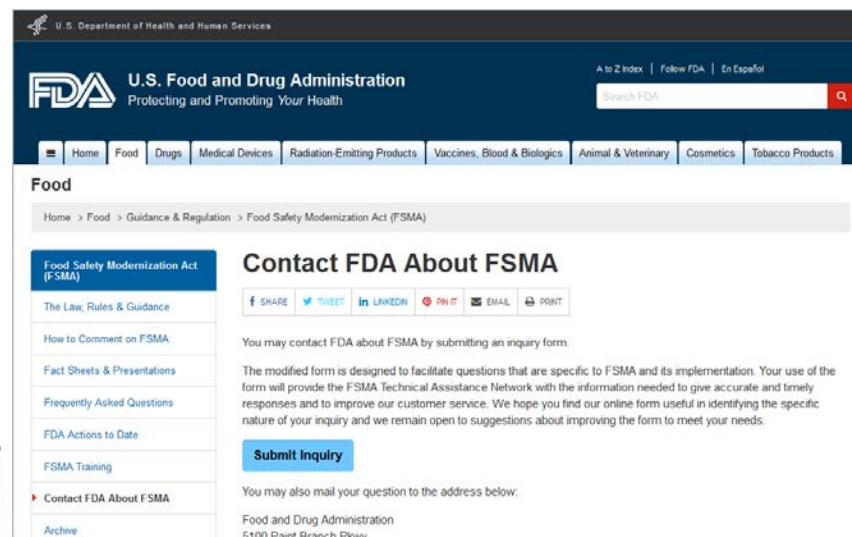
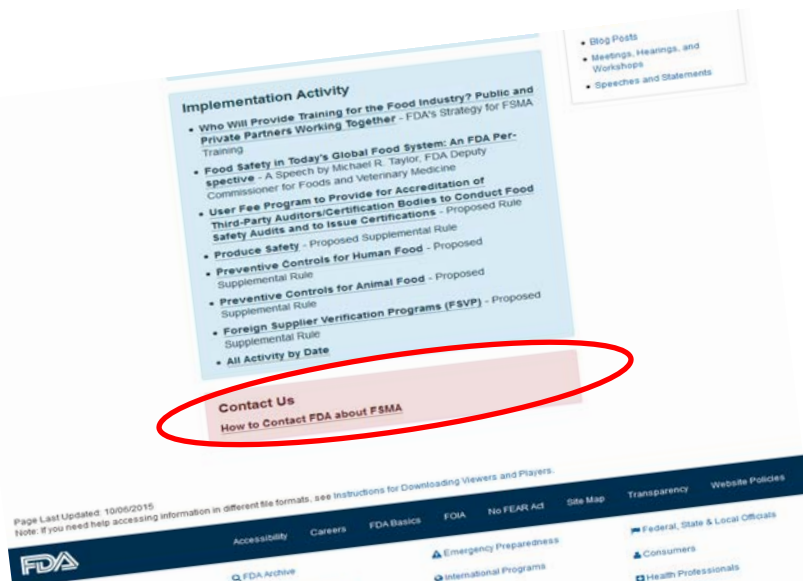
FDA Employees:

<http://inside.fda.gov:9003/ORA/ucm292925.htm>

- ***FSMA Implementation Fact Sheet - UPDATED***
- ***Questions and Answers Document – UPDATED***
- ***FSMA Presentations***
- ***FSMA Chat recordings & transcripts***

Public Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)





Questions?

