



Preventive Controls Inspections: *Technical Assistance, Training, Inspection Approaches*

National Grain and Feed Association and Pet
Food Institute Joint Conference

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Presentation Overview

- FSMA Guiding Principles
- Regulator Training Plans
- Regulator Technical Assistance
- Inspection 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/Regulator Education, Outreach and Technical Assistance

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

FDA FOOD SAFETY
MODERNIZATION ACT

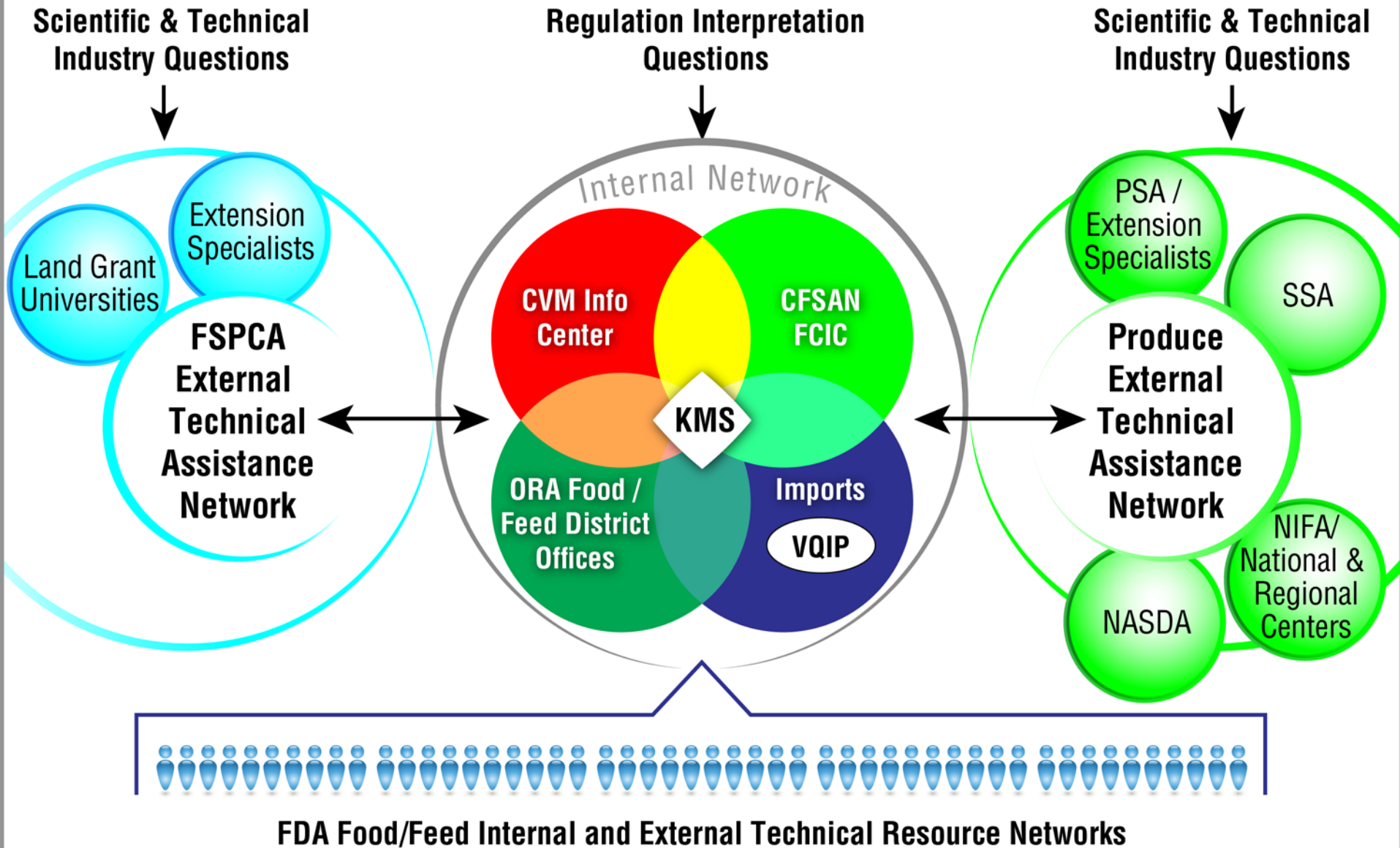
THE FUTURE IS NOW

Technical Assistance Network

Objective:

- Establish within FDA a consolidated Food Safety Technical Assistance Network to provide central, consistent sources of outreach and real-time technical assistance to industry and regulators before, during, and after inspections
- Leverage existing internal infrastructure, business processes and IT systems (Knowledge Management System)
- Leverage external resources, e.g. Alliances, Extension Specialists, Universities, NASDA, NIFA

FDA Food / Feed Internal and External Tech Assistance Networks



Technical Assistance for Regulators

- **Internal technical network** to provide consistent sources of technical assistance
 - Infrastructure – Field Staff through Subject Matter Experts (SMEs)
 - Resource Library
 - List of SMEs
 - Videos
 - Fact Sheets
 - Guidance Documents
- **Guidance documents**
 - Food Hazards and Controls Guide
 - Commodity Specific Guidance, *e.g. process validation*

FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW

General FSMA Implementation Guiding Principles

Industry/Regulator Education, Outreach and Technical Assistance

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

FSPCA and Regulator Training

FSPCA

- Focus of curriculum
- Curriculum as a pre-requisite to regulator training

PC Rule Readiness Training

Regulator training and delivery method

Food Safety Preventive Controls Alliance

DRAFT Curriculum for Human Food

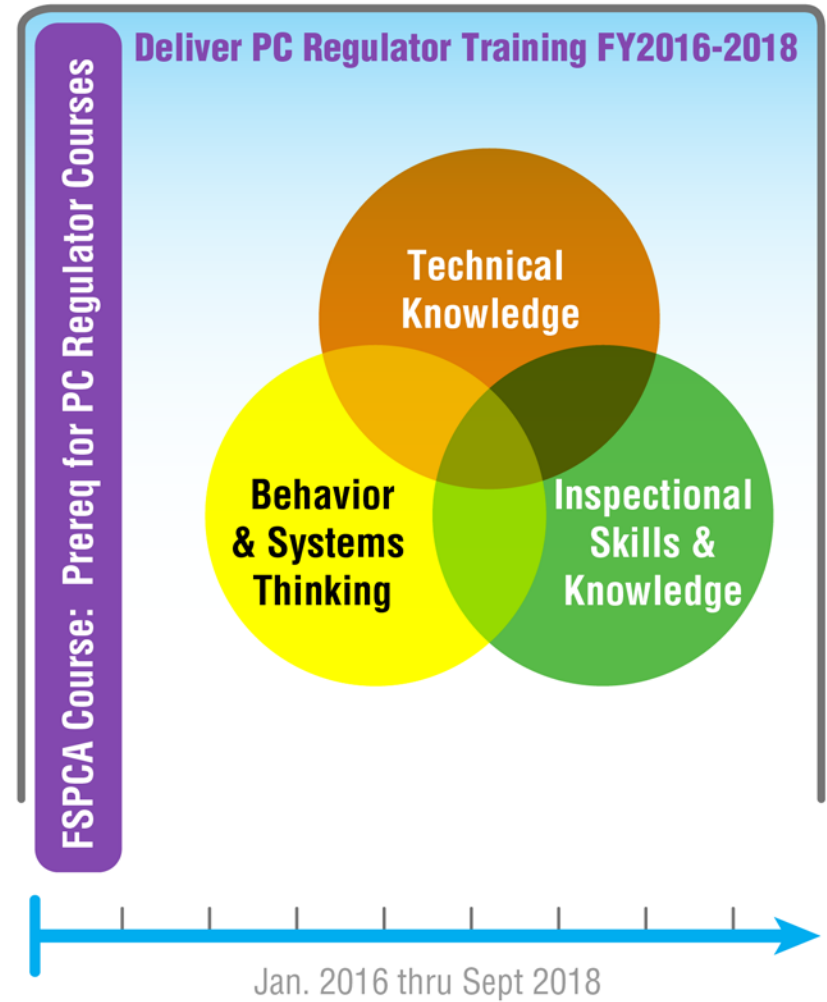
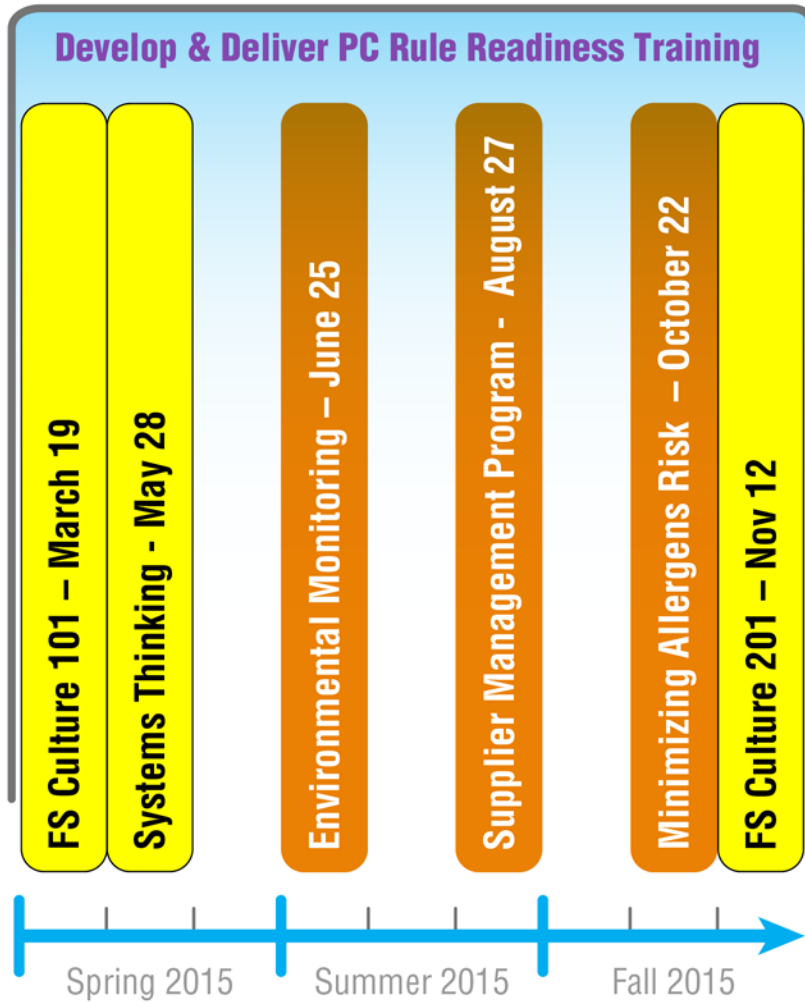
(Exercises Throughout)

Introduction to Course	Process Preventive Controls
Food Safety Plan Overview	Food Allergen Preventive Controls
GMPs and Prerequisite Programs	Sanitation Preventive Controls
Biological Food Safety Hazards	Supplier Preventive Controls
Chemical, Physical and Economically Motivated Food Safety Hazards	Verification and Validation Procedures
Preliminary Steps	Record-keeping Procedures
Resources for Preparing a Food Safety Plan	Recall Plan
Hazard Analysis and Preventive Control Determination	Regulation Overview

Animal Foods Training Curriculum

- The Animal Foods Subcommittee is utilizing the human food training curriculum as a starting point and altering it to make it applicable to the animal food industry.
 - Changes from the human food training curriculum include:
 - Added emphasis on cGMPs
 - Removal of allergen chapter
 - Addition of nutrient toxicity and deficiency information
 - Removal of hazards not applicable to animal food

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

General FSMA Implementation Guiding Principles

Conduct of 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

Conduct of 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

Clearly Defined Compliance Strategy Linked to Public Health Outcomes

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

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THE FUTURE IS NOW

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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

Summary

- **Regulator Technical Assistance** – resource library, e.g. videos, FACT Sheets, network of SMEs
- **Regulator Training** – FSPCA, PC Rule Readiness, Regulator Training, Delivery Model
- **Inspection Approaches** – staggered implementation, systems based, two-tier concept, rank violations



Questions?

