Training Update: FSMA Preventive Controls & MFRP Training

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Today’s Agenda

- FSMA Preventive Controls Training Plan – Pat Alcock
- National Curriculum Progress – Jerry Wojtala
- Short Term Training – Pat Alcock
- Questions
FY16-19

FSMA PREVENTIVE CONTROLS
TRAINING PLAN
### 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)

<table>
<thead>
<tr>
<th>Size of Business</th>
<th>Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualified facility (including very small business) as defined in § 117.3</td>
<td>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</td>
</tr>
<tr>
<td>Small business as defined in § 117.3</td>
<td>September 18, 2017</td>
</tr>
<tr>
<td>Businesses subject to the Pasteurized Milk Ordinance</td>
<td>September 17, 2018</td>
</tr>
<tr>
<td>All other businesses</td>
<td>September 19, 2016</td>
</tr>
</tbody>
</table>

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

**Very Small Business** – average less than $1M per year in sales of human food plus the value of such food manufactured, processed, packed or held without sale
# PC Rule for Animal Food Businesses

## Compliance Dates

<table>
<thead>
<tr>
<th>Business Size</th>
<th>CGMP Compliance</th>
<th>PC Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Businesses</td>
<td>1 year</td>
<td>2 years</td>
</tr>
<tr>
<td>Small Business*</td>
<td>2 years</td>
<td>3 years</td>
</tr>
<tr>
<td>Very Small Business◊</td>
<td>3 years</td>
<td>4 years</td>
</tr>
</tbody>
</table>

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

◊ Very Small Business – Average less than $2.5M per year in sales of animal food plus the market value of animal food manufactured, processed, packed or held without sale
Rationale for Revised Timeline Proposal

The PC regulator training plan will be separated into two timelines:

– Human and animal food due to the difference in industry compliance dates
– Animal food will focus on GMP inspections first followed by the PC inspections based on compliance rule rollout

The FSMA Training Workgroup is proposing a 3-year tiered approach:

– Ramping up number of trained Food Safety Staff (FSS) to include FDA and State and number/ type of inspections conducted (PC, Modernized Human Food GMP or Animal Food CGMP, or combination)
– Sending FSS to the FSPCA training in FY 2016
– Preparing all FSS in FY2106 with skills and knowledge to conduct Modernized Human Food GMP or Animal Food CGMP inspections of large firms in FY 2017
– Training a subset of FSS in Human Food PC regulator training in FY 2016 to allow refinement of new PC inspection approach as well as its curriculum from lessons learned during FY 2017 inspectional process
Trainers-the-Trainers (TTTs) train Instructor Cadre.

Instructor Cadre
Train Food Safety Staff

*Food Safety Staff: Managers/Supervisors, Subject Matter Experts, Compliance Officers, FDA Investigators, State Regulators
PC Regulator Training
Curriculum Development

• **Human Food:**
  – Modernized Human Food CGMP Webinar
  – Regulator Participants Course
  – Regulator Train the Trainer Course

• **Animal Food:**
  – CGMP Participants Course
  – Regulator Participants Course
  – CGMP / PC Train the Trainer Course
Development and Delivery Model

**Objective:** To develop and deliver PC Regulator & Train-the-Trainers (TTT) curricula including CGMPs

**Curricula Developers, TTT, and Instructor Cadre** will include experts from ORA/CFSAN/CVM/States

FSMA Training Workgroup established **Criteria** for Curricula Developers, TTTs and Instructor Cadre

### Curricula Development

- **Human Food**
  - Modernized CGMP Webinar
  - Regulator Participants Course
  - Regulator TTT Course

- **Animal Food**
  - CGMP Participants Course
  - Regulator Participants Course
  - CGMP / PC TTT Course

### Train-the-Trainers (TTT)

- **Human Food**
  - Deliver to All FSS
  - Modernized CGMP Webinar
  - Regulator Participants Course
  - Regulator TTT Course

- **Animal Food**
  - CGMP Participants Course
  - Regulator Participants Course
  - CGMP / PC Train the Trainer Course

### Instructor Cadre

- **Human Food**
  - Deliver to Instructor Cadre
  - Modernized CGMP Webinar
  - Regulator Participants Course
  - Regulator TTT Course

- **Animal Food**
  - CGMP Participants Course
  - Regulator Participants Course
  - CGMP / PC Train the Trainer Course

### Delivery

- **Conduct Inspections:**
  - **Human Food**
    - Conduct PC and modernized GMP Inspections Phased in over 3 fiscal years:
      - Large Firms FY 2017
      - Large & Small Firms FY 2018
      - Large, Small, & Very Small Firms - PMO products FY 2019
  - **Animal Food**
    - Conduct CGMP and PC Inspections Phased in over 4 fiscal years:
      - Large Firms FY 2017
      - Large & Small Firms CGMP and Large Firm PC FY 2018
      - Large, Small, & Very Small Firms CGMP and Large & Small Firms PC FY 2019
      - All firms phased in FY 2020

### Food and Feed Safety Staff*

- **Receive:**
  - 2016
    - FSPCA human and animal food courses (prerequisite)
  - Modernized CGMP Webinar (human food)
  - PC Regulator Training (human and animal food)

- **Conduct Inspections:**
  - **Human Food**
    - CGMP / PC and modernized GMP Inspections Phased in over 3 fiscal years:
      - Large Firms FY 2017
      - Large & Small Firms FY 2018
      - Large, Small, & Very Small Firms FY 2019
  - **Animal Food**
    - CGMP and PC Inspections Phased in over 4 fiscal years:
      - Large Firm CGMP FY 2017
      - Large & Small Firms CGMP and Large Firm PC FY 2018
      - Large, Small, & Very Small Firms CGMP and Large & Small Firms PC FY 2019
      - All firms phased in FY 2020

* Includes FDA investigators, supervisors/managers, compliance officers, Subject Matter Experts, and state regulators
Alliance Courses with Industry

FDA & State Food Safety Staff Will Attend FSPCA Training

• Prerequisite to PC regulator training
• Two courses: Animal Food and Human Food
• Provide basic understanding of PC rules, hazards & PCs (GMPs for animal food), and how to develop a food safety plan
• Food Safety Staff attend with Industry (2.5 day participant course)
  – First wave: SMEs and Supervisors (March – June 2016)
  – Second wave: Compliance Officers, FDA investigators, state regulators (July-Sept)
• FDA FSMA Training Workgroup will coordinate and fund FSPCA training for regulators
  – Point of Contact: kathy.gombas@fda.hhs.gov
FSMA Training Update

21 CFR 110 & 21 CFR 507 – CGMP UPDATE
Updated Human Food 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.
Human Food CGMPs

• 21 CFR 117 subpart B has most of the provisions in 21 CFR 110

• Become effective in
  – 3 years for very small businesses & PMO facilities (Sept 17, 2018)
  – 2 years for small businesses (Sept 18, 2017)
  – 1 year for others (Sept 19, 2016)

• Compliance dates apply to exempt facilities (e.g., those under seafood and juice HACCP)
Animal Food CGMPs – 21 CFR 507

- FSMA regulations includes new Current Good Manufacturing Practices for Animal Food
- Included in the phased in compliance dates for Animal Food Preventive Controls
- Effective Dates:
  - FY17: CGMPs for large firms
  - FY18: CGMPs for large, small firms  
    PC for Large firms
  - FY19: CGMPs for large, small, very small firms  
    PC for Large and small firms
  - FY20: CGMPS large, small, very small firms  
    PC for large, small and very small firms
2015 FDA/ORU Public Health and Regulatory Food and Feed Training Summit
September 28-30, 2015
Field Workforce Expectations

• Expects a career pathway
• Expects portability
• Expects not to waste time
• Expects highest quality training
• Applicable to the job
• Skills practice
• Highly-trained instructors
• Management commitment
• Career growth
Agency Expectations

- Be able to measure performance (against a standard) – comparability
- Metrics and accountability
- Reliance on work of own staff and partners
- Evaluation outcomes
- Meeting program standards
- Auditable systems
- Access to records across the spectrum, LMS linkages, reliance on records (up-to-date)
- Need for speed (short-, medium-, long-term)
- Preventive – anticipates emerging issues
Curriculum Development Process

- Audience
  - Placement in Curriculum
  - Quality Review
  - Development
- Competency FW
  - Curriculum FW
  - Broad Competencies
  - Narrow Competencies
- Learning Event Design
- Planning Documents
Progress of the National Curriculum

Main Framework

– 26 new online courses by August at Entry Level

50%

50%

100%
## Progress of the National Curriculum

### Animal Feed Framework

<table>
<thead>
<tr>
<th>Module</th>
<th>Milestone 1 (1-4000)</th>
<th>Milestone 2 (4001-8000)</th>
<th>Milestone 3 (8001-12000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership</td>
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<tr>
<td>Technical Skills (1-12)</td>
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<td></td>
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<tr>
<td>Leadership (1)</td>
<td></td>
<td></td>
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<tr>
<td>Animal Health (1A)</td>
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<tr>
<td>Disease (1B)</td>
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<tr>
<td>Compliance &amp; Enforcement (2A)</td>
<td></td>
<td></td>
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<tr>
<td>Food Safety (2B)</td>
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<td>Quality (3)</td>
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<td>Communication (4)</td>
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<td>Finance (5)</td>
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<td>Personnel (6)</td>
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<td>Health &amp; Safety (7)</td>
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<td>Environment (8)</td>
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<td>Laboratory (9)</td>
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</tbody>
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### Progress Percentage

- Milestone 1: 50%
- Milestone 2: 50%
- Milestone 3: 50%

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**MFRP Alliance**
Progress of the National Curriculum

Manufactured Food Framework

– High level competencies and framework developed
Progress of the National Curriculum
Retail Food Framework
– High level competencies and framework developed
Progress of the National Curriculum Laboratory Framework

– High level competencies and framework developed
Online Interactive Framework

IFPTI - Curriculum Framework Conceptual Overviews

<table>
<thead>
<tr>
<th>Competency Framework</th>
<th>Communication</th>
<th>Core</th>
<th>Critical Thinking</th>
<th>Organizational Awareness</th>
<th>Technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership</td>
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<tr>
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Competency Framework

The Competency Framework is a model that broadly defines the blueprint for excellent performance within the profession, at various points of one’s career. The framework helps identify high-level competencies (desired outcomes or behaviors), enumerates metrics by which competency can be measured, spells out observable and measurable characteristics, and provides evaluation criteria.

Five competency domains have been identified (Communication, Core, Critical Thinking, Organizational Awareness, and Technical), along with four professional levels, depending on the regulator’s current level (Entry, Advanced, Technical Specialist, and Leadership). Hovering the cursor over each “box” in the Competency Framework reveals the competencies specific to the individual’s professional level and competency domain. To illustrate, a regulator at the Advanced Level is expected to have the following competencies related to the Organizational Awareness domain:

- Collaborate as a member of workgroups

http://incs.ifpti.org/
Workforce Capacity Building

Expanding food safety course offerings for State and Local Regulators in the Integrated Food Safety System
Workforce Capacity Building

Recruiting IFSS SMEs for instructor workforce development

- manufactured food
- retail food
- milk
- shellfish
- emergency response
Workforce Capacity Building

Deliver courses

• Key courses for first phase
  – FD170 Application of Inspection and Investigation Techniques
  – FD218 Risked-based inspections
  – ER310 Food Safety Issues in the Event of Disasters
Questions