FSMA PCAF Implementation Update

Inspection & Sampling Committee
AAFCO Annual Meeting
August 2016  Pittsburgh, PA
Outline

• Training
  – Food Safety Preventive Controls Alliance (FSPCA)
  – Regulatory Training

• Inspections

• Exemptions

• Update on Technical Assistance Network (TAN)

• Medicated Feed Mill Inspections
Training - FSPCA

• Who is required to take the FSPCA training?
  – Regulators

• Who is recommended to take the FSPCA training?
  – Industry
  – PCQI

• Where can I get the FSPCA training?
  http://www.iit.edu/ifsh/alliance/
Regulator training – Curriculum Developers and Train-The-Trainers (TTT)

• There are 11 identified Curriculum Developers/TTT made up FDA and State:
  – CVM members
  – ORA members
  – State Regulator

• Curriculum Developers/TTT are responsible for:
  – Developing the Regulator courses
  – Training the Instructor Cadre
  – Assisting in training all regulators
Regulator Training – Overview

• Animal Food CGMP Regulator training course
• Animal Food CGMP/ Preventive Controls Regulator training course
Regulator training – Instructor Cadre

• Instructor Cadre is a force of 31 FDA (CVM & ORA) and State regulators
  – FDA investigators
  – FDA supervisors
  – FDA compliance officers
  – CVM Subject Matter Experts
  – State investigators
  – State supervisors

• Instructor Cadre responsible for:
  – Conducting first wave of CGMP inspections in FY17
  – Training next wave of regulators
Regulator training – Instructor Cadre

• Each instructor attends:
  – Instructor skills training
  – FSPCA training
  – CGMP Regulator training
  – PC Regulator training
  – CGMP/ PC TTT training
Regulator training – Instructor Cadre

• Instructor Cadre will begin the CGMP inspections for “other businesses” (large) in October 2016

• List of firms to inspect under CGMPs
Regulator training – Training the “Masses”

• Beginning first quarter in FY18, instructor cadre and TTT will train regulators both state and federal
• FDA anticipates a cadre team of 4 will teach a class of approximately 30 participants
• FDA identifies approximately 500 regulators who need the training
# Compliance Dates

<table>
<thead>
<tr>
<th>Business Size</th>
<th>Subpart B and related requirements</th>
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<tbody>
<tr>
<td>Other businesses (not small or very small)</td>
<td>September 19, 2016</td>
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<tr>
<td>Small business</td>
<td>September 18, 2017</td>
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<tr>
<td>A business, including any subsidiaries and affiliates, employing fewer than 500 full-time equivalent employees</td>
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<tr>
<td>Very small business</td>
<td>September 17, 2018</td>
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<tr>
<td>A business, including any subsidiaries and affiliates, averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).</td>
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Inspections – When and By Who

• “Other Businesses” aka “Large” businesses - (not defined in PCAF rule or FSMA law) a business having greater than or equal to 500 employees
  o Subject to CGMP September 2016 and PC September 2017
• * Inspection of “Large” businesses
  o CGMP inspections by instructor cadre and TTT begin October 2016
  o PC inspections by Instructor Cadre and TTT begin January 2018

*unless facility qualifies for an exemption
Inspections – When and By Who

• **Small businesses** (21 CFR 507.3)
  - Subject to CGMPs September 2017 and PC September 2018

• *Inspection of Small businesses*
  - CGMP inspections by regulators trained by the instructor cadre in last quarter FY17 and first quarter FY18 begin October 2017
  - PC inspections by Instructor Cadre, TTT, and regulators beginning in FY18/FY19

*unless facility qualifies for an exemption*
Inspections – When and By Who

• Very small business (21 CFR 507.3)
  o Subject to CGMP September 2018 and PC September 2019

• Inspection of Very small businesses
  o CGMP inspections by all regulators begin October 2018
  o PC inspections for all regulators begin January 2019

*unless facility qualifies for an exemption
Exemptions from CGMP
(21 CFR part 507, subpart B)

• Facilities not required to register as food facility under section 415 of the FD&C Act
• Establishments solely engaged in holding/transportation of RACs \textit{(without manufacturing/ processing)}
• Facilities that solely hull, shell, dry, pack, and/or hold nuts and hulls \textit{(without manufacturing/processing)}
• Facilities that solely gin cotton \textit{(without manufacturing/processing)}
Technical Assistance Network (TAN)

• Operational since September 9, 2015
• Provides technical assistance regarding FSMA implementation to:
  o Industry
  o Regulators
  o Academia
  o Consumers

  o [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm)
Inspection of Medicated Feed Mills

• Some facilities manufacturing processing, packing or holding medicated feed must comply with 21 CFR part 507 subpart B as well as 21 part CFR 225

• If a facility is not required to register under section 415 of the FD&C Act but manufactures a medicated feed must comply with 21 CFR part 225 but not 21 CFR part 507.
Questions?

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