

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

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Business Size	Subpart B and related requirements
Other businesses (not small or very small)	September 19, 2016
Small business A business, including any subsidiaries and affiliates, employing fewer than 500 full-time equivalent employees	September 18, 2017
Very small business 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).	September 17, 2018

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
 - Subject to CGMP September 2016 and PC September 2017
- * Inspection of “Large” businesses
 - CGMP inspections by instructor cadre and TTT begin October 2016
 - 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)
 - Subject to CGMP September 2018 and PC September 2019

- *Inspection of Very small businesses
 - CGMP inspections by all regulators begin October 2018
 - 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 (*without manufacturing/ processing*)
- Facilities that solely hull, shell, dry, pack, and/or hold nuts and hulls (without manufacturing/processing)
- Facilities that solely gin cotton (without manufacturing/processing)

Technical Assistance Network (TAN)

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