FSMA – Recap of 2017 and What's Next

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FSMA Regulations (2015-2016)

Rules applicable to Animal Food	Rules NOT applicable to Animal Food
Preventive Controls for Animal Food	Preventive Controls for Human Food
Foreign Supplier Verification Program	Produce Safety
Accredited Third-Party Certification	Intentional Adulteration
Sanitary Transportation	

PCAF – Status Report

- Compliance Dates
- CGMP Inspections
- Guidance Documents
- Common questions

Compliance Dates (Unchanged)

Business Size	CGMP Compliance	PC Compliance
Large	Sept 19, 2016	Sept 18, 2017
Small	Sept 18, 2017	Sept 17, 2018
Very Small	Sept 17, 2018	Sept 17, 2019

- Compliance dates for training provisions (21 CFR 507.4) coincide with date a facility is first subject to either CGMPs or PC
- Only changes to compliance dates announced in Federal Register Notice on August 24, 2016.

Compliance Dates (Unchanged)

- August 2017: FDA announced we will not conduct routine regulatory inspections to ensure compliance with Preventive Controls (Subpart C & E) requirements until the fall of 2018.

- August 2017 announcement: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm570439.htm

Compliance Dates (Unchanged)

- What does not starting routine regulation inspections for compliance with PC mean to me (large business)?
  - FDA has no planned PC inspections until Fall of 2018.
  - For large businesses only, you should have developed and be following your food safety plan.
  - FDA will NOT be inspecting your food safety plan for compliance with the PC requirements.
  - If a large business has a food safety issue, we will look at their food safety plan to see what controls they have outlined.
  - You have additional time to make sure your food safety plan is working correctly and to make adjustments if needed.

Reflections from 2017 CGMP Inspections

- Conducted ~230 CGMP inspections
- Inspections are more conversational (and will continue to be so)
- Questions were asked (and will continue to be) about PC readiness
- Overall industry report card is positive
- Most common findings

Reflections from 2017 CGMP Inspections

- Most common industry concerns
  - Why do inspectors ask to see compliant files?
  - Why do inspectors ask to see pest management records?

- General response to these concerns
  - That is standard procedure for FDA investigators
  - Procedures from Investigations Operations Manual (IOM)

CGMP Inspections (FY18): What to Expect

- Only inspections in FY18 will be for compliance with CGMPs for “large” and “small” businesses
- CGMP inspections expected to start October/November 2017
- Increased number of inspections
- Inspections will be done by FDA and state inspectors

CGMP Inspections (FY18): What to Expect

- We will NOT inspect all “large” and “small” businesses
- CGMP inspections may be combined with BSE inspections
- We will continue to “Educate Before and During” Regulation

PCAF "only" Guidance Documents

Available Guidance	Status
Small Entity Compliance Guidance (#241)	Final
Current Good Manufacturing Practice (#235)	Final
Human Food By-Product for Use as Animal Food (#239)	Draft
Future Guidance	**Status**
Hazard Analysis and Preventive Controls (chapters 1-5)	Not available
Supply-Chain Program	Not Available

Joint PCAF and other FSMA Regulation Guidance Documents

Guidance	Status
Qualified Facility Attestation	Draft
Disclosure Statement for Customer Provisions	Draft
Activities Classification	Draft
“Solely Engaged” Exemption Clarification	Draft

Non-PCAF FSMA Guidance of Interest

Available Guidance	Status
7th edition Registration Guidance	Draft
FSVP Unique Identifier	Final
Third-Party Certification Body: Model Accreditation Standards	Final
VQIP	Final
Sanitary Transportation Waiver Clarification	Final

CGMP Final Guidance

- Updated based on comments to guidance and feedback from industry
- Updates to be aware of:
  - Changes made to qualified individual training record retention explanation
  - Added more clarity around food grade lubricants
  - Removed discussion on 21 CFR 507.28 (human food by-products) and referenced that guidance
  - 507.27 discussion updated to reflect Sanitary Transportation regulation
  - Added Self-assessment tool

"Solely Engaged" Draft Guidance

- Developed because FDA has received numerous questions on what it means to be "solely engaged"
- Intended audience is those questioning whether they are "solely engaged"
- Provides policy direction when a facility is doing two activities at the same place that are both exempt under the "solely engaged" exemptions
- May not answer ever "solely engaged" question

Common Questions

Qualified Individual Training (21 CFR 507.4)

- Qualified Individuals are required:
  1. To be qualified to perform their job duties (such as through training)
  2. Be trained In the principles of animal food safety and animal food hygiene
- Training for item 2 above has to be documented in records

Qualified Individual Training (21 CFR 507.4)

- What does this training look like across the animal food industry?

  It can vary widely depending on the facility

- Does FDA expect a common format?

  No – due to the flexibility

- What individuals have to be trained?

  Those involved in manufacturing, processing, packing, or holding animal food

Customer Provisions Written Assurance (21 CFR 507.36)

- Regulation provides for a facility to rely on a customer to control of a hazard requiring a PC provided:
  - Customer is a manufacturing/processor
  - Disclose to the customer that the hazard has not been controlled
  - Obtain written assurance from the customer that they will:
    - Control the hazard
    - Provide to a subsequent customer who will control the hazard

Customer Provisions Written Assurance (21 CFR 507.36)

- Compliance date for the "written assurance" requirements were officially extended (August 2016 FR Notice)

Business size	Original Date	Current Date
Large	Sept 2017	Sept 2019
Small	Sept 2018	Sept 2020

- Compliance date extension ONLY applies to the "written assurance" requirements in 507.36
- Large facilities that are passing control to customers should be using the disclosure statement now

Customer Provisions Written Assurance (21 CFR 507.36)

- Is there an update on 507.36?
- How will FDA be inspecting for compliance with 507.36?
- What type of disclosure statements are allowed?
- Where can I provide comments?

What Can Industry Be Doing to Prepare?

- Solid foundation with implementation of CGMPs
- Large businesses – follow your food safety plan and make adjustments as needed
- Small businesses – use tools available to you to develop your food safety plans
- Ask questions through FSMA Technical Assistance or to your industry colleagues
- Training

What is FDA Doing to Prepare?

- Developing guidance
- Developing, delivering, and modifying training
- Listening to:
  - Fellow regulators (FDA and state)
  - Industry (TAN, feedback, questions, training)
- Working with NASDA and AAFCO to develop a framework for State agencies to build PC programs at the state level

Thank you!

Questions?