National Grain and Feed Association

WSDA Animal Food Industry Training

FSMA Implementation - Industry Perspectives

May 14, 2020

Conversation Topics

- FSMA Inspection Experiences
- Some Ideas on How to Prepare for/React to FDA Inspections
- Compliance Assistance - FSPCA Training Courses and Materials

FSMA Rules and Animal Food

- 21 CFR Part 507 – FSMA CGMP and Preventive Controls for Animal Food
- 21 CFR Part 1, Subpart L – FSMA Foreign Supplier Verification Program (foreign food importers)
- 21 CFR Part 1, Subpart M – Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications
- 21 CFR Part 1, Subpart O – FSMA Sanitary Transportation of Human and Animal Food

FSMA Inspections

- **Be prepared to:**
  - Have different inspection experiences
  - Tell your story
    - Inspections are conversation-based
    - There is a compliance expectation that local management will be able to explain the facility's food safety plan and how its contents were determined

FSMA Inspections

- **Be prepared to:**
  - Respond to requests for information or records that are not expressly required by the regulations; some examples:
    - Customer complaints files
    - Lists of top customers and suppliers
    - Business volume information
    - Organizational charts
    - Table of contents for QA manuals

FSMA Inspections

- **Be prepared to:**
  - Justify how you determined what hazards are known or reasonably foreseeable for your facility
    - Appendix E of FDA Draft GFI 245 for Hazard Analysis and Risk-Based Preventive Controls for Food for Animals lists hazards associated with different types of animal food
    - FDA recall information provides information about the types of hazards that have been associated with animal food safety incidents

FSMA Inspections

- **Be prepared to:**
  - Justify determinations made during your hazard analysis
    - Preamble of final rule and FDA guidance highlight certain hazards that have the potential to cause serious adverse health consequences or death

FSMA Inspections

- Hazard evaluation is to consider the effect of the following factors on the finished animal food for which it is intended - 21 CFR 507.33(d)

1. The formulation of the animal food;
2. The condition, function, and design of the facility and equipment;
3. Raw materials and other ingredients;
4. Transportation practices;
5. Manufacturing/processing procedures;
6. Packaging activities and labeling activities;
7. Storage and distribution;
8. Intended or reasonably foreseeable use;
9. Sanitation, including employee hygiene; and
10. Any other relevant factors such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

FSMA Inspections

- **Be prepared to:**
  - Demonstrate how the use a prerequisite program reduces the likelihood that the hazard will occur if you rely on the program to justify how you characterize a hazard within your food safety plan

FSMA Inspections

- **Be prepared to:**
  - Respond to investigator requests for last load hauled information for bulk conveyances
    - No rule (PC Animal Food, Sanitary Transportation, BSE-Prevention) requires last load hauled information, but this seems to be a common investigator expectation
  - Spend 4-5 days with an investigator during a PC inspection

FDA Inspections

- FDA mandated under FSMA to ***inspect*** <u>all</u> registered food facilities
  - Initial inspections within 5 (high risk) to 7 (low risk) years of FSMA enactment
  - Subsequent inspections every 3 (high risk) to 5 (low risk) years

FDA Inspection Authority

- FDA is authorized to:
  - Enter “any factory, warehouse, or establishment in which food [is] manufactured, processed, packed, or held …” and “any vehicle….”
  - Inspect “at reasonable times and within reasonable limits and in a reasonable manner”
  - Inspect “all pertinent equipment, finished and unfinished materials, containers, and labeling thereon”
- No warrant necessary for inspection

FDA Animal Food Inspections Some Compliance Areas…

- 21 CFR Parts 1.361-362 – Records access in the event of food-related serious adverse health consequence
  - FDA Recordkeeping *(traceability)* Requirements for Food
- 21 CFR 113 –Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers
- 21 CFR Part 225 – Medicated Feed CGMP
- 21 CFR Part 558 – Veterinary Feed Directive
- 21 CFR Parts 589.2000-2001 – BSE-Prevention Regulations
- FSMA Rules

During the Inspection

- **When the investigator arrives** –
  - Ask for credentials – investigators should have proper identification
  - Investigator should provide notice of inspection – Form FDA-482
  - It's acceptable (and often helpful) to ask why the inspection is being conducted

During the Inspection

- The investigator should be required to comply with all applicable personnel safety requirements
- A "designated" employee should:
  - Accompany the investigator throughout the inspection
  - Know the facility's rights and obligations – *investigators may ask for more information than they are expressly authorized to obtain or review*
  - Provide direct answers to questions – it's acceptable to not immediately provide a response if the answer is not readily available
  - Always provide truthful information
  - Remedy issues/conditions raised by the inspector immediately, if possible and if warranted

During the Inspection

- **Facility Tour:** The investigator typically will want to begin the inspection with a tour of the facility, then focus on specific areas of interest
- **Samples:** FDA has authority to take samples
  - If taken, ask for a "split" sample or obtain one from the same lot
  - If taken, ask the investigator what the sample will be tested for and expected timing of the results
  - Have a plan on what to do with sampled lot

During the Inspection

- **Taking Pictures:**
  - If the facility's inspection policy doesn't allow, the investigator likely will assert FDA has authority to take photos
  - If the facility's inspection policy allows, it is advisable to take "identical" pictures
- **Employee Interviews:**
  - FDA authority does not expressly provide for employee interviews
  - If the facility's inspection policy allows, the "designated" employee should be present to correct any potential inaccuracies provided during the interview

During the Inspection

- **Facility Operations:** FDA does not have authority to disrupt the facility's normal operations
- **Questionable Requests**: It is acceptable to ask the investigator to put the request in writing and the basis for why the information is needed to allow for further management and/or legal review
  - Example: Request for "excessive" review of records

Post Inspection

- Investigators typically conduct inspection exit interviews with facility management
- Form FDA-483 is used to document inspectional observations (alleged violations)
- Facility management should provide basis for any disagreement with inspectional findings during interview
- Investigators often ask management to sign an Affidavit or Declaration during exit interview – have a policy in place on how to respond

After the Inspection

- If Form FDA-483 issued, promptly begin work on developing a response to alleged violations
  - It may be beneficial for the facility to formally respond to FDA about the alleged violation before receiving further correspondence from FDA about its findings
  - FDA policy provides 15 days for such a response if the facility wishes the agency to consider the facility's position/actions prior to FDA determining whether enforcement action will be taken

After the Inspection

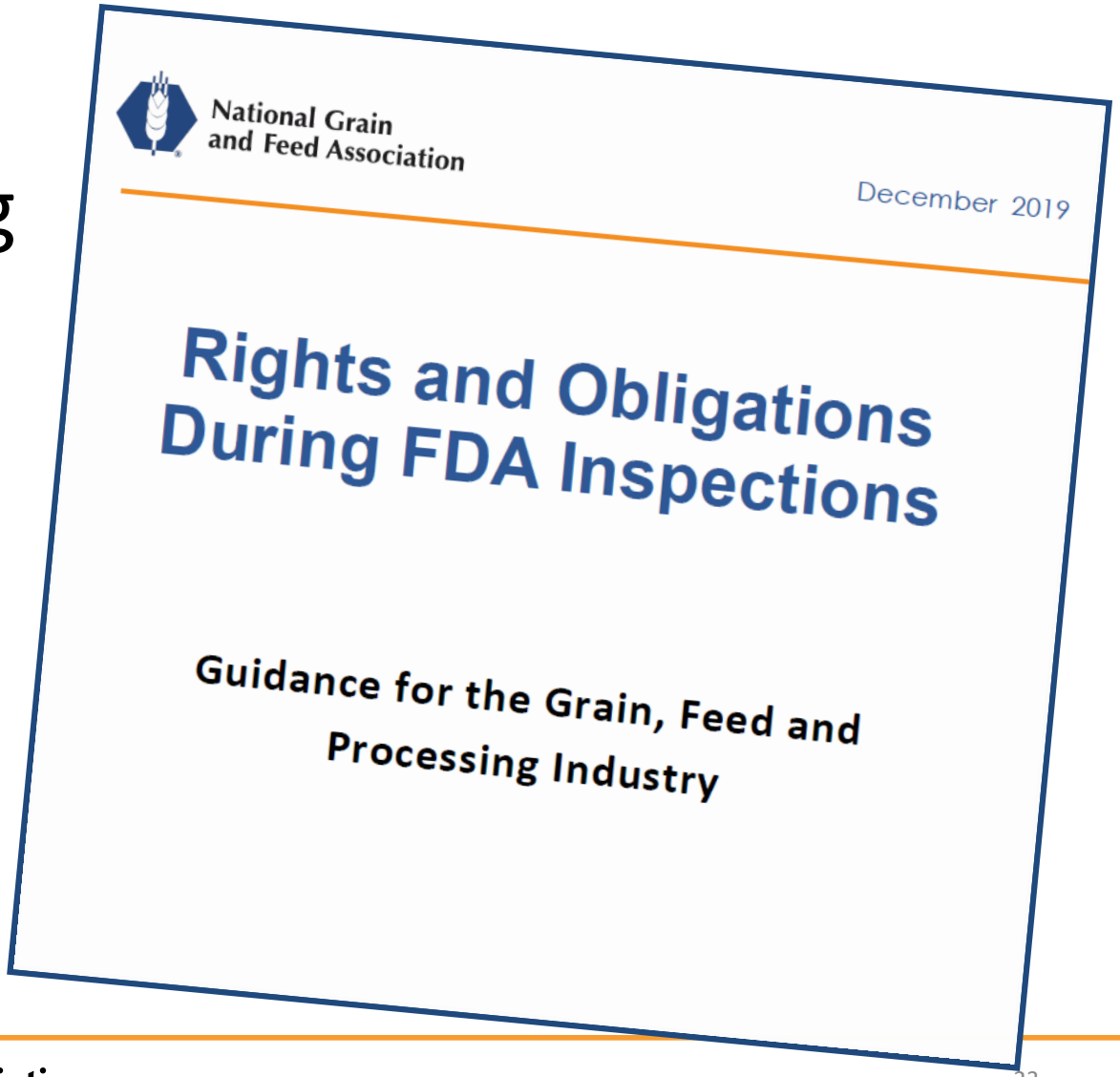
- FDA, if agency believes it is warranted, may issue either an “Untitled Letter” or “Warning Letter” to the facility based upon Form FDA-483 observations
  - Always provide a response to such letters in a timely manner. If more time is needed, inform FDA
  - When responding, note the observation(s) and state how facility will address the condition or observations made
  - It is advisable to consult legal counsel when responding to an untitled or warning letter
  - Always follow through on any corrective actions that the response letter commits the facility to perform

FDA Enforcement Actions

- Depending upon the significance of the non-compliant condition, FDA may:
  - Conduct re-inspection activities
  - Seize products
  - Initiate injunctions or consent decrees
  - Suspend a facility's registration – making it illegal to distribute food

NGFA FDA Inspection Guidance

- www.ngfa.org



FSPCA Public-Private Partnership

FSPCA Training Materials

Illinois Institute of Technology

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Menu

FSPCA Preventive Controls for Animal Food

Training & Materials

FSPCA Preventive Controls for Animal Food Course
FSPCA Preventive Controls For Animal Food Blended Course
FSPCA Preventive Controls for Animal Food Lead Instructor Training
FSPCA Preventive Controls for Animal Food Course AND Lead Instructor Training
Selection Criteria for Lead Instructor
Animal Food Lead Instructor Course Schedule
FSPCA PCAF Errata Sheet for Version 1.0 to 1.1
FSPCA Preventive Controls for Animal Food Participant Manual v1.1 (English)
FSPCA Animal Food Bookstore

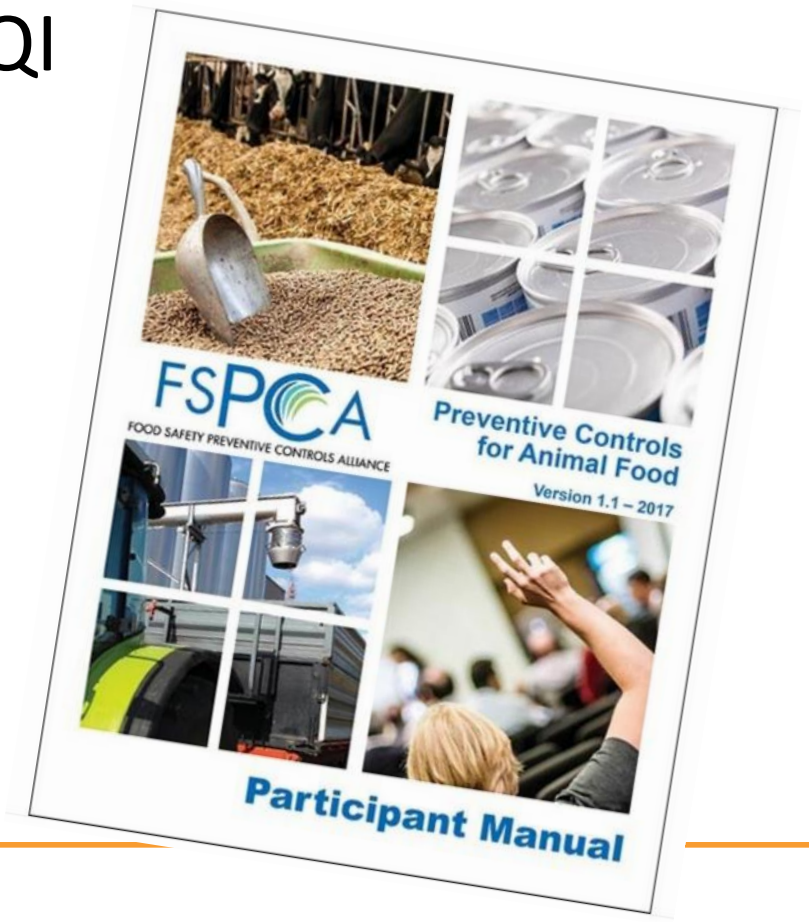
/0qa05cdjr5.cloudfront.net/c6f30ca0-84ae-4613-bec0-5439702d4b9e/FSPCA - Human Food/FSPCA_AF_Participant_Manual_v1.1_FINAL_PUBLIC_09.27.2017.pdf?230

« FSPCA HOME

+ THE ALLIANCE
− COURSES
  + FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP)
  - INTENTIONAL ADULTERATION
  - FSPCA IA VULNERABILITY ASSESSMENT LEAD INSTRUCTOR CRITERIA AND ONLINE APPLICATION
  - **FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD**
  - FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD
- LEAD INSTRUCTOR

FSPCA Animal Food Course

- Standardized curriculum recognized by FDA as being adequate for training an individual to be a PCQI
- 20-hour course
  - In-person
  - Virtual
  - Blended

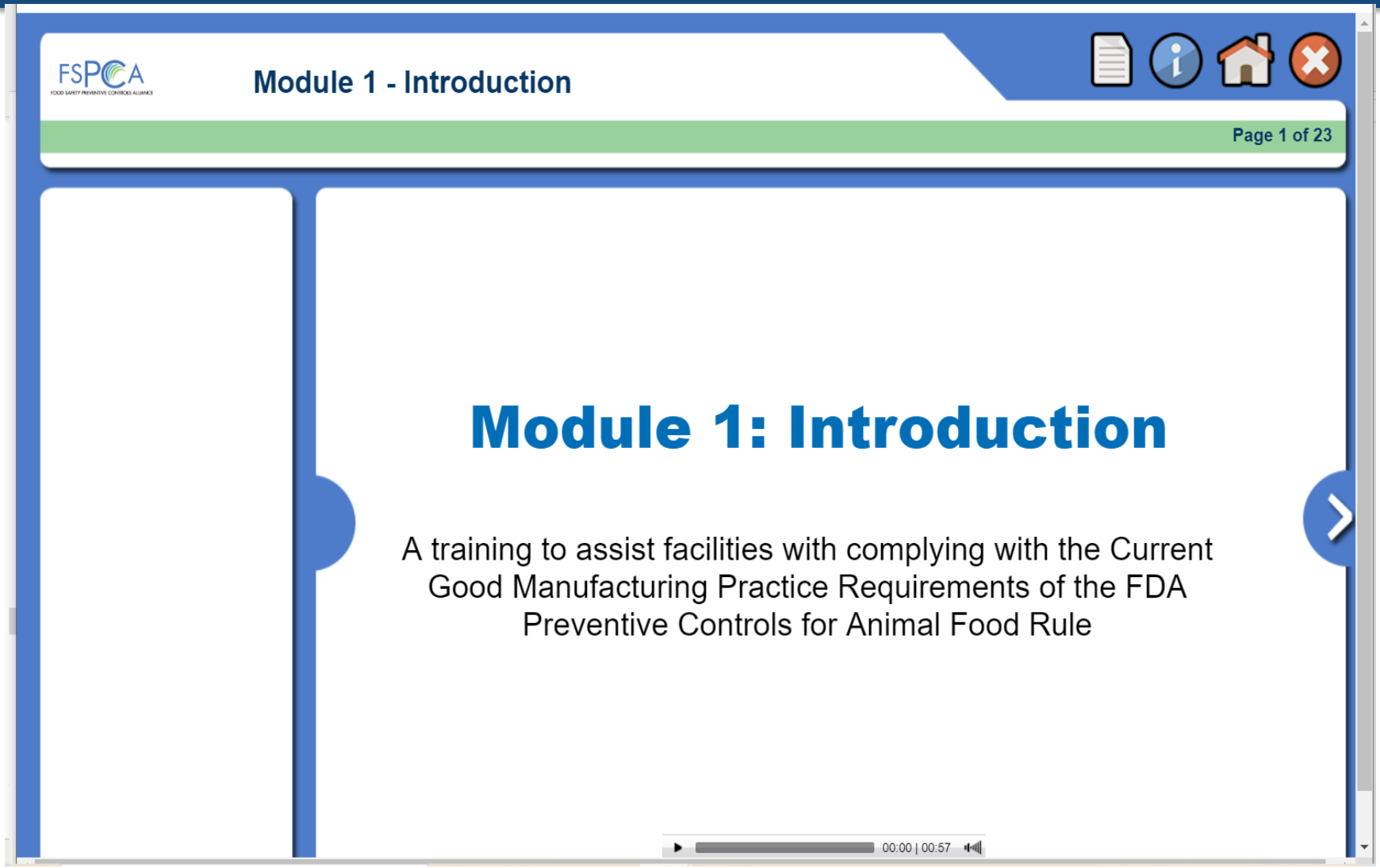


FSPCA Course Metrics – Animal Food

	Domestic	International	Total
AF PCQI Certificates Issued	8,801	982	9,783
AF Lead Instructor Certificates Issued	250	71	321
PCQI Courses Completed	544	103	647

May 5, 2020

CGMPs for Animal Food Online Course



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