Preventive Controls & cGMP’s for Animal Food Industry Perspective

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Preventive Controls Mini Conference:
“IIs Small Industry Exempt from FSMA Preventive Controls? Think Again…”
Final rule published on 17 September
  - Entry into force in mid-November

Staggered compliance, enforcement dates
  - Subpart B (CGMPs) compliance in September 2016
  - Subpart C (preventive controls in September 2017)

Training – industry, inspectors (FDA, states)
  - FDA public meetings
  - Preventive Controls Alliance
  - Industry Trade Groups
INDUSTRY CONCERNS DURING RULEMAKING

- Animal food is not human food
  - FDA made significant changes from the original
- CGMPs, hazard analysis, preventive controls
  - New requirements – not new concepts
- Flexibility is critical
  - Animal food industry is incredibly diverse
- Supplier verification provisions
  - Specific, detailed requirements
WHAT ARE CGMP’S?

- Current Good Manufacturing Practice regulations enforced by the FDA

- Address systems that assure proper:
  - Design
  - Monitoring
  - Control of manufacturing processes and facilities
HISTORY OF CGMP

- 21 CFR 110 inception: 1969
- FDA revision 1986
- 2002 Center for Food Safety & Applied Nutrition formed cGMP working group to study how GMP controls could affect food safety
- 2004 CFSAN presented findings
- 2015 – FSMA – proposed cGMP’s be more applicable to animal food industry
WHAT ARE FSMA CGMP’S?

- Good hygiene practice and protection of food from contamination from personal effects
- Plant and grounds include proper cleaning, maintenance and elimination of pests
WHAT ARE FSMA CGMP’S?

- **Sanitary operations:**
  - Maintaining clean and sanitary conditions of FCS
  - Proper use and storage of chemicals
  - Exclusion of pests

- **Sanitary facilities and controls:**
  - Plant’s water supply, plumbing, toilet and hand washing facilities

- **Equipment and utensils:**
  - Cleaning and maintenance of utensils
  - Protecting animal food from contamination
WHAT ARE FSMA CGMP’S?

- Process and controls for:
  - Adequate sanitation principles
  - Proper labeling of ingredients & finished product
  - Ensuring safety of raw materials
  - Preventing contamination of animal food during processing

- Warehousing to protect animal food against contamination and deterioration
CGMP’S = PREREQUISITE PROGRAMS
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Pre-Production
- Specifications
- HACCP Program
- Food Defense
- Vendor Approval
- Equipment
  Sanitary Design Standards

Production
- Training
- Documentation
- Mycotoxin Control
- Water Quality
- Air Quality
- Cleaning and Sanitization
- GMPs
- Foreign Material Control
- Glass and Brittle Plastic
- Chemical Control
- Pest Control
- Raw Material Receiving
- Micro
  - Environmental
  - Finished Product

Post Production
- Recall / Withdrawal
- Product Retrieval
- Warehouse and Distribution Center
- Customer Complaints

Taking these programs to new levels
Current Good Manufacturing Practices (CGMPs)
- Facility/grounds, employee hygiene requirements

Hazard Analysis and Risk-Based Preventive Controls
- Each facility is required to implement a written food safety plan that focuses on preventing hazards in animal foods
**ANIMAL FOOD RULE BASICS (CONT’D)**

- **Human food by-products**
  - Not subject to animal food rule (except for holding and distribution provisions) if human food:
    - Is produced in compliance with human food CGMPs and all applicable food safety requirements; and
    - Is not further processed

- **Supply-chain program**
  - Source from approved suppliers only
  - Regular checks to ensure compliance
Environmental monitoring
- Essentially mandatory for pet food makers
- Corrective actions tailored to the nature of a (+) test

Product testing
- Not required – available tool for pet food makers

Extensive reporting and record keeping requirements for employee training, monitoring, testing
CGMPs and preventive controls

- All CGMPs address a hazard to some extent – they serve a preventive control function
- Preventive controls are defined very broadly:
  - Process controls
  - Sanitation controls
  - Supply-chain controls
  - Recall plan

Supply chain controls

- Evaluation of longstanding versus new suppliers
PET FOOD INDUSTRY NEXT STEPS

- Review of final rule and pending guidance from FDA
  - CGMPs guidance due in the next year
  - Q&A with FDA – PFI webinar, FDA public meeting
- Identification/documentation of training for qualified individuals
  - CGMPs and preventive controls training
- Identification of preventive controls qualified individuals
  - Oversight of food safety plan, validation, verification activities
FSPCA - Public-Private Partnership
FSPCA Deliverables

• Develop a standardized hazard analysis and preventive controls curriculum – human food and animal food
  ▪ Training will be one means to become a “PC Qualified Individual” required by PC Rules
• Compile and disseminate scientific and technical information relevant to hazard analysis and preventive controls
• Create a technical assistance network for industry with emphasis on small and mid-sized food companies
  ▪ University and Extension Experts
• Function as a bridge between the FDA and the food industry to communicate technical elements of preventive controls
FSPCA - Animal Food Activities

Animal Food Subcommittee

Curriculum Committee

Example Animal Food Safety Plans Workgroup

Hazard Guidance Committee
<table>
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<tr>
<th>Introduction to Course</th>
<th>Supplier Preventive Controls</th>
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<tbody>
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<td>Food Safety Plan Overview</td>
<td>Recall Plan</td>
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<td>CGMPs and Prerequisite Programs</td>
<td>Verification and Validation Procedures</td>
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<tr>
<td>Biological Chemical, Physical and Economically Motivated Animal Food Safety Hazards</td>
<td>Recordkeeping Procedures</td>
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<tr>
<td>Preliminary Steps in Developing and Animal Food Safety Plan</td>
<td>Regulation Overview - CGMP and Hazard Analysis and Risk-Based Preventive Controls for Animal Food</td>
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<tr>
<td>Hazard Analysis and Preventive Control Determination</td>
<td>Resources for Preparing an Animal Food Safety Plan</td>
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<td>Process Preventive Controls</td>
<td>Animal Food Safety Plan Worksheets</td>
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<td>Sanitation Preventive Controls</td>
<td>Example Animal Food Safety Plans</td>
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Delivery of the Curriculum

• All materials developed by the Alliance will available on the FSPCA website and available for electronic download
  ▪ Animal Food curriculum, example templates, example plans....

• For the purpose of using the training material to become a “preventive controls qualified individual,” an individual must successfully complete a training course authorized by the FSPCA that is delivered by a FSPCA lead instructor
  ▪ Certificates will be issued to individuals who have successfully completed such a course
Delivery of the Curriculum

Animal Food Regulations Implementation Timeline *
(one year later for Preventive Controls)

- **Publication of Final Rule**: Sept. 17, 2015
- **Large Firm Compliance Date**: Sept. 17, 2016
- **Small Firm Compliance Date**: Sept. 17, 2017
- **Very Small Firm Compliance Date**: Sept. 17, 2018
Animal Food Curriculum – Timeline *(subject to change!)*

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<thead>
<tr>
<th>2015</th>
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- **2015**
  - Develop Animal Food Course

- **2015**
  - Modify Course

- **2016**
  - Pilot Course

- **2016**
  - Modify Course

- **2016**
  - Develop Segment 1 - Online

- **2016**
  - Develop Segment 2 - Classroom

- **2016**
  - Translate material

- **2016**
  - Animal Food Course Delivery Begins

- **2016**
  - Develop Train-the-Trainer

- **2016**
  - Pilot TTT

- **2016**
  - TTT Training
Curriculum Review Proposed Timeline

• Nov. 15: Curriculum Draft Due to CVM and FSPCA
  ▪ Revisions from CVM and FDA due back Dec. 15
• Dec. 16: Online Participant Curriculum Shakedown via WebEx
• Jan. 13 – 15: Participant Curriculum Shakedown in Raleigh
  ▪ Includes FSPCA Animal Food Sub-Committee (Beyond Editorial Group)
• Jan. 20: Example Animal Food Safety Plan Sub-Group Meeting
• Feb. 1: Curriculum Draft Due to CVM and FSPCA
  ▪ E-Supplement Example Animal Food Safety Plans Due
  ▪ Revisions from CVM and FDA due back Feb. 10
• Feb. 23 – 26: Participant and TTT Curriculum Shakedown in Kansas City
  ▪ Participants will be Lead Instructors
  ▪ Includes FSPCA Animal Food Sub-Committee (Beyond Editorial Group) and Selected Lead Instructor Applicants
• Mar. 1: Final Curriculum Due to CVM and FSPCA
• Apr. 5 – 8: Participant and TTT Hybrid Course in KC or Manhattan
  ▪ Participants will be Lead Instructors
• Apr. 15: Delivery Allowed to Begin
Curriculum Support Materials

For Students
• Participants Manual – (Open access)
  ▪ Slide images, supporting text, example forms, Food Safety Plan example, references
• Exercise Workbook

For FSPCA Lead Instructors
• Instructors Manual
  ▪ Annotated Participant’s Manual
• Slide set
• Instructor’s Exercise Guide
  ▪ Model foods teaching examples
• Adult learning and administration procedures
Technical Assistance Network - Domestic

Establish a network of University and Extension food safety experts that would be available to assist the industry with technical questions:

• Publish University and Extension specialists names on FSPCA’s webpage

• Experts answer scientific and technical questions using publically available materials including scientific literature
  ▪ Establish repository of technical resources

• Refer preventive controls regulation interpretation questions to FDA’s experts
• FAQs

The Alliance / FAQ

FAQ

What is the Food Safety Preventive Controls Alliance (FSPCA)?

The Food Safety Preventive Controls Alliance (FSPCA) is a public-private partnership of key stakeholders from the food industry, academia and government. The Alliance seeks to develop an industry-oriented food safety training program to help firms producing human and animal food for the U.S. market to comply with preventive controls regulations required by the Food Safety Modernization Act (FSMA).

What prompted the creation of the FSPCA?

The food safety preventive controls regulations that will be issued by the U.S. Food and Drug Administration (FDA) will require facilities that manufacture, process, pack or hold food for humans and animals put measures in place to help prevent foodborne illness by implementing preventive controls for hazards. The FDA funded FSPCA to develop training that will help industry, particularly small- and medium-sized companies, to comply with the new preventive controls rules.

How was the FSPCA created?

FSPCA was created from a one-year, $1 million partnership grant funded by the FDA Office of Foods to the Illinois Institute of Technology’s Institute for Food Safety and Health (IIT IFSH).
NEW TERMS, POTENTIAL ISSUES

- Hazard requiring a preventive control replaces significant hazard
  - No definition change

- Preventive controls qualified individual
  - All facility employees must be qualified individuals

- Economically motivated adulteration
  - Required hazard analysis element

- Shipping containers examined before use
  - Examination versus inspection
New definition of qualified individual
- Everyone involved in animal food production must be a qualified individual

New term – Preventive Controls Qualified Individual
- Qualified individual who has completed FDA-equivalent training or qualified through work experience
- Develops/oversees food safety plan
- Conducts/oversees validation, verification activities
New supplier verification requirements

- Close coordination with and approval of suppliers
- Audits, raw material/ingredient testing, other methods to confirm supplier compliance
- Written procedures for accepting raw materials/ingredients
- Parallels foreign supplier requirements, expected this October