Complying with Preventive Control Rules for Animal Food

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Objectives

- To make participants aware of the basics of Food Safety Modernization Act
- To help participants understand the requirements of Preventive Control Rules for Food for Animals

Part A
Introduction to
Food Safety Modernization Act (FSMA)

Responsibility for Food safety

- Primary responsibility for human and animal food safety- Food industry.
- Enforcing Regulation- Regulatory bodies (FDA- with the exception of meat, poultry, processed egg products, and catfish (USDA))
- Consumers- Due diligence

Responsibilities of FDA

- Establishing regulations and guidance.
- Inspecting industry (domestic and international) to ensure compliance.
- Taking action to protect U.S. consumers from unsafe products.
- Analyzing samples to confirm compliance.

Seven Rules of FSMA

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Produce safety Rule
- Foreign Supplier Verification Program
- Accreditation of Third-Party Certification Bodies
- Sanitary Transportation of Human and Animal Food
- Mitigation Strategies To Protect Food Against Intentional Adulteration

Why was FSMA Needed?

- CDC data on foodborne diseases:
  - 48 million Americans to get sick
  - 128,000 to be hospitalized
  - 3,000 to die
- Caused by both domestically produced foods and imported foods.
- Accountability of global food chain

Part B
Introduction to Preventive Control Rules for Animal Food

Animal Food Laws and Regulations

- 1906 Pure Food & Drug Act
- 1938 Federal Food, Drug & Cosmetic Act
- 1958 Food Additives Amendment
- 1976 Medicated Feed CGMPs
- 1996 Animal Drug Availability Act (VFDs)
- 1997 BSE/Ruminant Feed Regulations
- 2002 Bioterrorism Preparedness and Response Act
- 2007 Food and Drug Administration Amendments Act
- 2011 Food Safety Modernization Act (FSMA)
- 2014 Veterinary Feed Directive Revised Regulations

FSMA Rules Applicable to Animal Food

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	

Preventive Controls for Animal Food Timeline

- September 2015: Final rule published

Business Size	Subpart B Current Good Manufacturing Practice	Subpart C Hazard Analysis and Risk-Based Preventive Controls
All Others	Sept. 19, 2016	Sept. 18, 2017
Small Businesses (< 500 FTE)	Sept. 18, 2017	Sept. 17, 2018
Very Small Businesses (< $2.5 million/year)	Sept. 17, 2018	Sept. 17, 2019

21 CFR Part 507 – Preventive Controls for Animal Food

- Subpart A – General Provisions
- Subpart B – Current Good Manufacturing Practice
- Subpart C – Hazard Analysis and Risk-Based Preventive Controls
- Subpart D – Withdrawal of a Qualified Facility Exemption
- Subpart E – Supply-Chain Program
- Subpart F – Requirements Applying to Records That Must Be Established and Maintained

Who Must Comply?

- Facilities that manufacture, process, pack, or hold animal food for consumption in the United States
  - In general, those that register under Section 415 of the Federal Food, Drug, and Cosmetic Act (Bioterrorism Act).
  - Not complying is considered a prohibited act.
- Animal food covered by specific CGMP regulations must still comply with those regulations
  - Low-acid canned food
  - Medicated feed

Qualifications of Individuals

- Management must ensure all individuals who manufacture, process, pack or hold animal food are qualified to perform their assigned duties;
- Individuals engaged in manufacturing, processing, packing or holding animal food or in supervision must be a qualified individual and receive training in animal food hygiene and animal food safety;
- Supervisory personnel have the education training or experience to supervise production of safe animal food.

Preventive Controls Qualified Individual(s)

Must oversee:

1. Preparation of the food safety plan
2. Validation of the preventive controls
3. Determination that validation is not required
4. Review of records
5. Reanalysis of the food safety plan
6. Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production
7. Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days
8. Determination that reanalysis can be completed and additional preventive controls validated as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production

21 CFR 507.5 Exemptions

- Establishments, including farms, that are not required to register under § 415 of the Food, Drug, & Cosmetic Act
- Subpart B (CGMP) does not apply to establishments solely engaged in:
  - The holding and/or transportation of raw agricultural commodities.
  - Hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts).
  - Ginning of cotton (without manufacturing /processing, such as extracting oil from cottonseed).

21 CFR 507.5 Exemptions

- Subparts C and E do not apply to:
  - Activities subject to regulations for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (just those activities, not the whole facility)
  - Activities that are subject to Standards for Produce Safety Rule
  - Qualified Facilities (must follow modified requirements)
  - Small or very small businesses (Qualified Facilities) that are farm mixed-type facilities if the only packing or holding activities are specified low-risk packing or holding activity/animal food combinations, even if activities are for distribution into commerce
  - Facilities solely engaged in storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing

Farms and Feed Mills

- Feed mills that are part of a farm are exempt from registering as a food facility and <u>are not subject to rule</u>

- For the feed mill to be part of the farm:

  - Raising animals and feed mill are under same management in one general location, AND
  - Animal food made at the mill is only fed to animals under the farm's management

Part C

CGMP

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart B – Current Good Manufacturing Practice

- 507.14 Personnel
- 507.17 Plant and grounds
- 507.19 Sanitation
- 507.20 Water supply and plumbing
- 507.22 Equipment and utensils
- 507.25 Plant operations
- 507.27 Holding and distribution
- 507.28 Holding and distribution of human food by-products for use as animal food

Purpose of CGMP

- Necessary to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" (Preamble, II: Legal Authority).
- Establishes baseline standards for the production of safe animal food and the creation of a successful Food Safety Plan.

Other Programs Related to CGMP Regulations

- Other Animal Food Regulations with CGMP Regulations
  - 21 CFR Part 225 – Current Good Manufacturing Practice for Medicated Feeds
- Facility-Specific Prerequisite Programs
  - Employee Training
  - Facility Operations
    - Preventive Maintenance
    - Cleaning/Sanitation
    - Standard Operating Procedures
    - Quality Assurance
  - Animal Food Safety
    - HACCP
    - ISO
    - PAS 222

Which CGMP does this Concern?

§ 507.19(d)(2) Sanitation – Toxic materials described in paragraph (d)(1) of this section (*e.g.*, cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials;

Toxic materials stored improperly

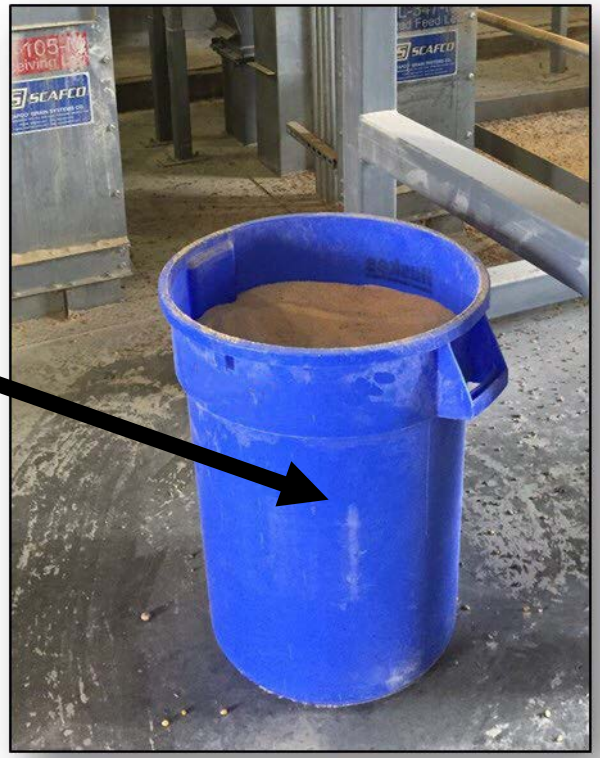
Toxic materials stored properly

Which CGMP does this Concern?

§ 507.25(a)(2) Plant operations – Animal food, including raw materials, other ingredients, or rework is accurately identified;

§ 507.25(c)(3) Plant operations – Work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms;

Rework / flush material not identified



Part 507, Subpart B – Current Good Manufacturing Practice

- *21 CFR 507.14 - Personnel*
- *21 CFR 507.17 - Plant and grounds*
- *21 CFR 507.19 - Sanitation*
- *21 CFR 507.20 - Water Supply and plumbing*
- *21 CFR 507.22 - Equipment and utensils*
- *21 CFR 507.25 - Plant operations*
- *21 CFR 507.27 - Holding and distribution*
- *21 CFR 507.28 - Holding and distribution of human food by-products for use as animal food.*

21 CFR 507.28 – Holding and Distribution of Human Food By-Products for Use as Animal Food

- *(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:*
  - *(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;*
  - *(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and*
  - *(3) During holding, human food by-products for use as animal food must be accurately identified.*

21 CFR 507.28 – Holding and Distribution of Human Food By-Products for Use as Animal Food

- *(b) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.*
- *(c) Shipping containers (e.g. totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.*

Part D

Hazard Analysis and Risk Based Preventive Controls

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart C – Hazard Analysis and Risk-based Preventive Controls

- 507.31 Food safety plan
- 507.33 Hazard analysis
- 507.34 Preventive controls
- 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control
- 507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4).
- 507.38 Recall plan
- 507.39 Preventive control management components
- 507.40 Monitoring
- 507.42 Corrective actions and corrections
- 507.45 Verification
- 507.47 Validation
- 507.49 Verification of implementation and effectiveness
- 507.50 Reanalysis
- 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food
- 507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor
- 507.55 Implementation records required for this subpart

21 CFR Part 507 – Preventive Controls for Animal Food

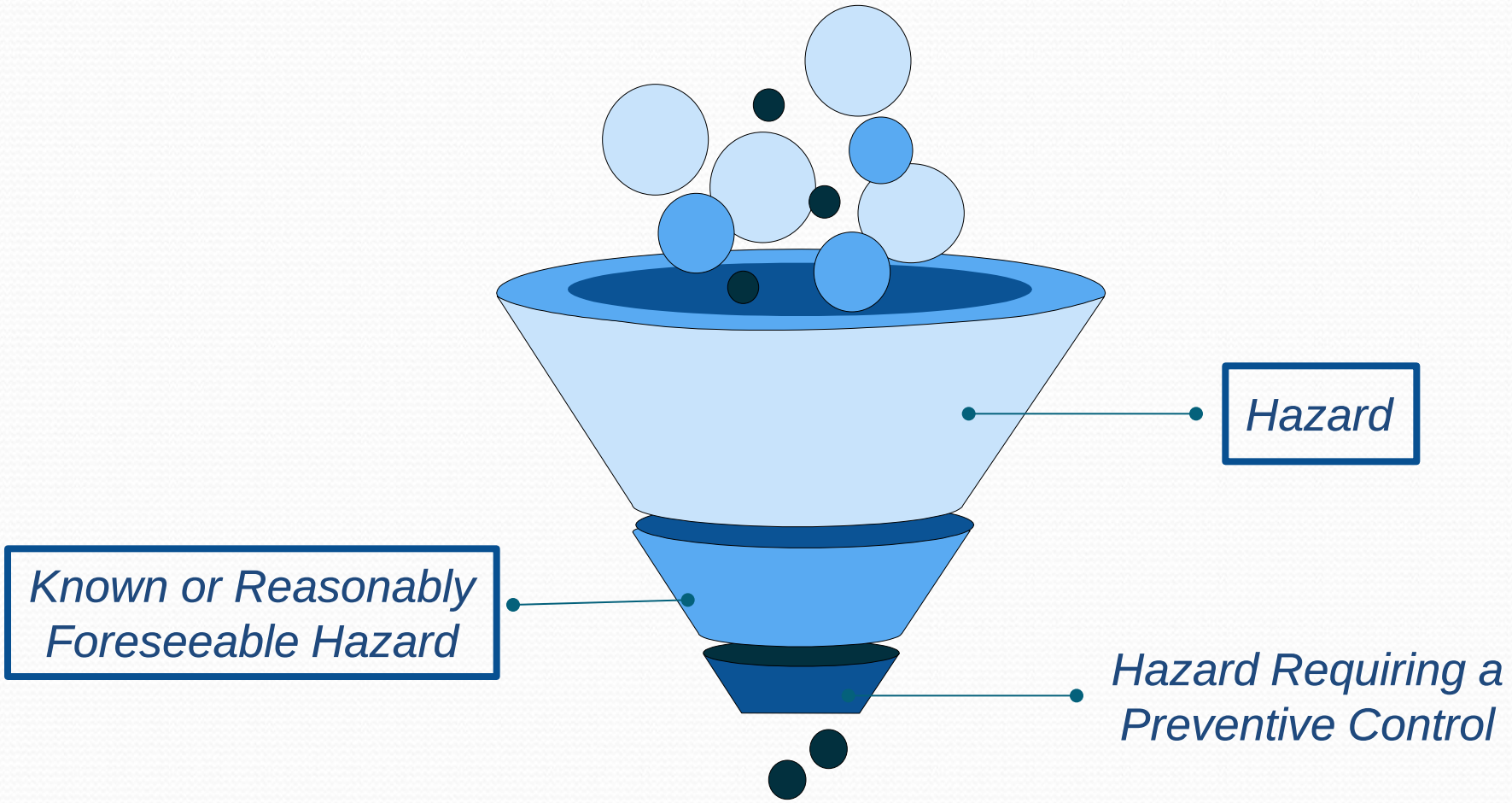
Subpart E – Supply-Chain Program

- 507.105 Requirement to establish and implement a supply-chain program
- 507.110 General requirements applicable to a supply-chain program
- 507.115 Responsibilities of the receiving facility
- 507.120 Using approved suppliers
- 507.125 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity)
- 507.130 Conducting supplier verification activities for raw materials and other ingredients
- 507.135 Onsite audit
- 507.175 Records documenting the supply-chain program

Hazard Identification in PC Rules for Human Food

- Biological hazards
- Chemical hazards (incl. Radiological)
- Physical hazards
- Economically motivated hazards

Hazard Analysis Process



Importance of Thorough Hazard Analysis

Crucial to the success of the overall food safety program

- A proper hazard analysis can:

☐ Identify hazards requiring a preventive control

☐ Focus resources on essential preventive controls

☐ Identify operations that require improvement

- An improper hazard analysis can result in:

☐ An ineffective Food Safety Plan

☐ An unmanageable Food Safety Plan

☐ Potential regulatory action

Unintentionally Introduced Chemical Hazards in Animal Foods

- Nutrient Deficiencies or Toxicities
  - Unlike human foods, animal food is typically intended to be fed as a sole source of nutrients
  - Some animals have particularly sensitive nutrient requirements, especially vitamins and minerals
    - Inadequate thiamine in cats
    - Excessive vitamin D in dogs
    - Excessive copper in sheep
  - Some animal food manufacturing processes may impact the stability of sensitive nutrients, especially vitamins

Components of a Food Safety Plan

Required Components

- Hazard Analysis
- Preventive Controls*
  - Supply-Chain Applied Controls*
  - Process Controls*
  - Sanitation Controls*
  - Other Controls*
- PC Management Components*
  - Monitoring*
  - Corrective Actions and Corrections*
  - Verification*
    - Validation*
    - Verification of Implementation and Effectiveness*
  - Recall Plan*
- Reanalysis
- Implementation Records

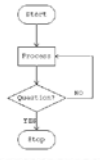
Other Useful Components

- Background Information
  - Food Safety Team
  - Facility Overview
  - Flow Diagram

Required, when appropriate, if hazard analysis identifies a *hazard requiring a preventive control

Hazard Analysis Process

1. List Ingredients and Steps/Equipment within the Process Flow (recommended)

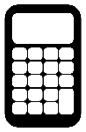


2. Identify *Known or Reasonably Foreseeable Hazards*

3. Assess Severity of Illness or Injury if Hazard were to Occur

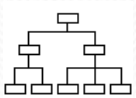
4. Assess Probability that the Hazard will Occur in the Absence of Preventive Controls

5. Determine if the Hazard Requires a Preventive Control



6. Justify the Classification of the Hazard

7. Determine the Control for the *Hazard Requiring a Preventive Control*



8. Assign a Preventive Control Number (recommended)

Types of Preventive Controls

Example of a Hazard Evaluation Form

Hazard Analysis			PAGE X of Y
PLANT NAME		ISSUE DATE	
ADDRESS		SUPERSEDES	

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							

Required Preventive Control Management Component Objectives

- Components required to manage preventive controls
  - Monitoring – 21 CFR 507.40
  - Corrective actions and corrections – 21 CFR 507.42
  - Verification – 21 CFR 507.45
    - Validation – 21 CFR 507.47
    - Verification of implementation and effectiveness – 21 CFR 507.49

Appropriate for Ensuring the Effectiveness of Different Controls

	Process Preventive Control	Sanitation Preventive Control	Supply-Chain-Applied Control	Other Control
Monitoring	✓	✓		As necessary to satisfy the requirements of Part 507.
Corrective Actions and Corrections	✓	✓	✓	
Validation	✓			
Verification of Implementation and Effectiveness	✓	✓	✓	

21 CFR 507.38 Recall plan

- (a) For animal food with a hazard requiring a preventive control you must:
  - (1) Establish a written recall plan for the animal food; and
  - (2) Assign responsibility for performing all procedures in the recall plan
- (b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:
  - (1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;
  - (2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;
  - (3) Conduct effectiveness checks to verify the recall has been carried out; and
  - (4) Appropriately dispose of recalled animal food, e.g., through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.

21 CFR 507.202
General requirements applying to records

- (b) All records must include:
  - (1) Information adequate to identify the plant or facility (e.g. the name, and when necessary, the location of the plant or facility);
  - (2) The date and, when appropriate, the time of the activity documented;
  - (3) The signature or initials of the person performing the activity;
  - (4) Where appropriate, the identity of the product and the lot code, if any.
- (c) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

21 CFR 507.208 Requirements for record retention

- (a)(1) All records required by this part must be maintained at the plant or facility for at least 2 years after the date they were prepared.
- (a)(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.
- (b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (e.g. because the facility has updated the written food safety plan (§ 507.31) or records that document validation of the food safety plan (§ 507.45(b))).

Questions?