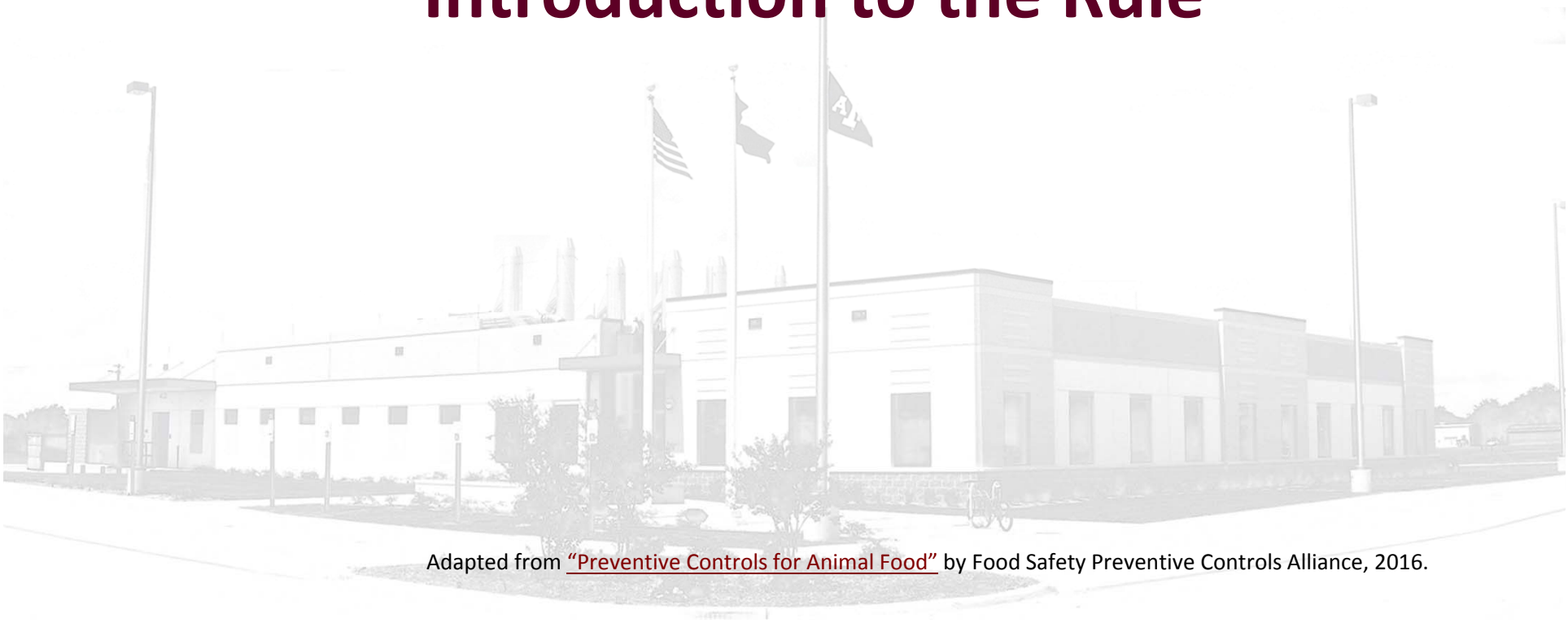
Chapter 1:
Regulatory Overview and Introduction to the Rule



Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

Objectives for Regulatory Overview and Introduction to the Rule

In this chapter, you will develop an awareness of:

- The requirements of 21 CFR Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals
- Learn the requirements of the following subparts:
  - Subpart A – General Provisions
  - Subpart D – Withdrawal of a Qualified Facility Exemption
  - Subpart F – Requirements Applying to Records That Must be Established and Maintained
- Note that subparts B, C, E will be covered more in depth in other chapters

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

Significant Animal Food Laws and Regulations

- 1906 Pure Food and 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

Adapted from "Preventive Controls for Animal Food"
by Food Safety Preventive Controls Alliance, 2016.

FSMA Snap Shot

Signed into law January 4, 2011

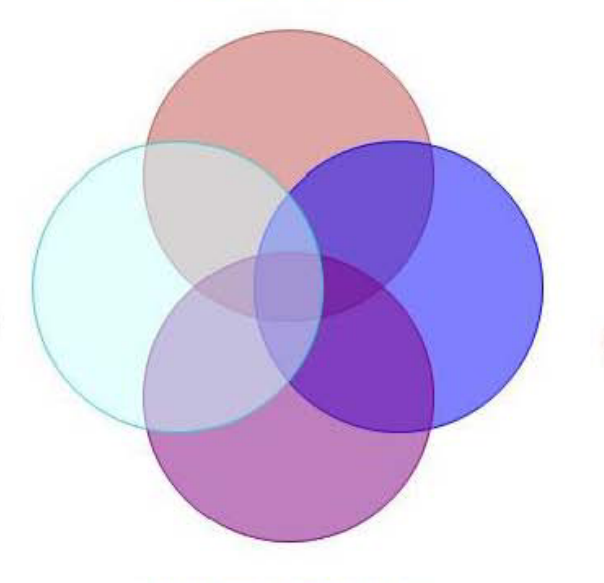
- The current food safety system has opportunity for improvement
  - 1 in 6 Americans (48 million) are sickened; 128,000 hospitalized; and 3,000 die each year from foodborne diseases (CDC, 2011)
- Identified by FDA as the most sweeping reform of food safety laws in more than 70 years
  - GOAL: Aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

FSMA Snap Shot

Prevention

Enhanced Partnerships



Inspections, Compliance, and Response

Import Safety

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

FSMA Snap Shot

This course covers just one of many rules created under the framework of FSMA:

1. Preventive Controls for Animal Food
2. Preventive Controls for Human Food
3. Produce Safety
4. Foreign Supplier Verification Programs (FSVP) for Importers
5. Sanitary Transportation of Human and Animal Food
6. Accredited Third-Party Certification
7. Mitigation Strategies to Protect Food Against Intentional Adulteration

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

Applicability to FSMA Rules to Animal Food

Rules applicable to Animal Food

- Preventive controls for Animal Food
- Foreign Supplier Verification Program
- Accredited Third-Party Certification
- Sanitary Transportation

Rules NOT applicable to Animal Food

- Preventive Controls for Human Food
- Produce Safety
- Intentional Adulteration

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

Preventive Controls for Animal Food Timeline

- January 2011: FSMA signed into law
- October 2013: First version issued (Proposed Rule)
- September 2014: Second version issued (Revised Rule)
- 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

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

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*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart A – General Provisions

- *507.1 Applicability and status*
- *507.3 Definitions*
- *507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food*
- *507.5 Exemptions*
- *507.7 Requirements that apply to a qualified facility*
- *507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food*
- *507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.1 – Applicability and Status

- *(a) The criteria and definitions in this part apply in determining whether an animal food is:*
  - *(1) Adulterated within the meaning of:*
    - *(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or*
    - *(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; and*
  - *(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.1 – Applicability and Status

- *(b) The operation of the facility that manufactures, processes, packs, or holds animal food for sale in the United Sates if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 415 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of this part and §507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.*
- *(c) Animal food covered by a specific current good manufacturing practice regulations is also subject to the requirements of those regulations.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

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

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.3 – Definitions

- *The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part.*
- Discussed throughout individual chapters

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.4 – Qualifications of Individuals who Manufacture, Process, Pack, or Hold Animal Food

- *(a)(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F of this part are qualified to perform their assigned duties; and*
- *(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F of this part are qualified to perform their assigned duties.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.4 – Qualifications of Individuals who Manufacture, Process, Pack, or Hold Animal Food

- *(b) Each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must:*
  - *(1) Be a qualified individual as that term is defined by §507.3 i.e. have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties; and*
  - *(2) Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personnel hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.4 – Qualifications of Individuals who Manufacture, Process, Pack, or Hold Animal Food

- *(c) Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food.*
- *(d) Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.3 – Definitions: *"Qualified Individual"*

- *A person who has the education , training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

What are the Qualifications of Individuals?

- All individuals who manufacture/process/pack/hold animal food must be qualified to perform their assigned duties:
  - Includes temporary and seasonal workers
  - Must be a *Qualified Individual* as defined by §507.3
    - Have education, training experience, or a combination thereof, to complete duties in a way that results in safe food
    - Receive training on animal food hygiene and safety, including importance of employee health and personnel hygiene as appropriate
- The responsibility for this assurance changes:
  - Subpart B: Management of an establishment
  - Subpart C: Owner, operator, or agent in charge of the facility

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.3 – Definitions:
"Preventive Controls Qualified Individual"

- *A Qualified Individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

Preventive Controls Qualified Individual(s)

- Must oversee:
  1. Preparation of the food safety plan
  2. Validation of 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

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

Exercise 1

1. How is a QI similar or dissimilar to a PCQI?
2. How are you going to train QI for required components and document that training?
3. As a PCQI, what tasks from the previous slide are you comfortable performing today?
    a) Which tasks are you hoping to learn?
    b) Which will you use outside resources to complete?
4. Who in your facility is it when the rule references 'management'?
5. Who in your facility is it when the rule references 'owner, operator, or agent-in-charge'?

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.5 Exemptions

- Establishments, including farms, that are not required to register under §415 of the Food, Drug, and 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)

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

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

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 1.227 – Definitions: *"Primary Production Farm"*

- An operation under one management in one general but not necessarily contiguous physical location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
- May conduct certain manufacturing, processing, packing, or holding activities of animal food as specified

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 1.227 – Definitions: *"Secondary Activities Farm"*

- An operation not located on a primary production farm that is devoted to harvesting, packing, and/or holding raw agricultural commodities
- The primary production farm(s) that grow, harvest, and/or raise the majority of those raw agricultural commodities must own or jointly own a majority interest in the secondary activities farm
- May also pack or hold raw agricultural commodities, or manufacture/process, pack, or hold processed foods so long as all such food is consumed on that farm or another farm under the same management or the manufacturing/processing falls into limited categories

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

Impact of Farm Definition on Feed Mills

- Feed mills that are part of a farm are exempt from registering as a food facility and are not subject to rule
- For the feed mill to be part of the farm:
  - Raising animals and feed mill under same management in one general location, AND
  - Animal food made at the mill is only fed to animals under the farm's management

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.3 – Definitions:
"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 fee or supplied to a farm without sale)*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.3 – Definitions: *"Qualified Facility"*

- *(when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both the following apply:*
  - *During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and*
  - *The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.7 Requirements that Apply to a Qualified Facility

- *Qualified facilities must submit attestations to the FDA that the facility:*
  - *Meets the "qualified facility" definition*
    - *Must determine status by July 31 of each calendar year*
    - *Records to support status must be retained beginning January 1, 2017, but do not need to be part of the attestation*
  - *Meets one of the following:*
    - *Option 1: Has identified potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure such controls are effective*
    - *Option 2: Is in compliance with state, local, county, tribal, or other applicable non-federal food safety laws*
- *Attestations must be submitted every 2 years (to coincide with biennial registration renewal) beginning in 2020.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.10 Applicability of Subparts C and E of this Part to a Facility Solely Engaged in the Storage of Unexposed Packaged Animal Food

- *(a) Subparts C and E of this part do not apply to a facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.*
- *(b) A facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in §507.51 for any unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

507.51 Modified Requirements that Apply to a Facility Solely Engaged in the Storage of Unexposed Packaged Animal Food

- If animal food requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens, the facility storing the animal food must:
  - Establish and implement temperature controls
  - Monitor temperature controls
  - Take corrective actions if there is a loss of temperature
  - Verify that temperature controls are consistently implemented
  - Establish and maintain records of monitoring, corrective action, and verification

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.12 Applicability of this Part to the Holding and Distribution of Human Food By-products for use as Animal Food

- *(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production, or the off-farm packing and holding of raw agricultural commodities, that are packed or held by the human food facility for distribution as animal food if:*
  - *(1)(i) The human food facility is subject to and in compliance with subpart B of part 117 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; or*
  - *(ii) For the off-farm packing and holding of produce (as defined in part 112 of this chapter), the human food facility is subject to and in compliance with §117.8 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and*
  - *(2) The human food facility does not further manufacture or process the by-products intended for use as animal food.*
- *(b) The human food by-products for use as animal food identified in paragraph (a) of this section must be held and distributed by that facility in accordance with §507.28 and §117.95 of this chapter.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.1 Applicability and Status

- *(d) Except as provided by §507.12, if a facility is require to comply with subpart B of part 507 and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food and animal food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, provided the food safety plan also addresses hazards for the animal food, if applicable, that require a preventive control. When applying the requirements of part 117 of this chapter to animal food, the term "food" in part 117 includes animal food.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart B – Current Good Manufacturing Practice

- *507.14 Personnel*
- *507.17 Plants 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*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

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*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart D – Withdrawal of a Qualified Facility Exemption

- *507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption*
- *507.62 Issuance of an order to withdraw a qualified facility exemption*
- *507.65 Contents of an order to withdraw a qualified facility exemption*
- *507.67 Compliance with, or appeal of, an order to withdraw a qualified facility exemption*
- *507.69 Procedure for submitting an appeal*
- *507.71 Procedure for requesting an informal hearing*
- *507.73 Requirements applicable to an informal hearing*
- *507.75 Presiding officer for an appeal and for an informal hearing*
- *507.77 Timeframe for issuing a decision on an appeal*
- *507.80 Revocation of an order to withdraw a qualified facility exemption*
- *507.83 Final agency action*
- *507.85 Reinstatement of a qualified facility exemption that was withdrawn*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

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 for 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*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507 – Preventive Controls for Animal Food

Subpart F – Requirements Applying to Records That Must be Established and Maintained

- *507.200 Records subject to the requirements of this subpart*
- *507.202 General requirements applying to records*
- *507.206 Additional requirements applying to the food safety plan*
- *507.208 Requirements for record retention*
- *507.212 Use of existing records*
- *507.215 Special requirements applicable to a written assurance*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.200 Records Subject to the Requirements of this Subpart

- *(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart.*
- *(b) Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.*
- *(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.*
- *(d) The requirements of §507.206 apply only to the written food safety plan.*
- *(e) The requirements of §507.202(a)(2), (4), and (5) and (b) do not apply to records required by §507.7.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.202 General Requirements Applying to Records

- *(a) Records must:*
  - *(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;*
  - *(2) Contain the actual values and observations obtained during verification activities;*
  - *(3) Be accurate, indelible, and legible;*
  - *(4) Be created concurrently with performance of the activity documented; and*
  - *(5) Be as detailed as necessary to provide history of work performed.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR Part 507.202 General Requirements Applying to Records

- *(b) All records must include:*
  - *(1) Information adequate to identify the plant of 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; and*
  - *(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.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

What Records are Needed?

- Records must:
  - Be kept as original records, true copies, or electronic record
  - Contain actual values and observations
  - Be accurate, indelible, and legible
  - Be created concurrently with performance of the activity
  - Be detailed as necessary
- Records must include:
  - Information adequate to identify the plant or facility (name and location)
  - Date and, when appropriate, time of the activity
  - Signature or initials of the person performing the activity
  - The identity of the product and lot code, if any, when appropriate
- These records are exempt from 21 CFR 11 requirements.

Adapted from "Preventive Controls for Animal Food"
by Food Safety Preventive Controls Alliance, 2016.

§507.206 Additional Requirements Applying to the Food Safety Plan

The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification.

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

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))).*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.208 Requirements for Record Retention

- *(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.*
- *(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonable accessible location but must be returned to the plant or facility within 24 hours for official review upon request.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

21 CFR 507.212 Use of Existing Records

- *(a) Existing records (e.g., records that are kept to comply with Federal, State, or local regulations, or for any other reasons) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of he required information and satisfy the requirements of this subpart.*
- *(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.*

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

§507.215 Special Requirements Applicable to a Written Assurance

- Any written assurance required by this part must contain:
  - Effective date
  - Printed names and signatures of authorized officials
  - Applicable assurances
- Written assurances for when the facility is not required to implement a preventive control include:
  - Acknowledgement that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions
  - Provision that if the assurance is terminated, responsibility for compliance with the applicable provisions reverts to the manufacturer/processor on the date of termination

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

Regulation Overview Summary

The full regulation, 21 CFR Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, is in Appendix 1.

- Sections include:
  - 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

*Underlined subparts have been reviewed here. Other subparts will be reviewed in Ch. 2 to 10.

Adapted from "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

END

Dr. Tim Herrman
Professor, State Chemist & Director
Office of the State Chemist
Texas A&M University
(979) 845-1121
tjh@otsc.tamu.edu

References

Content and images adapted from:

Food Safety Preventative Controls Alliance. (2016). *Preventive Controls for Animal Food*. Retrieved from: https://ifpti.absorbtraining.com/Files/FSPCA%20-%20Animal%20Food/FSPCA%20Instructor%20Resource%20Portal%20Animal%20Food/FSPCA%20AF%20Participant%20Manual%20v1.0_Final_06.14.2016.pdf