

THE PC RULE AND YOU

How to Use the Hazard Analysis and Risk-Based Preventive
Controls for Food for Animals (PCAF)
Draft Guidance for Industry #245

March 6, 2018

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

Objectives

- Scope and Purpose
- Guidance Structure
- Key Chapter Content
- Update on implementation
- Answer questions

PCAF Scope

Subparts Established in 21 CFR 507

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

Purpose of Guidance

- To help facilities develop a food safety plan (FSP) in accordance with the requirements of the PCAF Rule of part 507.
 - A written food safety plan (FSP)
 - Hazard analysis
 - Preventive controls
 - Monitoring
 - Corrective actions
 - Verification (including validation)
 - Recall plan
 - Associated records



Guidance Structure

Section	Subject
Chapter 1	The Food Safety Plan
Chapter 2	Conducting A Hazard Analysis
Chapter 3	Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Animal Food
Chapter 4	Preventive Controls
Chapter 5	Overview of Preventive Control Management Components
Appendix A	Glossary of Terms
Appendix B	Table of Abbreviations and Acronyms used in this Guidance
Appendix C	Flowchart – Hazard Analysis
Appendix D	Example Hazard Analysis Worksheet
Appendix E	Aid to Identifying Animal Food Hazards



Chapter 1: Food Safety Plan

- Overview of the FSP
- Key Personnel
- FSP and HACCP
- Formatting
- Reanalysis

Chapter 2: Hazard Analysis

- Key requirements
 - Written
 - Hazard Identification
 - Hazard Evaluation
- A definition for “Hazard Analysis”

Hazard Analysis

The process of identifying and evaluating known or reasonably foreseeable hazards to determine whether there are any hazards requiring a preventive control.

Chapter 2: Hazard Analysis

- Recommended Activities

- Preliminary steps

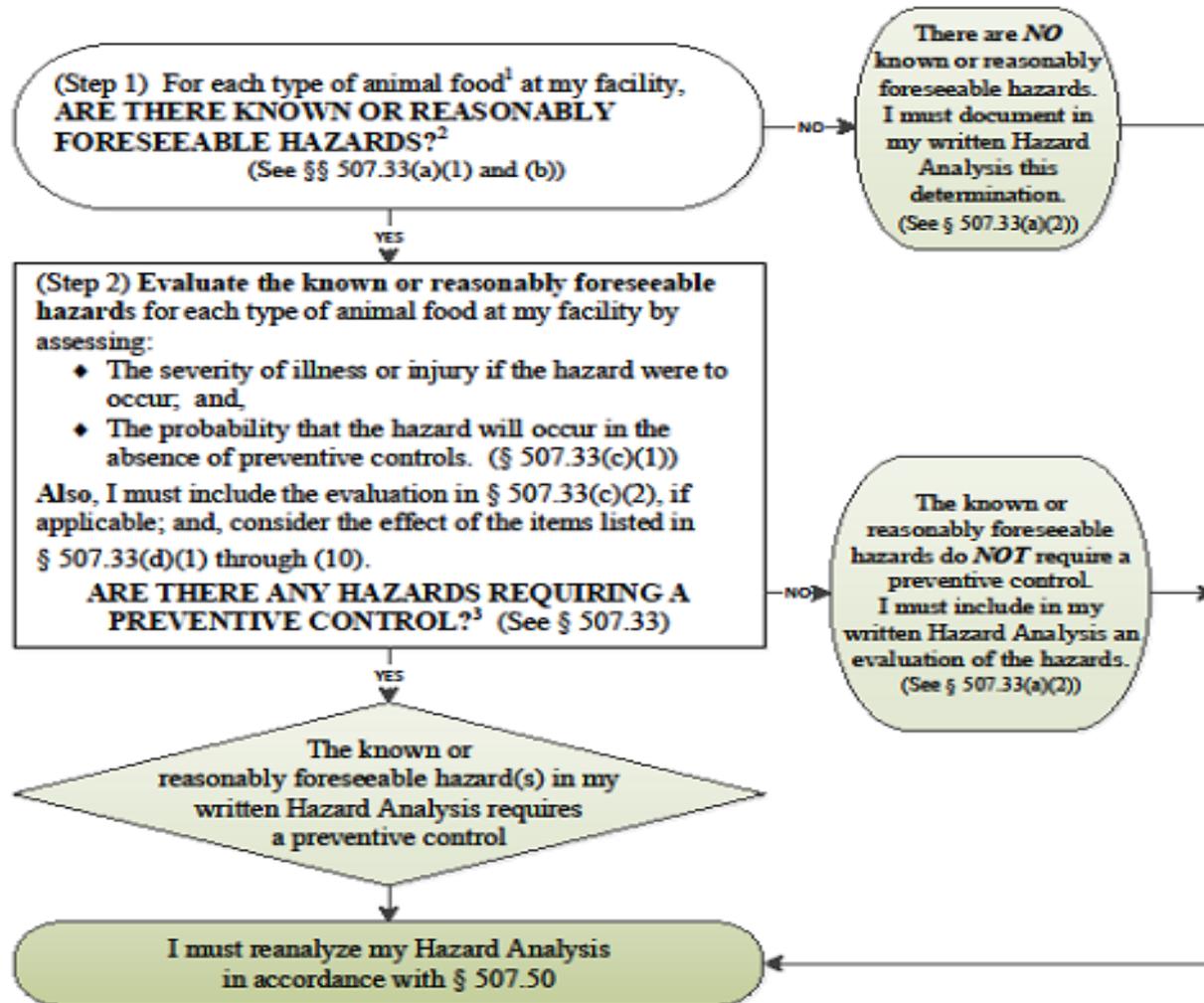
- Select your preventive controls qualified individual
- Describe the animal food, its distribution, intended use, and the intended animal species, life stage, or production class
- Develop a process flow diagram and verify this diagram onsite
- Describe the process



Chapter 2: Hazard Analysis

- Use of a Hazard Analysis Worksheet (optional)
- Conducting a Hazards Analysis
 - Severity
 - Probability
- Identify Hazards Requiring a Preventive Control
- Identifying Preventive Controls

Appendix C: Flowchart – Hazard Analysis



Chapter 2: Hazard Analysis

- Recommended Activities
 - Example Hazard Analysis Worksheet
 - Appendix D

(Column 1)	(Column 2)	(Column 3)	(Column 4)	(Column 5)	(Column 6)
Ingredient and Processing Step	Known or Reasonably Foreseeable Hazard	Does the Known or Reasonably Foreseeable Hazard Require a Preventive Control? "Yes" or "No"	Explanation/Justification	Preventive Control(s) Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"

Chapter 3: Animal Food Hazards

- Known or reasonably foreseeable hazards in animal food facilities and that may be applicable to the facility and animal food.
- Ingredient-related
- Process-related
- Facility-related

Chapter 3: Animal Food Hazards

- It does not provide an exhaustive compilation of hazards or extensive details about each hazard
- Hazards are generalized to animal food and the severity of illness for species and /or lifestage are not provided

Appendix E – Aid to Identifying Food Hazards

- Animal Protein Products
- Forage Products
- Grain Products
- Plant Protein Products
- Processed Grain By-Products
- Roughage Products
- Technical Additives and Other Substances Used for Manufacturing
- Fat and Oil
- Other Nutritional Products
- Mixed Ingredient Products

Appendix E – Aid to Identifying Food Hazards

TABLE 3. GRAIN PRODUCTS

SUB-CATEGORY	EXAMPLE PRODUCTS	Biological Hazards: Pathogenic Bacteria (e.g., <i>Salmonella</i> , <i>L. monocytogenes</i>)	Biological Hazards: Prions (e.g., BSE)	Biological Hazards: Viruses or Parasites	Chemical Hazards: Animal Drug residue and carryover	Chemical Hazards: Economic Adulterants (e.g., melamine; urea)	Chemical Hazards: Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	Chemical Hazards: Heavy Metals	Chemical Hazards: Natural Toxins (e.g., mycotoxins)	Chemical Hazards: Nutrient Deficiency or Toxicity	Chemical Hazards: Pesticides	Physical Hazards: Physical (e.g., metal, glass, plastic)
Whole Grain	Barley; Pearl Millet; Oats; Rice; Triticale; Wheat; Corn; Sorghum (milo)	-	-	-	-	-	-	-	Ref. 31-38	-	Ref. 39	-
Grain Flour	Barley Flour; Corn Flour; Rye Flour	-	-	-	-	-	-	-	Ref. 31-38	-	-	-
Grain Meal	Wheat Germ; Corn Meal; Corn Germ	-	-	-	-	-	-	-	Ref. 31-38	-	-	-



Chapter 4: Preventive Controls

The guidance in this chapter is intended to help facilities that manufacture, process, pack, or hold animal food to identify and implement preventive controls.

Chapter 4: Preventive Controls

Preventive Control	Chapter Section
Process Controls for Biological Hazards	4.5
Preventive Controls for Chemical Hazards	4.6
Preventive Controls for Physical Hazards	4.7
Sanitation Controls	4.8
Supply-Chain Controls	4.9
Recall Plan	4.10

Chapter 4: Preventive Controls

- Process controls include procedures, practices, and processes to ensure the control of parameters during operations
- Include
 - Parameters associated with control of the hazard
 - Maximum or minimum value, or combination of values
- Parameter Values vs. Operating Limits

Chapter 4: Preventive Controls

- Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling.
- Include procedures, practices, and processes for:
 - Cleanliness of animal food-contact surfaces
 - Prevention of cross-contamination from insanitary objects, personnel, and raw products

Chapter 4: Preventive Controls

- Supply-Chain Controls include:
 - Requirement to establish and implement a supply-chain program
 - General requirements applicable to a supply-chain program
 - Responsibilities of the receiving facility
 - Using approved suppliers
 - Determining appropriate supplier verification activities
 - Frequency of conducting the activity
 - Conducting supplier verification activities for raw materials and other ingredients
 - Onsite audit
 - Records documenting the supply-chain program

Chapter 5: Preventive Control (PC) Management Components

- The guidance provided in this chapter is intended to help facilities implement the preventive control management components (PC management components) that are part of their food safety plan.

Chapter 5:

PC Management Components

- Who is Responsible
- Monitoring
- Corrective Actions and Corrections
- Verification Activities
- Reanalysis

Guidance Summary

- The first five chapters provide guidance on:
 - the components of a food safety plan and the importance of each component
 - how to conduct a hazard analysis and develop a food safety plan for the animal food that you produce
 - the biological, chemical (including radiological), and physical agents that are known or reasonably foreseeable hazards in manufacturing, processing, packing, and holding of animal food
 - identifying preventive controls for biological, chemical, and physical hazards associated with animal food
 - preventive control management components
 - recordkeeping requirements associated with the food safety plan and implementation of the food safety plan

Things to Keep in Mind

- There is flexibility in how to apply these requirements
- Facilities should take a scientific-based, yet practical, approach to implementation
- Not all hazards will be a hazard for all facilities
- Focus on the parts that are relevant to you
- We want your comments and feedback

Implementation Update

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
Hazard Analysis and Preventive Controls (#245) (chapters 1-5)	Draft
Future Guidance	Status
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
“Co-manufacturer” supply chain supplier approval and verification	Final
Enforcement Discretion Policy	Final

CGMP Inspections (FY18): What to Expect

- Only inspections in FY18 will be for compliance with CGMPs for “large” and “small” businesses
- CGMP inspections started in October 2017
- Increased number of inspections
- Inspections being 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

Inspections – Looking beyond FY18

- PC Inspections starting:
 - Oct 2018 for “large” businesses
 - Jan 2019 (at earliest) for “small” businesses
- FDA working to update inspection program
 - Combining different types of inspections
 - Will impact our work planning for both FDA and states

Questions?

