Current Good Manufacturing Practice, Hazard Analysis, & Risk Based Preventive Controls for Animal Foods
21 CFR Part 507

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Center for Veterinary Medicine (CVM)
PREVENTIVE CONTROLS FOR ANIMAL FOODS (PCAF) RULE
21 CFR PART 507

Why was this put in place?

✓ FSMA was signed into law on January 4, 2011
✓ FSMA is the most extensive change to animal food regulation
✓ FSMA enables FDA to better protect public health by strengthening the food safety system.
Who is required to follow the rule?

✓ Facilities that are required to register as a food facility under section 415 of the FD&C Act because they manufacture, process, pack or hold animal food
✓ Applies to domestic and imported foods (including animal food and ingredients)
✓ There are some exemptions and modified requirements for certain facilities
✓ Farms are exempt
✓ Who has to register? Draft Guidance for Industry: [Questions and Answers Regarding Food Facility Registration (Seventh Edition)](https://www.fda.gov)
PCAF Rule - 21 CFR Part 507

How does this affect me as an animal food manufacturer?

✓ Develop and follow Current Good Manufacturing Practices (CGMPs) requirements in your facility
  ▪ CGMPs will provide baseline requirements necessary to prevent animal food from contamination.
  ▪ Proper implementation is necessary to produce safe animal food
  ▪ They can be flexible to address the variety of animal food facilities.
  ▪ They will be a pre-requisite program to the implementation of preventive controls.
## FSMA GUIDANCE DOCUMENTS MOST RELEVANT TO DISTILLERS GRAINS MANUFACTURERS

<table>
<thead>
<tr>
<th>Available Guidance</th>
<th>Status</th>
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<tbody>
<tr>
<td>Current Good Manufacturing Practices (#235)</td>
<td>Final</td>
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<tr>
<td>Hazard Analysis and Preventive Controls (#245)</td>
<td>Draft</td>
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<tr>
<td>Hazard Analysis and Risk-Based Preventive Controls for Food for Animals – Supply-Chain Program (#246)</td>
<td>Draft</td>
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<td>Questions and Answers Regarding Food Facility Registration (Seventh Edition)</td>
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Additional guidance can be found at [www.fda.gov/fsma](http://www.fda.gov/fsma) including these listed below:

<table>
<thead>
<tr>
<th>Guidance</th>
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<tbody>
<tr>
<td>Foreign Supplier Verification Programs for Importers of Food for Humans and Animals</td>
<td>Draft</td>
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<tr>
<td>Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities</td>
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<tr>
<td>Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards</td>
<td>Final</td>
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<tr>
<td>FDA's Voluntary Qualified Importer Program</td>
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The rule establishes CGMP provisions to ensure safe and wholesome animal food. Specifically by establishing baseline standards in the following areas:

- Personnel;
- Plant and grounds;
- Sanitation;
- Water supply and plumbing;
- Equipment and utensils;
- Plant operations;
- Holding and distribution; and
- Holding and distribution of human food by-products for use as animal food.

How does this affect me as an animal food manufacturer?
§ 507.14 PERSONNEL

**Personnel** - plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food.
Plants & Grounds - the grounds surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food, including provisions to keep areas from being a harborage for pests, maintaining areas so they are not a source of contamination, adequately draining areas, and treating and disposing of waste so it is not a source of contamination.
§ 507.17 PLANT AND GROUNDS

Provide adequate ventilation where necessary and appropriate to minimize fumes in areas where they may contaminate animal food;

Provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage.
§ 507.17 Plant and Grounds

The plant must protect animal food stored outdoors in bulk from contamination by any effective means, such as outdoor elements (e.g., rain, wind-blown debris) or pests (e.g., bird or rodent droppings, nesting materials).
Sanitation - buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming contaminated.
The only toxic materials that may be used or stored in the area of the plant where animal food is manufactured, processed, or exposed are those that are needed for cleaning and sanitizing, plant and equipment maintenance and operation, laboratory testing procedures, and use in the plant's operations.
§ 507.20 Water Supply and Plumbing

Water supply & Plumbing - the water supply must be adequate for the operations and must be derived from a suitable source. Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing or processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities.
All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained.
Plant management must ensure that all operations in the manufacturing, processing, packing, and holding of animal food are conducted in accordance with the CGMP requirements of this subpart.
§ 507.25 Plant Operations

- Raw materials and other ingredients must be examined to ensure they are suitable for manufacturing and processing into animal food.
- Raw materials must be cleaned as necessary to minimize contamination.
- If raw materials and other ingredients are susceptible to contamination with mycotoxins or other natural toxins, they must be evaluated and used in a way that does not result in an animal food that can cause injury or illness to animals or humans (21 CFR 507.25(b)(2)). Natural toxins include aflatoxin, vomitoxin, fumonisins, and alkaloids.
§ 507.27 Holding and Distribution

Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration.
PCAF RULE - 21 CFR PART 507
QUESTIONS ?? (at this point)
PCAF Rule - 21 CFR Part 507

PCAF HAPC Guidance Document

✓ If your facility is subject to the rule, and does not meet any exemptions from the Preventive Controls (subparts C & E) you must establish and implement a food safety plan which includes conducting a hazard analysis and implementing risk based preventive controls.

✓ The PCAF HAPC guidance #245 helps facilities develop a food safety plan in accordance with the requirements of 21 CFR part 507

- A written food safety plan;
- Hazard analysis;
- Preventive controls;
- Monitoring;
- Corrective actions and corrections;
- Verification;
- Supply-chain program;
- Recall plan; and
- Associated records.
# PCAF HAPC GUIDANCE STRUCTURE

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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 3: ANIMAL FOOD HAZARDS

• Known or reasonably foreseeable hazards in animal food facilities and that may be applicable to the facility and animal food.

• 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.

• References Appendix E

• Ingredient-related
• Process-related
• Facility-related
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.

• 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.
• Supply-chain controls
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.

• 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
Communications for Assistance

FSMA Technical Assistance Network
Web site: http://www.fda.gov/fsma
To contact FDA about FSMA and find the new online form for submitting questions:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm
QUESTIONS ??

The More I Think
The More Confused I Get