FSPCA Preventive Controls for Animal Food

Abbreviated Guide to Creating a Livestock Food Safety Plan Under the Preventive Controls for Animal Food (PCAF) Rule

2020

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Developed by the

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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The following individuals made significant contributions of time and expertise in developing the *Abbreviated Guide to Creating a Livestock Food Safety Plan Under the Preventive Controls for Animal Food (PCAF) Rule* and accompanying *Example Food Safety Plan – Medicated and Nonmedicated Feeds for Swine and Broilers* (affiliations at time of publication are noted):

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Hazard Analysis and Preventive Controls for Animal Food Training

The Food Safety Preventive Controls Alliance (FSPCA) developed this guide and example livestock food safety plan to be used in conjunction with the FSPCA Preventive Controls for Animal Food training curriculum to support compliance with FDA's *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Food for Animals* regulations. For the most current training curriculum information, please consult: https://www.ifsh.iit.edu/fspca.

Background

The Food Safety Modernization Act (FSMA) of 2011 was signed into law with the goal of refining the U.S. food safety system, changing the regulatory framework from reactive to proactive toward food safety hazards. The Preventive Controls for Animal Food (PCAF) rule[1] poses many new regulatory requirements, which may bring some implementation challenges for animal food manufacturers. The rule established requirements for both Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls (PC). Only certain animal food facilities that were producing medicated animal feed had previously been subject to federal CGMP requirements[2]. While some facilities had been required to follow the medicated feed CGMPs, the PCAF CGMPs and PCs are new for the entire animal food industry. With the implementation of new food safety standards, facilities are required to comply with CGMPs and create a food safety plan that addresses known or reasonably foreseeable hazards and how the facility will mitigate these hazards.

This *Abbreviated Guide to Creating a Livestock Food Safety Plan Under the Preventive Controls for Animal Food (PCAF) Rule* should be used in conjunction with other information provided within the Food Safety Preventive Controls Alliance (FSPCA) PCAF Training Curriculum. The curriculum teaches the requirements for developing an animal food safety plan, along with the principles of risk-based preventive controls. An electronic version of the participant manual for the FSPCA PCAF training curriculum may be downloaded free of charge at: https://d1vy0ga05cdjr5.cloudfront.net/c6f30ca0-84ae-4613-bec0-5439702d4b9e/FSPCA%20-%20Human%20Food/FSPCA_AF_Participant_Manual_v1.1_FINAL_PUBLIC_09.27.2017.pdf?230.

This guide outlines steps that a facility producing livestock food could follow when developing its required food safety plan. The guide is accompanied by an example food safety plan for a facility that produces medicated and nonmedicated feeds for swine and broilers. The example plan demonstrates the application of steps outlined in this guide and illustrates an acceptable food safety plan structure that contains required and best management practices information.

The example livestock food safety plan accompanying this guide is structured differently than the FSPCA example pet food plan included within the FSPCA PCAF participant manual, but it contains the same information. This example plan is different from other example plans included within the FSPCA PCAF participant manual in that identified hazards are listed only once—because a prerequisite program (for example, standard operating procedures [SOPs] and CGMPs) is used to reduce the probability of the hazard occurring throughout the facility. Examples of some of the

[1] The PCAF rule is found in Title 21 of the Code of Federal Regulations part 507 (21 CFR Part 507). In general, the PCAF rule applies to facilities that are required to register with the FDA as an animal food facility under section 415 of the Federal Food, Drug, and Cosmetic Act because they manufacture, process, pack, or hold animal food for consumption in the United States.

[2] The Medicated Feed rule is found in Title 21 of the Code of Federal Regulations part 225 (21 CFR Part 225). In general, the Medicated Feed regulation applies to facilities that are required to obtain a Medicated Feed Mill License with the FDA based on the facility handling Category II Type A medicated articles that could result in a residue in the milk, meat, or eggs if used improperly in medicated animal food.

prerequisite programs mentioned in the plan are included. These prerequisite programs need to be effective and implemented properly to reduce the probability of the hazard occurring within the facility (receipt through distribution).

Preventive Controls Qualified Individual

Food safety plans must be developed and implemented under the direction of a preventive controls qualified individual (PCQI), as required by the PCAF rule. The U.S. Food and Drug Administration (FDA) defines a PCQI as 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. The FSPCA provides the only standardized curriculum recognized by FDA for training in the development and application of risk-based preventive controls. The FSPCA curriculum teaches the requirements for developing a food safety plan, along with the principles of risk-based preventive controls needed for an individual to become a PCQI. In addition, the FSPCA curriculum uses examples that can be applied to animal food facilities making either pet food or livestock food.

Facility operators and PCQIs should keep two key ideas in mind while drafting a food safety plan:

1. Each plan should be specific to the facility named on the plan. Similar facilities with different practices are expected to have different plans. Copy-and-paste is not a good practice when developing a plan and leaves room for error.

2. A food safety plan should be a living document—information in the plan should be representative of current operations in the facility. For example, the facility should update the plan when processes change, when a food safety concern occurs, when there is a change in food safety team members, or if any new ingredients with new hazards are introduced into the facility.

Example Livestock Food Safety Plan

The following information outlines an acceptable food safety plan structure that contains required and best management practices information. The information also details steps that a facility could follow when developing its own plan. The accompanying example plan for medicated and nonmedicated feeds for swine and broilers demonstrates the application of these steps.

Title Page

The title or cover page of the food safety plan should state the facility information (name, location, personnel, and date). The plan must be signed by the owner, operator, or agent in charge upon initial completion and whenever modified. The FDA defines the owner, operator, or agent in charge as a person who has an ownership interest in, or management authority of, a facility or a portion of a facility. The designation of this person is up to the facility. In addition, the PCQI for the facility may be identified on the plan, but this is not required.

1. Background Information

This section contains optional information that may be helpful for plan development and implementation. While optional, the information would be included in the food safety plan if used to support decisions or evaluations in the hazard analysis and determinations of whether hazards require a preventive control (for example, if a hazard evaluation rubric is used as part of the hazard analysis). A facility may choose to include the background information as part of the plan or to keep this information in separate documents. Having this information on hand is a best business practice and provides easily accessible reference material during an audit or inspection.

Food Safety Team Members

The plan may include a list of food safety team members and their job titles at the facility, including the identity of the designated PCQI. In some cases, the list of team members may contain only one person. The PCQI does not have to be on staff, but there should be someone on site who is knowledgeable about the food safety plan and the decisions made in developing it.

Facility Overview

The facility overview provides basic information about the facility and its operations. The overview may include: general product description(s), the intended use of the product(s), the different groups of ingredients used, and medications used in animal feed. The ingredients may be grouped by commonality. For the example livestock plan, all animal proteins are grouped together because similar hazards were identified for all the animal protein ingredients in this facility. A facility may also choose to include additional information within the facility overview section that would be helpful to anyone reading and implementing the food safety plan.

Hazard Evaluation Rubric

Using a hazard evaluation rubric is not a requirement of the rule but when utilized and referenced becomes a component of the food safety plan. Facilities must conduct a hazard analysis, but they can use methods other than a rubric during their evaluation of hazards. If a rubric is used for the hazard analysis, the rubric would be considered part of the overall hazard analysis and would be included in the food safety plan. When using a rubric, the facility should customize the chart based on the operations of the facility. There should be distinctions between the levels of probability and severity, as well as definitions for each. A facility can use recall data, reportable food registry (RFR) data, or the facility's own data (such as consumer complaints related to food safety) to determine how hazards are classified. The hazard evaluation rubric in the example livestock plan addresses the combinations of probabilities and severities for hazards that will not require a preventive control, based on the criteria established by the facility.

Flow Diagram

A flow diagram is helpful when developing, updating, and explaining the hazard analysis. Process steps within the facility should be considered if they are points at which animal food hazards may

be introduced, amplified, or controlled. This optional diagram can be as general or as detailed as necessary.

2. Hazard Analysis and Preventive Controls Determination and Justification

Hazard Identification and Analysis

Step 1: Complete column 1 of the Hazard Identification Chart by listing (1) the ingredients or ingredient categories used in animal food produced at the facility and (2) the steps and equipment identified within the process flow diagram. Ingredients may be grouped based on similar composition or hazards. Though not required, making a diagram is helpful when evaluating where hazards could be introduced into the facility's animal food.

Step 2: Complete column 2 of the Hazard Identification Chart. For each ingredient or process step, begin by considering hazards that could potentially occur. Then, narrow to those that are known or reasonably foreseeable for the facility and the type of animal food being produced. These are hazards the facility will further evaluate. In the Hazard Identification Chart, the biological (B), chemical, including radiological (C), and physical (P) known or reasonably foreseeable hazards are listed on separate rows. A facility may use any number of available resources to determine which hazards are known or reasonably foreseeable, including the RFR (https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry); recent FDA recalls (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts); and issues at the facility or similar facilities, such as consumer complaints related to food safety. Another potential resource is the Guidance for Industry #245: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-245-hazard-analysis-and-risk-based-preventive-controls-food-animals).

Step 3: Transfer the known or reasonably foreseeable hazards from the Hazard Identification Chart into column 1 of the Hazard Analysis Chart.

Step 4: In column 2 of the Hazard Analysis Chart, make notes of where or why these hazards might occur. For instance, the specified hazard may be found in multiple ingredients or process steps, as illustrated in the example livestock plan where *Salmonella* spp. and aflatoxins are associated with various groups of ingredients or processing steps. Noting such information will enable employees to understand the decision making and intent of the food safety plan.

Step 5: In column 3 of the Hazard Analysis Chart, assess the severity of illness or injury to humans or animals if the hazard were to occur. For severity of illness to humans, a facility should consider the hazards from human consumption of meat, milk, and eggs, as well as hazards from exposure during handling of animal food, particularly within a home. Regulatory levels are established for some hazards, which can assist with this determination.

Step 6: In column 4 of the Hazard Analysis Chart, assess the probability that the hazard will occur. The example livestock plan relies on the use of prerequisite programs to reduce the probability of known or reasonably foreseeable hazards from occurring. When a facility relies upon a prerequisite

program to justify a reduced probability of occurrence, adequate information about the prerequisite program, such as a copy of the relevant SOPs, must be included as part of the evaluation in the hazard analysis. A facility may reference the same prerequisite program multiple times across hazards, ingredients, and/or processing steps.

Step 7: In column 5 of the Hazard Analysis Chart, determine if the hazard requires a preventive control. The purpose of this assessment is to consider the probability of known and reasonably foreseeable hazards that could occur in the final product and the severity posed by those hazards in the facility's final product. At this point, a facility can use a hazard evaluation rubric and available resources to assess whether, based on the combined severity and probability assessment, the identified hazard requires a preventive control. The example livestock plan includes boxes to check for yes or no. The facility will need to provide a hazard analysis justification. This justification is described later.

Steps 8 and 9: If a facility identifies a hazard requiring a preventive control, the appropriate control for the hazard would need to be determined (column 6) and a preventive control number could be assigned (column 7). The preventive control number is optional; it is assigned as a reference number for corresponding management components throughout the rest of the plan, not as a ranking order of importance or classification of preventive controls. The example livestock plan does not identify any hazards requiring a preventive control. If a preventive control is identified, please see other examples in the FSPCA training manual for additional details on these steps.

Hazard Analysis Justification

The facility associated with this example livestock food safety plan has determined there are no preventive controls required for the known or reasonably foreseeable hazards associated with the facility or the food. For hazards that do not require a preventive control, perhaps the most important component of the hazard analysis is the justification for why the hazard does not require a preventive control. For hazards that have a preventive control, the justification is not as critical because management components will address how the hazard is controlled.

Following the example within the plan of aflatoxin in swine and broiler food, the determination in the hazard analysis was that aflatoxins exceeding FDA action levels in finished feeds pose a high severity of illness or injury. The hazard analysis justification section discusses how this determination was reached. Specifically, the example plan indicates that the severity is high because in products consumed by animals, aflatoxin concentrations above FDA action levels can decrease feed intake and inhibit weight gain and even cause death. Further, aflatoxins are carcinogens that can be passed through production animals into meat, milk, and eggs intended for human consumption. Since this hazard can adversely affect human and animal health, the designation for the severity of this hazard was high.

The example plan further describes why the facility determined that the probability of aflatoxin occurring in finished products at concentrations exceeding FDA action levels is low. Specifically, the plan explains that this facility has prerequisite programs in place to test incoming ingredients that may be affected by aflatoxins. This prerequisite program is considered when determining the

probability that the hazard will occur in the facility. Additional prerequisite programs include reliance on environmental data and using suppliers with an acceptable compliance history.

References

This example plan includes a list of references—as the hazard analysis, in addition to evaluations made based on the professional experience of the PCQI, should be based on illness data, scientific reports, and other information available to the facility. References can be found through the FDA or other government institutions, universities, trade groups, scientific studies, or originate from in-house testing or studies. Any in-house testing or studies used as a reference should have followed the scientific method and be documented.

3. Preventive Controls and Management Components

The example livestock plan did not identify the need for preventive controls in its hazard analysis. It is not appropriate to include management components in a plan that does not identify preventive controls. An explanation can be included, or the section may be omitted.

4. Supporting SOPs

If a facility relies on prerequisite programs, such as SOPs, in the hazard analysis process, documents associated with the implementation of the prerequisite program need to be available during an inspection. Such documentation demonstrates that the prerequisite program reduces the probability that a known or reasonably foreseeable hazard identified in the hazard analysis will occur in that facility. If prerequisites are changed, a facility will need to re-analyze the food safety plan and update it.

This example food safety plan does not include examples for all prerequisites referenced in the hazard analysis. In practice, a facility should be prepared to provide documentation for any and all prerequisites. The example livestock food safety plan includes SOPs for Aflatoxin Evaluation Procedures (SOP 101.01), Deoxynivalenol (DON) Testing Procedures (SOP 102.01), and Bulk Grain and Grain Byproducts and Plant Protein Product Sampling Procedures (SOP 201.01). Each SOP should note the purpose of the procedure, the process to be followed, records associated with the actions taken, quality assurance protocols, and any references. In practice, SOPs should be step-by-step procedures that are easy to follow.

Following the example within the plan for the hazard analysis of aflatoxin, the justification for not having a preventive control for aflatoxin contamination of grains and grain byproducts is its low probability of occurrence, based on prerequisite programs in place that mitigate the hazard. The procedure identified was aflatoxin testing, outlined by SOP 101.01: Aflatoxin Evaluation Procedures.

Within the Aflatoxin Evaluation Procedures SOP, another SOP is referenced for sampling. The Bulk Grain and Grain Byproducts and Plant Protein Product Sampling Procedures (SOP 201.01) are based on the U.S. Department of Agriculture (USDA) Federal Grain Inspection Service (FGIS)

Sampling Handbook. These additional documents are referenced in the SOP and justification within the hazard analysis. A facility should be prepared to provide these documents too.

5. Recall Plan

A recall plan is not a required component of the food safety plan if the hazard analysis does not identify a hazard requiring a preventive control. However, having a recall plan is considered a best management practice, and facilities should consider developing such a plan, even if it is not part of the food safety plan.

The recall plan should be as detailed as possible, with contact information for each person involved at all levels. Keep the information up to date to reflect any changes in personnel or contact information for the facility and customers.

6. Implementation Records

No implementation records are associated with any preventive controls in the example livestock plan because the hazard analysis did not indicate the need for preventive controls due to the reliance on prerequisite programs to reduce the probability of the hazard. The facility keeps the PCQI's FSCPA training record on file, as this is a required implementation record. A facility may include a statement explaining that there are no preventive controls and therefore no associated implementation records, or the section may be omitted.

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

EXAMPLE FOOD SAFETY PLAN
MEDICATED AND NONMEDICATED FEEDS FOR SWINE AND BROILERS

Facility Name:
Address:

Owner, operator, or agent in charge: **Date:** _____

Preventive Controls Qualified Individual (PCQI): **Date:** _____

Disclaimer

This Food Safety Plan example is modeled after forms developed for the FSPCA Preventive Controls for Animal Food curriculum and can be modified to reflect the needs of individual establishments. FSPCA has no input on individual establishment of Food Safety Plans.

There is no standardized or mandated format for a Food Safety Plan, but the information should be arranged in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the Food Safety Plan.

This example does not represent any specific operation. Processing steps may have been omitted or combined to facilitate its development. It is not complete and contains both required and optional information. Because development of a Food Safety Plan is site specific, it is highly unlikely that this plan can be used in a specific facility without significant modification.

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1. Background Information

Food Safety Team Members

Name	Position
I.R. Charge*	Plant manager
F.S. Leader	Production supervisor
I.M. Quality	Quality supervisor
I.M. Fixer	Maintenance supervisor
**Preventive Controls Qualified Individual (PCQI).* Attended FSPCA Course for Animal Food. Completion certificate is in personnel file.	

Facility Overview

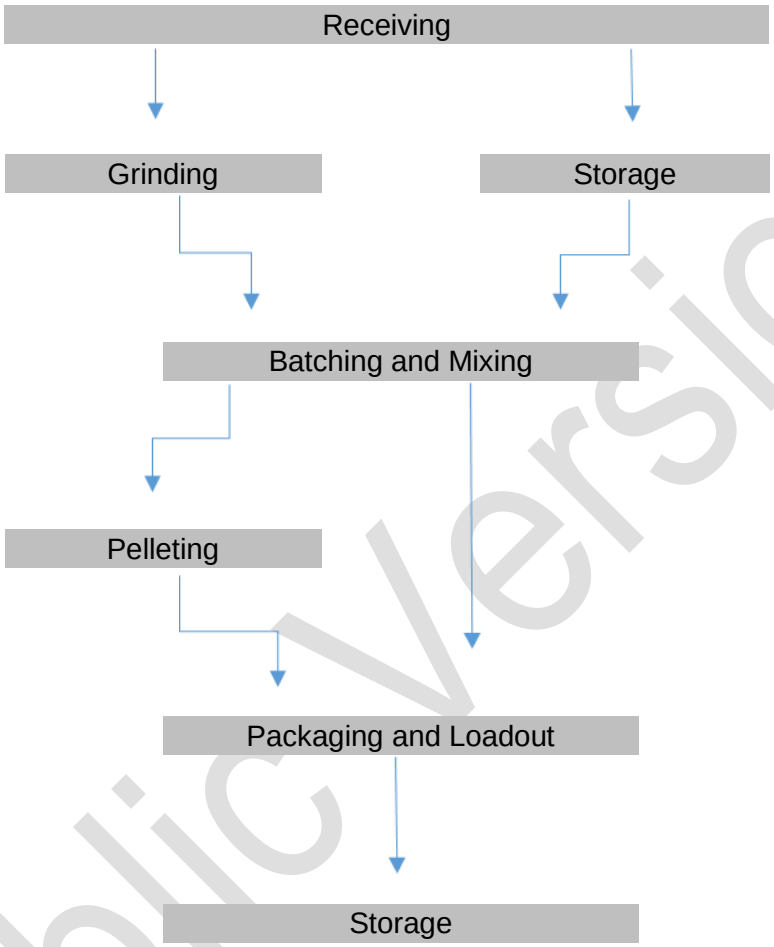
- **Product Description:**
  - Complete animal foods for broilers and swine of all ages.
  - Animal foods may be medicated or nonmedicated.
  - Animal foods may be pelleted or mash.
  - Animal food is distributed in bags and bulk.
- **Intended Use:** Animal foods are to be fed as the sole ration to their intended species.
- **Ingredients Used By the Facility:** animal protein products, grain products, plant protein products, processed grain byproducts, animal fat, vegetable oil, macrominerals, trace minerals, synthetic amino acids, feed additives, vitamins
- **Medications Used By the Facility:** Bacitracin methylene disalicylate, Carbadox, Decoquinate, Monensin, Oxytetracycline, Tylosin, Virginiamycin, Nicarbazin

Hazard Evaluation Rubric

SEVERITY / PROBABILITY		High (I)	Medium (II)	Low (III)	Very Low (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals; unlikely to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals; unlikely to impact humans.	Illness or injury is minor. Possible to impact animals; unlikely to impact humans.
High (A)	Immediate danger that the hazard will occur.	**I-A**	**II-A**	**III-A**	**IV-A**
Medium (B)	Hazard probably will occur in time if not controlled.	**I-B**	**II-B**	**III-B**	**IV-B**
Low (C)	Hazard possible to occur in time if not controlled.	**I-C**	**II-C**	**III-C**	**IV-C**
Very Low (D)	Hazard unlikely to occur; may assume hazard will not occur.	**I-D**	**II-D**	**III-D**	**IV-D**

Preventive Control (PC) Required	No PC Required

Flow Diagram



2. Hazard Analysis and Preventive Controls Determination and Justification

Hazard Identification Chart		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	**Identify *Known or Reasonably Foreseeable Hazards* (B – biological; C – chemical [including radiological]; P – physical)**	
Animal Protein Products (porcine meat and bone meal, poultry meal)	B	*Salmonella* spp.
	C	None
	P	Foreign Materials (metal, plastics)
Grain Products (corn)	B	*Salmonella* spp.
	C_1	Aflatoxin
	C_2	Deoxynivalenol
	C_3	Fumonisin
	P	Foreign Materials (metal, wood, stones)
Plant Protein Products (soybean meal, peanut meal)	B	*Salmonella* spp.
	C	Aflatoxin
	P	Metal
Processed Grain Byproducts (DDGs, wheat byproducts)	B	*Salmonella* spp.
	C_1	Aflatoxin
	C_2	Deoxynivalenol
	C_3	Fumonisin
	P	Metal
Animal Fat and Vegetable Oil	B	*Salmonella* spp.
	C	NONE

	P	NONE
Macrominerals (dicalcium phosphate, limestone, salt)	B	NONE
	C	NONE
	P	Metal
Trace Minerals (swine and poultry trace mineral premixes)	B	NONE
	C	NONE
	P	Metal
Synthetic Amino Acids (lysine, methionine, threonine)	B	NONE
	C	NONE
	P	NONE
Feed Additives (Direct-fed microbials, enzymes, yeast)	B	NONE
	C	NONE
	P	NONE
Vitamins	B	NONE
	C	NONE
	P	NONE
Medications	B	NONE
	C	NONE
	P	NONE
Receiving	B	*Salmonella* spp. (due to cross contamination and pests)
	C	Nutrient Deficiency or Toxicity (due to potential for wrong bin assignment, receipt of wrong ingredient and/or concentration)
	P	Foreign Materials (stones, glass, metal, wood, plastics)
Grinding	B	*Salmonella* spp. (due to cross contamination)

	C	NONE
	P	Metal
Batching and Mixing	B	*Salmonella* spp. (due to cross contamination)
	C_1	Medications (incorrect use, cross contamination, carryover to unapproved species)
	C_2	Nutrient Deficiency (salt, calcium) (incorrect amounts and/or use of wrong ingredient)
	C_3	Nutrient Toxicity (salt, selenium) (incorrect amounts and/or use of wrong ingredient)
	P	Metal
Pelleting	B	*Salmonella* spp. (due to cross contamination)
	C_1	Medications (cross contamination, carryover to unapproved species)
	P	Metal
Packaging and Loadout	B	*Salmonella* spp. (due to cross contamination)
	C	Medications (cross contamination, carryover to unapproved species)
	P	Metal
Storage (raw ingredient and finished feed)	B	*Salmonella* spp. (due to raw ingredient cross contamination or pests)
	C	Medications (cross contamination, carryover to unapproved species)
	P	NONE

Hazard Analysis Chart

Identification		Evaluation			Preventive Control(s)	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Identify *Known or Reasonably Foreseeable Hazards*	Identify Where the Specified Hazard is Found or Occurs in the Facility	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess the Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Control Number
Salmonella spp.	Animal Protein Products, Grain Products, Plant Protein Products, Processed Grain Byproducts, Animal Fat and Vegetable Oil, Receiving, Grinding, Batching and Mixing, Pelleting, Packaging and Loadout, Storage	Medium (II)	Very Low (D)	☐Yes ☒No	n/a	n/a
Foreign Materials (stones, plastics, glass, wood, metal)	Animal Protein Products, Grain Products, Receiving	Very Low (IV)	Very Low (D)	☐Yes ☒No	n/a	n/a
Aflatoxin	Grain Products, Plant Protein Products, Processed Grain Byproducts	High (I)	Low (C)	☐Yes ☒No	n/a	n/a
Deoxynivalenol (DON)	Grain Products, Processed Grain Byproducts	High (I)	Low (C)	☐Yes ☒No	n/a	n/a
Fumonisin	Grain Products, Processed Grain Byproducts	Medium (II)	Low (C)	☐Yes ☒No	n/a	n/a
Metal	Plant Protein Products, Processed Grain	Very Low (IV)	Low (C)	☐Yes ☒No	n/a	n/a

	Byproducts, Macrominerals, Trace Minerals, Grinding, Batching and Mixing, Pelleting, Packaging and Loadout					
Nutrient Deficiencies (salt, calcium)	Receiving, Batching and Mixing	Medium (II)	Low (C)	☐Yes ☒No	n/a	n/a
Nutrient Toxicities (salt, selenium)	Receiving, Batching and Mixing	Medium (II)	Low (C)	☐Yes ☒No	n/a	n/a
Medications	Batching and Mixing, Pelleting, Packaging and Loadout, Storage	Medium (II)	Very Low (D)	☐Yes ☒No	n/a	n/a

Hazard Analysis Justification

Hazard	Justification
Salmonella spp.	Although it is known or reasonably foreseeable that *Salmonella* spp. may be associated with the ingredients used in the facility and the type of animal food manufactured, their moderate severity (II – Medium) and very low probability (D – Very Low) determine that they are <u>not</u> a *hazard requiring a preventive control* because: • Severity: If the hazard were to occur, *Salmonella* may cause illness to animals, but only if it were the serotype pathogenic to the type of animal food being manufactured. According to the FDA Salmonella Compliance Policy Guide (CPG) 690.800, the serotypes of *Salmonella* this facility must be concerned with include poultry (*Pullorum, Gallinarum,* or *Enteritidis*) and swine (*Choleraesuis)*. In addition, there is limited contact between this type of animal food and humans because it is not typically used in the home. Thus, there is limited impact on human health. • Probability: Scientific research reported the frequency with which different *Salmonella* serotypes were found in animal food and ingredients. Of the serotypes relevant to this facility and identified in the severity section above, none were within the top 25 most prevalent serotypes reported (Li, X. et al. 2012).
Foreign Materials (stones, plastics, glass, wood)	Although it is known or reasonably foreseeable that foreign materials, such as stones, plastics, glass, or wood, may enter this facility through ingredient receiving or process steps, their very low severity (IV – Very Low) and very low probability (D – Very Low) determine that they are <u>not</u> a *hazard requiring a preventive control* because: • Severity: If the hazard were to occur, it is unlikely that foreign materials will be of a sufficient size to cause injury to animals and are not a hazard to humans. • Probability: It is unlikely that anything of sufficient size will make it through the entire processing system and be present in finished feed. Compliance with personnel (21 Code of Federal Regulations [CFR] 507.14), plant and grounds (21 CFR 507.17), sanitation (21 CFR 507.19), equipment and utensils (21 CFR 507.22), and plant operations (21 CFR 507.25) current good manufacturing practices (CGMPs) reduces the likelihood that foreign materials will be present in the final products.
Aflatoxin	Although it is known or reasonably foreseeable that aflatoxins may enter this facility through bulk ingredient receiving, their high severity (I – High) and low probability (C – Low) determine that they are <u>not</u> a *hazard requiring a preventive control* because: • Severity: If the hazard were to occur, aflatoxins are carcinogenic and can be passed through meat to humans. Additionally, aflatoxins may cause illness to animals if FDA action levels are exceeded. According to the FDA Action

	Levels for Aflatoxins in Animal Feeds Compliance Policy Guide 683.100, the action limit for immature swine and broilers is 20 parts per billion (ppb). FDA policies consider the following to be immature animals: ○ Swine: piglets less than 100 pounds ○ Chickens and ducks: chicks and ducklings younger than 8 weeks (including fryers, broilers, and roasters) Procedures are followed to prevent grains and other ingredients with more than 20 ppb aflatoxin into the facility. • Probability: Although the severity of this hazard is high, the probability of occurrence is low because testing procedures are in place (Standard Operating Procedure [SOP] 101.01: Aflatoxin Evaluation Procedures) to ensure only bulk ingredients with no more than 20 ppb aflatoxin enter the facility. Temporal data are also used to determine when and how often ingredients should be tested for aflatoxin.
Deoxynivalenol (DON)	Although it is known or reasonably foreseeable that deoxynivalenol (DON) may enter this facility through bulk ingredient receiving, its high severity (I – High) and low probability (C – Low) determine that it is <u>not</u> a *hazard requiring a preventive control* because: • Severity: According to Sobrova et al (2010), if the hazard were to occur, there is potential for DON to be passed to humans from animal products. The FDA advisory level for DON in grains and grain byproducts fed to swine is 5 parts per million (ppm) (not to exceed 20% of the diet) and 1 ppm for the complete diet (FDA 2010). In addition, the FDA advisory level for grains and grain byproducts fed to poultry is 10 ppm (not to exceed 50% of the diet) and 5 ppm for the complete diet. Procedures are followed to prevent ingredients with more than 5 ppm DON from entering the facility. In addition, ingredients are used in a manner that ensures that DON advisory limits for complete diets are not exceeded. • Probability: Although the severity of this hazard is high, the probability of occurrence is low because testing procedures are in place (SOP 102.01: Deoxynivalenol [DON] Testing Procedures) to ensure only bulk ingredients with less than 5 ppm DON enter the facility. In addition, ingredients used in swine and poultry feed are formulated into complete diets in a manner that complies with FDA guidance. Temporal data are also used to determine when and how often ingredients should be tested for DON.
Fumonisin	Although it is known or reasonably foreseeable that fumonisin may enter this facility through bulk ingredient receiving, its medium severity (II – Medium) and low probability (C – Low) determine that it is <u>not</u> a *hazard requiring a preventive control* because: • Severity: If the hazard were to occur, fumonisin has a medium severity due to its potential to cause liver damage and pulmonary edema in swine. In poultry, fumonisin has the

	potential to cause reduced growth and mild liver damage (Henry 2014). Animal studies suggest fumonisin does not accumulate in animal tissues and will not affect humans consuming animal products. The FDA has issued guidance levels for fumonisin in corn and corn byproducts (FDA 2001). FDA guidance levels for fumonisin (total FB_1+FB_2+FB_3) on a dry weight basis for corn and corn byproducts are 20 ppm (no more than 50% of the diet) for swine and 100 ppm (no more than 50% of the diet) for poultry being raised for slaughter. • Probability: Although the severity for this hazard is medium, the likelihood of occurrence is low because the facility has procedures in place to check suppliers and temporal data to predict when fumonisin levels could be high enough in ingredients to cause a feed safety concern. Historically, this facility has not had feed safety issues associated with fumonisin.
Metal	Although it is known or reasonably foreseeable that metal may enter the animal food manufacturing process, its very low severity (IV – Very Low) and low probability (C – Low) determine that it is not a *hazard requiring a preventive control* because: • Severity: If the hazard were to occur, metal has a very low severity due to the eating behavior of the animals being fed. Both swine and poultry have sorting behaviors that limit the likelihood of metal ingestion or damage to the animals. Additionally, metal is unlikely to be transferred from animals into the human food system. • Probability: Due to prerequisite programs in place, such as screens and magnets, it is unlikely that metal will end up in the final product. The facility's preventive maintenance plan requires screens to be checked daily and magnets to be checked at least once per week (SOP#).
Nutrient Deficiencies (sodium chloride [salt], calcium)	Although it is known or reasonably foreseeable that nutrient deficiencies may occur in receiving or during batching and mixing, their medium severity (II – Medium) and low probability (C – Low) determine that they are not a *hazard requiring a preventive control* because: • Severity: If the hazard were to occur, sodium chloride (salt) deficiencies have a medium severity because of their ability to adversely impact the health of animals. Salt deficiencies in swine and poultry diets can cause decreased growth parameters, dehydration, and even death (National Research Council 1980). If the hazard were to occur, calcium deficiencies have a medium severity because of their ability to adversely impact the health of animals. In swine and poultry, calcium deficiency in the diet can cause rickets. • Probability: Due to prerequisite programs in place, such as standard operating procedures for receipt of ingredients (SOP#), placement of materials in the correct bins (SOP#),

	qualified individual training (SOP#), proper labeling, batching system (alarms, record review), and testing procedures, it is unlikely that the finished feed will result in nutrient deficiencies.
Nutrient Toxicities (sodium chloride [salt], selenium)	Although it is known or reasonably foreseeable that nutrient toxicities may occur in receiving or during batching and mixing, their medium severity (II – Medium) and low probability (C – Low) determine that they are <u>not</u> a *hazard requiring a preventive control* because: • Severity: If the hazard were to occur, sodium chloride (salt) toxicity has a medium severity because of its ability to adversely impact the health of animals. Sodium chloride toxicity has been shown to cause polydipsia, diarrhea, ataxia, incoordination, tremors, sternal and lateral recumbency, and death in market age turkeys, which exhibit similar clinical signs of toxicity as other poultry (Wages et al. 1995). High dietary salt concentrations increase water intake in swine and poultry but do not influence performance in growing pigs or lactating sows (Chittavong et al. 2013; Seynaeve et al. 1996). If the hazard were to occur, selenium toxicity has a medium severity because of its ability to adversely impact the reproductive health of swine and poultry. Additionally, high levels of selenium accumulation can cause sudden death or severe distress, especially in grazing animals. Treatment of selenium toxicity is generally not effective, though removing the source may help (National Research Council 1980). • Probability: Due to prerequisite programs in place, such as standard operating procedures for receipt of ingredients (SOP#), placement of materials in the correct bins (SOP#), qualified individual training (SOP#), proper labeling, batching system (alarms, record review), and testing procedures, it is unlikely the finished feed will result in nutrient toxicities.
Medications	Although it is known or reasonably foreseeable that medications may cause hazards during batching and mixing, pelleting, packaging and loadout, and storage, their medium severity (II – Medium) and low probability (C – Low) determine that they are <u>not</u> a *hazard requiring a preventive control* because: • Severity: If the hazard were to occur, medications have a medium severity because there are two medications in this facility that are category II (Carbadox and Nicarbazin) and require withdrawals. • Probability: Due to prerequisite programs in place, such as batching records, system alarms, flushing, and sequencing procedures (SOP#), it is unlikely finished feed will contain unsafe levels of medications. In addition, this facility follows medicated feed CGMPs, 21 CFR 225, and has daily reconciliation records for all medications used in the facility regardless of category.

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3. Preventive Controls and Management Components

No management components are necessary since the hazard analysis did not indicate the need for preventive controls.

4. Supporting SOPs

(This section does not offer examples for **all** SOPs, nor does it offer fully developed documentation within the SOPs referenced in the hazard analysis.)

SOP 101.01: Aflatoxin Evaluation Procedures

Purpose: Evaluation of incoming grains and grain byproducts that are susceptible to aflatoxin contamination is important to ensure unsafe levels of aflatoxins aren't present in the finished feeds, thus ensuring the health of animals and humans consuming animal products.

Grain and Grain Byproducts and Plant Protein Product Evaluation: Prior to unloading, obtain a representative sample from the load, following sampling procedures (SOP 201.01: Bulk Grain and Grain Byproducts and Plant Protein Product Sampling Procedures). Test the sample obtained from every *nth* load for aflatoxin concentration following test kit instructions. Record aflatoxin levels for each test performed and retain these records. Reject any load that tests higher than the acceptable level (20 ppb). If a load is rejected, the next *"x"* loads from the supplier will be tested. If all loads tested have an acceptable aflatoxin content, the frequency of testing for the supplier will return to normal levels. If the aflatoxin content of one of the *"x"* loads is unacceptable, product will not be received from the supplier until additional assurances are received from the supplier that products will conform to specifications.

Records: Qualified individual training; sampling procedures; aflatoxin evaluation results; rejection records, as necessary.

Quality Assurance: Supervisor reviews aflatoxin evaluation results daily.

SOP 102.01: Deoxynivalenol (DON) Testing Procedures

Purpose: Evaluation of incoming grains and grain byproducts that are susceptible to DON contamination is important to ensure unacceptable levels of DON are not present in the finished feeds, thus ensuring the health of animals and humans consuming animal products.

Grain and Grain Byproduct Evaluation: Prior to unloading, obtain a representative sample from the load, following sampling procedures (SOP 201.01: Bulk Grain and Grain Byproducts and Plant Protein Product Sampling Procedures). Test the sample obtained from every *nth* load for DON concentration following test kit instructions. Record DON levels for each test performed and retain these records. Reject any load that tests higher than the acceptable level (5 ppm). If a load is rejected, the next *"x"* loads from the supplier will be tested. If all loads tested have an acceptable DON content, the frequency of testing for the supplier will return to normal levels. If the DON content of one of the *"x"* loads is unacceptable, product will not be received from the supplier until additional assurances are received from the supplier that products will conform to specifications.

Records: Qualified individual training; sampling procedures; DON evaluation results; rejection records, as necessary.

Quality Assurance: Supervisor reviews DON evaluation records daily.

SOP 201.01: Bulk Grain and Grain Byproducts and Plant Protein Product Sampling Procedures

Purpose: Collection of representative raw material and ingredient samples is important to ensure quality and safety analysis procedures will provide accurate results.

Bulk Grain and Grain Byproducts and Plant Protein Product Sampling Procedure: Visually inspect the load for debris, lumps, foreign material, or obvious adulteration. Insert the probe at a 10-degree angle from the top of the truck to collect 10 probed samples of approximately 1 lb each. Mix composite sample in bucket. Grind the entire composite sample. Divide sample using riffle divider to 1 lb sample. Prepare sample according to procedures for subsequent analysis.

Records: Qualified individual training; USDA FGIS Sampling Handbook; rejection records, as necessary.

Quality Assurance: Manager reviews records associated with sampling daily.

5. Recall Plan

A recall plan is not required within the Food Safety Plan since the hazard analysis did not indicate the need for preventive controls. This recall plan is being included as a voluntary best management practice.

Recall Team

Assignment	Person	Contact Information
Recall Coordinator: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Responsibility: The recall coordinator generally has the following duties: • Directs product recalls. • Directs the recall team and coordinates actions and communications. • Ensures that appropriate documentation related to the affected product is collected. • Determines the location and quantity of affected product involved in the recall. • Reports the status, findings, and recommendations related to the recall situation to senior management. • Notifies pertinent regulatory agencies. • Maintains the facility's written policies associated with the recall plan and its activities.		
Publicity and Public Relations: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Responsibility: As directed by recall coordinator, communicates with customers, the public, and regulatory agencies.		
Sales and Marketing: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Nutritionist or Veterinarian: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Purchasing: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Quality Assurance / Food Safety: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Accountant: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Attorney: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Administrative Support:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
FDA Recall Coordinator:		Office: xxx-xxx-xxxx
State Recall Coordinator:		Office: xxx-xxx-xxxx

Determining if Recall Action is Necessary

Problem Reported By	Initial Action	Decisions	Actions
Regulatory agency that believes product is causing illness or injury to animals and/or humans.	Assemble recall team and ask agency if recall is recommended.	Evaluate situation; decide whether a product should be recalled and, if so, how much product to recall.	**If no recall is needed**: Document reason and action taken.
News media story on problem with a type of animal food distributed by the facility.	Assemble recall team and review internal records.		**If recall is needed**: • Assign responsibilities. • Gather evidence. • Evaluate evidence. • Initiate communications. • Monitor recall. • Determine appropriate disposition of affected product. • Work with regulatory agencies to determine when recall should end. • Assemble recall team and debrief. • Prepare for legal issues.
Internal or customer information that suggests a potential food safety issue.	Assemble recall team and review internal records.		

Regulatory Agency Communication

Product Description Form:

Modify the **Product Description Form** developed as a component of the Food Safety Plan as necessary to reflect only the product involved in the recall, including:

- product name(s) (including brand name and generic name),
- product labels, and
- removal of any names of products that are not involved in the recall.

Product Labeling:

Assemble two complete sets of product(s) labeling to provide to the regulatory agency recall coordinator. Include:

- product labeling (including all private labels),
- individual package label,
- bag label (or photocopy),
- package inserts,
- directions for use, and
- promotional material, if applicable.

Codes (Lot Identification Numbers):

Identify the lot numbers of the affected product:

- Lot number(s) involved: _____
- Lot numbers coding system: (Describe how to read the product's code.)

  _____

  _____
- Expected shelf life of product: _____

Recall Company Contacts

Provide the following contact information for company personnel associated with the recall to the relevant regulatory agencies:

Manufacturer name: *[Name and address]*

Position	Name, Title	Contact Information
Recall coordinator		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Email:
Responsible individual		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Email:
Public contact (*May be one of the above or someone else. If possible, select a different individual to allow the coordinator to focus on retrieving product and resolving the issue.)*		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Email:

Notification of the Public

Example Press Release Template

[*Company Name]* Voluntarily Recalls *[insert summary info]* Representing *[X quantity] [--No Other Products Affected--]*

Contact Number for Consumers: XXX-XXX-XXXX

Contact Number for Media: XXX-XXX-XXXX

FOR IMMEDIATE RELEASE – *[date] – [Company name]* is voluntarily recalling *[xx]* Lot Codes of *[COMPANY/BRAND name] [insert specific product name and description]*, representing *[insert quantity]. [Insert reason for recall.*]

This action relates only to *[Company name]* products with any of these Lot Codes printed on the package:

- *[Insert lot codes]*

No other Lot Codes or any other *[Company name]* products are involved in this action.

Only these specific Lot Codes are subject to the recall. Customers are asked to remove from distribution immediately all product with codes listed below. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
[Company Name] [insert product name(s)]	*[insert product codes(s)]*	*[insert item number(s)]*

[Company name] is voluntarily recalling *[insert product name(s)]* due to [*insert reasons **or** "Although no reports of illness have been received associated with this product, we are voluntarily recalling this product out of an abundance of caution."]*.

For more information or assistance, please contact us at XXX-XXX-XXXX (Monday to Friday, 9:30 a.m. to 5 p.m. CST) or via our website at www.xxx.com.

Evaluation/Description of Recall

Explain in detail how product is defective or violative.	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk, if any, associated with the deficiency.	
If the recall is due to the presence of a foreign object, describe the foreign object's size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (for example, a toxin, metal, medication, or prohibited animal protein), describe the amount of contaminant in the product. Provide labeling, a list of ingredients, and the Safety Data Sheet for the product.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) on which it occurred.	
Explain whether the problem/defect affects all lot(s) subject to recall or just a portion of the lot(s) subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: • Date of complaint • Description of complaint (include details of any injury or illness) • Lot Number involved	
If a regulatory agency is involved in this recall, identify agency and contact.	

Quantity of Recalled Product

Total quantity of affected product	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on hold	
Indicate how the product is being quarantined.	
Estimate amount remaining in marketplace. • Facility warehouse level • Distributor level • Customer level	
Provide the status/disposition of marketed product, if known (for example, used, used in further manufacturing, on hold, or destroyed).	

Product Distribution Methods

Type of Accounts	Number
• Wholesalers/distributors	
• Repackers	
• Manufacturers	
• Retail	
• Consumers (internet or catalog sales)	
• Foreign consignees (specify whether they are wholesale distributors, retailers, or end users)	
• Geographic areas of distribution, including foreign countries	

Consignee List for Affected Product and Product Status

Name	***Street Address***	***City***	***State***	***Recall contact name***	***Contact phone number***	***Recalled product was shipped?***	***Recalled product was sold?***	***Recalled product may have been shipped or sold?***

Notification of Customers

Develop written procedures on how consignees will be notified (for example, mail, phone, facsimile, or email). It is advisable to include a written notification so customers will have a record of the recall and instructions on how to handle the recalled product(s). Such procedures may include:

- How to send letters to customers (for example, overnight mail, first-class mail, certified mail, facsimile, or email).
- Draft phone script, if notification includes use of phone. If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification for website and instructions for posting notification, if applicable. It is not recommended that the website be the sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. In the event of a recall, FDA will want a copy of final instructions.
- Draft procedures for how to address notifications to out-of-business distributors.

Effectiveness Checks

Effectiveness checks by account: Fill in the consignee's recall contact name and information to facilitate communication.

Consignee	Recall contact		Date contacted	Method of contact				Date of response	Number of products returned or disposed
	Name	Contact info		Phone	Email	Fax	Letter		

Effectiveness check summary: To be provided to FDA periodically.

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

Appropriate Disposition of Recalled Animal Food

- Provide a proposed method of destruction, if applicable.
- Contact the local FDA Division Recall Coordinator prior to product destruction. The FDA will review the proposed method of destruction and may choose to witness the destruction.
- Establish and maintain adequate documentation of product destruction (and whether destruction was witnessed by an FDA investigator or state inspector).
- Explain how and where any planned reconditioning will take place.
- Provide details of the reconditioning plan to the local FDA Division Recall Coordinator before implementation. Describe how reconditioned product will be identified so it is not confused with recalled product that has not been reconditioned yet.
- Conduct all reconditioning in accordance with applicable regulatory requirements. Notify the local FDA Division Recall Coordinator prior to release of reconditioned products.
- Perform field corrections (such as product relabeling) only by recalling firm representatives or under their supervision and control.

6. Implementation Records

Supporting Documentation

Re-analysis of plan as required.
Documents related to SOP implementation (for example, results of mycotoxin analysis).

Location of Records

According to CFR 507.55(a)(6) and 507.53(d), applicable training records for the PCQI are provided as implementation records. Since the PCQI for this facility attended the FDA-recognized training for the Preventive Controls for Animal Food Rule, applicable PCQI training records are located in personnel files.