
Animal Food Safety Plan

OWNER, OPERATOR, OR AGENT IN CHARGE SIGNATURE: _____

DATE: _____

C. Facility Overview

1. Physical Address

a. _____

2. Personnel

a. PCQI: _____ (certificate in Apx. A)

b. Mill Manager: _____

3. Volume/Tonnage

a. _____

4. Locations of Shipment

a. _____

5. Approximate Hours of Operation: _____

6. Qualified Individual Training:

a. Qualifications for Job Responsibilities:

i. _____

b. Qualifications for Animal Food Safety and Animal Food Hygiene:

i. _____

ii. Documentation training and assessment is located in Apx. B.

D. Process Flow

E. Ingredients and Raw Materials

DRY BULK INGREDIENTS	LIQUID BULK INGREDIENTS	DRY PACKAGED INGREDIENTS

II. Current Good Manufacturing Practice

FSMA CGMP Compliance Requirements - General

Purpose

The purpose of these Current Good Manufacturing Practice (CGMP) requirements include:

1. Meeting baseline requirements of the Current Good Manufacturing Practice outlined in Subpart B of 21 CFR 507, the Preventive Controls for Animal Food Rule.
2. Communicating the expectations of procedures to employees, customers, and regulatory personnel regarding:
 - a. Personnel
 - b. Plant and grounds
 - c. Sanitation
 - d. Water supply and plumbing
 - e. Equipment and utensils
 - f. Plant operations
 - g. Holding and distribution (of human food by-product and other product)

Compliance

We complete a CGMP self-audit every quarter to monitor compliance with these requirements. Our most recent audit can be found in Apx. C.

A. Personnel

1. Purpose

Establish baseline training requirements to ensure the production of safe animal food.

2. Scope

All individuals that manufacture, process, pack, or hold animal food.

3. Responsibilities

Management will: 1) verify that all relevant personnel complete required training prior to independently performing their assigned duties, 2) direct employees to report illness to supervisor, 3) ensure proper procedures are followed.

4. Procedure

1. Individuals will:

- a. Control personal items.
 - i. Items allowed in the manufacturing area that may be a potential source of contamination if dropped in animal food should be secured or stored properly, including jewelry, cell phones, pens, personal protective equipment, and tools.
- b. Ensure employee health does not contaminate animal food by:
 - i. Reporting vomiting, diarrhea, or fever to management.
 - ii. Washing hands, if necessary, prior to contact with animal food or contact surfaces.
- c. Maintain adequate personal hygiene and cleanliness by:
 - i. Keeping hands and arms clean so they do not introduce a source of contamination to animal food, animal food contact surfaces, or animal food packaging material.
 1. Hands should be properly washed or sanitized:
 - a. After using the toilet
 - b. If contaminated with toxic material
 2. Proper hand washing procedure includes:
 - a. Applying soap and warm water
 - b. Rubbing hands together vigorously (approximately 20 s)
 - c. Rinsing hands with warm, clean water
 - d. Drying hands with clean towel or air dryer
- d. Take other necessary precautions to protect against contamination of animal food, including:
 - i. Report the presence of any unauthorized personnel to management.
 - ii. Restricting belongings, such as clothing and food or drink, to designated areas where they do not constitute a source of contamination.

5. References

FDA Employee Health and Personal Hygiene Handbook
21 CFR 507.14

B. Plant and Grounds

1. Purpose

Establish baseline training requirements to ensure the production of safe animal food.

2. Scope

All individuals that manufacture, process, pack, or hold animal food.

3. Responsibilities

Management will: 1) verify that all relevant personnel complete required training prior to independently performing their assigned duties, 2 ensure proper procedures are followed.

4. Procedure

1. Grounds will be maintained to minimize sources of pest harborage or other potential contamination, including:
 - a. Storing equipment, litter, and waste in designated areas, including proper waste treatment and disposal.
 - b. Maintaining vegetation, driveways, and parking areas, including ensuring adequate drainage of grounds.
2. The animal food manufacturing area will be suitable for purpose, including:
 - a. Providing adequate space for cleaning and maintenance of equipment.
 - b. Controlling drip and condensate that may be a source of contamination.
 - c. Adequately ventilating vapors, steam, and fumes that may be a source of contamination.
 - d. Providing adequate and shatter-resistant lighting throughout handwashing, toilet, and areas where animal food is manufactured, processed, packed, or held.

5. Reference

21 CFR 507.17

C. Sanitation

1. Purpose

Establish baseline training requirements to ensure the production of safe animal food.

2. Scope

All individuals that manufacture, process, pack, or hold animal food.

3. Responsibilities

Management will: 1) verify that all relevant personnel complete required training prior to independently performing their assigned duties, 2 ensure proper procedures are followed.

4. Procedure

1. The areas where animal food is manufactured and animal food packaging material stored must be kept clean and in good repair.
2. Surfaces of utensils and equipment must be cleaned, maintained, and stored as appropriate to protect against the contamination of animal food, animal food contact surfaces, and animal food packaging material.
 - a. Surfaces in this facility are not wet-cleaned, and wet-processing is not used.
3. Cleaning compounds and sanitizing agents must be safe and adequate for their intended use.
4. Toxic materials will be allowed into areas where animal food is manufactured, processed, or exposed only if they are necessary for sanitation, laboratory testing, maintenance, or plant operations.
 - a. These materials must be identified, stored, and used appropriately so they are not a potential source of contamination.
5. Effective pest control must be implemented, and pesticides controlled so as to not be a potential source of contamination.
6. Trash must be conveyed, stored, and disposed of properly to protect against the contamination of animal food, animal food contact surfaces, or animal food packaging material, and from being a potential source of pest harborage.

5. Reference

21 CFR 507.19

D. Water Supply and Plumbing

1. Purpose

Establish baseline training requirements to ensure the production of safe animal food.

2. Scope

All individuals that manufacture, process, pack, or hold animal food.

3. Responsibilities

Management will: 1) verify that all relevant personnel complete required training prior to independently performing their assigned duties, 2 ensure proper procedures are followed.

4. Procedure

1. All water will:
 - a. Is safe for use, based on records from municipal water supplier or well certification.
2. Plumbing must avoid being a source of contamination and be capable of:
 - a. Carrying sufficient quantities of water to its designated location.
 - b. Conveying sewage and liquid waste, which must be disposed of adequately.
 - c. Providing adequate drainage within the plant.
 - d. Ensuring no backflow or cross-connection between systems for discharge waste water or sewage and those for water to be used in animal food manufacturing.
3. Clean and accessible toilet and hand washing facilities must be provided for employees.

5. Reference

21 CFR 507.20

E. Equipment and Utensils

1. Purpose

Establish baseline training requirements to ensure the production of safe animal food.

2. Scope

All individuals that manufacture, process, pack, or hold animal food.

3. Responsibilities

Management will: 1) verify that all relevant personnel complete required training prior to independently performing their assigned duties, 2 ensure proper procedures are followed.

4. Procedure

1. All equipment and utensils will be designed and constructed to be adequately cleanable and must be properly maintained.
 - a. Must be used properly so as to not be a source of adulteration.
 - b. Equipment must be installed to allow for its cleaning and maintenance, as well as the cleaning and maintenance of adjacent space.
 - c. Animal food contact surfaces must be nontoxic, maintained, and capable of withstanding their use, cleaning, and sanitation.
2. All systems, such as conveying and holding systems, must be designed, constructed, and maintained to protect against contamination of animal food.
3. Compressed air will only be used to clean when its use will not result in potential contamination of animal food.

5. Reference

21 CFR 507.22

F. Plant Operations

1. Purpose

Establish baseline training requirements to ensure the production of safe animal food.

2. Scope

All individuals that manufacture, process, pack, or hold animal food.

3. Responsibilities

Management will: 1) verify that all relevant personnel complete required training prior to independently performing their assigned duties, 2 ensure proper procedures are followed.

4. Procedure

1. Raw material and rework must be identified separately from finished product.
2. Animal food packaging materials must be safe and suitable for their intended use.
3. The overall cleanliness of the animal food area is under the supervision of the animal food manager or designee.
4. Precautions are taken so plant operations do not contribute to contamination.
5. Adulterated animal food must be reprocessed or disposed of, as appropriate.
6. Raw materials must be examined to ensure their suitability.
7. Rework must be handled to protect against contamination.

5. Reference

21 CFR 507.25

G. Holding and Distribution

1. Purpose

Establish baseline training requirements to ensure the production of safe animal food.

2. Scope

All individuals that manufacture, process, pack, or hold animal food.

3. Responsibilities

Management will: 1) verify that all relevant personnel complete required training prior to independently performing their assigned duties, 2 ensure proper procedures are followed.

4. Procedure

1. Finished product will be held in a manner to prevent against contamination and minimize deterioration Specifically:
 - a. Containers used to hold product before distribution must be designed, constructed, cleaned, and maintained to protect against contamination, such as trash.
 - b. The labeling for the animal food ready for distribution must contain, when applicable, information and instructions for safely using the animal food for the intended animal species.
 - c. Bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food.
 - d. Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.
 - e. Bulk animal food must be held in a manner that does not result in unsafe cross contamination with other animal food.

5. Reference

21 CFR 507.27 and 507.28

III. Hazard Analysis

Hazard Evaluation

			Critical	Moderate	Negligible
SEVERITY		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, possible 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.
PROBABILITY					
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

Plant Name: _____

Address: _____

Animal Food: _____

Intended Species: _____

Life Stage/Production Class: _____

Ingredient or Processing Step	Known or Reasonably Foreseeable Hazard	Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Probability that the Hazard Will Occur in Absence of Preventive Controls	Does the Known or Reasonably Foreseeable Hazard Require a PC?	Explanation/Justification	Preventive Control Applied	Is the Preventive Control Applied at this Step?
_____	_____	_____	_____	_____	_____	_____	_____
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IV. Preventive Controls

A. Control of _____

1. Monitoring

- Parameter: _____
- What is monitored: _____
- How: _____
- Frequency: _____
- Who: _____

2. Corrective Actions

- Correction:

- Corrective action:

3. Validation

- _____

4. Verification

- Record review:
 - Monitoring and corrective action records will be reviewed upon direction of the PCQI at least every 7 days
- Process monitoring instruments:

- Product testing:

V. Recall Plan

A. Assigned Responsibilities

- Responsible for the implementation and maintenance of the Recall Procedures

Recall Coordinator

- Has authority from management to make recall decisions on behalf of the company
- Will initiate the formation of a committee and will coordinate actions with FDA and our marketing and distribution agents.

B. Procedures

Decision to Recall - Determined by

The decision on whether to recall or withdraw a feed or not will be based on the identification of a hazard that makes a feed unsafe and its likelihood of affecting animal or human health. This will be determined by careful, considered risk assessment. A risk assessment will be conducted, and may include collaboration with regulatory authorities to determine if a recall is necessary.

Scope of Recall - Determined by

The scope of a recall is a very important part of the process; it ultimately ensures the effective identification of all affected product.

Notification of a product recall - Determined by

If the decision is taken to initiate a recall, we will notify:

- Senior management
- Regulatory authority
- Consignees (distribution chain and consumer)
- The public, via the media contact, if necessary

Communication - Determined by

Notification in respect to the recall needs to be done promptly and should cover the following areas:

1. Regulatory Authority: We will notify the appropriate regulator at the earliest opportunity, after an incident is identified that may lead to a recall. The regulatory authority will be updated throughout the process.

2. Distribution Chain: We will notify contacts by telephone and fax or email.

1. Notification of Direct Consignees

The following consignee list will be compiled:

Direct Account Types	Number

Consignees will be notified by mail, phone, facsimile or e-mail. NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions.

2. Notification of the public

If necessary, the public will be notified by press release using the template provided below:

Draft Recall Notice

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

Contact

Consumer:

1-xxx-xxx-xxx

Media Contact:

xxx-xxx-xxxx

FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] 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 impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. 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 conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at www.xxx.com

3. Effectiveness Checks

Effectiveness of the Recall - Determined by Recall Coordinator

To be effective, the product recall notification must reach as far as the product has been distributed. The effectiveness of the product recall is assessed on the basis of the amount of product controlled, and may be extended to include live animals or products from animals that consumed the recalled feed.

Effectiveness checks by account – Consider filling in the Consignee’s recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date if response	Quantity of returned or controlled
	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

4. Appropriate disposal of recalled animal food

Regaining control of affected stock - Determined by _____

If affected stock is returned, the recovered product/s will be stored in an area that is separated from any other feed products until it can be assessed for safety. Accurate records will be kept of the amounts recovered. If the recovered product/s is unfit for animal consumption, it may be destroyed under the supervision of the company management and/or the regulatory authority where legally required. Destruction will be via _____.

VI. Supporting Records

Appendix A: PCQI Certification

Appendix B: QI Documentation

Appendix C: Most Recent CGMP Self-Audit

Appendix D: Hazard Analysis Justification