

## Developing an Effective Animal Food Safety Plan

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# FDA's FSMA Rule Requirements for Animal Food

## § 507.30 Requirement for a food safety plan.

- a) The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a **written food safety plan**.
- b) The written food safety plan must be prepared by (or its preparation overseen by) a **qualified individual**.
- c) The written food safety plan must include:
  - 1) The **hazard analysis** as required by § 507.33;
  - 2) The **preventive controls** as required by § 507.36;
  - 3) The **recall plan** as required by § 507.38;
  - 4) The **procedures and the frequency** with which these procedures will be conducted for monitoring the performance of the preventive controls as required by § 507.39;
  - 5) The **corrective action procedures** as required by § 507.42; and
  - 6) The **verification procedures** and the frequency with which they will be performed as required by § 507.45.

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  - 2) The preventive controls as required by § 507.36;

## **3)The recall plan as required by § 507.38;**

- 4) The procedures and the frequency with which these procedures will be conducted for monitoring the performance of the preventive controls as required by § 507.39;
- 5) The corrective action procedures as required by § 507.42; and
- 6) The verification procedures and the frequency with which they will be performed as required by § 507.45.

# FDA's FSMA Rule Requirements for Animal Food

## § 507.38 Recall plan for animal food with a hazard that is reasonably likely to occur.

- a) The owner, operator, or agent in charge of a facility must develop a written recall plan for animal food with a hazard that is reasonably likely to occur and assign responsibility for performing all actions in the plan.
- b) The written recall plan must include procedures for:
  - 1) Directly notifying direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;
  - 2) Notifying the public about any hazard presented by the animal food when appropriate to protect animal and human health;
  - 3) Conducting effectiveness checks (as described in part 7 of this chapter) to verify the recall has been carried out; and
  - 4) The proper disposition (e.g., destroying, reprocessing, or diverting to another use that would not present a safety concern) of the recalled animal food.



# Recall Plan and Traceability

## ***“What could warrant a Recall?”***

The Food, Drug and Cosmetic Act (FD&CA) first enacted in 1938, with the primary intent to prevent adulteration or misbranding of food products in interstate commerce, and it is enforced by the FDA.

### ➤ **Class I**

- “a reasonable probability” that the use of the product will cause serious adverse health consequences or death.

### ➤ **Class II**

- the use of the product may cause temporary or medically reversible adverse health consequences, or the probability of serious adverse health consequences is remote.

### ➤ **Class III**

- the product violates federal regulations but is unlikely to cause adverse health consequences.



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## Recalls & Withdrawals

Recalls – of which there are three types – are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.

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### Recalls & Alerts

- [How to Report a Pet Food Complaint](#)
- [How to Report a Livestock Food Complaint](#)
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### Safety & Health

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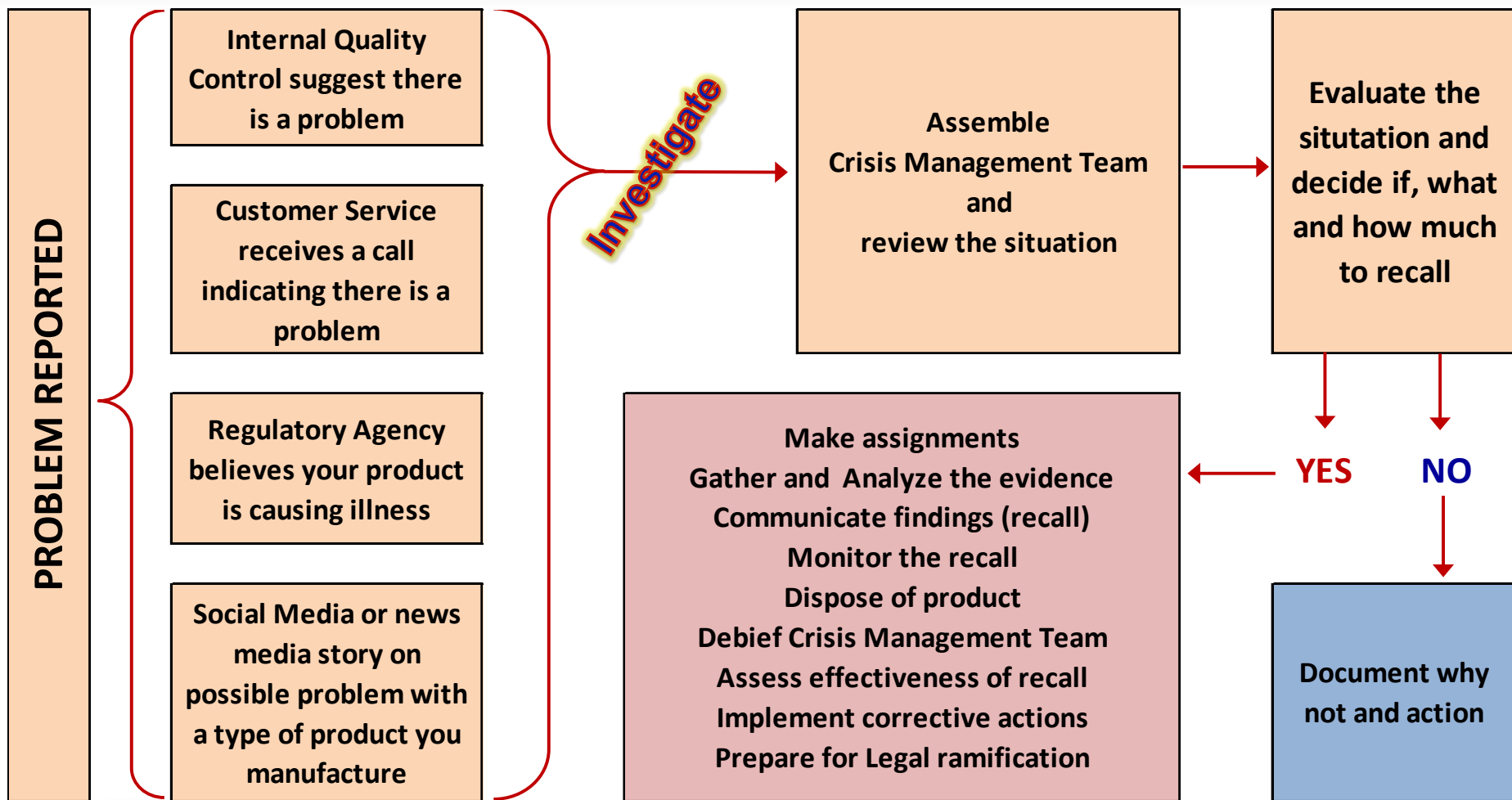
## How to Report a Livestock Food Complaint

[Report a Livestock Food Complaint](#)

You can report complaints about a livestock food product electronically through the [Safety Reporting Portal](#) or you can call your state's [FDA Consumer Complaint Coordinators](#).

Please have as much of the following information available when submitting your complaint:

# Establish a Recall Process





**Blue Bird Feed Mill**  
Sunny, FL  
**STANDARD OPERATING PROCEDURE**



Number:	Q025	Title:	RECALL PLAN
Version:	00		

**I. Policy**

Blue Bird Feed Mill shall maintain a plan to recall product, should a situation deem necessary. The objectives are: 1) stop the distribution and sale of any affected product; 2) effectively notify management, customers, and regulatory authorities (as needed); 3) efficiently remove affected product from the marketplace; take actions to prevent it from reoccurring.

**II. Scope**

A product recall is completed to protect animal health and safety.

**III. Requirements**

- 1) All potential problems reported to Blue Bird Feed Mill shall be reviewed and investigated to determine the severity of the issue. Each department manager is responsible for ensuring work instructions for investigating potential problems are followed.
- 2) Should an investigation of a potential problem reveal a potential food safety risk or company reputation issue, the department manager shall contact the Quality Manager for further investigation.
- 3) If warranted by the Quality Manager, the Crisis Management Team shall review situation and determine whether a recall is needed. Records of such meetings shall be maintained by the Quality Manager.
- 4) Should a recall be launched, Crisis Management Team members shall act urgently on assignments to determine the most appropriate actions. Assignments shall include (although not limited to):
  - a. Determine the depth of product to be recalled.
  - b. Determine which Customers are impacted.
  - c. Develop communications with customers, regulatory departments, sales force, and company personnel, as needed.
  - d. Plan to remove product from the market

- 5) The Quality Manager, or designate, shall keep the Crisis Management Team informed of progress of the recall and recommend to the group when it is complete. The Crisis Management Team is responsible for determining if the recall is complete.
- 6) After the recall is complete, the quality and food safety department shall coordinate a Root Cause Analysis and provide recommended corrective actions.
- 7) The Animal Food Safety Plan shall be reviewed after a recall to determine necessary changes, if any.
- 8) A Mock Recall shall be completed two times each year, as determined by the Quality Manager.
  - a. Any problems identified during the Mock Recall shall be corrected and repeated within a reasonable time frame as determined by the Quality Manager.
  - b. Results for Mock Recalls shall be reviewed during Management Review sessions.

#### IV. Approval

Prepared by: \_\_\_\_\_  
Name Date

\_\_\_\_\_  
Signature

Reviewed by: \_\_\_\_\_  
Name Date

\_\_\_\_\_  
Signature



# Recall Plan and Traceability

## ***Establish a Crisis Management Team***

*Team should be a core group who represent all the key departments or functions of the organization*

- **Senior Management leader** – “quick decision-making”
- **Public Relations specialist** – coordinate communication
- **Marketing specialist** – sales force, interaction with customers
- **Scientific advisor** – regulatory, food safety and quality aspects
- **Logistics/Receiving specialist** – shipping, tracking, storage
- **Quality Assurance specialist** – gather facts and investigation
- **Accounting** – estimate of cost options
- **Legal Counsel** – liability questions/confidential information



# Recall Plan and Traceability

***Traceability*** is required in the USA  
through the Bioterrorism Act

***“One Level Back, One Level Forward”***

Traceability is important to determine which products need to be recalled and allows you to limit the scope. Without specifics or details, the recall may broaden.





# Recall Plan and Traceability

## ***“What specifics are needed?”***

- Production lot numbers impacted.
- Lot numbers of ingredients used within the finished product.
- Current location of all finished product identified.
- Customers impacted.
- Personnel involved with the processes.
- Any other issues similar in nature.
- *“Book Ends”*





# Recall Plan and Traceability

## ***“How do I manage continuous flow bins?”***

- **Inspect ingredient prior to unloading.**
- **Schedule bin inspections for problems.**
  - Preventive Maintenance
  - Corrective Action
- **Document loads received.**
  - What, When, Where, Who



# Recall Plan and Traceability

***“If we initiate a recall, who do we notify?”***

- **Customers**
- **Public**
- **Key share holders**
- **Employees**
- **Regulatory agencies**
- **Certifying body, if applicable**

**Consult with Legal Counsel before communicating**  
**Provide directions within written procedure**

# Mock Recall

- Evaluates the effectiveness of the Recall Plan.
- Should be completed twice a year.
- If problems identified, implement corrective actions and repeat.



**Blue Bird Feed Mill**  
Sunny, FL



## MOCK RECALL RECORD

Date: \_\_\_\_\_ Time Initiated: \_\_\_\_\_ AM / PM  
Date: \_\_\_\_\_ Time Completed: \_\_\_\_\_ AM / PM

Description of Product or Raw Material: \_\_\_\_\_

Description of Scenario: \_\_\_\_\_

Problems Identified	Corrective Action

Completed by: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_



# Requirements for an Animal Food Safety Plan

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# “Why is TRAINING so important for an Animal Food Safety Plan?”

## § 507.30 Requirement for a food safety plan.

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# Animal Food Safety Program

**“Why is TRAINING so important?”**

**"What I hear, I forget.  
What I see, I remember.  
What I do, I understand."**

*- Confucius*



# Requirements for an Animal Food Safety Plan

## “*QUALIFIED INDIVIDUAL*” DEFINITION

### § 507.3 Definitions

***Qualified individual*** means a person 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.



# Effective Training Program

## ***TRAINING***

- Determine training requirements for each position
  - Job Description
  - OJT is typically most effective
  - Document training
- Company-wide training for all personnel
  - Control of documents, control of records, food safety training, personnel safety, etc.
- Written procedure provides direction

**“Qualified Individual”**



# Effective Training Program

***“What information effectively verifies that Training was completed?”***

- Signature of personnel on training log after training.
- Certification from a training seminar.
- Written test after a training session.
- Observation of completed work by personnel.

# EXAMPLE: Training SOP



## Blue Bird Feed Mill Sunny, FL STANDARD OPERATING PROCEDURE



Number:	Q026	Title:	GENERAL TRAINING REQUIREMENTS
Version:	00		

### I. Policy

Blue Bird Feed Mill ensures that all employees are properly trained for their roles. This training is a mixture of supervised work and training courses. Training needs are identified for specific personnel.

### II. Scope

This SOP applies to food safety, legality and quality topics for employees involved with receiving, manufacturing and shipping of products made on site as well as customer service and quality & food safety functions at the site.

### III. Requirements

- 1) Each position within the company has required training needs. The level of training depends on the employee's required role, responsibilities, objectives and goals within the company. Position roles, responsibilities, objectives and goals are on file for each employee.
- 2) The training records are maintained on file by the human resources department. A training log for each training session shall be maintained using Form-Q026F1 Training Log.
- 3) When certifications are issued for training completed by an employee, a copy of the certificate should be maintained within their personnel file by the human resources department.
- 4) Training needs are reviewed at least annually.
- 5) A Training Matrix for all positions will be maintained to assist with ensuring training is completed for each employee (Form-Q026F2). Human resources department is responsible for ensuring the form is updated annually.

# EXAMPLE: Job Description

## “What training is needed?”

- New employee
- Personnel safety
- Food safety training
- Maintenance SOP's and Work Instructions



**Blue Bird Feed Mill**  
Sunny, FL



JOB DESCRIPTION					
Title:	<b>MAINTENANCE SPECIALIST</b>				
Number:	M04	Version:	02	Last Updated:	January 1, 2014

### I. Job Summary

The Maintenance Specialist must be able to perform preventative maintenance on feed mill related equipment, as well as repair and install equipment as necessary. The Maintenance Specialist must be able to detect potential mechanical and electrical problems, maintain the required written records including perform corrective actions and install replacement parts. The Maintenance Specialist must work in compliance with all company policies, local, state and federal policies, laws, and regulations. The Maintenance Specialist reports to the Maintenance Manager.

### II. Essential Duties

- Repair any mechanical malfunction in the feed mill
- Detect any potential electrical or mechanical problems
- Check that equipment is functioning properly
- Prepare written and actions taken to correct equipment problems
- Respond to mechanical or electrical breakdowns and handle emergency situations
- Lubricate equipment
- Perform preventive maintenance according to a posted schedule
- Complete appropriate paperwork and reports

### III. Additional Duties

- Operate a forklift
- Perform other duties as assigned

### IV. Job Qualifications

- Minimum experience of two years in feed mill maintenance or related maintenance field
- High school degree or equivalent
- Ability to lift 60 pounds, climb ladders and operate a pallet jack with 2,000 pounds of material
- Ability to work at heights of 200 feet and in confined spaces
- Understanding of computerized preventive maintenance programs preferred.

*Blue Bird Feed Mill is an equal opportunity employer*



# EXAMPLE: Training Log



**Blue Bird Feed Mill**  
Sunny, FL



## TRAINING LOG

Training Topic: \_\_\_\_\_

Instructor: \_\_\_\_\_ Date/time: \_\_\_\_\_

Dept. (s): \_\_\_\_\_

Training details:

Training materials used:

Full Name (Print)	Department	Signature



# EXAMPLE: Training Matrix



Blue Bird Feed Mill  
Sunny, FL

## TRAINING MATRIX



What training is needed?

A matrix may be used to help HR or department managers keep track of training requirements.

	M002 Personnel Safety SOP	Q014 Food Safety Requirements	M032 Foreign Material Control	Q045 HACCP	Q026 Recall Plan	M033 Preventive Maintenance Plan	P014 Supplier Verification Process	M019 Manufacturing Processes	C103 Customer Services Processes	M008 Material Receiving Processes	M009 Material Shipping Processes	Q055 Internal Auditing
FREQUENCY	I,A,O	I,A,O	I,A,O	I,A	I,A,O	I,A,O	I,A,O	I,A,O	I,A,O	I,A,O	I,A,O	I,O
<i>I = Initial Full Training, A = Annual Full Training, O = Ongoing As Needed Training</i>												
Packing Operator	x	x	x					x		x		
Blending Operator	x	x	x					x		x		
Receiving Personnel	x	x	x					x		x	x	
Shipping Personnel	x	x	x				x	x	x	x	x	
Forklift Operator	x	x						x				
Maintenance Supervisor	x	x	x			x						x
Plant Manager	x	x	x	x	x			x	x	x	x	x
Shift Manager	x	x	x	x				x	x	x	x	x



# Requirements for an Animal Food Safety Plan

## Recall Plan

- Develop a process flow.
- Establish a Crisis Management Team.
- Ensure an effective traceability process.
- Complete Mock Recalls at least twice each year.
- Communicate plan needed.

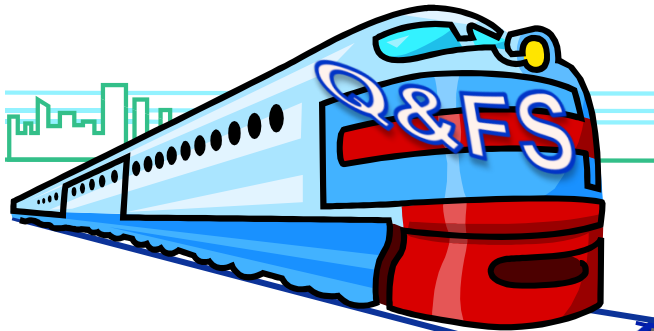
## Training Program

- Required to ensure a Food Safety Plan is effectively implemented.
- Establish the requirements for each job description.
- A Training Matrix may be a useful tool.
- Determine methods for verification of training.

**Records, Records, Records, Records**

## **Hazard Identification Preventive Controls Records**

# Quality & Food Safety Program



***“It is important to build an effective quality and food safety program!”***

CGMP's (Prerequisites)

Animal Food Safety Plan

Hazard Analysis

Preventive Controls

Records

***We need to prepare the tracks!!***

**Quality & Food Safety**

**Touches all aspects of “animal food”**

**manufacturing, processing and distribution**



# Hazard Identification and Analysis

***Hazard* means any *biological, chemical, physical*, or radiological agent that is reasonably likely to cause illness or injury in animals or humans in the absence of its control.**

FDA, Food Safety Modernization Act - Current Good Manufacturing Practices and Hazard Analysis Risk-Based Preventive Controls for Food for Animals

# Hazard Identification and Analysis

## BIOLOGICAL

### Severe Hazards

*Clostridium botulinum* types A, B, E, F

*Salmonella* Typhi; paratyphi A, B

*Vibrio cholerae* 01

*Vibrio vulnificus*

*Taenia solium*

*Trichinella spiralis*

### Moderate Hazards :Potentially Extensive

*Listeria monocytogenes*

*Salmonella* spp.

*Escherichia coli* (EEC)

Rotavirus

### Moderate Hazards: Limited

*Bacillus cereus*

*Campylobacter jejuni*

*Clostridium perfringens*

*Staphylococcus aureus*

FDA 2001 Food Code - Annex 5: HACCP Guidelines

# Hazard Identification and Analysis

## BIOLOGICAL

### ***Salmonella*-Contaminated Pet Food – All Serotypes**

- FDA considers a pet food to be adulterated under section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)) when it is contaminated with *Salmonella* and will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella*.

### ***Salmonella*-Contaminated Animal Feed – Serotypes Pathogenic to Animals**

- Poultry feed with *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis
- Swine feed with *Salmonella* Choleraesuis
- Sheep feed with *Salmonella* Abortusovis
- Horse feed with *Salmonella* Abortusequi
- Dairy and beef feed(s) with *Salmonella* Newport or *Salmonella* Dublin

FDA 2013. Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals



# Hazard Identification and Analysis

## CHEMICAL

### Naturally Occurring Chemicals

Mycotoxins (e.g., aflatoxin) from mold

### Added Chemicals

Agricultural chemicals:

Pesticides, fungicides, fertilizers, insecticides, antibiotics  
and growth hormones

Polychlorinated biphenyls (PCBs)

Industrial chemicals

Prohibited substances (21 CFR 189)

Direct or Indirect

Toxic elements and compounds:

Lead, zinc, arsenic, mercury, and cyanide

*FDA 2001 Food Code - Annex 5: HACCP Guidelines*

# Hazard Identification and Analysis

## PHYSICAL

Table 3. Main Materials of Concern as Physical Hazards and Common Sources<sup>a,b</sup>

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, fields, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

<sup>a</sup> Adapted from Corlett (1991).

*FDA 2001 Food Code - Annex 5: HACCP Guidelines*

<sup>b</sup> Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

# Hazard Identification and Analysis

## PURPOSE OF HAZARD ANALYSIS

The hazard analysis process accomplishes three purposes:

- 1) Hazards of significance are identified;
- 2) The hazard analysis provides a risk basis for selecting likely hazards;
- 3) Identified hazards can be used to develop preventive measures for a process or product to ensure or improve food safety.

*FDA 2001 Food Code - Annex 5: HACCP Guidelines*

# Hazard Identification and Analysis

## HACCP

**Hazard Analysis & Critical Control Points**

**Understanding HACCP principles**

**are important when developing an  
animal food safety program.**

# Hazard Identification and Analysis

## ***“So how does FSMA differ from HACCP?”***

### **FSMA Proposed Rule**

- 1) Conduct a Hazard Analysis.
- 2) Establish Preventive Controls.
- 3) Write a Recall Plan.
- 4) Monitor Performance of Preventive Controls.
- 5) Establish Corrective Action procedure.
- 6) Establish Validation and Verification Procedures.
- 7) Records, Records, Records.

### **HACCP Principles**

- 1) Conduct a Hazard Analysis.
- 2) Identify CCP's, if any.
- 3) Establish Critical limits.
- 4) Establish a system to monitor CCP's.
- 5) Establish Corrective Actions when monitoring fails.
- 6) Establish verification processes.
- 7) Establish documentation.

**FSMA = control of hazards**

**HACCP = control of CCP's**



# Hazard Identification and Analysis

## ***RECOMMENDED FIRST STEPS***

- 1) Establish an Animal Food Safety team**
  - Complete training on HACCP principles and concepts
- 2) Create a process flow diagram**
- 3) Describe products**
  - Ingredients, physical form, special traits
  - Intended use, target customers
- 4) Verify process flow diagram**

# EXAMPLE

**Product:** Senior Horse Feed

**Intended Use:** For Maintenance of Mature Horses

**Ingredients:**

Wheat Middlings, Dried Beet Pulp (Plain), Soybean Hulls, Ground Corn, Whole Oats, Dehydrated Alfalfa Meal, Vegetable Oil, Brewers Dried Yeast, Cane Molasses, L-Lysine, Calcium Carbonate, Dicalcium Phosphate, Salt, Sodium Bentonite, Vitamin A Supplement, Vitamin D3 Supplement, Vitamin E Supplement, Vitamin B12 Supplement, Riboflavin Supplement, Pyridoxine Hydrochloride, Folic Acid, Biotin, Thiamine, Manganous Oxide, Ferrous Sulfate, Copper Sulfate, Magnesium Oxide, Zinc Sulfate, Ethylenediamine Dihydroiodide, Cobalt Carbonate, Potassium Chloride, Sodium Selenite

# EXAMPLE

**Product:** Senior Horse Feed

**Guarantees:** Guaranteed Analysis

Crude Protein (Min)	14.0%
Crude Fat (Min)	7.0%
Crude Fiber (Max)	10.0%
Calcium (Min)	0.85%
Calcium (Max)	1.00%
Phosphorus (Min)	0.90%
Copper (Min)	25 ppm
Selenium (Min)	0.20 ppm
Zinc (Min)	50 ppm
Vitamin A (Min)	2,000 IU/lb

# EXAMPLE

**Product:** Senior Horse Feed

## Feeding Directions:

Feed to adult horses that are more than 5 years of age based on body weight and condition.

Weight of Horse	Daily Feeding Rate
When Fed Without Hay or Pasture	
800lb	10 - 12 lb
1,000lb	12 - 15 lb
1,250lb	15 - 17 lb
When Fed With Hay or Pasture	
800lb	4 - 7 lb
1,000lb	5 - 8 lb
1,250lb	6 - 9 lb

Increase feeding rate 1-2 lb daily based on body condition and work rate.

# EXAMPLE

**Product:** Senior Horse Feed

**Processing:**

Ingredients are blended per requirements of recipe and pelleted; pellets are blended with liquid molasses to desired texture.

**Packaging/Distribution:**

Product is packaged in 25kg bags and sold by dealers or distributors within a 100 mile radius. Product should be sold within 60 days of manufacturing and fed within 90 days of manufacturing.

**Target Customers:**

Horse owners within 50 miles of dealers or distributors

# EXAMPLE

**Ingredient:** Wheat Middlings

**Biological Risks:**

- **None** – based on FDA Guidance document, *Salmonella Abortusequi* is the only strain of Salmonella of concern for horse feed. History within the facility, as well as the industry, has not shown this strain is a concern.

# EXAMPLE

**Ingredient:** Wheat Middlings

## **Chemical Risks:**

- **Pesticides/hazardous chemicals** – Material specification requires the control of pesticides or hazardous chemicals. Supplier questionnaire (self-audit) reports preventive controls are maintained.
- **Aflatoxin and Zearalenone mycotoxins** – Controlled by supplier (see Supplier Verification records); supplier provides testing results for new crop materials (first 10 loads).

# EXAMPLE

**Ingredient: Wheat Middlings**

**Physical Risks:**

- **Metal** – controlled by supplier
- **Wood/Plastic/Glass** – controlled by supplier
- **Other Ingredients** – foreign material contamination from other ingredients is controlled by transportation provider (company specifications)

*(continue process for all ingredients or groupings)*



# EXAMPLE

## Process: BULK RECEIVING

### Biological Risks:

- **None** –History within the facility, as well as the industry, has not shown *Salmonella* to be a concern for livestock feed. No illnesses have occurred or documented related to the identified *Salmonella* serotypes to be controlled for animal feeds.
  - Poultry feed - *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis
  - Swine feed with *Salmonella* Choleraesuis
  - Sheep feed with *Salmonella* Abortusovis
  - Horse feed with *Salmonella* Abortusequi
  - Dairy and beef feed(s) with *Salmonella* Newport or *Salmonella* Dublin

# EXAMPLE

**Process: BULK RECEIVING**

## **Chemical Risks:**

- **Pesticides/hazardous chemicals** – documented procedure followed to control contamination from pesticides or hazardous chemicals in the bulk receiving area
  - (see SOP and records for verification of preventive controls).
- **Aflatoxin and Zearalenone mycotoxins** – Composite sample collected and tested for Aflatoxin and Zearalenone
  - (ELISA Quick Test) – positive release (see SOP and records for verification of preventive controls).

# EXAMPLE

## Process: BULK RECEIVING

### Physical Risks:

- **Metal** – material passes over a magnet upon arrival to remove metal (see SOP and records for verification of preventive controls).
- **Wood/Plastic/Glass** – screens for sieving material located at receiving, grinding and pre-blending; visual inspection upon arrival – positive release (see SOP and records for verification of preventive controls).
- **Other Ingredients** – visual inspections upon arrival – positive release (see SOP and records for verification of preventive controls).

*(continue hazard identification for all processes)*

# GROUP ASSIGNMENT

Area:Q&FS

SOP-Q001  
Version 000



## Blue Bird Feed Mill Sunny, FL STANDARD OPERATING PROCEDURE



Number:	Q001	Title:	HAZARD ANALYSIS PROCEDURE
Version:	000		

### I. Policy

Blue Bird Feed Mill shall complete a hazard analysis for all finished products and processes to ensure hazards are controlled.

### II. Scope

The hazard analysis covers all manufacturing processes and finished products specific for this manufacturing site.

### III. Requirements

- 1) The Animal Food Safety Team for the manufacturing site will complete a hazard analysis for all finished products and all manufacturing/distributing processes to ensure hazards are controlled.
- 2) Each product or product type will be described in such a manner to allow for a risk assessment of the ingredients, intended use and targeted customers (Form-Q001F1).
- 3) A process flow diagram (Form-Q001F2) shall be created and verified by the Animal Food Safety team annually.
- 4) The potential hazards from each product or product type will be assessed (Form-Q001F3).
- 5) The potential hazards from the manufacturing/distributing processes shall be assessed (Form-Q001F4).



# GROUP ASSIGNMENT



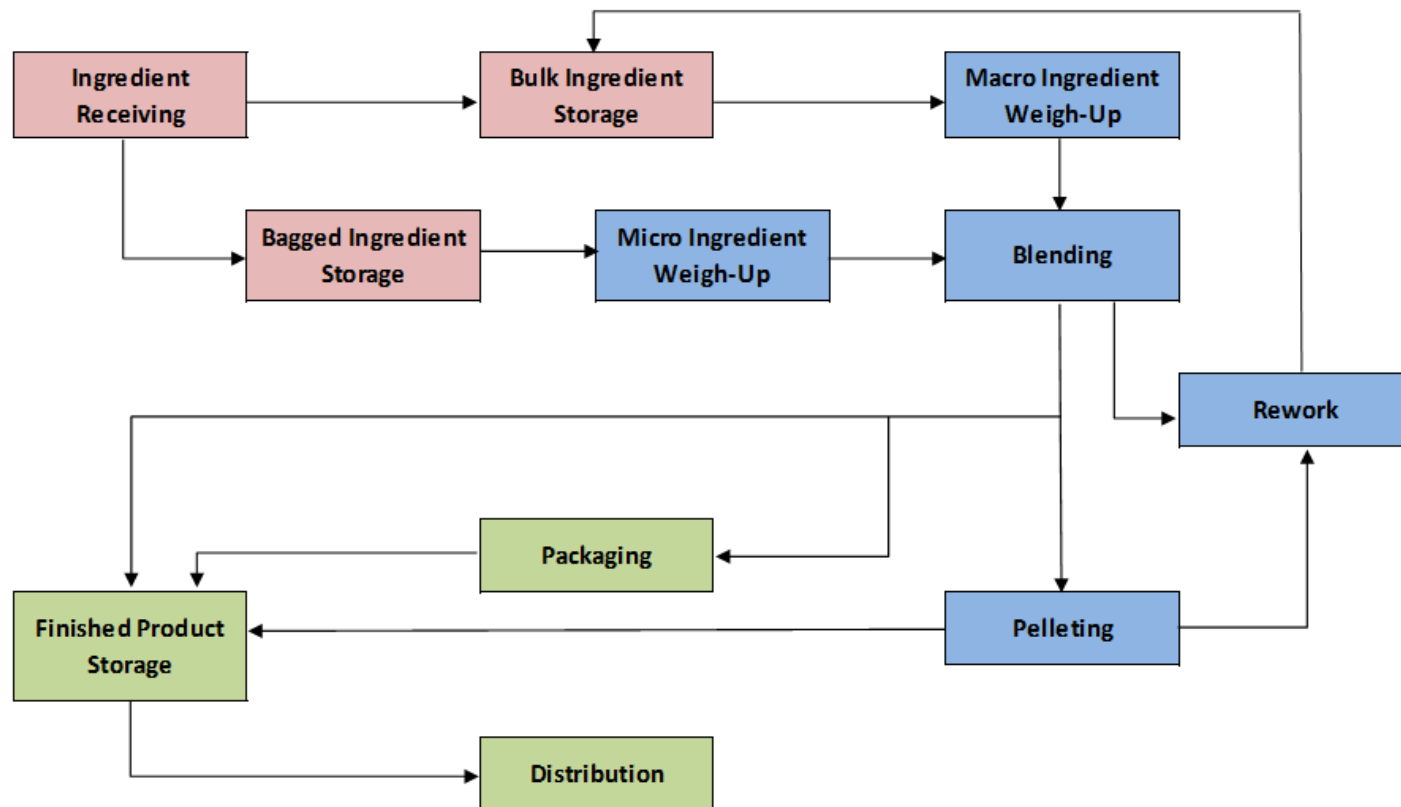
**Blue Bird Feed Mill**

Sunny, FL

HAZARD ANALYSIS



## MANUFACTURING PROCESS FLOW DIAGRAM



Form-Q001F2

# EXAMPLE DOCUMENTS



**Blue Bird Feed Mill**

**Sunny, FL**

**HAZARD ANALYSIS**

## **FINISHED PRODUCT ASSESSMENT**



**Product:** Complete Grower2 Pig Pellets – MEDICATED – BULK or BAGGED

<b>Ingredients</b>	<b>Potential hazard introduced, controlled or enhanced at this step</b> B= Biological C= Chemical P= Physical	<b>What control measures can be applied to prevent the significant hazards?</b>	<b>Additional Preventive Controls needed? Justify your decision.</b>
Grain Products	B-  C-  P-		
Plant Protein Products	B-  C-  P-		

# GROUP ASSIGNMENT



## Blue Bird Feed Mill

Sunny, FL



### PROCESS HAZARD IDENTIFICATION

Process Flow	Potential hazard introduced, controlled or enhanced at this step B= Biological C= Chemical P= Physical	What control measures can be applied to prevent the significant hazards?	Additional Preventive Controls needed? Justify your decision.
Ingredient Receiving			
Bulk Ingredient Storage			
Macro Ingredient Weigh-Up			

# EXAMPLE DOCUMENTS



## Blue Bird Feed Mill Sunny, FL HAZARD ANALYSIS



### CCP Determination (Decision Tree)

**Product:** *A critical control point is defined as a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. Only steps presenting a significant potential food safety risk (Q1, Hazard Analysis) are listed.*

Process step	Hazard B= Biological C= Chemical P= Physical	Q1. Does this step involve a hazard of sufficient risk and severity to warrant its control?	Q2. Does a preventive measure for the hazard exist at this step?	If Q2 is no: Is control at this step necessary for safety?	Q3. Is control at this step necessary to prevent, eliminate or reduce the risk of the hazard to consumers?	#CCP
Ingredient Receiving	B-					
	C-					
	P-					
Bulk Ingredient Storage	B-					
	C-					
	P-					
Bagged Ingredient Storage	B-					
	C-					
	P-					
Macro Ingredient Weigh-Up	B-					
	C-					
	P-					
Micro Ingredient	B-					
	C-					
	P-					



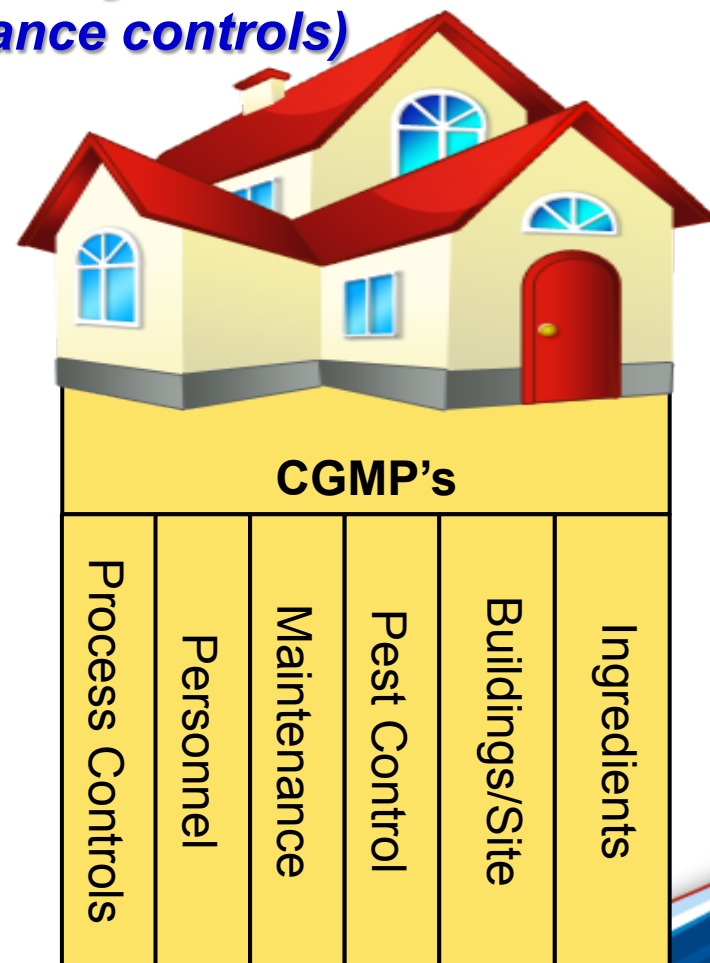


# Current Good Manufacturing Practices (CGMP's)

## CGMP's are often associated with a Quality Management System

*(do not always have performance controls)*

- CGMP's are more **“general”** and may apply throughout the operation.
- CGMP's programs deal **indirectly** with animal food safety issues while HACCP plans deal **solely and directly** with animal food safety issues.
- CGMP's **do not** control hazards.
- Failure to follow CGMP's **seldom** leads to a animal food safety risks.



# Current Good Manufacturing Practices (CGMP's)

## CGMP Activities

- **What is being done?**
- **How is it to be done?**
- **Who is doing it?**
- **How frequently shall it be done?**
- **Document that is was done**

**Say what you do. Do what you say. Prove it.**

# Hazard Identification and Analysis

## SUMMARY

- **Principles of HACCP are needed.**
  - FSMA controls all hazards, not just CCP's.
- **An Animal Food Safety Team is recommended.**
  - Some training on hazard analysis would be helpful.
  - Personnel from all process areas.
- **A defined process helps with identifying hazards.**
  - Maintain documentation.
  - CGMP's are the foundation.



# Thank you!

