

**National Grain
and Feed Association**

Preventive Controls

Food Safety Modernization Act Informational Seminar

March 10, 2016



**CALIFORNIA
GRAIN
& FEED
ASSOCIATION**

Disclaimer

- Some regulatory text from the final rule is included in this presentation, but not all text is provided! Also, in many instances the text provided is abridged to make it more brief and emphasize major concepts.
- Bottom line – this is a complicated rule and this presentation does not cover all aspects or all requirements!



Preventive Controls for Animal Food

- **PART 507—Current Good Manufacturing Practice, Hazard Analysis, and Risk–Based Preventive Controls for Food for Animals:**
 - Subpart A: General Provisions
 - Subpart B: Current Good Manufacturing Practices (CGMPs)
 - **Subpart C: Hazard Analysis and Risk-Based Preventive Controls**
 - Subpart D: Withdrawal of a Qualified Facility Exemption
 - Subpart E: Supply-Chain Program
 - Subpart F: Requirements Applying to Records That Must Be Established and Maintained



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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11, 16, 117, *et al.*

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Final Rule



Preventive Controls Requirements

- Preventive control requirements mandate that animal food facilities identify and evaluate ***“known and reasonably foreseeable ‘hazards’”*** associated with the facility and its animal food and implement one or more ***“preventive controls”*** and components to manage such controls (monitoring, verification, corrections and corrective actions, records, and recall plans) for ***“hazards requiring a preventive control”***
- A **written food safety plan** must be developed



Exempt from Preventive Controls

- Farms
- Facilities **solely engaged in the holding** of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, e.g., grain elevators
- Facilities **solely** engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens



Subject to Modified PC Requirements

- ***Very Small Business:*** A business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).



Subject to Modified PC Requirements

- A ***Very Small Business*** is subject to modified requirements:
 - Attest the facility is a ***very small business***; and
 - Attest that the facility has identified hazards and that preventive controls have been implemented and are being monitored; or
 - Attest that the facility is in compliance with an applicable non-federal feed safety law.
 - All required attestations are to be submitted to FDA

PCs *versus* HACCP

Principle	HACCP - National Advisory Committee on Microbiological Criteria for Foods	Preventive Control Requirements
----	Five Preliminary Steps: (1) Assemble HACCP team; (2) describe food and its distribution; (3) identify intended use/consumers; (4) develop flow diagram; (5) verify flow diagram	No
1	Conduct Hazard Analysis	Yes
2	Determine Critical Control Points	Yes, determine preventive controls, including critical control points, if any
3	Establish Critical Limits for Critical Control Points	Yes, establish parameters for controls
4	Establish Monitoring Procedures	Yes
5	Establish Corrective Actions	Yes
6	Establish Verification Procedures	Yes
7	Establish Record and Documentation Procedures	Yes

PCs *versus* HACCP

- Preventive controls are required to control “hazards requiring a preventive control,” while HACCP controls critical control points
- Preventive controls are broader than HACCP

PUBLIC LAW 111–353—JAN. 4, 2011

SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

(c) PREVENTIVE CONTROLS.—The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

- (1) hazards identified in the hazard analysis conducted under subsection (b)(1) will be significantly minimized or prevented;
- (2) any hazards identified in the hazard analysis conducted under subsection (b)(2) will be significantly minimized or prevented and addressed, consistent with section 420, as applicable; and
- (3) the food manufactured, processed, packed, or held by such facility will not be adulterated ... or misbranded ...



§ 507.3 – Definitions

- ***Preventive controls*** means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to **significantly minimize or prevent** the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis



§ 507.3 – Definitions

- **Hazard** means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals
- **Known or reasonably foreseeable hazard** means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food

§ 507.3 – Definitions

- ***Hazard requiring a preventive control*** means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system



Subpart C – Preventive Controls

- § 507.31 Food safety plan
- § 507.33 Hazard analysis
- § 507.34 Preventive controls
- § 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control
- § 507.37 Provision of assurances
- § 507.38 Recall plan
- § 507.39 Preventive control management components
- § 507.40 Monitoring



Subpart C – Preventive Controls

- § 507.42 Corrective actions and corrections
- § 507.45 Verification
- § 507.47 Validation
- § 507.49 Verification of implementation and effectiveness
- § 507.50 Reanalysis
- § 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food
- § 507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor
- § 507.55 Implementation records required for this subpart



§ 507.31 Food safety plan

- (a) You must prepare, or have prepared, and implement a written food safety plan
- (b) One or more **preventive controls qualified individuals** must prepare, or oversee the preparation of, the food safety plan
- (c) The written food safety plan must include:
 - (1) The written hazard analysis)
 - (2) The written preventive controls as required
 - (3) The written supply-chain program as required by subpart E of this part
 - (4) The written recall plan as required
 - (5) The written procedures for monitoring the implementation of the preventive controls as required
 - (6) The written corrective action procedures as required
 - (7) The written verification procedures as required
- (d) The food safety plan required ... is a record that is subject to the requirements of subpart F (records)



Preventive Controls Qualified Individual

- **§ 507.3 – *Preventive controls qualified individual*** means 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



§ 507.33 Hazard analysis

- (a)(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, **known or reasonably foreseeable hazards** for each type of animal food manufactured, processed, packed, or held at your facility **to determine whether there are any hazards requiring a preventive control**
- (a)(2) The hazard analysis must be **written** regardless of its outcome

§ 507.33 Hazard analysis

- (b) The hazard identification must consider:
 - (1) Known or reasonably foreseeable hazards that include:
 - (i) **Biological hazards**, including microbiological hazards
 - (ii) **Chemical hazards**, including **radiological hazards**, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep)
 - (iii) **Physical hazards** (such as stones, glass, and metal fragments)
 - (2) Known or reasonably foreseeable hazards that may be present ... for any of the following reasons:
 - (i) The hazard occurs **naturally**
 - (ii) The hazard may be **unintentionally introduced**
 - (iii) The hazard may be **intentionally introduced** for purposes of economic gain



§ 507.33 Hazard analysis

- (c)(1) The hazard analysis **must include an evaluation of the hazards identified ... to assess the severity of the illness or injury to humans or animals** if the hazard were to occur **and the probability** that the hazard will occur in the absence of preventive controls
- (2) The hazard evaluation ... must include an evaluation of **environmental pathogens** whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or otherwise include a control measure ...



§ 507.33 Hazard analysis

- (d) The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:
 - (1) The **formulation** of the animal food
 - (2) The **condition, function, and design** of the facility and equipment
 - (3) **Raw materials and other ingredients**
 - (4) **Transportation practices**
 - (5) **Manufacturing/processing** procedures
 - (6) **Packaging** activities and **labeling** activities
 - (7) **Storage** and **distribution**
 - (8) **Intended or reasonably foreseeable use**
 - (9) **Sanitation**, including **employee hygiene**
 - (10) Any **other relevant factors** such as the temporal (e.g., **weather-related**) nature of some hazards (e.g., levels of some natural toxins)



Conducting a Hazard Analysis

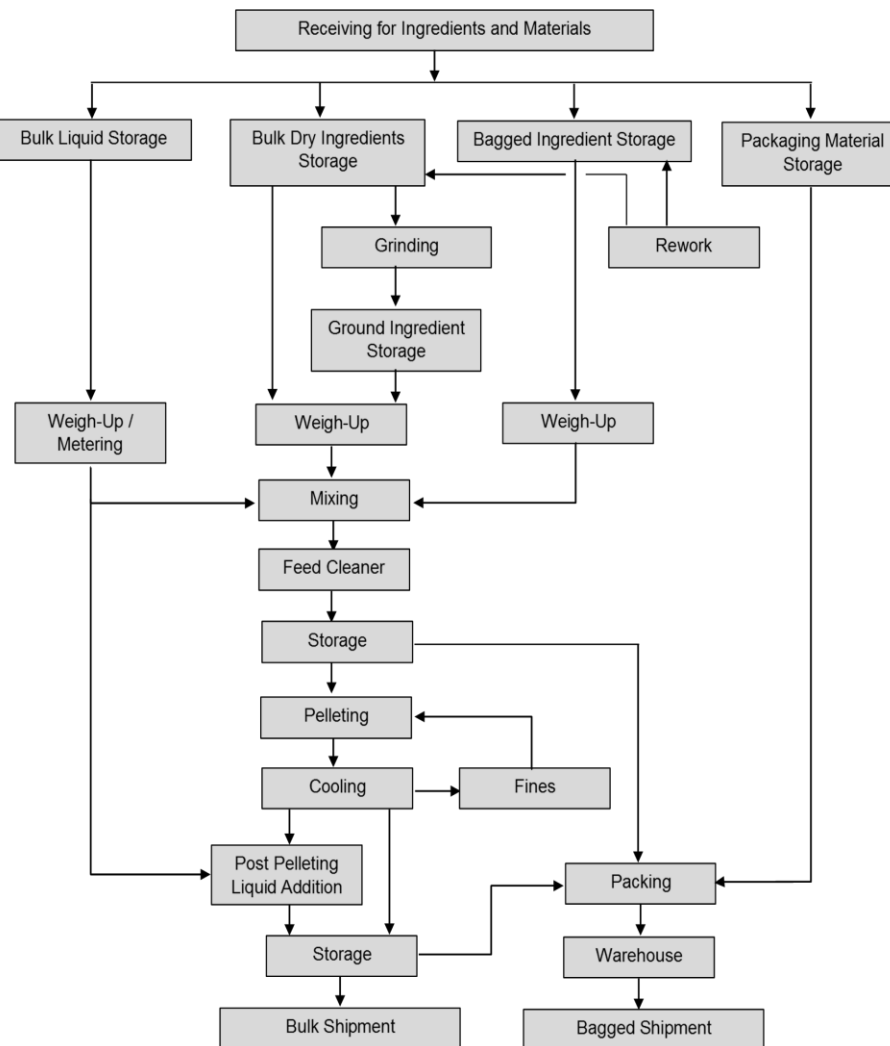
- Preliminary steps that may be helpful to the hazard analysis process (from HACCP) – **NOT REQUIRED BY RULE**
 - Assemble food safety team
 - Describe food and its distribution
 - Identify intended use/consumers
 - Develop flow diagram – helps identify where hazards may be introduced, be increased or occur in the process
 - Verify flow diagram



Example Flow Diagram – NOT REQUIRED

Identification of Known or Reasonably Foreseeable Hazards

1. List Ingredients and Steps/Equipment within the Process Flow
2. If a process flow diagram is used, the list may be reflective of a particular number or code on that diagram



1. Ingredients
2. Receiving
3. Grinding
4. Weighing
5. Mixing
6. Packing
7. Pelleting
8. Cooling
9. Fines
10. Post Pellet Liquid Addition
11. Bulk Storage
12. Warehouse
13. Shipment



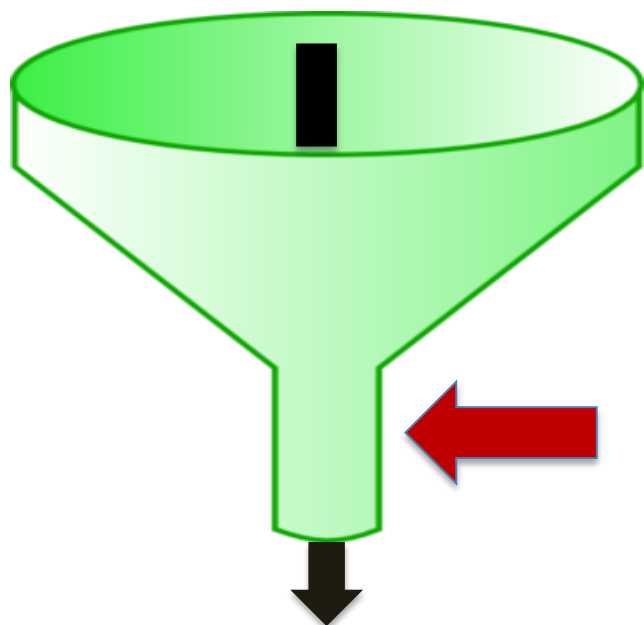
Hazard Analysis Form Example

Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Hazard Identification		
(1)	(2)	
Ingredient or Processing Step	Known or reasonably foreseeable animal food safety hazards (B, C, P)	
	B	
	C	
	P	
	B	
	C	
	P	

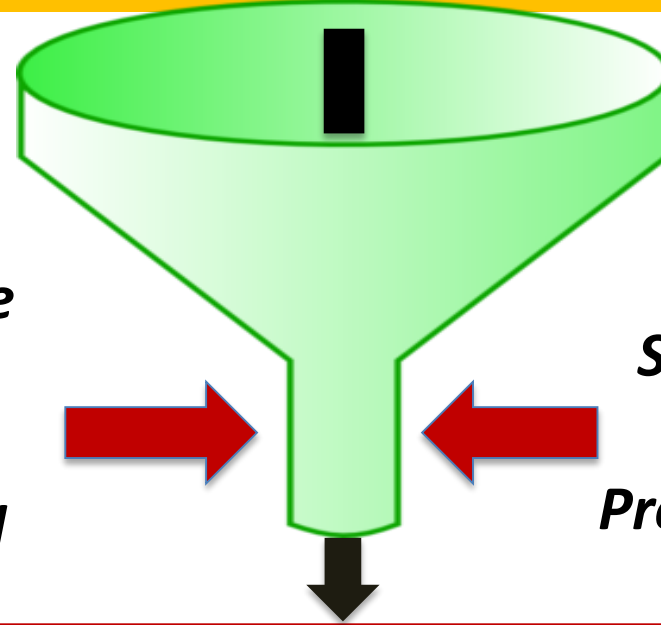
Evaluating Hazards

*Universe of Hazards
(human and animal)*



*Known or Reasonably
Foreseeable Hazards*

*Known or Reasonably
Foreseeable Hazards*



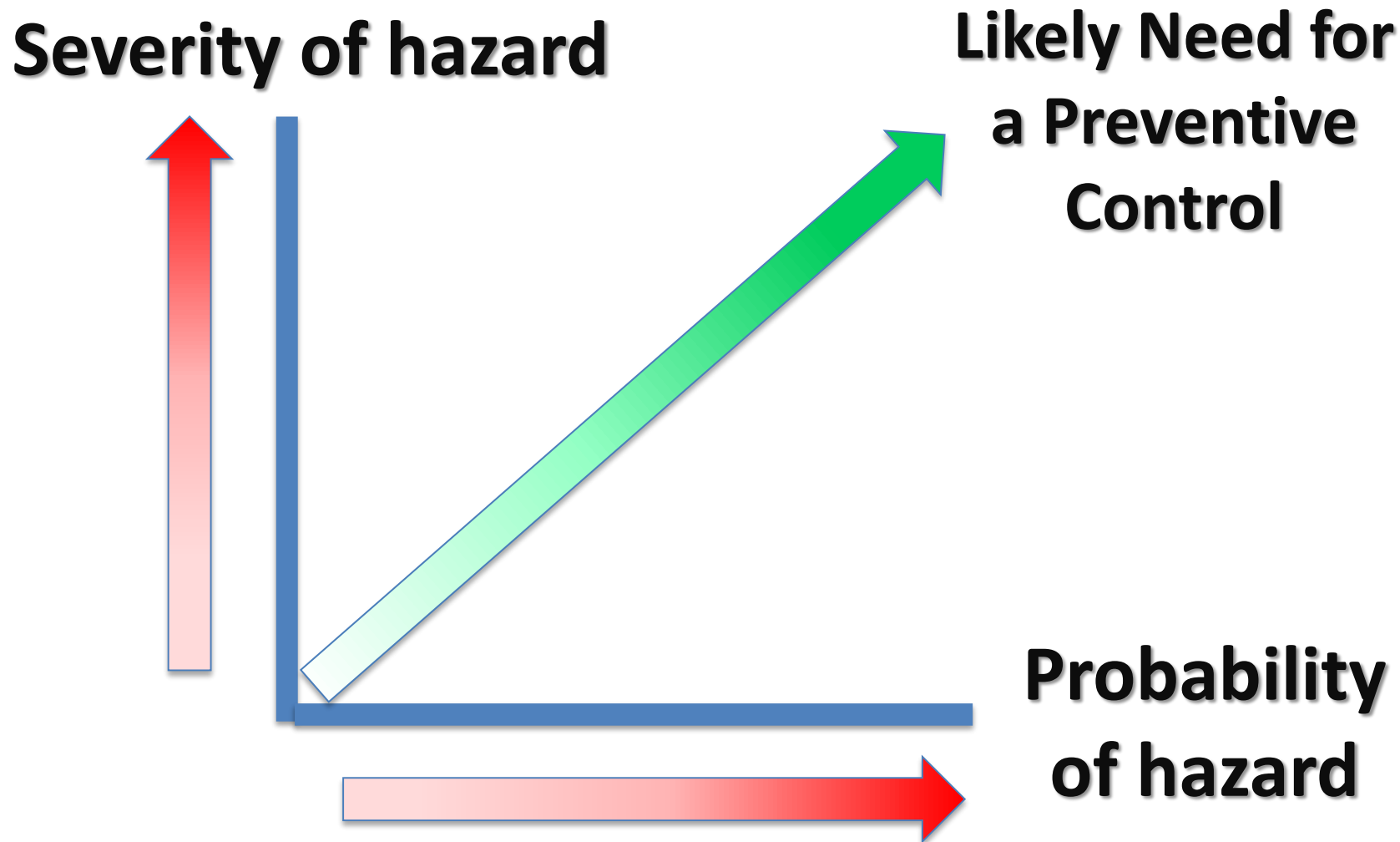
*Hazard Requiring a
Preventive Control*

*Preventive
Controls
Qualified
Individual*

*Severity
and
Probability*



Severity and Probability



Considering Probability

- CGMP requirements and use of prerequisite programs may reduce the probability of occurrence of a “known or reasonably foreseeable hazard” and influence the hazard analysis
- If compliance with CGMP requirements or use of prerequisite programs is used to make a determination that a hazard is not a “hazard requiring a preventive control,” when otherwise it would be determined as such, then FDA likely will want to observe compliance with the CGMP requirement or review documentation that the prerequisite program is in place and effective



Comparison of Hazard Evaluation

Example Hazard: Copper Toxicity

Hazard Evaluation	Facility 1	Facility 2
Is it a hazard?	Yes	Yes
Is the hazard known or reasonably foreseeable?	Yes	Yes
Severity	High	High
Probability	Low	Medium
Does the hazard require a preventive control?	No	Yes
Justification	Single copper premix is used by facility, weighed by automation. Prerequisite program ensures automation works properly	Multiple copper premixes are used by facility (sheep and beef (high copper content)) and weighed manually
Preventive Control	None	Process Control (copper premix inventory/use reconciliation)
Preventive Control Management Requirements	None	Monitoring, Corrective Actions, Verification, Record Review, Recall Plan

Resources to Help Establish Severity and Probability

- Food and Drug Administration (FDA)
 - Recalls and Withdrawals
 - Reportable Foods Registry (RFR) for animal food/feed
 - Guidance for Industry
- Centers for Disease Control and Prevention (CDC)
- European Food Safety Authority (EFSA)
- World Animal Health Information Database (WAHID)



FDA Established Limits on Contaminants in Food and Feed

1. Aflatoxin action levels (FDA's "Compliance Policy Guide" (CPG) 683.100);
2. Pesticide tolerances (EPA's Code of Federal Regulations (CFR), Title 40, Part 186 and FDA's CPG 575.100);
3. Pesticide action levels (FDA's CPG 575.100 & Federal Register (FR), Vol. 55, No. 74; April 17, 1990);
4. Temporary tolerances for PCB's (FDA's 21 CFR 509.30);
5. Guidance levels for Fumonisin (FDA's Guidance for Industry #112);
6. Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed;
7. Substances prohibited from use in animal food or feed (FDA's 21 CFR 589);
8. Tolerances established for drugs in food (FDA's 21 CFR 556);
9. Guidance levels for trace mineral contaminants (AAFCO's 2014 Official Publication; pg 302);
10. Salmonella in Food for Animals (FDA's CPG.690.800); and,
11. Regulatory limit for Salmonella (FDA's 21 CFR 500.35); and
12. Draft Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human Contact Animal Foods; Availability (Federal Register, Vol. 76, No. 56, Wednesday, March 23, 2011, 16425



Hazard Analysis Form Example

Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Hazard Evaluation			
(3)	(4)	(5)	(6)
Severity for the animal food safety hazard	Probability for the animal food safety hazard	Does the hazard require preventive control(s) (Yes or No)	Justify response made in column 5

§ 507.34 Preventive controls

- (a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food ... will not be adulterated ...
- (b)(2) Preventive controls required ... include:
 - (i) Controls at critical control points (CCPs), if there are any CCPs
 - (ii) Controls, other than those at CCPs, that are also appropriate ...



§ 507.34 Preventive controls

(b) Preventive controls must be written

(c) Preventive controls include ...

(1) **Process controls.** Process controls include procedures, practices, and processes to ensure the control of parameters during operations ... Process controls must include, as appropriate to the nature of the applicable control ...

(i) Parameters associated with the control of the hazard

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled ...



§ 507.34 Preventive controls

(c) Preventive controls include ...

(2) **Sanitation controls.** Sanitation controls ... ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards ... Sanitation controls must include, as appropriate ...

- (i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment
- (ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food-contact surfaces ...



§ 507.34 Preventive controls

(c) Preventive controls include ...

(3)**Supply-chain controls.** Supply-chain controls include the supply-chain program as required ...

(4)**A recall plan ...**

(5)**Other preventive controls.** These include any other procedures, practices, and processes necessary ... Examples of other controls include hygiene training and other current good manufacturing practices



§ 507.38 Recall plan

- (a) For animal food with a hazard requiring a preventive control, you must:
 - (1) Establish a written recall plan for the animal food
 - (2) Assign responsibility for performing all procedures in the recall plan
- (b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:
 - (1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food
 - (2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health
 - (3) Conduct effectiveness checks to verify the recall has been carried out
 - (4) Appropriately dispose of recalled animal food, e.g., through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food



§ 507.39 Preventive control management components

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls ... are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls ...

(1) Monitoring ...

(2) Corrective actions and corrections ...

(3) Verification ...

§ 507.39 Preventive control management components

- (b) The **supply-chain program** ... is subject to the following preventive control management components as appropriate to ensure [its] effectiveness ...
 - (1) **Corrective actions and corrections** ...
 - (2) **Review of records** ...
 - (3) **Reanalysis** ...
- (c) The **recall plan** ... is not [subject to management components]

Hazards and Preventive Controls

The universe of animal food hazards that could cause injury or illness to animals or humans



Identified known or reasonably foreseeable hazards associated with a facility and its type of food



Hazards requiring a preventive control as identified by hazard analysis



Preventive control(s) for hazard

Recall Plan

Supply-Chain
Applied
Control

Sanitation
Control

Process
Control

Other
Control

Example Description of Preventive Controls

Food safety Plan	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Preventive Controls and Management Components	
(7)	(8)
Preventive controls for the hazard requiring a preventive control	Hazard preventive control number

§ 507.40 Monitoring

You must:

- (a) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls
- (b) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed
- (c) (1) You must document the monitoring of preventive controls ... in records that are subject to verification ...



§ 507.42 Corrective actions and corrections

- (a)(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented...
- (2) The corrective action procedures must describe the steps to be taken to ensure that:
 - (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control
 - (ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur
 - (iii) All affected animal food is evaluated for safety
 - (iv) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated ...



§ 507.45 Verification

- (a) Verification activities must include, as appropriate ...
 - (1) Validation ...
 - (2) Verification that monitoring is being conducted as required ...
 - (3) Verification that appropriate decisions about corrective actions are being made ...
 - (4) Verification of implementation and effectiveness ...
 - (5) Reanalysis ...
- (b) All verification activities conducted ... must be documented in records

§ 507.47 Validation

- (a) You must validate that the preventive controls ... are adequate to control the hazard ...
- (b)(1) Must be performed ... by a preventive controls qualified individual
 - (i)(A) Prior to implementation of the food safety plan; or
 - (B) When necessary ...
 - (1) Within 90 calendar days after production of the applicable animal food first begins; or
 - (2) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares ... a written justification for a timeframe that exceeds 90 calendar days ...
 - (ii) Whenever a change to a control measure ... could impact whether the control measure ... will effectively control the hazards; and
 - (iii) Whenever a reanalysis of the food safety plan reveals the need to do so



§ 507.47 Validation

- (b)(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards
- (c) You do not need to validate:
 - (1) The sanitation controls ...
 - (2) The recall plan ...
 - (3) The supply-chain program ...
 - (4) Other preventive controls, if the preventive controls qualified individual prepares ... a written justification that validation is not applicable



§ 507.49 Verification of implementation and effectiveness

- (a) You must verify that the preventive controls are consistently implemented and are ... significantly minimizing or preventing the hazards. ... you must conduct activities that include the following ...
 - (1) Calibration of process monitoring and verification instruments (or checking them for accuracy)
 - (2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;
 - (3) Environmental monitoring ... if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control ...



§ 507.49 Verification of implementation and effectiveness

- (a)(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual
 - (i) Monitoring and corrective action records within 7-working days after the records are created or within a reasonable timeframe [as justified in writing]
 - (ii) Records of calibration, testing (e.g., product testing, environmental monitoring), and supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created
- (5) Other activities appropriate for verification of implementation and effectiveness



§ 507.49 Verification of implementation and effectiveness

- (b) ... you must establish and implement written procedures for the following activities:
- (1) The method and frequency of calibrating process monitoring instruments and verification instruments ...
 - (2) Product testing ...
 - (3) Environmental monitoring ...



§ 507.50 Reanalysis

- (a) You must conduct a reanalysis of the food safety plan ... at least once every 3 years
- (b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:
 - (1) Whenever a significant change ... at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;
 - (2) Whenever you become aware of new information about potential hazards ...
 - (3) Whenever appropriate after an unanticipated animal food safety problem ...
 - (4) Whenever you find that a preventive control ... or the food safety plan ... is ineffective



§ 507.50 Reanalysis

- (c) You must complete the reanalysis ... and validate ... any additional preventive controls needed ...
 - (1) Before any change in activities ... at the facility is operative; or
 - (2) When necessary to demonstrate the control measures can be implemented as designed:
 - (i) Within 90 calendar days after production of the applicable animal food first begins; or
 - (ii) Within a reasonable timeframe [as justified in writing]
- (d) You must revise the written food safety plan if a significant change ... at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are needed
- (e) A preventive controls qualified individual must perform (or oversee) the reanalysis
- (f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary ...



Food Safety Form Example

Food Safety Plan	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Description of Preventive Controls						
(9)	(10)	(11)	(12)	(12)	(13)	(14)
Preventive control(s) category	Parameters (if applicable)	Validation	Monitoring	Corrective Action	Verification Activities	Records

§ 507.53 Requirements applicable to a preventive controls qualified individual and qualified auditor

- (a) One or more preventive controls qualified individuals must do or oversee the following:
 - (1) Preparation of the food safety plan
 - (2) Validation of the preventive controls
 - (3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food;
 - (4) Determination that validation is not required
 - (5) Review of records
 - (6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7-working days;
 - (7) Reanalysis of the food safety plan
 - (8) Determination that reanalysis can be completed, and additional preventive controls validated ... in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food



507.53 Requirements applicable to a preventive controls qualified individual and qualified auditor

- (b) A qualified auditor must conduct an onsite audit (supply-chain program)
- (c) (1) To be a preventive controls qualified individual, the individual must have 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 be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility
- (2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function
- (d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained

§ 507.55 Implementation

records required for this subpart

- (a) You must establish and maintain the following records that document ...
 - (1) The basis for not establishing a preventive control ...
 - (2) The monitoring of preventive controls
 - (3) Corrective actions
 - (4) Verification, including, as applicable, those related to:
 - (i) Validation
 - (ii) Verification of monitoring
 - (iii) Verification of corrective actions
 - (iv) Calibration of process monitoring and verification instruments
 - (v) Product testing
 - (vi) Environmental monitoring
 - (vii) Records review
 - (viii) Reanalysis
 - (5) The supply-chain program
 - (6) Applicable training for the preventive controls qualified individual and the qualified auditor
- (b) The records that you must establish and maintain are subject to the requirements of subpart F



Compliance Dates for CGMPs and **PCs**

Business Size	CGMPs Compliance Date	Preventive Controls Compliance Date
Business Other than Small and Very Small	1 year – Sept. 19, 2016	2 years – Sept. 18, 2017
Small Business	2 years – Sept. 18, 2017	3 years – Sept. 17, 2018
Very Small Business	3 years – Sept. 17, 2018	4 years – Sept. 17, 2019

- **Small Business:** A business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees. The rule specifies that all employees within the business and all of its subsidiaries and affiliates, regardless of whether an employee is involved in animal food-related activities, is to be counted in this determination.



Summary

- A written food safety plan must be developed by (or overseen by) a preventive controls qualified individual that includes:
 - A hazard evaluation to identify any “hazards requiring a preventive control”
 - If a “hazard requiring a preventive control” is identified, one or more preventive controls must be implemented, along with required management components (e.g., monitoring, corrections and corrective actions, verification, records, recall plans)
- The food safety plan must be reanalyzed at least every three years, or more frequently if prescribed situations occur



Preventive Controls

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