


**Principle 1:
Hazard Analysis**

Chapter 8 Hazard Analysis
HACCP A Systematic Approach to Food Safety

OFFICE OF THE TEXAS STATE CHEMIST
Texas Feed and Fertilizer Control Service • Agriculture Analytical Service



HACCP Principles

1. Conduct a Hazard Analysis (HA)
2. Identify Critical Control Points (CCPs)
3. Establish Critical Limits (CLs)
4. Establish CCP Monitoring Requirements
5. Establish Corrective Actions (CA)
6. Establish Verification Procedures
7. Establish Record-Keeping Procedures

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HACCP Principle 1: Conduct a Hazard Analysis

- Definition of Hazard Analysis-The process of collecting and evaluating information on hazards associated with the product under consideration to decide which are significant and must be addressed in the HACCP plan
- The HACCP team conducts a hazard analysis and identifies appropriate control measures

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Purpose

The purpose of the hazard analysis is to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled.

NACMCF, 1998

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Hazard Analysis Criteria in FSMA

- (1) identify and evaluate know or reasonably foreseeable hazards of animal food manufactured, processed, packed, or held at the facility including-
 - (a) biological, chemical, physical and radiological hazards ... and
 - (b) Hazards that occur naturally or may be unintentionally introduced
- (2) Identify and evaluate hazards that may be intentionally introduced including by acts of terrorism and
- (3) Develop a written analysis of the hazards.

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Hazard Analysis Process

- 1) Hazard identification
- 2) Hazard evaluation

Identify and evaluate know or reasonably foreseeable hazards for each type of animal food manufactured, processed, packaged, or held at the facility to determine whether there are hazards that are reasonably likely to occur including biological, chemical, physical, and radiological hazards.

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Hazard Analysis Form

Product Category: Cattle protein/mineral medicated supplement

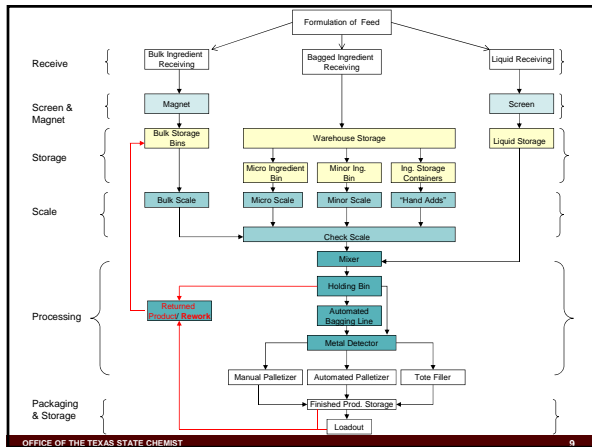
Ingredient or Processing step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? Severity: Likelihood		Justification for significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this a CCP?
		Animal	Human	Animal	Human		
Biological							
Chemical							
Physical							

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Stage 1 Hazard Identification

- Resembles a **brain storming** session in which the team considers each process step (using the flow diagram) and reviews information about
 - Raw material and ingredients in the product
 - Activities conducted at each process step
 - The equipment used to make the product
 - The method of storage and distribution
 - The intended use and consumers of the product

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Stage 1 Hazard Identification

- Develop a list of **potential** biological, chemical, physical and radiological hazards that may be introduced, increased or controlled at each step of the production process
- Use form to list potential hazards

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Hazard Analysis Form

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Ingredient or Processing step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? Severity: Likelihood		Justification for significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this a CCP?
		Animal	Human	Animal	Human		
Bulk receiving	Biological Prohibited animal protein E. coli O157:H7 Salmonella						
	Chemical Wrong ingredient or grade Aflatoxin						
	Physical None identified at this time						

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Biological Hazards Examples of Key Questions

Review the list of ingredients

- Are the hazardous biological agents inherently associated with the ingredients?
- Are the ingredients or finished product capable of supporting pathogens?

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Biological Hazards

Examples of Key Questions

Review the flow diagram

- ❑ Will a procedure allow pathogens to multiply to hazardous numbers?
- ❑ Will ingredients or the finished product become contaminated with pathogens?

Chemical Hazards

Examples of Key Questions

Review the list of raw materials, ingredients and packaging materials:

- ❑ Are there hazardous chemicals associated with growing, harvesting or packaging of any commodity or material?
- ❑ Are additives approved and do they meet ingredient spec's?
- ❑ Do labeling requirements apply and is the product labeled correctly?

Chemical Hazards

Examples of Key Questions

Review the flow diagram:

- ❑ Are feed grade lubricants used?
- ❑ Are salt and urea levels being monitored in the process?
- ❑ Are cleaning and sanitizing chemicals approved for use in feed mills and used appropriately?

Physical Hazards

Examples of Key Questions

Review the list of raw materials, ingredients and packaging materials:

- ❑ Are foreign objects capable of causing injury associated with any of the raw materials or ingredients?
- ❑ Are there physical hazards associated with any packaging material?

Physical Hazards

Examples of Key Questions

Refer to the flow diagram and inspect the physical facilities at the plant:

- ❑ Are there environmental sources of physical hazards in and around feed storage and manufacturing areas?
- ❑ Is any equipment capable of generating physical hazards?
- ❑ Are there tools, utensils, and other implements used on or near the feed production lines that may fall into the equipment or product?

Stage 2

Hazard Evaluation

HACCP team decides which of the potential hazards listed during the hazard identification stage present a significant risk to consumers using two factors

- 1) severity (serious of the potential illness or injury resulting from exposure to the hazard)
- 2) likelihood of occurrence

Stage 2 Hazard Evaluation

Factors that may influence the likelihood of occurrence of the potential hazard in the final product include:

- Effectiveness of prerequisite programs
- Frequency of association of the potential hazard with the food or an ingredient
- Method of preparation in the establishment
- Conditions during transportation
- Expected storage conditions
- The likely preparation steps prior to consumption

FSMA rule criteria for animal food

(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

Hazard Analysis Form

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		Animal	Human	Animal	Human		
Bulk receiving	Biological Prohibited animal protein	Yes	Yes				
	E. coli O157:H7	No	No				
	Salmonella	Yes	No				
	Chemical Wrong ingredient or grade	Yes	No				
	Aflatoxin	Yes	Yes				
	Physical None identified at this time						

Stage 2 Hazard Evaluation

More likely to be addressed in HACCP plan

Severity	Likelihood of Occurrence			
	H-R	H-L	H-M	H-H
High				
Medium	M-R	M-L	M-M	M-H
Low	L-R	L-L	L-M	L-H
	Remote	Low	Medium	High

Stage 2 Hazard Evaluation Justification for Determining Significance

Stage 1: Hazard ID	Prohibited animal protein fed to ruminants
Stage 2: Hazard Evaluation Assess severity of health consequences if potential hazard is not properly controlled	Epidemiological evidence indicates that the prion that causes BSE can also infect humans causing variant Creutzfeldt Jakob disease
Determine likelihood of occurrence of potential hazard if not properly controlled	Firewalls (prohibiting imported beef or bovine from the EU, prohibiting feeding of mammalian protein to ruminants, and inspections) has lowered the likelihood of this disease becoming established in the U.S.
Using this information, determine if this potential hazard is to be addressed in the HACCP plan	HACCP team decides that prohibited mammalian protein must be addressed in the HACCP plan, since this is key to avoiding the establishment of BSE in the US

Stage 2 Hazard Evaluation Justification for Determining Significance

Stage 1: Hazard ID	Enteric pathogen E. coli O157:H7 in incoming ingredients
Stage 2: Hazard Evaluation Assess severity of health consequences if potential hazard is not properly controlled	Epidemiological evidence indicates that this pathogen causes severe human health effects.
Determine likelihood of occurrence of potential hazard if not properly controlled	The likelihood of E. coli O157:H7 in the incoming ingredient is low and there is little evidence that demonstrates that feed is the source of this pathogen for animals or humans.
Using this information, determine if this potential hazard is to be addressed in the HACCP plan	HACCP team decides that the enteric pathogen E. coli O157:H7 is not a hazard for animals or humans.

Hazard Analysis Form

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Bulk receiving	Biological Prohibited animal protein	Yes	Yes	Cross contamination by prohibited animal protein (21 CFR 582.2000-1) is a potential source of bovine spongiform encephalopathy (BSE)	BSE in cattle can cause the human disease variant Creutzfeldt Jakob disease (vCJD)	Prohibited animal protein policy, approved supplier, carrier inspection	
	E. coli O157:H7	No	No	Low likelihood in animal feed ingredients	Low likelihood in human food		
	Salmonella	Yes	No	Moderate likelihood in ingredients, a potential source for Salmonellosis	Low likelihood of it causing a human food problem	Approved supplier, cleaning feed manufacturing equipment	
Chemical Wrong ingredient or grade	Aflatoxin	Yes	No	Potential source of toxin to animals	Low likelihood of transfer to human food	Approved supplier and testing	
	Aflatoxin	Yes	Yes	Toxic to finishing cattle at concentrations above 300 ppb	H likelihood of transfer to milk as M1 if fed to dairy cattle if corn is >20 ppb	Sampling and testing incoming ingredients prone to aflatoxin	
Physical	None identified at this time						

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Hazard Analysis

- Hazards that are reasonably likely to occur must be controlled
 - For human food safety hazards, they are addressed in the HACCP plan
 - For animal health hazards, they are addressed in the prerequisite program

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Control Measures

- The HACCP team must identify measures to control hazards that are reasonably likely to occur
- Control measure -Any action or activity that can be used to prevent, eliminate or reduce a significant hazard

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Control Measures

- More than one control measure may be required for a specific hazard
- Assists with tasks for Principle 2 identifying CCP's


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