

Principle 1: Conduct a Hazard Analysis

Tim Herrman
Professor, State Chemist and Director
Office of the Texas State Chemist



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

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

- 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 Process

- 1) Hazard identification
- 2) Hazard evaluation

Identify and evaluate known 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.

Hazard Analysis Form

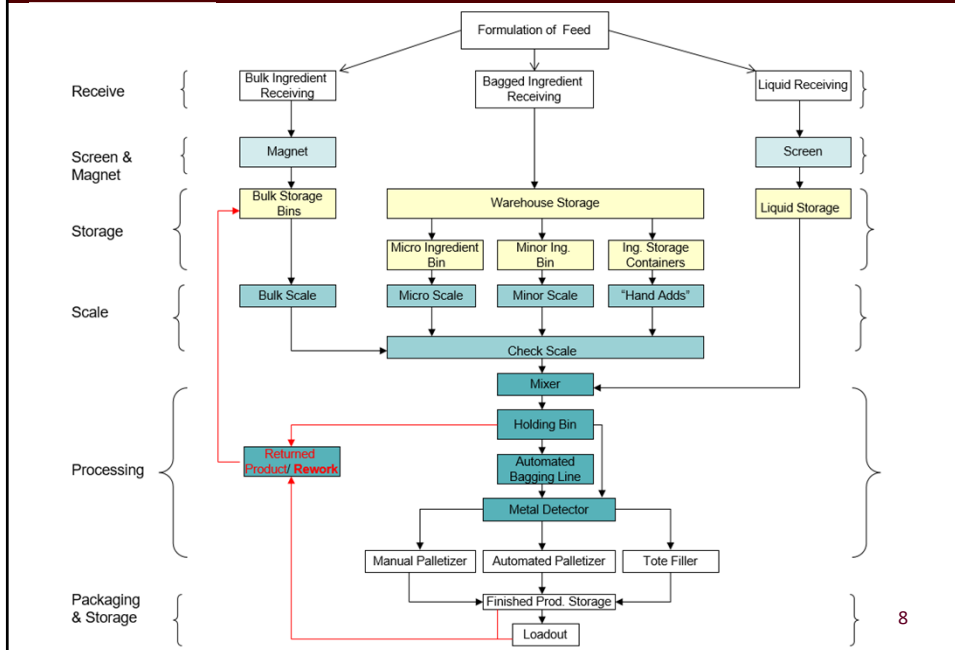
Product category – Cattle medicated feed

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

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

Hazard Analysis Form

Ingredient or Processing step	Potential hazards introduced, increased or controlled at this step	Do any potential feed hazards require a CCP? 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 <i>E. coli</i> O157:H7 <i>Salmonella</i>						
	Chemical Wrong ingredient or grade Aflatoxin Sulfur						
	Physical Metal Plastic Stones Glass						

Questions to Identify Biological Hazards

- 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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Questions to Identify Biological Hazards

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

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Questions to Identify Chemical Hazards

- 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 specifications?
 - Do labeling requirements apply and is the product labeled correctly?

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Questions to Identify Chemical Hazards

- 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?

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Questions to Identify Physical Hazards

- 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?

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Questions to Identify Physical Hazards

- 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?

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Stage 2: Hazard Evaluation

The 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), and
- 2) Likelihood of occurrence.

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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

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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

Ingredient or Processing step	Potential hazards introduced, increased or controlled at this step	Do any potential feed hazards require a CCP? 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	Yes	Yes				
	<i>E. coli</i> O157:H7	No	No				
	<i>Salmonella</i>	No	No				
	Chemical Wrong ingredient or grade	No	No				
	Aflatoxin	Yes	Yes				
	Sulfur	Yes	No				
	Physical Metal	No	No				
	Plastic	No	No				
	Stones	No	No				
	Glass	No	No				

Stage 2: Hazard Evaluation

Justification for Determining Significance

<i>Stage 1: Hazard ID</i>	Enteric pathogen E. coli 0157:H7 in incoming ingredients
<i>Stage 2: Hazard Evaluation</i> 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 0157: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 0157:H7 is not a hazard for animals or humans

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Ingredient or Processing step	Potential hazards introduced, increased or controlled at this step	Do any potential feed hazards require a CCP? 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	Yes	Yes	Cross contamination by prohibited animal protein (21 CFR:589.2000-1) is a potential source of bovine spongiform encephalopathy (BSE)	BSE in cattle can cause the human disease variant Creutzfeldt Jakob disease (vCJD)		
	<i>E. coli 0157:H7</i>	No	No	Low likelihood in animal feed ingredients	Low likelihood in human food		
	<i>Salmonella</i>	No	No	Low likelihood in ingredients for S. Newport and Dublin	Low likelihood of it causing a human food problem		
	Chemical Wrong ingredient or grade	No	No	Low likelihood resulting from approved supplier program	Low likelihood of transfer to human food		
	Aflatoxin	Yes	Yes	Toxic to finishing cattle at concentrations above 300 ppb	Transfer to human food when feed to lactating dairy cattle		
Sulfur	Yes	No	At high levels causes polyoencephalomalacia	Low likelihood of transfer to human food			
Physical Metal Plastic Stones Glass		No No No No	No No No No	Low likelihood of physical hazards damaging cattle due to Equipment (screens, de-stoning device, metal detectors, and magnets) in place to eliminate hazard	Low likelihood of transfer to food		

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 unless prescribed hazard by FDA, then address in HACCP plan

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Control Measures

- The HACCP team must identify measures to control hazards that are reasonably likely to occur
- Control measures – 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

Ingredient or Processing step	Potential hazards introduced, increased or controlled at this step	Do any potential feed hazards require a CCP? 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	Yes	Yes	Cross contamination by prohibited animal protein (21 CFR:589:2000-1) 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	
	<i>E. coli</i> O157:H7	No	No	Low likelihood in animal feed ingredients	Low likelihood in human food		
	<i>Salmonella</i>	No	No	Low likelihood in ingredients for S. Newport and Dublin	Low likelihood of it causing a human food problem		
	Chemical Wrong ingredient or grade	No	No	Low likelihood resulting from approved supplier program	Low likelihood of transfer to human food		
	Aflatoxin	Yes	Yes	Toxic to finishing cattle at concentrations above 300 ppb	Transfer to human food when feed to lactating dairy cattle	Sampling and testing incoming ingredients prone to aflatoxin	
Sulfur	Yes	No	At high levels causes polioencephalomalacia	Low likelihood of transfer to human food	Approved supplier		
Physical Metal Plastic Stones Glass	No No No No	No No No No	Low likelihood of physical hazards damaging cattle due to Equipment (screens, de-stoning device, metal detectors, and magnets) in place to eliminate hazard	Low likelihood of transfer to food			

Contact Information:
tjh@otsc.tamu.edu

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