

Overview of HACCP Principles

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HACCP Concept

- ❑ A systematic approach to be used in food production as a means to assure food safety.

National Advisory Committee on Microbiological Criteria for Foods (NACMCF)

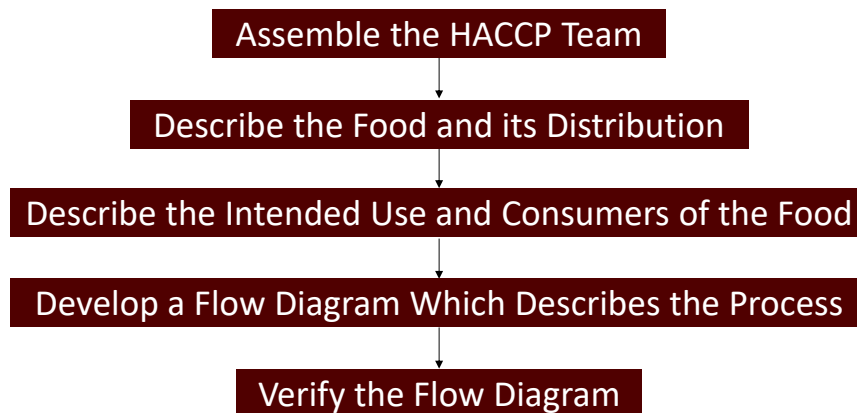
- ❑ The HACCP concept can be applied throughout the food chain including feed manufacturing.
- ❑ Food Safety Modernization Act and rules: Current Good Manufacturing Practice Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.

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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Preliminary Tasks Development of the HACCP Plan



U. S. Food and Drug Administration, U. S. Department of Agriculture, NACMCF
 Adopted August 14, 1997

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Codex General Principles of Food Hygiene

1. Assemble HACCP Team
2. Describe Product
3. Identify Intended Use
4. Construct Flow Diagram
5. On-site Confirmation of Flow Diagram
6. List all Potential Hazards, Conduct HA, Control
7. Determine CCPs
8. Establish Critical Limits for each CCP
9. Establish a Monitoring System for each CCP
10. Establish Corrective Actions
11. Establish Verification Procedures
12. Establish Documentation and Record Keeping

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Food Safety Modernization Act

FDA directed to promulgate regulations in 18 months

- *To establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of preventive controls ... and*
- *To define, for purposes of this section, the terms 'small business' and 'very small business',*

FDA promulgated two new rules after nearly 5 years

- Current Good Manufacturing Practices and second;
- Hazard Analysis and Risk-Based Preventive Controls for Food for Animal

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HACCP Preliminary tasks

Not included in HACCP or FSMA rules, present in global HACCP standards and training for a prevention-based food safety system

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Step 1

Assemble the HACCP Team

- The first task in developing a HACCP plan is to assemble a HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is the team's responsibility to develop the HACCP plan.

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Step 1

Such individuals should have the knowledge and experience to correctly: (a) conduct a hazard analysis; (b) identify potential hazards; (c) identify hazards which must be controlled; (d) recommend controls, critical limits, and procedures for monitoring and verification; (e) recommend appropriate corrective actions when a deviation occurs; (f) recommend research related to the HACCP plan if important information is not known; and (g) validate the HACCP plan.

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Assemble the HACCP Food Safety Team

Identify a HACCP Coordinator

- Overall responsibility for HACCP program
- Good communicator, interpersonal skills
- Possess technical skills necessary to assist in the development of a science-based plan

Preventive controls qualified individual 21 CFR§ 507.53

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Assemble the HACCP Food Safety Team

Purpose – Responsible for planning, developing and implementing the HACCP plan

- Select people with specific knowledge and expertise about the process and product
- Multi-disciplinary
- Line personnel, quality assurance, engineering, product development, management

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Step 2

Describe the food and its distribution

- The HACCP team first describes the food. This consists of:
 - a general description of the food,
 - ingredients, and
 - processing methods
- The method of distribution should be described and its intended use (retail, internal, further processing).

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List of Ingredients and Raw Materials

Product Name:		
Bulk Ingredients	Bag or Hand Add Ingredients	Medications
Liquids	Packaging Materials	Other Additives
Approved: _____ Date: _____		

List of Ingredients and Raw Materials Example for Feed Products

Product Name: Cattle medicated feed		
Bulk Ingredients	Bag and Hand Add Ingredients	Medications
Corn DDGS Soybean Meal Sunflower Meal Calcium carbonate Salt Cottonseed Hulls	Vitamin E Copper Sulfate Calcium Phosphate	Rumensin 80 Rabon
Liquids	Packaging Materials	Other Additives
Vegetable oil Cane Molasses	Bags & Totes Bag Label Bulk Label Delivery Truck	
Approved: _____ Date: _____		

Step 3

Describe the intended use and consumers

- Describe the normal expected use of the feed.
 - pet food
 - manufacturers of raw dog and cat food
 - Renderers and protein blenders
 - Meat reclaimers
 - Manufacturers of medicated and non-medicate livestock feed
 - Manufacturers of animal supplements
 - Manufacturers of vitamin/mineral premixes
 - Manufacturers of distillers products for fuel ethanol
 - Manufacturers of milk replacers

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Product Description

1. Product name (s)	
2. Product Safety Properties (Moist., Pro., etc.)	
3. Intended use and customer	
4. Type of packaging	
5. Shelf life	
6. Where will the product be sold?	
7. Labeling instructions	
8. Special distribution control	
Approved: _____ Date: _____	

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Product Description

1. Product name (s)	Product Name: Cattle medicated feed
2. Product safety properties	high moisture
3. Intended use and customer	Feed to animals per instructions on label
4. Type of packaging	Bag & bulk
5. Shelf life	Equal to or less than 90 days
6. Where will the product be sold?	Retail or wholesale
7. Labeling instructions	In compliance federal and state regulations
8. Special distribution control	Proper sequencing and flushing
Approved: _____ Date: _____	

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Ideas for Process Categories in HACCP Plans

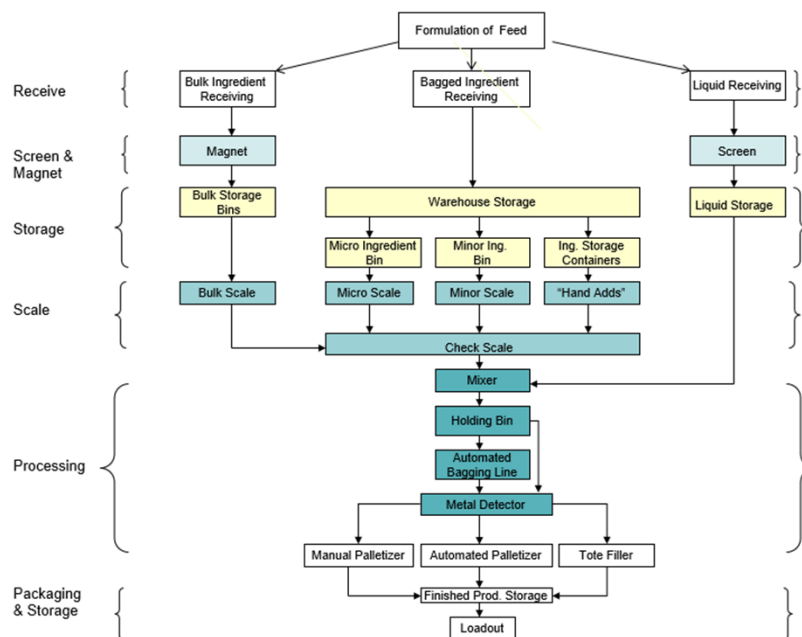
- ❑ Separate process lines
- ❑ Liquid versus dry
- ❑ Pet food versus cattle feed

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Step 4

Develop a flow diagram to describe the process

- The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process which are directly under the control of the establishment. A block type flow diagram is sufficiently descriptive.



Step 5

Verify the flow diagram

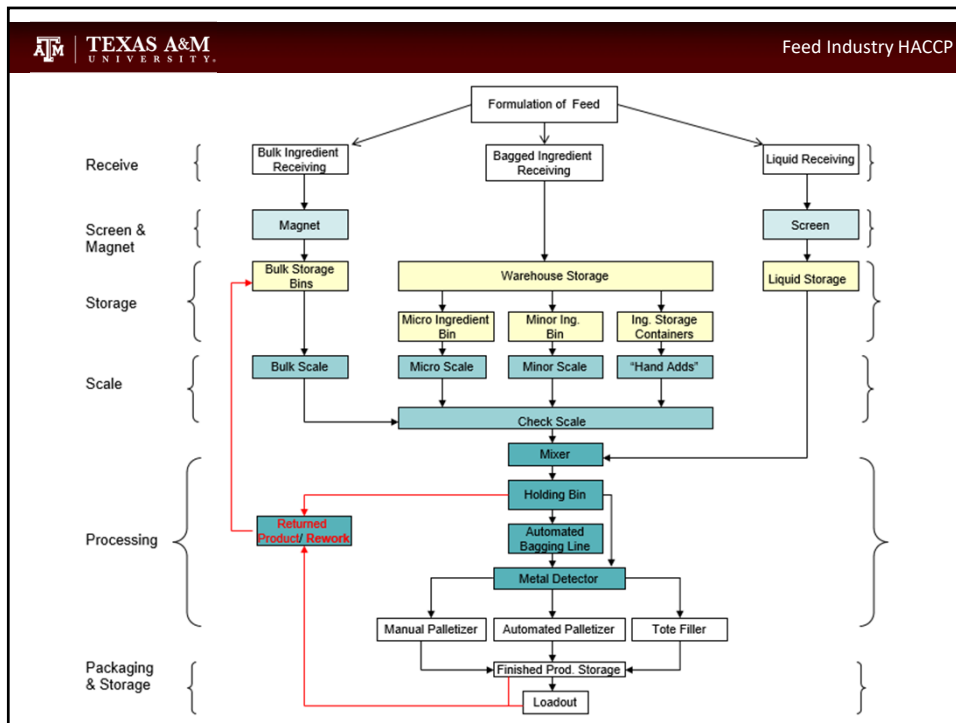
- The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modifications should be made to the flow diagram as necessary and documented.

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Flow Diagram

- Define returned product
- Define rework
- Verify process flow

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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.

Hazard

- Hazard* means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals

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Hazard Requiring a Preventive Control

- 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 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.

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HACCP Principle 2: Identify Critical Control Points

- Definition of Critical Control – A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level

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HACCP Principle 3: Establish Critical Limits

- Definition of Critical Limit – A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a feed or food safety hazard

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HACCP Principle 4: Establish Monitoring Procedures

- Definition of Monitor – To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification
- FSMA Definition to Monitor – To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended

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HACCP Principle 5: Establish Corrective Actions

- Definition of **Corrective Action**:
 Procedures followed when a deviation occurs
- Definition of **Deviation**:
 Failure to meet a critical limit

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HACCP Principle 6: Establish Verification Procedures

- Definition of **Verification**:
Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan

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HACCP Principle 7: Establish Record-Keeping

- The HACCP team sets up a record-keeping program which provides written documentation that the HACCP plan is being carried out as described in the written HACCP plan.

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What is the HACCP Plan?

- **Definition of HACCP Plan:**
 The written document which is based upon the principles of HACCP and which delineates the procedures to be followed

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What is a Food Safety Plan

You must prepared and implemented a written food safety plan. It must be prepared by one or more preventive control qualified individuals and it must include:

- The hazard analysis;
- Preventive controls;
- Written supply-chain program;
- Recall plan;
- The procedures and the frequency with which these procedures will be conducted for monitoring the performance of the preventive controls;
- Corrective action procedures; and
- Verification procedures

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Prerequisite Programs

- ❑ The production of safe feed products requires that the HACCP system be built upon a solid foundation of prerequisite programs
- ❑ Traditionally, this has been done through GMPs.
- ❑ Many of the prerequisite programs are proprietary
- ❑ The existence and effectiveness of prerequisite programs should be assessed during the design and implement of each HACCP plan
- ❑ Must be documented and audited

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Examples of Prerequisite Programs

Examples

- ❑ Facilities
- ❑ Supplier Control
- ❑ Ingredient specifications
- ❑ Production Equipment
- ❑ Cleaning and sanitation
- ❑ Training
- ❑ Chemical Control
- ❑ Receiving, Storage & Shipping
- ❑ Pest Control

Current CGMP Requirements

- ❑ Personnel
- ❑ Plant and grounds
- ❑ Sanitation
- ❑ Water supply and plumbing
- ❑ Equipment and utensils
- ❑ Plant operations
- ❑ Holding and distribution
- ❑ Holding and distribution of human food by-products for use as animal food

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Summary

- HACCP involves 7 principles, 5 preliminary tasks, and prerequisite programs
- Both the National Advisory Committee on Microbiological Criteria for Foods and Codex have guidelines for the adoption of HACCP
- The first preliminary step “Assemble a HACCP Team” is essential to successful adoption
- The Food Safety Modernization Act and rules require the adoption of prerequisites, hazard analysis and preventive controls for food for animals

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