

Prerequisites to HACCP

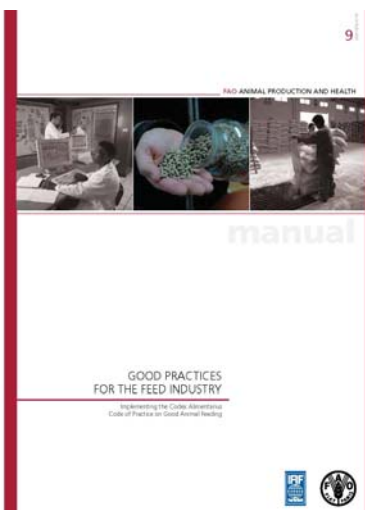
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Outline: Prerequisite Program Introduction

1. Prerequisite program characteristics
2. Code of Practices on Good Animal Feeding
3. Current Good Manufacturing Practices
 - Personnel
 - Plant and Grounds
 - Sanitation
 - Water Supply and Plumbing
 - Equipment and Utensils
 - Plant Operations
 - Holding and Distribution



Prerequisite Programs and HACCP

- ❑ Prerequisite programs should be in place and performing effectively to ensure feed safety
- ❑ Prerequisite programs simplify HACCP development and maintenance

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Prerequisite Programs and HACCP

Prerequisite programs

- Often deal with product quality in addition to feed and food safety
- General and applicable throughout the plant and across multiple product lines
- May not fit CCP criteria (failure to meet a prerequisite program seldom results in a food safety hazard)

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Establishing Prerequisite Programs

- Documentation**
 Well written prerequisite programs including Standard Operating Procedures (SOPs) & Sanitary SOPs
- Employee Training**
 Management must provide time for thorough education and training. Learning must be verified.
- Verification**
 Verify that the SOP is being performed correctly and that monitoring and record-keeping are completed.
- Resources**

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Verification of Prerequisite Programs

- Periodic review of the SOPs and audit reports to ensure that the programs are operating in a manner that should not require a change in the hazard analysis of HACCP plan

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Establishing Prerequisite Programs

Verification

- Is the SOP performed in the manner intended?
- Are the procedures monitored?
- Are the appropriate records kept?
- Is there an independent audit?
- Are programs revised as necessary?

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Establishing Prerequisite Programs

Resources

- Are the proper tools/equipment available?
- Are the appropriate personnel available to perform the task effectively?
- Are systems adequate for monitoring and storing data?

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Personnel

FSMA Personnel

All personnel conform to hygienic practices to the extent necessary:

- Maintaining adequate personal cleanliness
- Washing hands
- Removing jewelry and other objects
- Storing clothing and other personal belongings away from feed
- Take other precautions to protect against contamination of animal food

Codex Personal Hygiene

People known or suspected to be suffering from or to be a carrier of a disease or illness likely to be transmitted through feed, should be prevented from contaminating feed. Symptoms include:

jaundice, diarrhea, vomiting, fever, visibly infected skin lesions

Training: Personnel should be aware of their role in food safety.

same criteria as qualified employee in FSMA rule

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Plant and Grounds

FSMA – Plant

Suitable in size, construction, and design to facilitate cleaning, maintenance, pest control:

- Adequate space between equipment, walls, and stored material to permit cleaning and maintenance
- Constructed to avoid contamination by condensate
- Provide adequate ventilation
- Provide lighting and shatter resistant bulbs

Codex – Design & Layout

The internal design and layout should permit good hygiene practices, easy access for cleaning, and prevent entry of pests. Process flow should be designed to minimize feed contamination.

- Surface of walls and floors should be made of impervious material
- Surfaces of walls and floors should be smooth to enable cleaning
- Overhead light fixtures should minimize dust accumulation and bulbs protected to avoid breakage

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Plant and Grounds

FSMA – Grounds

Grounds around an animal food plant will protect against the contamination:

- Properly storing equipment, litter and waste removal
- Maintaining driveways, etc.
- Adequate draining
- Treating and disposing of waste

Codex – Grounds

Location of mill – establishments should normally be located away from:

- Environmentally polluted areas
- Areas subject to flooding
- Areas prone to infestations of pests
- Areas where wastes, either solid or liquid, cannot be removed effectively

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Sanitation

FSMA

- ❑ Buildings, structures, fixtures, and other physical facilities of the plant must be kept clear and in good repair
- ❑ Contact surface must be cleaned and maintained
- ❑ Cleaning compounds and sanitizing agents must be safe
- ❑ Toxic materials
- ❑ Effective measure to exclude pests
- ❑ Trash must be conveyed, stored, and disposed of to protect against contamination

Codex – Design & Layout

- ❑ Feed and feed ingredients, processing plants, storage facilities and their immediate surroundings should be kept clean and effective pest control programs.
- ❑ Containers and equipment should be kept clean. Cleaning programs should be effective and minimize residues of detergents and disinfectants.
- ❑ Machinery should be dried following any wet cleaning process.
- ❑ Special precautions should be taken when cleaning machinery used for moist and semi-moist feed and feed ingredients to avoid fungal and bacterial growth.

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Water Supply and Plumbing

FSMA

- ❑ Water must be adequate for the operations and from adequate source
- ❑ Running water at a suitable temperature, etc.
- ❑ Water containing surfaces must be safe
- ❑ Water reused not increase contamination
- ❑ Plumbing must be adequate to convey water and sewage
- ❑ Avoid being a source of contamination
- ❑ Provide adequate drainage
- ❑ Ensure no backflow
- ❑ Adequate toilet and hand-washing facilities

Codex

- ❑ Water used in feed manufacture should meet hygienic standards and be of suitable quality for animals
- ❑ Tanks, pipes and other equipment used to store and convey water should be of appropriate materials which do not produce unsafe levels of contamination
- ❑ Sewage, waste and rain water should be disposed of in a manner which avoids contamination of equipment, feed and feed ingredients

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Equipment and Utensils

FSMA

- ❑ Used in manufacturing, processing, packing and holding
 - *Adequately cleanable and maintained*
 - *Designed, constructed and used to avoid adulteration*
 - *Installed to facilitate cleaning*
 - *Animal contact surfaces nontoxic*
- ❑ Holding, conveying, manufacturing and processing systems protect against contamination
- ❑ Instruments and controls prevent growth of microorganisms
- ❑ Compressed air and other gases protect against contamination

Codex

- ❑ Equipment performance and maintenance:
 - *All scales and metering devices used in the manufacture of feed and ingredients should be appropriate for the range of weights and volumes measured*
 - *All mixers used in the manufacture of feed and feed ingredients should be appropriate for the range of weight and columns, dilutions, etc.*
 - *All other equipment used in the manufacture of feed and feed ingredients should be appropriate*

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Plant Operations

FSMA

- All operations ... are conducted in accordance with the CGMPs
- Animal food ... is accurately identified
- Animal food packaging materials are safe and suitable
- Overall cleanliness of the plant ...
- Plant operations do not contribute to contamination
- Testing procedures are used to identify sanitation failure and contamination
- Adulterated product ... eliminate
- Raw material examination, shipping, cleaned, stored, processed ...

Codex

- Equipment performance and maintenance:
 - *All scales and metering devices used in the manufacture of feed and ingredients should be appropriate for the range of weights and volumes measured*
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Holding and Distribution

FSMA

- Animal food held for distribution will protect against contamination and minimize deterioration
- Labeling must enable safe use
- Shipping containers examined prior
- Returned product must be assessed
- Handle bulk material to avoid cross-contamination
- Human food by-products used as animal food must be protected against contamination, labeled and shipped to protect against contamination
- Raw material examination, shipping, cleaned, stored, processed ...

Codex

- This prerequisite program provides the foundation for all receiving, storage and distribution procedures throughout the facility
- List of receiving, storage and distribution SOPs:
 - Bulk receiving
 - Bulk load-out
 - Warehouse receiving
 - Warehouse load-out
 - Inventory
 - Returns

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Examples of Prerequisite Programs

Ingredient specifications and supplier approval

These two items are interrelated since the supplier approval process with measure their performance against ingredients specifications and their ability to fulfill contract requirements.

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Examples of Prerequisite Programs

Ingredient specifications and supplier approval: Criteria

- Program title
- Purpose and scope
- Policy statement by management
- Work instructions
- SOPs and SSOPs
- Employee training requirements
- Verification activities including monitoring and record keeping
- Resources
- Plan for prerequisite program review

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Examples of Prerequisite Programs

Ingredient specifications and supplier approval: SOPs

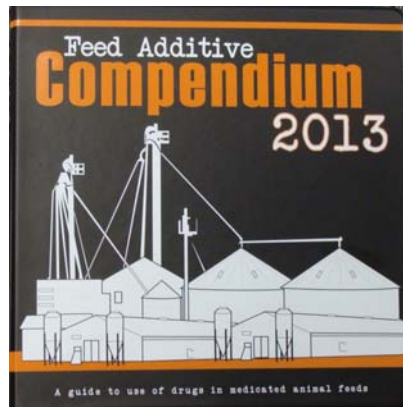
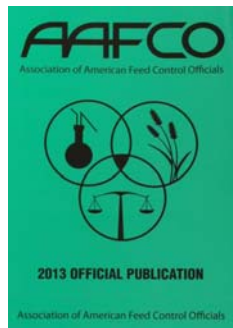
- A – Purchasing (SOP: Purchasing)
- B – Supplier qualification (SOP: Supplier qualification)
 - 1 – Supplier audits
 - 2 – Supplier requirements
 - 3 – New supplier (SOP: New supplier approval)
- C – Inspection of incoming trucks (SOP: Trailer/van inspection)
- D – Sampling of raw ingredients (SOP: Sampling of materials)
- E – Analysis of raw ingredients (SOP: Required tests for raw material)
 - 1 – Specifications
 - 2 – Analysis (SOP: Laboratory test methods)
- F – Training (SOP: Annual employee training, New employee training)
- G – Audit (SOP: Annual cGMP audit)

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Examples of Prerequisite Programs

Ingredient Specifications

- ❑ Association of American Feed Control Officials
- ❑ Feed Additive Compendium



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Examples of Prerequisite Programs

ISO 9001:2000

7.4.1 Purchasing Process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

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Examples of Prerequisite Programs

- ❑ Pest Control and Sanitation
- ❑ Receiving, Storage and Distribution
- ❑ Tracing and Recall
- ❑ Facilities
- ❑ Personnel
- ❑ Production Equipment
- ❑ Control of Raw Materials
- ❑ Environmental Monitoring
- ❑ Chemical Control
- ❑ Glass Control

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Prerequisite Program or HACCP?

- **Nature of the hazard**
 - Kill step versus sanitation/pest control
- **Nature of the control**
 - Quality versus food safety
 - Impact of the failure to control a prerequisite program
- **Overlap between Prerequisites and HACCP**
 - Dual purpose of a specific control
 - Conformance to regulatory standards

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Summary

- Criteria for a prerequisite program were discussed
- CGMPs provide requirements that must be addressed in prerequisite programs and/or food safety plan
- Types of prerequisite programs that help conform to CGMPs
- Standard operating procedures (SOPs)
- Sanitary standard operating procedures (SSOPs)

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