Principle 6: Establishing Verification Procedures

Chapter 13 Verification Procedures
HACCP A Systematic Approach to Food Safety

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 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

Validation

Definition of Validation- That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards

Verification and Validation

- Verification
  "Do we do what we say and say what we do?"

- Validation
  "Is it the right thing to do?"

Validation

Initial Validation
- Initial validation is conducted during implementation of the HACCP plan.
  - Includes a review of the hazard analysis
  - HACCP team also reviews CCPs, CLs, and monitoring
- Information needed to validate includes
  - Expert advice
  - Scientific studies
  - In-plant observations
### Validation

**Revalidation**
- Subsequent validation when changes are made to the process that could impact hazard analysis
- Annual reassessment required in seafood (21 CFR 123) and meat and poultry (9 CFR 417) regulations
- As new information becomes available

### Questions to ask during reassessment

- Are there additional hazards that should be addressed in the HACCP plan?
- Have any changes occurred or is there any new information for the hazard analysis?
- Are the CCPs and control measures still appropriate?
- Are the CLs adequate based on current information?
- Are the activities in each section of the plan still adequate and appropriate for identified hazards?

### FSMA Animal Feed Validation

The validation of the preventive controls:
1. Must be performed by a qualified individual:
   - Prior to the implementation of the food safety plan or, when necessary, during the first 6 weeks of production and
   - Whenever a reanalysis of the food safety plan reveals the need to do so.
2. Must include collecting and evaluating scientific and technical information to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur.

### Verification – three items

- Verification of Prerequisite Programs
- Verification of CCPs
  - Calibration
  - Records review
  - Independent check
- Verification of HACCP Plan

### Verification of CCP’s

- Involves the day-to-day compliance of the activities at each CCP to determine if they comply with the HACCP plan
- Verification activities developed by the HACCP team

### Verification of CCPs - Calibration

- HACCP plans rely on accurate measurements (e.g., temperature, pressure, pH, flow-rate, water activity)
- Specify instruments or equipment and their calibration frequency and individual responsible in the plan.
- Goal, accurate measurements
- Records for calibration activities
Verification of CCPs – Records Review

Purpose of record review is to verify that:
- Records were prepared correctly
- Monitoring activity and frequency were performed as required in the HACCP plan
- No monitoring activities were missed
- All monitoring results were within the CLs and any deviation was identified

Verification of CCPs – Corrective Action Records Review

Purpose of corrective action records review
- CA record for each deviation
- Documentation of the deviation (magnitude)
- Affected product was identified and isolated
- CA were conducted according to the HACCP plan
- Final product disposition
- Individuals who performed CA were identified
- All decisions justified
- Report was prepared correctly

Independent Check

Independent checks provide a second level of assurance that the CCP is providing adequate control of the hazard and/or that the hazard is being controlled as intended.

Microbial Testing to Verify CCP’s

- Useful for periodic CCP verification
- Example...
  - verify microbial safety of ingredients

HACCP Plan Verification

Conducted periodically
- Record review
- On-site Audit

HACCP Plan Verification - Records

- Current HACCP plan
- Audit reports of prerequisite programs
- Product/process description, flow diagram
- Monitoring, CCP verification, calibration and CA records
- Previous HACCP audit reports
HACCP Plan Verification
On-site Audit

- Confirm operation at the CCP
- Confirm operator’s knowledge of CCP’s operation, the CLs, and the monitoring and CA record-keeping activities required by the HACCP plan
- Observe the operator perform monitoring
- Examine in-process monitoring records

FSMA Animal Feed Verification

The owner, operator, or agent in charge of the facility must verify that:
1. Monitoring is conducted as required,
2. Appropriate decisions about corrective actions are being made as required,
3. The preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur,
4. The activities conducted must calibration of process monitoring and verification instruments.

FSMA Animal Feed Verification

- Verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazard
- Establish and implement written procedures, as appropriate to the facility and the animal food, for the frequency of calibrating process monitoring and verification instruments
- Conduct a reanalysis for the food safety plan at least one every 3 years, or whenever a significant change is made, or new information is made available about a hazard, or whenever a preventive control is not properly implemented or found to be ineffective, or whenever FDA requires reanalysis.

All verification activities must be documented

Identifying Recordkeeping and Verification

<table>
<thead>
<tr>
<th>Process Step CCP</th>
<th>Hazard Record</th>
<th>Responsibility CCP Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulk Receiving</td>
<td>Short Term</td>
<td>Daily review of receiving log and paperwork by QA/QC department</td>
</tr>
<tr>
<td></td>
<td>Long Term</td>
<td>Operational audit performed by designated management personnel to make sure Receiving Bulk Ingredients SOP is followed</td>
</tr>
</tbody>
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Approved: ______________________ Date: ______________________

END

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