Principle 6: Verification

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Feed Industry HACCP

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

Verification Definition

- Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan
- The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan

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Validation Definition

- 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
- Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards

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Validation Definition

- Verification

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

- Validation

  "Is it this 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
- 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 Rules for Animal Feed

§507.47 – Validation of preventive controls

(1) Must be preformed by a qualified individual:

(i) Prior to the implementation of the food safety plan, or when necessary, within 90 days or later if justified by the QI, and

(ii) Whenever a reanalysis of the food safety plan reveals the need

(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

Reanalysis

Reanalysis

a) Reanalysis every three years (§ 507.50)

b) Reanalysis whenever there is (1) a significant change in activities, (2) new information about potential hazards, (3) an unanticipated animal food safety problem, (4) instance in which preventive control(s) are found to be ineffective

c) Complete reanalysis before changes to food safety plan

d) Revisions should be written and performed by a qualified employee

e) Performed whenever FDA requires reanalysis

Verification Activities

- Verification of prerequisite programs
- Verification of CCPs
  - Calibration
  - Records review
  - Independent check
- Verification of HACCP plan

Verification of CCPs

- Evaluation of 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 is to produce accurate measurements
- Records of calibration activities able to be verified

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 – CA Records Review

- Purpose of CA record review is to verify that:
  - 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 Checks

- 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 for Verification of CCPs

- Useful for periodic CCP verification
- Example – verifying the microbial safety of ingredients

HACCP Plan Verification

- Conducted periodically
- Involves record review and on-site audit

HACCP Plan Verification – Record Review

- 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 Rules for Animal Feed

(a) You must verify that preventive controls are consistently implemented and effective:

(1) Calibration of monitoring and verification instruments

(2) Product testing for pathogen or other hazard,

(3) Environmental monitoring

(4) Review of records

(5) Other activities as appropriate

(b) You must establish and implement written procedures for the following:

(1) Method and frequency of calibrating process

(2) Product testing

(3) Environmental monitoring

Record Keeping and Verification

Processing category – Cattle medicated feed

Process step/CCP	Hazard	Record	Responsibility	CCP Verification
Bulk Receiving	Prohibited animal protein			**Short term** Daily review of receiving log and paperwork by QA/QC department **Long term** Operational audit performed by designated management personnel to make sure Receiving Bulk Ingredients SOP is followed

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