Principle 5: Corrective Actions

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

TEXAS A&M AGRILIFE RESEARCH

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

Corrective Action Definition – NACMF

- Procedures followed when a deviation occurs
  - Deviation is defined as failure to meet a critical limit

FSMA Rules for Animal Feed

§507.42

(a) As appropriate to the nature of the hazard and nature of preventive control …

(1) Establish and implement written corrective action procedures if preventive controls are not properly implemented …

(i) Presence of a pathogen or appropriate indicator organism …

(ii) Presence of an environmental pathogen through monitoring …

(2) Corrective action procedures must describe steps to be taken to ensure that: (i) appropriate action is taken to identify and correct problem, (ii) action taken to reduce likelihood of reoccurrence, (iii) all affected feed is evaluated for safety, (iv) all effected food prevented from entering commerce

FSMA Rules for Animal Feed (cont.)

If preventive controls are not properly implemented and a corrective action procedure has not been established, or if the whole food safety plan is found to be ineffective, or appropriate decisions were not made (b)(1), you must (b)(2):

(i) Take action to identify and correct the problem

(ii) Reduce the likelihood that the problem will recur

(iii) Evaluate all affected animal feed

(iv) Prevent affected feed from entering commerce

(v) Reanalyze the food safety plan

Corrective Actions – Product Recall

Protecting consumers and enhancing agribusiness through its feed and fertilizer regulatory compliance program, surveillance and monitoring of animal-human health and environmental hazards, and Regulatory Science outreach program.

Office of the Texas State Chemist

FDA Recall Notices & Alerts

Date	Product Type	Short Description
Dec 07, 2018	Pet Food	The J.M. Smucker Company Issues Voluntary Recall of Specific Lots of 9Lives® Protein Plus® Wet, Canned Cat Food Due to Low Levels of Thiamine (Vitamin B1) ...more
Dec 05, 2018	Pet Food	Kroger Louisville Division Recalls Abound Chicken and Brown Rice Dog Food Because of Elevated Vitamin D Levels ...more
Dec 05, 2018	Pet Food	King Soopers and City Market Recalls Abound Chicken and Brown Rice Dog Food Because of Elevated Vitamin D Levels ...more
Dec 05, 2018	Pet Food	Columbia River Natural Pet Foods Inc. Recalls Cow Pie Fresh Frozen Meats for Dogs and Cats Because of Possible Listeria monocytogenes Health Risk ...more
Nov 29, 2018	Pet Food	ELM Pet Foods Recall of Dry Dog Food Due to Elevated Levels of Vitamin D ...more

Next Last

What's new

- Fumonisin Risk Management in the Texas High Plains
- November 2018 OTSC Newsletter
- OTSC-TAMU Agrilife Proficiency Testing Program (2019 announcement)
- Regulatory Science in Food Systems Graduate Certificate
- Hazard Analysis and Preventive Controls for Feed Online Training
- One Sample Strategy Website
- Starting a Petfood Business

http://otscweb.tamu.edu/

Corrective Actions for each CCP

"Due to the diversities in possible deviations, corrective actions must be developed for each CCP when they are identified and the CL(s) and monitoring parameters are set."

Options for Corrective Action Implementation

Appropriate corrective actions must be taken whenever a critical limit is violated and include three of the following options:

1) Immediately adjust the process and keep the product in compliance within the set criteria. In this case, the corrective action is immediate, and no product is placed on hold because there has been no deviation.

Options for Corrective Action Implementation

2) Stop the line.

   Hold all product not in compliance and evaluate. Determination of subsequent disposition based on evaluation results.

Options for Corrective Action Implementation

3) If the deviation is the result of a problem in line design or equipment or equipment malfunction, a quick fix may be applied in order to continue running, but a long term solution must be sought.
   - Non-compliant product must be place on hold
   - The re-evaluation process also becomes part of the HACCP program as the system evolves
   - The system may be changed if warranted

Adjusting the Process

- An operator can intercede and can take corrective action through the decision process outlined in the HACCP program
- Some product may not be able to be saved, other product may be salvaged
- A corrective action should be designed into the product line and the HACCP system

Examples of Commonly Adjusted Factors

- Time
- Temperature
- Pressure of steam
- Personnel practices
- Ingredient concentration
- Flow rate
- pH
- Moisture
- Bulk density
- Rework

Elements of Corrective Actions

- Determining and correcting cause of non-compliance
- Determining disposition of non-compliant product
- Record corrective actions that have been taken

NAMCF (1998)

- Determining who is responsible for:
  - Initiating corrective action
  - Maintaining records
  - Oversight

Questions to Ask When Product is Held

1) What tests can be made to verify the safety of the product in question?
2) Does review of the data indicate the safety of the product is in serious question?
3) Can this product be diverted for use in another product where safety is assured?
4) Can the product be reprocessed or reworked to assure food safety?
5) If product cannot be reused, how to discard or destroy?
6) What forms to complete and records to keep?

Corrective Action Record

- All CA must be documented
- Records for deviations and CA should include:
  - Production records, actual or reference to products involved in deviation
  - Standard form
  - Recommendation regarding product disposition
  - Accurate accounting of all product involved
  - Records required by regulatory authority

Corrective Action Standard Form

- Hold number
- Description of deviation
- Quantity of bags or tons held
- Date product was placed on hold
- Production date and code of product held
- Disposition and/or release forms
- Name of the responsible individual

Responsibility for Decision Making

- Responsibility for decision making needs to be clearly delineated early on in the assignment of monitoring responsibilities
- An individual knowledgeable in CCP control must have the authority to make quick decisions on the production floor
- The individual responsible for the action must record on the CCP data sheet what action was taken and by whom

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Identifying Critical Limits, Monitoring and Corrective Actions

Processing category – Cattle medicated feed

Process step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
Bulk Receiving CCP1	Zero tolerance	**What will be measured?** - Cleanout certificate for carrier - Bill of lading from supplier - Letter of guarantee (LOG) - Approved supplier - Presence of prohib. animal protein **Where will the CL be measured?** Bulk receiving area **How will the CL be measured?** Visual observation of documentation and carrier for contamination; Purchase only from approved supplier **Who will monitor the CL?** Receiving employee **How often will the CL be measured?** Every load	**Cause of deviation?** - No cleanout certificate - No LOG - Unapproved supplier - Visual presence of contamination **How will the process be corrected?** Require proper paperwork; Reject if load is contaminated, report to State **Product disposition?** If rejected, return to supplier or handled by regulatory official **Measure to prevent recurrence?** Retaining **Who is responsible for implementing the CA?** Receiving supervisor

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Contact Information:

tjh@otsc.tamu.edu

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