Principle 3: Critical Limits

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

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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

HACCP Principle 3 – Establish Critical Limits

- For each CCP, one or more specific parameters, called critical limits (CLs), must be established to signify whether a CCP is "in" or "out" of control

Critical Limit Definition – NACMF

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

FSMA Rules for Animal Feed

(1)(ii) The maximum or minimum value, or combination of values to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control

Critical Limit Definition – Codex

- A criterion which separates acceptability from unacceptability

Examples of Parameters that may be CLs

- Temperature
- pH
- Moisture level
- Line speed
- Time
- Water activity
- Weight
- Viscosity

CLs and CCPs

- Used to distinguish between safe and unsafe operating conditions at a CCP
- Represents a science-based performance standard

Critical Limits vs. Operational Limits

- Critical limits are **not** operational limits
  - Operational limits are established for a manufacturing process to meet product specifications that may or may not include food safety
  - Critical limits are established for specific CCPs to prevent, eliminate or reduce an identified food safety hazard

Setting CLs

- Must be scientifically based
- May be derived from:
  - Regulatory standards and guidelines (also known as performance standards)
  - Scientific literature
  - Experimental results (validation studies)
  - Experts

Regulatory Considerations

- If an agency has a regulation on a critical control point, you must use the regulation

Performance Standards Examples

- Mandatory guideline for pasteurization times and temperatures for milk (e.g. 161^{o} F for 15 sec.)
- All feed must be labeled in conformance with state and federal regulations

Establishing CLs

For each CCP:

- If there are no regulatory CLs, you may consult outside experts or conduct validation studies
- It is possible to have several criteria for a CL
  - *Steam pressure and residence time in a feed conditioner*
- Document the process of establishing CLs

Identifying Critical Limits, Monitoring and Corrective Actions

Processing category – Cattle medicated feed

Process step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
Write in process step and CCP #	Write in CL for this CCP	What will be measured? Where will the CL be measured? How will the CL be measured? Who will monitor the CL? How often will the CL be measured?	Cause of deviation? How will the process be corrected? Product disposition? Measure to prevent recurrence. Who is responsible for implementing the CA?

Contact Information:

tjh@otsc.tamu.edu

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