

HACCP Validation The FSIS Perspective

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The HACCP Plan

- According to 9 CFR 417.2 (b), “every establishment shall develop and implement a written HACCP plan covering each product produced ... whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur”

Food Safety Hazard

- As stated in 9 CFR 417.2 (a), “A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.”

Hazard Analysis

- Requires supporting documentation that each step of a HACCP plan accounts for all hazards likely to occur.

Validation of the Adequacy of its HACCP plans

- Section 417.4 of the meat and poultry regulations requires “Every establishment shall validate the HACCP plan’s adequacy in controlling the food safety hazards identified during the hazard analysis....”

What This Means

- Validation is the process of demonstrating that the HACCP system, **if operated as designed**, can adequately control identified hazards to produce a safe product.

Verification

- Activities designed to determine that the system **is** operating as designed.
 - ◆ Plant
 - ◆ Agency

Elements of Validation

- The scientific or technical justification or documented basis for the system.
- The initial practical demonstration proving the system will perform as expected.

Scientific or Technical Basis

- The supporting documentation can consist of an article from:
 - ◆ A peer-reviewed scientific journal,
 - ◆ A documented challenge study,
 - ◆ Data underlying published guidelines, or
 - ◆ In-house data.

Scientific or Technical Basis

- The documentation must identify:
 - ◆ The hazard and pathogen, including the level of hazard prevention or pathogen reduction to be achieved,
 - ◆ All associated factors or conditions, identify which processing steps will achieve the specified reduction or prevention, and how these processing steps will be monitored.

Scientific or Technical Basis

- Related to the specific hazard or pathogen
- Identifies specific control parameters

Practical Demonstration

- Early testing in-plant through
 - ◆ Observation
 - ◆ Measurements
 - ◆ Test Results
- Designed to demonstrate that plant can routinely meet scientifically documented parameters
- Records kept

Agency's Verification

- FSIS verifies that the scientific and technical materials exist and provide a scientific and technical basis for the CCPs and Critical Limits.
- Ascertain the status of reference material in scientific community and review it.

Documentation Criteria

- Is the research widely accepted by the relevant professionals?
- Is this the best available scientific data?
- Is it considered dated, but still a reliable approach to control?

Documentation

- ◆ **Supporting Documentation - Study data (plant specific or broad based) - a copy of the article or study not just a reference to the article or study.**
- ◆ **Recorded Documentation (Practical Demonstration) - Records confirming that the parameters or specifications in the study, or article can be routinely met in the plant setting.**

CCP Example

Product

Beef Carcass

Hazard

Salmonella

CCP/ CL

Steam

pasteurization/

6.5 seconds

exposure at

180°F (82.2°C)

Documentation Example

- ◆ Supporting Documentation - **Published scientific articles stating time and temperature of process and the level of pathogen reduction**
- ◆ Recorded Documentation - **Records confirming the steam pasteurization process can be applied per specifications in the article in the plant setting.**

CCP EXAMPLE

- Product
- Hazard
- CCP / CL
- Ground Beef
- Foreign Material (Metal)
- Functioning Metal Detector Calibrated at 2mm.

Documentation Example

- ◆ Supporting Documentation – Documented **Risk Assessments, Journal Articles, Regulatory Compliance Guides**
- ◆ Recorded Documentation - **Records confirming that the equipment as installed can routinely detect material at sizes specified in the articles or guides.**

Reassessment

- According 417.4, every establishment shall reassess the adequacy of the HACCP plan and Hazard Analysis yearly or when changes are made.
- Reassessment includes reviewing scientific validation documentation and adding new information when possible.