

# Validation – In Plant Findings

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# Pathogen Reduction; HACCP Systems; Final Rule

- Validation involves scientifically demonstrating that a HACCP system as designed, is effective in addressing the food safety hazards.

# Pathogen Reduction; HACCP Systems; Final Rule

- Validation includes documentation that CCPs effectively address relevant hazards.
- This includes such microbiological hazards such as *E. coli* O157:H7 and *Listeria*.
- 9 Code of Federal Regulations 417.4 (a)(1)
  - Is the HACCP plan functioning as intended.

# Pathogen Reduction; HACCP Systems; Final Rule

Data assembled to validate a HACCP plan are usually of two types:

1. Theoretical principles, expert advice from processing authorities, scientific data, or other information demonstrating that process control measures can adequately address identified hazards.

# Pathogen Reduction; HACCP Systems; Final Rule

2. In-plant observations, measurements, test results, or other information demonstrating that control measures can be operated in an establishment to achieve the intended food safety objective.

# Food Safety Concerns

FSIS believes it is important that validation data include some practical data or information reflecting an establishment's actual early experience in implementing the HACCP plan.

# Food Safety Concerns

Why is this early practical experience important?

- Validation must demonstrate not only that the HACCP plan is theoretically sound, but also that the establishment can implement it and make it work.
- A firm must determine whether the theoretical program can be delivered in the establishment with its unique source materials, equipment, and in-plant processes.

# Food Safety Concerns

In assessing data from PBIS (an inspection activity database), Food Safety Assessments (FSA), recalls, and food borne illness outbreaks, FSIS has found that in-plant validation may not be consistently implemented by industry or enforced by inspection personnel.

# Food Safety Concerns

- FSIS has several concerns regarding industry's in-plant validation which include:
  - Not addressing and implementing all critical factors from scientific support into in-plant control processes.
  - Need to measure parameters (time, pressure, concentration) of a study to ensure they are being met.
  - If a critical factor is the reduction of a pathogen, measuring the outcome after applying the process may be needed.
  - However, it may not be necessary to measure the pathogen. Surrogates and/or indicators found within the supporting documentation could be utilized.

# Validation Example 1

- Regulatory Findings Example:
  - Scientific support was a study from a University for the use of lactic acid as an antimicrobial.
  - Critical factors within the study include concentration of lactic acid, temperature of lactic acid and product at point of delivery, and pressure at point of application.

# Validation Example 1

Inspection personnel findings:

- Establishment was not measuring pressure at point of application.
- Establishment was applying hot lactic acid on a cold carcass. Critical factor of the study was applying hot acid on a hot carcass.

## Validation Example 2

- Establishments utilizing processes within other establishments to support a hazard (*E. coli* O157:H7) not likely to occur in their operation.
- Regulatory Findings:
  - Establishment purchases intact primals and intends to make non-intact steaks (e.g., needle tenderized). Their suppliers are expected to have an intervention effective against *E. coli* O157:H7.
  - Hazard analysis contained a generic letter from each supplier stating that they use a validated intervention.

## Validation Example 2

- Regulatory Findings:
  - Hazard analysis contained no information for the expectations of the intervention.
    - Establishment needs to know whether the supplier intervention is a CCP or pre-requisite program, where in the process the intervention is applied (e.g., slaughter or processing), and how that intervention relates to the products (primals) they actually purchase.

## Validation Example 3

- Establishments using corporate data to validate plant specific processes.
  - Regulatory Finding:
    - Establishment developed an allergen control process from corporate data.
    - Control measures for the process were:
      - Filtering frying oil using a 20 micron filter.
      - “Dry Flush” for removing residue from breading equipment.

# Validation Example 3

- Regulatory Findings:
  - Based on data provided by corporate, the establishment assumed the control measures within the plants operation would work. However, the establishment had no in-plant data supporting the control measures developed.

# Food Safety Findings

- Increased use of prerequisite programs to support a hazard is not likely to occur.
- Prerequisite programs provide a foundation for the HACCP plan to operate effectively. Consequently, the program becomes a part of the HACCP system and validation activities.

# Food Safety Concerns

- Regulatory Findings:
  - Does the prerequisite program consistently prevent the occurrence of the hazard?
  - It does not if:
    - The establishment is not validating the prerequisite program.
    - The establishment's supporting documents lack on-going, meaningful, verification of the prerequisite program.

# Enforcement Action Example

- NOIE issued due to findings from an FSA.
- Establishment produced raw, pre-browned, stuffed poultry products.
- Establishment used validated cooking instructions as part of its support for a microbiological hazard not likely to occur.
- Scientific support was 165 F in finished product.

# Enforcement Action Example

- The FSA revealed several deficiencies with the establishments' "in-plant" validation process for the cooking instructions.
- The deficiencies included:
  - Validation protocol was very vague in describing the procedures.
  - Not all critical factors addressed within the validation protocol, e.g., location of oven temperature measurement, variation in product weights, hold time after cooking.

# Enforcement Action Example

- Protocol stated that each test would be repeated three times, but this was not done during the actual validation.
- Cooking instructions required an oven temperature of 375 F. for 35 minutes to reach an internal temperature of 165 F. Validation data could not support this decision.

# Summary

- Validation inconsistently implemented by industry, and enforced by FSIS.
- Agency has concluded this in reviews of PBIS data, FSAs, and recalls.
- To address this, the Agency is seeking public comment prior to publishing a Guidance Document.