



# HACCP Systems Validation

**NACMPI**

September 22-23, 2011  
Washington, DC

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# Objectives

- **Review HACCP Final Rule**
  - 9 CFR 417.4
  - Agency's understanding
- **Validation in 2 parts**
- **Validation Food Safety Concerns**
- **Guidance Document Overview**
- **NACMPI Committee Questions**



# HACCP Final Rule

- Published on July 25, 1996 Docket No. 93-016F
- Validation regulatory language:
  - 9 CFR 417.4 Validation, Verification, Reassessment
- Also included the Agency's understanding of how the regulatory language should be implemented
- Both pieces of information guide FSIS' implementation policies



# Validation

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

FSIS believes it is important that validation include some practical data or information reflecting an establishment's actual early experience in implementing a HACCP system within their unique processing environment.



# Agency Understanding

- **Validation includes the HACCP system**
  - Increased use of prerequisite programs to support hazard not reasonably likely to occur
  - Prerequisite programs are foundation for HACCP plan to operate effectively
- **Validation has 2 parts:**
  - 1) **Scientific or technical support for the HACCP system**
  - 2) **Initial practical in-plant demonstration proving the HACCP system can perform as expected**



# 1) Scientific Support

- Theoretical principles
- Expert advice from processing authorities
- Scientific data
- Peer reviewed journal articles
- Pathogen modeling programs
- Agency Issuances
- Other information demonstrating that particular process control measures can adequately address specific hazards



## 2) Initial In-Plant

- In-plant observations
- Measurements
- Microbiological test results
- Or other information demonstrating the control measures, as written into the HACCP system, can be implemented within a particular establishment to achieve the intended food safety objective



# Food Safety Concerns

- In assessing data from PBIS, FSAs, 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.
- Issues include:
  - Identifying critical operating parameters in supporting documents
  - Translating critical operating parameters into HACCP systems
  - Gather data demonstrating validation under actual in-plant conditions



# Example 1

- Context:
  - Scientific support was study from University for the use of lactic acid as an antimicrobial
  - Critical operating parameters included concentration, temperature of lactic acid and product at point of delivery, and pressure at point of application
- Findings:
  - Establishment not measuring pressure at point of application
  - Establishment was applying hot lactic acid to cold carcasses while study documented hot acid on a hot carcass



## Example 2

- Context:
  - Establishment utilizing processes from other establishment to support hazard (*E. coli* O157:H7) not reasonably likely to occur
  - Establishment purchases intact primals to needle tenderize
  - Suppliers were expected to have an intervention for *E. coli* O157:H7 and hazard analysis contained generic letter from each potential supplier
- Findings:
  - Hazard analysis had no expectations of intervention or description
  - Didn't specify what type of intervention (CCP or prerequisite), where located in food safety system (slaughter or fabrication), or how the intervention and letter related to actual products purchased



## Example 3

- **Context:**
  - Establishment developed an allergen control program from corporate data
  - Controls were to filter frying oil using a 20 micron filter and “dry flush” for removing residue from breading equipment
- **Findings:**
  - Based on data from corporate, establishment assumed control measures within plant operation would work without assessing corporate parameters in study compared to their parameters
  - Establishment did not gather data during initial experience to determine if control measures were met in their processing environment



## Example 4

- **Context:**
  - Establishment produced raw, pre-browned stuffed poultry products
  - Establishment used validated cooking instructions to support hazard not likely to occur (165F intern finished product)
- **Findings:**
  - Validation protocol was vague and did not address critical factors such as location of oven temperature measurement, variation in product weights, hold time after cooking
  - Protocol stated 3 replicates but not all three were performed
  - Cooking instructions required oven temp. of 375F for 35 minutes to reach 165F internal but data could not support parameters



# Compliance Guide Development

- Guidance intended to provide:
  - Validation concepts
  - Framework to follow when validating different types processes
  - Examples showing differences in expectations between slaughter, further NRTE processing, and RTE
- Timeline of Development



# Compliance Guide Overview

- Background and Definitions
- 2 elements of Validation
- Critical Operating Parameters Identification
- Types of Processes and Products
- Records
- HACCP Initial Validation Self-Assessment Worksheet
- Appendices
  - Identifying Critical Operating Parameters from Supporting Documentation
  - Document guidance for existing establishments
  - Validation worksheet examples



# NACMPI Input

- Agency is requesting feedback on particular points where consensus has been difficult
- Agency is requesting innovative ideas on how to convey this information to stakeholders
- 3 questions provided to initiate conversation



# Question 1

What innovative strategies can the Agency utilize to help establishment personnel identify critical operating parameters and then determine where in the HACCP system it is appropriate to ensure implementation?



## Question 2

The Agency realizes that often establishments produce a wide variety of products within one HACCP category and it may be impractical and unnecessary to gather in-plant data as part of initial validation for all products. The Agency on p. 14 of the guidance has described a set of principles when making those decisions with some examples. Does the committee have additional suggestions as to how the Agency can better describe this important concept?



## Question 3

What innovative strategies can the Agency use to help industry and FSIS inspection personnel better understand the concepts of HACCP systems validation to improve food safety?



# Questions?