

Validation

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Validation History

- In 2009, nine associations sent letter to FSIS
 - Micro testing focused
 - Use of prerequisite programs as part of HACCP program
 - Clarification of In-Plant Validation Requirements
- Since 2009;
 - NACMPI review
 - Two draft compliance guides (2012, 2013)
 - Final compliance guide issued April 2015

Validation History

- Validation work group formed with 14 members companies
- Output were comments that are included in 2015 Compliance Guide Appendix 4: Validation Worksheet Examples
- Since 2009 much discussion about validation- what it is and how it is completed

Demonstrating Compliance

- Not a change in regulatory requirement
- January and April deadlines focused on 2nd part of validation (execution), but 1st part also to be verified
 - Agency recognized expectation to maintain initial validation not well communicated
 - Compliance guide issued to explain how to comply, including the need to re-establish initial validation if not maintained

Demonstrating Compliance

- 1st part – Theoretical basis (design)
 - Scientific, technical or other basis for the plan(s)
- 2nd part – In-plant data (execution)
 - Does the theory work in your operation?
- Demonstrating compliance with both parts can look very different, plant to plant

Different Approaches

- Using a *safe harbor* as means of support
 - Appendix A & B for lethality and stabilization
 - Tompkin article for pathogen growth temperatures
- 1st part of validation covered by recognized science
- 2nd part of validation – demonstration that the process can routinely meet established limits
 - No question the science will work if implemented

Different Approaches

- Using a single Peer-reviewed Journal Article that specifies the expected level of pathogen reduction, and able to follow all *critical parameters*
 - If science is current, this approach works similarly to *safe harbor*
 - Must separate critical parameters from extraneous info
- 1st part of validation covered by current, peer reviewed science
- 2nd part of validation – demonstration that the process can routinely meet all *critical parameters*

Critical Operational Parameters

- Defined by FSIS as – *the specific conditions that the intervention must operate under in order for it to be effective.*
 - Not always easy to identify what parameters in a study are *critical* to be effective
 - Anecdotally, EIAOs often see every parameter in a study as *critical*
 - Need to be prepared to show otherwise e.g., humidity part of appendix A if product encased

Different Approaches

- Using multiple peer-reviewed articles or a combination of other scientific and technical support (often referred to as *cherry picking*)
 - Outcome can be reasonably presumed, but has not been proven (how much reduction can be expected?)
 - Will require additional support to demonstrate compliance with both parts of validation, such as;
 - Process authority assistance (limitations)
 - Pathogen modeling
 - Inoculation study
 - Other in-plant (typically micro) data
 - Limitation of surrogate organisms – what is the relationship to the pathogen?

Validation, Beyond the CCP

- Initial validation includes all of the operational functions of the HACCP system:
 - Prerequisite programs (used as support in hazard analysis)
 - Monitoring and verification procedures and frequencies (typically done more frequently than described in the HACCP plan during initial validation)

Demonstrating Compliance

- Should have the initial validation work completed by the January/April, 2016, deadline
- If you still have the original (from last appropriate time) validation data, ask;
 - Has the process changed since the last initial validation data was collected?
 - Are the products used in the initial validation of each process representative of the others?
 - At least one product from each process must be validated
 - The chosen product must represent the rest, does it? Worst case scenario?

Proactive Assessment

- HACCP Initial Validation Self-Assessment (page 34 of the compliance guide)
 - Provides a quick checklist to measure your system
 - If unsure of the answer, seek guidance!
- Appendix 4 of the compliance guide, provides examples of *validation worksheets*
 - Not required to use same format
 - Provides summary of the fact initial validation has been conducted, and provides foundation of support
 - Be sure to keep all of the supporting records!!
 - Additional monitoring and verification activities conducted during initial validation
 - Micro data collected for the purpose of initial validation (if any)

Use the Meat Institute

- Call upon the Meat Institute for guidance!
 - Regulatory Services Staff (510)763-1533
 - DC Office Staff (202)587-4200
- Thank you for attending the Meat Institute Outlook Conference!