



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:

Initial Validation Requirements:
Understanding the FSIS Compliance
Guideline for HACCP Systems Validation

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Food Safety Inspection Service (FSIS), USDA

Grocery Manufacturers Association Webinar
December 9, 2015

Food Safety and Inspection Service: Presentation Outline

- History of Initial Validation Requirements/Need for an Industry Compliance Guideline
- Compliance Guideline Development/Implementation
- Element 1: Scientific Support (Design)
- Element 2: Initial In-plant Validation Data (Execution)
- Timeframe for an establishment to complete initial validation
- Initial Validation vs. Ongoing Verification
- Next Steps/Key Points

Food Safety and Inspection Service: What is HACCP Systems Initial Validation?

- Initial validation is the process of demonstrating that the HACCP system as designed can adequately control potential hazards.
- Under 9 CFR 417.4(a)(1) establishments are required to assemble two types of supporting documentation to demonstrate the HACCP system has been validated:
 - Scientific or technical support (design) and
 - Initial in-plant validation data (execution)
- Initial validation encompasses activities designed to determine whether the entire HACCP system is functioning as intended.

Food Safety and Inspection Service: Need for Guidance

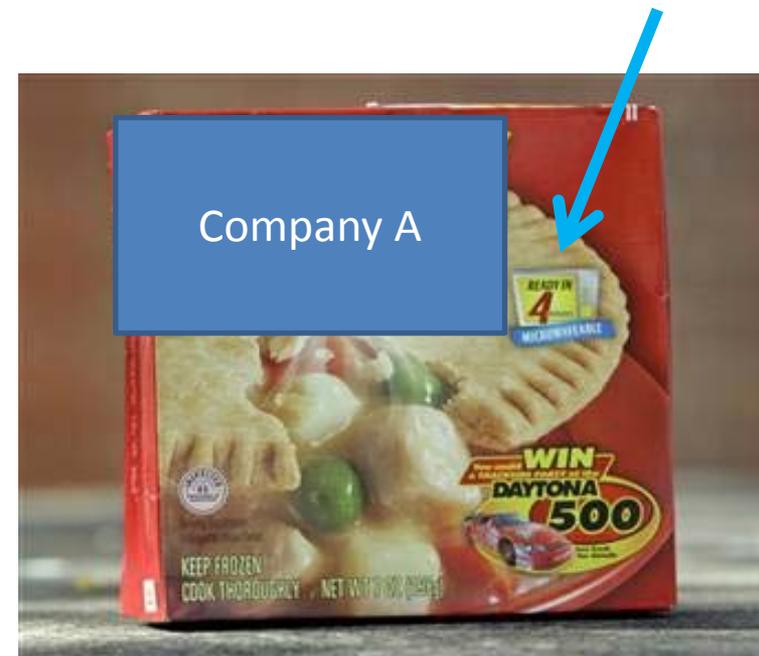
- Although the HACCP regulations were implemented over 15 years ago, FSIS has found through Food Safety Assessments (FSAs) and other verification activities that establishments have not complied with the initial validation requirement.
- In particular, establishments have not collected the necessary initial in-plant validation data demonstrating that the HACCP system is functioning as intended.

Food Safety and Inspection Service: Need for Guidance

- Inadequate initial validation has been linked to food safety problems:
 - Chicken pot pie *Salmonella* illness outbreak in 2007 and 2011 Turkey Burger *Salmonella* Illness outbreak;
 - 2011 Lebanon bologna *E. coli* O157:H7 illness outbreak; and
 - Veal *E. coli* O157:H7 and adulterant non-O157 STEC positives from FSIS testing in 2012.
- Therefore, FSIS determined that additional initial validation guidance for HACCP systems is needed.

Food Safety and Inspection Service: Need for Guidance – Chicken Pot Pie Outbreak

- In October 2007, frozen pot pies were linked to an outbreak of salmonellosis.
- The investigation revealed likely cause of illnesses was consumers not cooking the products in the microwave adequately.
- The primary conclusion of the investigation was that the cooking instructions on not ready-to-eat products must be validated when consumer cooking is used to support decisions in the hazard analysis.



[FSIS Recall Release
RC-044-2007](#)

Food Safety and Inspection Service: Compliance Guideline Development

- March, 2010 - Initial draft guidance posted
- June, 2010 – FSIS held a public meeting on the initial draft where it received input from stakeholders
- FSIS received over 2,000 comments on the initial guidance
- September 22-23, 2011 – FSIS shared another draft of the guidance with the National Advisory Committee on Meat and Poultry Inspection (NACMPI)
- May, 2012 – Revised guidance posted
- FSIS received 51 comments on the revised draft

Food Safety and Inspection Service: Compliance Guideline Development

- Fourth draft of the guidance was posted on May 29, 2013 for comment.
- June 25, 2013 FSIS held another public meeting where it received input from stakeholders
- FSIS received 21 public comments on the fourth draft.
- FSIS responded to the comments and published the final guidance:
http://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES.
- The final version was announced in the Federal Register on May 14, 2015:
<http://www.fsis.usda.gov/wps/wcm/connect/3ba826ec-6e79-4f17-85fc-29200f4e8d05/2009-0019-2015.pdf?MOD=AJPERES>.

Food Safety and Inspection Service: Compliance Guideline Development/Implementation

- The Federal Register Notice announced that establishments will have until January 4, 2016 (large) or April 4, 2016 (small and very small) to gather any data they may no longer have.
- At that time, FSIS will issue necessary instructions to field personnel for them to verify that establishments meet all validation requirements.
- Inspection Program Personnel (IPP) are continuing to follow the instruction in [FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification \(HAV\) Task*](#) and are instructed not to cite the lack of in-plant validation data as the only reason for the documentation of noncompliance.

Food Safety and Inspection Service

What are the 3 biggest differences between validation when we first announced it to industry and final guidance?

- Limits recommendation to gather in-plant microbiological data to cases when an establishment does not have sufficient scientific support or can not implement the scientific support consistent with its actual process (Initial guidance indicated microbiological data gathered in-plant would be valuable in all cases)
- Addresses when and how prerequisite programs need to be validated (limits to those prerequisite programs identified as supporting a decision in the hazard analysis)
- Goes into more depth on types of scientific support available including FSIS guidelines

Food Safety and Inspection Service: Is In-plant Microbiological Data Required?

- FSIS encourages establishments to collect microbiological data as part of initial in-plant validation data but does not require that they do so to comply with the initial validation requirements provided the establishment:
 - Has adequate scientific supporting documentation (the first element of initial validation),
 - Is following the same parameters in the scientific support, and
 - Can demonstrate that it can meet the critical parameters during operation (the second element of initial validation).

Food Safety and Inspection Service: What Must be Validated?

- Validation is the process of demonstrating that the HACCP system, as designed, can adequately control identified hazards to produce a safe, unadulterated product.
- The HACCP system is defined as the HACCP plan in operation, including the HACCP plan itself.
- The HACCP plan in operation includes the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

Food Safety and Inspection Service:

Do Prerequisite Programs Have to be Validated?

- The answer depends on whether the prerequisite program is considered part of the HACCP system.
- Prerequisite programs designed to support a decision in the hazard analysis are part of the HACCP system.
- When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and must be validated.

Food Safety and Inspection Service: Prerequisite Program Types

Prerequisite programs that may be used to support decisions in the hazard analysis and, if used as support, must be validated include:

- Sanitation SOPs
- Purchase specifications
- Antimicrobial interventions
- Sanitary dressing programs
- Allergen control programs

Prerequisite programs that are unlikely to be used to support decisions in the hazard analysis, and therefore, do not have to be validated include:

- Maintenance programs
- Facilities and grounds programs
- Pest control programs
- Written recall plans
- Traceability programs

Food Safety and Inspection Service: Prerequisite Program Example

Fresh Pork Hazard Analysis

Step	Potential Hazard	RLTO?	Basis/ Justification
Raw meat storage	Biological: Pathogen growth	No	Adherence to a temperature control program (storage temperature $\leq 45^{\circ}\text{F}$ and time product is in storage ≤ 5 days) prevents pathogen growth (Tompkin paper).

Since adherence to the temperature and time parameters in the program is used as justification that pathogen growth is not reasonably likely to occur the temperature control program must be validated.

Food Safety and Inspection Service: Prerequisite Program Example

Bruce Tompkin Ph.D.
Armour Swift-Eckrich

Table 1. Minimum growth temperatures for selected foodborne pathogens.

	Minimum Growth Temperatures	
Salmonellae ¹	7C	44.6F
Pathogenic <i>E. coli</i>	7-8C	44.6-46.4F
<i>L. monocytogenes</i>	-0.4C	31.3F
<i>Y. enterocolitica</i>	-1.3C	29.7F
<i>Campylobacter jejuni</i>	32C	89.6F
<i>Staphylococcus aureus</i>	7C	44.6F
<i>Bacillus cereus</i> ²		
psychrotrophic strains	4C	39.2F
<i>Clostridium perfringens</i>	12C	53.6F

Food Safety and Inspection Service: Two Elements of Initial Validation

Element 1: Scientific or Technical Support (Design)

- The theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards.

Element 2: Initial in-plant Validation Data (Execution)

- The in-plant observations, measurements, microbiological test results, or other information demonstrating the control measures in the HACCP system can perform as expected within a particular establishment to achieve the intended food safety objective.

Food Safety and Inspection Service: Two Elements of Initial Validation

Element 1: Scientific or Technical Support (Design)

- Gather scientific support (e.g., published processing guidelines, journal articles, challenge studies, etc.) that:
 - Closely matches the actual process, and
 - Shows that the establishment's process prevents, reduces, or eliminates the hazard identified in the hazard analysis; and
- Identify the critical operational parameters from the scientific support relevant to the establishment's process.

Element 2: Initial in-plant Validation Data (Execution)

- Implements critical operational parameters in the actual production process consistent with the parameters in the scientific or technical support;
- Identifies at least one product from each HACCP category to gather in-plant validation data;
- Collects in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least one product from each HACCP category; and
- Analyzes the data to determine whether the critical operational parameters are being implemented effectively.

Food Safety and Inspection Service: Critical Operational Parameters

- Critical operational parameters are the specific conditions that the intervention must operate under in order for it to be effective.



- Examples of critical operational parameters include:
 - Time
 - Temperature
 - Concentration
 - Humidity
 - Dwell Time
 - pH
 - Contact Time
 - Product Coverage
 - Pressure
 - Point of application

Food Safety and Inspection Service:

How Does the Establishment Meet Element 1: Scientific Support?

- To meet the first element of initial validation, establishments should:
 - Gather scientific or technical support (e.g., published processing guidelines, journal articles, challenge studies, etc.) for its HACCP system that:
 - Closely matches the actual process; and
 - Shows that the establishment's process will prevent, reduce, or eliminate the hazard identified in the hazard analysis; and
 - Identify the critical operational parameters from the scientific support relevant to the establishment's process.

Food Safety and Inspection Service:

What are the Types of Scientific or Technical Support an Establishment May Use?

- Published Processing Guidelines including FSIS Guidelines

FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments

2014 Compliance Guideline

This guidance document is designed to help very small meat and poultry establishments that manufacture jerky identify:

- The key steps in the jerky process needed to ensure safety; and
- The scientific support available to help develop a safe process and product.



Food Safety and Inspection Service:

What are the Types of Scientific or Technical Support an Establishment May Use?

- Best Practice Guidelines

Best Practices for Beef Slaughter

Developed By:

National Meat Association
Southwest Meat Association
American Meat Institute
National Cattlemen's Beef Association

Facilitated By:

Kerri B. Harris and Jeff W. Savell
Department of Animal Science
Texas A&M University

Food Safety and Inspection Service: What are the Types of Scientific or Technical Support an Establishment May Use?

- Peer-reviewed Scientific Data/Information

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Postpackage Pasteurization of Ready-to-Eat Deli Meats by Submersion Heating for Reduction of *Listeria monocytogenes*¹

P. M. MURIANA,^{1,2*} W. QUMBY,^{1,2} C. A. DAVIDSON,² AND J. GROOMS¹

¹Department of Animal Science and ²The Food and Agricultural Products Research and Technology Center, Oklahoma State University, Stillwater, Oklahoma 74075, USA

MS 01-291; Received 21 August 2001/Accepted 15 January 2002

ABSTRACT

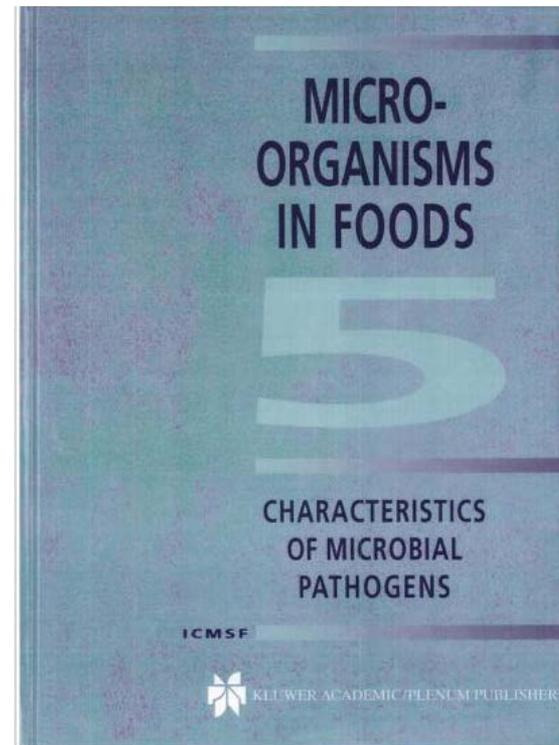
A mixed cocktail of four strains of *Listeria monocytogenes* was resuspended in product purge and added to a variety of ready-to-eat (RTE) meat products, including turkey, ham, and roast beef. All products were vacuum sealed in shrink-wrap packaging bags, massaged to ensure inoculum distribution, and processed by submersion heating in a precision-controlled steam injected water bath. Products were run in pairs at various time-temperature combinations in either duplicate or triplicate replications. On various *L. monocytogenes* inoculated RTE deli meats, we were able to achieve 2 to 4 log cycle reductions when processed at 195°F (90.6°C), 209°F (93.3°C), or 207°F (96.1°C) when heated from 2 to 10 min. High-level inoculation with *L. monocytogenes* ~10⁷ CFU/ml covered that cells infiltrated the least processed surface areas, such as surface cuts, folds, grooves, and skin. *D*- and *z*-value determinations were made for the *Listeria* cocktail resuspended in product purge of each of the three meat categories. However, reduction of *L. monocytogenes* in product challenge studies showed much less reduction than was observed during the decimal reduction assays and was attributed to a combination of surface phenomena, including surface imperfections, that may shield bacteria from the heat and the migration of chilled purge to the product surface. The current data indicate that minimal heating regimens of 2 min at 195 to 207°F can readily provide 2-log reductions in most RTE deli meats we processed and suggest that this process may be an effective microbial intervention against *L. monocytogenes* on RTE deli-style meats.

Listeria monocytogenes is a significant foodborne pathogen that is readily present on raw meat products used in the manufacture of processed meat (3). *L. monocytogenes* has several characteristics that make it a formidable pathogen and contaminant in food processing environments: relatively high heat and salt tolerance, ability to grow at refrigeration temperatures, and ability to form biofilms on all kinds of surfaces. Past and recent outbreaks associated with ready-to-eat (RTE) foods have shown it to be most problematic with processed meat products, presumably due to cross-contamination during packaging. Its persistence in food processing environments, the reduction of competing microflora on processed meats, and the potential for temperature abuse of these refrigerated RTE products contribute to problems experienced with *L. monocytogenes* on RTE meat products (9).

Outbreaks associated with *L. monocytogenes* have prompted governmental regulatory agencies to impose stricter regulations, especially in RTE foods. The U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration have maintained a longstanding zero tolerance for *L. monocytogenes* (and *Salmonella*) in RTE foods. More recently, the USDA Food Safety and Inspection Service (FSIS) implemented the Pathogen Reduction Act/hazard analysis and critical control point (HACCP)

plan to reduce meat- and poultry-related outbreaks due to *L. monocytogenes*, *Escherichia coli* O157:H7, *Campylobacter*, and *Salmonella* (2). Although RTE meat products are fully cooked, either in casings or cook-in bags, they are often reexposed to the processing environment to be packaged in a final retail packaging wrap. The reexposure of product to the processing environment after cooking could lead to possible contamination by bacteria that may be present on conveyors, on metal surfaces, in condensation drip-pans, in contaminated air filters, in splashed standing water, or on the workers themselves. With recent outbreaks of listeriosis attributed to RTE deli meat products, the USDA-FSIS has introduced additional directives and notices in regard to *Listeria* testing and verification of HACCP plans (5, 4).

Current efforts in food safety of meat and meat products have included both the reduction of microbes on raw meat at slaughter (carcass pasteurization, vacuum steaming, and acid or hot water rinse, etc.) and processes aimed at reduction of potential pathogens that may be acquired as incidental contamination on fully cooked products (e.g., acidulants, antimicrobials, irradiation, heat treatments). RTE products are most often consumed without further cooking, and therefore, the presence of pathogens presents a considerable food safety threat. This concern has prompted interest in applying postpackage or postprocess heat treatments



Food Safety and Inspection Service:

What are the Types of Scientific or Technical Support an Establishment May Use?

- Challenge or Inoculated Pack Study

Validation Study of Beef Snack Sticks on the Microbial Load Reduction of Major Foodborne Pathogens: *Listeria monocytogenes*, *Escherichia coli* O157:H7, and *Salmonella*

XYZ Laboratory|

December 12, 2013

Food Safety and Inspection Service:

What are the Types of Scientific or Technical Support an Establishment May Use?

- Pathogen Modeling Program

W CENTER FOR MEAT PROCESS VALIDATION HOME *Extension*

Shelf Stability Predictor

Developed by the Center for Meat Process Validation at the University of Wisconsin - Madison

About

Our **Shelf Stability Predictor** provides a set of models for predicting the growth of *Listeria monocytogenes* (LM) and *Staphylococcus aureus* (SA) on Ready-To-Eat meat products as a function of pH and water activity. Use these tools to help you decide if your product is **shelf stable**.



A **shelf stable product**:

- Will not support the growth of *L. monocytogenes* (LM) and,
- Will not support the growth of *Staphylococcus aureus* (Staph).
- A shelf-stable product may be packaged under vacuum, a modified atmosphere (MAP), or may be packaged under air.

Shelf Stability Predictor

Instructions

 1. Enter the **pH** and **water activity** of your product in the spaces indicated.¹
2. Select **Calculate**.

The predictor will indicate the probability of *L. monocytogenes* and *S. aureus* growth on this product, on a scale of 0 = growth very unlikely to 1 = growth very likely.

A value of 0.20 or lower is a clear indicator that *L. monocytogenes* and *S. aureus* will not grow, while a value of 0.80 or higher indicates that *L. monocytogenes* and *S. aureus* are likely to grow.²

Listeria growth predictor	Staph growth predictor
Enter data: <input type="text"/> pH (4.5 - 6.5) <input type="text"/> Water Activity (0.47 - 0.98) <input type="button" value="Calculate"/> Probability of Growth: <input type="text"/>	Enter data: <input type="text" value="5.2"/> pH (4.4 - 6.6) <input type="text" value="0.89"/> Water Activity (0.68 - 0.98) <input type="button" value="Calculate"/> Probability of Growth: 0.02

Food Safety and Inspection Service:

What are the Types of Scientific or Technical Support an Establishment May Use?

- Regulatory Performance Standards

§ 318.23 Heat-processing and stabilization requirements for uncured meat patties.

(a) **Definitions.** For purposes of this section, the following definitions shall apply:

(1) **Patty.** A shaped and formed, comminuted, flattened cake of meat food product.

(2) **Comminuted.** A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.

(3) **Partially-cooked patties.** Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(4) **Char-marked patties.** Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(b) **Heat-processing procedures for fully-cooked patties.**

(1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

Permitted Heat-Processing Temperature/Time Combinations for Fully-Cooked Patties

Minimum internal temperature at the center of each patty(Degrees)		Minimum holding time after required internal temperature is reached(Time)	
Fahrenheit	Or centigrade	Minutes	Or seconds
151	66.1	.68	41
152	66.7	.54	32
153	67.2	.43	26
154	67.8	.34	20
155	68.3	.27	16
156	68.9	.22	13
157 (and up)	69.4 (and up)	.17	10

(2) The official establishment shall measure the holding time and temperature of at least one fully-cooked patty from each production line each hour of production to assure control of the heat process. The temperature measuring device shall be accurate within 1 degree F.

(3) Requirements for handling heating deviations. (i) If for any reason a heating deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized FSIS program employee, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence.

Food Safety and Inspection Service:

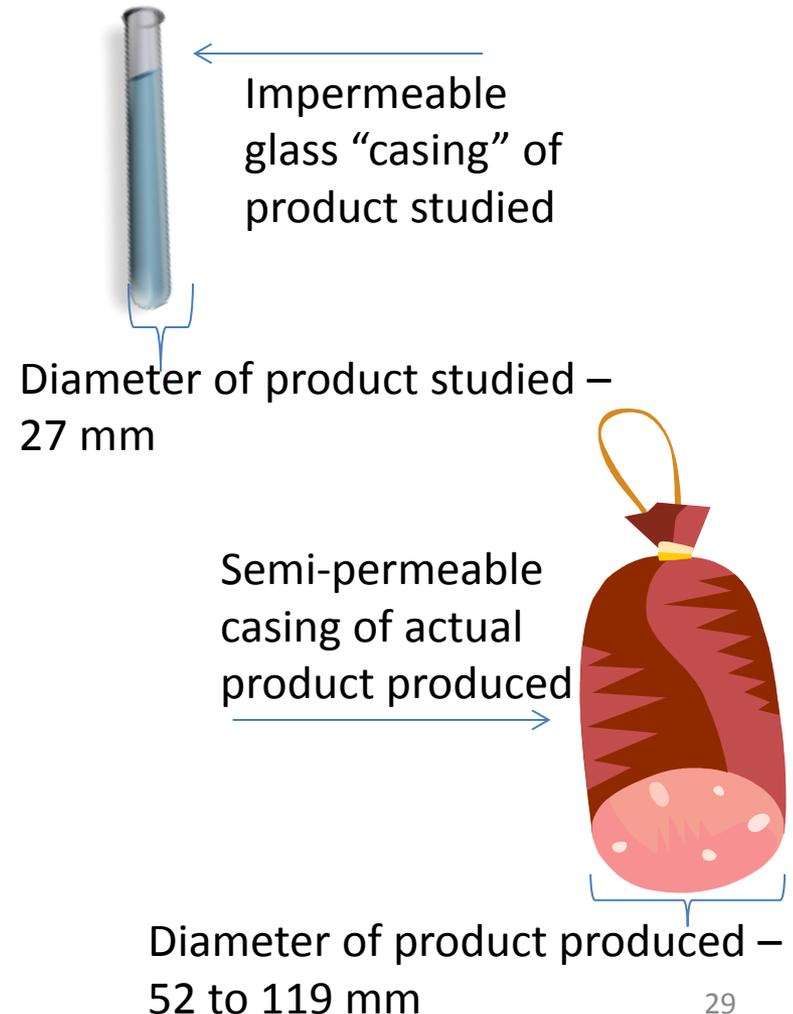
What is Considered Adequate Scientific or Technical Support?

- In all cases, the scientific support should identify:
 - The hazard (biological, physical, and chemical),
 - The expected level of hazard reduction or prevention to be achieved,
 - All critical operational parameters or conditions necessary,
 - The processing steps that will achieve the specified reduction or prevention, and
 - How these processing steps can be monitored.
- The establishment should evaluate the scientific support to determine whether it sufficiently relates to the process, product, and hazard identified in the hazard analysis.

Food Safety and Inspection Service:

Why is it Important the Scientific Support Matches the Actual Process?

- In March 2011, there was a recall of a Lebanon bologna product that was associated with a foodborne illness outbreak of *E. coli* O157:H7.
- An FSIS investigation revealed that the establishment had not properly validated their process.
- In particular, there were difference in the diameter and type of casing material between the product studied and the actual product that likely led to a lower reduction in foodborne pathogens of concern than what was demonstrated in the scientific support.



Food Safety and Inspection Service:

What are Some Examples of Inadequate Scientific or Technical Support?

- Scientific support for a product other than meat and poultry without additional scientific or technical support.
- Documentation in the form of a No Objection Letter or *FSIS Directive 7120.1* without additional scientific or technical support.
- Expert opinion from a processing authority stating the safety of a product without any reference to established scientific principles or peer-reviewed data.

Food Safety and Inspection Service: Examples

Bruce Tompkin Ph.D.
Armour Swift-Eckrich

Table 1. Minimum growth temperatures for selected foodborne pathogens.

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Salmonellae ¹	7C	44.6F
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psychrotrophic strains	4C	39.2F
<i>Clostridium perfringens</i>	12C	53.6F

Hazard

Level of prevention

Critical Operational Parameters

Food Safety and Inspection Service: Examples

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Postpackage Pasteurization of Ready-to-Eat Deli Meats by Submersion Heating for Reduction of *Listeria monocytogenes*[†]

P. M. MURIANA,^{1,2*} W. QUIMBY,^{1,2} C. A. DAVIDSON,² AND J. GROOMS¹

¹Department of Animal Science and ²The Food and Agricultural Products Research and Technology Center, Oklahoma State University, Stillwater, Oklahoma 74078, USA

Hazard

MS 01-291: Received 21 August 2001/Accepted 15 January 2002

ABSTRACT

A mixed cocktail of four strains of *Listeria monocytogenes* was resuspended in product purge and added to a variety of ready-to-eat (RTE) meat products, including turkey, ham, and roast beef. All products were vacuum sealed in shrink-wrap packaging bags, massaged to ensure inoculum distribution, and processed by submersion heating in a precision-controlled steam-injected water bath. Products were run in pairs at various time-temperature combinations in either duplicate or triplicate replications. On various *L. monocytogenes*-inoculated RTE deli meats, we were able to achieve 2- to 4-log cycle reductions when processed at 195°F (90.6°C), 200°F (93.3°C), or 205°F (96.1°C) when heated from 2 to 10 min. High-level inoculation with *L. monocytogenes* (~10⁷ CFU/ml) ensured that cells infiltrated the least processed surface areas, such as surface cuts, folds, grooves, and skin. *D*- and *z*-value determinations were made for the *Listeria* cocktail resuspended in product purge of each of the three meat categories. However, reduction of *L. monocytogenes* in product challenge studies showed much less reduction than was observed during the decimal reduction assays and was attributed to a combination of surface phenomena, including surface imperfections, that may shield bacteria from the heat and the migration of chilled purge to the product surface. The current data indicate that minimal heating regimens of 2 min at 195 to 205°F can readily provide 2-log reductions in most RTE deli meats we processed and suggest that this process may be an effective microbial intervention against *L. monocytogenes* on RTE deli-style meats.

Process
step

Log
reduction

Critical Operational Parameters (time, temperature, product type)

Food Safety and Inspection Service: Examples

Table 3. Antimicrobial effectiveness of several food-safe compounds used to eliminate meatborne pathogens from experimentally inoculated beef surfaces.

Antimicrobial rinses (continued)	<i>Escherichia coli</i> O157:H7			<i>Salmonella</i> Typhimurium			<i>Campylobacter</i> spp.		
	Before treatment	After treatment	Log reduction	Before treatment	After treatment	Log reduction	Before treatment	After treatment	Log reduction
Peroxyacetic acid 200 ppm	4.40	3.96	0.44	5.18	4.15	1.03	6.09	2.83	3.26
Peroxyacetic acid 1,000 ppm	4.48	0.70	3.78	5.86	1.11	4.75	5.28	1.17	4.11
Citric acid 1%	5.18	1.91	3.27	5.62	2.50	3.12	4.13	0.74	3.39
Citric acid 2%	5.24	1.64	3.60	6.78	2.93	3.85	5.28	0.70	4.69
Citric acid 5%	6.40	2.68	3.72	6.37	1.82	4.55	4.95	0.90	4.05
Acetic acid 1%	3.52	1.36	2.16	5.61	3.06	2.55	5.28	0.70	4.58
Acetic acid 2%	5.60	0.37	5.23	5.40	2.02	3.38	5.57	0.47	5.10
Acetic acid 5%	5.18	2.76	2.42	5.71	0.95	4.76	4.55	0.47	4.08
Lactic acid 1%	5.59	2.69	2.90	5.65	2.08	3.57	5.35	1.44	3.91
Lactic acid 2%	4.03	0.48	3.55	5.48	0.70	4.78	7.15	2.14	5.01
Lactic acid 5%	5.82	0.50	5.32	5.81	0.93	4.88	5.52	0.55	4.97
Purified water	5.48	4.25	1.23	5.89	4.56	1.33	5.01	3.62	1.38

Hazard

Log
reduction

Antimicrobial type and concentration. Other critical operational parameters not shown (distance of spray to carcass surface, carcass coverage, application method and pressure, contact time, temperature.)

Food Safety and Inspection Service:

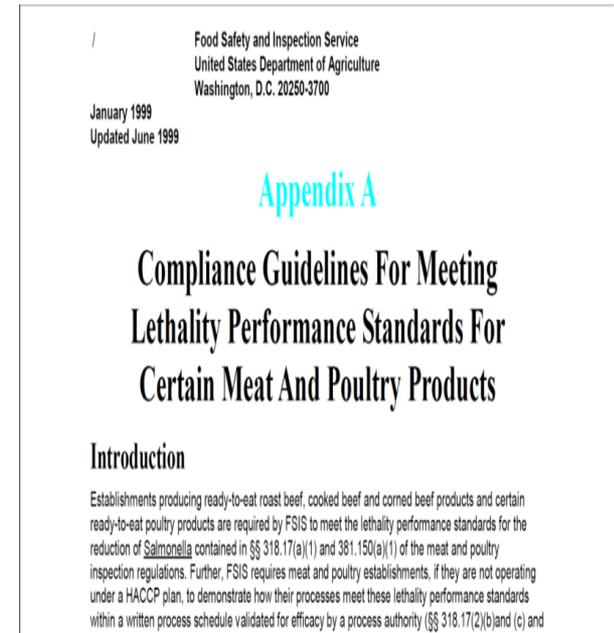
Do the Biological Hazards in the Scientific Support Have to Match Those Identified in the Hazard Analysis?

- In general, the biological hazards studied in the scientific support should be the same as those identified in the hazard analysis.
- Ensuring that the scientific support contains microbiological data for the hazard listed in the hazard analysis is particularly important for slaughter processes where interventions have different efficacy depending on the species of product and the pathogen.

Food Safety and Inspection Service:

When Can the Biological Hazards in the Scientific Support Not Match What's in the Hazard Analysis?

- Although Appendix A was developed based on experiments measuring the efficacy of thermal processes on *Salmonella*. *Salmonella* can be used as an indicator of lethality for other pathogens such as *E. coli* O157:H7 and *Listeria monocytogenes*.
- At this time, interventions validated to control *E. coli* O157:H7 should be effective in controlling non-O157 STEC.
- Data from indicator or surrogate organisms may be used if there is sufficient data to establish a relationship between the presence or level of a pathogen or toxin and the indicator organism.



Food Safety and Inspection Service:

How Does the Establishment Meet Element 2: In-plant Validation Data?

- To meet the second element of initial validation, establishments should:
 - Implements critical operational parameters in the actual production process consistent with the parameters in the scientific or technical support;
 - Identifies at least one product from each HACCP category to gather in-plant validation data;
 - Collects in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least one product from each HACCP category; and
 - Analyzes the data to determine whether the critical operational parameters are being implemented effectively.



Food Safety and Inspection Service: Implementing Critical Operational Parameters

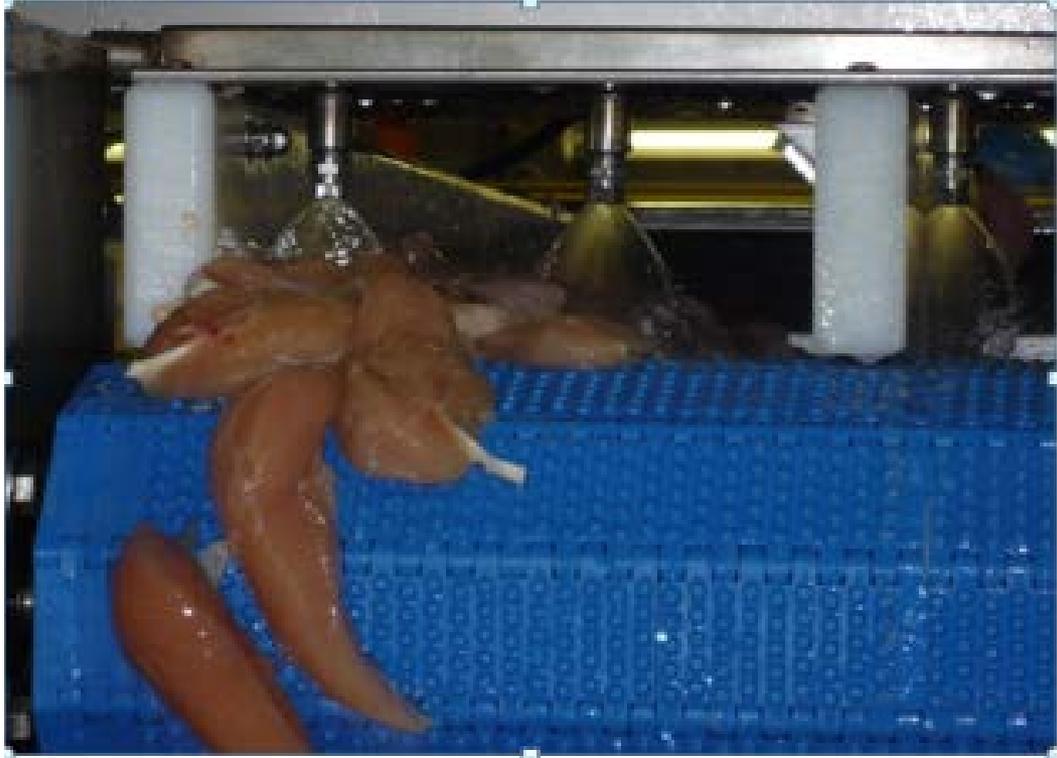
- To be effective, the process procedures should be consistent with the critical operational parameters in the supporting documentation.
- If all of the critical operational parameters from the support are not implemented, then an establishment can not expect to have the same efficacy in-plant.

Food Safety and Inspection Service: Implementing Critical Operational Parameters



- This image shows incomplete coverage. In particular, only part of the carcass is receiving the spray. If complete coverage can't be achieved then the intervention will not be as effective.

Food Safety and Inspection Service: Implementing Critical Operational Parameters



- This image also shows incomplete coverage. In particular, no spray is applied to the underside of products. In addition, not all pieces on the conveyor belt are being treated because the arc of the spray is too narrow to cover all product that could pass on the conveyor. The spray is also not being applied to all pieces due to product piling up and overlapping on the conveyor belt.

Food Safety and Inspection Service:

How Closely do the Parameters Implemented in the Actual Process Need to Match the Scientific Support?

- The establishment should implement:
 - the same parameters or
 - If it uses different parameters it should support why those different parameters would be equally as effective.
- For example, the Tompkin paper can be used to support a storage temperature CCP for raw meat of 45°F even though it cites 44.6°F as minimum growth temperature for *Salmonella*. This rounding is suitable because the growth rate of *Salmonella* at 45°F is not significantly different from its growth rate at 44.6°F.

Food Safety and Inspection Service:

How Closely do the Parameters Implemented in the Actual Process Need to Match the Scientific Support?

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC		
FSIS DIRECTIVE	7120.1 Rev. 26	4/8/15

SAFE AND SUITABLE INGREDIENTS USED IN THE PRODUCTION OF MEAT, POULTRY, AND EGG PRODUCTS

I. PURPOSE

This directive provides inspection program personnel (IPP) with an up-to-date list of substances that may be used in the production of meat, poultry, and egg products.

II. CANCELLATION

FSIS Directive 7120.1, Revision 25, *Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products*, dated March 9, 2015

III. REASON FOR REISSUANCE

This revision includes updates to the list of substances added since the March 9, 2015, issuance of the directive. Updates to this directive appear in Table 1. Changes are in bold in Table 2.

Table 1: Summary of Updates to list of substances

Substance	Page Number	Category	Type of Update
Aqueous mixtures of peroxyacetic acid (PAA), hydrogen peroxide, 1-hydroxyethylidine-1, 1-diphosphonic acid (HEDP), acetic acid and water	11	Antimicrobial	New
A blend of lactic acid (45-60%), citric acid (20- 35%), and potassium hydroxide (>1%)	13	Antimicrobial	Revision
A combination of sulfuric acid, ammonium sulfate, and water	14	Antimicrobial	New
Oat Fiber	48	Binders	New
Oat Hull Fiber	48	Binders	New
Tomato lycopene extract and concentrate	53	Coloring Agents	Revision

DISTRIBUTION: Electronic

OPI: OPPD

Subpart C—Food Ingredients and Sources of Radiation

§ 424.21 Use of food ingredients and sources of radiation.

(a)(1) *General.* No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, part 318 or part 319 of this chapter, or by the Administrator in specific cases.

(2)(i) Poultry products and poultry broth used in the processing of poultry products shall have been processed in the United States only in an official establishment or imported from a foreign country listed in §381.196(b), and have been inspected and passed in accordance with the regulations. Detached ova and offal shall not be used in the processing of any poultry products, except that poultry feet may be processed

Food Safety and Inspection Service:

Do All Critical Operational Parameters Need to Become Part of a CCP?

- If an establishment is using the scientific support as support for the development of a CCP and its critical limits (9 CFR 417.5(a)(2)) to prevent, reduce, or eliminate a hazard identified as RLTO, then it is **recommended** that the establishment incorporate all of the critical operational parameters into the critical limits of the CCP.
- An establishment may determine through decision-making that some of the critical operational parameters will be measured on an ongoing basis as part of a prerequisite program.
- An establishment may also determine that it only needs to check that some critical operational parameters are implemented consistent with the support during the initial validation period (e.g., spatial configuration, equipment type to the extent that it affects other parameters, or ingredient formulation provided it does not change).

Food Safety and Inspection Service:

How Many Products do Establishments Have to Collect In-plant Validation Data for?

- The HACCP Systems Validation Compliance Guideline, recommends that establishments collect initial in-plant validation data for at least one product from each HACCP process category utilized.
- Establishments should collect initial in-plant validation data for all CCPs and prerequisite programs used to support decisions in the hazard analysis related to that product to demonstrate they are being implemented as designed.

Food Safety and Inspection Service:

How Can an Establishment Determine which Product to Select for Initial In-plant Validation Data Collection?

- The Compliance Guideline contains food science principles establishments can use to select the product within each HACCP process category that represents the worst-case.

- ***Size and shape of the food:*** The size and shape of food affects heat penetration, heating rate, and heating uniformity. Irregularly shaped products, for example, are subjected to non-uniform heating because of differences in product thickness. In addition, in thicker products, more time will be needed for the heat to penetrate to the center of the product.
 - How this criterion could be used: If an establishment produces several fully cooked deli meat products of various thicknesses, the establishment should gather data on the thickest product because heat penetration is critical.

Food Safety and Inspection Service:

When Does an Establishment Only Need Initial In-plant Validation Data for the Critical Operational Parameters?

- In cases where the establishment's process is:
 - **Implemented consistent with** the process specifications described in the scientific support, **and**
 - **When the scientific support used contains microbiological data** specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the establishment should:
 - Demonstrate the critical operating parameters are being met by gathering in-plant data (e.g., data on quantifiable characteristics of the critical operational parameters such as pressure, temperature, and concentration).

Food Safety and Inspection Service:

Example of When an Establishment Only Needs Initial In-plant Validation Data for the Critical Operational Parameters

- If an establishment is using the Tompkin paper to support a storage temperature program for raw meat where the ambient storage temperature is maintained at $\leq 45^{\circ}\text{F}$ and time product is in storage ≤ 5 days then it should gather in-plant validation data demonstrating:
 - Ambient air storage temperature does not exceed 45°F and that product is not held in storage for more than 5 days and
 - Data demonstrating the product temperature correlates to the ambient storage temperature.

Food Safety and Inspection Service:

When Should Establishments Also Gather In-plant Microbiological Data?

- In cases where the establishment's process is:
 - **Not implemented in a manner that is consistent with the** process specifications described in the supporting documentation, **or**
 - **When the scientific support used does not contain microbiological data** specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the establishment should:
 - Demonstrate the modified critical operating parameters are being met (e.g., data on quantifiable characteristics of the critical operational parameters such as pressure, temperature, and concentration), **AND**
 - Demonstrate the intervention's effectiveness under actual in-plant conditions (e.g., through microbiological data).

Food Safety and Inspection Service:

Example of When In-plant Microbiological Data Should be Gathered

- If a poultry establishment is implementing an intervention that has been validated to reduce *Salmonella* for purposes of reducing *Campylobacter* and it can't find literature documenting the intervention's effectiveness against *Campylobacter*, the establishment should gather in-plant microbiological data along with data on the critical operational parameters.

Food Safety and Inspection Service:

What if an Establishment No Longer has its In-plant Data?

- Establishments are being given time (until January 4, 2016 or April 4, 2016 depending on size) to assemble the initial in-plant validation data if they did not keep it originally.
- This data will generally include 90 days of production records and any additional documents gathered to demonstrate the establishment is able to effectively execute the critical operating parameters in their HACCP system including:
 - HACCP records generated during 90 days when the current HACCP system is in operation.
 - Decision-making documents for the CCPs and critical operational parameters data gathering methods.
 - Records associated with initial equipment set up or calibration that contain data for any critical operational parameters that did not become CCPs to support that the parameters were met during the initial validation period.
 - Any establishment sampling results for the product and process of interest.

Food Safety and Inspection Service:

What is the Timeframe for an Establishment to Complete Initial Validation?

- **New establishments** are issued a conditional grant of inspection for a period up to 90 days in accordance with 9 CFR 304.3(b) and 381.22(b) during which they must complete initial validation as required in 9 CFR 417.4(a)(1).
- Additionally, 9 CFR 304.3(c) and 381.22(c) require establishments producing a **new product** to complete the initial validation of the **new HACCP plan** as required in 9 CFR 417.4(a)(1) during a period not to exceed 90 days after the date the new product is produced for distribution in commerce

Food Safety and Inspection Service:

What is the Timeframe for an Establishment to Complete Initial Validation?

- Consistent with these requirements, in-plant validation data should encompass the first 90 calendar days of an establishment's processing experience with a **modified HACCP plan** based on a reassessment as per 9 CFR 417.4(a)(3).

Food Safety and Inspection Service:

What do 90 Calendar Days Equate to in Production Days?

- In all cases,
 - For large establishments, 90 calendar days equates to approximately 60 production days.
 - A minimum of 13 production day records within those initial 90 calendar days should be used for the initial validation of a small or very small establishment's HACCP system.
 - A small or very small establishment may make a request to FSIS in writing for additional time.
- During this time, the establishment should gather its initial in-plant validation data at an increased frequency compared to the frequency listed in the HACCP plan or prerequisite program.

Food Safety and Inspection Service:

Example: Storage Temperature Control Program

Product	Hazard	Process	Critical Operational Parameters	Initial Validation	
				Scientific or Technical Support	In-Plant Validation Data
Post-lethality exposed ready-to-eat meats	Biological - <i>Listeria monocytogenes</i>	Packaging -Time and Temperature GMP's	<p>Packaging room temperature ≤ 50°F.</p> <p>Product remains in packaging < 5 hours prior to refrigerated storage.</p>	<p>Tompkin Paper. Table 2. http://www.meathaccp.wisc.edu/Model_Haccp_Plans/assets/raw_ground/TompkinPaper.pdf.</p>	<p>In plant records for 90 day period demonstrating ambient air temperature in the assembly room does not exceed 50°F and that product is not held during packaging for more than 5 hours. In plant records for 90 day period demonstrating a correlation between product temperature and ambient temperature.</p>

Food Safety and Inspection Service: Example: Storage Temperature Control Program

Bruce Tompkin Ph.D.
Armour Swift-Eckrich

□

Table 2. Estimated time (hours) for a ten fold increase at 50, 60 and 70F.

	Estimated Time (hours) to increase from 10 to 100 CFU/ml		
	50F (10C)	60F (15.6C)	70F (21.1C)
<i>Salmonellae</i>	107	24	9
<i>E. coli</i> O157:H7			
aerobic	50	21	9
anaerobic	123	38	16
<i>L. monocytogenes</i>			
aerobic	38	16	8
anaerobic	58	27	16
<i>Y. enterocolitica</i>	68	31	16

Source: USDA ARS Pathogen Modeling Program Version 4.0.

Conditions: broth medium, pH 6.0, salt 0.5%, sodium nitrite 0.0%

□

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Food Safety and Inspection Service:

Example: Antimicrobial Intervention

Product	Hazard	Process	Critical Operational Parameters	Initial Validation	
				Scientific Support	Initial In-Plant Data
Beef Carcass	<p>Biological – <i>E. coli</i> O157:H7, <i>Salmonella</i> Typhimurium</p> <p>Chemical - excessive levels of lactic acid</p> <p>Physical - none</p>	Lactic Acid Spray	<p>2% lactic acid applied within 12 inches of carcass surface and entire carcass covered using a stainless steel spray tank fitted with a pressure gauge and air compressor.</p> <p>Each side of beef should be sprayed for at least 1 minute and sprayed from top to bottom and sufficient lactic acid is applied such that some of it drips off.</p> <p>Note: The entire carcass is sprayed with lactic acid following washing each side of beef from top to bottom for at least 2 minutes with hot water and allowing a 5 minute drip time after the hot water wash.</p>	<p>Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments. Pennsylvania State University. 2005.</p> <p>Technical support from the manufacturer with instructions on mixing the lactic acid with water to achieve a concentration that is safe and suitable in accordance with:</p> <p>FSIS Directive 7120.1</p>	<p>In plant monitoring records for 90 day period recorded on Hot Water and Drip Time Monitoring Check Sheet (including parameters for the time the carcass is sprayed with hot water, carcass coverage, method application (from top to bottom and spray nozzle within 12 inches of carcass), and drip time.</p> <p>Records of lactic acid concentration. Trial Reports run under specified lactic acid critical parameters demonstrating complete carcass coverage, sufficient amount (lactic acid drips off carcass), contact time, method of application (spray nozzle within 12 inches of carcass and from top to bottom).</p>

Food Safety and Inspection Service: Example: Antimicrobial Intervention

Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments

Prepared by:

Department of Food Science
The Pennsylvania State University

Department of Animal Science and Food Technology
Texas Tech University

Department of Food Science and Nutrition
Washington State University

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Food Safety and Inspection Service:

Example: Antimicrobial Intervention

UNITED STATES DEPARTMENT OF AGRICULTURE
 FOOD SAFETY AND INSPECTION SERVICE
 WASHINGTON, DC

FSIS DIRECTIVE

7120.1
 Rev. 26

4/8/15

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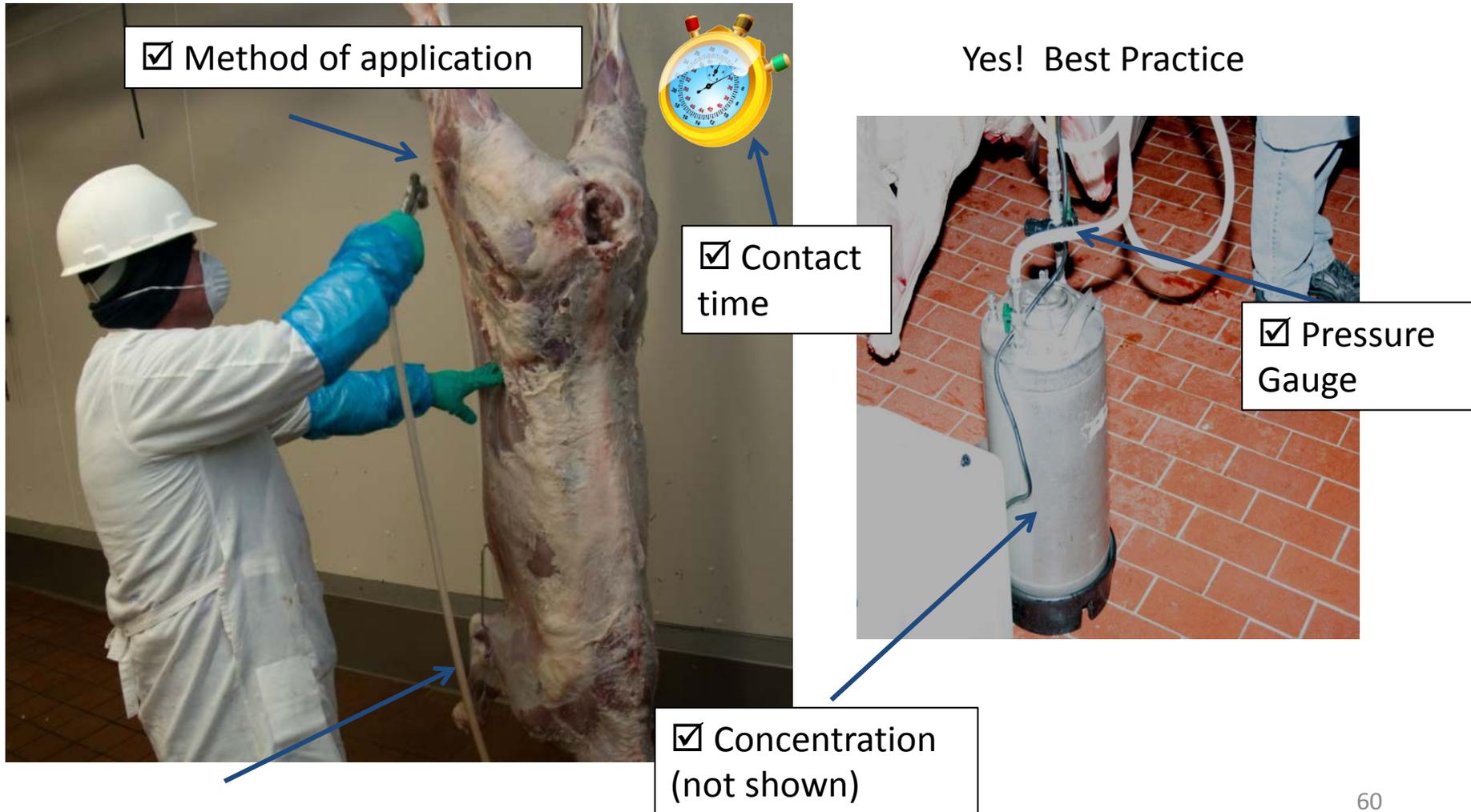
Substance	Page Number	Category	Type of Update
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Tomato lycopene extract and	53	Coloring Agents	Revision

Food Safety and Inspection Service:

Example: Antimicrobial Intervention

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Food Safety and Inspection Service: Are All of the Critical Operational Parameters Being Met?

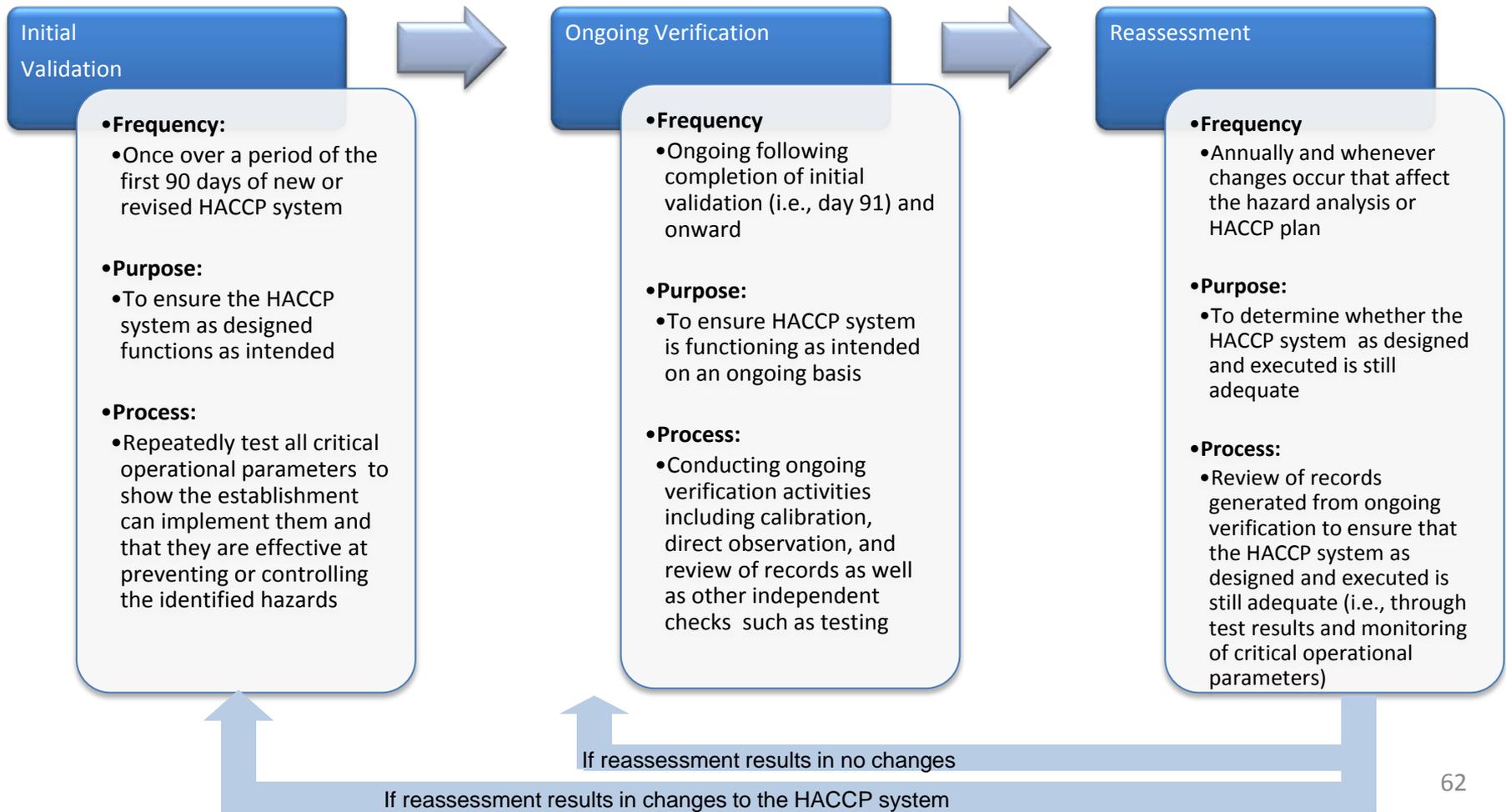


Food Safety and Inspection Service:

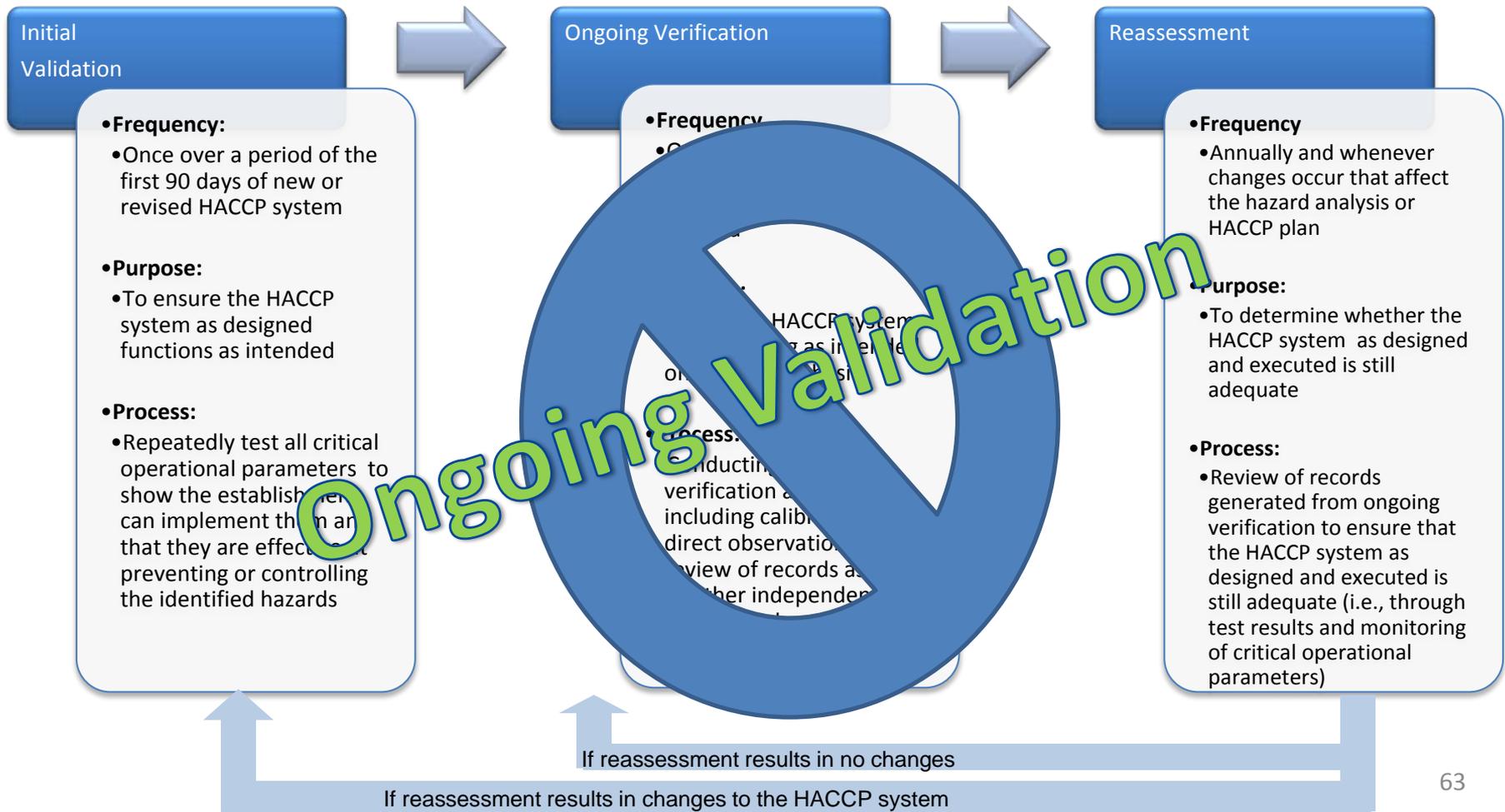
What is the Difference Between Initial Validation and Ongoing Verification?

- Initial validation should be a distinct function from ongoing verification.
- **During the 90 calendar day initial validation period** after completing the hazard analysis and developing the HACCP system, establishments validate the adequacy of their HACCP system.
- **Following the 90 calendar day initial validation period**, an establishment uses its findings from the initial validation period to fully implement its system and solidify its **monitoring** and **on-going verification** procedures and frequencies.

Food Safety and Inspection Service: What is the Difference Between Initial Validation and Ongoing Verification?



Food Safety and Inspection Service: What is the Difference Between Initial Validation and Ongoing Verification?



Food Safety and Inspection Service: What are the Next Steps for Implementation?

- As previously explained:
 - Establishments will be given time (until January 4, 2016 or April 4, 2016 depending on their size) to collect the necessary initial in-plant validation data.
 - FSIS will issue further instructions to IPP on how and when to document noncompliance if an establishment lacks initial in-plant validation data.
 - In the meantime, IPP are continuing to verify initial validation requirements following the instructions in [FSIS Directive 5000.6 Performance of the Hazard Analysis Verification \(HAV\) Task](#) and are instructed not to cite the lack of in-plant validation data as the only reason for the documentation of noncompliance.

Food Safety and Inspection Service: What Are the Key Points to Take Away?

- Initial validation encompasses activities designed to determine whether the entire HACCP system is functioning as intended.
- There are two elements to initial validation:
 - Element 1: Scientific Support Documentation (Design)
 - Element 2: Initial in-plant Demonstration Data (Execution)
- In most cases, initial in-plant validation data will consist of data related to critical operational parameters (not microbiological data).
- By ensuring that the HACCP system is designed and executed properly, establishments can reduce the likelihood for product contamination and foodborne illnesses in the future.

Food Safety and Inspection Service: Questions?

