# HACCP Systems Validation Training

# Objectives

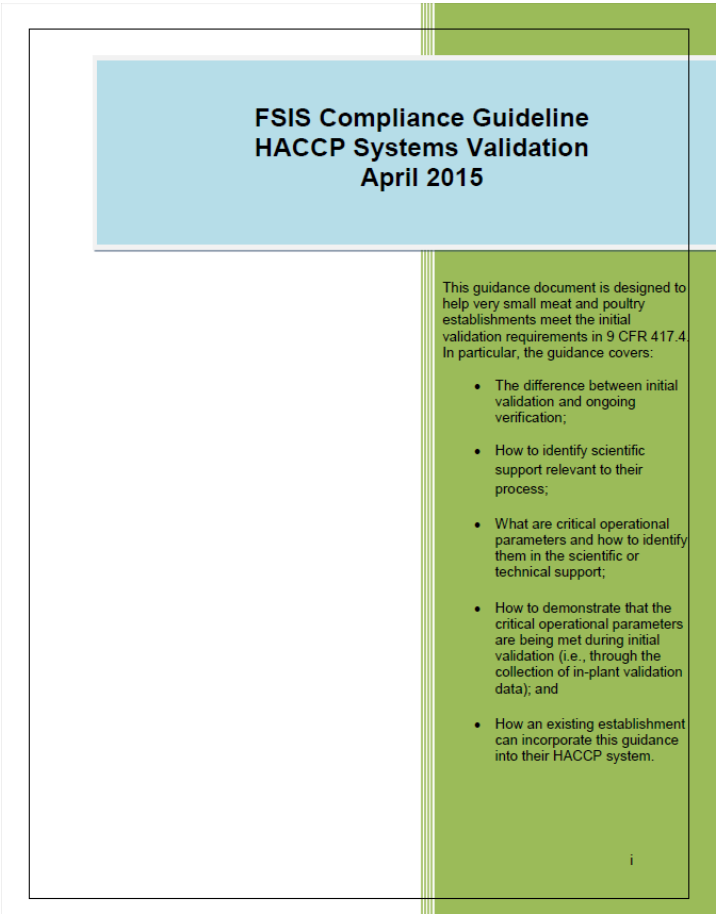
- Explain the two elements of validation
- Describe how validation documentation is a form of supporting documentation
- Identify situations clearly representing noncompliance with 9 CFR 417.5(a)(1) and 417.4(a)(1)

# Validation

- The act or process of ensuring the HACCP system is valid
- Valid: Well grounded or justifiable, relevant and meaningful, logically correct

# HACCP Validation Compliance Guideline

- HACCP Validation Compliance Guideline is available for industry



**FSIS Compliance Guideline**
**HACCP Systems Validation**
**April 2015**

This guidance document is designed to help very small meat and poultry establishments meet the initial validation requirements in 9 CFR 417.4. In particular, the guidance covers:

- The difference between initial validation and ongoing verification;
- How to identify scientific support relevant to their process;
- What are critical operational parameters and how to identify them in the scientific or technical support;
- How to demonstrate that the critical operational parameters are being met during initial validation (i.e., through the collection of in-plant validation data); and
- How an existing establishment can incorporate this guidance into their HACCP system.

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# HACCP Regulatory Requirements

## 9 CFR 417.4(a)

- "Every establishment shall *validate* the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall *verify* that the plan is being effectively implemented."


## 9 CFR 417.4(a)(1)

- *"Initial Validation*. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct *activities designed to determine that the HACCP plan is functioning as intended*. During this HACCP plan validation period, the establishment shall *repeatedly test* the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the *HACCP system*, in the context of other validation activities."

# HACCP Regulatory Requirements


**9 CFR 417.5(a)(1)**

- "The establishment shall maintain the following records documenting the establishment's HACCP plan:
  - The written hazard analysis prescribed in 417.2(a) of this part, including all supporting documentation

# Initial Validation Timeframe

- 9 CFR 304.3(b) and 381.22(b) require:
  - **New establishments** to complete initial validation within 90 days under a conditional grant of inspection
  - Establishments producing a **new product** to complete validation of the **new HACCP plan** within 90 days after the date the new product is produced for distribution in commerce
- In 90 calendar days, establishments may have varying amounts of production:
  - Large establishments could have 60 production days
  - Small or Very Small establishments should have a minimum of 13 production days

Note: Small or Very Small establishments may make a request to FSIS in writing for additional time.

# HACCP System


**What parts of a food safety system must be validated?**

# Validation Requirements

**Prerequisite programs that <u>may</u> support decisions in the hazard analysis:**

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

**Prerequisite programs <u>not likely</u> to be used to support decisions in the hazard analysis:**

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

# Validation of Prerequisite Programs

- Prerequisite programs support hazard analysis decisions by preventing hazards from being reasonably likely to occur.

- An effective HACCP system depends on:
  - prerequisite programs being designed to prevent hazards under actual plant conditions
  - the establishment implementing prerequisite programs as written

# Prerequisite Program Example

Fresh Pork Hazard Analysis

| Step | Potential Hazard | RLTO? | Basis/ Justification |
|---|---|---|---|
| Raw meat storage | **Biological:** Pathogen growth | No | temperature control program (storage temperature ≤45°F and time product is in storage ≤5 days) will prevent pathogen growth (Tompkin paper). |

The temperature control program must be validated.

# 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 *E. coli* | 7-8C | 44.6-46.4F |
| *L. monocytogenes* | -0.4C | 31.3F |
| *Y. enterocolitica* | -1.3C | 29.7F |
| *Campylobacter jejuni* | 32C | 89.6F |
| *Staphylococcus aureus* | 7C | 44.6F |
| *Bacillus cereus*[2] | | |
| psychrotrophic strains | 4C | 39.2F |
| *Clostridium perfringens* | 12C | 53.6F |

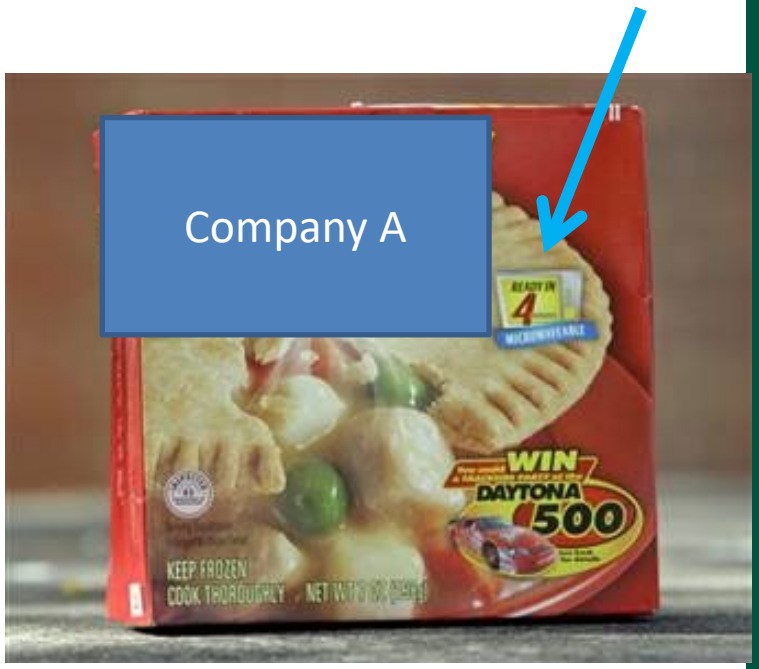
# Critical Operational Parameters

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

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

# Case Example of Inadequate Validation

- Inadequate initial validation has been linked to food safety problems
  - In October 2007, frozen pot pies were linked to an outbreak of Salmonellosis.
  - Consumers were not cooking the products in the microwave adequately.
  - The cooking instructions on not ready-to-eat products must be validated when consumer cooking is used to support decisions in the hazard analysis.



# Two Elements of Initial Validation

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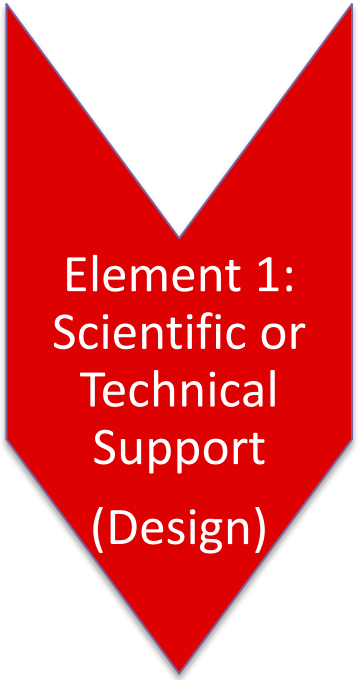
Element 1: Scientific or Technical Support (Design)

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

- Theoretical support
  - scientific or technical support for decisions made in designing the HACCP system
  - use 417.5(a)(1)
- Initial In-plant validation
  - evidence from the HACCP plan shows it achieves the parameters and results expected from the supporting documents
  - use 417.4(a)(1)

# Element 1: Scientific Support




- To meet the first element of initial validation:
  - Gather scientific support that:
    - Closely matches the actual process
    - Shows the establishment's process will prevent, reduce, or eliminate the hazard identified in the hazard analysis
  - Identify the critical operational parameters from the scientific support relevant to the establishment's process.

# Element 1: Scientific Support

- The scientific support should identify:
  - The specific hazard
  - The expected level of hazard reduction/prevention
  - All critical operational parameters
  - The processing steps where the reduction or prevention should occur
  - How these processing steps can be monitored

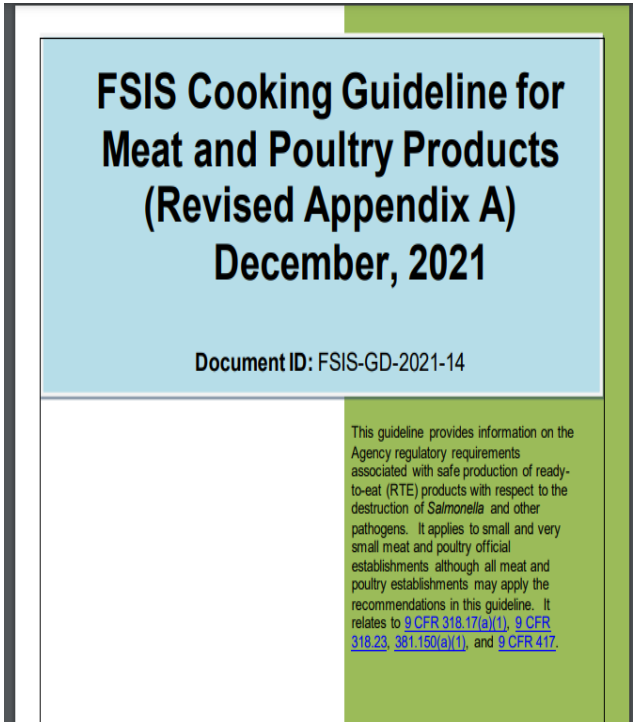
# Element 1: Scientific Support

What if the biological hazards in the scientific support don't match the hazard analysis?

- Appendix A may be used to support lethality temperatures to control *Salmonella* and other pathogens such as *E. coli* O157:H7 and *Lm.*

- Interventions validated to control *E. coli* O157:H7 should be effective in controlling non-O157 STEC.

- Data from indicator organisms may be used.



# Element 1: Examples of Scientific Support

- Published Processing Guidelines (FSIS Compliance Guidelines)
- Best Practice Guidelines
- Peer-reviewed Scientific Data/Information
- Challenge or Inoculated Pack Study
- Pathogen Modeling Program
- 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.

# Element 1: Examples of Scientific Support

Bruce Tompkin Ph.D.
Armour Swift-Eckrich

Table 1. Minimum growth temperatures for selected foodborne pathogens.

| | Minimum Growth Temperatures | |
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Hazard

Level of Prevention

Critical Operational Parameters

# Element 1: Examples of Scientific Support

*Journal of Food Protection, Vol. 65, No. 6, 2002, Pages 963–969*


Hazard

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

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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* (~$10^7$ 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)

# Element 1: Examples of Scientific Support

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

| Antimicrobial rinses (continued) | *Escherichia coli* O157:H7 | | | *Salmonella* Typhimurium | | | *Campylobacter* spp. | | |
|---|---|---|---|---|---|---|---|---|---|
| | Before treatment[a] | 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[c] | 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.)

# Element 1: Noncompliance

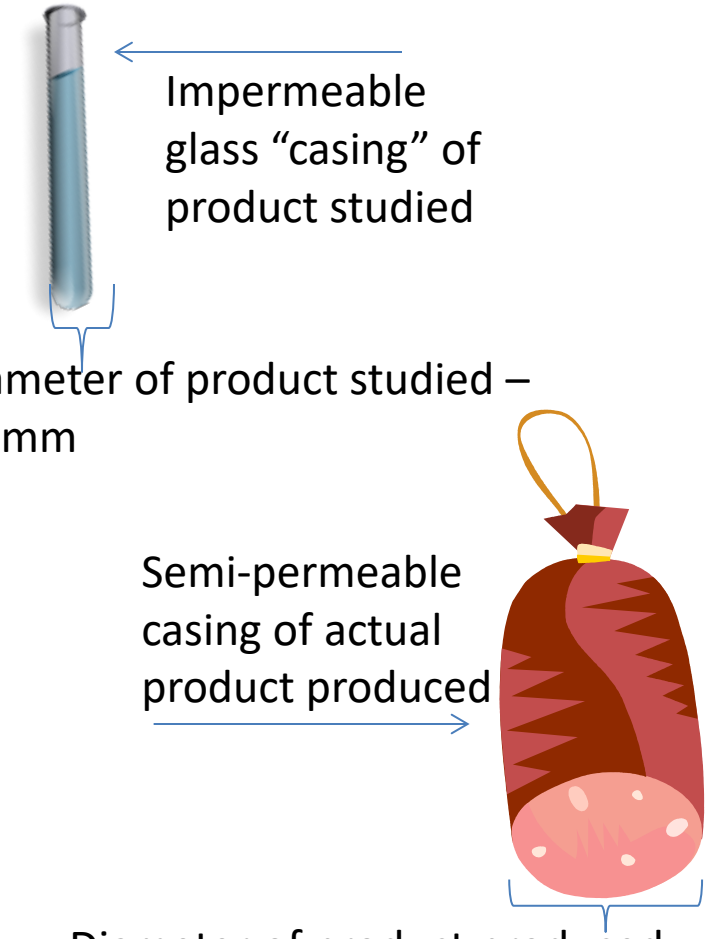
Element 1 Noncompliance is cited using 417.5(a)(1)
Examples:

- An establishment references a peer reviewed journal article, but can't produce the article upon request
- A process that is validated for a specific log reduction of a pathogen in a non-meat or poultry product is being used as sole supporting documentation
- Documentation in the form of a No Objection Letter without additional support
- Processing authority's opinion without any reference to established scientific principles or peer-reviewed data

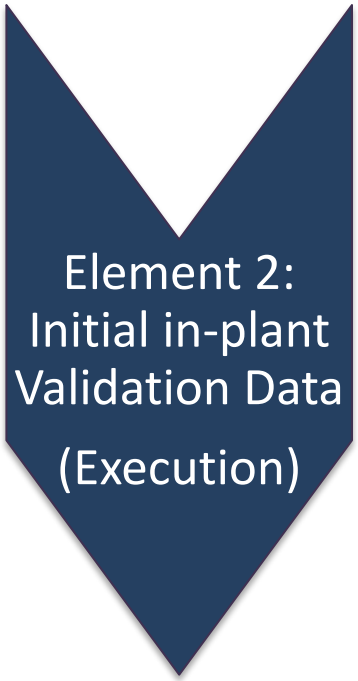
# Element 1: Inadequate Scientific Validation

## Case Example: Scientific support did not match the process

- March 2011- recalled Lebanon bologna was associated with a foodborne illness outbreak of *E. coli* O157:H7.
- The establishment had not properly validated their process.
- There were differences in the diameter and type of casing material on the product studied versus the actual product that likely led to a lower reduction in foodborne pathogens.



# Element 2: In-plant Validation Data

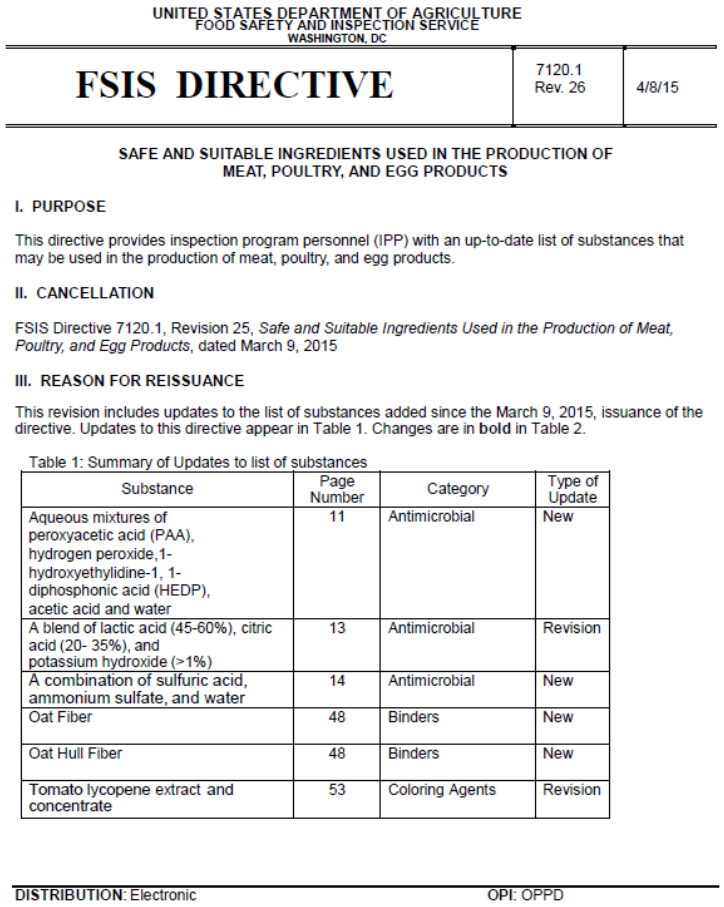



- To meet the second element of initial validation:
  - Implement parameters consistent with those in the scientific support
  - Collect in-plant data showing the establishment can meet the parameters for at least one product from each HACCP category
  - Analyze the data to determine whether the parameters are being implemented

# Element 2: In-plant Validation Data

## Implementing Critical Operating Parameters

- The establishment should implement:
  - the same parameters or
  - support the effectiveness of any difference in the parameters
- The establishment should incorporate:
  - all of the parameters into the critical limits of a CCP or
  - some parameters could be measured as part of a prerequisite program.



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.

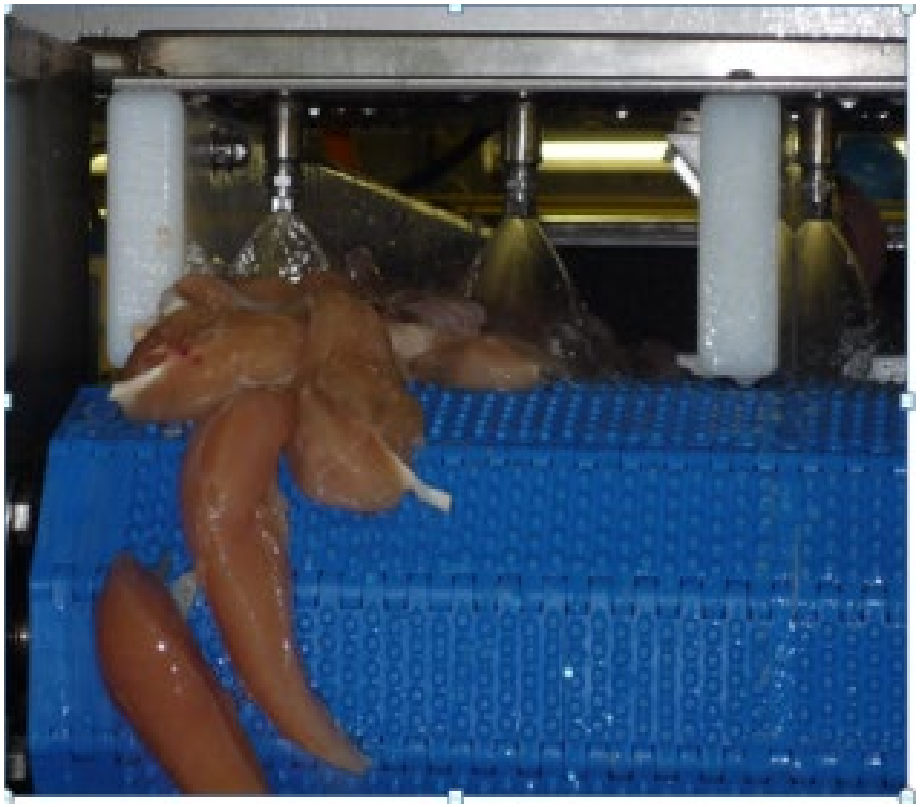
Table 1: Summary of Updates to list of substances

| 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

# Element 2: In-plant Validation Data

Incomplete Coverage of Antimicrobial Sprays



# Element 2: In-plant Validation Data

- Initial in-plant validation data should be collected for:
  - at least one product from each HACCP process category
  - all CCPs and prerequisite programs used to support decisions in the food safety system
  - product within each HACCP process category that represents the worst-case

# Element 2: In-plant Validation Data

- Microbiological data collection is encouraged (but not required) for initial in-plant validation, **if** the establishment:
  1. Has adequate scientific supporting documentation (the first element of initial validation)
  2. Is following the **same** parameters in the scientific support
  3. Can demonstrate that it **can meet the critical parameters** during operation (the second element of initial validation)

# Element 2: In-plant Validation Data

## Example- No Microbiological Data Is Needed

- An establishment may only need initial in-plant validation data for the critical operational parameters when:
  - Using the Tompkin paper to support a storage temperature CCP for raw meat of ≤45°F and
  - Time product is in storage is ≤5 days

- In-plant validation data gathered should demonstrate:
  - Ambient air storage temperature does not exceed 45°F
  - Product is not held in storage for more than 5 days and
  - Correlation between the product temperature and the ambient storage temperature.

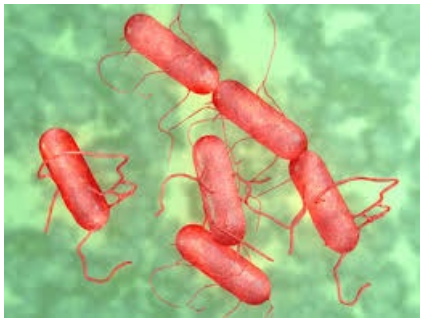
# Element 2: In-plant Validation Data

- In-plant microbiological data is needed when:
  - the process **does not** follow the same parameters in the supporting documentation, **or**
  - the scientific support **does not** contain microbiological data
- In either case, the establishment should demonstrate:
  - the modified critical operational parameters are being met, **and**
  - the intervention's effectiveness under actual in-plant conditions (e.g., through microbiological data)

# Element 2: In-plant Validation Data

## Example- Microbiological Data Is Needed

- A poultry establishment uses an intervention that has been validated to reduce *Salmonella.*
- The pathogen of concern is *Campylobacter,* but they can't find literature documenting the intervention's effectiveness on *Campylobacter.*
- The establishment should gather in-plant microbiological data along with data on the critical operational parameters.



# Example: Storage Temperature Control Program

| Product | Hazard | Process | Critical Operational Parameters | Initial Validation: Scientific or Technical Support | Initial Validation: In-Plant Validation Data |
|---|---|---|---|---|---|
| Post-lethality exposed ready-to-eat meats | Biological - *Listeria monocytogenes* | Packaging -Time and Temperature GMP's | Packaging room temperature ≤ 50°F.<br><br>Product remains in packaging < 5 hours prior to refrigerated storage. | Tompkin Paper. Table 2. http://www.meathaccp.wisc.edu/Model_Haccp_Plans/assets/raw_ground/TompkinPaper.pdf. | 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. |

# 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.

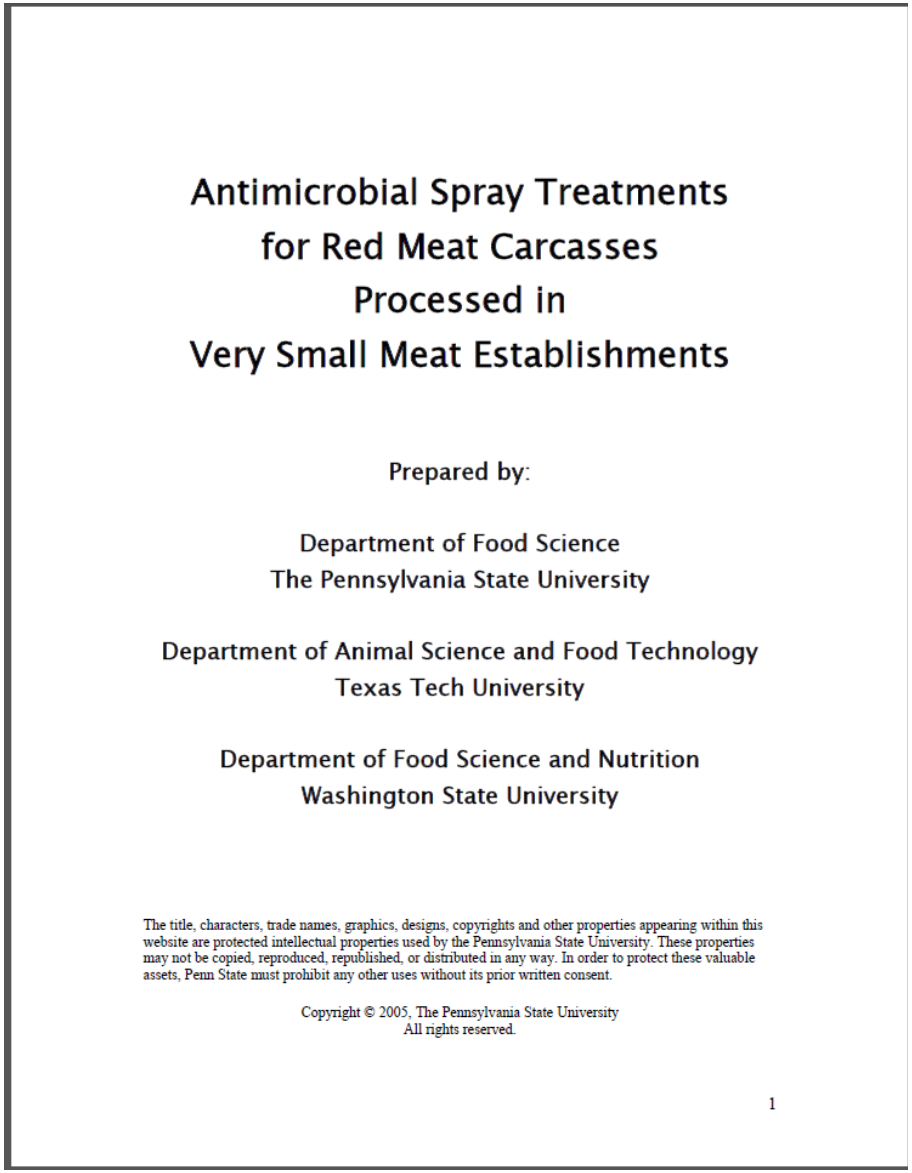
| | Estimated Time (hours) to increase from 10 to 100 CFU/ml | | |
|---|---|---|---|
| | 50F (10C) | 60F (15.6C) | 70F (21.1C) |
| Salmonellae | 107 | 24 | 9 |
| *E. coli* O157:H7 | | | |
| aerobic | 50 | 21 | 9 |
| anaerobic | 123 | 38 | 16 |
| *L. monocytogenes* | | | |
| aerobic | 38 | 16 | 8 |
|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

# Example: Antimicrobial Intervention

| Product | Hazard | Process | Critical Operational Parameters | Initial Validation: Scientific Support | Initial Validation: Initial In-Plant Data |
|---|---|---|---|---|---|
| Beef Carcass | Biological – *E. coli* O157:H7, *Salmonella* Typhimurium<br><br>Chemical - excessive levels of lactic acid<br><br>Physical - none | Lactic Acid Spray | 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.<br><br>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.<br><br>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. | Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments. Pennsylvania State University. 2005.<br><br>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:<br><br>FSIS Directive 7120.1 | 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.<br><br>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). |

# 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



1

# 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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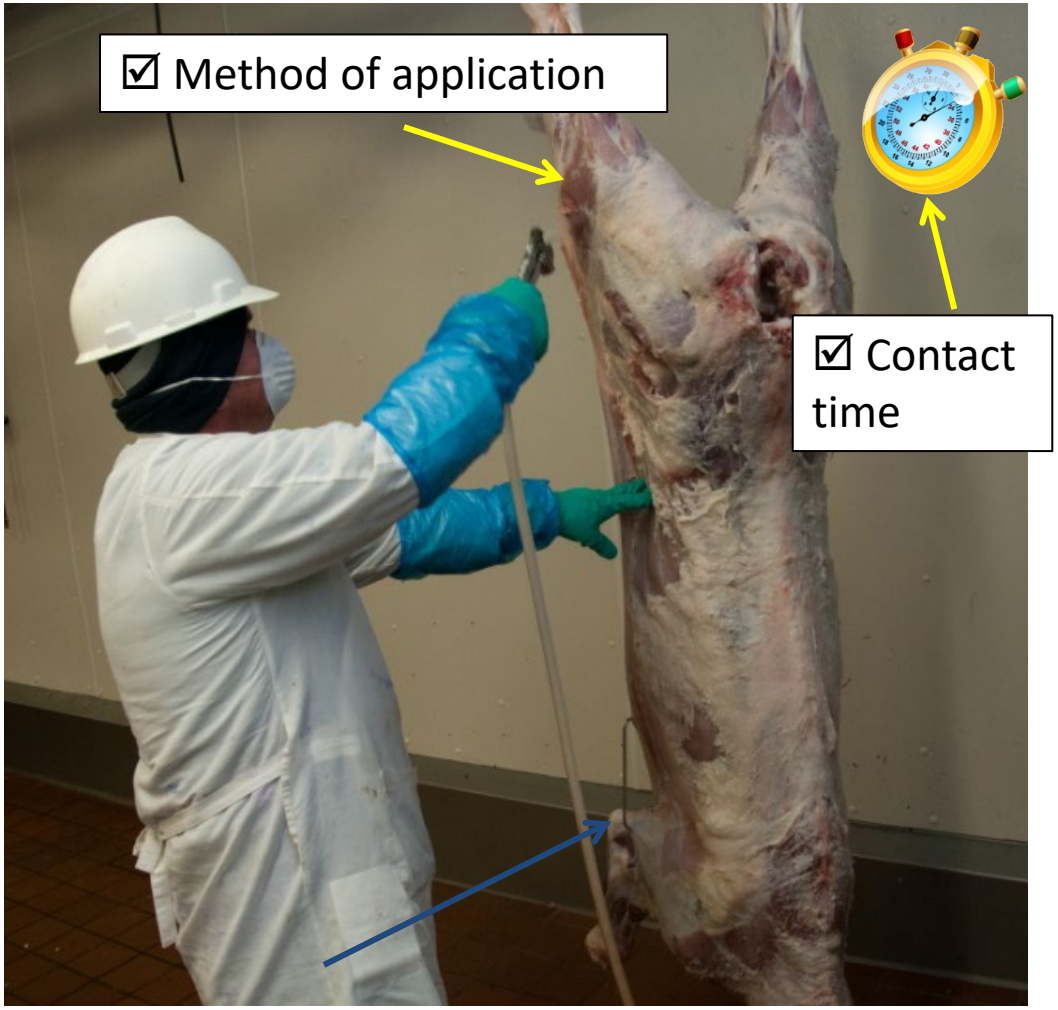
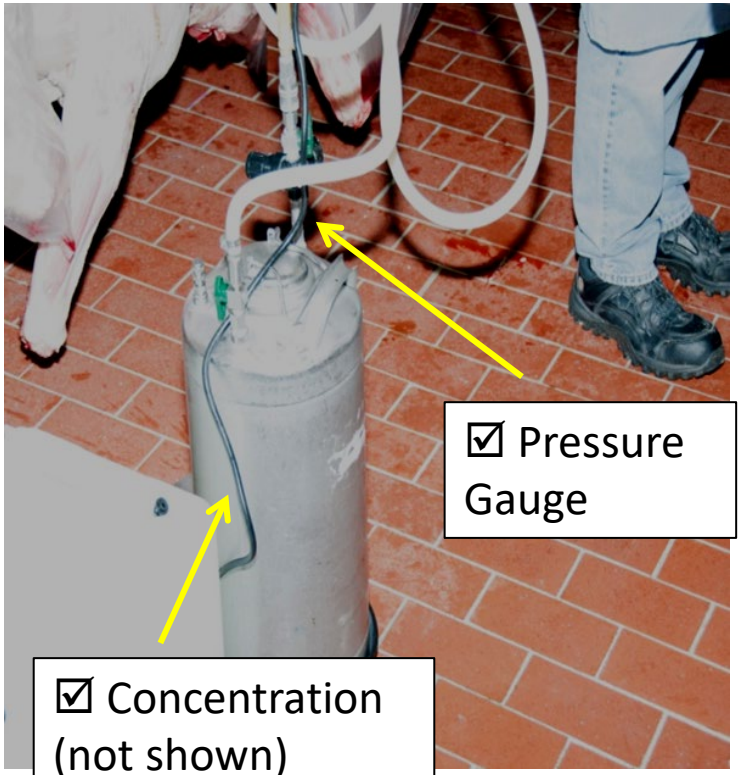
| Oat Fiber | 48 | Binders | New |
| Oat Hull Fiber | 48 | Binders | New |
| Tomato lycopene extract and | 53 | Coloring Agents | Revision |

# Example: Antimicrobial Intervention

## Are All of the Critical Operational Parameters Being Met?



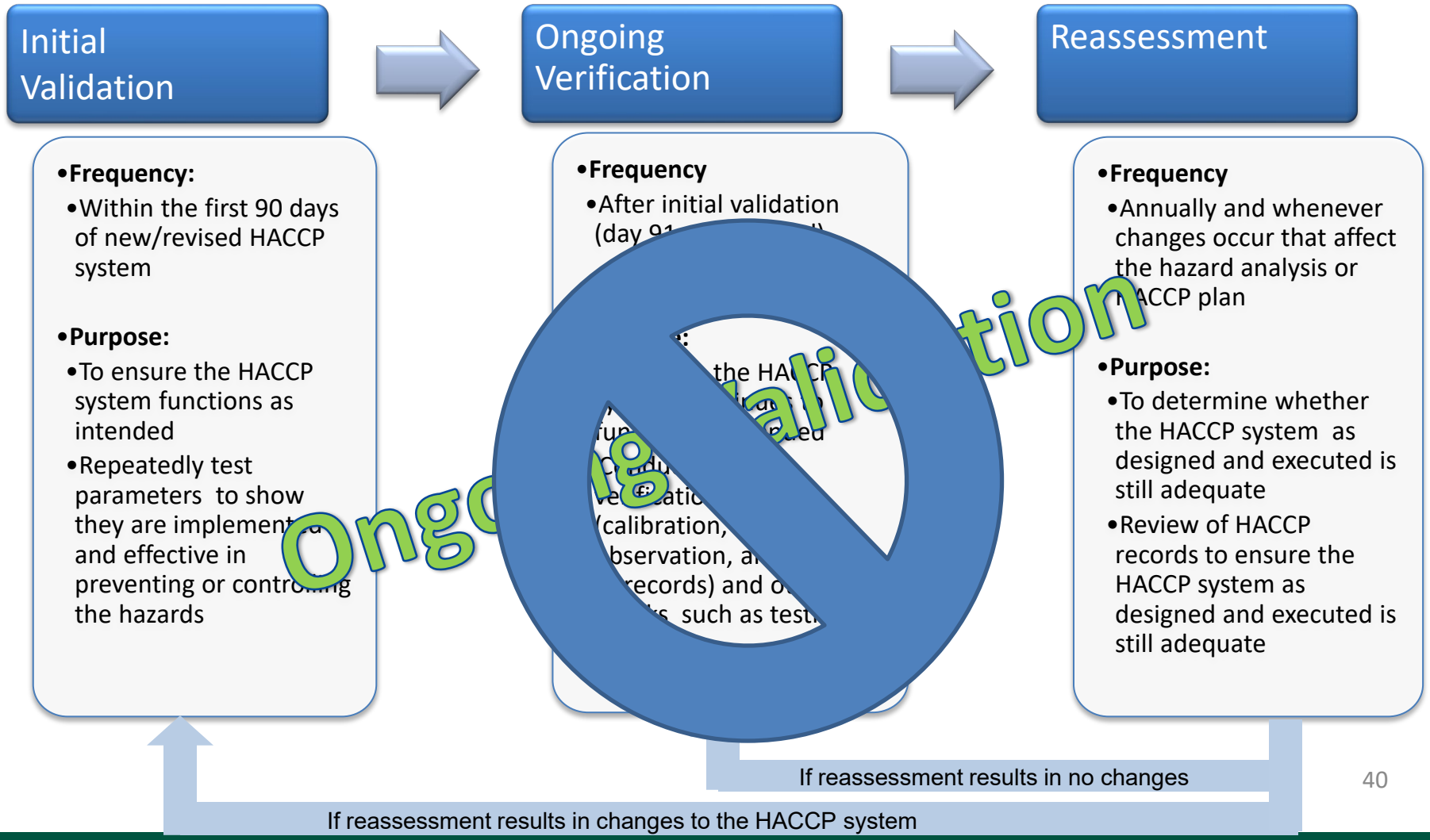

**Yes! Best Practice**

# Element 2: Noncompliance

Element 2 Noncompliance is cited using 417.4(a)(1)
Examples:

- The establishment does not maintain in-plant validation data for at least one product in each HACCP process category.
- In-plant validation records show the HACCP system does not control a food safety hazard.
- Prerequisite programs or CCPs do not incorporate the parameters from the scientific references and there is no additional support data.
- The establishment had a validated process on file but did not follow the process as described.
- The establishment references time and temperature values from Appendix A, but fails to reach the required values

# What is the Difference Between Initial Validation and Ongoing Verification?



# Summary

- Initial validation includes data that shows 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)

- Initial Validation is within the first 90 days

- Usually, initial in-plant validation data will consist of data related to critical operational parameters (not microbiological data).

# FSA Tools- Validation

**M11** Does the establishment maintain adequate scientific or technical support that relates to the establishment's actual process, product, and hazard identified in the hazard analysis, including chilling/cooling if the establishment slaughters (1st part of validation – design)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No, support does not relate – Click here to enter text.

☐No, establishment does not have support – Click here to enter text.

**M12** Does the establishment's scientific support demonstrate the process meets the performance standards or targets(i.e., pathogen reduction level)identified in the hazard analysis for each food safety system (limit 4,000 characters)?

☐Yes – Click here to enter text.

☐No, the support does not demonstrate that it meets the performance standards or targets –Click here to enter text.

☐No ,the establishment does not identify performance standards or targets – Click here to enter text.

# FSA Tools- Validation

**M13** Does the establishment use multiple interventions, including antimicrobial interventions, to meet the overall performance standard or target (i.e., multi-hurdle approach)?
☐Yes – If selected, answer the following question(s)
☐No

**M13a** In the event of a worst-case scenario when not all antimicrobial interventions are operational, does the establishment have support that the remaining antimicrobial interventions will adequately reduce the pathogen to an acceptable level?
☐Yes
☐No
☐Each antimicrobial intervention is required during production

# FSA Tools- Validation

**M14** Does the establishment incorporate the critical operating parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits? Briefly describe any vulnerabilities or noncompliances(limit 4,000 characters).
☐Yes – Click here to enter text.
☐No – Click here to enter text.

**M15** Does the establishment maintain in-plant validation data demonstrating the control measures, as written in the HACCP system, achieve the intended food safety outcome (2nd part of validation –execution)?Briefly describe any vulnerabilities or noncompliances(limit 4,000 characters).
☐Yes – Click here to enter text.
☐No – Click here to enter text.

**M16** Briefly describe any vulnerability or noncompliance finding with the establishment's HACCP system (i.e., HACCP plan, prerequisite program, or another program) validation that affect the establishment's ability to produce safe, wholesome, and unadulterated food not described above (limit 20,000 characters).
Click here to enter text.

# Questions

**What questions do you have?**