Valida&on of Dried and Fermented Meats: Tools for Small Processors

September 30, 2015

www.nichemeatprocessing.org

www.fsis.usda.gov
Outreach Partnership Division

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Today’s Speakers

- Meryl Silverman, USDA-FSIS
- Mohammad Koohmaraie, IEH Laboratories & Consulting Group
- Barbara Ingham, University of Wisconsin-Madison
One Team, One Purpose

Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
FSIS Perspective on Validating Processes for Niche Meat and Poultry Products

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September 30, 2015
• Background

• Lethality, Stabilization, and Shelf-stability Targets for Niche Meat and Poultry Products

• FSIS Validation Requirements for Niche Meat and Poultry Products
FSIS has seen increasing interest from processors in specialty fermented and dried meat products such as jerky, dried meat bars, biltong, pancetta, prosciutto, basturma, and soudjouk.

Such niche meat products typically do not rely on cooking alone to achieve lethality but rather rely on multiple hurdles (e.g., interventions, fermentation, drying, low temperature heat treatment, HPP).

There is limited publicly available research supporting adequate reduction in pathogens is achieved by processes that rely on such hurdles making validation difficult.

Inadequate validation of specialty meat products has led to outbreaks in the past.
Food Safety and Inspection Service: Outbreaks Associated with Niche Meat Products

• In 1994, an outbreak of *E. coli* O157:H7 was linked to commercially distributed dry-cured salami.
  – Blue Ribbon Task Force on *E. coli* O157:H7 responded by evaluating research needs and outcome was Blue Ribbon Task Force Document.

• 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.
  – Difference in 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.

![Diagram: Impermeable glass “casing” of product studied vs. Semi-permeable casing of actual product produced]

Diameter of product studied – 27 mm
Diameter of product produced – 52 to 119 mm
• FSIS considers all RTE meat and poultry products that are contaminated with *Salmonella*, *Listeria*, and other pathogens or their toxins to be adulterated under the Federal Meat Inspection Act and Poultry Products Inspection Act (21 U.S.C. 601(m)(1)) and 453(g)(1)).

• In addition, 9 CFR 430.1 (the *Listeria* Rule) defines RTE products as those that are edible without further preparation to achieve safety.
Under HACCP, all producers of RTE product are required to:
- Control the food safety hazards in their products (9 CFR 417.4(a)) and to
- Document that their Hazard Analysis and Critical Control Point (HACCP) systems work according to 9 CFR 417.5(a).

Establishments producing RTE products need to achieve lethality of pathogens (e.g., *Salmonella*) in the product, and stabilize the product to prevent or limit the growth of spore-forming bacteria (e.g., *C. botulinum* and *C. perfringens*).

In addition, producers of shelf-stable products need to ensure the growth of toxigenic microorganisms, such as *Staphylococcus aureus*, is controlled during the process and prevented during the distribution and storage of the finished product.
Establishments are required to design their HACCP systems to meet all applicable performance standards or targets.

For products such as those that are dried, fermented, or salt-cured, FSIS recommends the process should achieve at least a 5.0-log$_{10}$ reduction of *Salmonella* spp. in order to support that the product is RTE.

Research has supported that a 5.0-log$_{10}$ reduction in *Salmonella* is sufficient for such shelf-stable products. Indeed, the *FSIS Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products* found that there would not be a significant increase in the cases of salmonellosis if jerky and other shelf-stable products achieved a 5.0-log$_{10}$ instead of a 7.0-log$_{10}$ lethality.

Establishments have the ability to support alternative lethals supplied provided they provide an equivalent probability of no *Salmonella* organisms present in the finished product.
• The Blue Ribbon Task force for example, has an option for an alternative lethality in which the raw batter of sausage is tested in conjunction with the application of a process that achieves at least a 2-log reduction (see the *Salmonella* Compliance Guidelines for more information: http://www.fsis.usda.gov/wps/wcm/connect/2ed353b4-7a3a-4f31-80d8-20262c1950c8/Salmonella_Compile_Guide_091912.pdf?MOD=AJPERES)

• This option does provide less assurance of product safety so it is important that the raw material testing provides a high degree of confidence that there is no *Salmonella* present.
• The product must be stabilized to prevent or limit the growth of spore-formers (*C. botulinum* and *C. perfringens*).

• Products that are stabilized by fermentation or drying typically have characteristics (pH ≤ 4.6, $a_w < 0.93$) that preclude the growth of spore-formers.

• These processes typically render the product shelf-stable at room temperature. Shelf-stable products should have characteristics that ensure no growth of *Staphylococcus aureus* may occur during storage at room temperature (as well as during processing).

• Measures should also be taken to address mold growth.
Food Safety and Inspection Service:
How does an establishment support the design of its system results in adequate pathogen prevention or reduction?

- 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.
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.
• 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.
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;

- Identify the critical operational parameters from the scientific support relevant to the establishment's process.
- 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.
• 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.
To meet the second element of initial validation, establishments should:

- Implement 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.
• 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).
Available literature supports a 5-log reduction can be achieved for fermented and dried meat and poultry products using:

- A high fermentation temperature and achieving a low pH\textsuperscript{1}
- A low temperature heat step following fermentation\textsuperscript{2}
- A long drying time\textsuperscript{3}
- Appendix A time/temperature/humidity combination after fermentation before drying

However, these processes may not address all unique niche meat products. Therefore, establishments may need to conduct a challenge study for their process to support it achieves a 5-log reduction in \textit{Salmonella} or use the raw batter testing option from the Blue Ribbon Task Force if a 2-log reduction can be supported.

\textsuperscript{1}Blue Ribbon Task Force. 1996. Dry Fermented Sausage and \textit{E. coli} O157:H7.
• There is interest from small and very small establishments in having a generic HACCP model for these products. Such models should include scientific support for all hazards identified and address worst case scenarios/variability in production methods.
Food Safety and Inspection Service: Questions
In-Plant Validations

Mohammad Koohmaraie
IEH Laboratories & Consulting Group
Lake Forest Park, Washington
Presentation Outline

• General review of the FSIS “Compliance Guideline on HACCP System Validation” – The presentation quotes heavily from the document.

• Examples of in-plant validations for a component of the HACCP system or the entire HACCP system.

• Summary and conclusions
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.
FSIS Reasons for Issuing the Validation Guidance Document

• FSIS has determined from its HACCP verification activities that many establishments have not properly validated their systems.

• In particular, establishments have not conducted adequate activities during the initial validation period to translate all the required critical operating parameters from the scientific or technical support into their processes and gather in-plant validation data demonstrating the HACCP plan is functioning as intended.

• FSIS enforcement actions have identified instances in which inadequate validation has led to the production of adulterated product and in some cases even illnesses.

From the FSIS Validation Document
Elements of HACCP System Validation

• The scientific or technical support for the HACCP system design (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; and

From the FSIS Validation Document
Elements of HACCP System Validation

• The in-plant validation data (execution) - that is 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.

From the FSIS Validation Document
Components of a Sound Validation

1) Scientific Support
2) Initial In-Plant Validation – the first 90 days
3) Ongoing verification using critical parameters established during the in-plant validation study

From the FSIS Validation Document
A Detailed Protocol for In-plant Intervention Validation

• Establishments request in-plant validations for variety of reasons:
  – Initial validation
  – Installation of a new intervention
  – Getting ready for the high season
  – Food Safety Assessments (FSA)
  – Notice Of Intended Enforcement (NOIE)
  – Notice Of Suspension (NOS)
Validation vs. On-Going Verification

• Validation – Initial validation to demonstrate that the entire HACCP system or its components are performing as designed. During this process Critical Operating Parameters will be identified. Examples: pH, temperature, dwell time, water activity, etc.

• On-going verification: the routine monitoring using the critical operating parameters gathered during the (initial) validation studies.
Components of a Valid Intervention Validation Study

• Sampling:
  – Representative sampling to give true picture of the effect of the intervention.
  – Acceptance of the results by USDA-FSIS
  – Best method of sampling (sponge, excision, etc.)
  – Number of observations

• Microbiological analysis

• Conditions (parameters) of application
In-Plant Examples

- Components of the systems – Intervention
- Entire System
Components of a Valid Intervention Validation Study – Representative Sampling

- Carcass – portion of the carcass
- Offal – all exposed surfaces
- Subprimals – most external surface (more than one piece, if needed)
- Trim – random
- Special cases - TBD
Components of a Valid Intervention Validation Study

• Using a power of 80% and a standard deviation of 0.80 \cite{ICMSF2002}, the number of samples required to resolve differences between log transformed means are as follows (calculated using the power and sample size for 2-sided ‘t’ function of Minitab Statistical Software, Release 13.1).
## Components of a Valid Intervention Validation Study

<table>
<thead>
<tr>
<th>Desired Resolution in Separation of Log Transformed Means</th>
<th>N = Estimated Number of Samples Required (per case, i.e., Before and After)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.25 log units</td>
<td>162</td>
</tr>
<tr>
<td>0.50 log units</td>
<td>42</td>
</tr>
<tr>
<td>1.00 log units</td>
<td>12</td>
</tr>
</tbody>
</table>
Components of a Valid Intervention Validation Study

• Microbiological analysis:
  – Indicator Organisms
    • Aerobic Plate Counts (APC)
    • Total Coliforms Counts (TCC)
    • Generic E. coli Counts (ECC)
    • Enterobacteriaceae Count (EBC)
  – Pathogens ?
  – Pathogenic Index - Molecular Markers, a measure of microorganisms which carry one or more genetic virulence factors. Samples will first be incubated in enriched media and then analyzed by a qualitative polymerase chain reaction (PCR) method looking for selected marker gene fragments.
  – Surrogate for pathogen (s)
Components of a Valid Intervention Validation Study – Operating Parameters

- Equipment
- Time
- Temperature
- Humidity
- Dwell Time
- Water Activity

- pH
- Contact Time
- Product Coverage
- Spatial Configuration
- Pressure
- Concentration
Some Actual Field Examples

- Carcass intervention validation
- Subprimals Intervention Validation
Hot Water Validation

• Sampling – Sponge
• Carcass
• Number of samples – 45 before and 45 after
• Microbiological Analysis –
  – APC
  – TCC
  – ECC
  – Molecular Markers
Hot Water Validation

Leading Side

Trailing Side
Results

Table 3. Mean ± SD of APC, TCC and ECC (Log CFU/sponge) and percentage of molecular markers from samples taken before and after the application of carcass hot water pasteurization cabinet.

<table>
<thead>
<tr>
<th></th>
<th>APC Log CFU/sponge</th>
<th>TCC Log CFU/sponge</th>
<th>ECC Log CFU/sponge</th>
<th>Molecular Markers, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before (n=44)</td>
<td>4.5 ± 0.5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.7 ± 1.0&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.1 ± 1.0</td>
<td>14.1</td>
</tr>
<tr>
<td>After (n=45)</td>
<td>2.2 ± 0.8&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.4 ± 0.1&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.4 ± 0.0</td>
<td>2.2</td>
</tr>
<tr>
<td>Reduction</td>
<td>2.3</td>
<td>1.3</td>
<td>0.7</td>
<td>11.9</td>
</tr>
</tbody>
</table>

<sup>a</sup> Means, within column, lacking common superscript letters, differ (P ≤ .05).
Tying to the Support Document

• Treatments Using Hot Water Instead of Lactic Acid Reduce Levels of Aerobic Bacteria and Enterobacteriaceae and Reduce the Prevalence of Escherichia coli O157:H7 on Preeviceration Beef Carcasses.

• BOSILEVAC, NOU, BARKOCY-GALLAGHER, ARTHUR, AND KOOHMARAIE

• Journal of Food Protection, Vol. 69, No. 8, 2006, Pages 1808–1813
### TABLE 1. Effects of lactic acid wash, hot water wash, and combined treatment on the aerobic plate counts (APC) for previsceral carcasses

<table>
<thead>
<tr>
<th></th>
<th>Mean APC (log CFU/100 cm²)</th>
<th></th>
<th>Mean EBC (log CFU/100 cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lactic acid&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Hot water&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Both&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Before treatment&lt;sup&gt;e&lt;/sup&gt;</td>
<td>6.1</td>
<td>6.2</td>
<td>6.4</td>
</tr>
<tr>
<td>After treatment&lt;sup&gt;f&lt;/sup&gt;</td>
<td>4.5</td>
<td>3.5</td>
<td>4.2</td>
</tr>
<tr>
<td>Reduction&lt;sup&gt;g&lt;/sup&gt;</td>
<td>1.6 C</td>
<td>2.7 A</td>
<td>2.2 B</td>
</tr>
<tr>
<td>&lt;sup&gt;h&lt;/sup&gt;P value</td>
<td>0.0001</td>
<td>0.0001</td>
<td>0.0001</td>
</tr>
</tbody>
</table>
### TABLE 3. Effects of lactic acid wash, hot water wash, or combined treatment on the prevalence of E. coli O157:H7 on previsceration carcasses

<table>
<thead>
<tr>
<th></th>
<th>Lactic acid&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Hot water&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Both&lt;sup&gt;d&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>31 (79)</td>
<td>27 (69)</td>
<td>19 (48)</td>
</tr>
<tr>
<td>After treatment</td>
<td>20 (50)</td>
<td>5 (14)</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Reduction (%)&lt;sup&gt;e&lt;/sup&gt;</td>
<td>35 B</td>
<td>81 A</td>
<td>79 A</td>
</tr>
<tr>
<td>(P) value&lt;sup&gt;f&lt;/sup&gt;</td>
<td>0.01</td>
<td>0.001</td>
<td>0.001</td>
</tr>
</tbody>
</table>

<sup>a</sup> Carrcasses (per 356 per treatment) were tested for E. coli.

<sup>b</sup> Lactic acid wash at 0.5% for 10 minutes.

<sup>c</sup> Hot water wash at 60°C for 10 minutes.

<sup>d</sup> Combined treatment of lactic acid wash and hot water wash.

<sup>e</sup> Percentage reduction in the prevalence of E. coli O157:H7.

<sup>f</sup> \(P\) value for comparison of treatment effects.
Operating Parameters

- Chad Hot Water Cabinet
- Water temperature:
  - 195°F using temperature gauge for water temperature delivered to the hot water cabinet
  - 170°F on the carcass surface as measured by Wahl tags
- Exposure time – 10 seconds
Surface Carcass Temperature

Neck
Brisket
Flank
Round

05.12.2011
Table 4. Mean ± SD of APC, TCC and ECC (Log CFU/sponge) and percentage of molecular markers from samples taken before and after the application of carcass lactic acid spray cabinet.

<table>
<thead>
<tr>
<th></th>
<th>APC</th>
<th>TCC</th>
<th>ECC</th>
<th>Molecular Markers, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Log CFU/sponge</td>
<td>Log CFU/sponge</td>
<td>Log CFU/sponge</td>
<td></td>
</tr>
<tr>
<td>Before (n=45)</td>
<td>5.4 ± 0.6&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.1 ± 0.8&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.1 ± 0.9&lt;sup&gt;a&lt;/sup&gt;</td>
<td>21.3</td>
</tr>
<tr>
<td>After (n=45)</td>
<td>1.5 ± 1.3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.5 ± 0.4&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.5 ± 0.3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>6.2</td>
</tr>
<tr>
<td>Reduction</td>
<td>3.9</td>
<td>1.6</td>
<td>0.6</td>
<td>15.1</td>
</tr>
</tbody>
</table>

<sup>a</sup> Means, within column, lacking common superscript letters, differ (P ≤ .05).
## Combined Interventions

Table 6. Mean ± SD of APC, TCC and ECC (Log CFU/sponge) and percentage of molecular markers from samples taken before and after the application of the sequential antimicrobial interventions *(carcass hot water pasteurization, lactic acid, and Inspexx™)*.

<table>
<thead>
<tr>
<th></th>
<th>APC Log CFU/sponge</th>
<th>TCC Log CFU/sponge</th>
<th>ECC Log CFU/sponge</th>
<th>Molecular Markers, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before (n=44)</td>
<td>6.1 ± 0.7&lt;sup&gt;a&lt;/sup&gt;</td>
<td>3.4 ± 0.9</td>
<td>1.5 ± 1.2</td>
<td>28.9</td>
</tr>
<tr>
<td>After (n=45)</td>
<td>1.1 ± 0.7&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.4 ± 0.0</td>
<td>0.4 ± 0.0</td>
<td>16.9</td>
</tr>
<tr>
<td>Reduction</td>
<td>5.0</td>
<td>3.0</td>
<td>1.1</td>
<td>12.0</td>
</tr>
</tbody>
</table>

<sup>a</sup> Means, within column, lacking common superscript letters, differ (*P* ≤ .05).
Validation Study for Treatment of Beef Subprimal in Two Different Plants Using the Same Intervention
Subprimals Validation

• Sampling – Sponge
• Number of samples – 45 before and 45 after
• Microbiological Analysis –
  – APC
  – TCC
  – ECC
  – Molecular Markers
Protocol
## Results – Weight Gain

Table 4. Weight gain of beef trim after acidified sodium chloride treatment

<table>
<thead>
<tr>
<th>Stage</th>
<th>Weight (g)</th>
<th>% weight gain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before (n=45)</td>
<td>42.0</td>
<td>0.47%</td>
</tr>
<tr>
<td>After (n=45)</td>
<td>42.2</td>
<td></td>
</tr>
</tbody>
</table>
Results – Plant A

Table 2. Mean ± SD of TPC, TCC and ECC (Log CFU/sponge) and percentage of molecular markers from subprimal samples taken before and after the application of Compound Y.

<table>
<thead>
<tr>
<th></th>
<th>TPC</th>
<th>TCC</th>
<th>ECC</th>
<th>Molecular Markers, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Log CFU/sponge</td>
<td>Log CFU/sponge</td>
<td>Log CFU/sponge</td>
<td></td>
</tr>
<tr>
<td>Before (n=50)</td>
<td>4.37 ± 0.36(^a)</td>
<td>1.75 ± 0.81(^a)</td>
<td>0.22 ± 0.61(^a)</td>
<td>19.2</td>
</tr>
<tr>
<td>After (n=50)</td>
<td>4.62 ± 0.29(^b)</td>
<td>2.14 ± 0.57(^b)</td>
<td>0.61 ± 0.83(^b)</td>
<td>19.2</td>
</tr>
<tr>
<td>Reduction</td>
<td>-0.25</td>
<td>-0.39</td>
<td>-0.39</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^{ab}\) Means, within column, lacking common superscript letters, differ \((P \leq 0.05)\).
Table 1. Log mean (SE) aerobic plate counts and molecular index of loin tails before and after compound Z treatment.

<table>
<thead>
<tr>
<th>Stage</th>
<th>APC (CFU/sample)</th>
<th>Molecular index (%)</th>
<th>No. Molecular Signals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before (n=50)</td>
<td>3.33(^a) (0.05)</td>
<td>14.0(^a)</td>
<td>35</td>
</tr>
<tr>
<td>After (n=50)</td>
<td>1.78(^b) (0.11)</td>
<td>2.0(^b)</td>
<td>5</td>
</tr>
<tr>
<td>Reduction</td>
<td>1.55</td>
<td>12</td>
<td>30</td>
</tr>
</tbody>
</table>

\(^a\) Values in the same column bearing the same letter do not differ significantly at \(P \leq 0.05\)
Reasons for varying effect

• Variations in operating parameters
  – Intervention does not make contact with the product (bacteria)
  – Block nozzles
What is the Reason for Different Results?

• Deviation from relevant parameters?
Complete Treatment

• A verification of treatment must be put in place to ensure complete and adequate coverage.

• The pictures to the right depict a method of fluorescent dye to check coverage.
Effective Interventions-
Saving Cream
Challenge Studies

• The study design has to address the following:
  – The types and number of strains of surrogate microorganisms to use as an inoculum.
  – Methods of production, enumeration and standardization of inoculum.
  – Size of inoculum to be used
  – Method of inoculation to be used
  – Sample size, sampling time, sampling location and number of samples to test
  – Methods of microbial analysis
  – Number of replicates
  – Measurement of process parameters/key ingredients at each key stage of production
Challenge Studies

• I highly recommend that the study be designed by qualified people and the study be submitted to FSIS’s Risk & Innovations Management Division (RIMD) for review BEFORE initiating the project (AskFSIS).
Special Cases

• Must use surrogate for pathogens of concern that are accepted by FSIS.

• Surrogates for:
  – *E. coli* O157:H7
  – *Salmonella*
  – *Staphylococcus* aureus

• When to use surrogates

• Concern about the use of surrogates
Special Cases - Example

• In 2011, there was a foodborne illness outbreak associated with XXX.
• The establishment recalled the product
• FSIS investigation found that the scientific support for the process did not match actual commercial process used.
• The establishment asked for a study to validate their process.
• Inoculated the trim used at a very high level with a cocktail of surrogate organisms (8 or more logs) – Objective was to determine the antimicrobial capacity of the system.
• Proceed with the entire process as it is normally practiced by the same employees using the same equipments.
• Three replications using the thickest product they produce
<table>
<thead>
<tr>
<th>Step in Process</th>
<th>Surrogate (log)</th>
<th>Log reduction</th>
<th>pH</th>
<th>Temperature °F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw Materials</td>
<td>0.18</td>
<td>0.00</td>
<td>5.85</td>
<td>42.0</td>
</tr>
<tr>
<td>After inoculation</td>
<td>7.54</td>
<td>0.00</td>
<td>5.85</td>
<td>42.8</td>
</tr>
<tr>
<td>Step 2</td>
<td>7.17</td>
<td>0.37</td>
<td>5.75</td>
<td>42.9</td>
</tr>
<tr>
<td>Step 3</td>
<td>5.11</td>
<td>2.43</td>
<td>6.83</td>
<td>119.3</td>
</tr>
<tr>
<td>Step 4</td>
<td>1.55</td>
<td>5.99</td>
<td>4.74</td>
<td>124.6</td>
</tr>
<tr>
<td>Step 5</td>
<td>0.96</td>
<td>6.58</td>
<td>4.61</td>
<td>70.4</td>
</tr>
<tr>
<td>Finish Product</td>
<td>0.00</td>
<td>7.54*</td>
<td>4.62</td>
<td>41.4</td>
</tr>
</tbody>
</table>

1- Water activity, moisture content, salt concentration and humidity
2- Repeated the process 3 times
Shelf – Stable Products Validation

- Establishment Y wanted to scientifically validate supporting information to determine the growth of *Staphylococcus aureus* and the lethality of their process toward *Salmonella* and *E. coli O157: H7* in their Cured Meat and Pork Offal production processes.

- The validation process was conducted at the establishment and used the process, equipment, employees and facilities that are utilized in the routine production of Cured Meat and Pork Offal Validation.
Shelf – Stable Products Validation

• Surrogate for *Salmonella*: Saga 200 (*Pediococcus* spp.)
• Surrogate for *Staphylococcus aureus*: *Staphylococcus carnosus*
• 3 replicates each with 3 observations per product
• 60 lbs batches
• Inoculation: $10^{1}$-$10^{2}$ CFU of *Staphylococcus carnosus* and $10^{5}$-$10^{6}$ Saga 200 surrogates per g
• The relevant critical operating parameters (e.g., time, temperature, humidity, $A_w$ etc.) for each processing step were recorded.
Shelf – Stable Products Validation

- Products: strips and whole offal's
- Whole offal's challenge
Shelf – Stable Products Validation

• Products: strips and whole offal's
• Whole offal's challenge
Special Cases - Example

- Validating finished ground beef sampling
- Inoculated a portion of a combo bin with green fluorescence labeled *E. coli* (GFP- *E. coli*)
- Combo #1 un-inoculated
- Combo #2 Inoculated
- Combo bins #s 3, 4, 5 un-inoculated
- Ground in sequence and sample every other chub
- Screening for GFP- *E. coli* (culture) and GFP
Results

• None of the samples taken from the pre-inoculation combo bin were positive.
• Every one of the samples from inoculated combo were positive.
• The first 50% of the combo #3 were positive.
• No other samples from combo bins #4, 5 and left over products were positive.
• Company developed a finished product sampling based on these results.
When to Use Surrogate Organisms

• The last resort
• When the process cannot be replicated in a laboratory settings
• When wanting to determine the capacity of the system.
Summary & Conclusions

• In-plant validation could be an eye opening experience.
• Design your study correctly (have a professional carry it out or have a professional review your plan).
• I strongly recommend that you have RIMS review the validation study protocol before it is conducted.
• Ongoing (several times a day) verification after validation.
• Some inspectors or EAIOs have a poor understanding of validations.
Thank you for listening

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University-Based Resources to Support Processors in Validating Processes for Niche Meat Products

Dr. Barbara Ingham
Elements to Scientific Validation

- Identify: prerequisite program, product formulation, processing step where control is applied
- Identify: level of control
  - Hazard prevention
  - Pathogen reduction
- Identify: control parameters

- Always accompanied by Monitoring and Verification

Answering the question: Will the HACCP system meet specified food safety objectives?
The Science & Practice of Validation

- Scientific or technical documentation.
  - Peer-reviewed scientific journal article
  - Challenge study performed under appropriate conditions
  - Data supporting published guidelines
  - Data gathered in-house
  - Mathematical modeling programs

- Practical demonstration that the HACCP system is effective.
The Science of Validation: Documentation

Criteria:

❖ Is the research accepted by professionals?
  • Has the research undergone a peer-review process?

❖ Is the research appropriate to the situation?
  • Was the research conducted under conditions appropriate to the in-plant environment?

❖ Is the research current?
  • Data may be ‘historical’ yet still be seen as reliable
  • Alternately, advancements in science may make prior research obsolete
(Processor) Pitfalls in Validation

- HACCP system is poorly conceived
- Target for control is incorrect or undefined
- Level of control needed is incorrect or undefined
- Scientific support is........ absent/inaccurate/outdated/incorrectly applied (choose any or all of the above)
- AND monitoring and verification may be missing (and often are)
Missing in Supporting Documentation Knowledgebase

- Pathogen trials in products resembling an industry standard
- Pathogen trials under conditions found in ‘real’ processing facilities
- Pathogen trials using strains appropriate for the situation
  - Strains sourced appropriately
  - Strains screened for stress tolerance: acid, heat, cold, low $a_w$, etc.

⇒ **ALL** available to industry, government, and universities in a format that is user-friendly and clearly understandable
The Role of University Research & Extension

- Applied research: practical solutions to industry problems
  - Funded so that results can be widely distributed

- Outreach:
  - Model HACCP plans
  - Validation support
  - Decision-making tools
  - One-on-one processor support
    - Review individual HACCP plans
    - Serve as a technical resource
    - Trouble shooting
    - Respond to deviations – process authority work
  - Training
HACCP Support

- Generic HACCP Models
  - HACCP Alliance
    http://www.haccpalliance.org/alliance/haccpmodels.html
  - USDA Guidebook (search http://www.fsis.usda.gov/)
  - University of Nebraska-Lincoln
    http://www.foodsafety.unl.edu/haccp/plans/plans.html
  - University of Wisconsin-Madison (meathaccp.wisc.edu)
- USDA-FSIS Small Plant Help Desk InfoSource@fsis.usda.edu
- State HACCP Contacts
meathaccp.wisc.edu

- Model HACCP Plans
- Supporting Documentation
- Validation Support
- SOP Examples

Shelf Stability Predictor. Predicts the probability of growth of LM and Staph as a function of pH and $a_w$.

THERM. Evaluate temperature deviations for beef, bratwurst, pork, poultry and seasoned beef.
Questions?

Niche Meat Processor Assistance Network

www.nichemeatprocessing.org

Small Plant Help Desk
infosource@fsis.usda.gov
1-877-FSISHELP (374-7435)