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## Food Safety and Inspection Service Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service

**National Advisory Committee on Meat and Poultry Inspection**

# **NACMPI Charge**

**Validation of Ready-to-eat (RTE) Shelf-Stable  
Multi-hurdle Lethality Treatments**

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# Food Safety and Inspection Service: Outline

- Overview
- Lethality Targets
- Validation Challenges
- Questions for NACMPI



## Food Safety and Inspection Service:

### Overview

- There is an increasing interest in producing artisanal/niche shelf-stable RTE fermented, salt-cured, or dried products that rely on multiple hurdles (i.e., salt, nitrite, reduced pH, reduced water activity; rather than heat) for lethality.
- FSIS recognizes that there is little scientific support available for establishments to use to support lethality for some of these products and is seeking input on the best way to fill this scientific gap.
- Guidance is in development, but the lack of scientific support may raise enforcement questions that FSIS is going to need to address.

## Food Safety and Inspection Service: Food Safety Objectives for RTE Products

- FSIS considers all RTE meat and poultry products that are contaminated with *Salmonella*, *Listeria monocytogenes*, Shiga-toxin producing Escherichia coli (STEC), or *Staphylococcus aureus* enterotoxin 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.

## Food Safety and Inspection Service: Lethality Targets

- For RTE shelf-stable meat and poultry products, FSIS recommends the process should achieve at least a 5.0- $\log_{10}$  reduction of *Salmonella* in order to support that the product is RTE under the Acts.
- Establishments may support an alternative lethality (reduction) that provides an equivalent probability of no *Salmonella* organisms present in the finished product.
- FSIS also recommends ensuring *S. aureus* outgrowth is limited to 2.0- $\log_{10}$  or less during processing to ensure no enterotoxin production.

## Food Safety and Inspection Service: Blue Ribbon Task Force

- 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 the outcome was the Blue Ribbon Task Force Document.

[https://www.beefresearch.org/cmdocs/beefresearch/safety\\_meeting\\_exec\\_summaries/1996\\_dry\\_fermented\\_sausage.pdf](https://www.beefresearch.org/cmdocs/beefresearch/safety_meeting_exec_summaries/1996_dry_fermented_sausage.pdf)

## Food Safety and Inspection Service: Alternative Lethality

- The Blue Ribbon Task Force has an option for an alternative lethality:
  - Raw batter of sausage is tested in conjunction with the application of a process that achieves at least a 2-log reduction in STEC (or *Salmonella*).
  - Provides less assurance of product safety.

## Food Safety and Inspection Service:

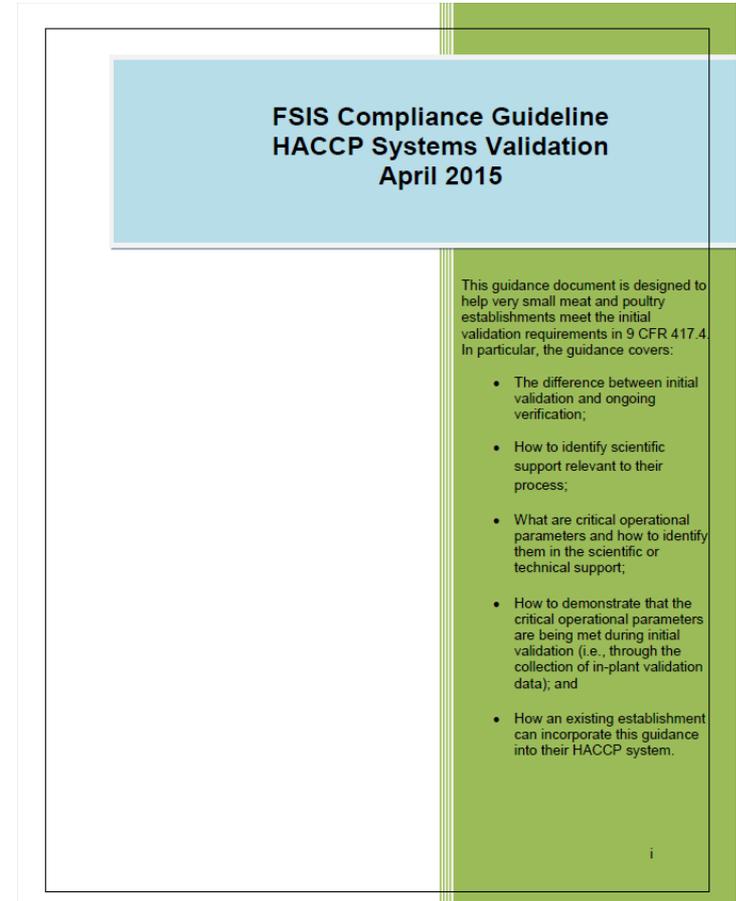
### AMI's GMP's for Fermented Dry and Semi-dry Sausage Products

- In the early 1970s there were several outbreaks due to *S. aureus* growth and enterotoxin production in fermented meats.
- In response, industry adopted:
  - Widespread use of commercial starter cultures and addition of fermentable sugars
  - “Degree-hours” concept
- There have been no reported cases of staphylococcal foodborne illness from fermented meats in the U.S. for over 30 years.

## Food Safety and Inspection Service:

### How does an establishment support that 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:
  - Scientific or technical support (design) and
  - Initial in-plant validation data (execution)



## 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.
  - Identify the critical operational parameters from the scientific support relevant to the establishment's process.

## Food Safety and Inspection Service:

### Element 1: Scientific or Technical Support

Examples include:

- Published Processing Guidelines including FSIS Guidelines
- Best Practice Guidelines
- Peer-reviewed Scientific Data/Information
- Challenge or Inoculated Pack Study
- Pathogen Modeling Program
- Regulatory Performance Standards

## Food Safety and Inspection Service:

### Challenges for Identifying Scientific Support for Niche Meat and Poultry Products

- 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
  - A low temperature heat step following fermentation
  - A long drying time
  - Appendix A time/temperature/humidity combination after fermentation before drying
- However, these processes may not address all unique niche meat products.

# Food Safety and Inspection Service:

## Critical Operational Parameters

### Fermentation:

- Fermentation temperature,
- Target pH, time to reach target pH,
- Smoke
- Relative humidity
- Type and use of starter cultures
- Product characteristics

### Dry-Curing and Salt-Equalization:

- Curing temperature
- Curing time
- Relative humidity
- Air flow
- Salt coverage of exposed muscle tissue
- Product characteristics

### Low-Temperature Heat Step (Optional):

- Come-up time (CUT) to low temperature step
- Hold time and temperature for low-temperature step
- Equipment used to generate heat
- Relative humidity during the heating step
- Product characteristics

### Drying:

- Drying room temperature
- Drying time
- Relative humidity
- Air velocity
- Target water activity
- Product characteristics

# Food Safety and Inspection Service:

## Summary

- There is an increasing interest in producing artisanal/niche shelf-stable RTE fermented, salt-cured, or dried products that rely on multiple hurdles for lethality. There have been a few outbreaks associated with these types of products (approximately 8 outbreaks in the U.S. over the last 50 years).
- Little scientific support is available for establishments to support lethality and when it is available it can be difficult to match the critical operational parameters to those used in the actual process.
- Guidance is in development, but the lack of scientific support may raise enforcement questions that FSIS is going to need to address.

## Food Safety and Inspection Service:

### NACMPI Committee Questions

1. What actions should FSIS take when it determines an establishment lacks scientific support for the lethality treatment of a fermented, salt-cured, or dried product? For example, should FSIS:
  1. Take enforcement action and require adequate scientific support per 9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1).
  2. Allow establishments to test and hold indefinitely.
  3. Allow establishments to combine multiple scientific support documents (e.g., journal articles) or use scientific support that demonstrates < 5.0-log reduction. May be in combination with increased FSIS testing.
  4. Use regulatory discretion and allow establishments to produce without scientific support.
  5. Combination of above.

## Food Safety and Inspection Service:

### NACMPI Committee Questions

2. How can FSIS assist industry in gathering scientific support and facilitate filling research gaps, even though it is not a research-funding organization?



Questions

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