FSIS Webinar on Revised Appendix A & B Guidelines
Agenda

• Welcome

• Overview

• 2021 FSIS Cooking Guideline (Revised Appendix A)
  • Followed by open question session

• 2021 FSIS Stabilization Guideline (Revised Appendix B)
  • Followed by open question session

• Scientific Gaps: Updates and Next Steps
  • Followed by open question session
History of Guidelines and Reason for Reissuance

Command and Control
- Prescriptive cooking & cooling regulations
- Defined *how* step-by-step

HACCP 1996
- Removed command-and-control
- Establishment chooses *how* based on scientific support

Performance Standards
- Set required 6.5/7 log *Salmonella* reductions
- Limited *C. perfringens* growth ≤1 log
- Applied to certain products
- No instructions on *how*

Appendix A 1999/2017/2021
- Optional safe harbors
- Originally for products with performance standards
- Easy support for *how*

Appendix B 1999/2017/2021
Comments Received on 2017 Versions

• 52 comments were received.

• Comments on the 2017 versions led to a delay of implementation until the next revisions were issued.

• FSIS received comments related to common cooking and stabilization processes for which establishments have used Appendix A and B as support, even though these processes cannot achieve the critical operational parameters included in the revised guidelines. FSIS responded by creating scientific gaps.

• FSIS responded to all of the comments in the Federal Register (86 FR 71007).
2021 Revisions

• Guidelines were updated in response to comments received on the previous version. In addition, the guideline has been revised to include recommendations from previous versions and new updates based on up-to-date science.

• The 2021 guidelines represents FSIS’s current thinking on these topics. Establishments that utilized previous versions of Appendix A or B as support should either:
  • Update to the 2021 Guideline(s) or
  • Identify alternative support by December 14, 2022
FSIS Notice 59-21

• Instructs inspection program personnel (IPP) to notify establishments that revisions to Appendix A and B are available and that they have until December 14, 2022 to begin using the 2021 guidelines or identify alternative support.

• Provides instructions for Enforcement, Investigation, and Analysis Officers (EIAOs) when performing Food Safety Assessments (FSAs) in establishments using FSIS’s Appendix A or B as scientific support.

• Includes attachments with changes from the previous versions of Appendix A and B.

• FSIS will provide further instructions before the implementation date (December 14, 2022).
2021

FSIS Cooking Guideline
(Revised Appendix A):
What is lethality?

- **Lethality** is the process or combination of processes that ensures a specific, significant reduction in the number of *Salmonella* and other pathogens in the product; as well as reduces other pathogens and their toxins or toxic metabolites.

- **Examples of lethality process:**
  - Cooking
  - Fermenting
  - Salt curing
  - Drying

Focus of 2021 Cooking Guideline
Biological Hazards of Concern During Cooking

• The following hazard is present in raw products whose outgrowth during the heating come-up time of cooked products should be controlled:
  • *Staphylococcus aureus* (*S. aureus*)

• The following are hazards present in raw products that the lethality treatment should be designed to destroy:
  
  • *Salmonella*
  • Shiga toxin-producing *Escherichia E. coli* (STEC) (in beef)
  • *Campylobacter* (in poultry)
  • *Listeria monocytogenes* (*Lm*)
  • *Trichinae spiralis* and *Toxoplasma gondii* (in pork, especially feral or non-confinement raised swine)

**NOTE:** Although all of these hazards are a concern, *Salmonella* is considered an indicator of lethality because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 732).
Regulatory Performance Standards for Certain Cooked Products

• Roast, cooked, and corned beef at least a 6.5-log *Salmonella reduction* per 9 CFR 318.17(a)(1).*

• Cooked uncured meat patties at least a 5.0-log *Salmonella reduction* per 9 CFR 318.23.

• Cooked poultry products at least a 7-log *Salmonella reduction* per 9 CFR 381.150(a)(1).*

*or achieve an alternative lethality (see later slides)
2021 Cooking Guideline

• This guideline includes information on:

  • Biological hazards during cooking.

  • Regulatory requirements associated with the safe production of cooked ready-to-eat (RTE) products.

  • Options establishments can use to achieve lethality of *Salmonella* and other pathogens.

  • Processes that do not have validated research available (referred to as “scientific gaps”) and options establishments can use until research is available.

  • Resources for alternative support (Attachment A1).

  • Recommendations for evaluating cooking deviations (Attachment A2).
2021 Cooking Guideline – Summary of Changes

• Specifies those products that are covered by the guidance and those that are not.

• Includes the food safety significance of the relative humidity recommendation.

• Specifies relative humidity should be addressed for all cooked products unless establishment can support it does not need to be addressed.

• Provides additional resources for selecting a relative humidity option (options have not changed).

• Provides more information about situations when relative humidity does not need to be addressed (including that natural casings maintain relative humidity)

• Includes critical operational parameters from 1999 guidance for products included in a scientific gap.

• Provides more details for evaluating heating deviations.
• Guideline addresses lethality of pathogens (e.g., *Salmonella*) in meat and poultry products by heat treatment (cooking) including for products that are cooked to lethality but classified under a not-ready-to-eat HACCP plan.

• Throughout the document references to “meat and poultry products” may be considered inclusive of meat by-products, meat food products, and poultry food products as defined in 9 CFR 301.2 and 9 CFR 381.1, unless otherwise stated.
Products NOT Covered

• Fish of the Order Siluriformes (e.g., catfish)
• Pork Rind Pellets
• Rendered Lard and Tallow*
• Dried Products Processed Under Dry Conditions
• RTE Fermented, Salt-cured, and Dried Products
• Partially heat-treated not ready-to-eat (NRTE) Products

*Establishments can continue to support rendered lard and tallow that is hot-filled at 160°F or higher is not post-lethality exposed per FSIS’ Listeria Guideline.
Critical Operating Parameters for Cooking All Meat and Poultry Products
Critical Operating Parameters for Cooking All Meat and Poultry Products

- Internal Endpoint Temperature + Hold Time
- Heating Come-Up-Time (CUT): Time product is between 50 – 130 °F
Heating Come-up Time (CUT)

• Refers to time product is between 50 – 130 °F while heating.

• Time should be limited to control outgrowth of hazards such as *Staphylococcus aureus*.

• The amount time depends on the scientific support. Options include:
  • 2021 Guideline recommends ≤6 Hours.
  • Custom time using alternative support (e.g. Therm 2.0, DMRI Staph Tox Model).
  • 2021 Scientific Gap: Ham and Brisket are examples of products with long heating come-up times that may use the 1999 Appendix A critical operational parameters in the 2021 guideline as scientific support for not addressing come-up-time.
Internal Endpoint Temperature + Hold Time

• Internal endpoint temperature and hold time will depend on the scientific support.

Time-Temperature Combinations for Meat (6.5/7-log)

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<tr>
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5-log Table

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Times for given temperature and fat level of Turkey needed to obtain 7-log lethality of Salmonella

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Times for given temperature and fat level of Chicken needed to obtain 7-log lethality

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Internal Endpoint Temperature + Hold Time: Monitoring

• Cooking procedures should be designed to ensure all products in a batch or lot achieve lethality.

• Monitoring procedures should be designed to detect a deviation when it occurs.

• Establishments should carefully consider the selection of the critical limit, as well as the design of their monitoring procedures.

• Lessons learned from several recalls attributed, in part, to insufficient monitoring procedures are included in the guideline.
Relative humidity promotes lethality on the product surface in two ways:

- Reduces surface evaporation from the product during heating (evaporative cooling).
- Keeps the product surface (and any pathogens) wet which prevents product drying.
When you get too hot, you produce sweat... when that sweat evaporates... it cools you down.

Evaporation = Cooling
More Humidity = Less Cooling

Dry Heat = Cooling Down
### Appendix A

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### 5-log Table

**FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks (5-log Table)**

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**Step 1:** **Select Time/Temperature**

### Poultry

#### Times for given temperature and fat level of Turkey needed to obtain 7-log lethality of Salmonella*

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<td>28.7 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>142</td>
<td>61.2</td>
<td>16.8 min</td>
<td>17 min</td>
<td>18 min</td>
<td>19.5 min</td>
<td>20.6 min</td>
<td>21.6 min</td>
<td>22.8 min</td>
<td>24.2 min</td>
<td>25.7 min</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Times for given temperature and fat level for Chicken needed to obtain 7-log lethality of Salmonella*

<table>
<thead>
<tr>
<th>Degrees Fahrenheit</th>
<th>Degrees Centigrade</th>
<th>1% fat</th>
<th>2% fat</th>
<th>3% fat</th>
<th>4% fat</th>
<th>5% fat</th>
<th>6% fat</th>
<th>7% fat</th>
<th>8% fat</th>
<th>9% fat</th>
<th>10% fat</th>
<th>11% fat</th>
<th>12% fat</th>
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<tbody>
<tr>
<td>136</td>
<td>57.8</td>
<td>64.5 min</td>
<td>65.7 min</td>
<td>67 min</td>
<td>68.4 min</td>
<td>69.9 min</td>
<td>71.4 min</td>
<td>73 min</td>
<td>74.8 min</td>
<td>76.7 min</td>
<td>78.9 min</td>
<td>81.4 min</td>
<td></td>
</tr>
<tr>
<td>137</td>
<td>58.3</td>
<td>51 min</td>
<td>52.1 min</td>
<td>53.2 min</td>
<td>54.3 min</td>
<td>55.5 min</td>
<td>56.8 min</td>
<td>58.2 min</td>
<td>59.7 min</td>
<td>61.4 min</td>
<td>63.1 min</td>
<td>65.5 min</td>
<td></td>
</tr>
<tr>
<td>138</td>
<td>58.9</td>
<td>41 min</td>
<td>42.5 min</td>
<td>43.9 min</td>
<td>44.8 min</td>
<td>45.3 min</td>
<td>46.4 min</td>
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<td>50.9 min</td>
<td>53.9 min</td>
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<tr>
<td>139</td>
<td>59.4</td>
<td>32.9 min</td>
<td>33.6 min</td>
<td>34.4 min</td>
<td>35.2 min</td>
<td>36.2 min</td>
<td>37.2 min</td>
<td>38.3 min</td>
<td>39.6 min</td>
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<tr>
<td>140</td>
<td>60.0</td>
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<td>27.5 min</td>
<td>28.2 min</td>
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<td>30.8 min</td>
<td>32 min</td>
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<tr>
<td>141</td>
<td>60.6</td>
<td>21.5 min</td>
<td>22.6 min</td>
<td>23.2 min</td>
<td>24 min</td>
<td>24.8 min</td>
<td>25.9 min</td>
<td>27.1 min</td>
<td>28.7 min</td>
<td></td>
<td></td>
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<tr>
<td>142</td>
<td>61.2</td>
<td>18 min</td>
<td>19.5 min</td>
<td>20.6 min</td>
<td>21.6 min</td>
<td>22.8 min</td>
<td>24.2 min</td>
<td>25.7 min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step 2: Support Relative Humidity

Table 1. Critical Operating Parameters for FSIS Humidity Options

| OPTION 1: | The relative humidity of the oven is maintained by **continuously introducing steam** for **50 percent** of the cooking time or 1 hour, whichever is longer. | ≥145 °F + hold time | ≥1 hour |
| OPTION 2: | The relative humidity of the oven is maintained by a **sealed oven** for at least **50 percent** of the total cooking time or 1 hour, whichever is longer. | ≥145 °F + hold time | ≥1 hour |
| OPTION 3: | The relative humidity of the oven is maintained at **90 percent** or above for at least **25 percent** of the total cooking time or 1 hour, whichever is longer. | Any | ≥1 hour |
| OPTION 4 | The relative humidity of the oven is maintained at **90 percent** for the **entire cooking time**. | Any | Any |
Situations that do not need Relative Humidity

Inherently Maintained by Cooking Conditions

• Products ≥10 lbs., if
  • Oven temperature ≥250 °F, and
  • Appendix A time/temperature end point
• Immersion cooking
• Cook-in-bag
• Cooking in casing (including natural casings)

Direct heating methods

• Grill,
• Heating coil,
• Flame, or
• Certain rotisserie systems

Processes that match one of these exceptions do not need to monitor relative humidity as a critical operating parameter in their cooking procedure using the guidance as support.
How to use Alternative Lethality (5.0-log Options)

• Establishments may support achieving a 5.0 log reduction (instead of 6.5 log reduction) for cooked meat products, with or without a performance standard, if providing additional support.

• Examples of additional support:
  • Use source materials that have been tested or treated to reduce pathogens.
    • Received with Letters of Guarantee (LOG), or Certificate of Analysis (COA)
  • Conduct a baseline study for *Salmonella* in raw source material.
    • FSIS removed detailed recommendations since it was interpreted to apply to all establishments when it was only intended for establishments that wanted to support a lower level of pathogen reduction from cooking.
Ingredients Added Post-lethality

• Establishments must consider any potential food safety hazards at the step in the process where the non-meat ingredient is ‘received’ into the food safety system (9 CFR 417.2(a)(1)) and document any controls it needs to support its decisions (9 CFR 417.5(a)(1)) about those hazards.

• Establishments should have LOGs, COAs, or other information (e.g., sampling by the receiving establishment) to support the safety of the ingredients:
  • LOG alone would not be sufficient to support the safety of the ingredients added to the product unless they indicate how each lot of ingredients is processed, tested or otherwise treated to ensure its safety.
  • LOG would be sufficient support for the safety of pre-packaged ingredients (e.g., ketchup or mustard) that have not been associated with previous recalls or outbreaks.
Scientific Gaps

• Additional FSIS guidance that can be used as support for common cooking procedures where:
  • The Agency could not identify scientific literature as support and is seeking more research.
  • While research is being conducted, establishments can continue to use older 1999 version parameters included in the 2021 guideline as scientific support because there is insufficient evidence showing any imminent food safety concern resulting from the continued application of the older recommendations to these processes.

• These older parameters included in the gap are intended to be used as part of the scientific support for decisions in the hazard analysis (9 CFR 417.5(a)(1)).
Scientific Gaps: Vulnerabilities

- Processes have not been validated to address all hazards of concern.

- If a process deviation occurs for a process that is included as a scientific gap, it is unlikely an establishment would be able to identify adequate support for product safety without performing product testing.

- If FSIS or the establishment collects RTE sample that is positive for *Salmonella*, or the establishment is implicated in a food safety investigation related to *Salmonella* (i.e., is associated with reports of illness or outbreak), FSIS would verify, as part of the corrective actions (9 CFR 417.3), that the establishment can support inadequate lethality **was not** the root cause, if it wants to continue to use the older recommendation.

- As additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps.
Scientific Gap: Short-Time, High-Temperature Cooking (1/6)

• Products cooked for **short times at high temperatures** that cannot maintain 90% humidity per **Option 4** and do not meet the **Situations when Humidity is Not Needed** (page 31).

• **Processes that meet this gap include those in which product is:**
  - Cooked for less than 1 hour, at dry bulb oven temperatures above 212°F.

---

**1999 Parameters**
Any FSIS time-temperature guidance addressing all critical operational parameters except relative humidity.

---

NOTE: Following 1999 Parameters may lead to insufficient lethality of *Salmonella* and other pathogens of concern or excessive growth of *S. aureus*.
• Products cooked using **microwave cooking methods that are not designed** to control relative humidity.

• **Processes that meet this gap include those in which a meat or poultry product is cooked using a continuous or non-continuous microwave oven.**

**1999 Parameters**

Any FSIS time-temperature guidance addressing all critical operational parameters except relative humidity.

NOTE: Following 1999 Parameters may lead to insufficient lethality of *Salmonella* and other pathogens of concern or excessive growth of *S. aureus*. 
Scientific Gap: Other Cooking Methods (3/6)

• Products cooked using cooking methods that are not designed to control relative humidity other than microwave ovens.

• Processes that meet this gap include those where product is either:
  • Cooked in ovens that are not designed to be sealed (e.g., no dampers) and designed without a mechanism to introduce steam.
  
  Or

• Barbecue products cooked under dry heat to meet labeling requirements (e.g., 9 CFR 319.80; and 9 CFR 381.164).

1999 Parameters
Any FSIS time-temperature guidance addressing all critical operational parameters except relative humidity.

NOTE: Following 1999 Parameters may lead to insufficient lethality of Salmonella and other pathogens of concern or excessive growth of S. aureus.
• Other processes that may inherently maintain relative humidity around the meat and poultry filling but cannot follow one of the relative humidity options.

• Processes that meet this gap include those that involve:
  • Use of an edible wrapping that fully encloses a raw meat or poultry filling before cooking.
  • Example wrappings include:
    o dough,
    o leaves, and
    o edible rice paper.

NOTE: Following 1999 Parameters may lead to insufficient lethality of *Salmonella* and other pathogens of concern or excessive growth of *S. aureus*.
Scientific Gap: Drying Comes Before Cooking (5/6)

- Processes where the **drying** step comes **before cooking** under **moist conditions**.

- **Processes that meet this gap include those in which products are:**
- Dried to reduce the water activity and then cooked using one of the following options that ensures high relative humidity
  - Option 1, or
  - Option 3, or
  - Option 4, or
  - Cook-in-bag, or
  - Immersion cooking.

**1999 Parameters**
- Any FSIS time-temperature guidance addressing all critical operational parameters and use relative humidity
  - Option 1, or
  - Option 3, or
  - Option 4, or
  - Cook-in-bag, or
  - Immersion cooking.

**NOTE:** Following 1999 Parameters may lead to insufficient lethality of *Salmonella* and other pathogens of concern or excessive growth of *S. aureus*
Scientific Gap: Products with Long Heating Come-Up-Times (6/6)

Products with **long heating come-up-times (CUTs)**.

This gap applies to processes such as ham and brisket that require a:
• Heating come-up-time longer than 6 hours.

1999 Parameters
Any FSIS time-temperature guidance addressing all critical operational parameters including relative humidity without addressing CUT as a critical operational parameter.

NOTE: Following 1999 Parameters may lead to insufficient lethality of *Salmonella* and other pathogens of concern or excessive growth of *S. aureus*.
## Products NOT Covered vs Scientific Gap

<table>
<thead>
<tr>
<th>Reasons Product Can Not Follow 2021 Options</th>
<th>Products NOT Covered</th>
<th>Scientific Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reason product can not follow 2021 options</td>
<td>Research or outbreaks demonstrate FSIS guidance is insufficient to result in a safe product</td>
<td>No evidence showing any imminent food safety concern but current parameters can not be applied</td>
</tr>
<tr>
<td>FSIS Guidance Use</td>
<td>Can not use FSIS guidance as scientific support and must identify alternative support</td>
<td>Can use FSIS guidance – 2021 revision includes 1999 parameters that can be applied</td>
</tr>
<tr>
<td>Example</td>
<td>Salt-cured and dried country cured ham cooked multiple times – contributing factor in an outbreak</td>
<td>Salt-cured and dried country cured ham cooked once – FSIS guidance was not designed for this process but no evidence showing imminent concern</td>
</tr>
</tbody>
</table>
Three Common Types of Heating Deviations

1. The establishment fails to meet a time/temperature parameter in its lethality CCP for meat or poultry products,

2. The establishment fails to maintain sufficient humidity during the cooking step, or

3. Slow heating come-up time occurs which allows product to remain at between 50°F to 130°F for > 6 hours.

• Guideline **Attachment A2** has information on how to use pathogen modeling and sampling to determine product disposition.
Revised Appendix A Summary

• FSIS revised its **Cooking Guidance** in 2021 in response to public comments.

• Guidance contains time-temperature and relative humidity recommendations for cooking meat and poultry.

• Guidance specifies those products that are covered by the guidance and those that are not. It also includes older parameters for some common cooking processes that can be used until further research is conducted (scientific gaps) because there is insufficient evidence showing any imminent food safety concern.

• Establishments that utilized previous versions of Appendix A (or B) as support should either:
  • Update to the 2021 Guideline(s) or
  • **Identify alternative support by December 14, 2022.**
IPP Takeaways FSIS Cooking Guideline (Revised Appendix A)

- Per FSIS Notice 59-21, IPP are to make establishment management aware of the revised guidelines.

- FSIS will provide further instructions to IPP in an FSIS Notice before the December implementation date.

- The specific changes from the previous versions are listed on pages 6-8 of the guideline.
IPP Takeaways FSIS Cooking Guideline (Revised Appendix A)

• The options in the body of the 2021 guideline (time, temperature, relative humidity parameters) may be used as support by establishments producing RTE products to meet Element 1 of validation.

• Time, temperature, and relative humidity options from previous versions of the guideline (1999 and 2017) did not change and are included in the revision.

• Establishments are not required to follow the parameters in Appendix A and may use a customized process and alternative support.
IPP Takeaways FSIS Cooking Guideline (Revised Appendix A)

• Establishments using common cooking processes that used the 1999 version of Appendix A but can not achieve the relative humidity or heating come-up-time in the revised guidelines may be able to use a scientific gap as support for not addressing the critical operational parameter.

• There is a vulnerability with using the scientific gap as support for not addressing the critical operational parameter, but FSIS has determined there is not an imminent public health concern and that establishments can use the scientific gap as support until more research is conducted.
FSIS Stabilization Guideline (Revised Appendix B):
What is Stabilization?

• The process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product or in the human intestine after consumption.

• Stabilization processes typically include cooling and hot-holding.

• Establishments may support drying and fermentation/acidification as stabilization processes for:
  • Products with pH ≤ 4.6 before cooling, or
  • Products with water activity (aw) < 0.93 before cooling, or
  • Products with other validated pH and aw combinations
Biological hazards of concern during Stabilization

• The primary hazards of concern during cooling and hot holding are:

  • *Clostridium (C.) perfringens* and
  
  • *C. botulinum*.

https://www.cdc.gov/foodsafety/diseases/clostridium-perfringens.html
Life Cycle: Spores vs. Vegetative

- **Spores & vegetative cells**
  - **Cook**
    - **Only Spores Survive**
    - **Re-Cook**
    - **Cool Slow**
      - **Active Growth (>1 log)**
      - **potential hazard**
    - **Cool Rapid**
      - **Some Growth (<1 log), no hazard**

- **Spores**
- **Sporulating Cells**
- **Vegetative Cells**
Regulatory Performance Standards for Certain Cooked Products

- FSIS requires no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* during stabilization for:
  - RTE cooked beef, RTE roast beef, RTE cooked corned beef (*9 CFR 318.17(a)(2)*).
  - RTE uncured beef patties (*9 CFR 318.23(b)(3)(ii)(c)*).
  - RTE cooked poultry *9 CFR 381.150(a)(2)*.
  - NRTE partially cooked and char-marked meat patties, and partially cooked poultry breakfast strips (*9 CFR 318.23(c)(1)* and *9 CFR 381.150(b)*).
2021 Stabilization Guideline

• This guideline includes information on:
  
  • Biological hazards during stabilization.
  
  • Regulatory requirements associated with the safe production of stabilized heat treated and partially heat-treated products.
  
  • Options establishments can use to prevent the growth of *C. perfringens* and other pathogens.
  
  • Processes that do not have validated research available (Scientific Gaps), and options establishments can use until research is available.
  
  • Recommendations for evaluating cooling deviations.
  
  • Resources for alternative support.
• Specifies those products that are covered by the guidance and those that are not.

• Clearly delineates which cooling options may be used for products with a full lethality and which may be used for partially heat treated products.

• Added additional cooling options for certain formulated products.

• Provides journal articles for processes like bacon and scrapple.

• Includes critical operational parameters from older guidance for products included in a scientific gap.

• Better describes steps for evaluating cooling deviations.
Critical Operating Parameters for Cooling

- Pre-Cooling Conditions
- Time
- Temperature
FSIS Cooling Options for Products Cooked to Full Lethality: Table 1

<table>
<thead>
<tr>
<th>Option</th>
<th>Pre-Cooling Conditions</th>
<th>1st stage of cooling (temperature reduction/time)</th>
<th>2nd stage part of cooling (temperature reduction/time)</th>
<th>Total cooling time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1.1</td>
<td>Chilling must begin within 90 minutes after the cooking cycle is complete</td>
<td>130 to 80 °F ≤ 1.5 hours</td>
<td>80 to 40 °F ≤ 5 hours</td>
<td>≤ 6.5 hours</td>
</tr>
<tr>
<td>Option 1.2</td>
<td>≥ 100 ppm sodium nitrite* + ≥ 250 ppm sodium ascorbate or erythorbate</td>
<td>120 to 80 °F ≤ 1 hour</td>
<td>80 to 55 °F ≤ 5 hours; Continuous chilling until 40 °F</td>
<td>≤ 6 hours</td>
</tr>
<tr>
<td>Option 1.3</td>
<td>130 to 80 °F ≤ 5 hours</td>
<td>80 to 45 °F ≤ 10 hours</td>
<td>≤ 15 hours</td>
<td></td>
</tr>
<tr>
<td>Option 1.4</td>
<td>≥ 40 ppm sodium nitrite** + ≥ 6% brine concentration OR Aw ≤ 0.92</td>
<td>120 to 40 °F ≤ 20 hours; Continuous temperature drop</td>
<td>NA</td>
<td>≤ 20 hours</td>
</tr>
</tbody>
</table>

*Note: Full lethality can be achieved by following options in FSIS Revised Appendix A or alternative support. If Appendix A is used, establishments must address all critical operational parameters including relative humidity or provide justification.
FSIS Cooling Options for Products Cooked to Full Lethality: Table 1

<table>
<thead>
<tr>
<th>Option</th>
<th>Pre-Cooling Conditions</th>
<th>1st stage of cooling (temperature reduction/time)</th>
<th>2nd stage part of cooling (temperature reduction/time)</th>
<th>Total cooling time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1.1</td>
<td></td>
<td>130 to 80 °F ≤ 1.5 hours</td>
<td>80 to 40 °F ≤ 5 hours</td>
<td>≤ 6.5 hours</td>
</tr>
<tr>
<td>Option 1.2</td>
<td>Chilling must begin within 90 minutes after the cooking cycle is complete</td>
<td>120 to 80 °F ≤ 1 hour</td>
<td>80 to 55 °F ≤ 5 hours; Continuous chilling until 40 °F</td>
<td>≤ 6 hours</td>
</tr>
<tr>
<td>Option 1.3</td>
<td>≥ 100 ppm sodium nitrite* + ≥ 250 ppm sodium ascorbate or erythorbate</td>
<td>130 to 80 °F ≤ 5 hours</td>
<td>80 to 45 °F ≤ 10 hours</td>
<td>≤ 15 hours</td>
</tr>
<tr>
<td>Option 1.4</td>
<td>≥ 40 ppm sodium nitrite** + ≥ 6% brine concentration OR Aw ≤ 0.92</td>
<td>120 to 40 °F ≤ 20 hours; Continuous temperature drop</td>
<td>NA</td>
<td>≤ 20 hours</td>
</tr>
</tbody>
</table>

Intention is for chilling to begin whichever happens first: 90 minutes is over or product reaches 120°F.

Gray boxes are parameters that changed from the 1999 version of Appendix B or are new.
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<table>
<thead>
<tr>
<th>Option</th>
<th>Critical Operating Parameters</th>
<th>Pre-Cooling Conditions</th>
<th>1st stage of cooling (temperature reduction/time)</th>
<th>2nd stage part of cooling (temperature reduction/time)</th>
<th>Total cooling time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1.5</td>
<td></td>
<td></td>
<td>130 to 80°F</td>
<td>80 to 40°F ≤ 5 hours</td>
<td>≤ 7 hours</td>
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<tr>
<td>Option 1.6</td>
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<td></td>
<td>126 to 80°F ≤ 1.75 hours</td>
<td>80 to 55°F ≤ 4.75 hours; chilling until 40°F</td>
<td>≤ 6.5 hours</td>
</tr>
<tr>
<td>Option 1.7</td>
<td>pH ≤ 6.0</td>
<td></td>
<td>126 to 80°F ≤ 2.25 hours</td>
<td>80 to 55°F ≤ 3.75 hours; Continuous</td>
<td>≤ 6 hours</td>
</tr>
</tbody>
</table>
Cooling Options for Products that Do NOT Receive a Full Lethality: Table 2

<table>
<thead>
<tr>
<th>Option 2.1</th>
<th>Option 2.2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-Cooling Conditions</strong></td>
<td><em><em>Come-up time between 50 to 130 °F ≤ 3 hours; ≥ 2% salt; ≥ 150 ppm sodium nitrite</em> + cure accelerator or natural source of ascorbate (sufficient for purpose)</em>*</td>
</tr>
<tr>
<td><strong>1st stage of cooling</strong></td>
<td><strong>Come-up time between 50 to 130 °F ≤ 1.5 hours</strong></td>
</tr>
<tr>
<td>130 to 80 °F ≤ 1.5 hours</td>
<td>130 to 80 °F ≤ 1.5 hours</td>
</tr>
<tr>
<td><strong>2nd stage of cooling</strong></td>
<td><strong>80 to 40 °F ≤ 5 hours</strong></td>
</tr>
<tr>
<td>80 to 40 °F ≤ 5 hours</td>
<td>80 to 40 °F ≤ 5 hours</td>
</tr>
<tr>
<td><strong>Total cooling time</strong></td>
<td><strong>≤ 6.5 hours</strong></td>
</tr>
</tbody>
</table>

Gray boxes are parameters that changed from the 1999 version of Appendix B or are new.

Revised Appendix B
Pre-Cooling Conditions

• Critical operational parameters that must be met in order to follow the Option (9 CFR 417.5(a)(1)).

• Intent is that these parameters are met “pre-cooling” but logistically some parameters may be monitored at different points.

• For example:
  • Nitrite and ascorbate/erythorbate levels may be calculated based on the “ingoing” formulated amount.
  • Brine concentration is calculated from the total salt content and total water content values obtained by a lab analysis of cooked and cooled product.
  • pH must be monitored after cooking prior to cooling or the establishment must support how the monitoring location represents the pH “pre-cooling”.
Policy Clarifications in Revision

• Better clarified that products that are fully cooked but reclassified to be NRTE can follow any option.

• Clarified that temperatures referred to in Tables 1 and 2 are internal product temperatures. However, establishments may provide support for monitoring surface temperatures of intact products (such as beef brisket or a picnic shoulder that is not injected or vacuum tumbled).

• Clarified that if a process incorporates multiple full lethality treatments (i.e., by achieving FSIS Cooking Guideline conditions), the establishment needs to assess the growth of Clostridia during the cooling step following each individual lethality treatment and does not need to assess the cumulative growth over the multiple steps.
Alternative Cooling Options for Specific Products

**Bacon:** Taormina and Bartholomew (2005)
- Products with a 6-hour heating come up time could be safely cooled from 120°F to 80°F in 5 hours and 80°F to 45°F in 10 hours (15 hours total cooling time)
- Must achieve specific formulation critical operating parameters

**Scrapple:** Juneja et al. (2010)
- Two cooling schedules for pork scrapple cooked to ≥ 200°F for ≥ 20 minutes (12.0 hours and 14.0 hours total cooling time)
- Must achieve specific formulation critical operating parameters
# Summary of Options for Bacon

<table>
<thead>
<tr>
<th>Partially heat-treated (NRTE)</th>
<th>Cooked to fully lethality (RTE or NRTE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article: Taormina and Bartholomew (2005)</td>
<td>Appendix B Table 1 Option 1.3</td>
</tr>
<tr>
<td>Appendix B FSIS Scientific Gap 2</td>
<td>Appendix B FSIS Scientific Gap 3</td>
</tr>
</tbody>
</table>

**Appendix B Scientific Gap 4** addresses immersion or dry-cured products

*Establishments producing bacon must also consider permitted uses for nitrite and ascorbate or erythorbate in 9 CFR 424.22 and natural sources of these ingredients in FSIS Directive 7120.1.*
### Partially heat-treated (NRTE)

**Article:** Taormina and Bartholomew (2005)
Products with a 6-hour heating come up time could be safely cooled from 120°F to 80°F in 5 hours and 80°F to 45°F in 10 hours (15 hours total cooling time).

Must achieve specific formulation critical operating parameters.

### Cooked to fully lethality (RTE or NRTE)

Apply a time-temperature and **relative humidity option** listed in the Cooking Guideline and apply cooling Option 1.3.

Under Option 1.3, product is cooled:
- From 130°F to 80°F in ≤ 5 hours;
- From 80°F to 40°F in ≤ 10 hours; and
- To 40°F ≤ 15 hours total.

Applies to products that contain at least 100 ppm nitrite (synthetic or natural), and at least 250 ppm erythorbate or ascorbate (synthetic or natural).*

### Appendix B FSIS Scientific Gap 2:
Apply Option 1.3 with **no CUT parameter**.

Under Option 1.3, product is cooled:
- From 130°F to 80°F in ≤ 5 hours;
- From 80°F to 40°F in ≤ 10 hours; and
- To 40°F ≤ 15 hours total.

Applies to products that are **smoked**, contain at least 100 ppm nitrite (synthetic or natural), and at least 250 ppm erythorbate or ascorbate (synthetic or natural).*

### Appendix B FSIS Scientific Gap 3:
Apply a time-temperature listed in the Cooking Guideline **without addressing relative humidity** and apply cooling Option 1.3.

Applies to products that contain at least 100 ppm nitrite (synthetic or natural), and at least 250 ppm erythorbate or ascorbate (synthetic or natural).*

*Appendix B Scientific Gap 4 addresses immersion or dry-cured products that contain nitrate and/or nitrite and use of equilibration time instead of erythorbate or ascorbate but cannot meet cooling options without nitrite in Table 1 or Table 2.
Policy Clarifications Continued

• Removed discussion of waiver option for 2-log growth.

• Clarified use of natural sources of nitrite and ascorbate.
Natural Sources of Nitrite

• Not considered a “curing agent” but this is a labeling distinction.

• Some sources such as cultured celery powder are used as antimicrobials (along with natural sources of ascorbate) and may be used to meet Option 1.3. These are listed in FSIS Directive 7120.1.

• FSIS recommends that establishments use natural sources of nitrite containing pre-converted nitrite because the quantity of nitrite in these sources is known. When using pre-converted nitrite, establishments should:
  
  • Request information from their supplier regarding the nitrite level in each lot of product (for example by receiving a COA) and calculate the amount of the natural source needed to achieve the appropriate nitrite concentration from each lot as it will vary; or
  
  • Receive formulation information from their supplier if the concentration is standardized from lot to lot.
Scientific Gaps

• Additional FSIS guidance that can be used as support for common cooling procedures where:
  • The Agency could not identify scientific literature as support and is seeking more research.
  • While research is being conducted, establishments can continue to use older 1999 version parameters included in the 2021 guideline as scientific support because there is insufficient evidence showing any imminent food safety concern resulting from the continued application of the older recommendations to these processes.

• These older parameters included in the gap are intended to be used as part of the scientific support for decisions in the hazard analysis (9 CFR 417.5(a)(1)).
Scientific Gaps: Vulnerabilities

- Processes have not been validated to address all hazards of concern.

- If a process deviation occurs for a process that is included as a scientific gap, it is unlikely an establishment would be able to identify adequate support for product safety without performing product testing.

- If FSIS or the establishment collects a RTE sample that is positive for a pathogen, or the establishment is implicated in a food safety investigation (i.e., is associated with reports of illness or outbreak), FSIS would verify, as part of the corrective actions (9 CFR 417.3), that the establishment can support inadequate stabilization was not the root cause, if it wants to continue to use the older recommendation.

- As additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps.
Scientific Gap: Large Mass, Non-intact products (1/6)

• Large mass non-intact products that cannot cool quickly enough to follow the revised options.

• **Processes that meet this gap include those in which product is:**
  
  • Cooked to full lethality.

  • Non-intact (intact products may cool based on surface temperature).

  • Large product size or weight (> 4.5 inches or > 8 pounds)

**Parameters**

Cooling begins within 90 minutes after the cooking cycle is complete. Cooling occurs from 120 to 55°F in ≤ 6 hours. Continuous cooling until 40°F.

NOTE: Following 1999 Parameters may lead to excessive growth of *C. perfringens*
Scientific Gap: Partially heat-treated, smoked with nitrite erythorbate/ascorbate (2/6)

- Partially heat-treated, smoked products that contain nitrite and erythorbate/ascorbate and have long come up times and cooling times.

- **Processes that meet this gap include those in which product is:**
  - Partially heat-treated.
  - Smoked.
  - Sufficient nitrite and erythorbate/ascorbate per the gap.

**Older Parameters**

130 to 80°F in ≤ 5 hours and 80 to 40°F in ≤ 10 hours, with 15 hours total.

No CUT parameter.

NOTE: Following 1999 Parameters may lead to excessive growth of *C. perfringens*
Scientific Gap: Smoked bacon cooked without humidity (3/6)

- Smoked bacon that contains nitrite and erythorbate/ascorbate but cannot use option 1.3 because the product was not cooked with humidity.

- **Processes that meet this gap include those in which product is:**
  - Cooked to lethal time and temperature but humidity option not addressed.
  - Sufficient nitrite and erythorbate/ascorbate per the gap.

**Older Parameters**

130 to 80°F in ≤ 5 hours and 80 to 40°F in ≤ 10 hours, with 15 hours total.

No CUT parameter.

NOTE: Following 1999 Parameters may lead to excessive growth of *C. perfringens*
Scientific Gap: Immersion or Dry Cured Products (4/6)

- Dry-cured products that contain nitrate and/or nitrite and use equilibration time instead of ascorbate or erythorbate.

- Processes that meet this gap include those in which product is:
  - Fully or partially heat treated.
  - Immersion or dry-cured.
  - Sufficient nitrite and or nitrate per the gap.
  - Minimal equilibration time (at least 2-3 days).

**Older Parameters**

130 to 80°F in ≤ 5 hours and 80 to 40°F in ≤ 10 hours, with 15 hours total.

**NOTE:** Following 1999 Parameters may lead to excessive growth of *C. perfringens*
Scientific Gap: Cured products with Low Brine (5/6)

• Products that contain nitrite and use equilibration time instead of a cure accelerator, but do not have a brine concentration >6%.

• **Processes that meet this gap include those in which product is:**
  • Any heat treatment.
  • Pumped with nitrite or nitrate.
  • Brine concentration >3.5% (but<6%).
  • Minimal equilibration time (at least 2-3 days).

**Older Parameters**
120 to 40°F ≤ 20 hours; Continuous temperature drop.

NOTE: Following 1999 Parameters may lead to excessive growth of *C. perfringens*
Scientific Gap: Scalded Offal (6/6)

- Scalded offal that cannot cool quickly enough to follow the new options.

- **Processes that meet this gap include those in which product is:**
  
  - Edible offal which is partially heat treated or scalded.

**Parameters**
Product chilled to 45 F in < 24 hours.

NOTE: Following these Parameters may lead to excessive growth of *C. perfringens*
# Products NOT Covered vs Scientific Gaps

<table>
<thead>
<tr>
<th>Products NOT Covered</th>
<th>Scientific Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reason product can not follow 2021 options</td>
<td>Can not use FSIS guidance as scientific support and must identify alternative support</td>
</tr>
<tr>
<td>FSIS Guidance Use</td>
<td>Can not use FSIS guidance as scientific support and must identify alternative support</td>
</tr>
<tr>
<td>Example</td>
<td>Fish of the Order Siluriformes</td>
</tr>
</tbody>
</table>
Cooling Deviations

• Guideline has information on how to use pathogen modeling to assess a cooling deviation and recommended criteria for assessing results.

• Guideline also has information on using sampling and recooking to support product disposition.
Cooling Deviations

- Guideline has information on how to use pathogen modeling to assess a cooling deviation and recommended criteria for assessing results:

  - If there is no more than $1.0 \log_{10}$ growth of \textit{C. perfringens} and no \textit{C. botulinum} growth (mean net growth $\leq 0.30 \log_{10}$), then the process meets the stabilization performance standard or policy and the product can be released.

  - If there is more than a $1.0 \log_{10}$ growth of \textit{C. perfringens}, no \textit{C. botulinum} growth (mean net growth $\leq 0.30 \log$) then product may be either:
    - Recooked, or
    - Microbiologically tested ($N \geq 10$), or
    - Destroyed

  - If there is greater than a $1.0 \log_{10}$ growth of \textit{C. perfringens} and greater than a $0.30 \log_{10}$ increase of \textit{C. botulinum}, then the product should be destroyed.
Revised Appendix B Summary

• FSIS revised its Stabilization Guidance in 2021 in response to public comments.

• Guidance contains critical operating parameters for hot holding and stabilization and updated pathogen modeling guidance for deviations.

• Guidance specifies those products that are covered by the guidance and those that are not. It also includes older parameters for some common cooling processes that can be used until further research is conducted (scientific gaps) because there is insufficient evidence showing any imminent food safety concern.

• Establishments that utilized previous versions of Appendix B (or A) as support should either:
  • Update to the 2021 Guideline(s) or
  • Identify alternative support by December 14, 2022
IPP Takeaways FSIS Stabilization Guideline (Revised Appendix B)

• The options in the body of the 2021 guideline (time, temperature, pre-cooling conditions) may be used as support by establishments producing products cooked to lethality and heat-treated products to meet Element 1 of validation.

• Cooling options from previous versions of the guideline (1999 and 2017) and the cancelled Directive 7110.3 are included in the revision. There are some changes to the original options and several new options have been added.

• Establishments are not required to follow the parameters in Appendix B and may use a customized process and alternative support.
IPP Takeaways FSIS Stabilization Guideline (Revised Appendix B)

- Establishments using common cooling processes that used the 1999 version of Appendix B but can not achieve the heating come-up-time for partially heat-treated products, cooling time-temperature, or pre-cooling conditions in the revised guidelines may be able to use a scientific gap as support for not addressing the critical operational parameter.

- There is a vulnerability with using the scientific gap as support for not addressing the critical operational parameter, but FSIS has determined there is not an imminent public health concern and that establishments can use the scientific gap as support until more research is conducted.
IPP Takeaways

• Per Notice 59-21, IPP are to refer questions to their supervisor or as needed to the Office of Policy and Program Development through askFSIS and select **HACCP Deviations & HACCP Validation** as the Inquiry Type or by telephone at **1-800-233-3935**.

• Establishments can also submit questions through askFSIS using the same Inquiry Type.

https://www.fsis.usda.gov/contact-us/askfsis
fsis.usda.gov

fsis.usda.gov/contact-us/askfsis
Scientific Gaps: Updates and Next Steps
Scientific Gaps

• FSIS posted research priorities on its website to communicate scientific gaps with USDA Agricultural Research Service (ARS) and academic researchers.

• FSIS has an Interagency Agreement with ARS to complete several studies including:
  • Determining lethality of *Listeria monocytogenes* and *Salmonella* in low water activity cured meat products such as country cured hams and
  • Identifying acceptable lethality treatments for baked goods that contain raw meat and poultry components.

• As additional data becomes available, FSIS will update the recommendations for these scientific gaps with the latest available scientific support.
C. *perfringens* Market Basket Survey

- Between May and September 2021, FSIS conducted a study to assess levels of *C. perfringens* in federally inspected RTE large mass non-intact meat and poultry products sold at retail locations.

- Samples were collected at retail locations and analyzed by Food Emergency Response Network (FERN) laboratories.

- Results are being analyzed by FSIS and will be used to assess whether changes are needed to the cooling recommendations in Appendix B for these products, or if a larger, more comprehensive study is needed.
Research Priorities

Food Safety Research Priorities & Studies

The Food Safety and Inspection Service (FSIS) has developed a listing of the top food safety research areas of interest. FSIS has also identified key data gaps and laboratory methods that are needed to fulfill our mission.