FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021

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This guideline provides information on the Agency regulatory requirements associated with safe production of ready-to-eat (RTE) products with respect to the destruction of *Salmonella* and other pathogens. It applies to small and very small meat and poultry official establishments although all meat and poultry establishments may apply the recommendations in this guideline. It relates to 9 CFR 318.17(a)(1), 9 CFR 318.23, 381.150(a)(1), and 9 CFR 417.

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Table of Contents

Preface *4*
Purpose of this Guideline 4
History of this Guideline and Reason for Reissuance 5
Changes from the Previous Versions 6
How to Effectively Use this Guideline 8
Questions Regarding Topics in this Guideline 9
Background *10*
What is Lethality? 10
Products and Processes Covered by this Guideline 10
Products and Processes Not Covered by this Guideline 11
Biological Hazards of Concern During Cooking 13
General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking *18*
Addressing Lethality in the HACCP System 18
Alternative Lethality 20
Monitoring, Calibration, and Recordkeeping 20
Corrective Actions under HACCP Cooking Deviations 22
FSIS Critical Operating Parameters for Cooking *23*
Come-Up-Time (CUT) 23
Relative Humidity 25
Table 1. Critical Operating Parameters for FSIS Humidity Options 26
Relative Humidity Resources 28
Situations when Humidity is Not Needed 31
Endpoint Time-Temperature 34
Table 2. Time-Temperature Combinations for Meat Products to Achieve Lethality 35
Additional Critical Operating Parameters for Poultry Products 36
Table 3. Time-Temperature Combinations for Chicken Products to Achieve Lethality 37
Table 4. Time-Temperature Combinations for Turkey Products to Achieve Lethality 38
Resources for Customized and Alternative Support *40*
Scientific Gaps Identified by FSIS *41*
Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used 43
References *49*
Attachment A1. Customized Processes and Alternative Lethality Support *55*

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Supporting an Alternative Lethality Target (*e.g.,* 5-Log) 57
Table 6. Time-Temperature Combinations for Meat Products to Achieve a 5-Log Reduction 59
Predictive Microbial Modeling to Support CUT 62
Designing Challenge Studies for Cooking 63
Attachment A2. Cooking Deviations 66
Corrective Actions to Perform When a Cooking Deviation Occurs 66
Type 1. Missed Endpoint Time-Temperature 67
Type 2. Insufficient Humidity During Cooking 69
Type 3. Long Heating CUT 70
Predictive Microbial Modeling 72
Product Testing 77
Table 7. FSIS Recommendations for Product Sampling and Testing After Each Type of Cooking Deviation to Determine Product Disposition 77
Disposition after Testing Results 79
Attachment A3. When can Products be Labeled as Pasteurized? 81
Attachment A4. Sources of Salmonella Contamination in RTE Products and Best Practices to Address It 82
Under-Processing 82
Cross-Contamination 82
Ingredients Added After the Lethality Treatment 84
Food Handlers 86
Animals 86
Attachment A5. RTE Salmonella Self-Assessment Tool 87
Attachment A6. Cooking Country-Cured Hams 90

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Preface

This is a revised version of the *FSIS Cooking Guideline for Meat and Poultry Products* (Revised Appendix A). It has been updated in response to comments received on the previous version and renamed. In addition, the guideline has been revised to include recommendations from previous versions and new updates based on up-to-date science. The guideline also includes changes to improve its readability.

This guideline represents FSIS's current thinking on these topics. Establishments that utilized previous versions of Appendix A as support should either:

- Update to this 2021 FSIS Cooking Guideline (Revised Appendix A) or
- Identify alternative support **by December 14, 2022**.

The information in this guideline is provided to assist meat and poultry establishments in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. Under the regulations, meat and poultry establishments may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how those procedures are effective.

This guideline is focused on small and very small plants in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all meat and poultry establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazards Analysis and Critical Control Point (HACCP) systems. Although large plants can benefit from the information, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them.

Purpose of this Guideline

This guideline contains information to assist meat and poultry establishments producing products that undergo cooking in complying with the HACCP regulatory requirements in 9 CFR 417. 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.

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- 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.

- Recommendations for evaluating cooking deviations.

Establishments can always seek guidance from State university extension service specialists and HACCP Coordinators on developing programs and plans not provided in this guideline to comply with HACCP regulatory requirements.

History of this Guideline and Reason for Reissuance

In the 1970s and 1980s, FSIS included prescriptive time, temperature, and humidity operating parameters in the regulations for cooked beef, roast beef, and cooked corned beef (42 FR 44217; 47 FR 31854; 48 FR 24314) in response to several outbreaks associated with these products and research performed to determine how to prepare them safely. When the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) final rule published in 1996, FSIS eliminated the prescriptive cooking regulations and replaced them with performance standards requiring a 6.5-Log reduction in *Salmonella* or alternative lethality for roast beef, cooked beef, and corned beef, minimum internal temperature and holding times for fully cooked patties that achieve a 5-Log reduction in *Salmonella*, and a 7-Log reduction in *Salmonella* or alternative lethality for poultry products (9 CFR 318.17(a)(1), 9 CFR 318.23, 9 CFR 381.150(a)(1); see General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18. FSIS converted these former regulations to "Safe Harbors" in an appendix to the final rule called Appendix A (64 FR 732). Establishments have been using FSIS's Appendix A, as published in 1999, as support for cooking processes for many years. The original requirements and subsequent guidance have been important to prevent human illness outbreaks and ensure the production of safe food. See General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18 for more information on the current regulatory requirements.

Over time, FSIS determined that some of its recommendations in the 1999 version of Appendix A were vague, putting establishments at risk of producing unsafe products. Additionally, some elements of the 1999 version of Appendix A were misunderstood or overlooked, resulting in FSIS guidance being applied in ways that increased food safety risks to consumers and potential risks to industry, including the risk of foodborne illness outbreaks. FSIS also determined establishments were broadly applying the recommendations for operating parameters in Appendix A beyond those meat and poultry products it was originally designed to support.

To provide the needed updates and clarifications, FSIS issued revisions of both its Cooking (Appendix A) and Stabilization (Appendix B) guidelines in 2017. The 2017 version of the guidelines took into account new and emerging technologies, processes, and science. FSIS has updated this guideline in response to comments received on the 2017 version and has included additional options for cooking support based on updated

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science and technology. **The Agency is releasing this current 2021 version of the *FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)* to replace all previous versions.**

Changes from the Previous Versions

This guideline dated December 14, 2021 is final. FSIS will update this guideline, as necessary, should new information become available.

FSIS made the following changes to this guideline to reflect the comments received on the previous version during the comment period and to include additional scientific information.

For Appendix A, FSIS made changes to specify:

- The following products are not covered by the guideline (page 11): Fish of the Order Siluriformes, pork rind pellets, rendered lard and tallow, dried products processed under dry conditions, partially heat-treated NRTE products, and RTE multi-hurdle products.

- The food safety significance of FSIS's recommendations for relative humidity (page 17).

- That relative humidity should be addressed for all cooked products (including poultry) unless the establishment can support that humidity does not need to be addressed. FSIS has not changed the relative humidity options (page 26) other than re-emphasizing that they apply to all products.

- Additional resources for selecting a relative humidity option when following FSIS's cooking guidance (page 28).

- The situations when relative humidity does not need to be addressed including by providing more information about situations considered to be direct heating (page 31) (*e.g.,* by clarifying that relative humidity does not need to be addressed for meat patties cooked using FSIS's time-temperature table for meat, if the patties are cooked using direct heat (on page 31)). Previous guidance indicated it did not need to be addressed for meat patties with the assumption all meat patties are cooked using direct heat which is no longer the case.

- That natural casings become semipermeable during cooking, maintaining moisture in the product, so that additional documentation to address relative humidity is not needed (page 33).

- More detailed information for evaluating product safety following a heating deviation (page 66). The revision also removes the recommendation for using the ComBase model for *Staphylococcus aureus* growth (which was not validated)

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because of the development and validation of the Danish Meat Research Institute (DMRI) Staphtox model in 2018.

- Where gaps exist, recommendations from its older cooking guidance can be used until research is completed (see, Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used, page 43) for:

    1. Products cooked for **short times at high temperatures.**

    2. Products cooked using **microwave cooking methods that are not designed** to control relative humidity.

    3. Products cooked using **cooking methods that are not designed** to control relative humidity.

    4. Other processes **that may inherently maintain relative humidity** around the meat and poultry filling but cannot follow one of the relative humidity options.

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

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

- That information is included about a listeriosis outbreak associated with a cooked country-cured ham product and recommendations for establishments that cook a similar product once (page 90).

For Appendix A, FSIS removed:

- Information about how establishments could remove poultry rolls from the cooking medium before product has achieved the target endpoint temperature and immediately apply another heating or processing method (64 FR 732). Since FSIS has clarified that limiting heating CUT is a critical operating parameter for applying any of FSIS cooking guidance (including these older options), the parameter to "immediately fully cook" poultry rolls subject to multiple heating mediums and processes has been removed.

- Specific recommendations for conducting a *Salmonella* baseline study on raw source materials as support for using cooking critical operating parameters that achieve a 5-Log reduction in *Salmonella* for meat products instead of a 6.5 or 7-Log reduction. This information was removed 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. In addition, FSIS is not aware of any establishments that have pursued such baseline sampling.

In addition to these changes, the guidelines format was restructured to make it easier to use as described in the next section. This list of changes is not comprehensive, so

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establishments should read the section titled FSIS Critical Operating Parameters for Cooking and other relevant sections as needed.

How to Effectively Use this Guideline

As explained above in the Changes from the Previous Versions, the guidelines format was restructured to make it easier to use. Specifically, the guideline is organized to include the following topics in the body of the guideline:

- 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.

Information included in the body of the guideline is intended as scientific support that can be used alone by establishments to meet Element 1 of validation (9 CFR 417.4(a)(1)) and to support decisions in the hazard analysis (9 CFR 417.5(a)(1)).

The following topics are included in attachments to the guideline:

- Resources for alternative support and
- Recommendations for evaluating cooking deviations.

Information provided in the attachments is not sufficient to use as sole support and additional documentation is needed. For example, Attachment A1. Customized Processes and Alternative Lethality Support (page 55), contains descriptions or brief summaries of available scientific articles. However, the summaries are not considered adequate support on their own because they do not contain the details of each study. For this reason, establishments must have the full copy of the article on-file as scientific support for their HACCP System. The summaries are provided to help establishments identify journal articles related to their process. Each establishment needs to determine if the operating parameters of a particular study match the establishment's process. Establishments are not limited to using the scientific articles listed and summarized as support. In addition, Attachment A2. Cooking Deviations (page 66), contains recommendations for evaluating product safety in the event of a deviation but this information is not considered adequate support on its own because establishments should perform predictive microbial modeling and may conduct sampling and testing in order to support product disposition. Other information included in attachments is intended to be supplementary.

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Questions Regarding Topics in this Guideline

If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles ("Public Q&As") in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select **HACCP Deviation & HACCP Validation** as the Inquiry Type or by telephone at 1-800-233-3935.

Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

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FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)

Background

What is Lethality?

Lethality treatments are processes used by establishments to eliminate *Salmonella* and other pathogens in RTE products. Lethality treatments achieve a specific reduction in the number of *Salmonella* and other pathogens in the product (*i.e.,* an "X-Log_{10} colony forming units per gram[1] (CFU/g)" reduction). The combination of one or more lethality treatments must be sufficient to eliminate or adequately reduce *Salmonella* and other pathogens to undetectable levels and prevent the production of toxins or toxic metabolites in the RTE product (*e.g.,* from *Staphylococcus aureus*). Establishments may use a variety of different lethality processes, such as:

- Cooking the product (covered in this guideline).
- Fermentation.
- Drying.
- Salt-curing.
- Other processes that make the product safe for consumption.

Products and Processes Covered by this Guideline

This guideline addresses lethality of pathogens (*e.g., Salmonella*) in meat and poultry products[2] by heat treatment (cooking) including for products that are cooked to lethality but classified under a not-ready-to-eat HACCP plan.

NOTE: FSIS has provided additional information about the safe production of meat and poultry jerky products in

KEY DEFINITIONS

A ready-to-eat (RTE) product is defined as a meat or poultry product that is in a form that is edible by the end consumer without additional preparation to achieve food safety and that may receive additional preparation for palatability, aesthetic, or culinary purposes (9 CFR 430.1).

Lethality is the process (or combination of processes) that ensure a specific, reduction in the number of *Salmonella* and other pathogens in the product (*i.e.,* an "x-Log" reduction). Lethality processes eliminate or adequately reduce *Salmonella* and other pathogens and prevent the formation of their toxins or toxic metabolites, facilitating the production of a safe RTE food product.

[1] In the rest of this document, Log_{10} colony forming units per gram (Log_{10} CFU/g) will be annotated simply as "Log." All notations of "Log" should be read as in the unit Log_{10} CFU/g unless other information is provided.

[2] Throughout this 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 (*e.g.,* Products and Processes Not Covered by This Guidance).

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the *FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments*. The information for jerky production remains in a separate guideline because of the complexities of the process, including drying procedures, and to help address questions from small and very small processing establishments.

Products and Processes Not Covered by this Guideline

The recommendations in this guideline do not apply to the following specific products:

Fish of the Order Siluriformes (e.g., catfish)

FSIS cooking guidance was not validated for fish of the order Siluriformes. Therefore, this guidance should not be used for fish.

Fish establishments may use the cooking guidance in Table A-3 of The Food and Drug Administration's (FDA's) *Fish and Fishery Products Hazards and Control Guidance* as support for the cooking step of fish products. The time-temperature recommendations are designed to achieve a 6-Log reduction in *Listeria monocytogenes* (*Lm)*.

Pork Rind Pellets

Establishments may cook pork skins in pork fat or oil for several hours rendering the fat and reducing the skin into pellets. This intermediate product is then further processed by frying to produce a finished product such as pork rinds, cracklins (cracklings), or chicharrones. FSIS cooking guidance does not apply to the cooking or rendering of pork skins into a pellet. Establishments may use the cooking requirements in 9 CFR 94.8(b)(4) as support for cooking pork skins into a pellet. Although these are Animal Plant and Health Inspection Service (APHIS) requirements for imported pork skins from countries where foot-and-mouth disease, African swine fever, classical swine fever, or swine vesicular disease exist, these cooking requirements ensure at least a 6.5-Log reduction of *Salmonella (*Juneja, *et al.,* 2001a; Murphy *et al.,* 2003; Murphy *et al.,* 2004).

NOTE: FSIS cooking guidance may be used for cooking of pork skins for products other than pork rind pellets (*e.g.,* for use in pickled products) and for frying of pork rind pellets into popped pork skins. Guidance for monitoring the cooking critical limit for these products can be found in the Key Question on page 21.

Rendered Lard and Tallow

FSIS cooking guidance does not apply to the rendering of animal fats, such as lard and tallow, which, due to the high fat content, generally need to reach higher temperatures and longer dwell[3] times to achieve the same reductions in *Salmonella* (Ramirez-Hernandez *et al.*, 2018). However, based on the D values (time at a constant temperature necessary to destroy 90% or 1-Log of the target organism) reported by Ramirez-Hernandez *et al.* (2018), the cooking requirements for rendering in 9 CFR 315.1(a) are adequate to ensure an animal fat rendering process achieves at least 6.5-

[3] "Dwell time" refers to the time a product is held at a specific temperature. Other commonly used terms such as "hold time" or "rest time" may be considered synonymous for the purpose of this guideline.

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Log reductions of *Salmonella.* Therefore establishments may use 9 CFR 315.1 as support for a lard or rendering process, provided the critical operational parameters (≥ 170°F for ≥ 30 minutes) are met throughout the product.

Dried Products Processed Under Dry Conditions

FSIS cooking guidance does not support lethality for a process that relies on drying alone (*e.g.,* biltong), nor does this guidance support a process where the drying step comes before a cooking step that does not apply humidity or does not apply humidity during cooking at sufficient levels to rehydrate the product surface (*e.g.,* biltong or country-cured ham that is cooked in an unsealed oven after drying). This guidance also does not support lethality for a dried product cooked under moist conditions several times after drying (*e.g.,* country-cured ham that is cooked in a sealed oven several times after the hams have been salt-cured and dried).

Such dried products are typically considered intermediate moisture foods (*i.e.,* those foods that do not require refrigeration to control pathogens). The water activity range of foods considered intermediate moisture varies in the literature. For example, FDA classifies intermediate moisture foods as those with a water activity between 0.60 and 0.85 (FDA, 2018). However, some meat and poultry products may have a water activity > 0.85 and still be considered "intermediate moisture" because of other factors such as pH and salt concentration (Leistner, 1987). For example, country-cured ham has an average water activity of 0.88 but is considered shelf-stable due to the combination of water activity, high salt, and nitrite (Mikel and Newman, 2003; Reynolds *et al.*, 2001).

KEY DEFINITIONS

Stabilization is 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 may include cooling, hot-holding, or meeting and maintaining a certain pH or water activity level and other processes, such as drying and fermentation/ acidification that render the product shelf-stable or safe at room temperatures.

Establishments that apply these types of processes must identify other support for their HACCP System (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)).

NOTE: This guidance includes critical operating parameters for cooking products which are dried, then cooked **under moist conditions**. Scientific Gaps Identified by FSIS describes critical operating parameters (page 47) and Attachment A6. Cooking Country-Cured Hams includes additional tips, specific to country-cured hams (page 90).

Partially Heat-Treated NRTE Products

This guideline does not cover partially heat-treated products that are not ready-to-eat (NRTE) and did not reach a validated lethality time-temperature combination (for example: partially heat-treated bacon and hams). These products are addressed in the *FSIS Stabilization Guideline for Meat and Poultry Products* because cumulative growth of *Clostridium perfringens* and *Clostridium botulinum* are hazards of concern over the course of partial cooking and cooling processes.

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NOTE: As noted under the Products and Processes Covered by this Guideline, this guideline may be used for products that are cooked to lethality but classified under a Not RTE (NRTE) HACCP plan. For such products, please refer to the product reclassification guidance in the *Listeria Guideline*, Attachment 1.2 on pages 22-23 and Appendix 1.2 on pages 28-29 for guidance related to labeling, HACCP categorization, and intended use.

RTE Multi-hurdle Products

This guidance does not address the safe production of products that rely on multiple hurdles to achieve lethality and shelf-stability (*e.g.,* fermented and dried sausage). However, some regulatory information associated with such products is included in General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18.

NOTE: Stabilization requirements and recommendations for cooling meat and poultry products after heat treatment are described in the *FSIS Stabilization Guideline for Meat and Poultry Products*.

Biological Hazards of Concern During Cooking

The following section is designed to complement *FSIS's Meat and Poultry Hazards and Control Guide* and to further assist establishments in conducting a hazard analysis for cooked meat and poultry products as required by 9 CFR 417.2(a)(1) and for supporting decisions in their hazard analysis as required by 9 CFR 417.5(a)(1).

The following hazard is present in raw products whose outgrowth during the heating come-up time 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)
- *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).

More details about *S. aureus* and *Salmonella* (an indicator of lethality) can be found on the following page.

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S. aureus

S. aureus is a bacterial pathogen that causes nausea, vomiting, and abdominal cramping with or without diarrhea. The Centers for Disease Control and Prevention (CDC) estimates over 240,000 illnesses annually in the U.S. are attributed to *S. aureus* (Scallan *et al.,* 2011). *S. aureus* causes illness when the bacteria grows to high levels in food and one or more heat-stable enterotoxins are produced (Kadariya *et al.,* 2014). Various types of foods serve as the optimum vehicle for *S. aureus.* The pathogen has been identified in meat products, such as fermented salami and brine-injected hams. In the 1980s, *S. aureus* enterotoxin outbreaks were frequently attributed to hams. Continued outbreaks at hotels, restaurants and institutions as documented in the National Outbreak Reporting System (NORS)[4] highlight that *S. aureus* is still a concern in hams particularly when prepared in these settings. For example, between 2013 to 2018, at least six *S. aureus* enterotoxin outbreaks at hotels, restaurants and institutions were reported in NORS in which ham was the suspected food vehicle. *S. aureus* can contaminate raw meat and poultry from the animal hide, skin, or tissue during slaughter. After slaughter and cooking, RTE meat or poultry products can be contaminated with *S. aureus* from handling by individuals carrying the organism. This pathogen is the main food safety concern during long heating come-up-times (CUT) (that is the amount of time product temperature is between 50 to 130°F while heating). *S. aureus* can be present on the raw meat or poultry and grow to high enough levels to produce a toxin in the food. Growth occurs from 45 to 118°F, but effectively begins at 60˚F, especially in raw meats where the growth of other bacteria is inhibited by nitrite or salt. The critical level for human illness is 5-Log or higher which allows enterotoxin production (Kadariya *et al.,* 2014). The toxin is not destroyed by the critical operating parameters described in this cooking guideline.

FSIS recommends limiting the growth of *S. aureus* during processing to 2-Log or less. Normal levels of *S. aureus* in raw meat are usually 2-Log (Doyle and Buchanan, 2013; IFT, 2003; Waldroup, 1996). Limiting growth to 2-Log or less allows for a margin of safety before *S. aureus* would produce toxins. Conditions that allow 3-Log growth are considered a public health concern because they would result in a total of 5-Log *S. aureus* in the product which is considered the minimum critical level for human illness (Kadariya *et al.,* 2014).

To limit *S. aureus* growth, some establishments formulate products with antimicrobials such as phosphate or lactate. But the most common practice is to limit the amount of time products spend in the temperature range where *S. aureus* grows the fastest (i.e., 50 to 130°F). This guideline identifies CUT as a critical operating parameter to ensure lethality by cooking when applying the time-temperature tables (see FSIS Critical Operating Parameters for Cooking on page 23). FSIS is aware that establishments preparing some products (*e.g.,* ham or beef brisket) may not be able to follow FSIS's *Come-Up-Time Option* because of the thermodynamics of the heating process. Therefore, FSIS identified long CUT as a Scientific Gap since support does not exist for many common processes (page 48). This gap supports the use of any of FSIS's applicable time-temperature combinations (pages 35, 37, 38) and relative humidity,

[4] https://www.cdc.gov/nors/index.html

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without considering CUT as a critical operating parameter until research can be complete.

Salmonella

Salmonella is a bacterial pathogen that causes diarrhea and fever. Infection with *Salmonella* may result in arthritis (Ajene *et al.,* 2013). The CDC reports that nontyphoidal *Salmonella* species (spp.) is one of the leading causes of foodborne illness, with an estimated 1 million cases of foodborne *Salmonella* infection annually in the U.S (Scallan *et al.,* 2011). *Salmonella* spp. infections are the second leading cause of foodborne illness in the United States. Meat and poultry outbreaks are frequently associated with *Salmonella spp.*

Salmonella occurs naturally in raw animal products; however, *Salmonella* should not be found in RTE meat and poultry products because these products have undergone a lethality treatment. Also, RTE products are intended to be consumed without further preparation for safety (*i.e.,* cooking), and if pathogens are present, their consumption may cause illness. FSIS considers all RTE meat and poultry products that are contaminated with *Salmonella,* as well as *Listeria monocytogenes* and STEC, 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)). Any detectable *Salmonella* or other pathogens of concern adulterates RTE products (64 FR 732).

Salmonella as an Indicator of Lethality

Meat and poultry products may be contaminated with *Salmonella* during the slaughter and dressing process and by cross-contamination in the processing environment when insanitary conditions are present. For cooked products, FSIS recommends that establishments use *Salmonella* as an indicator of lethality because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 732). If the establishment's scientific support demonstrates that the lethality treatment achieves sufficient reduction in *Salmonella*, it does not need to provide additional support that adequate reduction of other pathogens such as STEC, *Campylobacter*, *Lm*, *Trichinae spiralis* or *Toxoplasma gondii* is achieved. As stated in the *FSIS Compliance Guideline HACCP Systems Validation*, establishments should not use pathogens other than *Salmonella* as indicators of lethality for cooked products unless the alternate pathogen displays similar or higher resistance to the lethality processes.

NOTE: While *Salmonella* is considered an indicator of lethality for validation purposes, in the event of a deviation where the establishment missed its time-temperature parameters or applied insufficient relative humidity, FSIS recommends testing for other pathogens of concern (e.g., *E. coli* O157:H7 and *Lm*) because the absence of *Salmonella* does not

KEY DEFINITIONS

Critical operating parameters are those parameters of an intervention that must be met for the intervention to operate effectively and as intended. Such parameters include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study).

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assure the absence of other pathogens since the establishment was unable to follow the critical operational parameters in its scientific support. In addition, depending on the type of deviation, other pathogens may also be of concern (e.g., *C. perfringens* and *C. botulinum*). For more information see Attachment A2. Cooking Deviations, page 66.

How to Control Salmonella

Establishments must ensure the target Log reduction of *Salmonella* and other vegetative pathogens is achieved throughout the product. To ensure vegetative pathogens, including *Salmonella*, are killed on the interior of the product, the endpoint time-temperature combination the product achieves is a critical operating parameter. Most often, the target temperatures used during cooking reported in scientific support documents and this guideline are the internal temperatures that the product should reach. FSIS has found that some establishments use the recommendations established for internal product temperature to set critical limits for the oven temperature. However, setting the oven temperature to the temperature identified in the FSIS time-temperature tables is not appropriate because doing so does not ensure that the product will reach the same target internal temperature.

In addition to the product temperature, the amount of time the product is held at this temperature (also known as the dwell time) is also critical to ensuring that adequate lethality is achieved. If the product is held at the target temperature for less time than specified in the time-temperature tables in this guideline, then adequate lethality may not be achieved.

To ensure a process achieves the target Log reductions of *Salmonella* on the surface of the product, moisture during cooking is a critical factor. Moisture (*e.g.*, relative humidity) around a product during cooking promotes lethality on the product surface in two ways:

- Moist cooking reduces surface evaporation from the product during heating (evaporative cooling). Producing products under conditions of high moisture early in the cooking process reduces evaporative cooling allowing product surfaces to reach higher temperatures resulting in a greater reduction in microorganisms; and

- Moist cooking keeps the product surface (and any pathogens) wet which prevents product drying. Product drying reduces the water activity and concentrates solutes (*e.g.,* sugar and salt). Research has demonstrated that bacteria can become more heat tolerant as their moisture levels decrease, and increased concentrations of solutes, especially salt, increase the heat resistance of bacteria (Buege *et al.,* (2006), Boles *et al.,* (2004), and Sindelar *et al.,* (2016)). Therefore, drying of the product surface before pathogens are destroyed will increase pathogen heat resistance and allow the pathogens to survive the heating process.

By incorporating moisture (*e.g.,* relative humidity) to minimize evaporation and the loss of surface moisture from the product, the D values (time at a constant temperature necessary to destroy 90% or 1-Log of the target organism) that are the basis for the

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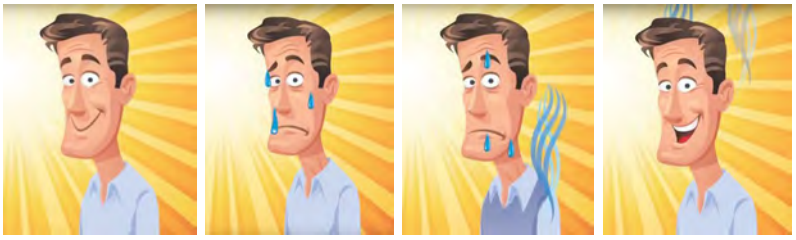
time-temperature combinations, will remain valid (Goepfert, 1970; Goodfellow and Brown, 1978). If evaporation, drying, or an increase in solute concentration is likely to occur, the times and temperatures in scientific studies and supporting documentation are not likely to be sufficient to provide the required lethality.

How does Moisture Ensure Bacteria on the Surface are Killed During Cooking?

During cooking, achieving a high oven temperature and internal product temperature alone are not enough to ensure the final product is free of harmful bacteria. Establishments need to make sure that cooking is done in a moist environment to ensure lethality. When relative humidity is low, oven air is dry, and a process called evaporative cooling increases, which is something we do not want. **Evaporative cooling** is the same thing that allows humans to keep cool by sweating. When you get too hot, you produce sweat, and when that sweat evaporates, it cools you down. Evaporation equals cooling.

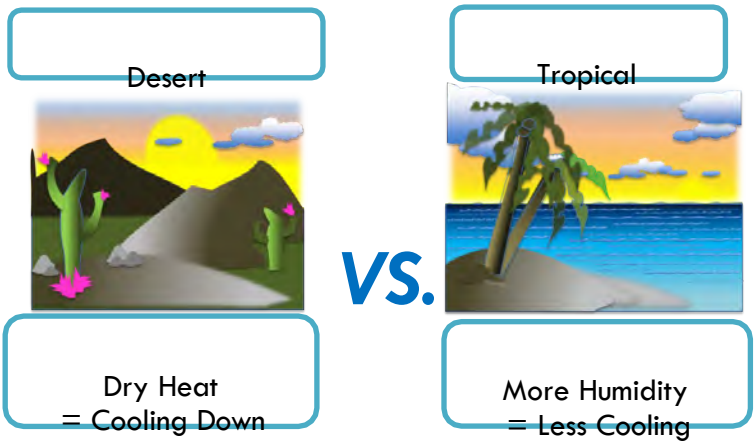


When you get too hot... ...you produce sweat. When that sweat evaporates... ...it cools you down.

Evaporation = Cooling

Just like on a person's skin, evaporative cooling cools down the surface of meat and poultry during cooking. Although the oven is hot, because the surface of the product is cooling down, that moisture evaporation can actually prevent the surface of the product from becoming hot enough to kill off harmful bacteria. We can reduce evaporative cooling by keeping the humidity in the oven high. That way the moisture in the product does not evaporate as quickly, keeping the meat's surface moist and hot and resulting in an adequate bacterial kill. Why does this work?

Imagine that you are in New Mexico or Nevada where it is really hot, but dry. If you're outside, you're more likely to sweat and that sweat will cool you down, so you don't feel as hot. Now imagine you're in Florida where it is not only really hot, but also humid. If you're outside where it is humid, your skin's surface will stay sweaty and hot, your sweat will not



evaporate, and you will not cool down. Since the air is already saturated, or full of moisture (humid), there is less evaporation from your body and, therefore, less cooling. The way humidity keeps you hot in Florida is the same way moisture keeps meat and

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poultry products hot, too.

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General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking

Addressing Lethality in the HACCP System

FSIS has established performance standards in the regulations for specific ready-to-eat (RTE) products. The performance standards for specific products set required levels of *Salmonella* lethality during cooking as follows:

- **Cooked poultry products** must be processed to achieve at least a 7-Log reduction of *Salmonella* or an alternative lethality per 381.150(a)(1).
- **Roast, cooked, and corned beef** must be processed to achieve at least a 6.5-Log reduction of *Salmonella* or an alternative lethality (*e.g.,* at least a 5-Log reduction)) per 9 CFR 318.17.
- **Cooked uncured meat patties** must be processed to meet or exceed the time-temperature combinations listed in 9 CFR 318.23, which will achieve a 5-Log reduction of *Salmonella* (and other pathogens including STEC).

For products that are not subject to a performance standard, FSIS recommends the following pathogen Log reductions (*i.e.,* targets) be achieved in order to support decisions in the hazard analysis (9 CFR 417.5(a)(1)):

- For **cooked meat products**, FSIS recommends that establishments achieve a target 6.5-Log or 5-Log reduction of *Salmonella* in their process. To use a target 5-Log reduction, establishments should provide additional support for the safety of their process (see Supporting an Alternative Lethality Target (e.g., 5-Log) page 57).
- For **shelf-stable meat products**, FSIS recommends that establishments achieve a target 5-Log reduction of *Salmonella* (see How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness? page 57).

KEY DEFINITIONS

Performance standards described in this guideline are quantifiable pathogen reduction levels or growth limit requirements **set by FSIS** for lethality and stabilization of certain meat and poultry products.

A **Log reduction** is a 90% reduction of a pathogen. For example, a 2-log reduction is a 99% reduction of a pathogen and a 3-log reduction is a 99.9% reduction of a pathogen in a product.

Targets are quantifiable pathogen reduction levels or growth limits **set by the establishment** to produce safe products in the absence of regulatory performance standards.

An **alternative lethality** is a treatment that achieves a different (often lower) Log reduction than what is prescribed in the regulations for certain products, but still achieves an equivalent probability that no viable *Salmonella* cells remain in the finished product, nor other pathogens and their toxins or toxic metabolites. An alternative lethality prevents adulteration and must be demonstrated to be achieved throughout the product (9 CFR 318.17(a)(1)).

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An establishment should identify the performance standard or specific Log reduction target its process is designed to achieve in its HACCP plan or supporting documentation. If it does not, and FSIS cannot determine the pathogen reduction level the process achieves, FSIS may determine the establishment lacks support for its decisions related to *Salmonella* control (9 CFR 417.5(a)(1)). In addition, according to 9 CFR 417.2(c)(3), establishments must design their critical limits for Critical Control Points (CCPs) to meet all applicable performance standards and targets.

NOTE: If an establishment uses the time-temperature tables provided in this guideline or cooks beef patties according to 9 CFR 318.23, it does not need to indicate the specific Log reduction that its process achieves. It would be sufficient for the establishment to indicate that it uses time-temperature combinations from one of these documents as these regulations were designed to achieve a 5-log reduction in *Salmonella* and other pathogens including STEC.

Establishments are also required to validate that their HACCP system works as intended to address these hazards (9 CFR 417.4(a)). For more information on validation see the *HACCP Systems Validation Guideline*.

Key Question

Question: When a RTE meat food product is a mixture of meat and poultry such that the product has a meat legend, and the establishment is following this cooking guideline, does the RTE meat food product need to comply with the regulatory requirement found in 9 CFR 381.150(a)(1)?

Question: If a RTE meat food product has any amount of poultry in it, does it automatically have to meet the poultry Log reduction in the FSIS Time-Temperature Tables?

Answer: Yes to both questions.

RTE meat or poultry food products consisting of any combination of meat and poultry must meet the poultry lethality performance standard in 9 CFR 381.150(a)(1). Under the published final rule "Performance Standards for the Production of Certain Meat and Poultry Products," cooked product with any amount of poultry needs to meet the lethality requirements for the production of fully cooked poultry products (9 CFR 381.150(a)(1)) which stipulate a 7-Log *Salmonella* reduction or an alternative lethality that achieves an equivalent probability that no viable Salmonella organisms remain in the finished product. This provision is based on the FSIS national microbiological "baseline" survey of raw whole and ground meat and poultry products, which found higher levels of *Salmonella* in poultry than in meat (USDA 1994, 1996a-f). Consequently, FSIS established a higher lethality performance standard for RTE poultry products than for meat (based on highest "worst case" levels).

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Alternative Lethality

An **alternative lethality** is a treatment that achieves a different (often lower) Log reduction than what is prescribed in the regulations but still achieves an equivalent probability that no viable *Salmonella* cells remain in the finished product, as well as ensures the reduction of other pathogens and their toxins or toxic metabolites (e.g., from *S. aureus*) necessary to prevent adulteration. Establishments may use alternative lethality treatments to meet the performance standards (9 CFR 318.17(a)(1) and 9 CFR 381.150(a)(1)). When using an alternative lethality treatment (*e.g.,* at least a 5-Log reduction of *Salmonella*), the establishment must validate its HACCP system to ensure that no viable *Salmonella* organisms (that is no organisms capable of causing human illness) remain in the finished product. Risk assessments have demonstrated that achieving a 5-Log reduction of *Salmonella* (instead of a 6.5-Log reduction) in cooked meat and poultry products that are not shelf stable is less protective of public health (Refer to text box: How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness? page 57). Therefore, to use these lower targets, the establishment must provide additional support for its process as described in Attachment A1. Customized Processes and Alternative Lethality Support: Supporting an Alternative Lethality Target (e.g., 5-Log) on page 55. In contrast, risk assessments have shown that for shelf-stable meat and poultry products, a 5-Log reduction of Sa*lmonella (*instead of a 6.5-Log or 7-Log reduction) is sufficient. Therefore, no additional support is needed to use a 5-Log reduction process in these shelf-stable products (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)).

Monitoring, Calibration, and Recordkeeping

The establishment's cooking procedures should be designed to ensure all products in a batch or lot achieve lethality, and the monitoring procedures should be designed to detect a deviation when it occurs. To achieve these goals, 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 shared on page 22.

Selection of the critical limit

Establishments producing cooked meat and poultry products should have sufficient monitoring equipment, including recording devices, to assure that the time, temperature, and relative humidity operating parameters of their processes are being met. With any monitoring equipment, the establishment should take the normal variation of the monitoring equipment into account when designing the critical limits. For example, if a minimum internal temperature of 165°F is necessary to destroy pathogens in a product and the thermometer has an accuracy of ± 1°F (plus or minus one degree), then the critical limit should be set no lower than 166°F. The written reasoning and equipment specification materials should be kept as part of the establishment's supporting documentation for its HACCP plan and the selection of its critical limit (9 CFR 417.5(a)(2)). All supporting documents and data from the recording devices must be made available to FSIS employees upon request (9 CFR 417.5).

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Selection of the monitoring procedures

Establishments are required to maintain documents supporting the selection of monitoring procedures and associated monitoring frequencies (9 CFR 417.5(a)(2)). It is important that establishments take into account variation within the cooking process when developing monitoring procedures to ensure the procedures they develop can identify any deviations.

In addition, to accurately measure the internal temperature of the meat or poultry product, an establishment should understand the factors that can affect this temperature. These factors include cold spots in the oven, as well as variations in oven temperature during different seasons. Establishments should be aware that updated smokehouses that contain alternating or rotating dampers that result in varying breakpoints throughout the oven do reduce the temperature difference throughout the oven, but they do not eliminate it. Although monitoring the internal product temperature is strongly encouraged, an establishment can use the oven or smokehouse temperature in place of the product temperature, provided that the establishment has a consistent product and process and has sufficient data on file correlating the oven temperature selected with the internal product temperature in the scientific support.

A disadvantage with monitoring oven temperature alone is that it may make supporting product disposition after a cooking deviation more difficult. In many cases, FSIS recommends using predictive microbial modeling programs to evaluate potential hazards (see Attachment A2. Cooking Deviations on page 66). Microbial modeling programs use product temperature to predict pathogen growth and potential Log outgrowth or reductions achieved. Without product temperature records, the establishment would need other support (*e.g.,* product testing) to determine product disposition.

Key Question:

Question: How does an establishment develop a monitoring procedure for measuring endpoint temperature in meat or poultry products that are fried crispy such that a probe cannot be inserted into the product to measure internal temperature (*e.g.,* popped pork skins, and bacon slices, pieces, or bits) because the product is too thin or hard or because the thin product cools as soon as the product exits the cooking medium?

Answer: Depending on the product type, there are different recommendations. For example, for a product such as bacon slices, it may be possible to cut a slice twice as thick as normal so that the probe can be inserted. If this thicker piece reaches the lethality temperature, the thinner pieces should as well. This procedure is also recommended for jerky. It is not recommended to fold a piece of product over the thermometer, as this has been found to result in inaccurate temperatures (Buege *et al*., 2006). For small products, such as bacon pieces or bits, it may be possible to pile the pieces or bits around the thermometer for measurement. If none of these procedures can be used, establishments may use other quantifiable measures such as a color scale value that is correlated to crispiness or the number of pieces that pass as "fried until crispy in all parts" based on a visual assessment as the critical limit for lethality for these products due to the physical challenges in monitoring the internal temperature, and the lack of outbreaks associated with them.

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Lessons Learned from Undercooked Product Recalls

In 2016 and 2017, there were five recalls associated with under-cooked RTE poultry products (RC-106-2016, RC-110-2016, RC-115-2016, RC-017-2017, and RC-037-2017). For each of these recalls, FSIS determined that even though the establishments had documentation showing the critical limit (either 160°F or 165°F) was met, there were still pieces that may have entered commerce undercooked, indicating a loss of process control and insufficient monitoring procedures to identify a process deviation.

Investigations revealed a variety of concerns related to monitoring procedures, including taking temperatures from products not in the coldest spot, taking multiple product temperatures, and averaging the results of multiple temperature measurements as opposed to recording the lowest temperature.

Investigations also revealed a variety of contributing factors for inadequate cooking including:

- Raw product was partially frozen.
- Belt speed was increased.
- Shorter dwell time and lower oven temperature than normal were used.
- Product was stacked during sous vide cooking, preventing full immersion of the bags into the liquid cooking medium.
- Higher than normal product load overwhelmed the oven.

Each of these practices may have led to uneven or inadequate cooking. These findings also highlight the importance of maintaining process control of critical operating factors, such as oven temperature, product load, and belt-speed that affect the final product temperature, dwell time, and relative humidity. The establishment is required to validate that the entire HACCP system is operating as intended and to verify that it is producing a safe and wholesome product on an ongoing basis.

Complete failure to document critical limit monitoring has also contributed to the recall of cooked poultry products in the past due to a processing defect (RC-009-2017). Such a failure highlights the importance of accurate records documenting the implementation of the critical operating parameters to support the production of safe products.

Corrective Actions under HACCP Cooking Deviations

Cooking deviations occur when an establishment fails to meet its cooking CCP critical limit or cooking humidity option. Common causes for cooking deviations include product overlap, power failures, or breakdown of cooking equipment. The HACCP regulations require establishments to take corrective actions in response to these deviations, regardless of whether the cooking process is addressed through a CCP or prerequisite program. Corrective actions include ensuring no product that is injurious to health or otherwise adulterated because of the deviation enters commerce and supporting product disposition decisions (9 CFR 417.3(a) and (b)).

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When cooking is addressed through a CCP, establishments are required to determine the cause of all cooking deviations, no matter how small (9 CFR 417.3(a)(1)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). Continual or repetitive process deviations from the critical limit demonstrate that the establishment is unable to control its process.

When cooking is addressed through a prerequisite program, establishments are required to reassess their HACCP system to determine whether the newly identified deviation or unforeseen hazard should be addressed and incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Also, an establishment may not be able to continue to support the decision in its hazard analysis that pathogens are not reasonably likely to occur, if it has continual or repetitive deviations from its cooking prerequisite program (9 CFR 417.5(a)(1)). For more information on evaluating product disposition after a cooking deviation see Corrective Actions to Perform When a Cooking Deviation Occurs (page 66).

FSIS Critical Operating Parameters for Cooking

(Time-Temperature Tables)

Establishments that cook products to achieve lethality by applying the time-temperature combinations from this guideline need to consider the critical operating parameters that may affect pathogen Log reductions, specifically:

- Come-up-time (CUT),
- Relative Humidity, and
- Endpoint Time-Temperature.

Additionally, establishments cooking poultry products need to consider product species composition and fat content if applying FSIS cooking lethality guidance in the tables on pages 37 and 38. The FSIS Cooked Poultry Rolls Options (page 39) apply to all poultry products regardless of poultry species or fat content. For information about why product species should be considered when applying cooking lethality guidance on pages 37 and 38 and not when applying the FSIS Cooked Poultry Rolls Options see page 36.

Come-Up-Time (CUT)

When applying one of the time-temperature tables from this guideline, an establishment must also consider the heating CUT to be a critical operating parameter unless the establishment can provide a science-based rationale why heating CUT does not need to be addressed. For example, products that are fermented and then cooked to lethality may control *S. aureus* outgrowth by lowering the pH following the degree-hour concept as recommended in the American Meat Institute's *Good Manufacturing Practices for Fermented Dry & Semi-Dry Fermented Sausathge Products* and therefore would not address CUT.

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FSIS has developed a CUT Option that establishments may use to support its process control of *S. aureus* growth, specifically ≤ 2-Log that also prevents enterotoxin formation:

Come-Up-Time Option: Total time product temperature is between 50 and 130°F is 6 hours or less.

NOTE: This CUT Option is only for products that were cooked to lethality (including those cooked to lethality but classified as NRTE under a heat treated, not fully cooked, not shelf-stable HACCP plan). Please refer to the *FSIS Stabilization Guideline for Meat and Poultry Products* for the Agency's recommendations regarding CUT in partially cooked products that do not receive a full lethality. Please also refer to the product reclassification guidance in the *Listeria Guideline*, Attachment 1.2 on pages 22-23 and Appendix 1.2 on pages 28-29.

FSIS is aware that establishments preparing some products (*e.g.,* ham or beef brisket) may not be able to follow FSIS's *Come-Up-Time Option* above because of the thermodynamics of the heating process. Therefore, FSIS identified long CUT as a Scientific Gap since support does not exist for many common processes (page 48). Additionally, alternative support for certain long CUT processes have been included in Attachment A1. Customized Processes and Alternative Lethality Support (page 55).

Temperatures referred to in FSIS's *Come-Up-Time Option* above, are internal temperatures. However, establishments may monitor surface temperatures during CUT, if the establishment provides support the product is intact and processed so pathogens have not been introduced below the product surface. Non-intact product temperatures should be taken internally at the center of the product (see Key Definitions panel to the right for an explanation of intact and non-intact products). Establishments should also take temperatures at the center of the product for products such as deboned and rolled hams where a portion of the product is rolled or folded over and pathogens may be internalized.

NOTE: FSIS time-temp tables list internal endpoint temperatures during cooking. It is not supportable to use surface temperature to address endpoint temperature. FSIS is only making this recommendation for its CUT option.

KEY DEFINITIONS

Come-up-time refers to the amount of time product temperature is between 50-130°F while heating.

Intact refers to products where the interior remains protected from pathogens migrating below the exterior/outside (such as beef brisket or a picnic shoulder that is not injected or vacuum tumbled).

Non-Intact refers to products where pathogens may have been introduced below the surface. Examples include products that have been mechanically tenderized (including those that have been injected with marinade or solution) or vacuum tumbled.

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Key Question

Question: An establishment cooks a brisket to full lethality but realizes the smoke coloring is too light and wants to recook it to deepen the color. Can the establishment apply a new 6 hour CUT for the second cook?

Answer: Yes. Once a product achieves a lethal time-temperature combination, the allowed CUT is reset for the next cook. If the establishment chooses to recook the product, it may apply a new 6 hour CUT limit (page 23). However, if the product did not achieve a lethal time-temperature combination during the first cooking process, the CUT does not start over. The establishment should support the total time product temperature is between 50 and 130°F is 6 hours or less. Please review Attachment A2. Cooking Deviations subsection Missed Time-Temperature Parameter (page 67) for additional information.

Relative Humidity

FSIS time-temperature tables use relative humidity as a critical operating parameter to ensure moist cooking and adequate surface lethality. An establishment that uses the FSIS time-temperature tables to support its cooking process must address humidity, unless it meets one of the criteria listed in Situations when Humidity is Not Needed (page 31) or provides additional support for why humidity would not be needed in its process to ensure lethality on the product surface. FSIS has included specific relative humidity options for use with the time-temperature tables (page 26). Additional resources for determining which relative humidity option to adopt are included in Relative Humidity Resources (page 28).

NOTE: FSIS is aware that some establishments may not be able to use FSIS's humidity options because of the nature of the cooking process. Examples include products cooked for short times at high temperatures (*e.g.,* for meat balls or chicken tenders) or other processes that do not allow the use of humidity (*e.g.,* barbecue products cooked under dry heat including those cooked in smokehouses or open pits). Please refer to Scientific Gaps Identified by FSIS (page 41).

Selection of the proper relative humidity option depends on the endpoint time-temperature. Products cooked to endpoint time-temperatures of at least 145°F plus the dwell time, may apply any of the relative humidity options in Table 1. Critical Operating Parameters for FSIS Humidity Options.

KEY DEFINITIONS

Maintaining humidity means keeping the humidity at the same level throughout the cooking process. If the humidity drops during the cooking process, the establishment will need to provide additional support for the safety of the product

A **sealed oven** is generally defined as one in which the smokehouse doors and oven dampers are closed to prevent moisture loss.

The **cooking time** includes the time the product is placed in the heated oven (including surface preparation and color setting) until the product reaches the desired lethality time-temperature combination (also referred to as the "lethality treatment").

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However, products cooked to an endpoint less than 145°F, should select Option 3 or 4 in Table 1. Critical Operating Parameters for FSIS Humidity Options depending on total cooking time.

NOTE: To be most effective, humidity needs to be applied during the lethality treatment, before drying. Using this guideline to support lethality processes in which the **drying step comes before the moist cooking step** (*e.g.,* country-cured ham) creates a vulnerability in the establishment's HACCP system. Establishments using this guideline for these processes should read Attachment A6. Cooking Country-Cured Hams (page 90) for recommendations to reduce this vulnerability, such as measuring water activity after cooking to verify it increases and the product surface was rehydrated during cooking.

To ensure that adequate humidity is attained, the establishment should monitor the humidity throughout the lethality treatment. The process should be monitored using wet and dry bulb thermometers (used to determine relative humidity) or a humidity sensor. FSIS recommends that establishments monitor relative humidity for every lot or batch of product produced.

Table 1. Critical Operating Parameters for FSIS Humidity Options

	CRITICAL OPERATING PARAMETERS		
	Relative Humidity	Endpoint Temperature	Cooking Time
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 + dwell 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 + dwell 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**

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Key Question

Question: To follow the sealed oven or steam injection options, must establishments achieve a specific relative humidity?

Answer: No. Establishments do not need to achieve a specific relative humidity level in the oven if they are following the steam injection or sealed oven options in this guideline as their scientific support. Based on expert opinion, the *2014 FSIS Jerky Guideline* recommended that establishments producing jerky that monitor relative humidity try to achieve a wet bulb temperature of at least 125-130°F for 1 hour or more along with a corresponding dry bulb temperature needed to achieve at least 27-32% relative humidity or more. However, the *Jerky Guideline* also noted, achieving a wet bulb temperature of at least 125-130°F and at least 27-32% relative humidity for 1 hour or more is not adequate on its own to support that the process is being implemented consistently with FSIS Humidity Options. Rather, establishments should ensure that all critical operating parameters described in this guidance are met. Relative Humidity Resources (page 28 contains specific guidance for how to implement Option 1 steam injection and Option 2 sealed oven in a validated HACCP system. In addition, establishments should not apply the wet-bulb and relative humidity recommendations in the *Jerky Guideline* to other products without additional support.

Current Support for FSIS Relative Humidity Options

Although the research cited as the basis of FSIS guidance dates as far back as 1978, newer research by McMinn *et al.,* (2018) supports that the time-temperature parameters in FSIS's cooking guidance achieves sufficient reductions of *Salmonella.* This research by McMinn *et al.* (2018) was conducted with product cooked in vacuum-sealed bags supporting the importance of cooking in a high moisture environment. While newer research has not been conducted to validate the sealed oven and steam injection relative humidity options, research does continue to support the importance of moisture during cooking. For example, Mann and Brashears (2007), support the need for at least 30% relative humidity during cooking of roast beef. Based on FSIS knowledge of establishments' processes through its verification activities, the Agency believes when the oven is sealed, or steam is introduced, at least 30% relative humidity is maintained, suggesting that these practical recommendations result in adequate relative humidity. The Agency is also not aware of any establishments that have had *Salmonella* positives or been associated with a salmonellosis outbreak when following FSIS temperature, time, and relative humidity guidance while using effective monitoring procedures.

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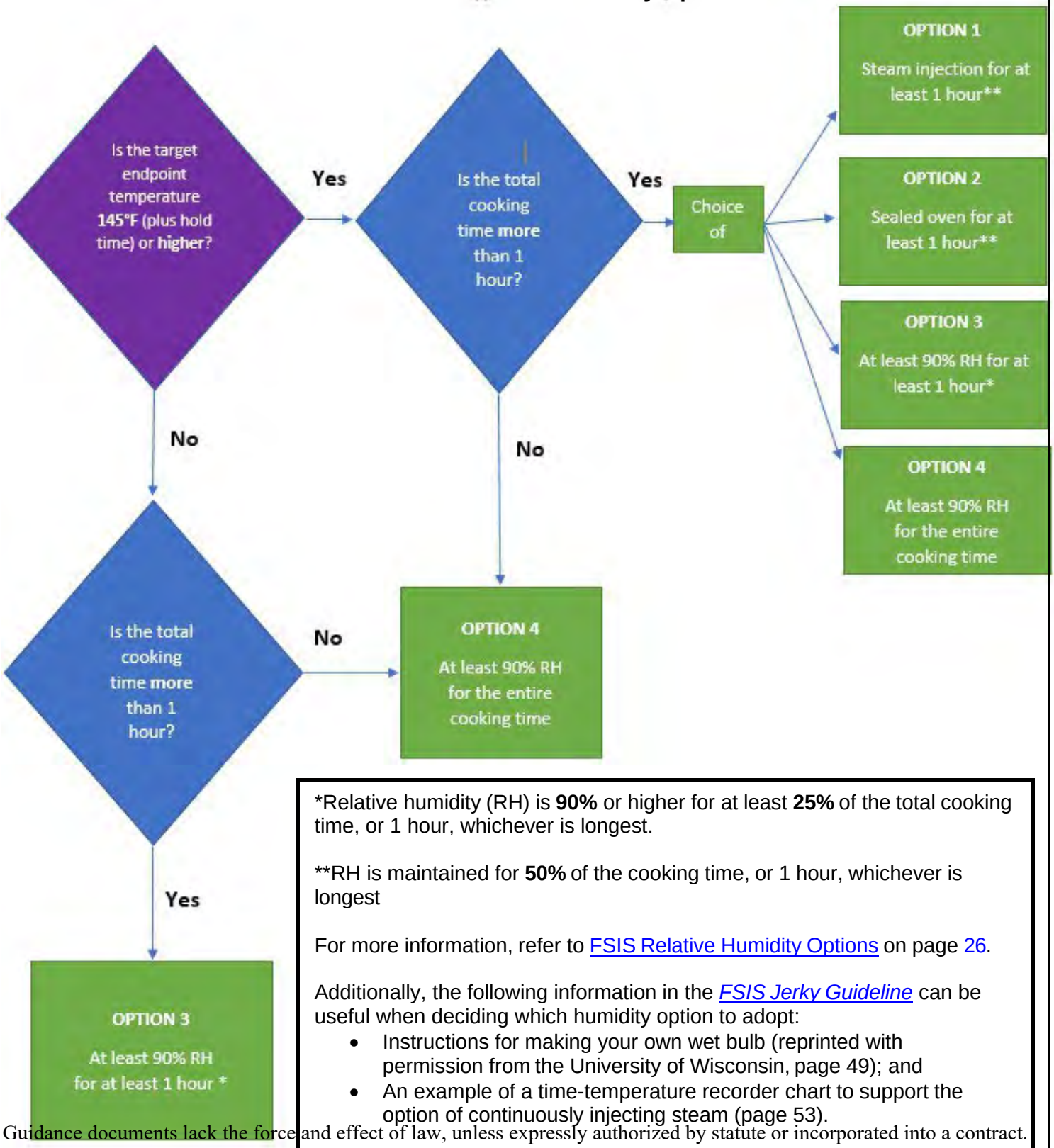
Relative Humidity Resources

The following flow chart contains specific guidance for how to choose a humidity option and the resources on the next two pages are designed to help establishments implement Option 1 steam injection and Option 2 sealed oven in a validated HACCP system.

Flow Chart to Choose a Humidity Option



*Relative humidity (RH) is **90%** or higher for at least **25%** of the total cooking time, or 1 hour, whichever is longest.

RH is maintained for **50% of the cooking time, or 1 hour, whichever is longest

For more information, refer to FSIS Relative Humidity Options on page 26.

Additionally, the following information in the *FSIS Jerky Guideline* can be useful when deciding which humidity option to adopt:

- Instructions for making your own wet bulb (reprinted with permission from the University of Wisconsin, page 49); and
- An example of a time-temperature recorder chart to support the option of continuously injecting steam (page 53).

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Specific Guidance for Using the "Sealed Oven" Option

To support the use of the **sealed oven option** for addressing relative humidity, FSIS recommends establishments follow all 4 steps below:

1) **Maintain documentation that supports that the product achieves an internal product temperature equal to or greater than 145°F (plus the required dwell time) from the FSIS time-temperature tables.** Such documentation could include:
   a. Records of internal product temperature and time held at that temperature, (if applicable); or
   b. Records of the oven or smokehouse temperature in place of internal product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the internal product temperature in the scientific support;

2) **Maintain documentation that supports that the oven dampers are closed for at least one hour or 50% of the cooking time, whichever is longer.** Such documentation could include:
   a. Records from a computerized system that document the time at which the oven dampers were open and were closed; or
   b. Records, made manually, of the times at which the oven dampers were open and closed;
   c. Records demonstrating that the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time, whichever is longer (*e.g.,* by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) with correlation data supporting a relationship between the relative humidity level in the oven and the time at which the oven dampers were open and closed;

3) **Maintain documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens.** Such documentation could include:
   a. Records demonstrating the relative humidity level in the ovens is maintained (*e.g.,* by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humiditysensor that provides a direct measurement), or
   b. Data gathered during the initial validation period along with ongoing verification that demonstrate that the relative humidity in the oven is maintained while the dampers are closed; and

4) **Perform routine checks to ensure the oven dampers are properly working along with a maintenance program that includes periodic monitoring to ensure oven seals are intact and functional, and that when the oven dampers are closed, a tight seal is obtained.**

   A tight seal is one that prevents a significant loss of humidity. FSIS acknowledges that a small amount of smoke or vapors might be seen escaping the smokehouse even when a tight seal is obtained. FSIS also recommends establishments consider whether there are other openings, particularly in older smokehouses, such as drain valves or air intake valves that need to be closed to ensure that a seal is obtained. Finally, some older ovens may have a stack or other opening that cannot be closed. For those establishments with older ovens that cannot be completely closed, the sealed oven method should not be used. However, the establishment may choose to close the parts of the oven it can, then add moisture in the system either by continuouslyintroducing steam, or by using another validated method.

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Specific Guidance for Using the "Continuously Introducing Steam" Option

To support the use of the **continuously introducing steam option** for addressing relative humidity, FSIS recommends establishments follow all 3 steps below:

1) **Maintain documentation that supports that the product achieves an internal product temperature equal to or greater than 145°F (plus the required dwell time) from the FSIS time-temperature tables.** Such documentation could include:
   a. Records of internal product temperature and time held at that temperature, (if applicable); or
   b. Records of the oven or smokehouse temperature in place of internal product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the internal product temperature in the scientific support;

2) **Maintain documentation that supports that steam is continuously introduced for at least one hour or 50% of the cooking time, whichever is longer.** Such documentation could include:
   a. Records from a computerized system that contains the time at which the steam is turned on and off; o r
   b. Records, made manually, of the times at which the steam is turned on and off; or
   c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time, whichever is longer (*e.g.,* by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), along with correlation data supporting a relationship between the relative humidity level in the oven and the time steam is turned on or a letter from the manufacturer stating that when the relative humidity is rising, it is because of live steam injection; and

3) **Maintain documentation that supports that when steam is injected, humidity is maintained in the ovens.** Such documentation could include:
   a. Records demonstrating the relative humidity level in the ovens is maintained (*e.g.,* by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
   b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while steam is being injected.

NOTE: The "continuously introducing steam" option refers to the use of live steam. This option may also apply to establishments that spray water onto hot heating elements, which creates steam that in turn produces humidity in the smokehouse. "Continuous" does not mean that the steam is injected for at least one hour during one stage. Rather, steam could be injected during specific stages or time intervals during the lethality (cooking) treatment as long as the total amount of time the steam is introduced adds up to at least one hour or 50% of the cooking time, whichever is longer. Furthermore, the establishment may turn the steam on and off throughout the cooking time when the target humidity is reached.

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Establishments that use processes that match one of these situations do not need to monitor relative humidity as a critical operating parameter in their cooking procedure.

Situations when Humidity is Not Needed

FSIS recognizes two situations when humidity does not need to be addressed to ensure adequate lethality:

1. When moisture is inherently maintained; or
2. When product is cooked using direct heat.

Relative humidity does not need to be addressed when moisture is inherently maintained around the product. Examples of these types of processes include, but are not limited to:

- Completely immersing the meat or poultry product in a liquid cooking medium throughout the entire cooking process;
  - *E.g.,* unbagged, in water
- Cooking the product in a sealed, moisture impermeable bag (*e.g.,* cook-in-bag meat or poultry);
  - Cook-in-bag products may be eligible to be labeled as "pasteurized" (see Attachment A3. When can Products be Labeled as Pasteurized? page 81).
- Cooking product in a casing that holds moisture (*e.g.,* natural casings, cellulose casings, collagen casings, fibrous casings and plastic casings (sometimes called "synthetic" casings)).
  - See the question box on page 33 for information on cooking using natural casings.
- Heating meat or poultry products that weigh 10 pounds or more in an oven maintained at 250°F (121°C) or higher throughout a process achieving one of the time-temperature combinations in this guideline.

NOTE: Humidity is not needed for products that weigh 10 pounds or more in an oven maintained at 250°F (121°C) or higher because they have a low surface to mass ratio (Goodfellow and Brown, 1978). Therefore, the surface dries out slower than smaller products and *Salmonella* is less likely to become heat tolerant.

KEY DEFINITIONS

During **convective heating** the food product is indirectly heated by the movement of hot air. This type of heating is typical for solid foods cooked in a smoke house oven.

Conductive Heating: Heat is transferred directly into the food product by physical contact with the heating medium (*e.g.,* heating product in a skillet).

Radiant Heating: Heat is transferred directly into the food product by radiant energy without the movement of air or physical contact between the source and the food. Two common examples: are (1) broiling where food is exposed to direct, intense radiant heat or (2) certain types of rotisserie ovens where a flame emits radiant energy to heat food.

Forms of radiant energy also include gamma rays, electron beams, and x-rays.

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Relative humidity also does not need to be addressed for processes that apply direct heat via conduction or radiant heating. Unlike convective heating, which uses moving hot air or steam to heat the product (*e.g.,* smoke house ovens, spiral ovens, impingement ovens), direct heating (*e.g.,* conductive heating, radiant heating) puts the product in direct contact with the heating medium. Direct heat ensures the product surface quickly reaches lethality temperatures before bacteria can develop heat tolerance due to the product's surface quickly drying out.

How is indirect heating identified?

Moving air or steam is a sign of convective (indirect) heating. Ovens that use moving air to heat the product **need to address relative humidity** to ensure sufficient Log reductions for pathogens are achieved.

Examples of direct heat include:

- Grill.
- Broil (exposure to direct, intense radiant heat).
- Heating coil,
- Flame.
- Certain rotisserie ovens that cook the meat or poultry over the heat source resulting in a product with a grilled quality.

NOTE: Direct heat cooking is rarely used in conjunction with rotisserie cooking. Indirect heat cooking is most often used because it allows the meat or poultry to cook slowly and evenly, which is the primary purpose for using a rotisserie for cooking. For indirect heat cooking, the rotisserie is positioned in front of or next to the heat source and it is the heated air that cooks the product (convection cooking).

Cooking meat patties per 9 CFR 318.23 does not include humidity considerations because these products were assumed to be cooked with direct heat such as a grill, heating coil, or flame. Meat patties cooked per 9 CFR 318.23 do not need to address relative humidity. For the definition of a patty see 9 CFR 318.23.

NOTE: Products cooked using microwave cooking methods that are not designed to control relative humidity is considered a Scientific Gap because these common cooking processes can't achieve the relative humidity options included in this guideline; however, there is a lack of research to support alternative parameters. For the critical operating parameters in this guideline that can be used for these processes, if using FSIS guidance as scientific support, see Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used page 44.

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Do Products Cooked in Natural Casings Made from Animal Gastrointestinal Tracts Need to Address Relative Humidity?

No, establishments using FSIS cooking guidance as support **do not need to address relative humidity** for products that are **cooked** in a natural casing, including products that are cooked and then dried.[1]

Natural casings made from animal gastrointestinal tracts are typically considered permeable and many establishments take advantage of their permeability to produce dried products or smoked products. However, depending on how they are used, the permeability of natural casings may be reduced. Most cooking processes likely reduce the permeability of natural casings early in the process so that humidity around the product is inherently maintained throughout the remainder of cooking and does not have to be added or monitored. According to Sebranek, (2010), establishments will apply smoke early in the process while the casing is still moist and permeable to the smoke. Prior to smoke application, the casing surface should be "tacky" or "sticky." After smoke deposition and color development, further cooking denatures the proteins in the casing reducing permeability to the point that later cooking can be applied without great moisture loss from the product. Proteins in natural casings begin denaturing at 126°F (Tornberg, 2005). However, most drying processes use lower temperatures and address relative humidity to maintain casing permeability so that moisture can evaporate from the product during drying.

Although most cooking processes likely result in reduced permeability of natural casings early in the cooking process, little research has been performed to study the critical operating parameters that impact the reduction of permeability such as the length of the initial smoke application step, cooking temperature, total cooking time, use of steam, size of casings, composition of sausage batter, etc. For this reason, FSIS has posted a research study on its website to "Determine if natural casings maintain sufficient moisture to ensure product lethality using Appendix A time and temperature tables." Without this additional research, the Log reduction of *Salmonella* is less certain if meat products in natural casings are cooked using one of the time-temperature parameters in this FSIS cooking guidance without following one of the humidity options. So, while FSIS has indicated establishments using FSIS cooking guidance as support do not need to address relative humidity for products that are cooked in a natural casing, if an establishment uses one of the time-temperature parameters in FSIS cooking guidance without addressing relative humidity has a positive *Salmonella* test result through FSIS or its own testing, it should, as part of corrective actions, provide evidence that lack of relative humidity was not the cause. In addition, if research is completed and data becomes available that indicates relative humidity needs to be addressed when products are cooked in a natural casing, FSIS may change its recommendation.

[1]**NOTE:** As described in the Products and Processes Not Covered by This Guidance, this guideline is not appropriate support for lethality of a process that relies on drying alone or to support a process where the drying step comes before a cooking step that does not apply humidity or does not apply humidity during cooking at sufficient levels to rehydrate the product surface during the cooking step under dry conditions.

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Key Question

Question: When an establishment decides to use a FSIS time-temperature table (*i.e.,* the 5-Log Meat Table, 6.5-Log Meat Table, or the 7.0-Log Poultry Time-Temperature Tables) from this guideline as its scientific support for its cooking/lethality step, can the establishment use the entire table as its critical limit in its HACCP plan?

Answer: Yes, the establishment can use the entire table to comply with 9 CFR 417.2(c)(3). The establishment needs to make a sound determination and support its decision in selecting and monitoring the time-temperature parameter(s) it uses for its production (9 CFR 417.5(a)(2)). In addition, establishments must collect in-plant data for at least one product from each HACCP category demonstrating the implementation of the critical operational parameters of the scientific support (9 CFR 417.4(a)(1)). At a minimum, the establishment will need to demonstrate that it is able to consistently meet a specific time-temperature from the table identified during the initial validation period to support the cooking/lethality process is validated (9 CFR 417.4(a)(1)).

Endpoint Time-Temperature

FSIS time-temperature tables in this guideline (Meat Table, the 5-Log Table, and the Poultry Time-Temperature Tables) list internal product temperatures and the corresponding dwell times needed to achieve specific Log reductions of *Salmonella*. These tables may be used as scientific support to ensure that the process meets regulatory requirements (see General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18).

NOTE: To apply an alternative lethality and use Table 6. Time-Temperature Combinations for Meat Products to Achieve a 5-Log Reduction (page 59), an establishment must provide additional documentation showing that the product meets the performance standard (if applicable) and that potentially hazardous pathogens have been controlled (see Attachment A1. Customized Processes and Alternative Lethality Support subsection: Supporting an Alternative Lethality Target (e.g., 5-Log) on page 57). The support should demonstrate the incoming load of *Salmonella* is lower than FSIS estimated based on its baseline studies, and therefore, a lower reduction from cooking would result in no viable *Salmonella* in the finished product.

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Table 2. Time-Temperature Combinations for Meat Products to Achieve Lethality

Temperatures stated are the minimum internal temperatures that must be met in all parts of the meat product for the total dwell time listed.[5] An establishment must ensure both time and temperature parameters are met to use this table to support its process achieves the Log reduction target. **Relative humidity**[6] and heating **come-up-time (CUT)**[7] are also **critical operating parameters** when using this table. (See pages 37 and 38 for poultry endpoint time-temperature tables).

Degrees Fahrenheit	Degrees Centigrade	6.5-log $_{10}$ Lethality	7-log $_{10}$ Lethality
130	54.4	112 min.	121 min.
131	55.0	89 min.	97 min.
132	55.6	71 min.	77 min.
133	56.1	56 min.	62 min.
134	56.7	45 min.	47 min.
135	57.2	36 min.	37 min.
136	57.8	28 min.	32 min.
137	58.4	23 min.	24 min.
138	58.9	18 min.	19 min.
139	59.5	15 min.	15 min.
140	60.0	12 min.	12 min.
141	60.6	9 min.	10 min.
142	61.1	8 min.	8 min.
143	61.7	6 min.	6 min.
144	62.2	5 min.	5 min.
145	62.8	4 min.	4 min.
146	63.3	169 sec.	182 sec.
147	63.9	134 sec.	144 sec.
148	64.4	107 sec.	115 sec.
149	65.0	85 sec.	91 sec.
150	65.6	67 sec.	72 sec.
151	66.1	54 sec.	58 sec.
152	66.7	43 sec.	46 sec.
153	67.2	34 sec.	37 sec.
154	67.8	27 sec.	29 sec.
155	68.3	22 sec.	23 sec
156	68.9	17 sec.	19 sec.
157	69.4	14 sec.	15 sec.
158	70.0	0 sec.**	0 sec.**
159	70.6	0 sec.**	0 sec.**
160	71.1	0 sec.**	0 sec.**

[5] The required Log reductions are achieved instantly (0 seconds) when the internal temperature of a cooked meat product reaches 158°F or above.

[6] Time-Temperatures ≥ 145°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page 26).

[7] FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).

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Additional Critical Operating Parameters for Poultry Products

The following are additional critical operational parameters that should be considered when cooking poultry products using FSIS newer guidance in the poultry time-temperature tables.

Note: The older poultry recommendations for Cooked Poultry Rolls on page 39 apply regardless of species or fat because these were not considered critical operating parameters at the time the recommendation was developed. FSIS is not aware of any outbreaks or food safety incidents as a result of applying these recommendations to products of varying species or fat level.

Product Species

Generally, FSIS accepts that research for an intervention's effectiveness on one species of poultry (*i.e.,* chickens, turkeys, ducks, geese, ratites, and squabs) can be applied to another species of poultry without additional support (FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification Task*). However, research by Juneja *et al.* (2001a) demonstrated that in cooking processes, *Salmonella* heat tolerance depends on the poultry species. Therefore, when FSIS developed its time-temperature tables for poultry it developed two unique poultry time-temperature tables: one for chicken (page 37), another for turkey (page 38).

When making poultry products containing **poultry species other than chicken or turkey**, or products made with a **mixture of poultry species**, FSIS recommends selecting an endpoint temperature, then using the longest dwell time recommended for the product fat content and endpoint temperature in either the chicken or turkey table. Comparing the tables and using the longest recommended dwell time ensures the HACCP system is designed to address the worst-case scenario for *Salmonella* survival in the product. Products that are a **mixture of poultry and meat** must achieve a 7-Log reduction of *Salmonella* (see Key Question on page 19).

Fat Content

In the presence of fats, the heat tolerance of some microorganisms generally increases (Jay *et al.,* 2000). This is sometimes referred to as fat protection and is presumed to increase heat tolerance by affecting cell moisture. Juneja *et al.,* (2001b) showed that higher fat levels in beef result in increased heat resistance of *Salmonella*, which is in agreement with publications regarding other food borne pathogens (Line *et al.,* 1991; Ahmed *et al.,* 1995). The Poultry Time-Temperature Tables (pages 37 and 38) provide establishments with time-temperature combinations that can be used to cook chicken and turkey products with different fat levels.

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Table 3. Time-Temperature Combinations for Chicken Products to Achieve Lethality

Times for given temperatures and fat levels that are needed to obtain a 7-Log reduction of *Salmonella* in chicken products.[8] As described on page 23, **relative humidity**[9] and heating **come-up-time (CUT)**[10] are **critical operating parameters** when using this table.

Degrees Fahrenheit	Degrees Centigrade	1% fat	2% fat	3% fat	4% fat	5% fat	6% fat	7% fat	8% fat	9% fat	10% fat	11% fat	12% fat
136	57.8	63.3 min	64.5 min	65.7 min	67 min	68.4 min	69.9 min	71.4 min	73 min	74.8 min	76.7 min	78.9 min	81.4 min
137	58.3	50.1 min	51 min	52.1 min	53.2 min	54.3 min	55.5 min	56.8 min	58.2 min	59.7 min	61.4 min	63.3 min	65.5 min
138	58.9	39.7 min	40.5 min	41.3 min	42.2 min	43.2 min	44.2 min	45.3 min	46.4 min	47.7 min	49.2 min	50.9 min	52.9 min
139	59.4	31.6 min	32.2 min	32.9 min	33.6 min	34.4 min	35.2 min	36.2 min	37.2 min	38.3 min	39.6 min	41.1 min	43 min
140	60.0	25.2 min	25.7 min	26.2 min	26.8 min	27.5 min	28.2 min	29 min	29.8 min	30.8 min	32 min	33.4 min	35 min
141	60.6	20.1 min	20.5 min	21 min	21.5 min	22 min	22.6 min	23.2 min	24 min	24.9 min	25.9 min	27.1 min	28.7 min
142	61.1	16.1 min	16.4 min	16.8 min	17.2 min	17.6 min	18.1 min	18.7 min	19.4 min	20.1 min	21 min	22.1 min	23.5 min
143	61.7	13 min	13.2 min	13.5 min	13.8 min	14.2 min	14.6 min	15.1 min	15.6 min	16.3 min	17.1 min	18.1 min	19.3 min
144	62.2	10.4 min	10.6 min	10.8 min	11.1 min	11.4 min	11.8 min	12.2 min	12.6 min	13.2 min	13.9 min	14.8 min	15.9 min
145	62.8	8.4 min	8.6 min	8.7 min	8.9 min	9.2 min	9.5 min	9.8 min	10.2 min	10.7 min	11.3 min	12.1 min	13 min
146	63.3	6.8 min	6.9 min	7 min	7.2 min	7.4 min	7.6 min	7.9 min	8.2 min	8.6 min	9.1 min	9.8 min	10.6 min
147	63.9	5.5 min	5.5 min	5.6 min	5.7 min	5.9 min	6.1 min	6.3 min	6.6 min	6.9 min	7.4 min	7.9 min	8.6 min
148	64.4	4.4 min	4.4 min	4.5 min	4.5 min	4.7 min	4.8 min	5 min	5.2 min	5.5 min	5.8 min	6.3 min	6.8 min
149	65.0	3.5 min	3.5 min	3.5 min	3.6 min	3.6 min	3.8 min	3.9 min	4.1 min	4.3 min	4.6 min	4.9 min	5.4 min
150	65.6	2.7 min	2.7 min	2.7 min	2.7 min	2.8 min	2.9 min	3 min	3.1 min	3.3 min	3.5 min	3.8 min	4.2 min
151	66.1	2.1 min	2 min	2 min	2.1 min	2.1 min	2.1 min	2.2 min	2.3 min	2.5 min	2.6 min	2.9 min	3.1 min
152	66.7	1.5 min	1.5 min	1.5 min	1.6 min	1.6 min	1.6 min	1.7 min	1.7 min	1.8 min	1.9 min	2.1 min	2.3 min
153	67.2	1.2 min	1.2 min	1.2 min	1.2 min	1.3 min	1.3 min	1.3 min	1.3 min	1.4 min	1.4 min	1.4 min	1.6 min
154	67.8	55.9 sec	56.9 sec	58 sec	59.1 sec	1 min	1 min	1 min	1.1 min	1.1 min	1.1 min	1.1 min	1.1 min
155	68.3	44.2 sec	45 sec	45.9 sec	46.8 sec	47.7 sec	48.6 sec	49.5 sec	50.4 sec	51.4 sec	52.4 sec	53.4 sec	54.4 sec
156	68.9	35 sec	35.6 sec	36.3 sec	37 sec	37.7 sec	38.4 sec	39.2 sec	39.9 sec	40.7 sec	41.4 sec	42.2 sec	43 sec
157	69.4	27.7 sec	28.2 sec	28.7 sec	29.3 sec	29.8 sec	30.4 sec	31 sec	31.6 sec	32.2 sec	32.8 sec	33.4 sec	34 sec
158	70.0	21.9 sec	22.3 sec	22.7 sec	23.2 sec	23.6 sec	24 sec	24.5 sec	25 sec	25.4 sec	25.9 sec	26.4 sec	26.9 sec
159	70.6	17.3 sec	17.6 sec	18 sec	18.3 sec	18.7 sec	19 sec	19.4 sec	19.8 sec	20.1 sec	20.5 sec	20.9 sec	21.3 sec
160	71.1	13.7 sec	14 sec	14.2 sec	14.5 sec	14.8 sec	15 sec	15.3 sec	15.6 sec	15.9 sec	16.2 sec	16.5 sec	16.9 sec
161	71.7	10.8 sec	11 sec	11.2 sec	11.5 sec	11.7 sec	11.9 sec	12.1 sec	12.4 sec	12.6 sec	12.8 sec	13.1 sec	13.3 sec
162	72.2	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	9.6 sec	9.8 sec	10 sec	10.2 sec	10.3 sec	10.5 sec
163	72.8	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**
164	73.3	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**
165	73.9	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**

[8] A 7-Log reduction of *Salmonella* is achieved instantly at internal temperatures in which the holding time is 0 seconds (0 sec.).

[9] Time-Temperatures ≥ 145°°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page 26).

[10] FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).

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Table 4. Time-Temperature Combinations for Turkey Products to Achieve Lethality

Times for given temperatures and fat levels that are needed to obtain a 7-Log reduction of *Salmonella* in turkey products.[11] As described on page 23, **relative humidity**[12] and heating **come-up-time (CUT)**[13] are **critical operating parameters** when using this table.

Degrees Fahrenheit	Degrees Centigrade	1% fat	2% fat	3% fat	4% fat	5% fat	6% fat	7% fat	8% fat	9% fat	10% fat	11% fat	12% fat
136	57.8	64 min	64.3 min	64.6 min	64.9 min	65.3 min	65.8 min	66.3 min	66.9 min	67.6 min	68.4 min	69.5 min	70.8 min
137	58.3	51.9 min	52.2 min	52.4 min	52.8 min	53.2 min	53.6 min	54.1 min	54.7 min	55.3 min	56.2 min	57.2 min	58.5 min
138	58.9	42.2 min	42.5 min	42.7 min	43 min	43.4 min	43.8 min	44.2 min	44.8 min	45.4 min	46.2 min	47.2 min	48.5 min
139	59.4	34.4 min	34.6 min	34.9 min	35.1 min	35.4 min	35.8 min	36.2 min	36.7 min	37.3 min	38.1 min	39.1 min	40.4 min
140	60.0	28.1 min	28.3 min	28.5 min	28.7 min	29 min	29.3 min	29.7 min	30.2 min	30.8 min	31.5 min	32.5 min	33.7 min
141	60.6	23 min	23.2 min	23.3 min	23.5 min	23.8 min	24.1 min	24.4 min	24.9 min	25.5 min	26.2 min	27.1 min	28.2 min
142	61.1	18.9 min	19 min	19.1 min	19.3 min	19.5 min	19.8 min	20.1 min	20.5 min	21.1 min	21.7 min	22.6 min	23.7 min
143	61.7	15.5 min	15.6 min	15.7 min	15.9 min	16.1 min	16.3 min	16.6 min	17 min	17.4 min	18 min	18.8 min	19.8 min
144	62.2	12.8 min	12.8 min	12.9 min	13 min	13.2 min	13.4 min	13.7 min	14 min	14.4 min	15 min	15.7 min	16.6 min
145	62.8	10.5 min	10.6 min	10.6 min	10.7 min	10.8 min	11 min	11.3 min	11.5 min	11.9min	12.4 min	13 min	13.8 min
146	63.3	8.7 min	8.7 min	8.7 min	8.8 min	8.9 min	9 min	9.2 min	9.5 min	9.8 min	10.2 min	10.8 min	11.5 min
147	63.9	7.1 min	7.1 min	7.1 min	7.2 min	7.3 min	7.4 min	7.5 min	7.7 min	8 min	8.4 min	8.8 min	9.4 min
148	64.4	5.8 min	5.8 min	5.8 min	5.8 min	5.9 min	6 min	6.1 min	6.3 min	6.5 min	6.8 min	7.2 min	7.7 min
149	65.0	4.7 min	4.7 min	4.7 min	4.7 min	4.7 min	4.8 min	4.9 min	5 min	5.2 min	5.4 min	5.8 min	6.2 min
150	65.6	3.8 min	3.7 min	3.7 min	3.7 min	3.7 min	3.8 min	3.9 min	4 min	4.1 min	4.3 min	4.5 min	4.9 min
151	66.1	3 min	2.9 min	2.9 min	2.9 min	2.9 min	2.9 min	3 min	3.1 min	3.2 min	3.3 min	3.5 min	3.8 min
152	66.7	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.4 min	2.5 min	2.7 min	2.8 min
153	67.2	1.8 min	1.8 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	2.1 min
154	67.8	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.6 min	1.6 min	1.6 min
155	68.3	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.3 min	1.3 min	1.3 min	1.3 min	1.3 min
156	68.9	59 sec	59.3 sec	59.5 sec	59.8 sec	1 min	1 min	1 min	1 min	1 min	1 min	1 min	1 min
157	69.4	47.9 sec	48.1 sec	48.3 sec	48.5 sec	48.8 sec	49 sec	49.2 sec	49.5 sec	49.7 sec	49.9 sec	50.2 sec	50.4 sec
158	70.0	38.8 sec	39 sec	39.2 sec	39.4 sec	39.6 sec	39.8 sec	40 sec	40.1 sec	40.3 sec	40.5 sec	40.7 sec	40.9 sec
159	70.6	31.5 sec	31.7 sec	31.8 sec	32 sec	32.1 sec	32.3 sec	32.4 sec	32.6 sec	32.7 sec	32.9 sec	33 sec	33.2 sec
160	71.1	25.6 sec	25.7 sec	25.8 sec	26 sec	26.1 sec	26.2 sec	26.3 sec	26.4 sec	26.6 sec	26.7 sec	26.8 sec	26.9 sec
161	71.7	20.8 sec	20.9 sec	21 sec	21.1 sec	21.2 sec	21.3 sec	21.4 sec	21.5 sec	21.6 sec	21.7 sec	21.8 sec	21.9 sec
162	72.2	16.9 sec	16.9 sec	17 sec	17.1 sec	17.2 sec	17.3 sec	17.3 sec	17.4 sec	17.5 sec	17.6 sec	17.7 sec	17.7 sec
163	72.8	13.7 sec	13.7 sec	13.8 sec	13.9 sec	13.9 sec	14 sec	14.1 sec	14.1 sec	14.2 sec	14.3 sec	14.3 sec	14.4 sec
164	73.3	11.1 sec	11.2 sec	11.2 sec	11.3 sec	11.3 sec	11.4 sec	11.4 sec	11.5 sec	11.5 sec	11.6 sec	11.6 sec	11.7 sec
165	73.9	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**

[11] A 7-Log reduction of *Salmonella* is achieved instantly at internal temperatures in which the holding time is 0 seconds (0 sec.).
[12] Time-Temperatures ≥ 145°°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page 26).
[13] FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).

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Key Question

Question: Can establishments that produce poultry products with higher than 12% fat use values for 12% fat in the Poultry Time-Temperature Tables?

Answer: Yes. The time-temperature combinations listed in the tables for poultry products with 12% fat can be used for products with higher percentages of fat and for products with unknown fat content. These time-temperature combinations will achieve sufficient lethality as long as adequate humidity (FSIS Relative Humidity Options page 26) is applied during the process.

Cooked Poultry Rolls Options

FSIS recommends establishments use the options in the Poultry Time-Temperature Tables (page 37 and 38) (which include dwell times at 160°F that vary based on fat content and species) because they have been validated with updated research to address species and fat content as critical operating parameters to ensure adequate Log reductions of *Salmonella.* However, FSIS is including the two older options below for cooking poultry rolls and other poultry products because they still may be used by some establishments. Applying the cooked poultry rolls options below may achieve the same Log reductions as the time-temperature combinations in the Poultry Time-Temperature Tables, particularly when applied to a lean product, because the product may be maintained at 160°F for the recommended dwell times (between 13.7 to 26.9 seconds depending on species and fat) during the time it takes to complete temperature monitoring. Regardless, FSIS recommends establishments monitor the dwell time in the Poultry Time-Temperature Tables as opposed to relying on the older guidance for cooked poultry rolls below to better assure safety.

The options below can be applied to any poultry product (not just cooked poultry rolls) regardless of fat content or poultry species. However, if FSIS collects a RTE sample that is positive for *Salmonella* or if the establishment is implicated in a food safety investigation related to *Salmonella* (i.e., is associated with reports of illness or outbreak), FSIS will review and determine the adequacy of the establishment's required corrective actions (taken under 9 CFR 417.3), to address process deviations. The establishment will need to show FSIS that inadequate lethality was not the root cause of the process deviation if it wants to continue to follow the cooked poultry rolls options.

To use a cooked poultry rolls option, the establishment **must address** all critical operating parameters for cooking identified in this guideline (other than species or fat), including relative humidity (page 26) and CUT (page 23).

1. **Cooked poultry rolls** and other cooked poultry products must reach an internal temperature of at least **160°F** (instantaneous) during the cooking process.

2. **Cured and smoked poultry rolls** and other cured and smoked poultry must reach an internal temperature of at least **155°F** (instantaneous) during the cooking process.

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Resources for Customized and Alternative Support

FSIS recognizes that not all meat and poultry products can be cooked using the FSIS critical operating parameters (humidity, CUT and endpoint time-temperature) included in this guideline. To assist establishments in cooking their products, FSIS has identified additional resources which may provide scientific support for a specific process or part of a process. Attachment A1. Customized Processes and Alternative Lethality Support includes information on the following:

- **Alternative Lethality Target**: Under certain circumstances and with additional support, establishments may be able to use an alternative lethality target (e.g. 5-Log). See Attachment A1. Supporting an Alternative Lethality Target, page 57 of this guideline.
- **Journal Articles**: Establishments could identify a published journal article which shows a specific process meets the performance standard and use this as scientific support. See Attachment A1. Common Topics and Journal Articles Used for Alternative Support page 60 of this guideline.
- **Customized Cooking Schedule**: Establishments may design a customized cooking plan using validated microbial models. See Attachment A1. Predictive Microbial Modeling for Critical Operating Parameters, page 62 of this guideline.
- **Challenge Studies**: Establishments could conduct challenge studies to determine if their proposed process would meet the performance standard. See Attachment A1. Designing Challenge Studies for Cooking, page 63 of this guideline.

In addition to information for developing customized critical operating parameters, this guideline contains additional resources, listed below, to address common questions and issues establishments may have regarding cooking of meat and poultry products.

- **Pasteurized Label**: Establishments may be able to label their cooked meat or poultry product as "Pasteurized." See Attachment A3. When can Products be Labeled as Pasteurized?, page 81 of this guideline.
- **Common Sources of *Salmonella***: *Salmonella* contamination may occur on cooked products for a variety of reasons. For information on sources of *Salmonella* contamination and Best Practices to implement to address it, see Attachment A4. Sources of *Salmonella* Contamination in RTE Products and Best Practices to Address It page 82 of this guideline.
- **Ready-to-eat (RTE) Self-Assessment Tool**: FSIS has included a self-assessment tool that establishments can use to identify areas in their process where they could improve *Salmonella* control. See Attachment A5. RTE *Salmonella* Self-Assessment Tool page 87 of this guideline.

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Scientific Gaps Identified by FSIS

FSIS has identified several common cooking processes that can't achieve the critical operating parameters included in this guideline. FSIS encourages establishments to conduct challenge studies when other support is not available (page 63). However, the Agency realizes it may not be cost effective for establishments to conduct individual challenge studies for commonly produced meat and poultry products. To address these common processes, which lack readily available scientific support, FSIS has identified and communicated scientific gaps and is working to facilitate filling these gaps. FSIS posted research priorities on its website to communicate clear research needs with USDA Agricultural Research Service (ARS) and academic researchers. As additional data becomes available, FSIS will update the recommendations for these scientific gaps with the latest available scientific support.

An establishment producing products **using processes that fall under an identified scientific gap** may use the critical operating parameters in this guideline as scientific support (see Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used page 43). Table 5 also describes specific vulnerabilities with using the gaps as scientific support and recommends steps to reduce the vulnerabilities. In addition to those specific vulnerabilities, FSIS has the following concerns with establishments continuing to process products using the critical operating parameters in Table 5:

- Use of these critical operating parameters represents a vulnerability because these processes have not been validated to address all hazards of concern. The original research used to develop these critical operating parameters was performed on only the few products covered by the performance standard to be included in the 1999 version of Appendix A [64 FR 732].

- 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 ready-to-eat (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.

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NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Additionally, Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical operating parameters listed in Table 5.

*Scientific gaps are processes which have **not** been validated to achieve sufficient lethality and to address all potential hazards during cooking, but establishments may continue to use this guidance as support to allow additional time for research to be conducted and gaps filled.*

FSIS will update this guideline as more research becomes available and new options can be developed.

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NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
1. 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. **NOTE:** Above 212°F the maximum relative humidity decreases as the temperature increases making it impossible to achieve 90% relative humidity in the oven regardless of the amount of moisture present.	Cooking meatballs or poultry tenders using impingement, spiral, and steam-injected inline ovens. **NOTE**: Jerky products are not included under this gap. There are many validated lethality processes available for jerky products.	Apply FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity. **NOTE**: Relative humidity does not need to be addressed for products cooked in completely immersed in water (page 31).	These parameters may allow the surface of the product to dry out during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive the heating process. In addition, shorter cooking processes allow for limited additional lethality during the heating come-up time (sometimes called cumulative or integrated lethality) which reduces the safety margin the process provides. To minimize these vulnerabilities, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure moist cooking and demonstrate surface lethality: o Wet-bulb temperature. o Dew point temperature. o Percent moisture by volume. o Increase dwell time or endpoint temperature. o Increase total cooking time to increase integrated lethality. **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* as part of on-going verification.

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NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
2. 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.**	Sliced bacon or bacon chips cooked using continuous microwave ovens.	Apply FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity.	These parameters may not ensure surface lethality. In addition, shorter cooking processes allow for limited additional lethality during the heating come-up time (sometimes called cumulative or integrated lethality) which reduces the safety margin the process provides. To minimize these vulnerabilities, an establishment may choose to implement, validate, and monitor, any of the following to ensure moist cooking and demonstrate surface lethality: o Increase dwell time or endpoint temperature. o Increase total cooking time to increase integrated lethality. **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* as part of on-going verification. **NOTE:** There is an additional vulnerability with microwave cooking that the microwave energy may not result in lethality of pathogens on continuous belt surfaces (Taormina *et al.*, 2011).

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NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
3. 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). **NOTE**: This does not include smokehouses where the gaskets or dampers are broken or have been removed.	Rotisserie chicken Products such as pork butt or beef brisket cooked using restaurant or foodservice type convection ovens. Barbecue products cooked under dry heat including those cooked in smokehouses or open pits. **NOTE**: Jerky products are not included in this gap. There are many validated lethality processes available for jerky products.	Apply FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity. **NOTE**: Relative humidity does not need to be addressed for products 10 pounds or more cooked in an oven at 250°F or higher (page 31).	These parameters may allow the surface of the product to dry out during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive the heating process. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor, any of the following to ensure moist cooking and demonstrate surface lethality: o Wet-bulb temperature. o Dew point temperature. o Percent moisture by volume. Depending on the process, pans of water may be added to increase moisture in the cooking chamber. **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* as part of on-going verification.

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NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
4. 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**: Products **cooked** in a natural casing are not included in this gap, since FSIS includes natural casing in Situations when Humidity is Not Needed (page 31).	Baked pasties, empanadas, pot-stickers, and dumplings.	Apply FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity.	These parameters may allow the surface of the filling or wrapping to dry during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive cooking. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure sufficient lethality on the outside and inside of the wrapped products: o Cook filling first. o Measure water activity of filling before and after cooking to support moisture is inherently maintained (water activity stays the same or increases after cooking). FSIS recommends establishments achieve the highest water activity possible during cooking. Values ≥ 0.96 have been shown to prevent pathogen heat tolerance, but this water activity may not be possible to achieve for all processes (Kieboom, *et al.* 2006). o Cook to a higher endpoint temperature than the FSIS time-temperature tables, to compensate for the low humidity conditions. **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* as part of on-going verification.

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NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
5. 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 o Option 1, or o Option 3, or o Option 4, or o Cook-in-bag, or o Immersion cooking. **NOTE**: This gap does NOT apply products cooked after drying without applying relative humidity (*e.g.,* cooking under dry conditions or direct heat), or to dried products cooked multiple times. It is not supportable for dried products to apply direct heat instead of addressing relative humidity, without additional support for surface lethality (page 31).	Country-cured hams that are cooked-in-bag one time. Soups that have a reduced water activity due to a high salt concentration but are a liquid medium. **NOTE**: Jerky products are not included in this gap. There are many validated lethality processes available for jerky products.	Apply: FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) and use **relative humidity:** o Option 1, or o Option 3, or o Option 4, or o Cook-in-bag, or o Immersion cooking. **NOTE:** FSIS does not consider a sealed oven (Option 2) to be adequate support that the surface of the product is rehydrated during cooking of reduced water activity products.	There is a **vulnerability** if pathogens develop heat tolerance during drying which could allow them to survive the cooking process. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure sufficient moisture during cooking: o Take water activity measurements of the surface of the product before and after cooking to support the surface is rehydrated (water activity increases after cooking). o Achieve the highest water activity possible during cooking. Values ≥ 0.96 have been shown to prevent pathogen heat tolerance, but this water activity may not be possible to achieve for all processes (Kieboom, *et al.* 2006). **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* and *Lm* as part of on-going verification. Additional recommendations are included in Attachment A6. Cooking Country-Cured Hams on page 90.

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NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
6. Products with **long heating come-up-times (CUTs).** **This gap applies to processes that require a:** • Heating come-up-time longer than 6 hours (page 23). **NOTE**: See page 62 for references supporting longer CUTs for fully cooked products formulated with antimicrobials to inhibit *S. aureus* that are cooked to lethality.	Ham and beef brisket. **NOTE:** Dry-cured or immersion cured products produced under this Cooking Guideline Scientific Gap may also be produced under a *Stabilization Guideline* Scientific Gap if formulated without erythorbate or ascorbate.	Apply any of FSIS's applicable time-temperature combinations (pages 35, 37, 38) and **relative humidity**, without considering CUT as a critical operating parameter. **NOTE**: For intact products, establishment may be able to monitor the surface temperature to allow for longer CUTs, instead of addressing this gap (page 24).	A **vulnerability** exists in that *S. aureus* may grow to levels that result in the production of a heat-stable enterotoxin if CUTs are longer than 6 hours without the use of antimicrobials. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure *S. aureus* outgrowth is limited: o Critical parameters from a published journal article that supports extending the come-up-time in products and processes. (page 62). o Reduce product diameter to reduce CUT. o Conduct predictive pathogen modeling for a particular product and process (page 55). o Limit CUT between 50 – 130°F and set a defined limit based on the shortest CUT possible for the establishment's specific process. o Apply smoke, which may inhibit *S. aureus* and *C. perfringens* growth. **Or** perform a challenge study (page 63). **Or** conduct finished product verification testing for *S. aureus* enterotoxins (page 77); or

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Attachment A1. Customized Processes and Alternative Lethality Support

Following FSIS Critical Operating Parameters for Cooking (Time-Temperature Tables) (page 23) will yield product that meets the lethality performance standards and targets. However, some establishments may want to develop customized processing procedures to achieve lethality. Establishments or their process authorities may develop customized processes or an alternative lethality that meets the performance standards or targets by using information obtained from the literature or by comparing their processes with established processes. However, all processes must achieve a supported Log reduction of pathogens and prevent the production of toxins or toxic metabolites (*e.g., Staphylococcus aureus*) to meet HACCP requirements and produce safe food (General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18). Regardless of the scientific support used, the establishment's actual process must match the critical operating parameters in the scientific support in order to achieve adequate lethality and meet validation requirements.

In addition to the recommendations provided in the *HACCP Systems Validation Guideline*, FSIS recommends that establishments and processing authorities address the following questions when evaluating how journal articles and other sources of alternative support may apply to a cooking process:

1. Does the scientific support (*e.g.,* book chapters, journal articles) demonstrate that sufficient lethality of *Salmonella* (or a supported surrogate) is achieved in the product?

    - Negative results obtained from finished product sampling alone (without inoculation) are not sufficient to demonstrate that the product meets the performance standards or targets because they do not support any particular reduction in pathogens is achieved by the process.

    - Studies should evaluate the survival of a mixture (cocktail) of *Salmonella*, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the strains selected should be those with known heat-tolerance properties.

2. Does the scientific support identify all critical operating parameters used to achieve lethality (*e.g.,* relative humidity)?

    - Many research studies designed to determine D-values of pathogens in different food matrices use enclosed systems that maintain moisture, such as sealed glass tubes, or impermeable bags immersed in hot water. These studies, as published in journal articles, may not specifically list controlling moisture during cooking as a critical operating parameter, but the methods used inherently maintain moisture in the system. To achieve

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the same result as the study, an establishment would need to consider how its process will apply moisture to ensure lethality on the product surface during cooking (see page 16).

Acceptability of Challenge Study Results

There are different ways to evaluate the results of challenge studies and scientific literature, such as journal articles. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), in its 2010 article "*Parameters for Determining Inoculated Pack/Challenge Study Protocols*" recommends a statistical analysis be performed on results or, if not, a clear justification be provided.

Below are three acceptable ways to determine if the results of the research are sufficient to support an establishment's lethality process:

1. The mean (average) is ≥ performance standard or target log reduction.

2. Results for all replicates are ≥ performance standard or target.

3. The lower 95% confidence limit for the results from the study is ≥ performance standard or target.

    - What this means is the reduction is calculated based on the mean log reduction minus 1.94 times the standard deviation. The recommendation to subtract 1.94 times the standard deviation from the mean log reduction is based on a study with an n of 6 (*i.e.*, three replicates and two samples per replicate or two replicates and three samples per replicate).

The approaches are listed in order of increasing confidence the results support an acceptable lethality process. The first approach (using the mean or average result) provides the least confidence the lethality process will consistently achieve the performance standard or target because it does not take into account variation found in the results. The third approach (using the lower 95% confidence limit) provides the greatest confidence but is also the most conservative because it takes into account a confidence interval based on variation found during the study.

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Supporting an Alternative Lethality Target (*e.g.*, 5-Log)

Establishments that use an alternative lethality (*e.g.*, FSIS 5-Log Table) need to consider a number of factors that were identified in the *Salmonella* risk assessment, specifically:

- Product categorization (shelf-stable or not shelf-stable).
- Pathogen load in raw materials.
- Storage and growth.
- Consumer reheating.

How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness?

Historically, FSIS has recommended that establishments achieve at least a 6.5-Log reduction of *Salmonella* in cooked meat products (other than beef patties which require a 5-Log reduction). The previous recommendations were due to the Risk Assessment of the Impact of Lethality Standards on Salmonellosis from RTE Meat and Poultry Products, 2005 (*Salmonella* Risk Assessment), which showed that a 5-Log reduction of *Salmonella* (instead of a 6.5-Log reduction) would result in a greater risk of illness in cooked meat products.

The regulations for cooked beef, corned beef, and roast beef in 9 CFR 318.17(a)(1) allow for the use of alternative lethality, provided it provides equivalent probability that no viable *Salmonella* cells remain in the finished product, as well as ensures the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration. FSIS is providing guidance to establishments regarding how to validate the alternative lethality option of achieving at least a 5-Log reduction of *Salmonella* in **cooked** meat products other than beef patties to ensure the lower reduction does not result in a greater risk of illness. For **shelf-stable** products, that primarily rely on means other than cooking to achieve lethality, the *Salmonella* Risk Assessment did not show a substantially higher risk of illness for product with a 5-Log reduction compared to a 6.5-Log reduction, so FSIS continues to recommend a 5-Log reduction of *Salmonella* for shelf-stable products. Therefore, establishments do not need to provide additional support for decisions in the hazard analysis (9 CFR 417.5(a)(1)) if they identify a 5-Log reduction of *Salmonella* as the lethality target for shelf-stable.

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An establishment can use the following bulleted options to support an alternative lethality target. The alternative lethality target may be from alternative supporting documentation (Attachment A1. Customized Processes and Alternative Lethality Support page 55) or with the time-temperature combinations in Table 6. Time-Temperature Combinations for Meat Products to Achieve a 5-Log Reduction (page 59).

- Use source materials that have been tested or treated to reduce pathogens. The establishment can use a cooking process that achieves a 5-Log lethality of *Salmonella* if it uses source materials that have been tested or treated to reduce pathogens. The establishment should maintain support (*e.g.,* Letters of Guarantee (LOG), Certificates of Analysis (COA), or sampling information) for each lot demonstrating that the levels of *Salmonella* are low enough to be controlled by a process achieving 5-Log reduction with an appropriate safety margin (*e.g.,* 2-Log). For example, an establishment may provide a LOG indicating that a certain Log reduction (*e.g.,* 1.5-Log or 2-Log) is achieved in the source materials using a validated antimicrobial intervention.

- Conduct a *Salmonella* baseline study on the raw source material. The baseline study should be designed such that the establishment can demonstrate, with reasonable confidence, that less than 0.01% of the raw, formulated product contains concentrations > 10 CFU/gram of *Salmonella* before cooking. This is based on the premise that a 5-Log lethality step would reduce a *Salmonella* level of < 10 CFU/gram to < 1 CFU/ 100 grams and provide a 2-Log margin of safety (NACMCF, 2010).

Key Question

Question: Do establishments that want to use the 6.5-Log Time-Temperature Tables need to perform raw product testing or provide other support?

Answer: No. The times and temperatures listed in the tables for 6.5-Log or 7.0-Log reductions can be used without any additional support or testing. These time-temperature combinations will achieve sufficient lethality as long as adequate humidity (page 26) is applied during the process.

Challenges Supporting a 5-Log Alternative Lethality for Cooked Beef Products

FSIS recognizes that extensive baseline sampling and testing needed to apply a 5-Log lethality may be cost prohibitive for small and very small establishments. However, this document provides multiple options for meeting the performance standards for certain RTE products. As noted in the question box above, establishments do not need additional testing or support to apply the 6.5-Log Meat Table, or the 7.0-Log Poultry Time-Temperature Tables in their process.

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Table 6. Time-Temperature Combinations for Meat Products to Achieve a 5-Log Reduction

Temperatures stated are the minimum internal temperatures that must be met in all parts of the product for the total dwell time listed[14, 15]. An establishment must ensure both time and temperature parameters are met to use this table to support that its process achieves a 5-Log reduction of *Salmonella*. As described on page 23, **relative humidity**[16] and heating **come-up-time (CUT)** [17] are **critical operating parameters** when using this table.

Degrees Fahrenheit	Degrees Centigrade	Time for 5.0 log Reduction
130	54.4	86 min.
131	55	69 min.
132	55.6	55 min.
133	56.1	44 min.
134	56.7	35 min.
135	57.2	28 min.
136	57.8	22 min.
137	58.4	18 min.
138	58.9	14 min.
139	59.5	11 min.
140	60	9 min.
141	60.6	7 min.
142	61.1	6 min.
143	61.7	5 min.
144	62.2	4 min.
145	62.8	3 min.
146	63.3	130 sec.
147	63.9	103 sec.
148	64.4	82 sec.
149	65	65 sec.
150	65.6	52 sec.
151	66.1	41 sec.
152	66.7	33 sec.
153	67.2	26 sec.
154	67.8	21 sec.
155	68.3	17 sec.
156	68.9	14 sec.
157	69.4	11 sec.
158	70	0 sec.**
159	70.6	0 sec.**
160	71.1	0 sec.**

[14] A 5-Log reduction of *Salmonella* is achieved instantly (0 seconds) when the internal temperature of a cooked meat product reaches 158°F or above.
[15] When using this table for not shelf-stable products other than meat patties, establishments must provide additional support to show why a 5-Log reduction is sufficient to ensure pathogens are eliminated (Supporting an Alternative Lethality Target (e.g., 5-Log) page 50).
[16] Time-Temperatures ≥ 145°°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply to FSIS Relative Humidity Options 3 and 4 (page 26).
[17] FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).

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Common Topics and Journal Articles Used for Alternative Support

Many journal articles have been published that have increased scientific understanding of the critical role of certain operating parameters during cooking including relative humidity. FSIS recognizes that many of these journal articles, including that by Buege et al., (2006), support the use of less than 90% relative humidity (FSIS Relative Humidity Option 4; page 26). Establishments may use these journal articles as scientific support as long as establishments ensure the published critical operating parameters match the critical operating parameters being used in the establishment's process. FSIS agrees that wet-bulb temperature is a good indicator of surface lethality during cooking but does not believe there is enough information at this time to make a general recommendation that a single wet-bulb temperature can be used in place of the FSIS relative humidity options for all products. For more information see FSIS' wet-bulb video available at: https://youtu.be/as-c2bCsoHQ.

Other commonly used alternatives to relative humidity include dew point temperature and percent moisture by volume. Alternative measures are particularly valuable in products cooked at high dry bulb temperatures. However, at this time, there is no consensus or scientifically supported recommendation for how to use those parameters or a targeted value to reach for each parameter. Consequently, FSIS has posted an FSIS research priority on its website and is aware that researchers are actively investigating this issue (Scientific Gaps Identified by FSIS page 41).

Journal articles or reports establishments may consider using as scientific support, grouped by topic area, include:

- Validated cook schedules for making beef jerky by controlling dry bulb and wet bulb temperatures.
    - Buege, D.R., Searls, G., Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against Salmonella serovars and *Escherichia coli* O157: H7. Journal of Food Protection. 69(9):2091-2099.
    - Porto-Fett, A.C., Call, J.E., Luchansky, J.B. 2008. Validation of a commercial process for inactivation of *Escherichia coli* O157: H7, *Salmonella Typhimurium*, and *Listeria monocytogenes* on the surface of whole muscle beef jerky. Journal of Food Protection. 71(5):918-926.
    - Borowski, A. G., Ingham, S. C., Ingham, B. H. 2009. Lethality of home-style dehydrator processes against *Escherichia coli* O157: H7 and *Salmonella* serovars in the manufacture of ground-and-formed beef jerky and the potential for using a pathogen surrogate in process validation. Journal of Food Protection. 72(10): 2056-2064.
    - Dierschke, S., Ingham, S.C., Ingham, B.H. 2010. Destruction of *Escherichia coli* O157: H7, *Salmonella*, *Listeria monocytogenes*, and *Staphylococcus aureus* achieved during manufacture of whole-muscle beef jerky in home-style dehydrators. Journal of Food Protection. 73(11):2034-2042.

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- Validated cook schedules for making turkey jerky by controlling dry bulb and wet bulb temperatures.
    - Porto-Fett, A.C.S., Call, J.E., Hwang, C.A., Juneja, V., Ingham, S., Ingham, B., Luchansky, J.B. 2009. Validation of commercial processes for inactivation of *Escherichia coli* O157: H7, *Salmonella Typhimurium*, *and Listeria monocytogenes* on the surface of whole-muscle turkey jerky. Poultry Science, 88(6):1275-1281.

- Use of high temperature, short time cooking procedures and monitoring a wet bulb temperature target. The research provides scientific support for alternative processes including use of a wet-bulb temperature target.
    - Sindelar, J.J., Glass, K., Hanson, R. 2016. Investigating the development of thermal processing tools to improve the safety of Ready-To-Eat meat and poultry products. Foundation for Meat and Poultry Research and Education Final Report. https://meatpoultryfoundation.org/research/investigating-development-thermal-processing-tools-improve-safety-ready-eat-meat-and-poultry Accessed 19 December 2018.

      NOTE: Establishments may use this final report as scientific support until a peer-reviewed journal article is published.

Why do some journal articles support using different critical operating parameters for cooking than those recommended by FSIS?

FSIS guidance is designed to ensure lethality for a large number of meat and poultry products across broad product categories. Research on specific processes and product types may support adequate lethality can be achieved using different critical operating parameters for certain products (*e.g.,* shorter dwell time or lower endpoint temperature), but research is not always available to support using those parameters across the many product categories and product types that this guidance covers. Establishments may choose to follow journal articles or other peer-reviewed scientific data instead of FSIS guidance, provided the same critical operating parameters are met (*e.g.,* product type, dry-bulb temperature, wet-bulb temperature, internal product temperature, and intrinsic factors) and the process achieves sufficient reductions for *Salmonella* based on the establishment's desired target.

CUT Option

FSIS's CUT option (page 23) was developed to support a wide variety of products. It is designed to use product characteristics that would allow the most *S. aureus* growth (worst-case scenario). Using worst-case conditions ensures that the option prevents *S. aureus* from being a hazard in all products. Establishments may be able to identify

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journal articles with longer CUT for products with specific characteristics that inhibit pathogen growth (*e.g.,* formulated with antimicrobials like sodium lactate).

Example:

- This following journal article provides critical limits for the brine injection and the thermal process that control *S. aureus* growth and enterotoxin production during a 14-hour CUT.
    - Ingham, S.C., Losinski, J.A., Dropp, B.K., Vivio, L.L., Buege, D.R. 2004. Evaluation of *Staphylococcus aureus* growth potential in ham during a slow-cooking process: use of predictions derived from the US Department of Agriculture Pathogen Modeling Program 6.1 predictive model and an inoculation study. Journal of food protection, 67(7):1512-1516. https://foodsafety.wisc.edu/meat-haccp/.

- This following journal article provides critical operating parameters for hams formulated with phosphate and cooked to lethality while applying a long CUT.
    - Sindelar, J., Glass, K., Hanson, R., Sebranek, J.G., Cordray, J., Dickson, J.S. 2019. Validation for lethality processes for products with slow CUT: Bacon and bone-in-ham. Food Control. 104:147-151.

NOTE: Although Sindelar *et al*. (2019) contains information on the growth of pathogens during the heating CUT for partially heat-treated bacon, the article is not adequate sole support for controlling the growth of *C. perfringens* and *C. botulinum*. Please review the *FSIS Stabilization Guideline for Meat and Poultry Products* for additional details.

Predictive Microbial Modeling to Support CUT

Alternatively, establishments may use predictive microbiology modeling to develop custom critical operating parameters. Predictive food microbiology uses models (*i.e.,* mathematical equations) to describe the growth, survival, or inactivation of microbes in food systems from knowledge of the intrinsic and extrinsic factors of the food over time. There are many free predictive microbial models available to establishments either online or through a download. Please refer to Predictive Microbial Modeling (page 72) for FSIS recommendations on using predictive microbial models to evaluate *S. aureus* growth during heating CUT deviations. These same recommendations can be applied when validating a custom CUT for a HACCP system.

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Designing Challenge Studies for Cooking

One of the most definitive tools at the disposal of an establishment or processing authority for validating a process is the challenge study.

As stated in the *HACCP Systems Validation Guideline*, establishments may perform challenge (or inoculated pack) studies to provide scientific support for their processes. These studies are performed in a laboratory or pilot plant by a processing authority or expert. The documentation on file should specify the level of pathogen reduction, elimination, or growth control; describe the process, including all critical operating parameters affecting the reduction or elimination of the pathogen of concern; and give the source of the documentation. Such studies are often not published in peer-reviewed journal articles but should contain the same level of detail as is provided for peer-reviewed studies.

Challenge studies should be designed and conducted to accurately simulate the commercial process. Challenge studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in *Salmonella* research. Challenge studies should be based on a sound statistical design (*i.e.,* a statistical design that ensures confidence in the data) and should also employ positive and negative controls. The statistical design should include the number of samples collected at each time interval and the number of study replicates needed to ensure the validity of the study. There are quantitative methods for assessing the statistical quality of a study (*e.g.,* power analysis). As per the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the minimum number of samples to be analyzed initially and at each time interval during processing or storage should be at least two. However, NACMCF highly recommends analysis of three or more samples at each time interval. According to NACMCF, challenge studies should include replicates. Replicates should be independent trials using different lots of product and inoculum to account for variations in product, process, inoculum, and other factors. When the number of samples analyzed at each time interval is only two, NACMCF suggests it is better for the study to be repeated (replicated) more than two times. In studies with three or more samples tested at each time interval, two replicates are usually adequate. A cocktail of various serotypes of *Salmonella* should be used in an inoculated pack study to demonstrate that the lethality performance standard or target is met. At least five strains of the pathogen should be used in the inoculum. Relatively heat tolerant pathogenic strains should be included in the cocktail to develop a worst case. The serotypes/strains selected should be among those that have been historically implicated in an appreciable number of outbreaks.

FSIS does not require establishments to validate that their process achieves a specific reduction of STEC or *Lm* in cooked product if they achieve sufficient reductions of *Salmonella* because FSIS considers *Salmonella* an indicator of lethality for cooked products. Without further scientific support, establishments should not use pathogens other than *Salmonella* as indicators of lethality. For example, establishments should not

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use reductions in *Lm* to support similar reductions in *Salmonella* without support that *Lm* is at least equally as heat tolerant as *Salmonella* under the conditions being studied.

If an establishment chooses to conduct a challenge study in a testing laboratory, the study should use at least five strains of *Salmonella*, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the *Salmonella* strains selected should be those with known heat-tolerance properties. FSIS recommends that establishments and their laboratories include a justification for the strains chosen (*e.g.*, associated with human illness or isolated from meat or poultry products) in the challenge study report.

Key Question

Question: Should a Challenge Study use *S.* Senftenberg 775W?

Answer: Not necessarily. FSIS would not require that. The *FSIS Jerky Guideline* states, "*One good* [strain] *choice, for example, might be* Salmonella enterica *serovar Senftenberg strain 775W, which displays heat resistance properties (Ng et al., 1969).* Salmonella enterica *serovar Senftenberg occurs in the top 10 serotypes seen in FSIS testing for both cow/bull carcass testing and ground beef, as well as in turkeys (carcass and ground) (FSIS testing data, 2012), so it would also be an appropriate choice for what might be seen in these products being tested."* However, additional studies have determined that *Salmonella* Senftenberg has much higher heat tolerance than other pathogens (McMinn, *et al.*, 2018; Veeramuthu, *et al*., 1998). In addition, more recent data does not continue to identify it in the top 10 serotypes seen in FSIS testing.

In addition, the inoculum level should be at least 2-Log greater than the Log reduction to be demonstrated. FSIS recommends that establishments use *Salmonella* as an indicator of lethality (Goodfellow and Brown, 1978; Line *et al.,* 1991) or an appropriate surrogate of *Salmonella* that has similar heat and drying-tolerance properties. For example, *Enterococcus faecium* has been validated as a suitable surrogate for *Salmonella* during cooking of ground beef (Ma *et al.*, 2007). FSIS considers all *Salmonella* serotypes to be pathogens of public health concern. At a minimum, a study for a microbiological food safety hazard should identify:

- The hazard (including the specific strains studied).
- The expected level of hazard reduction or prevention to be achieved.
- The processing steps that will achieve the specified reduction.
- All critical operating parameters or conditions (*e.g.,* time, temperature, and humidity) necessary to achieve the reduction.
- Procedures to monitor the critical operating parameters or conditions.
- The critical ingredients (*e.g.,* concentration of salt, sugar, and cure).
- The critical product characteristics (*e.g.,* pH, water activity, moisture level, and fat content).

NOTE: For more information on conducting challenge studies, please review the article, "*Parameters for Determining Inoculated Pack/Challenge Study Protocols,*"

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published by the NACMCF in the Journal of Food Protection in 2010. For more information on the use of positive and negative controls in challenge studies as well as general guidance on how to select a microbiological testing laboratory please review FSIS' *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*.

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Attachment A2. Cooking Deviations

Corrective Actions to Perform When a Cooking Deviation Occurs

Cooking deviations occur when an establishment fails to meet its cooking CCP critical limit for endpoint time-temperature, cooking humidity option, or heating come-up time option. Common causes for cooking deviations include product overlap, power failures, or breakdown of cooking equipment. Establishments are required to take corrective actions, as required by the HACCP regulations, regardless of whether the cooking process is addressed through a CCP or prerequisite program. This includes ensuring no product that is injurious to health or otherwise adulterated because of the deviation enters commerce (9 CFR 417.3(a) or (b)).

- **When cooking is addressed through a CCP,** establishments are required to determine the cause of all cooking deviations, no matter how small (9 CFR 417.3(a)(1)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). If the cause of each small cooking deviation is not traced and corrected when first noticed, the problem will likely recur and become more frequent and more severe. The establishment should consider an occasional small process deviation to be an opportunity to find and correct a process control problem. Large process deviations or continual small ones always constitute unacceptable risk. Also, continual or repetitive process deviations from the critical limit demonstrate that the establishment is unable to control its process and that its corrective actions are not preventing recurrence as intended.

- **When cooking is addressed through a prerequisite program** and a deviation occurs, establishments are required to reassess their HACCP system to determine whether the newly identified deviation or unforeseen hazard should be addressed and incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Also, an establishment may not be able to continue to support the decision in its hazard analysis that pathogens are not reasonably likely to occur, if it has continual or repetitive deviations from its cooking prerequisite program (9 CFR 417.5(a)(1)).

To assist establishments in determining and supporting product disposition as required 9 CFR 417.3(a) or (b), FSIS is including information regarding potential pathogens of concern during different types of cooking deviations and recommendations for using pathogen modeling and sampling. Establishments should carefully evaluate each deviation as each situation is unique and needs to be evaluated individually. Ultimately, the establishment should rely on the expertise of a processing authority to determine the severity of cooking deviations and subsequent appropriate disposition of the product in question. Knowledge of the specific product and factors that would favor or inhibit the growth of various bacterial pathogens is essential to determine product safety. As stated in the *HACCP Systems Validation Guideline*, the advice of processing authorities should include reference to established scientific principles as well as reference to peer-reviewed scientific data.

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Pathogens of Concern During Cooking Deviations

Cooking deviations can allow pathogens that are controlled under normal cooking procedures to become a hazard, depending on the type of cooking deviation (described below) that occurs. Specific pathogens of concern may include:

- *Salmonella,* STEC (in beef products), and *Lm,* which could grow as vegetative cells to levels that overwhelm the Log reductions achieved by cooking.
- *S. aureus,* if allowed to grow to high levels, may produce heat-stable enterotoxins in the food.
- *Bacillus cereus* (*B. cereus*) (in rare cases), if allowed to grow to high levels in the food, may produce a heat-stable emetic toxin in the food or enterotoxins in the small intestine.
- *Clostridium perfringens* (*C. perfringens*) and *Clostridium botulinum* (*C. botulinum*) spore-forming pathogens that can germinate and grow in product held at higher temperatures (*e.g.,* > 80°F).

Again, it is important someone knowledgeable such as a processing authority evaluates each deviation to determine the pathogens of concern.

Three Common Types of Cooking Deviations

When cooking products to lethality, deviations may occur due to three main reasons:

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.

3. Slow heating CUT allows product to remain at temperatures that allow pathogen growth (*e.g.*, product remains at temperatures 50°F to 130°F for more than 6 hours; see FSIS Critical Operating Parameters for Cooking Come-Up-Time (CUT), page 23).

Specific recommendations for evaluating each type of cooking deviation, including the pathogens of concern, are provided below. Alternatively, the establishment can provide additional support for the safety of the product (*e.g.,* a journal article, or support from a processing authority). These are general recommendations; the specific responses will vary based on the unique factors of each deviation.

Type 1. Missed Endpoint Time-Temperature

When evaluating product disposition after the process fails to meet an endpoint time or temperature parameter, the first step is to assess whether the process met a different time-temperature combination in the reference table. In some cases, the process may not have achieved an instantaneous lethality temperature (*e.g.,* 158°F for meat) identified in the CCP but may have achieved the dwell time needed for a lower

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temperature in the same table (*e.g.,* 154°F for 27 seconds) when considering the total time product temperature was at or above the lower temperature.

Did the process meet a **different validated** time-temperature combination?

- If yes, then product is safe to release.

- If no, then FSIS recommends contacting a processing authority who may help you identify proper D and z values to calculate **integrated process lethality** considering the product come-up -time and come-down-time. One common tool for calculating integrated lethality is the AMI Process Lethality Determination Spreadsheet. If properly conducted, the AMI lethality spreadsheet is a sound scientific approach for determining the overall lethality of a cooking process (Scott and Wedding, 1998). The D-values at the reference temperature for the three main pathogens of concern (*Salmonella* spp. *E. coli* O157:H7, and *Lm*) are generally conservative values and should be valid for most cooked meat ready-to-eat (RTE) processes provided that the product is moist when cooked (high relative humidity). However, if the product is not moist when cooked and the product surface is allowed to dry out during the lethality step, the D-values referenced in the AMI lethality spreadsheet are not valid.

  NOTE: There are many complexities involved in identifying appropriate D and z values needed as inputs for calculating integrated pathogen lethality. FSIS advises establishments to work with a processing authority or someone knowledgeable in thermal death-time values, to ensure they select appropriate values and are properly using the lethality calculator.

- Establishments may consider **recooking** the product, but only if all critical operating parameters (including relative humidity and CUT time) were met during the initial heating and during recook.

  - If the relative humidity option in the scientific support was not applied, the establishment should also follow recommendations for evaluating a Type 2 Deviation: Insufficient Humidity During Cooking described on page 69, or

  - If the CUT parameter was not met, the establishment should also follow recommendations for evaluating a Type 3 Deviation: Long Heating CUT described on page 70, and contact a **processing authority** for assistance.

    NOTE: Cooking deviations that combine a missed time-temperature parameter with a long CUT are complex situations which may require considering *C. perfringens* and *C. botulinum* as described in the *Stabilization Guideline*, in addition to the other pathogens of concern.

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- If establishments cannot **recook** the product, they should consider the following alternative actions:

    - Provide **alternative support** (page 55) (*e.g.,* information from a processing authority that includes scientific citations that product is safe to release);

    - **Sample and test the product** (see Product Testing recommendations for Type 1 deviations, page 77); or

    - **Destroy the product** (renderer or landfill).

Type 2. Insufficient Humidity During Cooking

As described on page 16, some bacteria can become more heat tolerant when they are exposed to moderate levels of heat, drying, and other factors. Bacteria can then survive at higher temperatures than they normally would. Below are general recommendations for an establishment to consider when evaluating products after a Type 2 cooking deviation resulting from insufficient humidity (*i.e.,* the relative humidity option in the scientific support was not followed) during cooking.

- Consider **sampling and testing** product for *Salmonella*, *Lm*, and *E. coli* O157:H7 (if a beef product), using a statistically based sampling program as described in Product Testing on page 77.

- If **recooking**, apply a **higher time-temperature** combination validated to achieve lethality in a product with similar intrinsic factors (*e.g.,* water activity).

    - It would not be appropriate to recook the product following FSIS Relative Humidity Options (page 26) without additional support that recooking conditions adequately rehydrate the product surface (see Attachment A6. Cooking Country-Cured Hams, page 90).

    - Under these circumstances, FSIS would need to verify that such scientific support is adequate in the context of the specific product, process, and situation. Examples of acceptable support may include support that:

        - Demonstrates that a validated wet bulb temperature target has been met to ensure lethality. To show that the surface has been rehydrated, the wet bulb target should be higher than the product surface temperature.

        - Includes water activity testing: A water activity increase after recooking (compared to water activity before recooking), may indicate that the surface has been rehydrated.

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NOTE: FSIS is not aware of any research validating recooking procedures for products that may have heat tolerant *Salmonella* because of a lack of relative humidity during the initial cook. However, FSIS plans to update these recommendations as more research becomes available.

Type 3. Long Heating CUT

If the total time between 50 and 130°F is longer than hours 6, recooking alone may not be sufficient to ensure the safety of the product. That is because during the extended CUT toxigenic pathogens could grow rapidly (*e.g., S. aureus*), allowing enterotoxins to form. Some enterotoxins are extremely heat-stable and are not inactivated by normal cooking temperatures. Therefore, it is not always possible to recook the product alone to ensure its safety. The establishment should continue to recook the product to address vegetative pathogens (*e.g.,* STEC, *Lm*, and *Salmonella*). It should also provide additional support that heat-stable enterotoxins do not present a hazard in the product after the recooking step.

As noted in Type 1. Missed Endpoint Time-Temperature, cooking deviations that **combine** a missed time-temperature parameter with a long CUT are complex situations that may require considering *C. perfringens* and *C. botulinum* as described in the *Stabilization Guideline*, in addition to the other pathogens of concern. The establishment may want to contact a processing authority for assistance.

To determine product disposition after a long heating CUT deviation, the establishment should:

1. Address growth of vegetative pathogens that do not produce toxins, AND
2. Address the potential enterotoxin formation as described below.

If either hazard is not controlled to safe levels, then product should be destroyed. Further guidance on these two recommendations is provided below:

1. **Address growth of vegetative pathogens:** (*e.g.,* STEC, *Lm*, and *Salmonella*).

    - FSIS recommends that establishments use microbial modeling (page 72) and other information (*e.g.,* scientific journal articles, book chapters, and processing authorities) to estimate growth of *E. coli*, *Lm*, and *Salmonella.*

        - If modeling estimates the growth of vegetative pathogens to be **1-Log or less**, provided the predictive microbial modeling program is validated, modeling is adequate to show that the process prevented vegetative pathogen outgrowth and the establishment can address the potential for enterotoxin formation (see 2 on the next page).

        - If modeling estimates **more than 1-Log growth** of any vegetative pathogen, establishments should **recook product** OR **sample and**

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test for vegetative pathogens to determine the safety of the product (see Type 3 deviation recommendations in Product Testing, page 77).

- Many establishments avoid the cost of sampling and testing by recooking the product or consulting a processing authority to identify alternative support that vegetative pathogens are addressed.

- **If product is recooked**, it should be done to a higher time and temperature that has been shown to achieve enough additional Log reductions to address the amount of vegetative cell growth the model predicted. Using a recook procedure that achieves the correct additional Log reduction is important to ensure increased pathogen load will not overwhelm the Log reductions achieved during the recook procedure (see page 72). For example, if predictive microbial modeling showed a 2.5-Log and 3.0-Log increase for *Salmonella* and *E. coli* O157:H7, respectively, in a roast beef product, the recook step should be adjusted so that the cooking time-temperature combination can achieve at least a 9.5-Log reduction of *Salmonella* instead of a 6.5-Log reduction. The AMI Process Lethality Determination Spreadsheet discussed on page 68 may be used to support the cooking time-temperature combination can achieve sufficient Log reductions.

2. **Address potential enterotoxin formation:** (*e.g., S. aureus)* by demonstrating that toxigenic pathogens **did not** grow to levels of public health concern or **produce enterotoxin**.

    o FSIS recommends that establishments use microbial modeling (page 72) and other information (*e.g.,* scientific journal articles, book chapters, and processing authorities) to provide additional information to determine product safety.

    - If predictive microbial modeling estimates a **< 3-Log growth of *S. aureus***, modeling is adequate to show that the process prevented enterotoxin formation provided the predictive microbial modeling program is validated. **If growth of vegetative pathogens is also addressed the product can be released**.
      NOTE: Due to the rapid growth of *S. aureus* in meat and poultry products, modeling for *B. cereus* (which grows slower) is not needed when *S. aureus* growth is controlled (< 3-Log).
    - If microbial modeling estimates a **≥ 3-Log growth of *S. aureus***, then product should be **tested** for *S. aureus* **enterotoxins** A, B, C,

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D, and E using a statistically representative sampling procedure. If the product contains non-meat ingredients previously associated with *B. cereus* associated illnesses (*e.g.,* rice, or pasta) and microbial modeling estimates > 3-Log growth of *S. aureus*, then establishments may also want to consider testing for *B. cereus* emetic toxin (Product Testing page 77).

NOTE: As stated previously, **conditions that allow for 3-Log or higher growth of *S. aureus* are a public health concern** (ICMSF, 1996). Furthermore, this level of growth (*i.e.,* 3-Log) for *S. aureus* is consistent with the pass/fail criteria developed by the Institute of Food Technologists (IFT) for the FDA to control for this food safety hazard (IFT, 2003).

*To support safe release of the product, **both** the vegetative pathogens **and** enterotoxin formation must be addressed with supporting documentation. If either hazard is not controlled to safe levels, then product should be **destroyed**.*

Predictive Microbial Modeling

Establishments may use predictive microbial modeling to estimate the relative growth of bacteria during a long heating CUT deviation (Type 3). As explained above for Type 3 heating deviations, modeling results can be used to support various product disposition options including release, recooking, sampling and testing, or destruction provided the model used has been validated. Predictive microbial modeling tools may be used to evaluate product disposition in the event of other types of deviations (*e.g.,* for Type 1 deviations establishments may use the AMI Process Lethality Determination Spreadsheet). However, this section is focused on evaluating product disposition during Type 3 heating deviations due to their complexity.

When performing predictive microbial modeling, it is important that establishments:

1. Use validated models (see examples below):
    - It is not appropriate to rely solely on one model unless the model has been validated for the particular food of interest. A validated cooking model is a model whose predictions have been found to agree with or are more conservative than actual observed results. If a model has not been validated for a particular food of interest, the establishment should provide additional supporting documentation to support the results from the model (*e.g.,* sampling data or comparison with other model results).
2. Enter accurate product formulation information:

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- FSIS recommends entering the raw product formulation values for Type 3 Deviations: Long CUT, since the high moisture values at the start of cooking will support faster pathogen growth and therefore represents the worst-case scenario. If using finished product values, establishments should provide reasoning for how that represents the product matrix during CUT.

3. Enter accurate time and temperature information in the model:

    - When entering time and temperatures into the model, the establishment should include all parts of the process, including cooking and recooking CUTs after a Type 1 or 3 cooking deviation. If the establishment does not include all parts of the process, it may underestimate pathogen growth.

    - When determining the temperature, the establishment should take into account both the temperature at the coldest internal area (center) of the product and at the surface of the product.

    - It is important to obtain an internal time and temperature profile of the product, and a wet bulb time and temperature profile of product since wet bulb can be used to describe the product's surface temperature. If an establishment does not have wet bulb temperature data, it can conduct predictive microbial modeling using the internal time-temperature profile of the product, provided that sufficient humidity was used during cooking. However, the establishment should take into account that the product surface temperature will be higher than the center of the product under high relative humidity conditions.

    - For cases with large time gaps between known temperature observations, establishments may consider interpolating to estimate additional time-temperature data points between known observations assuming linear heating. However, if the product temperature dwells or holds between 90 and 120°F (the optimal growth range of *S. aureus*) for an extended period of time, excess *S. aureus* growth could result in a potential hazard in the product being uncontrolled. The establishment should consider the likely accuracy of the predicted growth when making a product disposition determination using linear interpolation.

    - Assume **no *S. aureus* growth above 120°F.**

      NOTE: FSIS has included the time that product remains from 120 to 130°F in the heating CUT option (page 23) to reduce the risk *B. cereus* (a spore-former) could germinate and then grow at these higher temperatures, potentially producing a heat-stable emetic toxin.

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4. Address model limitations in a conservative manner:

    - If product characteristics or other conditions are outside the range of the model, accuracy is not guaranteed. Establishments should support how the model results represent the product or the worst-case scenario for the hazard in the product or should compare the results to several other pathogen models and should make decisions based off the model that shows the worst-case scenario (i.e., for *S. aureus* that is the model that estimates the most outgrowth).

NOTE: This guidance contains recommendations for addressing certain limitations in two recommended models at the time the guidance was written. Neither modeling program is controlled by USDA-FSIS and may change. FSIS will update its modeling recommendations in future revisions to be consistent with any changes made to the modeling programs.

Recommended Models

- **Therm 2.0 model** (*S. aureus*, *Salmonella*, and *E. coli* O157:H7).
  The University of Wisconsin Therm 2.0 model is designed to allow processors to input the product's time-temperature profile and it has been validated for estimating the growth of *S. aureus*, *Salmonella*, and *E. coli* O157:H7.

  The three input variables and their ranges for entering into the growth model are provided below (Ingham *et al.,* 2009):

    - **Input variables and ranges:**
        - Temperature profile: 50°F to 110°F (10ºC to 43.33ºC)
        - Date/time: the model allows for entry of calendar date and time
        - Meats:
            - **In meat and poultry products containing salt** (≤ 2.5%), establishments should use the Therm 2.0 model for **Bratwurst** for predicting pathogen growth. This model should be used because it was designed to take into account the bacterial pathogen's behavior in pork sausage and related products that contain higher fat levels, sodium chloride, and spices. For example, adding salt to product will inhibit the competing microorganisms, but allow for greater growth of salt tolerant *S. aureus*; the Therm 2.0 model will predict this. Because the Therm 2.0 model for Bratwurst was developed with data from a pork product, establishments should compare the results with another model, such as the DMRI Staphtox Predictor when evaluating deviations involving poultry products.

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- **In meat and poultry products without any added salt**, establishments should use the Therm 2.0 model for **Beef, Pork, or Poultry** based on the product type (Ingham *et al.,* 2009).

  - **Overcoming model temperature limitations**: (maximum 110°F)

    - The Therm 2.0 model **does not automatically interpolate** (estimate a linear change) between time-temperature data points entered by the user. Therefore, FSIS recommends establishments enter temperature observations for at least every 30 minutes, or at the lowest time interval available.

    - For temperatures >110°F, substitute 110°F for any temperature above 110°F up to 120°F. *S. aureus* grows fastest at 110°F. The growth rate slows as temperatures increase from 110 to 120°F. Modeling using 110°F for temperatures observed from 110 to 120°F will slightly overestimate the growth of *S. aureus*.

    - For temperatures between 120 and 130°F assume no growth of *S. aureus* (leave this out of the model).

- **DMRI Staphtox Predictor (Version 1.0)** (*S. aureus*)
  The Danish Meat Research Institute's (DMRI) Staphtox predictor (Version 1.0) may also be used to predict the growth of *S. aureus* in meat and poultry products, with added salt (*i.e.,* 1.8% to 4.2%). This model has been validated and was specifically designed to predict the growth of *S. aureus* in different meat product processes based on product composition and changes in temperature.

  The six input variables and their ranges for entering product composition information into the growth model are provided below (Gunvig *et al.,* 2018):

  - **Input variables and ranges:**
    - Temperature profile: 32°F to 105.6°F (0ºC to 40.9ºC)
    - pH: 4.4 – 6.1
    - % sodium chloride (NaCl) in product (based on the total weight of the product formulation): 1.8 – 4.2%.

      NOTE: The model converts % sodium chloride (NaCl) into the % water-phase salt.

    - % potassium chloride (KCl) in product (based on the total weight of the product formulation): 0.0 – 4.2%
    - Sodium nitrite added to product: 0 – 150 ppm
    - % water in final product (as determined through laboratory analysis): 62 – 78%

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- **Worst Case Scenario**: FSIS recommends using the values listed below as model inputs for any products where the values are unknown. These values represent a worst-case scenario for the growth of *S. aureus* based on product composition:

    - pH: 6.1
    - % NaCl in product: 1.8%
    - % KCl in product: 0.0
    - Sodium nitrite added to product: 0 ppm
    - % water in final product: 78% (highest allowed in model)
    - Initial level *S. aureus*: 100 CFU/g

- **Overcoming model temperature limitations:** (maximum 105.6°F)

    - For temperatures > 105.6°F (40.9°C), substitute 105.6°F for any temperature above 105.6°F (40.9°C), up to 120°F (48.9°C). The fastest growth in this model is at 105.6°F. As described above, *S. aureus* continues growing at higher temperatures, but the growth rate slows as temperature increases up to 120°F (48.9°C). For modeling, use 105.6°F for temperatures observed from 105.8°F (41°C) up to 120°F (48.9°C), which will slightly overestimate the growth of *S. aureus* (fail-safe).

    - For temperatures between 120°F (48.9°C) and 130°F (54.4°C) assume no growth of *S. aureus* (leave out of the model).

NOTE: Establishments may use the ComBase *S. aureus* model as support. However, this model has not been validated and establishments should follow the recommendation for using models that are not validated (*i.e.,* compare the results of several models and make decisions using the worst-case results) as described above.

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Product Testing

As described in the cooking deviation and the microbial modeling recommendations (pages 67-72), if the establishment is unable to support the product disposition through predictive microbial modeling or some other means, the establishment can test a statistically-based number of samples of the product to support its safety. Table 7 identifies the hazards to be tested for according to the type of cooking deviation that took place. These are general recommendations; it is important that someone knowledgeable such as a processing authority evaluate each deviation to determine the appropriate sampling and testing plan.

Table 7. FSIS Recommendations for Product Sampling and Testing After Each Type of Cooking Deviation to Determine Product Disposition

Type of Heating Deviation*	Vegetative Pathogens			Heat-stable Enterotoxins
	Salmonella	*Lm*	*E. coli* O157:H7 **	*S. aureus* Enterotoxins A, B, C, D, and E
1 - Missed Time-Temperature	X	X	X	
2 - Insufficient Humidity	X	X	X	
3 - Long CUT				X
Multiple Types in Combination (*i.e.,* missed time-temperature AND long CUT)	Contact a **processing authority** for assistance evaluating product disposition in a complex deviation which combined multiple types of heating deviation. May need to consider *C. perfringens* and *C. botulinum* in addition to the hazards listed in this table.			

*Cooking deviation Types 1-3 are described on page 66.
***E. coli* O157:H7 testing recommended only for products containing beef. Establishments may also choose to test for other STEC; however, testing for *E. coli* O157:H7 alone is sufficient.

Sampling in Response to a Cooking Deviation

- The establishment should test a statistically representative number of samples per lot depending on the bacterial pathogen. FSIS recommends testing at least 10-15 products per lot as outlined by the two-class sampling plan (Case 11 and Case 13, respectively) per the International Commission on Microbiological Specifications for Foods (ICMSF, 2002).

- If the product contains non-meat ingredients previously associated with *B. cereus* associated illnesses (*e.g.,* rice, or pasta) and microbial modeling estimates >3-Log growth of *S. aureus*, then establishments may also want to consider testing for *B. cereus* emetic toxin.

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NOTE: FSIS does not recommend all products to be tested for *B. cereus* emetic toxin due to the low incidence of *B. cereus* in raw meat and poultry. If you are uncertain if the formulation of product affected by a cooking deviation may need to address *B. cereus* emetic toxin as a potential hazard, please contact askFSIS (page 9).

Key Question

Question: Can samples be composited for lab testing?

Answer: It depends on what the sample is being tested for:

- **Enterotoxins? No.** FSIS does not recommend compositing samples to be tested for enterotoxins. Combining multiple samples for a single test (*i.e.,* compositing) could prevent the test from detecting enterotoxins in the product.

- **Vegetative pathogens? Yes.** However, the number of samples that can be combined depends on the pathogen. Additionally, establishments should ensure the lab method has been validated for the larger test portion.

    - *Salmonella* and *E. coli* O157:H7: FSIS recommends compositing up to 3 samples (total 75g) for a total of 5 analyses although establishments may also be able to support compositing up to 15 – 25-g samples (total 375 grams). The establishment would collect 15 samples from different pieces of product. The lab would combine the 25g sample from each of 3 different pieces, to make a 75g composited sample for analysis. The lab analyzes 5 composited samples. When compositing, establishments should ensure the method has been validated for the larger test portion. FSIS has validated a 325g test portion size for its analysis of RTE product samples collected under the RTEPROD program (see the *FSIS' Microbiology Laboratory Guideline Salmonella* Chapter).

    - *Lm:* FSIS recommends compositing up to 5 samples (total 125g) and 3 lab tests total. The establishment would collect 15 samples from different pieces of product. The lab would combine the 25g test sample from each of 5 different pieces, to make a 125g composited sample for analysis. The lab analyzes 3 composited samples. When compositing, establishments should ensure the method has been validated for the larger test portion. FSIS has validated a 25g and 125g test portion size for its analysis of RTE product samples collected under the RTEPROD and R*Lm* programs, respectively (see the *FSIS' Microbiology Laboratory Guideline Listeria monocytogenes* Chapter).

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Disposition after Testing Results:

To support the safe release of the product, **every hazard** associated with the type of heating deviation identified (see Table 7) must be controlled for the safe release of product. If any single hazard is not controlled, then product should be **destroyed** (renderer or landfill).

- **Enterotoxins:**
  - If the product tests negative for enterotoxins, product can be **released,** unless insanitary (or other) conditions exist that could adulterate the product (*e.g.,* vegetative pathogens).
  - If any enterotoxin is found, the lot is adulterated, and product should be **destroyed** (renderer or landfill).)

- **Vegetative Pathogens:**
  - If the product tests negative for vegetative pathogens, product can be **released**, unless insanitary (or other) conditions exist that could adulterate the product (*e.g.,* enterotoxins).

    NOTE: It would be inappropriate to test for live *S. aureus* instead of enterotoxin because it is possible for *S. aureus* to produce enterotoxins prior to the death of the bacteria (*e.g.,* during cooking). The food product would still cause illness even though no vegetative bacteria were found.

  - If any vegetative pathogens are found, the lot is adulterated. Product may be:
    - **Recooked** per Type 1 or Type 2 recommendations (pages 67-69); or
    - **Destroyed** (rendered or denatured per 9 CFR 314.3(a), 9 CFR 325.11(a), 9 CFR 325.13(a)(1) through 325.13(a)(7), or 9 CFR 381.95 and sent to a landfill).

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Common Mistakes made by Establishments when Evaluating Heating Deviations—and the Recommended Solutions

1) The establishment did not input an accurate internal time-temperature profile into the model. The establishment should be using a data logger or collecting time and temperature data at regular intervals during cooking. The establishment should take into account all parts of the process and temperatures at both the center and surface of the product (Monitoring Endpoint Temperature page 21 and Monitoring Surface Temperature page 24).

2) In Type 1 or 3 deviations with a missed time-temperature parameter, the establishment failed to take into consideration the amount of bacterial growth that could occur during the cooking come-up-time when the cooking cycle was restarted. To address this issue, the establishment should consider both the original come-up-time, the initial cooling, and second come-up-time when the cooking is restarted as part of its modeling.

3) The establishment did not address whether additional growth of *Salmonella*, *E. coli* O157:H7 and *Lm* could have occurred during the Type 1 heating deviation and whether heat tolerance could have developed. To address this issue, when recooking the product, the establishment should increase endpoint time-temperature and apply sufficient humidity (FSIS Relative Humidity Options page 26).

4) The establishment failed to address the amount of growth of *S. aureus* and other bacterial pathogens that could occur on the product's surface. Measuring the temperature both at the product center and at the surface (wet bulb) temperature would address this issue.

5) The establishment failed to take into account the initial levels of *S. aureus* commonly found in raw meat and poultry. Levels of pathogens in raw product are approximately 2-Log. Increases of 3-Log or more could result in conditions where enterotoxin could be formed. Establishments should limit *S. aureus* growth to 2-Log or less, to support safe release of product based on microbial modeling. See Biological Hazards of Concern During Cooking subsection: *Staphylococcus aureus* (page 14) for more information.

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Attachment A3. When can Products be Labeled as Pasteurized?

FSIS defines pasteurization as any process, treatment, or combination thereof, that eliminates or reduces the number of pathogenic microorganisms to achieve at least a 5-Log reduction of either *Salmonella* or *Lm,* on or in ready-to-eat (RTE) meat or poultry products in the **final finished package**.

With adequate validation, pasteurization processes **may include** alternative technologies other than traditional cooking (*e.g.,* high pressure processing (HPP)). FSIS considers products **with a raw appearance** that have been treated with a lethality process that renders the product RTE, and that are not post-lethality exposed (*e.g.,* "steak tartare" subjected to a HPP treatment) as pasteurized.

For the product to be labeled "pasteurized," the treatment needs to:

1) Be applied in the final package (product is not post-lethality exposed);
2) Be sufficient to eliminate the number of pathogenic microorganisms to make the product safe for human consumption (so there are no detectable pathogens; RTE), and
3) Be effective for at least as long as the product shelf life.

Irradiation is not a pasteurization process. Although the effect is similar to pasteurization, FSIS considers ionizing radiation a food additive under 9 CFR 424.22.

Establishments may label products as "pasteurized." However, the term "pasteurized" is a **special statement and claim** that needs to be submitted to the Agency for label approval under 9 CFR 412.1(c)(3). The request for label approval needs to include supporting documentation providing evidence that the process achieves a 5-Log reduction of *Salmonella* or *Lm*. For more information see the *FSIS Compliance Guidance for Label Approval*.

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Attachment A4. Sources of *Salmonella* Contamination in RTE Products and Best Practices to Address It

Although the *Salmonella* percent positive found in ready-to-eat (RTE) products is low, the presence of *Salmonella* in RTE products may indicate a serious processing and public health problem. Common sources of *Salmonella* in RTE products include:

- Under processing.
- Cross-contamination.
  - Product contact surfaces that are contaminated with *Salmonella*; or,
  - Raw product contact with RTE product.
- Ingredients added to the product or the sauce after the cooking step.
- Improper handling by establishment employees.
- Insect or animal vectors.

Each common source of *Salmonella* contamination on RTE products and best practices to prevent the hazard are discussed in detail below.

Under-Processing

Under-processing occurs when the lethality treatment is not adequate to eliminate the pathogens of concern. For heat-treated product, under-processing may result from inadequate cooking or the development of bacterial heat tolerance due to drying of the product's surface before completion of the lethality step because of inadequate humidity (see FSIS Critical Operating Parameters for Cooking (Time-Temperature Tables) page 23).

Cross-Contamination

Cross-contamination of product can occur from situations such as the following:

- Using the same equipment (*e.g.,* slicers) for both raw and cooked products without complete cleaning and sanitizing of the equipment (as should be addressed in the establishment's Sanitation Standard Operating Procedure (SOP)) after raw production and prior to RTE production.
  - In a for-cause Food Safety Assessment (FSA) in response to a *Salmonella* positive in a RTE head cheese product, FSIS identified equipment used to grind both raw and cooked ingredients for head cheese was not cleaned and sanitized between use for raw and cooked meat potentially resulting in *Salmonella* cross-contamination.

- Placing cooked product on the same surface (*e.g.,* cutting table) as raw product without complete cleaning and sanitizing of the surface before reuse.

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- Using the same utensils or containers (*e.g.,* scoops or buckets) for both raw and cooked product.
    - In two FSAs, popped pork skins were most likely contaminated with *Salmonella* when the same buckets and tongs were used for handling both raw and RTE product.

- Condensation or aerosolization in the processing environment.

Best Practices to Prevent Cross-Contamination

Under the HACCP regulations, establishments are required to prevent contamination of product with pathogens after the lethality step. Establishments are required to maintain sanitation in the RTE area to ensure that food contact surfaces are free of contamination from pathogens such as *Lm* and *Salmonella*. Best practices include:

- Completely separating the processing areas by time or space (*e.g.,* scheduling raw and RTE processing on different days).

- Installing separate air ventilation systems that are designed to prevent or minimize condensation and other potential air contaminants. If separate ventilation systems are not feasible, ensure that airflow is directed from the RTE areas to the raw areas.

- Using separate equipment for RTE and raw processing. If this is not possible, schedule use of equipment first for RTE processing and then for raw processing.

- Restricting travel of personnel from the non-RTE area to the RTE area during processing.

- Establishing proper sanitation procedures for equipment that is moved from a non-processing area to an RTE processing area to prevent product contamination from the equipment during operation.

- Avoiding passing raw product through RTE areas and passing RTE product through raw production areas.

- Not allowing RTE product in coolers to come into contact with raw products or surfaces that may be contaminated.

- Discarding products that touch environmental surfaces (*e.g.,* product that has fallen on the floor) if the product cannot be properly reconditioned to ensure that any possible contamination is eliminated.

- During cleaning and sanitizing, following proper sanitation procedures to ensure that no food residue is left on the equipment.

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- When adding ingredients to a second container, avoiding any contact between the ingredient container and the interior of the second container.

Ingredients Added After the Lethality Treatment

Salmonella contamination may occur from the addition of uncooked vegetables (*e.g.,* tomatoes and onions), fresh herbs, eggs, spices (that may or may not have been treated to eliminate *Salmonella*), or other ingredients (*e.g.,* nuts, hydrolyzed vegetable protein (HVP)) to processed meat and poultry products after the primary lethality treatment. Sauce that has not undergone a lethality treatment may also be a source of contamination of the finished product, even if the pH is low. The safety of all ingredients added to the product after the lethality step should be considered, even if they are normally considered RTE. In some cases, FSAs determined the addition of seasonings or other ingredients after the cooking step resulted in the contamination of RTE product with *Salmonella*. Failure to identify all steps in a process, including the addition of contaminated ingredients and sauces, can result in an inadequate food safety system.

Outbreaks related to ingredients added after lethality treatment

An outbreak and several recalls of meat and poultry products that were prepared using *Salmonella*-contaminated ingredients exemplify the need to ensure the safety of all ingredients added to the product after the lethality treatment. Examples include a 2010 outbreak-related recall of salami products coated with contaminated pepper (RC-006-2010) and recalls involving products containing HVP that was the subject of an FDA recall (*i.e.,* bacon base, RC-015-2010; beef tornados, RC-016-2010, and beef taquitos and chicken quesadillas, RC-017-2010). RC-055-2010 may have been due to contaminated sauce added to the product after the lethality step. There have also been two recalls of meat and poultry salads containing *Salmonella* contaminated tomatoes recalled by the supplier (RC-033-2011 and RC-79-2011), and Caesar salad containing contaminated cilantro that was the subject of an FDA recall (RC-059-2012). In 2018, there were 12 recalls due to potential vegetable contamination with *Salmonella* and *Lm* that were triggered by an FDA investigation and subsequent recall from the same supplier (RC-092-2018, RC-093-2018, RC-094-2018, RC-095-2018, RC-096-2018, RC-097-2018, RC-098-2018, RC-099-2018, RC-100-2018, RC-101-2018, RC-102-2018, and RC-103-2018).

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Requirements and Best Practices to Prevent Hazards from Ingredients Added Post-Lethality

Establishments are required to:

- Ensure all ingredients and other articles used in the preparation of any meat or poultry product are clean, sound, healthful, wholesome and otherwise such as will not result in the product being adulterated (9 CFR 318.6 and 9 CFR 424.21).

- 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 may choose to use COAs that include negative test results for each lot of the non-meat ingredient as support or may test each lot of non-meat ingredients upon receipt; however, establishments have flexibility and do not have to only rely on testing.

    - Alternatively, establishments may maintain supporting documentation demonstrating that the ingredients such as spices, have been treated by processes to kill pathogens (e.g., irradiation, ethylene dioxide, steam treatment of spices), or they can apply a lethality treatment to the ingredients (e.g., cook the sauce of a pork BBQ).

    - In most cases, a LOG alone would not be sufficient to support the safety of non-meat ingredients added to a product unless they indicate how each lot of ingredients is processed, tested, treated, or otherwise processed to ensure its safety as described in the bullet above.

    - A LOG can be used to support the safety of pre-packaged ingredients (*e.g.,* ketchup or mustard) that have not been associated with previous outbreaks or recalls.

NOTE: Many frozen vegetables are considered NRTE by the producing facility. FSIS recommends establishments that do not receive a COA or LOG as described in the bullets above, treat all frozen vegetables as NRTE and address potential hazards from this ingredient (*e.g.,* by testing each lot of non-meat ingredients upon receipt or applying a validated lethality treatment). Additionally, any vegetables labeled with cooking instructions are to be treated as NRTE.

- Developing procedures to ensure that spices or other source materials are maintained under sanitary conditions and are not contaminated by the introduction of pathogens during repeated opening of the container and removal of the ingredient for use in multiple production lots.

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- Taking steps to ensure sauce used for RTE products is also not contaminated by exposure to unclean surfaces, untreated ingredients, or contact with raw products.

Food Handlers

There is a high incidence of salmonellosis in the US. Additionally, some people can be asymptomatic carriers that spread *Salmonella* without appearing ill. Establishment employees that are asymptomatic carriers may be a source of *Salmonella* in RTE products.

Best Practices to Prevent Hazards from Food Handlers

Food handlers, employees, and supervisors at food preparation facilities should:

- Stay home from work when having symptoms of vomiting or diarrhea and wait to resume work until at least 24 hours have passed since the vomiting and diarrhea symptoms ended.
- Wash hands upon resuming duties after breaks and before putting on gloves.
- Wear separate or color-coded frocks in RTE areas of the establishment and control employee traffic between raw and RTE production areas.
- Train employees in proper hygiene practices, and regularly monitor those practices, and retrain employees at least annually.
- Develop and maintain procedures to ensure that sanitizer concentrations in footbaths are monitored and maintained adequately.

Animals

Animals (*e.g.,* birds and rodents) and insects may also contaminate food products with *Salmonella*. It is possible for animal fecal contamination within and outside the establishment to be introduced into the RTE production area.

Best Practices to Prevent Hazards from Animals

- Maintaining an effective pest control program to maintain sanitary conditions and ensure that product is not adulterated (9 CFR 416.2(a)). Rats, mice, birds, and insects are sources of pathogen contamination.
- Product and ingredients should always be protected from contamination and adulteration during processing, handling, and storage (9 CFR 416.14).

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Attachment A5. RTE *Salmonella* Self-Assessment Tool

FSIS recommends that establishments use this tool to determine whether they have adopted the appropriate procedures to control *Salmonella,* or whether they should adopt new procedures. If establishments find that they are not meeting the recommendations in this guideline, FSIS recommends they consider changing practices to better control *Salmonella* in the product.

The questions are related to evaluating the following:

- Hazard Analysis/HACCP Plan
- Ingredients
- Corrective Actions in Response to *Salmonella* Positives

Hazard Analysis/HACCP Plan	YES	NO	N/A
1. Have you considered whether *Salmonella* is a hazard reasonably likely to occur (RLTO) in your Hazard Analysis?	□	□	□
2. If you determined that *Salmonella* was RLTO, did you establish CCPs to control or prevent it?	□	□	□
3. If you established CCPs, do you have sufficient supporting documentation to support the effectiveness of the measures you are taking?	□	□	□
4. If you produce roast, cooked, or corned beef, does your process achieve at least a 6.5-Log or other supportable (*e.g.,* 5-Log) reduction of *Salmonella*?	□	□	□
5. If you produce cooked uncured meat patties, does your process achieve at least a 5-Log reduction of *Salmonella*?	□	□	□
6. If you produce cooked poultry, does your process achieve at least a 7-Log reduction of *Salmonella*?	□	□	□
7. If you produce other cooked RTE meat products, does your process achieve at least a 6.5-Log or other supportable (*e.g.,* 5-Log) reduction of *Salmonella* in the product?	□	□	□
8. If you are using an alternative lethality Log reduction target (*e.g.,* 5-Log reduction) do you have additional support such as COA, LOG, combined interventions, or baseline testing?	□	□	□
9. As part of your critical limits, have you identified the target or performance standard that your	□	□	□

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process is designed to achieve (9 CFR 417.2(c)(3))?			
10. If you produce cooked products and use a time-temperature table, are you applying humidity during the cooking process?	□	□	□
11. If "no" to the question above, do you have support for why relative humidity is not a critical operating parameter?	□	□	□
12. If "no" to the question above, are you applying a scientific gap for lack of relative humidity? Which one? (fill in here)	□	□	□
13. If you produce cooked products and use a FSIS time-temperature table, have you limited product heating come-up-time (50 to 130°F) to 6 hours or less?	□	□	□
14. If "no" to the question above, do you have alternative support for applying a long come-up-time?	□	□	□
15. If "no" to the question above, are you applying a scientific gap for long come-up-time?	□	□	□

Ingredients	**YES**	**NO**	**N/A**
16. Do you add ingredients to the product after the lethality treatment? (if "no," move to the next section)	□	□	□
17. Do you maintain COAs, LOGs, or other information (*e.g.,* sampling data) to support the safety of the ingredients?	□	□	□
18. If you use LOGs, do they indicate how each lot of ingredients is processed, tested, or otherwise treated to ensure its safety?	□	□	□
19. Are the ingredients that you add to the product included in your flow chart or hazard analysis?	□	□	□
20. If you use pre-packaged ingredients that are included in the final package with the finished product do you have LOGs or other information to support their safety?	□	□	□

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Corrective Actions in Response to *Salmonella* Positives	YES	NO	N/A
21. Has a RTE product sample tested positive for *Salmonella* from FSIS or establishment testing? (If "no" the assessment is complete).	☐	☐	☐
22. If you control *Salmonella* in your HACCP plan, did you take corrective actions according to 9 CFR 417.3(a)? (If you prevent *Salmonella* through a Sanitation SOP or other prerequisite program, skip to #26).	☐	☐	☐
23. Did you take steps to identify and eliminate the cause of the deviation, according to 9 CFR 417.3(a)(1)?	☐	☐	☐
24. If the cause of the positive result is under-processing, did you immediately review your processing system and bring the process back into compliance?	☐	☐	☐
25. If the cause of the positive result is lack of support for your lethality process, did you change your process or provide additional support for the safety of the process, in light of the positive result?	☐	☐	☐
26. If you prevent *Salmonella* through a Sanitation SOP or another prerequisite program, did you take corrective actions according to 9 CFR 417.3(b)?	☐	☐	☐
27. As part of your corrective actions, did you reassess your HACCP plan according to 9 CFR 417.3(b)(4)?	☐	☐	☐
28. As a result of your reassessment, did you address the pathogen in a CCP or make substantive changes to your prerequisite program?	☐	☐	☐

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Attachment A6. Cooking Country-Cured Hams

In October 2018, an establishment recalled cooked country-cured ham product that was associated with a listeriosis outbreak (Recall 084-2018; CDC: Outbreak of Listeria Infections Linked to Deli Ham). FSIS's investigation at the establishment found that the country-cured hams were cooked in a sealed bag **multiple times.** Before being cooked multiple times, the ham was salt-cured and dried, thus reducing its water activity. Additionally, after an initial cooking step in a sealed bag, the ham was removed, drained of its juices, and placed into a second bag; during this process, the ham may have been cross-contaminated from the processing environment. Additionally, the draining of juices may have resulted in drier conditions during cooking. The establishment used FSIS cooking guidance (Appendix A) as scientific support that cooking achieved lethality of pathogens, including *Lm*. However, as discussed on page 12, Appendix A guidance was not intended for lower water activity products cooked under dry conditions or for dried products cooked multiple times. Hence the process may not have been lethal to *Lm* (USDA/FSIS, 2020). Establishments that apply these types of processes must identify other support for their HACCP System (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)).

During the outbreak investigation, FSIS also discovered that several establishments cook country-cured hams **once** under moist conditions using FSIS cooking guidance as support. FSIS cooking guidance was also not intended for lower water activity products cooked even under moist conditions; however, FSIS is not aware of any imminent food safety issues with this practice. Therefore, page 47 (Table 5), includes critical operating parameters that may be applied to cook dried products like country cured hams if they are cooked **once** under moist conditions to rehydrate the surface. While cooking under moist conditions should rehydrate the surface, there is no research validating this process so it is considered a scientific gap. As with other scientific gaps, there is a vulnerability because FSIS's lethality guidance is not designed for processes where the drying step comes before the moist cooking step. This is because cooking under low moisture conditions results in product with a lower water activity. These conditions lead to pathogens, such as *Lm,* becoming more heat-tolerant and the organism could survive the cooking process. To minimize this vulnerability, FSIS recommends:

If the product is cooked **once:**

- Establishments should gather support such as water activity measurements after drying (before cooking), then again after cooking to demonstrate that the water activity increased, and product surface was rehydrated during cooking. This recommendation applies even if the product is cooked-in bag, because the water activity may not be high enough to ensure that pathogens are killed on the product without addition of moisture.

- Establishments should achieve the highest water activity possible during cooking. Values ≥ 0.96 have been shown to prevent bacterial heat tolerance

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(Kieboom, *et al.* 2006), but this water activity may not be possible for all processes to achieve.

- Establishments conduct finished product testing for *Salmonella* and *Lm* as part of on-going verification.

Establishments should also ensure that the cooking bag is completely sealed, so that moisture is contained in the bag and the product is not exposed to the environment or contaminants. Cooking bags may be compromised during steps such as molding or shaping. The establishment should have a process to verify the package integrity, and if leaks are observed, the establishment should reprocess/recook the product, using a supported process.

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