

FSIS

***Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A**

June 2017

This guidance document provides information that small and very small meat and poultry establishments producing RTE products can use to produce safe products with respect to *Salmonella* and other pathogens. In particular, this guideline covers:

- Regulatory requirements associated with the safe production of RTE products.
- Options establishments can use to achieve lethality and stabilization of *Salmonella* and other pathogens.
- Steps that establishments can take to ensure that the safety of ingredients added after the lethality treatment.
- Lessons learned from Food Safety Assessments (FSAs) performed in RTE establishments.
- Information from Appendix A and other previously issued compliance guidelines.

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Purpose

This guidance document is intended to assist small and very small meat and poultry establishments understand the regulatory requirements associated with safe production of ready-to-eat (RTE) products with respect to *Salmonella* and other pathogens. Previously, this guideline was issued in April 2011 and was re-issued in September 2012 to respond to comments on the April 2011 version.

FSIS has revised this guideline to provide clarification of regulatory requirements for RTE products. It also provides additional options for achieving lethality of *Salmonella* in RTE products, updates the lessons learned from food safety assessments (FSAs), and combines and replaces information from previously issued guidance documents including:

- Appendix A Compliance Guidelines for Meeting Lethality Performance Standards for certain Meat and Poultry Products (Appendix A)¹, see pages 16 and 33.
- Time-Temperature Tables for Cooking RTE Poultry Products (Poultry Time- Temperature Tables), see pages 12 and 34.
- FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks (5-log Table), see pages 14 and 36.
- Appendix A Guidance on Relative Humidity and Time/Temperature for Cooking/Heating and Applicability to Production of Other RTE Meat and Poultry Products (Appendix A Humidity Guidance), see pages 15-18 and 32.

This version of the document replaces previous versions of the *Salmonella* Guidelines, Appendix A, and the other guidance documents listed above. Although FSIS has not made changes to most of the information from the previous versions of the guidance documents (including the time-temperature table in Appendix A), it has revised the guideline to include information that may not have been clear in previous versions, such as recommendations for the use of humidity. Therefore FSIS recommends that establishments use this newer version of the guideline as support for their process.

This document provides **guidance** to assist establishments in meeting FSIS regulations. Guidance represents **best practices** recommended by FSIS, based on the best scientific and practical considerations, and does not represent **requirements** that must be met.

This guideline is focused on small and very small establishments in support of the Small Business Administration's initiative to provide small and very small establishments with compliance assistance under the Small Business Regulatory Flexibility Act (SBRFA). However, all FSIS regulated meat and poultry establishments may be able to 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 HACCP systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides them with information that may be otherwise unavailable to them.

¹ Appendix A of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products" 64 FR 732.

Request for Comments

FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days. The document may be updated in response to comments; however, FSIS encourages establishments to start using it.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMS, Docket Clearance Unit, Mail Stop 3782, Patriots Plaza III, 8-164, 355 E Street, SW, Washington D.C. 20024-3221.

All items submitted by mail or electronic mail must include the Agency name and title of the guidance document. Comments received will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

Introduction

Salmonella is a bacterial pathogen that causes diarrhea and fever and may result in *Salmonella*-induced chronic conditions such as aseptic reactive arthritis and Reiter's syndrome (a combination of urethritis, conjunctivitis, and arthritis). The Centers for Disease Control and Prevention (CDC) reported that nontyphoidal *Salmonella* spp. is one of leading causes of foodborne illness, with an estimated 1 million cases of foodborne *Salmonella* infection annually in the U.S (Scallan et al., 2011). FSIS tests RTE products for *Salmonella* in the RTEPROD_RISK and RTEPROD_RAND project codes.

The following table provides an analysis of data from FSIS random and risk-based sampling projects from 2009 to 2014. It shows that the incidences of *Salmonella* positive samples from the two programs ranged from 0.03% to 0.12% for the random program and 0.03% to 0.09% for the risk-based program. The low incidence of positive results indicates that establishments have been following the guidance and producing safe products.

Table 1. *Salmonella* spp. in RTE Product Samples, CY 2009-2014

| Year | Random | Positive Samples | | Risk Based | Positive Samples | |
|--------------|---------------|------------------|-------------|---------------|------------------|-------------|
| | Total Tested | No. | % | Total Tested | No. | % |
| 2009 | 2,761 | 1 | 0.04 | 8,158 | 3 | 0.04 |
| 2010 | 3,152 | 1 | 0.03 | 8,707 | 3 | 0.03 |
| 2011 | 3,293 | 3 | 0.09 | 8,865 | 8 | 0.09 |
| 2012 | 3,353 | 1 | 0.03 | 7,650 | 5 | 0.07 |
| 2013 | 3,263 | 4 | 0.12 | 8,898 | 3 | 0.03 |
| 2014 | 3,356 | 2 | 0.06 | 9,750 | 3 | 0.03 |
| 2015 | 3,399 | 2 | 0.06 | 9,788 | 5 | 0.05 |
| Total | 19,178 | 12 | 0.06 | 52,028 | 25 | 0.05 |

All of the *Salmonella*-positive samples were obtained from establishments with Hazard Analysis and Critical Control Point (HACCP) sizes of small or very small.² In addition, most positive samples were obtained from establishments applying *Listeria* control Alternatives 2b and 3.³ This finding indicates that control measures applied by establishments to control *Listeria* are likely effective against *Salmonella*. Establishments in Alternatives 2b and 3 were sampled at a higher rate than Alternative 1 establishments in risk-based sampling programs, which could have led to an increased level of positives from these establishments, but the higher level of positives may also be indicative of lack of adequate sanitation and control procedures. Many of the same sanitation practices that establishments use to address *Listeria monocytogenes* (*Lm*) can also be used to address *Salmonella* cross contamination. See the [FSIS Compliance Guideline: Controlling *Lm* in Post-lethality Exposed RTE Meat and Poultry Products \(*Listeria* Guideline\)](#).

The data analysis also showed pork products were the sources of over half (21/37) of all *Salmonella*-positive RTE samples. FSIS recommends that establishments producing all RTE products, and especially pork products, ensure that the products are processed and handled safely to prevent *Salmonella* contamination.

Example

FSIS performed an analysis of *Salmonella* positives from 2005 to 2010, and found that pork barbecue products with vinegar and pepper-based sauce were implicated in 7/30 (23%) of *Salmonella* positive samples from RTE meat and poultry products. Although the pH of the sauce is low, *Salmonella* may still survive if the sauce (or the ingredients in the sauce), are not treated with a lethality treatment (e.g., cooking). If contaminated ingredients or sauce are added after the cooking step, the product could become adulterated, in the absence of a post lethality treatment.

In 2011, FSIS issued a notice (which was later finalized in [Directive 10,240.4](#), *Verification Activities for the *Lm* Regulation and the RTE Sampling Program*), instructing Inspection Program Personnel (IPP) to verify that establishments producing pork barbecue with vinegar and pepper-based sauce assess the hazards associated with the product. From 2011 to 2014 there was one *Salmonella* positive in a pork barbecue sample, indicating that the guidance and industry actions were effective. However, in 2015 and 2016 there were 4 more *Salmonella* positives and 2 *Lm* positives in these products. Therefore, FSIS continues to focus its resources on establishments producing pork barbecue and other products that are handled after the cooking step, and included updated instructions in [Directive 7111.1](#), *Verification Procedures for Lethality and Stabilization*, for IPP to verify that establishments are addressing hazards from *Salmonella* in ingredients.

² HACCP production size classes: large establishments, with 500 or more employees; small establishments, with 10-499 employees; and very small establishments, with fewer than 10 employees or annual sales of less than \$2.5 million

³ 9 CFR part 430 (The *Listeria* Rule) lays out three alternative approaches establishments can take to control *Listeria* in their environment. These include:

Alternative 1: use of a post-lethality treatment and an antimicrobial agent.

Alternative 2a: use of a post-lethality treatment.

Alternative 2b: use of an antimicrobial agent.

Alternative 3: use of sanitation alone.

Although most RTE establishments test their food contact surfaces for *Lm* or an indicator organism as required by the *Listeria* Rule, to FSIS's knowledge, many RTE establishments do not actively monitor for *Salmonella*. However, because *Salmonella* may contaminate RTE products after the lethality treatment, prudent establishments should assess potential food-safety hazards from *Salmonella*, and test food contact surfaces when appropriate.

Any detectable *Salmonella* or other pathogens in RTE products adulterates these products (64 FR 732, 736). FSIS requires establishments to hold or control products that it tests for pathogens such as *Salmonella* and *Lm*. FSIS will perform "for cause" FSAs along with Intensified Verification Testing (IVT) in establishments with *Salmonella* positives in RTE products. FSIS evaluates the results of these assessments on an ongoing basis. A summary of lessons learned from analyses of *Salmonella* FSAs is included in the Lessons Learned from RTE *Salmonella* Food Safety Assessments (FSAs) Section of this document.

Sources of *Salmonella* Contamination

Salmonella contamination of RTE products often occurs due to under processing. However, it may also occur due to cross-contamination in the post-processing environment. In this environment, contamination of the product can be introduced from:

- Product contact surfaces that are contaminated with *Salmonella*,
- Improper handling by establishment employees,
- Insect or animal vectors, and
- Ingredients (e.g., herbs, onions, hydrolyzed vegetable protein (hvp), or spices) added to the product or the sauce after the cooking step.

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 (FSIS [RC-006-2010](#)) and recalls involving hvp (i.e., bacon base, [RC-015-2010](#); beef tornados, [RC-016-2010](#), and beef taquitos and chicken quesadillas, [RC-017-2010](#)). FSIS Recall [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 ([RC-033-2011](#) and [RC-079-2011](#)), and Caesar salad containing contaminated cilantro ([RC-059-2012](#)).

Although the percent positive rate of *Salmonella* in RTE products is low, the presence of *Salmonella* in RTE products may indicate a serious processing and public health problem. Although *Salmonella* in an establishment may be an environmental contaminant, it is more likely to be associated with under processing or serious deficiencies in sanitary practices. In several cases, *Salmonella* has been associated with the addition of untreated ingredients added after the lethality step.

Salmonella can contaminate RTE products in the following ways:

1. Under-processing

- a. 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 resistance due to drying of the

product's surface before completion of the lethality step because of inadequate humidity (see the Lethality Section for more information).

b. Inadequate drying, curing, or fermentation are causes of under-processing in salt-cured, dried, and fermented products.

2. Contamination from ingredients added after the lethality treatment

a. *Salmonella* contamination may occur from the addition of uncooked vegetables (e.g., tomatoes), fresh herbs, eggs, spices (which may or may not have been treated to eliminate *Salmonella*), or other ingredients (e.g., 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.

b. Raw meat and poultry, or ingredients that are processed in the same physical area, may contaminate finished products by direct or indirect routes (e.g., contaminated equipment surfaces, environmental sources, food handlers, or aerosolization).

3. Contamination from food handlers

a. Given the incidence of human salmonellosis in the U.S. and the potential for asymptomatic carriage in humans, there is potential for product contamination from establishment employees.

b. Effective employee training programs and consistent execution of Sanitation Standard Operating Procedures (Sanitation SOPs) are necessary to ensure that contamination does not occur.

4. Contamination from insect or animal vectors

a. Animals (e.g., birds and rodents) and insects may also contaminate food products with *Salmonella*. Establishments should have effective pest control programs in place to maintain sanitary conditions and ensure that product is not adulterated (9 CFR 416.2(a)).

b. It is possible for animal fecal contamination within and outside the establishment to be introduced into the RTE production area. Product and ingredients should always be protected from contamination and adulteration during processing, handling, and storage (9 CFR 416.4(d)).

In some cases, post lethality treatments (PLTs) and antimicrobial agents or processes (AMAPs) that are designed to address post-lethality contamination from *Lm* can also be used for *Salmonella* (Mbandi and Shelef, 2002; Jofré et al., 2008). However, PLTs alone should not be relied on to control *Salmonella* because they may not be effective against high levels of contamination. Instead, establishments should focus their efforts on ensuring that RTE product is not contaminated after the lethality step, by cross contamination or the addition of contaminated ingredients.

RTE Processes

As stated above, *Salmonella* is a hazard found on most raw meat or poultry products. To control *Salmonella* and other pathogens in RTE products, establishments apply lethality treatments. Lethality treatments are processes that achieve a specific reduction in the number of *Salmonella* and other pathogens in the product (i.e., an “x-log” reduction). The lethality treatment should be sufficient to eliminate or adequately reduce *Salmonella* and other pathogens and prevent the production of toxins or toxic metabolites to produce a safe RTE product. A RTE meat or poultry product is in a form that is edible without additional preparation, such as cooking, to achieve food safety. Establishments most often achieve lethality by cooking the product, but they can also use other lethality treatments, such as fermentation, drying, salt curing, and other processes that make the product safe for consumption.

Lethality

FSIS has established performance standards in the regulations for the lethality processes for the RTE products listed below. However, to meet HACCP requirements and produce unadulterated product, all RTE products must be produced to achieve product safety. The HACCP regulations require establishments to consider the food safety hazards that are reasonably likely to occur in their processes and establish steps to prevent, eliminate, or reduce those hazards to acceptable levels (9 CFR 417.2). Establishments also required to list the critical limits that must be met at each of the critical control points (9 CFR 417.2(c)(3)). The critical limits must be designed to ensure that applicable targets and performance standards are met. To meet these requirements, establishments should identify the performance standard or target their process is designed to achieve as part of their HACCP system.

NOTE: If an establishment uses Appendix A 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 or from other validated scientific support for its HACCP system.

In addition, establishments are required to validate that their system works as intended to address these hazards (9 CFR 417.4(a). For more information see the [FSIS Compliance Guideline: HACCP Systems Validation](#) (FSIS Validation Guideline).

The following describes the regulatory requirements for safe production of RTE products.

In particular:

Key definitions

Lethality is the process or combination of processes that ensures a specific, significant reduction in the number of *Salmonella* and other pathogens in the product (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 to produce a ready-to-eat (RTE) product.

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.

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

Stabilization is the process of preventing or limiting the growth of *C. perfringens* and *C. botulinum* (spore-forming bacteria capable of producing toxins either in the human intestine after consumption or in the product).

- **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\(a\)\(1\)](#).
- **Cooked uncured meat patties** must be processed to meet or exceed the times and temperatures listed in [9 CFR 318.23](#), which will achieve a 5-log lethality.
- **Cooked poultry products** must be processed to achieve at least a 7-log reduction of *Salmonella* per [9 CFR 381.150\(a\)\(1\)](#).
- **For other RTE meat products**, establishments must ensure the products are safe for consumption (i.e., are free of pathogens) to produce unadulterated product and meet HACCP requirements.
 - For **cooked products**, FSIS recommends that establishments achieve a 6.5 log or 5 log reduction of *Salmonella* in their process. To use a 5-log reduction, establishments should provide additional support for the safety of their process (see box below and the 5-log Lethality Options for Cooked Meat Products section).
 - For **shelf stable** products, FSIS recommends that establishments achieve a 5-log reduction of *Salmonella* (see the box below).

Historically, FSIS has recommended that establishments achieve at least a 6.5 log reduction of *Salmonella* in **cooked meat** products. 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. However, since that time FSIS has issued the FSIS Validation Guideline which clarifies the types of data establishments must gather to support the effectiveness of their HACCP systems to achieve safe products. Therefore, FSIS is providing establishments with the option of achieving at least a 5-log reduction of *Salmonella* in these products, if they provide additional support for their process. For **shelf stable** products, the *Salmonella* Risk Assessment did not show a substantially higher risk of illness compared to a 6.5-log reduction, so FSIS continues to recommend a 5-log reduction of *Salmonella* for these products.

Indicators of Lethality

For cooked products, FSIS recommends that establishments use *Salmonella* as an indicator of lethality because it tends to be more heat resistant than most other pathogens. If the establishment's scientific support demonstrates that its lethality treatment achieves sufficient reduction in *Salmonella*, it does not need to provide additional support

An **alternative lethality** is a lethality treatment, other than ones prescribed in the regulations, that an establishment uses to meet performance standards (9 CFR 318.17 (a)(1) and 381.150(a)((1))). When using an alternative lethality, the establishment should ensure that its HACCP system is validated to ensure that no viable *Salmonella* organisms remain in the finished product.

Performance standards are quantifiable pathogen reduction or growth limit **requirements** set by FSIS for lethality and stabilization of certain products.

Targets are quantifiable pathogen reduction levels or growth limits set by establishments to produce safe RTE products. Targets are used by establishments to demonstrate that their lethality and stabilization process prevents, eliminates, or reduces pathogens to acceptable levels. Establishments can choose to use FSIS guidelines or identify and support their own targets.

that adequate reduction in other pathogens is achieved. As stated in the FSIS Validation Guideline, establishments should not use pathogens other than *Salmonella* as indicators of lethality for cooked products unless they provide support that the pathogen studied displays similar resistance to the process that destroys the bacteria. For dried, salt-cured and fermented products, FSIS recommends that establishments use lethality of *Salmonella*, *Lm*, and *E. coli* O157:H7 (in products containing beef) as the indicators of lethality. That is because *Lm* or *E. coli* O157:H7 may be more resistant to drying or fermentation and acidification in these products. Therefore, the establishment should consider the impact of the process on those pathogens in addition to *Salmonella*.

NOTE: FSIS has provided information about the safe production of meat and poultry jerky products in the [FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments](#) (FSIS Jerky Guideline). That information remains in a separate guideline due to the complexities of the process, and to help address questions from small and very small producers.

Pasteurization

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 *Salmonella* on or in meat or poultry products in the final finished package. In cases where the products are known to be positive for *Lm*, because they test positive or cross over a surface that is positive for *Lm*, the process would need to achieve a 5-log reduction of *Lm* on or in meat or poultry products in the final package to make them safe for human consumption. This process should be effective for a period that is at least as long as the shelf life of the food (as determined by the manufacturer) when it is stored under normal and moderate abuse conditions.

With adequate validation, pasteurization processes may include alternative technologies other than traditional cooking (e.g., high pressure processing (HPP)). FSIS will not, however, consider irradiation a pasteurization process or treatment. Although the effect is similar to pasteurization, FSIS considers ionizing radiation a food additive under 9 CFR 424.22. 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 “pasteurized,” The HPP treatment needs to be sufficient to eliminate the number of pathogenic microorganisms to make the product safe for human consumption (so there are no detectable pathogens) and be effective for at least as long as the product shelf life. 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*.

NOTE: Stabilization requirements and recommendations are described in the [FSIS Compliance Guideline for Stabilization \(Cooling and Hot-Holding\) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B](#).

Customized Processes

Although compliance with these guidelines will yield product that meets the lethality performance standards and targets, some establishments may want to develop customized processing procedures to achieve lethality. As previously stated, establishments also may want to develop and implement processes using an alternative lethality. However, all processes must achieve an appropriate reduction of pathogens of concern and prevent the production of their toxins or toxic metabolites to meet HACCP requirements.

Establishments or their process authorities may develop customized procedures or an alternative lethality that meets the performance standards or targets by using information obtained from the literature or by comparing their methods with established processes. However, statistical calculations on results obtained from sampling alone are not sufficient to demonstrate that the product meets the performance standards or targets. Instead, scientific support (e.g., book chapters, journal articles, etc.) is needed to demonstrate that sufficient lethality of the bacterial pathogens of concern is achieved in the product.

One of the most definitive tools at the disposal of an establishment or processing authority is the challenge study. 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 salmonellae research. A cocktail of various serotypes of *Salmonella* should be used in an inoculated pack study to demonstrate that the lethality performance standard is met. Relatively heat resistant 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. For more information on conducting challenge studies, see the FSIS Validation Guideline, page 8.

Lethality Requirements for Specific RTE Products

The following sections review the lethality requirements for specific types of RTE products. More general information on cross-contamination and findings from FSAs follows in later sections.

Fully Cooked Not Shelf Stable HACCP Category

The following information is for the Fully Cooked Not Shelf Stable HACCP Category. Although there are several types of products produced under this category, most RTE products are produced using this HACCP category.

Cooked Beef, Roast Beef, and Cooked Corned Beef

As previously stated, producers of cooked beef, roast beef and cooked corned beef must meet the regulatory requirements in 9 CFR 318.17. These state that the process must achieve at least a 6.5-log reduction of *Salmonella* or an alternative lethality (e.g., a 5-log reduction) in the finished product. Establishments may use the time and temperature tables in Appendix A (now included in this document) to achieve a 6.5 or 7 log reduction of *Salmonella*. If establishments choose to achieve an alternative lethality in the product, they need to have sound decisions in the hazard analysis that supports that the alternative lethality results in the production of safe products. See the 5-log Lethality Options Section for more information.

NOTE: Appendix A, the 5-log Table, and the Poultry Time-Temperature Tables can be used as scientific support to meet the first element of validation (9 CFR 417.4(a)(1), as described in the FSIS Validation Guideline.

If meat or poultry products are slow cooked, the cooking come-up time (time it takes to reach the final internal temperature), should be no more than 6 hours between 50-130°F to ensure that *S. aureus* growth is limited. If the come-up time is longer than 6 hours, the establishment should provide additional support demonstrating that *S. aureus* will not grow to unacceptable levels (i.e., >3 logs) in the product. Outbreaks have been attributed to meat and poultry products (in particular hams) produced using a slow come up time that allowed *S. aureus* to grow to high levels and produce a heat stable enterotoxin. *S. aureus* can contaminate meat and poultry during slaughter and dressing and also has been found in brine injected into products like hams.

Relative humidity (or moisture during cooking) is a critical factor for ensuring adequate lethality for pathogens in meat and poultry products as described in the Relative Humidity Section. The establishment should incorporate humidity in its cooking process, unless it meets one of the criteria listed in the Situations when Humidity is not needed Section on page 18, or provides additional support for why humidity would not be needed in its process. When incorporating humidity into its HACCP plan, the establishment should include the humidity levels it is using as part of its critical limits for its cooking critical control point (CCP), or humidity should be incorporated into a prerequisite program associated with the cooking CCP. If the establishment has not included humidity as part of its HACCP plan or prerequisite programs and can't support why humidity is not needed in its processes, FSIS will likely find that it is not meeting the requirements of 9 CFR 417.5(a)(1).

Establishments producing meat and poultry products should have sufficient monitoring equipment, including recording devices, to assure that the time (accuracy assured within 1 minute), the temperature (accuracy assured within 1°F), and relative humidity (accuracy assured within 5%) limits of these processes are being met. Data from the recording devices should be made available to FSIS program employees upon request.

Cooked Meat Patties

A temperature/time table for achieving lethality requirements in meat patties titled "Permitted Heat-Processing Temperature/Time Combinations for Fully-Cooked Patties" appears in 9 CFR 318.23 "[Heat-Processing and Stabilization Requirements for Uncured Meat Patties](#)". Although not explicitly stated in the regulation, the temperature and time combinations provided are designed to achieve at least a 5-log reduction of *Salmonella* and *E. coli* O157:H7.

The lethality performance standard for uncured, cooked meat patties did not include humidity considerations because these products are cooked with direct heat. Therefore, for these products, the times and temperatures listed in the lethality requirements and in Appendix A are deemed to be sufficient to achieve the necessary lethality for safety, without the need to also consider humidity.

Cooked Poultry

As previously stated, establishments producing cooked poultry products must achieve at least a 7-log reduction of *Salmonella* in the product (9 CFR 381.150). To assist establishments in meeting this requirement, FSIS developed the Poultry Time-Temperature Tables.

Establishments can also follow the guidelines for cooked poultry rolls and other cooked poultry products that were previously found in Appendix A (see below) or develop their own procedures for safely cooking poultry products. When using the Poultry Time-Temperature tables, the establishment should incorporate humidity into its process, as described below.

Appendix A Guidelines for Cooked Poultry Rolls and Other Cooked Poultry Products

FSIS is including these recommendations because they still may be used by some establishments, although additional time-temperature options were later provided in the Poultry Time-Temperature tables. These recommendations can be used for any poultry product (not just cooked poultry rolls and breakfast strips).

1. Cooked poultry rolls and other cooked poultry products should reach an internal temperature of at least 160 °F or another time temperature combination from the Poultry Time-Temperature Tables during the cooking process. Cured and smoked poultry rolls and other cured and smoked poultry should reach an internal temperature of at least 155 °F during the cooking process. Cooked RTE product to which heat will be applied incidental to a subsequent processing procedure may be removed from the cooking medium (e.g., oven or hot water tank) for such processing provided that it is immediately fully cooked to the 160°F internal temperature.

2. Establishments producing cooked poultry rolls and other cooked poultry products should have sufficient monitoring equipment, including recording devices, to assure that the temperature (accuracy assured within 1°F) limits of these processes are being met. Data from the recording devices should be made available to FSIS program employees upon request.

3. Although not previously mentioned in Appendix A, humidity should be maintained as appropriate when cooking poultry rolls and other cooked poultry products (see the humidity discussion below).

Poultry Time-Temperature Tables

The Poultry Time-Temperature Tables (now included in this guideline) provide establishments with time and temperature combinations that can be used to cook chicken and turkey products with different fat levels. The time-temperature tables were developed based on a study performed by Agricultural Research Service (ARS) to determine the times and temperatures of cooking chicken and turkey to achieve a 7- log reduction of *Salmonella* (Juneja et. al., 2001). Prior to the issuance of these tables, some establishments were using the 7-log lethality recommendations for roast beef, cooked beef, and corned beef in Appendix A. However, those time and temperature combinations are not appropriate to cook poultry products, because of the difference in bacterial heat resistance due to the type of meat species. As stated previously, the cooking come-up time should be no more than 6-hours between 50-130°F, or the establishment should provide additional support for the safety of its product. When using the Poultry Time-Temperature tables, establishments should consider the use of humidity (see below).

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

Answer: Yes. The times and temperatures listed in the tables for products with 12% fat can be used for products with higher percentages of fat. These time and temperature combinations will achieve sufficient lethality as long as adequate humidity (as described in the Humidity Section) is applied during the process.

Use of Humidity for Poultry Products

Similar to meat products, humidity is a critical operational parameter for poultry products. Because humidity was not specified in the Appendix A Guidelines for Cooked Poultry Rolls and Other Cooked Poultry Products, some establishments may have thought it was not needed. However, the same scientific principles and reasoning apply to poultry products. To apply humidity to poultry products, establishments can use the options described in the Relative Humidity Section. As stated previously, if the establishment has not included humidity as part of its HACCP plan or prerequisite programs and can't support why humidity is not needed in its processes, FSIS will likely find that it is not meeting the requirements of 9 CFR 417.5(a)(1).

Other Fully Cooked Meat Products

As previously stated, establishments producing other fully cooked meat products must control pathogens to meet HACCP requirements. In addition, a part of their critical limits, establishments must identify the performance standards or targets that their CCP will meet. Since there are no performance standards for these products, establishments must establish targets (e.g., at least a 6.5 or 5-log reduction of *Salmonella*) or use a validated time temperature combination from their scientific support.

Although Appendix A was intended primarily as guidance for processors of cooked beef, corned beef, and roast beef, the time and temperature tables in Appendix A also can be used to achieve a 6.5 or 7 log reduction of *Salmonella* in other RTE meat products, including pork. As previously stated, producers of other RTE meat products can cite Appendix A as the support for their process and do not need additional scientific support for their process. However, as stated below, establishments should incorporate relative humidity as part of their HACCP plan or prerequisite program, unless they have support for why humidity would not be needed in their process.

Alternatively, establishments can choose to implement a process that achieves at least a 5-log reduction of *Salmonella* in the product. As stated previously, establishments need to provide scientific support that the 5-log reduction will result in the production of a safe product as part of their validation process. Establishments may use the [5-log table](#) to achieve this reduction in cooked products. Additionally, establishments need to consider a number of factors that were identified in the *Salmonella* Risk Assessment, specifically:

- Categorization (shelf stable or not shelf stable)
- Pathogen load in raw materials
- Storage and Growth
- Consumer Reheating

5-log Lethality Options

Establishments can use the following options to support a 5-log reduction of *Salmonella*:

- 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 provide support (e.g., Letters of Guarantee (LOG), Certificates of Analysis (COA), or sampling information) for each lot demonstrating that levels of

Salmonella are low enough to be controlled by a process achieving 5-log reduction with an appropriate safety margin (e.g. 2 logs). For example, an establishment may provide a LOG indicating that a certain log reduction (e.g. 1.5 or 2 logs) is achieved in the source materials through the use of a validated antimicrobial intervention.

- For shelf stable products, use a combination of factors to achieve at least a 5-log reduction (e.g., treatment of source materials, marinating in low pH marinade, heat treatment, drying, and HPP). For example, if an establishment can support that treating the source materials achieves a 2-log reduction of *Salmonella*, marinating achieves a 2-log reduction, and drying achieves another 2 log reduction, it would be able to support the safety of the product.
- Conduct a 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 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). Consequently, the establishment should plan to collect about 10 samples per week (e.g., 500 samples per year). In addition, once the baseline is complete, the establishment should collect at least as many verification samples over a year as it did in its baseline study to ensure the ongoing effectiveness of the program.

When designing the baseline study, establishments should consider seasonality of *Salmonella* contamination. Generally, the incidence of *Salmonella* on beef and pork products is highest during the three months of July through September and the lowest during the months of January through March (USDA/FSIS, 2007b). Establishments should consult references to determine the optimal study design (e.g., Williams et. al., 2013). For example, if the proportion of screen-test positive samples is less than 10%, then the establishment should increase the dataset size in order to obtain a sufficient number of screen-test positive samples that can be enumerated for *Salmonella*.

Relative Humidity

“Relative humidity” is defined as the ratio of the amount of water vapor in the air to the maximum capacity of the air at the same temperature. Because Appendix A focused on particular products, some establishments may have thought that humidity is only needed for those products. **However, as stated previously humidity is needed for all cooked RTE products (including poultry products), unless the establishment meets one of the criteria in the Situations when Humidity is not needed Section or it provides additional support that humidity would not be needed.** Humidity is a critical factor that affects the lethality that is achieved during the cooking step. Consequently, humidity should be part of the CCP’s critical limit or incorporated into a prerequisite program associated with the Cooking CCP.

High relative humidity around a product during cooking promotes heat process lethality in two ways:

- First, the humidity reduces surface evaporation and the energy or heat that evaporation removes from the product during heating. If sufficient relative humidity surrounding the product is not maintained during the lethality treatment, undesirable evaporative cooling at the surface will occur, and the product will not reach the desired temperature.

Producing products under conditions of high humidity early in the cooking process reduces evaporative cooling allowing products to reach higher product surface temperatures which results in a greater reduction in microorganisms.

- Second, the humidity keeps the product surface (and any pathogens) more moist and prevents unwanted concentration of solutes (e.g., sugar and salt) as a result of drying. Research has demonstrated that bacteria can become more heat resistant as their moisture levels decrease, and increased concentrations of solutes, especially sugars, increase the heat resistance of bacteria.

Therefore, drying of the product surface before the pathogens are destroyed will increase pathogen heat resistance and allow them to survive the heating process. By incorporating 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 time-temperature combinations in Appendix A will remain valid (Goepfert, 1970; Goodfellow and Brown, 1978). If evaporation or an increase in solute concentration are likely to occur, the times and temperatures in Appendix A are not likely to be sufficient to provide the required lethality.

Appendix A and the Appendix A Humidity Guidance provided options for roast beef, cooked, beef and corned beef as well as other RTE products which are provided below. FSIS also recommends that producers use the following information in the FSIS Jerky Guideline when deciding which humidity options to adopt:

- A flow chart for using Appendix A humidity options (pages 19-24).
- Instructions for making your own wet bulb (reprinted with permission from the University of Wisconsin, page 49).
- An example of a time-temperature recorder chart to support the option of continuously injecting steam (page 53).

Appendix A Humidity Options

Meat and poultry products should be moist cooked throughout the process or cooked as described below. As stated previously, establishments should use one of these options when using the time-temperature combinations in Appendix A, the Poultry Time-Temperature Tables, or the 5-log Table (see How to Use the Time-Temperature Tables, page 37). The moist cooking may be accomplished by:

- Placing the meat or poultry in a sealed, moisture impermeable bag, removing the excess air, and cooking.
- Completely immersing the meat or poultry, unbagged in water throughout the entire cooking process.
- Using a sealed oven or steam injection to raise the relative humidity above 90 percent throughout the cooking process.

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

Relative humidity may also be addressed by using one of the following methods:

- Heating meat or poultry products that are 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 Appendix A or the Poultry Time-Temperature Tables.

NOTE: Humidity is not needed for products that are 10 pounds or more because they have a low surface to mass ratio. Therefore, the surface dries out slower than a small mass product and *Salmonella* is less likely to become heat resistant.

- Heating meat or poultry products of any size **when the cooking time is at least 1 hour** to:

- A minimum internal temperature of 145 °F (62.8 °C) with applicable rest time (e.g., 4 minutes for meat products and 8.4 minutes for chicken products with 1% fat). The relative humidity of the oven should be maintained by:

- Continuously introducing steam for **50 percent** of the cooking time or 1 hour (whichever is longer)
- Using a sealed oven capable of producing and **maintaining the recommended humidity** for **50 percent** of the cooking time or 1 hour (whichever is longer).

NOTE: pages 21 and 22 of the FSIS Jerky guideline provide further guidance for using a sealed oven or injecting steam to maintain humidity. Establishments should use this guidance to support that their system is capable of producing and maintaining humidity, as stated above.

Maintaining humidity is defined as keeping the humidity at the same level or rate throughout the process. If the humidity drops during the cooking process, the establishment would need to provide additional support for the safety of the product.

- 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 internal temperature and time combinations in Appendix A, the Poultry Time-Temperature Tables, and the 5-log table. 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). The relative humidity may be achieved by the use of steam injection or sealed ovens capable of producing and maintaining the required relative humidity.
- Heating meat or poultry products of any size **when the cooking time is less than 1 hour** to any internal temperature and time combinations in Appendix A, the Poultry Time-Temperature Tables, and the 5-log table. Relative humidity of the oven is maintained at 90 percent for the entire cooking time. The relative humidity may be achieved by the use of steam injection or sealed ovens capable of producing and maintaining the required relative humidity.

Situations when Humidity is not needed

As stated above, humidity is not needed when meat or poultry products that are above 10 pounds are cooked as specified. For certain other processes, humidity around the product is inherently maintained and does not have to be added or monitored. Such processes include, but are not limited to:

1. Immersing the product in a liquid cooking medium.
2. Cooking the product in a sealed, moisture impermeable bag (e.g., cook-in-bag meat or poultry).
3. Applying direct heat, such as a grill, heating coil, flame, or rotisserie, which will heat the surface rapidly enough to attain a lethal effect before evaporation or surface cooling does occur.
4. Using a semi-permeable or impermeable product casing – almost all casings will prevent or inhibit moisture loss, so that the heat resistance of pathogens is not affected during the cooking process (e.g., sausages cooked in casings).
5. Cooking beef patties - The phrase “cooked beef” in Appendix A was intended to refer to a large mass product, such as a brisket, and not to cooked beef patties that generally are small mass products. Also, humidity is not needed for these products because they are cooked using direct heat.

Heating Deviations

In fully cooked products (i.e., products in the Fully Cooked-not Shelf Stable HACCP Category), heating deviations may occur due to the following 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, or
3. Slow heating come-up time occurs due power outage or equipment malfunction which allows product to remain at temperatures that allow pathogen growth (50°F to 130°F) for greater than 6 hours.

Establishments must perform corrective actions in response to a heating deviation (9 CFR 417.3). As part of these corrective actions, the establishment may recook the product (unless the dwell time is longer than 6 hours, as described below). Alternatively, the establishment can provide additional support for the safety of the product (e.g., another time/temperature combination from Appendix A was achieved).

If the dwell time is longer than 6 hours (e.g., due to slow cooking come-up time), recooking alone may not be sufficient to ensure the safety of the product. The establishment should continue to recook the product to address vegetative pathogens (e.g., *E. coli*, *Lm*, and *Salmonella*). It should also provide additional support for the safety of the product after the recooking step. That is because after six hours, growth of toxigenic pathogens could occur, (e.g., *Staphylococcus aureus* (*S. aureus*) and *Bacillus Cereus* (*B. cereus*)) allowing enterotoxins to form. These 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 (see the sidebar on the next page about pathogens of concern).

Establishments can use computer modeling and other information (e.g., from scientific journal articles, book chapters, and from processing authorities) to provide additional information to support product safety. The establishment may also be able to test the product to support its safety (see information below).

Computer Modeling

Establishments may use computer modeling to estimate the relative growth of bacteria during a heating deviation. The purpose of this modeling is to determine if conditions exist where toxin formation could occur. Normally, levels of pathogens (e.g., *S. aureus*) in raw meat are about 2 log/gram. The critical level for toxin formation is 5 logs/gram or higher. Therefore, conditions that allow for 3-log growth or higher are a public health concern (ICMSF, 1996).

When performing computer modeling, it is important that establishments:

1. Use validated models (see examples below), and
2. Enter accurate temperature information in the model.

When entering temperatures into the model, establishments should include all parts of the process, including re-cooking come-up time after the heating deviation. If the establishment does not include all parts of the process, it may underestimate pathogen growth.

Some predictive microbial models allow processors to estimate the growth of bacterial pathogens under dynamic temperature conditions. The University of Wisconsin [Therm 2.0 model](#) (Therm 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. In addition, the ComBase growth models (e.g., *S. aureus* and *B. cereus*) are also designed to allow processors to input the product's time/temperature profile.

Recommended Models

- **In meat and poultry products containing salt,** establishments should use the Therm model for Bratwurst for predicting pathogen (e.g., *S. aureus*) 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. Specifically, adding salt to product will inhibit the competing microorganisms, but allow for greater growth of salt tolerant *S. aureus*.

Bacterial pathogens commonly associated with heating deviations

***S. aureus*:** This pathogen is the main food safety concern during heating deviations. Growth occurs from 45 to 118°F, but effectively begins at 60°F, especially in raw meat where the growth of other bacteria is inhibited by nitrite and/or salt. The toxin is not destroyed by the heat and humidity conditions described in Appendix A.

***B. cereus*:** This pathogen is a food safety concern during heating deviations. Growth occurs from 40 to 130°F, with optimal growth occurring at 86 to 104°F. The emetic toxin is thermostable at 259°F for 90 minutes (ICMSF, 1996), which means that it is not destroyed by the heat and humidity conditions described in Appendix A.

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

As previously stated, it is important that establishments enter accurate temperature information into the model. When determining the temperature, the establishment should take into account both the temperature at the coldest area (geometric center) of the product and at the surface of the product. Consequently, it is important to obtain an internal time and temperature profile of the product and a wet bulb (reflects product surface temperature) time and temperature profile of product. If establishments do not have wet bulb data, they can conduct predictive microbial modeling using the internal time/temperature profile of the product, provided that sufficient humidity was used during cooking. However, they should take into account that the product surface temperature will be higher than the geometric center of the product under high relative humidity conditions.

Additionally, establishments should take into account whether growth of *Salmonella*, *E. coli* O157:H7, and *Lm* could have occurred during the heating deviation, and if they could have become heat resistant. Some bacteria can become more heat resistant when they are exposed to low levels of heat, drying and other factors, which allows them to survive at higher temperatures than normal. To address this issue, establishments should increase the time and temperatures they use for cooking or re-cooking the product and ensure that they are incorporating humidity into the process.

Ultimately, establishments should rely upon the expertise of a processing authority to determine the severity of heating 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 FSIS Validation Guideline, the advice of processing authorities should include reference to established scientific principles as well as reference to peer-reviewed scientific data.

Product Testing

As stated above, if the establishment determines through computer modeling or some other means that enterotoxin formation may have occurred, the establishment can test a statistically based number of samples of the product to support its safety (see below). In that case, the establishment should test the product for *S. aureus* enterotoxin and *B. cereus* emetic toxin at minimum. If the product tests negative for enterotoxins, FSIS will likely consider the product to be safe, unless insanitary (or other) conditions exist that could adulterate the product. Testing for additional pathogens would not be needed if the establishment continued the cooking process or re-cooked the product after the heating deviation. However, if the establishment did not continue the cooking process or re-cook the product, testing for additional pathogens (e.g. *C. perfringens*, *Salmonella*, *E. coli* O157:H7, and *Lm*) would be needed to support the safety of the product. The establishment should test sample at least 10-15 products per lot (ICMSF, 2002), depending on the bacterial pathogen. If any enterotoxin is found, the lot is adulterated and the establishment should condemn the product.

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

- 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 on a frequent basis during the heating deviation. As previously stated, the establishment should take into account all parts of the process, and both the temperature at both the center and surface of the product.
- 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 and come-up time when the cooking is restarted as part of its modeling.
- The establishment did not address whether additional growth of *Salmonella*, *E. coli* O157:H7 and *Lm* could have occurred during the heating deviation and whether heat resistance could have occurred. To address this issue, establishments should increase the cooking time and temperature after the heating deviation and apply sufficient humidity during the cooking process.
- 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 geometric center and at the surface (wet bulb) temperature would address this issue.
- The establishment failed to take into account the initial levels of *S. aureus* commonly found in raw meat and poultry. As previously stated, levels of pathogens in raw product are approximately 2 log/gram. Increases of 3 log/gram or more could result in conditions where enterotoxin could be formed.

Dried, Fermented, and Salt-Cured Products

Establishments must control pathogens in dried, fermented, and salt-cured products (i.e., Not Heat Treated Shelf Stable/Heat Treated Shelf Stable/Product with Secondary Inhibitors—Not Shelf Stable HACCP Categories) to produce unadulterated product and meet HACCP requirements. In addition, since there are no performance standards for these products, they must identify the targets that their critical limits will meet or follow validated production methods. Research has shown that *E. coli* O157:H7 and *Lm* are more resistant than *Salmonella* to fermentation and drying in these products. Therefore, FSIS recommends that establishments achieve at least a 5-log reduction of *Salmonella* in these products and address lethality of *Lm* and *E. coli* O157:H7 (if product contains beef).

Reclassification of a RTE Product as NRTE

When establishments are unable to support the safety of an RTE product, they may be able to reclassify the product as NRTE, following the product reclassification guidance in the *Listeria Guideline*, Attachment 1.2 on pages 22-23 and Appendix 1.2 on pages 28-29. A product may be reclassified as NRTE, as long as it is not defined by a standard identity as a fully-cooked product (e.g., hot dogs or barbeque) according to 9 CFR 319 or 381 or by a common or usual name as fully cooked. Among the recommendations in the guideline, the establishment would need to ensure that the following are addressed:

- **Labeling.** The label must accurately represent the product as one that is NRTE and requires cooking for safety so that the product label is accurate and not misleading in

compliance with 9 CFR 317.8 and 381.129. For example, use of the terms "Baked" or "Broiled" on the label of a NRTE product (e.g., "baked chicken") would be false and misleading because they indicate that the product is cooked and, therefore, suggest the product is RTE. Guidance on the labeling of RTE and NRTE products is included in Appendix 1.2 on pages 29-29 of the *Listeria* Guidelines.

- **HACCP category.** FSIS expects that products in the Fully-Cooked Not Shelf Stable processing category are RTE, as explained in [FSIS Directive 5,300.1 Managing the Establishment Profile in the Public Health Information System \(PHIS\)](#), Attachment 1: HACCP Processing Categories. Therefore, categorizing the product in a Fully-Cooked Not Shelf Stable HACCP processing category would not be consistent with a NRTE product.
- **Intended use.** Establishments should clearly state the intended use in the flow chart or hazard analysis according to 9 CFR 417.2(a)(2). In addition, to be consistent with a NRTE product, establishments should describe the customary preparation practices for the safe consumption of the product and the basis for this determination.

Post-Processing Handling and Sanitation

Establishments need to control their processes to prevent contamination of product with pathogens from product handling after the lethality step.

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 described in the establishment's Sanitation SOP) between production lots.
- Placing cooked product on the same surface (e.g., cutting table) as raw product without complete cleaning and sanitizing of the surface before reuse.
- Using the same utensils or containers (e.g., scoops or buckets) for both raw and cooked product.
- Condensation, aerosolization, or dusting of dry ingredients into the processing environment.

It is the establishment's responsibility to maintain sanitation in the RTE area to ensure that food contact surfaces are free of contamination from pathogens such as *Lm* and *Salmonella*. In addition to equipment sanitation, the establishment should address the following sanitation topics using the methods suggested in the bullets:

1. Employee hygiene

- Washing hands upon resuming duties after breaks and before putting on gloves.
- Wearing separate or color-coded frocks in RTE areas of the establishment and controlling employee traffic between raw and RTE production areas.

- Training employees in proper hygiene practices, and monitoring their practices.

2. Separation of raw and RTE production areas

- 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, then 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 to and from the non-RTE area during RTE processing.
- Establishing procedures for moving equipment from a nonprocessing 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 to come into contact with raw products or surfaces that may be contaminated in coolers.

3. Recordkeeping

- Keeping records of sanitation procedures to be used for the processing of RTE products that are covered by 9 CFR 430.
- Maintaining monitoring records of sanitation procedures.
- Maintaining records of corrective actions taken if product adulteration or a food contact surface noncompliance occurs to ensure appropriate disposition of products, restore sanitary conditions, and prevent recurrence. Record the date of the noncompliance and the initials of the plant employee conducting the corrective action.

4. Miscellaneous

- Maintaining an effective rodent and insect infestation control program. Rats, mice, and insects are sources of pathogen contamination.
- Developing and maintaining procedures to ensure that sanitizer concentrations in footbaths are monitored and maintained adequately.
- Maintaining records and verifying the correct procedures for the concentrations and mixing of sanitizers.

- 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, making sure that no food residue is left on the equipment.
- Maintaining procedures for routine cleaning, and developing procedures for intensified cleaning.
- When adding ingredients to a second container, avoiding any contact between the ingredient container and the interior of the second container.
- Developing procedures to ensure that spices or other source materials are maintained in a sanitary condition 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.
- 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.

Potential Hazards Associated with Ingredients

As previously stated, there have been several outbreaks and recalls associated with the addition of contaminated ingredients added to RTE products. As part of their hazard analysis, establishments should determine what potential hazards are associated with the ingredients that are added post-lethality to an RTE product, as well as what treatment has been used as an effective intervention to control the pathogens associated with the ingredient. As part of the supporting documentation for their hazard analysis, establishments should have LOGs, COAs, or other information (e.g., sampling by the receiving establishment) to support the safety of the ingredients. In addition, the establishment should maintain ongoing verification of these analyses. A new hazard analysis through a reassessment of the HACCP plan is required at least annually and whenever any changes (such as changes in product formulation) occur that could affect the hazard analysis (9 CFR 417.4 (a)(3)).

If establishment has made a change in its process (e.g., using a new ingredient or supplier), it should address possible hazards associated with use of the ingredient. As part of this evaluation, the establishment should consider whether any allergens could have been included as part of the ingredient, or whether the ingredient could have been manufactured in a facility that produces allergens (e.g., peanuts) which could have contaminated the ingredient.

The establishment should include the ingredients it adds to RTE products in its flow chart and hazard analysis. In addition, as stated above, the establishment should maintain support for the safety of the ingredients it uses. This supporting documentation may include COAs, LOGs, or other forms of documentation (e.g., sampling data) establishing the safety of the ingredients, spices, or sauces that it adds to the product. The establishment may also perform any verification testing it has identified as necessary to support the safety of the ingredients.

NOTE: LOG alone would not be sufficient to support the safety of the ingredients added to the product unless they indicate how each lot of ingredients is processed, tested or otherwise treated to ensure its safety.

The establishment should also evaluate the safety of pre-packaged ingredients (e.g., lettuce, glaze packets, or ketchup) that it includes in the final package with the finished product, in accordance with 9 CFR 417.2(a)(1).

NOTE: A LOG would be sufficient support for the safety of pre-packaged ingredients (e.g., ketchup or mustard) that have not been associated with previous recalls or outbreaks.

In addition, the establishment should ensure that it has adequately incorporated into its food safety system (e.g., HACCP plans, Sanitation SOPs, or prerequisite programs) procedures for properly formulating the product and accurately labeling it to fully disclose the use of all ingredients.

Corrective Actions in Response to FSIS Positive Results

As previously described, if an RTE product tests positive for *Salmonella* or *Lm*, it is adulterated. The establishment is required to take corrective actions according to 9 CFR 417.3(a) and (b), depending on whether the establishment controls *Salmonella* or *Lm* through its HACCP plan or prevents it through a pre-requisite program.

HACCP Plan to Control Hazards

If the establishment controls hazards from *Salmonella* as part of its HACCP plan and FSIS finds the product positive for *Salmonella*, it must take corrective actions, as stated above. As part of its corrective actions, the establishment must take steps to identify and eliminate the cause of deviation, according to 9 CFR 417.3(a)(1). If the establishment finds that the positive result is likely due to its lethality process, and the establishment has addressed lethality as a CCP, it must take corrective actions to ensure that its CCP is under control (9 CFR 417.3(a)(2)). The establishment will not be allowed to produce and ship RTE product until its CCP is under control and it has taken steps to prevent recurrence 417.3(a)(3)).

- If the cause of the positive result is under-processing, the establishment must immediately review its processing systems to find the cause of the deviation and bring the process back into compliance.
- If the cause of the positive result is due to lack of support for the lethality process, and the establishment's process is not achieving a sufficient log reduction of pathogens (e.g., at least a 5-log reduction of *Salmonella*) in the process, the establishment must change its process or provide additional support for why the process is safe, in light of the positive result.
- Alternatively, the establishment may choose to reclassify the product as NRTE, as previously described.

Prerequisite Program to Prevent Hazards

If the establishment prevents *Salmonella* through a Sanitation SOP or another prerequisite program, it must take corrective actions as per 9 CFR 471.3(b). The finding of positive results indicates that the establishment's prerequisite programs are not effectively designed or not consistently implemented, and that the hazard analysis is not supported. When Sanitation SOPs

or prerequisite programs inadequately address pathogens, FSIS considers the Sanitation SOP or prerequisite program to be ineffective and that an unforeseen hazard has occurred. In this case, FSIS would consider that the hazard is reasonably likely to occur when a positive result is found from FSIS testing.

In this case, because an “unforeseen hazard” has occurred, establishments that address *Salmonella* in a Sanitation SOP or prerequisite program are required to take corrective actions, including reassessment. If the reassessment shows that the hazard is reasonably likely to occur, the establishment would be required to implement a CCP (9 CFR417.2). Alternately, the establishment would need to make substantive changes to strengthen its prerequisite programs so it can continue to support its decision that the hazard isn’t reasonably likely to occur.

NOTE: In most cases, retraining employees would not be sufficient to address the issues alone. Changes such as additional lethality steps or sanitation controls may be necessary to address the positive results.

The following are some possible scenarios that may result in the development of a CCP or changes to the prerequisite program.

- The establishment finds that a positive result was likely due to contaminated ingredients, and it identifies a CCP or prerequisite program to control the safety of ingredients added after the lethality treatment. The CCP or prerequisite program could include COAs from the supplier demonstrating that the ingredients have been tested or treated for safety, establishment testing of incoming ingredients, final product testing, or treatments to the final product (e.g., HPP) to address pathogen contamination from ingredients.
- The establishment finds that the positive result was likely due to sanitation, and it identifies a CCP or makes changes to its prerequisite program to control the sanitation issues that could have led to the positive result. The CCP or prerequisite program could include sampling food contact surfaces for *Salmonella* in the post-lethality exposed processing environment, final product testing, or treatments to the final product (e.g., HPP) to decrease contamination of the product. An example of a sampling CCP is described on page 55 of the FSIS Validation Guideline. Although the example is specific for *Listeria*, it can also be used for *Salmonella*.

Lessons Learned from RTE *Salmonella* Food Safety Assessments (FSAs)

The following “lessons” from *Salmonella* FSAs could be useful for RTE establishments:

1. Do not use the same utensils or containers for handling RTE product that are used for raw product without cleaning and sanitizing between uses for each. In two instances, popped pork skins were most likely contaminated with *Salmonella* when the same buckets and tongs were used for handling both raw and RTE product.
2. Clean and sanitize all equipment used for processing both raw and cooked product. In some cases, equipment used to grind both raw and cooked ingredients for head cheese was not cleaned and sanitized between use for raw and cooked meat.

3. Ensure the safety of uncooked vegetables, herbs, spices, or hydrolyzed vegetable protein added after the cooking step. In some cases, the addition of seasonings or other ingredients after the cooking step resulted in the contamination of RTE product with *Salmonella*. Establishments should not assume that all ingredients (e.g., spices) have been irradiated or treated in some manner to address the pathogens of concern.
4. Establishments should identify and consider all hazards associated with all steps in their hazard analysis, including the addition of ingredients or untreated sauce after the lethality step. Failure to identify all steps in a process including contaminated ingredients and sauces can result in an inadequate food safety system.
5. If an establishment uses a process that is designed to achieve a lower level of pathogen reduction in the lethality step than recommended in FSIS guidelines, the establishment should have a validated method for testing the raw ingredients for the presence of *Salmonella* or *E. coli* O157:H7, to be certain that the lower level of lethality is sufficient to ensure the safety of the product. In addition, a statistically based number of samples should be selected. In one example, an establishment producing fermented sausage product failed to test the raw ingredients even though the HACCP plan stated that the testing must be done.

Most Recent FSA Data

For this revision of the guideline, FSIS reviewed 16 FSAs from RTE establishments with *Salmonella* positive results between 2009 and 2014. The results showed that 9/16 (56%) of the establishments had sanitation issues, 9/16 had HACCP issues (56%), and 10/16 (63%) had cross contamination issues. Three of the FSAs had multiple issues.

Of the 9 FSAs with sanitation issues, FSIS found pests and insects, both inside and outside of the establishment, in 2 establishments. FSIS found dirty utensils or processing equipment, including condensation, rust, and meat particles, in 2 establishments. FSIS found failure to include procedures to clean equipment in the Sanitation SOP in 1 establishment, and contamination of a food contact surface (i.e., a table touching the floor during cleaning) in 1 establishment. FSIS found employee failure to comply with cleaning procedures in 1 establishment, failure to follow product handling and employee hygiene practices in 1 establishment, and a lack of support for the establishment's less than daily sanitation program in 1 establishment.

Of the 9 FSAs with HACCP issues, FSIS found noncompliance with HACCP in 4 establishments. Of these, FSIS found noncompliance with product flow chart requirements in 2 establishments and inadequate record keeping noncompliance in 2 establishments. Three establishments had inadequate HACCP plans or had inadequately addressed hazards in the Hazard Analysis. FSIS found *Salmonella* outgrowth issues in 2 establishments, and of these, FSIS found noncompliance with validation requirements (a lack of critical variables or an initial validation of the process) in 1 establishment.

Of the 16 FSAs, 10 had issues with cross contamination, which was most likely the cause of the *Salmonella* positive. FSIS found cross contamination from the raw area to the cooked area in 7 establishments likely caused *Salmonella* contamination. FSIS couldn't identify the cause of *Salmonella* contamination in 3 establishments. In one of these establishments, FSIS found that that cross contamination could have occurred due to the shared processing rooms for raw and cooked products.

Other issues found during the FSAs were that the term “broiled” on the label may have contributed to consumers and retail store workers treating this product as RTE and not following the cooking instructions; the establishment was not appropriately holding product and “sublotting” lots to release; or *Salmonella* was not seen as a common hazard reasonable likely to occur, so many establishments that had positives did not sample for *Salmonella*.

To address these issues, FSIS has included additional information in the guideline describing steps that establishments can take to address common HACCP and sanitation issues found during FSAs. In addition, FSIS has provided information about preventing cross contamination in the *Listeria* Guideline.

RTE *Salmonella* Self-Assessment Tool

Establishments should 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 guidance, they should consider changing practices to better control *Salmonella* in the product.

| Hazard Analysis/HACCP Plan | YES | NO | N/A |
|--|--------------------------|--------------------------|--------------------------|
| 1. Have you considered whether <i>Salmonella</i> is a hazard reasonably likely to occur (RLTO) in your Hazard Analysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. If you determined that <i>Salmonella</i> was RLTO, did you establish CCPs to control or prevent it? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. If you established CCPs, do you have sufficient supporting documentation to support the effectiveness of the measures you are taking? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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 <i>Salmonella</i> ? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. If you produce cooked uncured meat patties, does your process achieve at least a 5-log reduction of <i>Salmonella</i> ? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. If you produce cooked poultry, does your process achieve at least a 7-log reduction of <i>Salmonella</i> ? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. If you produce other cooked RTE meat or poultry products, does your process achieve at least a 6.5-log or other supportable (e.g., 5-log) reduction of <i>Salmonella</i> in the product? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. As part of your critical limits, have you identified the target or performance standard that your process is designed to achieve (9 CFR 417.2(c)(3))? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9a. If you produce cooked products and use Appendix A, the Poultry Time-Temperature Table or the 5-log table, are you applying humidity during the cooking process? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9b. If “no” to the question above, do you have support for why relative humidity is not a critical operational parameter? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. If you produce dried, fermented, or salt-cured products, do you have scientific support demonstrating that your process achieves a 5-log (or other supportable) reduction of <i>Salmonella</i> in the product and addresses <i>Lm</i> and <i>E. coli</i> O157:H7 (if the product contains beef)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Ingredients | YES | NO | N/A |
|---|--------------------------|--------------------------|--------------------------|
| 11. Do you add ingredients to the product after the lethality treatment? (if no, move to the next section) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12a. Do you maintain COAs, LOGs, or other information (e.g., sampling data) to support the safety of the ingredients? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12b. If you use LOGs, do they indicate how each lot of ingredients is processed, tested, or otherwise treated to endure its safety? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Are the ingredients that you add to the product included in your flow chart or hazard analysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. 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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Do you properly formulate the product and accurately label it to disclose all ingredients? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Corrective Actions | YES | NO | N/A |
|---|--------------------------|--------------------------|--------------------------|
| 16. Has a RTE product sample tested positive for <i>Salmonella</i> ? (If "no" the assessment is complete). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. If you control <i>Salmonella</i> in your HACCP plan, did you take corrective actions according to 9 CFR 417.3(a)? (If you prevent <i>Salmonella</i> through a Sanitation SOP or other prerequisite program, skip to #22). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. Did you take steps to identify and eliminate the cause of the deviation, according to 9 CFR 417.3(a)(1)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. If the cause of the positive result is under-processing, did you immediately review your processing system and bring the process back into compliance? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. 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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. If you prevent <i>Salmonella</i> through a Sanitation SOP or another prerequisite program, did you take corrective actions according to 9 CFR 417.3(b)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 22. As part of your corrective actions, did you reassess your HACCP plan according to 9 CFR 417.3(b)(4)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 23. As a result of your reassessment, did you address the pathogen in a CCP or make substantive changes to your prerequisite program? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

References

- American Meat Institute Foundation. 1997. Good Manufacturing Practices for Fermented Dry & Semi-Dry Sausage Products.
- Blankenship, L. C. 1978. Survival of a *Salmonella typhimurium* experimental contaminant during cooking of beef roasts. *Appl. Environ. Microbiol.* 35:1160.
- Genigeorgis, C., and S. Lindroth. 1984. Proceedings of the 30th European Meeting of Meat Research Workers, Bristol, United Kingdom, pp. 217–224.
- Goepfert, J. M., I. K. Iskander and C.H. Amundson. 1970. Relation of the heat resistance of salmonellae to the water activity of the environment. *Appl. Microbiol.* 19(3):429-33.
- Goodfellow, S. J. and W. L. Brown. 1978. Fate of *Salmonella* inoculated into beef for cooking. *J. Food Prot.* 41(8):598-605.
- ICMSF (International Commission on Microbiological Specifications for Foods). 1996. *Microorganisms in Foods 5. Characteristics of Microbial Pathogens.* Blackie Academic & Professional, London, United Kingdom.
- ICMSF (International Commission on Microbiological Specifications for Foods). 2002. *Microorganisms in Foods 7. Microbiological Testing in Food Safety Management.* Kluwer Academic/Plenum Publishers, New York, New York.
- Ingham, S. C., B. H. Ingham, D. Borneman, E. Jaussaud, E. L. Schoeller, N. Hoftiezer, L. Schwartzburg, G. M. Burnham, and J. P. Norback. 2009a. Predicting pathogen growth during short-term temperature abuse of raw sausage. *Journal of Food Protection.* 72:75-84.
- Ingham, S. C., S. Vang, B. Levey, L. Fahey, J. P. Norback, M. A. Fanslau, A. G. Senecal, G. M. Burnham, and B. H. Ingham. 2009b. Predicting Behavior of *Staphylococcus aureus*, *Salmonella* Serovars, and *Escherichia coli* O157:H7 in Pork Products during Single and Repeated Temperature Abuse Periods. *Journal of Food Protection.* 72:2114-2124.
- Jofré, A., M. Garriga, and T. Aymerich. 2008. Inhibition of *Salmonella* spp., *Listeria monocytogenes* and *Staphylococcus aureus* in cooked ham by combining antimicrobials, high hydrostatic pressure and refrigeration. *Meat Sci.* 78:53–59.
- Juneja, J. K., Eblen, B. S., and H. M. Marks. 2001. Modeling non-linear survival curves to calculate thermal inactivation of *Salmonella* in poultry of different fat levels. *Int. J. Food Micro.* 70:37-51.
- Mbandi, E., and L. A. Shelef. 2002. Enhanced antimicrobial effects of combination of lactate and diacetate on *Listeria monocytogenes* and *Salmonella* spp. in beef bologna. *Int. J. Food Microbiol.* 76:191–198.
- NACMCF (National Advisory Committee on Microbiological Criteria for Foods). 2010. Parameters for Determining Inoculated Pack/Challenge Study Protocol. *J. Food Prot.* 73:140-202.
- Reynolds, A. E., M. A. Harrison, R. Rose-Morrow, and C. E. Lyon. 2001. Validation of Dry Cured Ham Process for Control of Pathogens. *J. Food Sci.* 66:1373–1379.

Scallan, E., R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M. A. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin. 2011. Foodborne Illness Acquired in the United States – Major Pathogens. *Emerg. Infect. Dis.* 17:7-15.

9 CFR 300 to end

9 CFR 417 “Hazard Analysis and Critical Control Point (HACCP) Systems.”

9 CFR 430 “Requirements for Specific Classes of Product.”

FDA Food Code and 21 CFR “Food and Drugs.”

USDA/FSIS. Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products. 2007a. Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C.

USDA/FSIS. Quarterly Progress Report on *Salmonella* Testing of Selected Raw Meat and Poultry Products: Preliminary Results, April 2006 to June 2007. 2007b. Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C.

USDA/FSIS. Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products. 2014. Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C.

Williams, M. S., Y. Cao, and E. D. Ebel. 2013. Sample size guidelines for fitting a lognormal probability distribution to censored most probable number data with a Markov chain Monte Carlo method. *International Journal of Food Microbiology.* 165:89-96.

How to Use the Time Temperature Tables: Appendix A, Poultry Time-Temperature Tables and 5-log Table

1

Select a **time** and **temperature** from one of the tables in this compliance guideline

2

Select a **Relative Humidity (RH)** option

*If you selected a time and temperature ≥ 145 °F plus applicable hold time, (eg, 4 minutes from Appendix A) with a cooking time of longer than 1 hour, **select from the following options to maintain Relative Humidity:***

Option 1: Steam Injection for 50% of the cooking time, or 1 hour (whichever is longer)

Option 2: Sealed oven for 50% of the cooking time, or 1 hour (whichever is longer)

Option 3: At least 90% RH for at least 25% of the cooking time, or 1 hour (whichever is longer)

If you have selected a time/temperature <145 °F plus applicable hold time maintain RH:

Option 4: At least 90% RH for at least 25% of the cooking time, or 1 hour, whichever is longer.

For any time/ temperature combination, If your products total cooking time is less than 1 hour maintain RH:

Option 5: At least 90% RH for the entire cooking time.

NOTES:

- Roasts that are 10 pounds or greater may be heated in an oven maintained at 250 °F or higher throughout the process to address RH.
- See page 15 for processes where humidity around the product is inherently maintained and does not have to be added or monitored.

Appendix A Compliance Guidelines for Meeting Lethality Performance Standards for certain Meat and Poultry Products (Appendix A)

Meat products can be prepared using one of the following time and temperature combinations. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for at least the stated time. **Establishments should apply humidity when using this table or additional support should be provided for the process.**

| <i>Degrees Fahrenheit</i> | <i>Degrees Centigrade</i> | <i>6.5-log₁₀ Lethality</i> | <i>7-log₁₀ Lethality</i> |
|---------------------------|---------------------------|---------------------------------------|-------------------------------------|
| 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.** |

** The required lethality is achieved instantly when the internal temperature of a cooked meat product reaches 158° F or above.

Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products (Poultry Time-Temperature Tables)
Times for given temperature and fat level for Chicken needed to obtain 7-log lethality of *Salmonella**

| <i>Degrees Fahrenheit</i> | <i>Degrees Centigrade</i> | <i>1% fat</i> | <i>2% fat</i> | <i>3% fat</i> | <i>4% fat</i> | <i>5% fat</i> | <i>6% fat</i> | <i>7% fat</i> | <i>8% fat</i> | <i>9% fat</i> | <i>10% fat</i> | <i>11% fat</i> | <i>12% fat</i> |
|---------------------------|---------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|----------------|
| 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 | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | 9.6 sec | 9.8 sec | 10 sec | 10.2 sec | 10.3 sec | 10.5 sec |
| 163 | 72.8 | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec |
| 164 | 73.3 | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec |
| 165 | 73.9 | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec |

* The required lethalties are achieved instantly at the internal temperature in which the holding time is < 10 seconds. **Establishments should apply humidity when using this table or additional support should be provided for the process.**

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

| <i>Degrees Fahrenheit</i> | <i>Degrees Centigrade</i> | <i>1% fat</i> | <i>2% fat</i> | <i>3% fat</i> | <i>4% fat</i> | <i>5% fat</i> | <i>6% fat</i> | <i>7% fat</i> | <i>8% fat</i> | <i>9% fat</i> | <i>10% fat</i> | <i>11% fat</i> | <i>12% fat</i> |
|---------------------------|---------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|----------------|
| 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 | 11.9 min | 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 | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec | <10.0 sec |

*The required lethalties are achieved instantly at the internal temperature in which the holding time is < 10 seconds. **Establishments should apply humidity when using this table or additional support should be provided for the process.**

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

| <i>Degrees Fahrenheit</i> | <i>Degrees Centigrade</i> | <i>Time for 5.0 log Reduction</i> | <i>Unit Time</i> |
|---------------------------|---------------------------|-----------------------------------|------------------|
| 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. |

The required lethalties are achieved instantly when the internal temperature of a cooked meat product reaches 158 °F or above. **Establishments should apply humidity when using this table or additional support should be provided for the process.**

This Time/Temperature table is based on Thermal Death Curve for *Salmonella* in Beef Emulsions in tubes (Derived from Goodfellow & Brown, 1978) Regulatory Curve obtained

from Jerry Carosella, Deputy Director, Microbiology Division, Science and Technology. All times that were a fraction of a minute or second was rounded up to the next whole number (e.g., 16.2 seconds for 155 °F was round up to 17 seconds).