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

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I. PURPOSE

This guidance document is intended to assist small and very small meat and poultry establishments that manufacture ready-to-eat (RTE) meat and poultry products in understanding the regulatory requirements associated with safe production of these products with respect to *Salmonella* and other pathogens. This document also provides information about processing and safe handling of RTE products after the lethality step to control pathogens, such as *Salmonella* and *Listeria monocytogenes* (*Lm*). In addition, this document provides lessons learned from Food Safety Assessments (FSAs). FSIS has updated this finalized guidance document to provide more options for achieving lethality in RTE meat and poultry products and to further clarify information that was previously provided. FSIS has also added an appendix to respond to public comments received on the draft version issued in April 2011.

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.

II. DEFINITIONS

Antimicrobial agent: A substance in or added to an RTE meat or poultry product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *Lm* or *Salmonella,* or that has the effect of suppressing or limiting growth of *Lm* or *Salmonella* in the product throughout the shelf life of the product.

Antimicrobial process: An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *Lm* or *Salmonella,* in the product throughout the shelf life of the product.

Log_{10} reduction: A 90% reduction of a pathogen. For example, a 2-log_{10} reduction is a 99% reduction of a pathogen and a 3-log_{10} reduction 99.9% reduction.

Post-lethality treatment (PLT): A lethality treatment that is applied to the final product or sealed package of product in order to reduce or eliminate pathogens resulting from contamination due to post-lethality exposure.

Process authority: A person or organization with expert knowledge of meat or poultry production process control and relevant regulations. This definition does not apply to subpart G of 9 CFR 318 or subpart X of 9 CFR 381.

Process schedule: A written description of processing procedures consisting of any number of specific sequential operations directly under the control of the establishment

employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production.

Ready-to-eat (RTE) product: 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. RTE products are not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(1) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

III. BACKGROUND

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 from 2000 to 2008 (Scallan et al., 2011). FSIS tests for *Salmonella* in RTE products in two testing programs: the random testing program (ALLRTE) and the risk-based testing program (RTE001).

The FSIS report "Analysis of ALLRTE and RTE001 Sampling Results for *Salmonella* species, Calendar Years 2005 through 2008" indicated that incidences of *Salmonella*-positive samples from the ALLRTE and RTE001 sampling programs ranged from 0 to 0.13% for ALLRTE samples and from 0.01% to 0.08% for RTE001 sample (see Table 1).

Table 1. Detection of *Salmonella* spp. in ALLRTE and RTE001 RTE Product Samples, Calendar Years 2005-2008

	ALLRTE	Positive Samples		RTE001	Positive Samples	
Year	**Total Tested**	**No.**	**%**	**Total Tested**	**No.**	**%**
2005	2,813	1	0.04	7,137	4	0.06
2006	2,938	0	0.00	8,546	2	0.02
2007	2,951	3	0.10	8,672	7	0.08
2008	3,120	4	0.13	8,921	1	0.01
Total	**11,822**	**8**	**0.07**	**33,276**	**14**	**0.04**

RTE products found positive for *Salmonella* spp. are considered adulterated. FSIS would typically request that establishments recall such products if they have been released into the marketplace. The report also showed that head cheese, pork barbecue, and sausage products were the sources of about half of all *Salmonella*-positive samples. This may have been the result of under processing or post-lethality contamination of these products.

All but one of the *Salmonella*-positive samples were obtained from establishments with Hazard Analysis and Critical Control Point (HACCP) sizes of small or very small. In addition, most positive samples were obtained from establishments applying *Listeria* control Alternatives 2b and 3.[1] This finding indicates that control measures applied by establishments to control *Listeria* may also be 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.

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; prudent establishments should assess potential food-safety hazards from *Salmonella*, and test when appropriate.

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 Section VIII of this document.

Consumers expect that RTE meat and poultry products are free of pathogens of public health concern, and, therefore, that they can consume these products from the package without further preparation to achieve food safety. If establishments do not address pathogen reduction in their HACCP plans or do not have a process that is validated to achieve the necessary level of reduction, adulterated products may be released into commerce.

Salmonella contamination in RTE products also occurs in the post-processing environment. In this environment, contamination can be introduced from contact with product contact surfaces that are contaminated with *Salmonella*, from improper handling by establishment employees, from ingredients added after the lethality step, and from insect or animal vectors. Ingredients (e.g., herbs, onions, hydrolyzed vegetable protein (HVP), or spices) added to the product after the cooking step can also be a source of contamination. Sauce may also be a source of contamination. FSIS performed an analysis of *Salmonella* positives from 2005 to 2010, and found that pork barbecue products with vinegar and pepper-based sauce have been implicated in 23% of *Salmonella* positive samples from meat and poultry products. Although the pH of the sauce is low, *Salmonella* may still survive if the sauce, or ingredients in the sauce, is not

[1] 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.

treated with a lethality treatment (e.g., irradiation or treatment with a halogen gas). If contaminated ingredients or sauce are added after the cooking step, the product could be adulterated, in the absence of a post lethality treatment. The 2010 outbreak-related recall of salami products coated with contaminated pepper (FSIS Recall Release RC-006-2010) and the recalls involving HVP (i.e., bacon base, FSIS Recall Release RC-015-2010; beef tornados, FSIS Recall Release RC-016-2010; and taquitos and quesadillas, FSIS Recall Release RC-017-2010) exemplify the need to ensure that the safety of all ingredients added to the product is considered before the product is released into the marketplace. FSIS Recall RC-055-2010 may have been due to contaminated sauce added to the product after the lethality step.

Information on the Incidence of *Salmonella*

While the incidence of *Salmonella* in RTE products is lower than the incidence of *Lm* in such products, 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 underprocessing or serious deficiencies in sanitary practices. In several recent 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. Underprocessing

    a. Underprocessing occurs when the lethality treatment is not adequate to eliminate the pathogens of concern. For heat-treated product, underprocessing may result from applying an inadequate temperature for an inadequate time to the product or the development of bacterial heat resistance due to drying of the product's surface before completion of the lethality step due to inadequate humidity (see page 7 for more information on lethality treatments for *Salmonella*).

    b. Inadequate drying, curing, or fermentation are causes of underprocessing in cured and fermented products.

2. Contamination from ingredients added after the lethality treatment

    a. *Salmonella* contamination may occur from the addition of uncooked vegetables, 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, 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)).

Post lethality treatments (PLTs) and antimicrobial agents or processes (AMAPs) that are designed to address post-lethality contamination by *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 appropriate for all products (e.g., chicken salad). 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.

IV. PROCESSES

In developing the processing steps for an RTE product, as part of their HACCP process, establishments must consider all possible hazards from all the steps, from receipt of the raw materials and ingredients to packaging of the final product (9 CFR 417.2(a)). Effective processing depends on proper sanitation throughout the production process. For RTE meat and poultry products, improper handling of the product (e.g., use of the same equipment or utensils for both raw and processed product without proper sanitation) after the lethality step is a common source of contamination by *Salmonella*

and other pathogens. FSIS has established regulatory requirements for the lethality processes for some products (see section V on page 9). In particular:

- Roast, cooked, and corned beef must be processed to achieve at least a 6.5-$\log_{10}$ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product per 9 CFR 318.17(a)(1), found at http://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec318-17.pdf

- Cooked uncured meat patties must be processed to achieve a 5-$\log_{10}$ lethality by meeting or exceeding the time and temperatures listed in 9 CFR 318.23, found at http://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec318-23.pdf, and

- Cooked poultry products must be processed to achieve at least a 7-$\log_{10}$ reduction of *Salmonella* per 9 CFR 381.150(a)(1), found at http://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec318-150.pdf.

To help establishments in meeting the lethality requirements in 9 CFR 318.17(a)(1) and 381.150(a)(1), FSIS issued the Compliance Guidelines for Meeting Lethality Performance Standards for certain Meat and Poultry Products (Appendix A of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products") found at: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F_Appendix_A.htm, as well as the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, found at : http://www.fsis.usda.gov/oppde/rdad/fsisnotices/rte_poultry_tables.pdf

Although there are no specific lethality requirements for other fully cooked products (except cooked beef, roast beef, and cooked corned beef products, uncured meat patties, and poultry), they may also be processed following the Guidance in Appendix A to achieve a 6.5 $\log_{10}$ lethality. Alternatively, establishments may choose to implement a customized process that is designed to achieve at least a 5-$\log_{10}$ lethality for *Salmonella* and a sufficient reduction for *Lm* and *E. coli* O157:H7.

Establishments should be aware that implementing a 5-$\log_{10}$ lethality process provides less assurance of safety then a 6.5-$\log_{10}$ lethality process. Establishments implementing a customized process will need to validate their process schedule (9 CFR 417.4(a)(1)). In addition, if an establishment chooses to implement a 5-$\log_{10}$ lethality process, it is critical that it implements more stringent controls, such as using source materials prepared under Good Manufacturing Practices (GMPs) designed to minimize contamination and the presence and growth of pathogens of public health concern and implementing tighter verification controls over its products (e.g., finished product testing programs). The verification controls implemented by the establishment should take into account the safety of the product with respect to *Salmonella*, as well as *Listeria* and *E. coli* O157:H7. A time-temperature table establishments can use to

achieve a 5-log lethality in fully cooked products can be found at: http://askfsis.custhelp.com/ci/fattach/get/4648/.
Establishments producing dry, fermented, and salt cured products may also implement a process achieving a 5-$\log_{10}$ lethality of *Salmonella* for meat products and a 7-$\log_{10}$ lethality of *Salmonella* for poultry products, as long as they implement stringent control measures as described for fully cooked products above. In addition, the lethality treatment of meat and poultry products should achieve at least a 5-$\log_{10}$ lethality of *E. coli* O157:H7 for products containing beef and a 3-$\log_{10}$ reduction of *Lm,* although a 5-$\log_{10}$ reduction or greater is desirable for providing an even greater safety margin for ensuring that *Lm* doesn't grow during cold storage to detectable levels. However, establishments are not expected to validate that their process achieves reduction in *Lm* if it achieves sufficient reductions in *Salmonella* because *Salmonella* is considered an indicator of lethality. Regardless of the lethality process used, all establishments that produce RTE meat and poultry products must provide supporting documentation that the process for their RTE products achieves the required or recommended reduction of *Salmonella*. This supporting documentation must be provided as part of an establishment's hazard analysis decision-making documents, and validation data must be included in its HACCP records (9 CFR 417.5(a)(1) and (2) and 417.4(a)).

The scientific supporting documentation should be sufficiently related to the establishment's product and process. The supporting documentation can be:

- A scientific article published in a peer-reviewed journal.

- Processing guidelines published by a regulatory agency (e.g., Appendix A and Appendix B of the final rule, "Performance Standards for the Production of Certain Meat and Poultry Products").

- Regulatory requirements (e.g., the temperature/time table "Permitted Heat-Processing Temperature/Time Combinations for Fully-Cooked Patties" in 9 CFR 318.23 (http://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec318-23.pdf)).

- A challenge study or data gathered in-house as part of a research project or other study designed to determine the $\log_{10}$ reduction of *Salmonella* that is achieved by the process.

See http://www.fsis.usda.gov/Science/HACCP_Validation/index.asp#4 for more information on the types of documents FSIS expects for HACCP validation.

It is particularly important that, as part of initial validation, the establishment identifies all of the critical operational parameters (e.g., pH, water activity, humidity, pressure, etc.) identified in the scientific supporting documentation that may influence the effectiveness of the process. During the initial validation period, the establishment should verify that it is able to implement all of the critical operational parameters as used in the scientific support to ensure that the process can be successfully implemented in its own system.

Establishments producing RTE roast, cooked, and corned beef products, cooked patties, and certain partially cooked and RTE poultry products are required by FSIS to meet the stabilization performance standards for preventing the growth of spore-forming bacteria (9 CFR 318.17(a)(2), 318.23(c)(1), and 381.150(a)(2)).

Establishments should determine what hazards are associated with the ingredient to be 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. In addition, establishments should have Letters of Guarantee and Certificates of Analysis (COA) on these types of ingredients and 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)).

V. LETHALITY REQUIREMENTS FOR SPECIFIC RTE PRODUCTS

The following sections review the lethality requirements for specific types of RTE products. More general information on stabilization and cross-contamination follows in sections VI and VII.

A. Cooked, Roast, and Corned Beef Products

The regulatory requirement in 9 CFR 318.17 "Requirements for the Production of Cooked Beef, Roast Beef, and Cooked Corned Beef Products" (http://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec318-19.pdf) is for the process to achieve at least a 6.5-$\log_{10}$ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product The current regulations allow establishments to achieve a lower $\log_{10}$ reduction, if the establishment uses source materials known to be low in pathogens. FSIS is considering changing regulatory requirements to allow a 5-$\log_{10}$ reduction in cooked, roast, and corned beef products. However, until that time, establishments still must adhere to the 6.5 $\log_{10}$ reduction unless they have additional controls in place to support a lower reduction. Assistance for establishments in meeting the time and temperature combinations and humidity recommendations to achieve at least a 6.5-$\log_{10}$ reduction of *Salmonella* is found in Appendix A of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products," located at http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F_Appendix_A.htm. Regardless of the option used for maintaining humidity in the oven (e.g., closing the dampers, adding steam, or using 90% humidity), an establishment can ensure that the proper levels are maintained by either of two procedures:

1. Monitoring the humidity level of its ovens (e.g., use of dry or wet bulb thermometers to calculate the relative humidity, or use of a humidity sensor that

provides a direct measurement). This is the preferred approach because it provides evidence that the system is operating effectively on a day-to-day basis.

2. Providing supporting documentation that humidity is maintained in the ovens when the oven dampers are closed. (The establishment should have an established procedure for checking that the dampers are working properly if it is using documentation as support that the humidity is maintained in the ovens when the dampers are closed.) If the oven has any other process that allows steam to escape, such as a drain system, this should be closed as well to ensure that proper humidity is maintained.

For products other than those covered by Appendix A, a guideline on humidity titled "Appendix A, Guidance on Relative Humidity and Time/Temperature for Cooking/Heating and Applicability to Production of Other Ready-to-Eat Meat and Poultry Products" is available at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/Appendix_A_guidance_95-033F.pdf.

In addition to Appendix A, establishments have the option of using a number of types of scientific support documents including published journal articles, challenge studies and in-plant data provided they support that the cooking times and humidity options they are using achieve adequate lethality in the product. Adequate lethality is considered to be at least 6.5-$\log_{10}$ reduction of *Salmonella,* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product is achieved. If an establishment elects not to use FSIS' Appendix A, and elects to use alternative support, then they should choose supporting documentation that closely matches their process. In addition, the establishment should follow the same time, temperature and humidity parameters in their actual process that were used in their scientific support.

B. 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" (http://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec318-23.pdf). Although not explicitly stated in the regulation, the temperature and time combinations provided are designed to achieve at least a 5-$\log_{10}$ reduction of *Salmonella* and *E. coli* O157:H7.

The temperatures and times listed in Appendix A could also be used to cook an uncured meat patty. Guidance on relative humidity and times/temperatures for cooking/heating products other than those listed in Appendix A is located at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/Appendix_A_guidance_95-033F.pdf).

C. Cooked Poultry

The regulatory requirement in 9 CFR 381.150 "Requirements for the Production of Fully Cooked Poultry Products and Partially Cooked Poultry Breakfast Strips" is for the process to achieve at least a 7-$\log_{10}$ reduction of *Salmonella*. To assist establishments in meeting this requirement, the time and temperature combinations to achieve at least a 7-$\log_{10}$ reduction of *Salmonella* in chicken and turkey are provided at http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/RTE_Poultry_Tables.pdf. Establishments could also follow the cooking recommendations for cooked poultry rolls and other cooked poultry products in Appendix A, found at: http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F_Appendix_A.htm.

Appendix A states that "Cooked poultry rolls and other cooked poultry products should reach an internal temperature of at least 160 °F prior to being removed from the cooking medium, except that cured and smoked poultry rolls and other cured and smoked poultry should reach an internal temperature of at least 155 °F prior to being removed from the cooking medium." Other time/temperature combinations listed in Appendix A for cooked beef, roast beef, and cooked corn beef would not be sufficient to ensure the safety of poultry products.

In addition, the establishment should maintain humidity during cooking for poultry products, according to Appendix A. Appendix A Guidance on Relative Humidity and Time/Temperature for Cooking/Heating and Applicability to Production of Other Ready-to-Eat Meat and Poultry Products, found at: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/Appendix_A_guidance_95-033F.pdf states that "Although the use of relative humidity during cooking is not specified in the Guidelines for Cooked Poultry Rolls and Other Cooked Poultry Products in Appendix A, the same scientific principles and reasoning apply to poultry products."

D. Other Fully Cooked Products

There are no regulatory requirements for lethality of fully cooked products other than cooked beef, roast beef, corned beef, cooked poultry, and uncured meat patties; however, the time and temperature tables in Appendix A can be used to achieve a 6.5 $\log_{10}$ lethality in these products. The time and temperature tables in Appendix A are primarily intended for cooked beef, corned beef, roast beef, and cooked poultry products, however they also can be used for the heat treatment of other RTE meat and poultry products, as described in http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/Appendix_A_guidance_95-033F.pdf.

If Appendix A is used as the scientific supporting documentation for the process, the relative humidity should also be maintained during processing, as described in the Appendix A guidance. Establishments may also choose to implement an alternative lethality process that achieves at least 5-$\log_{10}$ lethality. Because a 5-$\log_{10}$ lethality

treatment could result in less assurance of safety of the product, the establishment should implement more stringent control measures, such as using source materials that have been prepared under good GMPs, and implementing tighter verification controls with respect to *Salmonella*, *Listeria*, and *E. coli* O157:H7, as described on page 7. A time-temperature table establishments could use to achieve a 5-$\log_{10}$ lethality in non-intact meat chops, roasts, and steaks can be found at: http:askfsis.custhelp.com/ci/fattach/get/4648/. When using these time-temperature recommendations, establishments should maintain humidity using the options in Appendix A.

E. Dried, Fermented, and Salt-Cured Products

This section provides information applicable to dried and semi-dried fermented sausages and salt-cured products.

Dried and Semi-Dried Fermented Sausages

There are no regulatory requirements regarding the level of reduction of *Salmonella* in RTE dried, fermented sausage. However, FSIS considers that a 5-$\log_{10}$ reduction of *Salmonella* in meat products and a 7- $\log_{10}$ reduction of *Salmonella* in poultry products would produce a product safe for consumption. This guidance is based on FSIS's "Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products," located at http://www.fsis.usda.gov/PDF/Salm_RTE_Risk_Assess_Sep2005.pdf (see Table 6–15, page 62). Establishments should also achieve at least a 5-log reduction of *E. coli* O157:H7 for products containing beef and a 3-$\log_{10}$ reduction of *Lm,* as described on page 8 of this document.

Other than guidelines posted in conjunction with the proposed rule "Performance Standards for the Production of Processed Meat and Poultry Products" in 2001 and the Blue Ribbon Task Force recommendations on dry, fermented sausages in the 1990s, FSIS has not published any guidance on this topic. Establishments would have to obtain supporting documentation for their process from published studies, a processing authority, or challenge studies. State agricultural extension services may be able to provide the necessary documentation or assist in obtaining it.

The American Meat Institute Foundation (AMIF) has published guidelines for control of *Staphylococcus aureus* in fermented sausages (http://www.meathaccp.wisc.edu/assets/Heat_Treated_Shelf_Stable/AMIF_degreehours.pdf). Page 4 of the AMIF guidelines provides a list of options developed by the Blue Ribbon Task Force for the control of *Escherichia (E.) coli* O157:H7. These options could be used for *Salmonella* if supporting documentation were provided showing that a 5-$\log_{10}$ reduction of *E. coli* O157:H7 would also achieve a 5-$\log_{10}$ reduction of *Salmonella*. Options involving testing also include testing for other pathogens of public health concern (e.g., *Salmonella*).

The options listed are as follows:

Option 1—Utilize a heat process as listed in 9 CFR 318.17 (e.g., 145 ºF for 4 minutes).

Option 2—Use a validated 5-$\log_{10}$ inactivation treatment.

Option 3—Conduct a "hold and test" program for the finished product. This would involve testing the final product at a specified frequency and holding the product at the establishment until the results are received.

> **NOTE:** This option may provide less assurance of product safety than other options because the contamination may not be uniformly distributed and may not be detected during testing. At least 15 to 30 samples per lot should be tested to help ensure that contamination is detected.

Option 4—Propose other approaches to ensure at least a 5-$\log_{10}$ reduction of *Salmonella.*

> Processors can propose any combination of steps, the sum of which would result in at least a 5-$\log_{10}$ reduction of *Salmonella*. This requires precise documentation that the process achieved the 5-$\log_{10}$ reduction.

Option 5—Testing of raw batter (sausage filling before lethality treatment) and achieving at least a 2-$\log_{10}$ reduction of *E. coli* O157:H7.

> Under this option, the raw batter is sampled for *E. coli* O157:H7, and then a process is applied to achieve at least a 2-$\log_{10}$ reduction. The number of samples, sample size, and compositing procedure need to provide a detection level of one (1) colony forming unit (CFU)/g. A minimum of fifteen 25-gram samples should be analyzed. The 25-gram samples could be composited into samples of 75 grams or less for testing.
>
> The method the establishment uses for testing the raw batter should be one that is: (1) used by a regulatory body (e.g., Food and Drug Administration laboratories), (2) validated by a recognized independent body (e.g., AOAC International, the Association française de normalisation (AFNOR), or the International Organization for Standardization (ISO), or (3) validated by a scientifically robust study using an FSIS method as a reference method. Methods validated by scientific studies may be subject to FSIS review, and if the method is not found to be scientifically supportable, the test results may not be considered valid.
>
> If the laboratory results show that *E. coli* O157:H7 has been detected in the raw batter, then the finished product should be treated with a process that results in a 5-$\log_{10}$ reduction or destroyed. If the product already had been released into the

marketplace before the testing results were received, then the product would be subject to recall.

NOTE: This option may provide less assurance of product safety than other options because a 2-$\log_{10}$ reduction may not be sufficient to address possible levels of *E. coli* O157:H7 in the product. However, it can still be considered a viable option, if the establishment has controls in place to assure that contamination levels are low on incoming product.

The requirements of 9 CFR 318.10 (or recommendations in the FSIS compliance guideline for *Trichinae*) cannot be used by themselves to address the reduction of *Salmonella* because they were written to ensure that the process in the establishment results in elimination of *Trichinae,* but not necessarily *Salmonella*.

Salt-Cured Products

Overall, research has shown that in order for salt-cured processes to achieve sufficient $\log_{10}$ reductions of the bacterial pathogens of public health concern (≥ 5 $\log_{10}$ of *Salmonella*, sufficient $\log_{10}$ reduction of *Lm*, and ≥ 5 $\log_{10}$ of *E. coli* O157:H7 for beef, lamb, and goat RTE products), the drying times should take place over an extended period of time at room temperature or higher, or a low-temperature heat step must be applied after the curing step. For example, one study showed that country style ham achieved a mean $\log_{10}$ reduction of 5.5, 5.5, and 4.8 CFU/cm^3 for *Salmonella*, *E. coli* O157:H7, and *Lm*, respectively, on inoculated hams when dry aged for 20 days at 84.9°C (65% relative humidity) and then, at day 69, placed in ambient (68° to 75.2°F) storage through day 120 (Reynolds et al., 2001).

Another study demonstrated that *Salmonella* survived in basturma made under traditional methods that used limited curing and drying times of 9 to 14 days. Consequently, based on the research results, the researcher developed thermal processing approaches to ensure the destruction of *Salmonella* in basturma (Genigeorgis and Lindroth, 1984).

VI. STABILIZATION

Stabilization requirements for RTE roast, cooked, and corned beef products, cooked patties, and certain partially cooked and RTE poultry products can be found in 9 CFR 318.17(a)(2), 318.23(c)(1), and 381.150(a)(2).

To assist establishments in meeting the stabilization requirements, FSIS has issued Appendix B to the final rule "Performance Standards for the Production of Certain Meat and Poultry Products," (http://www.fsis.usda.gov/OA/fr/95033F-b.htm). FSIS Directive 7110.3, "Time/Temperature Guidelines for Cooling Heated Products" (http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7110-3Rev1.pdf) also contains relevant information. Establishments may choose to employ these guidelines as their

process schedules. FSIS considers these guidelines, if followed precisely, to be validated process schedules since they contain processing methods already accepted by FSIS as effective.

In following the stabilization guidelines, it is very important that cooling be continuous through the given time/temperature control points. Excessive dwell time in the range of 130° to 80°F is especially hazardous, as this is the range of most rapid growth for *Clostridia*. Therefore, cooling between these temperature control points should be as rapid as possible. The primary stabilization guidelines from Appendix B are as follows:

1. During cooling, the product's maximum internal temperature should not remain between 130°F and 80°F for more than 1.5 hours nor between 80°F and 40°F for more than 5 hours. This cooling rate can be applied universally to cooked products (e.g., partially cooked or fully cooked, intact or non-intact, meat or poultry) and is preferable to (2) below.

2. Over the past several years, FSIS has allowed product to be cooled according to the following procedures, which are based upon older, less precise data: Chilling should begin within 90 minutes after the cooking cycle is completed. All product should be chilled from 120°F (48°C) to 55°F (12.7°C) in no more than 6 hours. Chilling should then continue until the product reaches 40°F (4.4°C). The product should not be shipped until it reaches 40°F (4.4°C).

This second cooling guideline is taken from the former "Requirements for the production of cooked beef, roast beef, and cooked corned beef," 9 CFR 318.17(h)(10)). It yields a significantly smaller margin of safety than the first cooling guideline above, especially if the product cooled is non-intact product. If an establishment uses this older cooling guideline, the establishment should ensure that cooling is as rapid as possible, especially between 120°F and 80°F, and should monitor the cooling closely to prevent deviation. If product remains between 120°F and 80°F for more than 1 hour, compliance with the performance standard is less certain.

A company may continue to use the second cooling option of Appendix B under certain conditions. For example, when the establishment cannot chill product from 120°F to 80°F within 1 hour, the company should provide additional supporting documentation demonstrating that the process is effective in controlling pathogen growth (e.g., output from a cooling model showing that the growth of *Clostridium perfringens* based on the worst-case time/temperature cooling profile for the product will result in no more than a 1-$\log_{10}$ increase of *Clostridium perfringens* and no growth of *Clostridium botulinum* (mean net growth ≤ 0.30 $\log_{10}$) within the product).

NOTE: At this time, the regulations allow no more than 1-$\log_{10}$ growth of *Clostridium perfringens* in roast beef, per 318.17(a)(2), beef patties per 318.23(c), and fully cooked poultry products and partially cooked breakfast strips per 381.150(a)(2). FSIS is considering loosening the standards for *Clostridium perfringens* growth for other fully

cooked products and roast beef, when the proposed rule "Performance Standards for the Production of Processed Meat and Poultry Products" is finalized.

3. The following process may be used for the slow cooling of RTE meat and poultry cured with nitrite: Products cured with a minimum of 100 ppm ingoing sodium nitrite may be cooled so that the maximum internal temperature is reduced from 130°F to 80°F in 5 hours and from 80°F to 45°F in 10 hours (15 hours of total cooling time). This cooling process provides a narrow margin of safety. If a cooling deviation occurs, an establishment should assume that its process has exceeded the performance standard for controlling the growth of *Clostridium perfringens* and should take corrective action. The presence of the nitrite, however, should ensure compliance with the performance standard for *Clostridium botulinum*.

NOTE: Additional recommendations for the slow cooling of some cured products may be found in FSIS Directive 7110.3 "Time/Temperature Guidelines for Cooling Heated Products." http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7110-3Rev1.pdf

Within the Appendix B guidelines, FSIS has provided recommendations for product disposition following cooling deviations; a discussion of the use of computer modeling in relation to product safety; and advice on the development of customized procedures for meeting the stabilization performance standards.

VII. 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., grinders or mixers) 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.

VIII. LESSONS LEARNED FROM *SALMONELLA* FOOD SAFETY ASSESSMENTS

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 HVP 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 significant 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.

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X. APPENDIX: FSIS RESPONSE TO COMMENTS

FSIS received two comment letters in response to the April 2011 "*Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce RTE Products" (RTE *Salmonella* Guidelines). Comment summaries and Agency responses follow.

Comment: Both commenters questioned why the RTE *Salmonella* guidelines focused on small and very small establishments. According to one commenter, small and very small meat processors in the U.S. represent 5 percent of the total meat production volume, but 95 percent of the total meat processing businesses in the U.S. This commenter suggested that the guidelines not be limited to small and very small establishments but rather should be addressed to the whole industry.

Response: FSIS focused the RTE *Salmonella* Guidelines 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). 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.

Comment: One commenter stated that they believed that most meat processors lack the technology to address or monitor humidity and dwell time guidelines in Appendix A[2] and believed that the guidance document fails to adequately present alternative processing options. That commenter requested clarification about FSIS's expectations related to the application of the parameters outlined in Appendix A (specifically, relative humidity and dwell time) to all RTE products - not just cooked, roasted, and corned beef products. In addition, both commenters strongly encouraged FSIS to fund research that would update existing Agency resources to reflect modern processing practices.

Response: Although this comment is outside the scope of this guidance document, FSIS plans to revise Appendices A and B[2] as part of its efforts to revise guidance materials for RTE products. The Agency plans to provide clarification of its expectations with respect to dwell time and humidity as part of this revision. FSIS has also recently issued "FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments," which provides more flexible options for achieving humidity in RTE products.

Comment: One commenter stated that although many of the items in the RTE *Salmonella* Compliance Guidelines are especially useful to industry, a 5-$\log_{10}$ reduction

[2] Appendix A (64 FR 732; Jan. 6, 1999, at 746) and B (64 FR 732; Jan. 6, 1999, at 748) are separate guidance documents that are referred to in the RTE *Salmonella* Guideline.

of *Salmonella* in finished product will be hard to demonstrate for a plethora of products, including low-temperature fermented products and non-fermented products. The commenter said that if small and very small establishments are able to demonstrate adequate support for using a science-based approach, the Agency should view the product as scientifically safe and wholesome, regardless of whether the 5-$\log_{10}$ reduction is achieved. The commenter encouraged FSIS, in consultation with ARS, to develop more resources, along the lines of safe harbors, for small and very small establishments to use as support for the processing of non-heat treated RTE products.

Response: FSIS recognizes that a 5-$\log_{10}$ reduction of *Salmonella* in finished product may be hard to demonstrate for some products. To address this difficulty, the guidance provides establishments with alternative lethality approaches within the guidelines, including utilizing good manufacturing practices and incoming product testing to support the safety of lower levels of lethality (see section V. of the document). In addition, FSIS intends to develop further guidance that establishments can use to achieve lethality in specific RTE meat and poultry products.