Chapter 1

FSIS *Listeria* Guideline: Requirements of the *Listeria* Rule

This chapter provides information establishments can use to meet the regulatory requirements of 9 CFR part 430 (the *Listeria* Rule).

1.1 Background

After several large outbreaks of **listeriosis** starting in the 1980s, FSIS and FDA worked together to implement strategies to decrease foodborne illness from ***Listeria monocytogenes* (*Lm*)**. In 2001, FDA and FSIS published the draft "Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods." "The final 2003 version can be found at: (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm). This risk assessment indicated that deli meats and hotdogs posed the greatest per serving risk of illness/death from *Lm*. In February 2002, FSIS initiated the "FSIS Risk Assessment *for Listeria monocytogenes* in Deli Meats*."* The final version can be found at (http://www.fsis.usda.gov/PDF/Lm_Deli_Risk_Assess_Final_2003.pdf. This FSIS risk assessment indicated that the **use of a combination of intervention methods** to control *Lm* in deli meats exposed to the environment after the lethality treatment **has the greatest impact on lowering the risk of illness or death from *Lm*.** The Agency used these risk assessments as resources in developing the regulations to control *Lm* in RTE meat and poultry products.

In 2003, FSIS issued 9 CFR part 430, Control of *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Products (the *Listeria* Rule) http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F.htm. The *Listeria* Rule codified the regulations establishments are required to follow to produce safe RTE products. According to the *Listeria* Rule, *Lm* is a hazard that establishments producing **post-lethality exposed** RTE products must control. Establishments can control *Lm* in the product through their Hazard Analysis and Critical Control Point (HACCP) plans, or prevent *Lm* in the **post-lethality processing environment** through a Sanitation Standard Operating Procedure (SOP), or

other prerequisite program. According to the *Listeria* Rule, post-lethality exposed RTE products are considered adulterated if they contain *Lm* or come in direct contact with a **food contact surface** (FCS) that is contaminated with *Lm*.

The *Listeria* Rule established three **alternative** methods establishments can take in controlling *Lm* contamination of post-lethality exposed RTE products.

- Under Alternative 1, an establishment applies a **post-lethality treatment (PLT)** to reduce or eliminate *Lm* and an **antimicrobial agent** **or** **process** **(AMA or AMP)** to suppress or limit growth of *Lm* (see Chapter 2 for more information on PLTs and AMAs or AMPs).

- Under Alternative 2, an establishment applies either a PLT or an AMA or AMP.

- Under Alternative 3, the establishment does not apply any PLT, AMA, or AMP; instead it relies on its sanitation program to control *Lm*.

These alternatives increase in the stringency of their control from Alternative 3 to Alternative 1. **The *Listeria* Rule only applies to products that are RTE and exposed to the environment after the lethality step (post-lethality exposed)**. The lethality step can be defined as cooking or another process (such as fermentation or drying) that results in a product that is safe for consumption without further preparation.

NOTE: Products that are considered RTE but not post-lethality exposed are not subject to the *Listeria* Rule but are still sampled under the ALLRTE sampling program (see Appendix 3.1 for more information on FSIS sampling programs).

1.2 How Do I Determine if My Product is Covered by the *Listeria* Rule?

Step 1. Determine if the product is **ready-to-eat (RTE)**

- A product is considered RTE if there is a standard of identity[1] (e.g., hotdogs or barbeque) or a common or usual identity (e.g., pâtés) defining the product as fully cooked, or it meets the definition in the *Listeria* Rule (9 CFR 430.1).
- Examples of RTE products: **deli products**, **hotdog products**, whole hams, sausages, meat salads, and other products that have been treated with a lethality step.
- See Attachment 1.2 for further determination if a product is RTE or not ready-to-eat (NRTE)
- **NRTE products are not covered by the *Listeria* Rule**

Step 2. Determine if the product is **post-lethality exposed**

- If the product is RTE, determine if the product is exposed to the environment after the lethality treatment (e.g., cooking) and before packaging
- Examples of post-lethality exposure:
  - Product that is exposed to the environment after the lethality step during processing, slicing, freezing, or packaging;
  - Product that is removed from the cooking bag and sliced or cut up and re-packaged; and
  - Product that is acidified/fermented or salt-cured or dried and smoked and then packaged.
- Examples of post-lethality exposed RTE products may include: sliced roast beef, cooked ham for slicing, hotdogs, fermented sausages, cured ham, and jerky.

Product Considerations

Note: See Appendix 1.1 for more examples.

- **Frozen** products may be considered RTE if they do not contain safe handling instructions and they do not need to be cooked for safety (although they may be heated to increase palatability).
- **Cook-in-bag** products that remain in the same bag until the product reaches the consumer are not considered post-lethality exposed.
- **Hot-filled** products at 160°F, such as fats and lards, are considered RTE but not considered post-lethality exposed.
- **Soups** and other products that are cooked to eliminate pathogens and hot packed in the final packaging are RTE but not post-lethality exposed.
- **Country cured ham** (and other similar products) may be considered either RTE or NRTE, depending on how they are processed and labeled.

Step 3. Determine if the product is covered by the *Listeria* Rule:

- **If product is RTE and post-lethality exposed it is subject to the *Listeria* Rule.**
- **If product is RTE but not post-lethality exposed it is not subject to the *Listeria* Rule.**

1.3 The *Listeria* Rule Alternatives

Listeria alternatives are designed to address post–lethality contamination of *Lm* in RTE products. Each establishment must designate which alternative it intends to implement for a particular product. Each alternative consists of a single control method or combination of control methods which establishments must apply (see Table 1.1). Establishments may utilize one alternative for all of their products or produce product under multiple alternatives (see the section below on establishments

[1] Standards of identity for meat and poultry products can be found in 9 CFR 319.

under multiple alternatives). For more information on control measures (e.g., PLT and AMA and AMP), see Chapter 2.

Table 1.1 *Listeria* Control Alternatives	
Alternative 1 (Alt. 1)	The establishment uses a post-lethality treatment (PLT) to reduce or eliminate *Lm* in the product and an antimicrobial agent (AMA) or antimicrobial process (AMP) to limit or suppress growth of *Lm* in the product.
Alternative 2, **Choice 1 (Alt. 2a)**	The establishment uses a PLT to reduce or eliminate *Lm* in the product.
Alternative 2, Choice 2 (Alt. 2b)	The establishment uses an AMA or AMP to limit or suppress growth of *Lm* in the product.
Alternative 3 (Alt. 3)	The establishment relies on sanitation alone to control *Lm* in the processing environment and on the product. There are separate requirements for deli meat and hotdogs under this alternative.

Establishments may also change the production process to meet the requirements for a particular alternative. For example, if an establishment employs only sanitation procedures to control *Lm* (Alt. 3) but later implements an AMA or AMP, it could then meet the requirements for Alt. 2. **Establishments are encouraged to use AMAs or PLTs, if possible, to reduce the risk of *Lm*.** Further information describing the requirements and recommendations for the three alternatives is provided below.

NOTE: The following sections describe both requirements in the *Listeria* Rule and recommendations to meet these requirements. When the word "**must**" is used, it refers to a requirement. When the word "**should**" is used, it refers to a recommendation.

Attachment 1.1 outlines the 9 CFR 430.4 requirements for Alt. 1, 2, and 3.

Alternative 1 (9 CFR 430.4(b)(1))

Alt. 1 requires the use of a PLT to reduce or eliminate *Lm* **and** an AMA or AMP to suppress or limit the growth of the pathogen.

- The establishment must apply a PLT to control *Lm* in the product and must include the PLT in its HACCP plan.[2]
- The establishment must validate the effectiveness of the PLT in accordance with 9 CFR 417.4.
- The PLT should demonstrate at least a 1-log decrease before the product is released into commerce.
- The establishment must use an AMA or AMP to control *Lm* in the product and must include the agent or process in the establishment's HACCP plan, Sanitation SOP, or other prerequisite program.
- The establishment must document in its HACCP plan, Sanitation SOP, or other prerequisite program that the AMA or AMP, as used, is effective in suppressing or limiting growth of *Lm*.

[2] According to 9 CFR 417.

The AMA or AMP should demonstrate that no more than 2-logs of growth of *Lm* will occur over the shelf life of the product.

- If *Lm* control measures are incorporated into the establishment's Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.4. If *Lm* control measures are addressed in a pre-requisite program other than the Sanitation SOP, the establishment must include the program and results of the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

- Because Alt. 1 includes a combination of controls, the Agency does not require establishments using Alt. 1 to have a testing program for FCS**.** However, testing is recommended (see Table 3.1). Testing FCS in Alt. 1 could be minimal and primarily serve as a means to verify that the sanitary conditions in the establishment will not overwhelm the PLT.

- As with all control alternatives, an establishment with products in Alt. 1 must maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416.

An example of a product that would fall under Alt. 1 would be deli and hotdog products that receive a PLT (such as steam pasteurization after packaging) and has an AMA or AMP (such as the addition of lactates or diacetates in the formulation).

Alternative 2 (9 CFR 430.4(b)(2))

Alt. 2 requires the use of either a PLT (Alt. 2a) or an AMA or AMP that controls the growth of *Lm* over the shelf life of the product (Alt. 2b).

1. Alternative 2, Choice 1 (Alt. 2a)

- The establishment must apply a PLT to control *Lm* in the product and must include the PLT in its HACCP plan.

- The establishment must validate the effectiveness of the PLT in accordance with 9 CFR 417.4.

- The PLT should demonstrate at least a 1-log decrease before the product is released into commerce.

- As with Alt.1, establishments in Alt. 2a are not required to test FCS; however, FSIS recommends that establishment test the surfaces on a regular basis to demonstrate that its system is in control (for more information on testing for Alt. 2, see Table 3.1).

- As with all control alternatives, an establishment with products in Alt. 2a must maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416

An example of a product in Alt. 2a is a hotdog or deli product that is treated with a post-pasteurization treatment after packaging, such as a steam treatment, and DOES NOT contain antimicrobials, such as lactate and diacetate.

2. Alternative 2, Choice 2 (Alt. 2b)

- The establishment must use an AMA or AMP to control growth of *Lm* in the product and must include the agent or process in the establishment's HACCP plan, Sanitation SOP, or other prerequisite program.

- The establishment must document in its HACCP plan, Sanitation SOP, or other prerequisite program that the AMA or AMP, as used, is effective in suppressing or limiting growth of *Lm*. The AMA or AMP should demonstrate no more than 2-logs of growth of *Lm* will occur over the shelf life of the product.

- If *Lm* control measures are incorporated into the establishment's Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.4. If *Lm* control measures are addressed in a pre-requisite program other than the Sanitation SOP, the establishment must include the program and results of the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

- Under Alt. 2b, the establishment must test FCS in the post-lethality environment to ensure that the surfaces are sanitary and free of *Lm* or its indicator organisms (*Listeria* spp. or *Listeria*-like organisms). It must also indicate testing frequency, identify the size and location of sites to be tested, explain why the testing frequency is sufficient to control *Lm,* and identify conditions for hold and test when an FCS is positive for *Lm* or an indicator organism. Recommended testing frequencies for this alternative are included in Table 3.1.

- As with all alternatives, the establishment must maintain sanitation in the post-lethality environment according to 9 CFR 416.

An example of products in Alt. 2b is deli and hotdog products with AMA such as lactates and diacetates added to the formulation, but with no PLT. Another example of a product under Alt. 2b would be a frozen RTE product.

Alternative 3: Non-deli or Hotdog Producers (9 CFR 430.4(b)(3)(i))

Under Alt. 3, the establishment does not apply a PLT to reduce or eliminate *Lm* or an AMA or AMP to control the growth of *Lm* in the post-lethality exposed product. Instead, it relies on sanitation alone to control *Lm* in the product.

- The establishment must control *Lm* in its post-lethality processing environment through the use of sanitation control measures, which may be incorporated in the establishment's HACCP plan, Sanitation SOP, or prerequisite program (*Listeria* Control Program).

- If *Lm* control measures are incorporated into the establishment's Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.4. If *Lm* control measures are addressed in a pre-requisite program other than the Sanitation SOP, the establishment must include the program and results of the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

- As with establishments in Alt. 2b, establishments in Alt. 3 must provide for testing FCS in the post-lethality processing area to ensure that surfaces are sanitary and free of *Lm* or its indicator organisms, indicate testing frequency, identify the size and location of sites to be

tested, explain why the testing frequency is sufficient to control *Lm,* and identify conditions for hold and test when an FCS is positive for *Lm* or an indicator organism. Recommended testing frequencies are included in Table 3.1.

An example of a product in Alt. 3 is refrigerated chicken nuggets that are not treated with a PLT and are not formulated using AMAs.

NOTE: According to the *Listeria* Rule, products and the processing environment under Alt. 3 are likely to be subject to more frequent verification testing by FSIS than products and the processing environment in Alt. 1 or 2. In fact, Alt. 3 products are sampled at a higher rate in FSIS risk-based sampling program (RTE001). See Appendix 3.1.

Alternative 3: Deli or Hotdog Producers (9 CFR 430.4(b)(3)(ii))

In addition to meeting the above requirements for Alt. 3 products, there are special requirements for establishments that produce **deli or hotdog** products under Alt. 3.

- Establishments must verify that the corrective actions taken after an initial positive test for *Lm* or its indicator organisms on an FCS in the post-lethality processing treatment are effective. This is achieved by performing follow-up testing for *Lm* or an indicator organism after the FCS positive test that includes a targeted test of the specific site on the FCS that is the most likely source of contamination and additional tests in the surrounding FCS area.

- If follow-up testing yields a second positive result, hold and test products that may be contaminated using a sampling method and frequency that will provide a level of statistical confidence that will ensure that lots are not adulterated.

NOTE: According to the *Listeria* Rule, RTE products are considered adulterated if they are contaminated with *Lm* or pass over a surface that is contaminated with *Lm*. Holding and testing can not be used as a means to release adulterated product (see Section 4.3).

An establishment in Alt. 3 that produces deli meat or hotdog products will be subject to more frequent FSIS verification testing than one that does not produce such products because deli and hotdog products were ranked as higher risks for *Lm* contamination in the FDA/FSIS risk assessment.

Examples of deli and hotdog products in Alt. 3 include sliced turkey breast luncheon meat and packaged hotdogs that are not held frozen and not formulated using an AMA.

NOTE: Deli salads and wraps are not considered deli products because they are not sliced and are also not typically used in a sandwich.

Establishments under Multiple Alternatives

FSIS recognizes that establishments may produce products under multiple alternatives. These products may be produced under multiple HACCP plans or grouped under a single HACCP plan. Products can be grouped in a single HACCP plan when the hazards, CCPs, and critical limits are essentially the same. Thus, a single HACCP plan could cover hotdogs formulated with and without

antimicrobial agents (Alt. 2 and 3), provided that the HACCP plan clearly distinguishes any critical differences. If an establishment produces products using two (or three) alternative control programs, FSIS's sampling focus will be on product manufactured under the riskiest alternative (i.e., Alt. 3, then 2, then 1).

1.4 Requirements for Establishments Under all Three Alternatives

According to the *Listeria* Rule (9 CFR 430.4(c)), establishments in all three alternatives:

- May use verification testing for *Lm* or an indicator organism (e.g., *Listeria* spp.) to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.
- Sanitation measures for controlling *Lm* and AMA's or PLT's may be incorporated into the establishment's HACCP plan (required for PLT's) or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or other prerequisite programs, the establishment **must** have documentation that supports the decision in its hazard analysis that *Lm* is not a hazard that is reasonably likely to occur.
- The establishment must maintain sanitation in the post-lethality processing environment accordance with 9 CFR part 416.
- If the *Lm* control measures are included in the HACCP plan, the establishment must validate and verify the measures in accordance with 9 CFR 417.4.
- If the *Lm* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14.
- If the *Lm* control measures are included in a prerequisite program other than the Sanitation SOP, the establishment must include **the program and the results** produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.
- The establishment must make verification results available upon request to FSIS personnel.

1.5 Labeling

According to the *Listeria* Rule, an establishment that controls *Lm* by using a PLT or an AMA or AMP may declare this fact on the label, provided that the establishment has validated the claim (9 CFR 430.4(e)). The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary and may be of value to consumers, especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims, as described in Appendix 2.1. For further labeling resources, see Attachment 1.2 and Appendix 1.2.

1.6 Glossary

Alternative: A method of control for *Lm* adopted by an establishment to meet the requirements of the *Listeria* Rule.

Antimicrobial Agent (AMA): A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *Lm*, or that has the effect of

suppressing or limiting growth of a pathogen, such as *Lm*, in the product throughout the shelf life of the product. Examples: potassium lactate and sodium diacetate, which limit the growth of *Lm* (9 CFR430.1).

Antimicrobial Process (AMP): An operation, such as freezing, that is applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *Lm*, in the product throughout the shelf life of the product. Other examples are processes that result in a pH or water activity that suppresses or limits microbial growth (9 CFR 430.1).

Cook-in-bag: Product that is cooked in an impermeable package or casing and is not exposed to the environment of the establishment after the lethality treatment.

Deli product: A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption (9 CFR 430.1).

Food contact surface (FCS): A surface in the post-lethality processing environment that comes in direct contact with RTE product (9 CFR 430.1).

Hotdog product: A RTE meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181 (9 CFR 430.1).

***Listeria monocytogenes* (*Lm*):** A foodborne pathogen that can cause the disease listeriosis in humans.

Listeriosis: A disease caused by *Lm*. In most healthy individuals, listeriosis causes flu like symptoms; however in the elderly, pregnant women and their fetuses, and immunocompromised individuals, listeriosis can lead to spontaneous abortion, septicemia, meningitis, and death**.**

Post-lethality Exposed Product: Ready-to-eat product that comes into direct contact with an FCS after the lethality treatment (e.g., cooking) in a post-lethality processing environment. Examples of post-lethality exposed products: hotdogs after the casings are removed; cooked roast beef after removing the cooking bag (9 CFR 430.1).

Post-lethality Processing Environment: The area in an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures (9 CFR 430.1).

Post-lethality Treatment (PLT): A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure (9 CFR 430.1).

Ready-to-eat (RTE): A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear 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 or poultry products (9 CFR 430.1).

1.7 References

FDA and FSIS. Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, 2003.

FSIS, Risk Assessment for *Listeria monocytogenes* in Deli Meats, 2003.

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 part 430 Control of *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Products

Attachment 1.1: Control Requirements for *Listeria monocytogenes*

Requirements	→ Increasing Risk Levels and Frequency of FSIS Verification Testing →				
	ALTERNATIVE 1	ALTERNATIVE 2		ALTERNATIVE 3	
	Post-lethality Treatment AND Antimicrobial Agent or Process	Post-lethality Treatment OR Antimicrobial Agent or Process		Sanitation and Testing Program	
		Choice 1: Post-lethality Treatment	Choice 2: Antimicrobial Agent or Process	Non-deli, Non-hotdog	Deli or hot-dog product
Validate effectiveness of post-lethality treatment (PLT). Must be included as a CCP in the establishment's HACCP Plan and should show at least a 1-log reduction in *Lm* prior to distribution of the product into commerce	X	X			
Document effectiveness of antimicrobial agent or process: Must be included as part of the establishment's HACCP, Sanitation SOP, or Prerequisite Program and should demonstrate no more than 2-logs growth of *Lm* over the estimated shelf life.	X		X		
Sanitation Program Requirements			X	X	X
Testing food contact surfaces (FCS) in the post-lethality processing environment for *Lm* or an indicator organism.			X	X	X
State testing frequency.			X	X	X
Identify size and location of sites to be sampled.			X	X	X
Explain why testing frequency is sufficient to control *Lm* or an indicator organism.			X	X	X
Identify conditions for Hold-and-Test, when FCS (+) for *Lm* or an indicator organism.			X	X	X
Additional Sanitation Program Requirements					
Follow-up testing to verify corrective actions are effective after 1st FCS (+) for *Lm* or an indicator organism. Includes testing of targeted FCS as most likely source and additional testing of the surrounding area.					X
If follow-up testing yields 2nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.					X
Hold and test product lots using a sampling plan that provides statistical confidence that the lots are not contaminated with *Lm* or an indicator organism. Release, rework, or condemn products based on results. Document results and product disposition.					X
Establishments in all three alternatives must maintain sanitation in accordance with 9 CFR 416.	X	X	X	X	X

Attachment 1.2: Chart of RTE vs. NRTE Products: Resource 1

TYPE	CLASS	HACCP CATEGORY	REQUIRED LABELEING	WHAT THE HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e., raw or partially cooked product). *Or* A product containing a meat/poultry product (in whole or in part) which has received an adequate lethality treatment for pathogens, that is **not** defined by a standard of identity or common or usual identity as an RTE product and does not meet the definition of RTE in 9 CFR 430.1.	Not-ready-to-eat	• Raw Product Ground – ISP 03B • Raw Product Not Ground – ISP 03C • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated –shelf stable – ISP 03F • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H • Products with secondary inhibitors Not Shelf Stable – ISP 03I •	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers, if not shelf stable. Use of Safe Handling Instruction (SHI) labeling required.	• Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” • Validation that: a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that has received an adequate lethality treatment for pathogens in combination with non-meat/poultry components that needs to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees.	Not-ready-to-eat	• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	• Validation that: a. The meat/poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked”, “see cooking instructions”, or “cook before eating.” • If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.

A product containing a meat/poultry component that has received an adequate lethality treatment for pathogens that **may or may not** be defined by a standard of identity or common or usual identity for an RTE product. Includes products that are in combination with a non-meat/poultry component that does not need to receive a lethality treatment by the intended user. RTE products must meet the requirements of 9 CFR part 430.	Ready -to-eat	• Not Heat Treated Shelf Stable – ISP 03E • Heat Treated Shelf Stable – ISP 03F • Fully Cooked Not Shelf Stable – ISP 03G • Products with secondary inhibitors Not Shelf Stable – ISP 03I	If the product is not shelf stable, labeling such as keep refrigerated or frozen is required.	• See part 417 of the meat and poultry regulations.

Appendix 1.1: Product Types

Overview of products covered under *Listeria* Rule

Establishments that produce post-lethality exposed RTE meat and poultry products are covered by the *Listeria* Rule. Accordingly, the establishment should determine the alternative(s) to which it will adhere to in its processes to control *Lm* during the post-lethality exposure.

The following product types, if post-lethality exposed, would fall under the *Listeria* Rule. The classification of deli products and hotdog products, salad/spread/pâté products, cook-in bag products, frozen, and hot-packed products will be described.

I. Deli and Hotdog Products

Like all RTE products exposed to the processing environment, deli and hotdog products that are exposed to the post-processing environment are subject to the *Listeria* Rule. If the RTE product is not exposed to the post-processing environment, it is not subject to the Rule. Depending on the method that an establishment chooses to control *Lm* contamination in its processing, deli and hotdog products may be in Alt. 1, 2, or 3.

As defined in 9 CFR 430.1, a deli product is "a ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption." RTE hotdog (or hot dog) products are defined in 9 CFR 430.1 as "a ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181." Cooked sausages (e.g., bratwurst), as defined in 9 CFR 319.140, would be considered RTE, but would not be considered to be deli or hotdog products.

Question: A scrapple product receives a full-lethality treatment at the establishment. Is the product required to be RTE?

Answer: No. Unless the product has a standard of identity requiring it to be RTE (9 CFR 319 and 9 CFR 381), it can be considered to be NRTE. NRTE products are required to bear safe handling instructions, and should be labeled with validated cooking instructions. In addition, if the product is NRTE but appears to be RTE, it should be labeled conspicuously so that intended user is fully aware that product must be cooked for safety (see Attachment 1.2). The establishment's HACCP plan and intended use statement should also be consistent with a NRTE product (see Appendix 1.2 part II below).

Deli and hotdog products that receive a PLT and AMA or AMP fall under Alt. 1. An example is a hotdog that includes lactates or diacetates in the formulation and is steam pasteurized after repackaging. Deli and hotdog products with antimicrobial agents such as lactates or diacetates added in the formulation, but with no post-process lethality treatment, would fall under Alt. 2b. An example of an Alt. 2a product is a hotdog product that received only a PLT, such as being packaged in casings with an antimicrobial agent that reduces the level of *Lm*. If an establishment does not use a PLT or an AMA or AMP in the processing of deli and hotdog products, these products would fall under Alt. 3.

II. Salad/Spread/Pâté Products

Salads/spreads/pâtés are also RTE post-lethality exposed, so they are covered by the *Listeria* Rule. Deli meats that are used in salads receive additional handling after they are removed from their packages and are mixed with other ingredients, thus exposing them to cross-

contamination. An establishment producing salads with the meat and poultry components that receive a PLT or antimicrobial agent needs to have supporting documentation showing that the antimicrobial action is sufficient to control *Lm* in all the salad ingredients if it chooses to have its product in Alt. 1 or 2. A salad/spread/pâté product with a final pH below 4.39 in all ingredients of the salad (e.g., due to the salad dressing or other ingredients added) would fall under Alt. 2, if an antimicrobial agent is used. Salads/spreads/pâtés are not considered deli products under the *Listeria* Rule because they are not typically sliced.

III. Cook-in Bag products

A cook-in-bag product such as a cooked ham or poultry roll that is shipped intact in its cooking bag is not covered by the *Listeria* Rule. It is also not considered a deli product because simply selling a product in a deli does not result in a product that is defined in 9 CFR 430 as a deli product. However, if it is sold to an establishment where it will be sliced and served in a sandwich or sold to the consumer, it is considered to be a deli product.

IV. Frozen Products

Frozen products are covered under the *Listeria* Rule if they are considered RTE and post-lethality exposed. Although freezing controls the growth of *Lm*, the organism can still survive the freezing process. Frozen products generally fall under Alt. 2b. In order to qualify for Alt. 2b, the product would need to remain frozen over its estimated shelf life. If the product is meant to be thawed and held refrigerated either at the establishment or at a retailer, the product would be considered Alt. 3. An example of a frozen product would be RTE sliced chicken strips that are frozen at the establishment and held frozen until prior to consumption. They may heated by the consumer for palatability prior to eating.

V. Hot-packed Products: Edible Oils and Fats, Lard, and Soups

Edible oils and fats resulting from a rendering process that processes them to 180º F and maintains them at 160º F, with a water activity of less than 0.2 making them shelf stable, are considered RTE. Rendering is intended to make this meat food product a ready-to-use ingredient in the preparation of other foods, e.g., edible tallow and lard used as shortening. They do not require additional lethality treatment before being consumed. If these products are hot filled (as defined above) and packaged, they are not considered post-lethality exposed and therefore are not covered by the Rule. However, these products would be considered NRTE and not covered by the *Listeria* Rule if the process calls for partial rendering of the animal fat for tallow or lard and then further processing or finishing rendering in another plant.

Soups and other products that are cooked to eliminate pathogens and hot-packed in the final packaging material are RTE, but are not considered post-lethality exposed. Therefore, the *Listeria* Rule does not apply.

Appendix 1.2 Labeling

I. Post-lethality Treatments (PLT) and Antimicrobial Agents (AMA)

According to the *Listeria* Rule, an establishment that controls *Lm* by using a PLT or an AMA may declare this fact on the label, provided that the establishment has validated the claim (9 CFR 430.4(e)). The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary and may be of value to consumers, especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims as described in Appendix 2.1. An example of a statement that can be made is: "Potassium lactate added to prevent the growth of *Listeria monocytogenes*." All labeling claims and label changes to add such claims must be submitted for evaluation and approval to the FSIS Labeling and Program Delivery Division.

In addition, antimicrobial agents that are added to RTE products, either to the formulation or to the finished RTE product, and those that are included in the primary packaging material of RTE products must to be listed in the ingredients statement of the product. An establishment does not need to submit a label to the Agency for evaluation and approval when it adds an antimicrobial agent (e.g., sodium diacetate) to a product formulation that is approved or listed by FDA and FSIS as safe and suitable, provided that the label can be approved in accordance with the generic labeling regulations in 9 CFR 317.5 and 381.133, (i.e., the product must have a standard of identity in Title 9 of the Code of Federal Regulations (CFR) or the Food Standards and Labeling Policy Book and the labeling must not bear special claims, guarantees, or foreign language). All ingredients including antimicrobial agents require declaration on the label. Establishments may submit for temporary approval to use existing stocks of labels with revised formulations (up to six months) in order to update and produce new labels.

Approval of Labels Bearing Claims

As with all claims on labels, if there is a labeling claim about the use of antimicrobial agents or lethality treatments, the labels must be submitted to the Agency for evaluation and approval before use. Documents for validation of the effectiveness of the PLT or antimicrobial agent must be included with the label application. An establishment cannot put labeling claims of enhanced protection on RTE products that are not post-lethality exposed, such as cook-in-bag that are opened only by the consumer, because these are not covered by the *Listeria* Rule.

Special Considerations for Antimicrobial Agents in Comminuted Beef Products

The standard of identity for ground beef, chopped beef, and their cooked versions does not provide for the addition of ingredients, with the exception of non-fluid condimental seasonings, e.g., salt and pepper. Therefore, these products cannot be formulated with or treated with antimicrobial agents that are classified as having a lasting technical effect, e.g., sodium lactate and sodium diacetate, unless these products are descriptively labeled to reflect the use of the antimicrobial agents. For example, if sodium lactate is added, the product name on the label should be "Ground Beef with Sodium Lactate".

However, for beef patties, which are standardized products, the regulations permit the addition of ingredients such as antimicrobial agents. Therefore, comminuted beef products formulated with antimicrobial agents and other approved or listed safe and suitable food ingredients can be labeled as "beef patties" and can be generically approved if the labeling does not bear any

special claims, guarantees, or foreign language.

The labeling for other products with standards of identity that permit the addition of antimicrobial agents (e.g., luncheon meats, hotdogs, cooked whole muscle cuts (such as roast beef)) may be approved in accordance with the regulations on generic label approval to reflect the addition of new, approved safe and suitable antimicrobial agents on labeling. The addition applies provided that no special claims, guarantees, or foreign language appear on such labels, per the generic labeling regulations.

II. Differentiating Products as RTE or Not RTE (NRTE)

Some products are expected to be lethality treated and RTE as shipped as part of their common or usual identity, e.g., pâtés. Other products are defined by a standard of identity as RTE, that is, cooked, e.g., hotdogs. Some products are RTE based on labeling features, including Nutrition Facts, which declare nutrients in a product on a ready-to-serve or ready-to-eat basis. When these factors do not prevail, manufacturers may decide whether to classify products as RTE or NRTE products. However, care should be taken to ensure that is clear whether the product is RTE or NRTE (see Attachment 1.2).

The following should be taken into account when differentiating RTE from NRTE product:

(1) Decide on the HACCP category that best fits the product based on the processing operations that are involved. The HACCP categories most often used for RTE products include fully cooked—not shelf stable, not heat treated – shelf stable, heat treated – shelf stable, and product with secondary inhibitors – not shelf stable. In the situation where a product has been produced as an RTE product and it is not a product that is defined by a common or usual identity (e.g., pepperoni) or standard of identity (e.g., hotdog) as a lethality-treated (e.g., cooked/fermented/dried) product, the manufacturer can decide whether the product is RTE or NRTE based on HACCP category. The establishment would need to ensure that documentation exists to support the HACCP category selected by the establishment for the product and that the appropriate category is reflected in the HACCP plan and labeling records. **The establishment's hazard analysis and intended use of the product should also be consistent with a RTE or NRTE product.**

> **NOTE**: **It is FSIS's expectation that products in the fully cooked – not shelf stable category will be considered RTE**.

(2) Generate data that validate the cooking instructions that appear on the labeling of NRTE products (and include in all the alternative methods of cooking the temperature that the product must reach, i.e., 160ºF) to ensure that consumers provide the lethality step. When the product has historically been viewed by the consumers as a "heat and eat" type of product, it is especially important for the establishment to make the distinction between the RTE product and the NRTE product. In addition, the "cooking instructions" should not be the same "heating" instructions that were previously used on the labeling for the RTE products. **Cooking instructions would need to include the internal temperature the product is expected to reach and the method of cooking (time and temperature) so that it is safe for consumption by the consumer.**

(3) Assess the label to ensure that it adequately reflects the features that are necessary on the principal display panel to convey that the product is a ready-to-cook product, e.g., "cook and serve," "cook and eat," "cook thoroughly," as well as safe handling instructions. **It would not be appropriate to label raw products using terms such as "cooked," or broiled.** FSIS regulations require the labeling of safe handling instructions if the meat or poultry component is uncooked. In comparison, if the meat or poultry component is cooked, but another non-meat or poultry component requires cooking for safety, the display of safe handling instructions is not required, but highly recommended. In addition, the basis for the Nutrition Facts declarations, e.g., serving size, must be on a ready-to-cook basis, not on a ready-to-serve basis (the company has to establish a ready- to-cook basis for serving size if the regulations do not provide one). The reference amount customarily consumed (RACC) for ready-to-cook and ready-to-serve meat and poultry products are found in 9 CFR 317.312 and 381.412, respectively. Nutrition labeling is not changed by this rule, but the serving size will be affected, depending on whether the product is classified as RTE or NRTE.

(4) Consider whether the label for the product can be approved consistent with the regulations on generic label approval (i.e., it is a label for a standardized product that bears no claims, special statements, guarantees, or foreign language). Such labels would not need to be sent to the Agency to be evaluated and approved prior to use.

If a meat or poultry product that is processed to a time/temperature that traditionally is considered to attain a full cook, but the intended use of the product is such that the product is intended to receive a lethality treatment by the consumer, the product does not have to be labeled as RTE unless the product is defined by a standard of identify as an RTE product (e.g., hotdogs, franks, and pork with barbecue sauce). Such product may be identified as an NRTE product, provided that the labeling and validated cooking instructions (SHI) are adequate to discern that the product must be cooked for safety by the purchaser. An example of such product is a cooked, thick-sliced, center-cut ham slice on which the labeling indicates that the product is ready-to-cook and for safety the product must be cooked to attain a minimum temperature. On the other hand, a thin sliced ham product in case-ready packaging may state that the product is RTE without additional cooking and, as such, would not be required to bear preparation/cooking instructions. Both products may have been heat treated in the same manner, but the establishment would only have control for *Lm* in the RTE product.

Furthermore, some establishments also add a "cooking" statement on the label of a fully cooked, RTE product for consumers to cook to a specific temperature. Therefore, the establishment is adding **heating** rather than **cooking** instructions on the label in order to specify the temperature to which the product must be heated for palatability. In this case, the establishment does not need to have cooking instructions that have been validated to eliminate or reduce pathogens nor does it need safe handling instructions on the label and the other requirements mentioned above.

Chapter 2

FSIS *Listeria* Guideline: FSIS Control Measures for *Listeria*

This chapter provides technical information about control measures that are used to meet the requirements for the three alternatives and provides examples establishments can use to apply these control measures to their particular product.

2.1 Post-lethality Treatments (PLT)

According to the *Listeria* Rule, **post-lethality treatments (PLT)** are treatments that are designed to reduce or eliminate levels of *Lm* contamination on RTE products. Establishments may choose to use PLT to meet the requirements of Alt. 1 (use of a PLT and **antimicrobial agent** (AMA) or **antimicrobial process** (AMP)) or Alt. 2a (use of a PLT alone). According to the *Listeria* Rule, establishments that use PLTs must include the treatment as a CCP in their HACCP plan and validate the effectiveness of the PLT.

Examples of Post-lethality Treatments (PLT)
PLT for *Lm* may include: • Steam pasteurization, • Hot water pasteurization, • Radiant heating, • High pressure processing (HPP), • Ultraviolet (UV) Treatment,[3] • Infrared Treatment, • Drying (Low water activity) (see example 1), and • Other validated processes.

It is FSIS's expectation that PLTs will be designed to achieve at least a 1-log lethality of *Lm* before the product leaves the establishment. The PLT must be validated according to 9 CFR 417.4 and 430.4 as being effective in eliminating or reducing *Lm*. The establishment must also verify the effectiveness of the PLT and other control measures and make these results available upon request to FSIS personnel

[3] Ultraviolet treatment can be used either as a post-lethality treatment or antimicrobial agent or process depending on whether it eliminates, reduces, or suppresses growth of *Lm*.