

Listeria monocytogenes (Lm) Regulations

Introduction:

- ✓ *Listeria monocytogenes (Lm)* is a widespread pathogen capable of surviving under various environmental conditions.
- ✓ *Lm* is very tolerant of freezing, drying, salt, and heat, and will grow at temperatures as low as 31.3°F or as high as 113°F.
- ✓ It can adapt to significant changes in pH values and reproduce at a pH as low as 4.39 and as high as 9.4.
- ✓ *Lm* can also reproduce with a water activity (a_w) as low as 0.92.
- ✓ *Lm* can produce a disease called listeriosis.
- ✓ High risk groups include pregnant women and their fetuses, young children, the elderly, and immuno-compromised people.
- ✓ A common link in *Lm* outbreaks is contamination of RTE products in the post-lethality environment prior to packaging.
- ✓ The organism can also form a durable biofilm.

FSIS has developed regulatory requirements specifically for controlling *Lm* in post-lethality exposed RTE products. In addition, the agency has developed *Lm* sampling programs as part of its public health strategy for protecting consumers against *Lm*.

Establishment Responsibilities: An establishment that produces post-lethality exposed RTE meat and poultry products must maintain its facility in a sanitary manner. The sanitation program must be designed and implemented to prevent contamination of food contact surfaces (FCS) and adulteration of RTE product.

Sampling Program: Under 9 CFR 430.4(b)(2)(iii)(A) and (3)(i)(A), establishments that produce post-lethality exposed RTE products are required to provide for FCS testing in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or indicator organism.

Note: While sampling is not required under Alternative 1 or Alternative 2, Choice 1, FSIS recommends the establishment collect from each post-lethality exposed production line a minimum of 2 *Lm* FCS samples per year (every 6 months) under Alternative 1 and a minimum of 4 *Lm* FCS samples per year (quarterly) under Alternative 2, Choice 1. FCS sampling is required for Alternative 2, Choice 2 and Alternative 3.

IPP Responsibilities for Verifying Compliance with 9 CFR Part 430.4:

To verify compliance with 9 CFR 430.4:

- ✓ IPP must be familiar with the establishment's RTE products and processes.
- ✓ IPP should ask the establishment which of the three *Listeria* control alternatives was chosen for each post-lethality exposed RTE product produced
- ✓ IPP should verify that the establishment is meeting the requirements of the alternative it selected by performing the appropriate SSOP or HACCP tasks. If the establishment decides to produce different products using different alternatives, the inspector should verify that each post-lethality exposed RTE product meets the requirements for the alternative selected.

- ✓ In addition to verifying the effectiveness of the *Listeria* control alternatives selected, IPP will verify that the establishment is maintaining sanitary conditions sufficient to prevent product contamination, including *Lm*. Sanitation is the foundation for controlling *Lm* and without it, no alternative will successfully control *Lm*.

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

Alternative 1 uses a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product **AND** an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

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

Alternative 2 uses either a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product **OR** an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

Under Alternative 2, an establishment may select either **Choice 1** or **Choice 2** as follows.

- **Alternative 2, Choice 1** - The establishment chooses to use a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates *Lm* on the product.
- **Alternative 2, Choice 2** - The establishment chooses to use an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

Alternative 3 - 9 CFR 430.4(b)(3):

Alternative 3: involves the use of sanitation measures alone to prevent *Lm* in the processing environment and on the RTE product. There are separate FCS sampling requirements for deli meat and hot dogs produced under this alternative.

Determining Compliance

Gather Information

IPP should use the GAD thought process to verify compliance with Alternatives 1, 2, or 3. Alternative 2 is based on the same requirements as Alternative 1 except that the establishment can choose to use only a post-lethality treatment (Choice 1) or an antimicrobial agent or process (Choice 2). When verifying compliance with Alternative 1 and Alternative 2 requirements, IPP should seek answers to the following questions:

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in a HACCP plan?
2. Does the establishment have scientific documentation supporting the effectiveness of its post-lethality treatment in accordance with 9 CFR 417.5(a)(2)?
3. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?

4. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?
5. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?
6. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program, and can it scientifically support how the antimicrobial agent or process is being used?
7. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?
8. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

When verifying compliance with Alternative 2, Choice 2, or Alternative 3 requirements, IPP should seek answers to these questions regarding the establishment's sanitation procedures.

1. Has the establishment incorporated sanitation measures in a HACCP plan, SSOP, or other prerequisite program?
2. Is the establishment's food contact surface testing used to verify the on-going effectiveness of its sanitation procedures?
3. Does testing of food contact surfaces in the post-lethality processing environment ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism?
4. Did the establishment identify the conditions under which it will implement hold-and-test procedures following a positive test of a food contact surface for *Lm* or an indicator organism?
5. Did the establishment state the frequency with which testing will be done?
6. Did the establishment identify the size and location of the sites that will be sampled?
NOTE: establishments should identify all possible FCS sites (AskFSIS QA dated 2-17-12)
7. Did the establishment include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained?

If an establishment produces a RTE deli product or a hot dog product under Alternative 3, IPP should verify that the establishment:

1. Effectively implemented corrective actions (with respect to sanitation after an initial positive result on a food contact surface in the post-lethality processing environment) by follow-up testing that includes targeted testing of the specific site on the food contact surface area and other sites as necessary to ensure effectiveness of the corrective actions.

2. Holds product lots that may have become contaminated by contact with the food contact surface when the establishment obtains a second positive test for *Lm* or an indicator organism during follow-up testing until the problem is corrected as indicated by negative follow-up test results.
3. Sample and test product lots for *Lm* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *Lm*.
4. Documents testing results.
5. Reworks held product using a process that is destructive to *Lm*.

Assess Information

To answer these questions, IPP should:

- Review the HACCP plan,
- Review validation data (supporting documentation) for the post-lethality treatment,
- Review HACCP records,
- Review the Sanitation SOP and/or prerequisite programs associated with the use of the antimicrobial agent or process (as necessary), and
- Review Sanitation SOP and/or prerequisite program records (as necessary).

Determine Compliance

IPP must determine regulatory compliance after all available information pertaining to the *Listeria* Control Alternative selected has been gathered and assessed. There is no noncompliance if the establishment has met all regulatory requirements. If the establishment has not met all regulatory requirements, the noncompliance should be documented on an NR under the appropriate PHIS task as described in FSIS Directive 5000.1 Rev. 5, citing the appropriate sections of 9 CFR 430.4(b), Part 417 for HACCP and prerequisite programs, and/or Part 416 for sanitation. IPP should verify that the establishment has taken effective corrective and preventive actions to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative.

Documentation and Enforcement

If noncompliance with the *Lm* regulations is found, IPP are to issue an NR under the appropriate HACCP or SSOP task as described in FSIS Directive 5000.1, citing 9 CFR 430.4(b)(1), (2), or (3) and the appropriate sections of 9 CFR 417 or 416 if applicable. IPP are to verify that the establishment has taken effective corrective actions to bring itself into compliance with 9 CFR Part 430. Such actions may include, but are not limited to, a reassessment of the HACCP plan and the establishment's choosing of another alternative or determining that the decisions it made in the hazard analysis regarding the use of a prerequisite program remain valid.

If an establishment is producing post-lethality exposed products and has failed to meet any of the requirements of 9 CFR 430, IPP should contact the District Office through supervisory channels. A NOIE may be issued if the establishment HACCP system and/or SSOP is inadequate due to failure to meet the 430 regulations.

ATTACHMENT 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 <i>Lm</i> 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 Pre-requisite Program and should demonstrate no more than 2-logs growth of <i>Lm</i> over the estimated shelf life.	X		X		
Sanitation Program Requirements					
Testing food contact surfaces (FCS) in the post-lethality processing environment for <i>Lm</i> 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 <i>Lm</i> or an indicator organism.			X	X	X
Identify conditions for Hold-and-Test, when FCS (+) for <i>Lm</i> or an indicator organism.			X	X	X
Additional Sanitation Program Requirements					
Follow-up testing to verify corrective actions are effective after 1 st FCS (+) for <i>Lm</i> 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 2 nd 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 <i>Lm</i> 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

Definitions Related to *Listeria monocytogenes* (Lm)

9 CFR 430.1 provides a several definitions that are specific to ready-to-eat (RTE) products.

Two RTE product definitions are ***deli products*** and ***hotdog products***.

A ***deli product*** is an RTE meat or poultry product that is typically sliced, either in an official establishment or after distribution, and assembled in a sandwich for consumption.

A ***hotdog product*** is an RTE meat or poultry frank, frankfurter, or wiener product with a standard of identity defined in 9 CFR 319.180 and 319.181.

Note: A risk assessment performed jointly by FSIS and the FDA indicated that on a per serving basis, deli meats and hotdogs (not reheated) posed the greatest risk of illness and death from *Lm*.

A ***lethality treatment*** is the initial process RTE meat and poultry products undergoes to eliminate or reduce the number of pathogenic microorganisms on or in a product. Examples of lethality treatments that will make an RTE product safe for human consumption include cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

The ***post-lethality processing environment*** is the area in an establishment into which product subjected to an initial lethality treatment has been routed. The product may be exposed to the environment through slicing, peeling, re-bagging, cooling semi-permeable encased product in a brine solution, or other procedures.

Post-lethality exposed product is RTE product that comes into direct contact with a food contact surface in the post-lethality processing environment after an initial lethality treatment. Only post-lethality exposed RTE products are subject to 9 CFR 430.

The following three terms are associated with the ***three Listeria control alternatives*** used to control or prevent *Lm* in an RTE product in the post-lethality environment:

- ***Post-lethality treatment (PLT)*** - an additional lethality treatment, following the initial lethality treatment, applied to the final product or sealed package of product to reduce or eliminate the risk of *Lm* contamination during post-lethality exposure. Examples of post-lethality treatments include steam pasteurization, hot water pasteurization, radiant heating, and high pressure processing (HPP). Some antimicrobial agents may also function as post-lethality treatments.
- ***Antimicrobial agent*** - a substance in or added to an RTE product that suppresses or limits growth of *Lm* in the product throughout the shelf life of the product. Examples of antimicrobial agents used in RTE products are sodium lactate, potassium lactate, and sodium diacetate. For additional antimicrobial agents see [FSIS Directive 7120.1](#).
- ***Antimicrobial process*** - an operation (e.g., freezing) applied to an RTE product that suppresses or limits the growth of *Lm* in the product throughout the shelf life of the product. Examples include: Drying and fermenting

While not defined in 9 CFR 430.1, *indicator organism* is defined in 9 CFR 430 as bacteria used to determine if the sanitary conditions of food processing equipment, production areas, or storage rooms allow for the presence of objectionable microbes (i.e., pathogens).