

Food Safety and Inspection Service U.S. DEPARTMENT OF AGRICULTURE

> Listeria monocytogenes Regulations 9 CFR 430 – "Listeria Rule"

Module Objectives

- 1) Discuss why *Listeria monocytogenes* (*Lm*) is a public health concern in post-lethality exposed (PLE) ready-to eat (RTE) meat and poultry products
- 2) Address establishment alternatives for controlling *Lm* in RTE products exposed to the environment after an initial lethality treatment
- 3) Describe how to verify regulatory compliance with 9 CFR 430 regulations ("*Listeria* Rule") using FSIS Directive 10,240.4

Listeria monocytogenes

Public Health Concerns

- Widespread; very tolerant of freezing, drying, salt, heat, low pH, low water activity
- Can be serious or fatal if left untreated; may cause **listeriosis**, rarely neurolisteriosis
- Pregnant women, newborns, young children, elderly, and immuno-compromised individuals at highest risk
- Most illnesses linked to RTE meat and poultry products

CDC Annual Lm Estimates

- Nearly 1,600 illnesses
- More than 1,400 related hospitalizations
- About 260 related deaths

9 CFR 430 – Listeria Rule

- 9 CFR 430 *Listeria* Rule applies to RTE products exposed to processing environment following a full lethality step
 - Listeria Rule does not apply to NRTE products or RTE products not post-lethality exposed
- Use HACCP Verification Task to verify not post-lethality exposed RTE products are correctly classified

9 CFR 430.1 – Definitions

Ready-to-Eat (RTE) Product - A meat or poultry product that is edible without additional preparation to achieve food safety

- May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes
- **Deli Product** RTE meat or poultry product that is typically sliced and usually assembled in a sandwich for consumption

Hotdog Product - RTE meat or poultry sausage product meeting a standard of identity defined in 9 CFR 319.180 and 319.181 (e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, knockwurst, similar products, and cheese furter)

9 CFR 430.1 – Definitions (2)

Lethality Treatment – A process, including use of an antimicrobial agent, that eliminates or reduces number of pathogens on or in product to acceptable levels

- 7-log reduction of Salmonella in poultry products
- 6.5-log reduction of Salmonella in cooked meat products
- 5-log reduction of Salmonella for other products with support; jerky

Post-Lethality Processing Environment – Area in an establishment where product is conveyed for further processing or packaging following an initial lethality treatment

• Commonly called **post-lethality environment** (PLE)

9 CFR 430.1 – Definitions (3)

Post-Lethality Exposed Product - RTE product that has direct contact with a food contact surface in the post-lethality environment

Post-Lethality Treatment - Additional lethality treatment applied to either post-lethality exposed final product or sealed product packaging

- FSIS recommends establishment achieve at least 1-log reduction of *Lm* before product leaves establishment
- Establishment must validate PLT effectiveness

9 CFR 430.1 – Definitions (4)

Antimicrobial Agent - Substance in or added to RTE product to suppress or inhibit *Lm* growth in product throughout that product's shelf life

Antimicrobial Process - An operation or process applied to RTE product to suppress or inhibit *Lm* growth in product throughout product shelf life

- Antimicrobial agent/antimicrobial process (AMAP) must allow no more than 2-log outgrowth of *Lm*
- Establishment must document AMAP effectiveness in HACCP plan, Sanitation SOP, or other prerequisite program

Post-Lethality Exposed Products

HACCP Processing Categories Subject to Listeria Rule

- Not Heat Treated Shelf Stable; Heat Treated Shelf Stable
 - Acidified/fermented, dried, or salt cured RTE meat or poultry
- Product with Secondary Inhibitors Not Shelf Stable
 - Salt cured RTE meat or poultry
- Fully Cooked Not Shelf Stable
 - Fully cooked RTE meat or poultry

Controlling Listeria monocytogenes – 9 CFR 430.4

- *Listeria* controls intended to reduce risk of *Lm* in postlethality exposed RTE meat and poultry products
- Establishments must use a *Lm* control alternative
 - FSIS Compliance Guideline, "Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products"
- *Lm* hazard addressed in HACCP plan, SSOP, or PRP
 - Contact DO if establishment fails to meet Part 430
- Effective sanitation required

Listeria monocytogenes Control Alternatives

- Establishments must demonstrate effectiveness of one of three alternatives selected to control *Lm* in the post-processing environment
- IPP must determine effectiveness of establishment *Lm* control measures as instructed in Directive 10240.4
- Establishment compliance with chosen Alternative 1, 2, or 3 determined through HACCP or SSOP verification task

FSIS Listeria Guideline	January 2014
FSIS Compliance Guideline: Controlling <i>Listeria monocytogenes</i> Exposed Ready-to-Eat Meat and P	s in Post-lethality oultry Products
January 2014	

Listeria Rule Verification – Directive 10240.4

Directive 10240.4 – *Listeria* Rule Verification Activities

Listeria Control Options

- Alternative 1 430.44(b)(1)
- Alternative 2, Choice 1 430.4(b)(2)(i)
- Alternative 2, Choice 2 430.4(b)(2)(ii)
- Alternative 3 (non-deli) 430.4(b)(3)(i)
- Alternative 3 (hotdogs, deli meat) -430.4(b)(3)(ii)

Listeria Control Alternative Type	Listeria Control Alternative Description	Regulatory Testing Requirements	Regulatory Citation
Alternative 1 (Alt. 1)	The establishment uses a post-lethality treatment (PLT) to reduce or eliminate <i>Lm</i> in the product <u>and</u> an Antimicrobial Agent or Antimicrobial Process (AMAP) to limit or suppress growth of <i>Lm</i> in the product	None	• <u>9 CFR</u> <u>430.4(b)(1)</u>
Alternative 2, Choice 1 (Alt. 2a)	The establishment uses a PLT to reduce or eliminate Lm in the product	None	• <u>9 CFR</u> <u>430.4(b)(2)(i)</u>
Alternative 2, Choice 2 (Alt. 2b)	The establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product	 Testing FCS in post-lethality processing environment for <i>Lm</i> or an indicator organism State testing frequency Identify size and location of sites to be sampled Explain why testing frequency is sufficient to ensure Lm or indicator organism control Identify conditions for hold and test, when FCS (+) for an indicator organism 	• <u>9 CFR</u> <u>430.4[b)(2)(ii)</u>
Alternative 3 (Ait. 3)	The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product	 Testing FCS in post-lethality processing environment for <i>Lm</i> or an indicator an indicator organism State testing frequency Identify size and location of sites to be sampled Explain why testing frequency is sufficient to ensure <i>Lm</i> or indicator organism control Identify conditions for hold and test, when FCS (+) for an indicator organism 	• 9 CFR 430.4(b)(3)(j)
Alternative 3 (Alt. 3) Additional Requirements for beli Meats and Hot Dogs	The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product	 Testing FCS in post-lethality processing environment for <i>Lm</i> or an indicator an indicator angainsm State testing frequency Identify size and location of sites to be sampled Explain why testing frequency is sufficient to ensure <i>Lm</i> or indicator organism control Hold and test product after a second consecutive FCS (+) for an indicator organism 	• 9 CFR 430.4(b)(3)(j)

Listeria Control Testing Requirements

- Establishments must identify:
 - Target organism (either Lm or indicator organism)
 - Size, location of food contact surface (FCS) test sites
 - Sampling frequency
 - Support for selected testing frequency
 - Conditions to hold-and-test product for positive sample results
 - For hotdogs and deli meats, hold-and-test product after 2nd consecutive FCS (+) for indicator organism

Listeria Control Alternative 1 – 430.4(b)(1)

 Post-lethality treatment (PLT) to reduce or eliminate Lm on product

AND

- Antimicrobial agent or process (AMAP)
 - Suppresses or limits Lm growth throughout product shelf life
 - May also be PLT
- Sanitation

Listeria Control Alternative 1 Chart



Listeria Control Alternative 1 – Table 1

Listeria Control	Listeria Control Alternative	Regulatory Testing Requirements	Regulatory
Alternative Type	Description		Citation
Alternative 1 (Alt. 1)	The establishment uses a post-lethality treatment (PLT) to reduce or eliminate <i>Lm</i> in the product and an Antimicrobial Agent or Antimicrobial Process (AMAP) to limit or suppress growth of <i>Lm</i> in the product	• None	 <u>9 CFR</u> <u>430.4(b)(1)</u>

Listeria Control Alternative 2 – 430.4(b)(i), (ii)

- **Choice 1**: Post-lethality treatment, may be antimicrobial agent or process 430.4(b)(i)
- Sanitation

OR

- Choice 2: Antimicrobial agent or process 430.4(b)(ii)
- Sanitation
 - FCS testing each line at least 4X year

Listeria Control Alternative 2 Chart



Listeria Control Alternative 2 – Table 1

Listeria Control Alternative Type	Listeria Control Alternative Description	Regulatory Testing Requirements	Regulatory Citation
Alternative 2, Choice 1 (Alt. 2a)	The establishment uses a PLT to reduce or eliminate Lm in the product	None	 <u>9 CFR</u> <u>430.4(b)(2)(i)</u>
Alternative 2, Choice 2 (Alt. 2b)	The establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product	 Testing FCS in post-lethality processing environment for <i>Lm</i> or an indicator organism State testing frequency Identify size and location of sites to be sampled Explain why testing frequency is sufficient to ensure Lm or indicator organism control Identify conditions for hold and test, when FCS (+) for an indicator organism 	• <u>9 CFR</u> <u>430.4(b)(2)(ii)</u>

Listeria Control Alternative 3 - 430.4(b)(3)(i), (ii)

- Sanitation only HACCP, SSOP, PRP
- Test post-lethality environment FCS for Lm or indicator organism
- FSIS recommends sampling frequency based on establishment size
 - Non-deli products: at least 1 sample per month per line
 - Deli, hot dog products:
 - > Very small establishments minimum once per month/line
 - > Small establishments at least every 2 weeks per line
 - Large establishments minimum weekly per line

Listeria Control Alternative 3 Chart



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Alternative 3 – Table 1: Non-Deli

Alternative 3 (Alt. 3)

The establishment relies on **sanitation alone** to prevent *Lm* in the processing environment and on the product

- Testing FCS in post-lethality processing environment for Lm or an indicator organism
- State testing frequency
- Identify size and location of sites to be sampled
- Explain why testing frequency is sufficient to ensure Lm or indicator organism control
- Identify conditions for hold and test, when FCS (+) for an indicator organism

 9 CFR 430.4(b)(3)(j)

Alternative 3 – Table 1: Deli Meats & Hotdogs

Alternative 3 (Alt. 3)

Additional Requirements for Deli Meats and Hot Dogs

The establishment relies on sanitation alone to prevent *Lm* in the processing environment and on the product

- Testing FCS in post-lethality processing environment for Lm or an indicator organism
- State testing frequency
- Identify size and location of sites to be sampled
- Explain why testing frequency is sufficient to ensure Lm or I indicator organism control
- Hold and test product after a second consecutive FCS (+) for an indicator organism.

9 CFR 430.4(b)(3)(ii)

Alternative 3 Sanitation: Non-deli Products

- Establishment Requirements:
 - Test for Lm or indicator organism
 - State sampling frequency
 - Identify size, location of food contact surface sample sites
 - Explain why testing frequency is sufficient
 - Identify conditions to hold-and-test product for positive Lm results
- Non-deli product FSIS recommended sampling frequency:
 At least 1 FCS sample per line per month

Alternative 3 Sanitation: Deli, Hotdog Products

- Establishment Requirements:
 - Test for Lm or indicator organism
 - State sampling frequency
 - Identify size, location of food contact surface sample sites
 - Explain why testing frequency is sufficient
 - Hold-and-test product after 2nd consecutive positive Lm result
- Deli meat and hotdog recommended FCS sampling frequency:
 - Very small establishments once per line per month
 - Small establishments once per line every 2 weeks
 - Large establishments once per line weekly

Listeria Control Compliance Verification

Directive 10240.4 - Provides instructions for verifying establishments that produce post-lethality exposed RTE products control *Lm* through a HACCP plan, SSOP, or other prerequisite program

- Verify establishment compliance with *Listeria* Rule
- Verify establishment sampling and testing programs comply with *Listeria* Rule regulatory requirements
- Verify corrective actions and preventive measures

Listeria Rule Verification

- Verify establishment produces post-lethality exposed RTE products using HAV Task, HACCP Verification Task
 - Record Review
 - Review and Observation
- If not post-lethality exposed product (i.e., cook-in-bag), verify lethality steps included in process flow chart, hazard analysis
 - Observe product container to verify integrity is maintained

Determining Alternative 1 & Alternative 2, Choice 1 Compliance

- Verify compliance with Alternative 1 and Alternative 2, Choice 1
 - Is PLT (may be an AMAP) described in a HACCP plan?
 - Does the establishment have validation data supporting PLT effectiveness?
 - Is AMAP described in a HACCP plan, SSOP, or PRP?
 - Is selected alternative implemented as documented?
 - Are supporting documents, sample results, and process monitoring, ongoing verification, and corrective action records maintained?

Determining Alternative 2, Choice 2 Compliance

- Verify regulatory compliance with Alternative 2, Choice 2
 - Is AMAP addressed in a HACCP plan, SSOP, or PRP?
 - Is AMAP used as described and validated if necessary?
 - Does the establishment test FCS in post-lethality processing environment as required?
 - Are supporting documents, sample results, and process monitoring, ongoing verification, and corrective action records maintained?
 - Is sanitation in the post-lethality environment adequate?

Determining Alternative 3 Compliance

- Verify compliance with Alternative 3:
 - Are sanitary procedures in a HACCP plan, SSOP, or PRP?
 - Are FCS in post-lethality processing environments sampled?
 - Is sample location, size, testing frequency, and sufficient support for testing frequency identified?
 - Are corrective actions and hold-and-test conditions for positive FCS test results documented for non-deli products?

Alternative 3 Compliance – Deli Meats, Hotdogs

- Did establishment:
 - Document conditions to hold-and-test product after 2nd consecutive positive Lm result?
 - Verify corrective actions on FCS positive for Lm or indicator organism and conduct follow-up tests?
 - Hold product lots that contacted FCS after 2nd positive followup test result?
 - Sample and test product before it entered commerce?
 - Document sampling results?
 - Rework any positive product?

Alternative 1 Example – Compliance

You are verifying compliance with 9 CFR 430.4(b)(1) for RTE meat and poultry deli products processed under Alternative 1. You review the hazard analysis and see the establishment previously controlled *Lm* under Alternative 2, Choice 2. You review decision-making documents and determine a sodium diacetate solution was added to deli products as an antimicrobial agent but caused concerns of undesirable flavors. The establishment changed to Alternative 1 and added a post-lethality treatment CCP prior to the vacuum packaging step. The CCP is a solution containing *Lm*-specific bacteriophage and sodium lactate as an antimicrobial agent sprayed on the surface of deli products. You review supporting documentation, which includes published research and data addressing Lm bacteriophage effectiveness as a post-lethality treatment and sodium lactate ability to inhibit *Lm* growth throughout deli product shelf life. Initial validation data supports the CCP location, critical limits, process monitoring, and ongoing verification procedures. After verifying that the HACCP plan was reassessed, you determine the establishment meets 430.4(b)(1) and Alternative 1 requirements.



Alternative 2 Example - Compliance

You are verifying compliance with 9 CFR 430.4(b)(2) in an establishment that produces post-lethality exposed RTE product. You review the hazard analysis and determine *Lm* is identified as a hazard not reasonably likely to occur NRLTO. You review the establishment's prerequisite program and verify that an antimicrobial agent or process is used to suppress or limit growth of *Lm* under Alternative 2, Choice 2. You review scientific support documentation, initial validation data, process monitoring records, and ongoing verification records supporting antimicrobial agent or process effectiveness. Since a post-lethality treatment was not used, you also review the establishment's Lm sampling program and FCS test results from the post-lethality environment. Test results support that the FCS were sanitary and free of Lm or an indicator organism as required in 430.4(b)(2)(iii). You determine the establishment is in compliance with 9 CFR 430.4(b)(2).



Alternative 3 Example - Compliance

While verifying Alternative 3 compliance with 9 CFR 430.4(b)(3) for a cooked RTE breakfast sausage product, you review the establishment's hazard analysis. You determine that *Lm* is a food safety hazard considered NRLTO at the packaging step because it will be controlled through sanitation. You review the SSOP, initial validation data, *Lm* sampling procedures, and FCS test results (all negative). You also review recent records for process monitoring, ongoing verification, and sanitation monitoring. You verify the establishment identified FCS sample site size and locations, testing frequency with support, and hold-and-test procedures following a positive *Listeria* spp. test. You verify the establishment has adequately documented and effectively implemented its sanitation program. Based on your review, you determine the establishment is in compliance with 9 CFR 430.4(b)(3) and Alternative 3.



Knowledge Check - Alternative 1 Noncompliance

• 430.4(b)(1) • 417.5(a)(1), (2)

Establishment PLT included in a HACCP plan but AMAP not in a HACCP plan, SSOP, or PRP • 430.4(b)(1) • 417.5(a)(1), (2) **Establishment** tests FCS in post-lethality environment but PLT not in a HACCP plan, or AMAP not in a HACCP plan, SSOP, or PRP

• 430.4(b)(1) • 417.4

Establishment PLT in a HACCP plan but effectiveness not validated

Knowledge Check - Alternative 2 Noncompliance

430.4(b)(2)
417.2
417.5(a)(1), (2)

Establishment tests FCS but PLT not in a HACCP plan, or AMAP not in a HACCP plan, SSOP, or PRP 430.4(b)(2)
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417.5(a)(1), (2)

Alternative 2, Choice 2 only addresses non-FCS testing • 430.4(b)(2) • 417.5(a)(1), (2)

Establishment PLT in a HACCP plan but effectiveness not validated

Knowledge Check - Alternative 3 Noncompliance

• 430.4(b)(3) • 417.5(a)(1), (2)

Establishment did not address sanitation in a HACCP plan, SSOP, or PRP • 430.4(b)(3) • 417.5(a)(1), (2) Deli meat and hotdog establishment does not conduct follow-up testing on FCS after an initial positive *Lm* sample

• 430.4(b)(3) • 417.5(a)(1), (2)

Deli meat and hot dog establishment does not holdand-test product during follow-up testing for second positive *Lm* FCS sample

Time to test your knowledge of *Listeria monocytogenes* with a group exercise!



Establishments are required to comply with 9 CFR 430.4 (Control of *Listeria monocytogenes*) if they produce:

- a) Ready-to-eat products processed and sold in impermeable packaging.
- b) Not ready-to-eat products with secondary inhibitors.
- c) Ready-to eat products.

d) Ready-to-eat products exposed to the environment following the lethality step.

Match the *Lm* Control Alternatives below with the correct definition.

a) Alternative 1b) Alternative 2, Choice 1c) Alternative 2, Choice 2d) Alternative 3

1) Use of only a post-lethality treatment that reduces or eliminates microorganisms on the product.

2) Use of a post-lethality treatment AND an antimicrobial agent or process that suppresses or limits *Lm* growth in the product.

3) Only sanitation documented in a HACCP plan, SSOP, or prerequisite program, including testing of food contact surfaces to verify sanitation effectiveness.

4) Use of only an antimicrobial agent or process, including testing of food contact surfaces.

Α

B

D

An establishment must implement hold-and-test procedures for a second consecutive positive *Lm* or indicator organism result on a food contact surface during follow-up testing if what type of product(s) is being produced?

- a. Deli and hot dog type RTE products exposed to the environment after the initial lethality treatment using Alternative 2, Choice 1.
- b. RTE products exposed to the environment following the initial lethality treatment under Alternative 2, Choice 2, or Alternative 3.
- c. Deli and hot dog type RTE products exposed to the environment after the initial lethality treatment using Alternative 3.
- d. Non-deli and hot dog type RTE products exposed to the environment following the initial lethality treatment under Alternative 3.

An establishment MUST identify the conditions that trigger hold-and-test procedures when a positive FCS test result is received if it is producing what type of product(s)?

- a. Non-deli, deli, or hot dog type RTE products exposed to the environment after the initial lethality treatment using either Alternative 2, Choice 2 or Alternative 3.
- b. Deli and hot dog type RTE products exposed to the environment after the initial lethality treatment under Alternative 2, Choice 1.
- c. Deli and hot dog type RTE products exposed to the environment after the initial lethality treatment using Alternative 1.
- d. RTE products exposed to the environment after the initial lethality treatment using Alternative 2, Choice 1.

Case Study Answer Key:

- a. At what point during production are the random food contact surface samples taken?
- The FCS sites are tested twice weekly at the end of production prior to cleaning.

Lm Regulations Exercise - #5 (cont. 2)

Case Study Answer Key:

b. Does this program identify conditions under which the establishment will implement hold-and-test procedures following a positive test of a food contact surface? If so, what are those conditions?

Yes.

Following an initial positive *Listeria* spp. sample result on a FCS, the establishment must implement a 5-day period of intensified cleaning and sanitation, followed by daily testing. Hold-and test procedures will be initiated if during that 5-day period a FCS tests positive for *Listeria* spp.

Lm Regulations Exercise - #5 (cont. 3)

c. Does this program identify the frequency with which testing will be done? If so, what is that frequency?

Yes. Five FCS sites are randomly selected and tested for *Listeria* spp. monthly.

If a FCS sample result is positive, that site is re-tested daily for 5 days following intensified cleaning and sanitation.

If the FCS site tests positive again for *Listeria* spp. during this 5-day period, the food contact surface is taken out of production and retested every two hours during production.

Lm Regulations Exercise - #5 (cont. 4)

d. Does this program identify the size and location of the sites that will be sampled? If so, what is the size and location?

Yes.

The sample size of the 20 FCS sample sites is equivalent to 1 square foot. The food contact surfaces identified include tabletops, packaging equipment, and knife blades.

Lm Regulations Exercise - #5 (cont. 5)

e. When are product samples for *Listeria monocytogenes* taken?

Product samples will be collected and tested for *L. monocytogenes* if a FCS site tests positive for *Listeria* spp. during the 5-day intensified cleaning and sanitation period implemented in response to an initial positive FCS result. Product samples will be collected from a 2-hour time period and from each period on either side of the positive result in accordance with a statistically derived sampling plan.

Lm Regulations Exercise - #5 (cont. 6)

f. Would you review records associated with this program? If so, when? Please explain your answer.

Yes. Records reviews should include:

- Sanitation SOP and monitoring records.
- Alternative 2, Choice 2 documentation.
- FCS sample sites and sampling procedures.
- Product sampling procedures.
- Listeria spp. and L. monocytogenes sample results.
- Corrective action logs.

Lm Regulations Exercise - #5 (cont. 7)

- g. Would you observe employees performing the sampling procedures? If so, when? Please explain your answer.
- Yes. Establishment employees should be observed:
- Collecting random routine FCS samples.
- Collecting FCS samples following any required intensive cleaning and sanitation activities.
- Collecting product samples to test for *Lm* following a 2nd positive FCS sample.
- Performing corrective actions.
- Disposing of any product that tests positive for *Lm*.

Objective Summary

- 1) Discussed why *L. monocytogenes* is a public health concern in post-lethality exposed (PLE) ready-to eat (RTE) meat and poultry products
- 2) Addressed establishment alternatives for controlling *Lm* in RTE products exposed to the environment after an initial lethality treatment
- 3) Described how to verify regulatory compliance with 9 CFR
 430 regulations ("*Listeria* Rule") using FSIS Directive
 10,240.4