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

Listeria monocytogenes Regulations

9 CFR 430 – "*Listeria* Rule"

1

Module Objectives

1) Explain why *Listeria monocytogenes* (*Lm*) is a public health concern in post-lethality exposed (PLE) ready-to eat (RTE) meat and poultry products
2) Identify 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

2

2

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

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3

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

4

4

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)

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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)

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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

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7

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

8

8

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

9

9

Controlling *Listeria monocytogenes* – 9 CFR 430.4

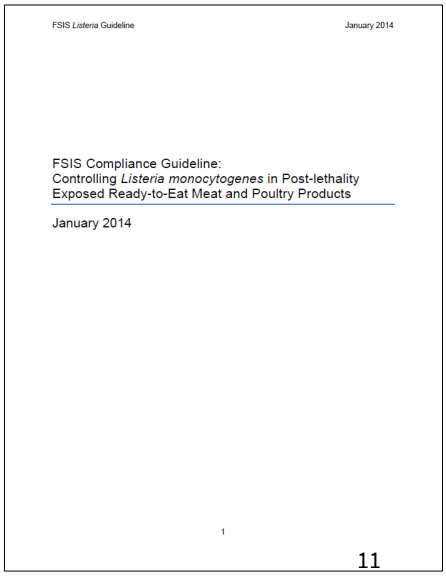
- *Listeria* controls intended to reduce risk of *Lm* in post-lethality exposed RTE meat and poultry products
- Establishments must use a *Lm* control alternative
  - FSIS Compliance Guideline, "Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products"
- *Lm*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

10

10

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 *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products

January 2014

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11

11

Listeria Rule Verification – Directive 10240.4

Directive 10240.4 – *Listeria* Rule Verification Activities

***Listeria* Control Options**

- Alternative 1 - 430.4(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 *Lm* in the product **and** an Antimicrobial Agent or Antimicrobial Process (**AMAP**) to limit or suppress growth of *Lm* in the product	• None	• 9 CFR 430.4(b)(1)
Alternative 2, Choice 1 (Alt. 2a)	The establishment uses a **PLT** to reduce or eliminate *Lm* in the product	• None	• 9 CFR 430.4(b)(2)(i)
Alternative 2, Choice 2 (Alt. 2b)	The establishment uses an **AMAP** to limit or suppress growth of *Lm* in 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)(2)(ii)
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 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)(i)
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 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 • Hold and test product after a second consecutive FCS (+) for an indicator organism	• 9 CFR 430.4(b)(3)(i)

12

12

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

13

13

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

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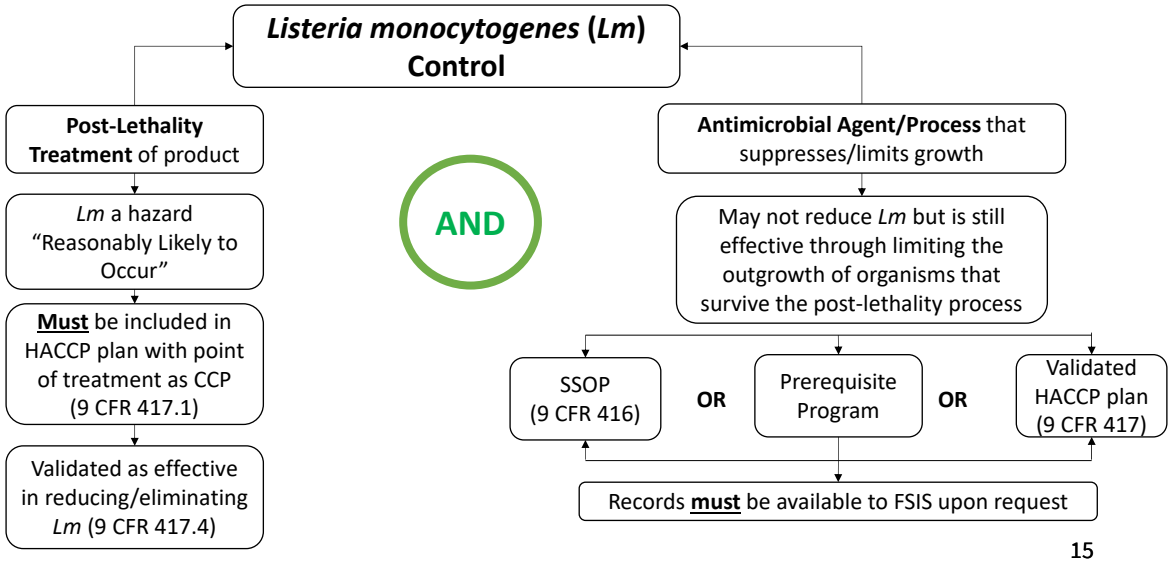
14

Listeria Control Alternative 1 Chart



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Listeria Control Alternative 1 – Table 1

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 *Lm* in the product **and** an Antimicrobial Agent or Antimicrobial Process (**AMAP**) to limit or suppress growth of *Lm* in the product	• None	• 9 CFR 430.4(b)(1)

16

16

Listeria Control Alternative 2 – 430.4(b)(2)

- **Choice 1**: Post-lethality treatment, may be antimicrobial agent or process
- Sanitation

OR

- **Choice 2**: Antimicrobial agent or process
- Sanitation
  - FCS testing each line at least 4X year

17

17

Alternative 2, Choice 2 – 430.4(b)(2)(iii)

Use of only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*

430.4(b)(2)(iii) – Establishment sanitation program must:
(A) Test FCS in post-lethality environment for *Lm* or indicator organism
(B) Identify hold-and-test procedures following a positive FCS indicator organism sample
(C) State testing frequency
(D) Identify size, location of FCS sample sites
(E) Document why testing frequency sufficient to effectively control *Lm* or indicator organisms

18

18

Alternative 2, Choice 2 – 430.4(b)(2)(iv)

- Post-lethality treatment under Alternative 2, Choice 1 subject to more frequent FSIS verification testing than Alternative 1
- Antimicrobial agent or process under Alternative 2, Choice 2 subject to more frequent FSIS verification testing than a PLT under Alternative 2, Choice 1

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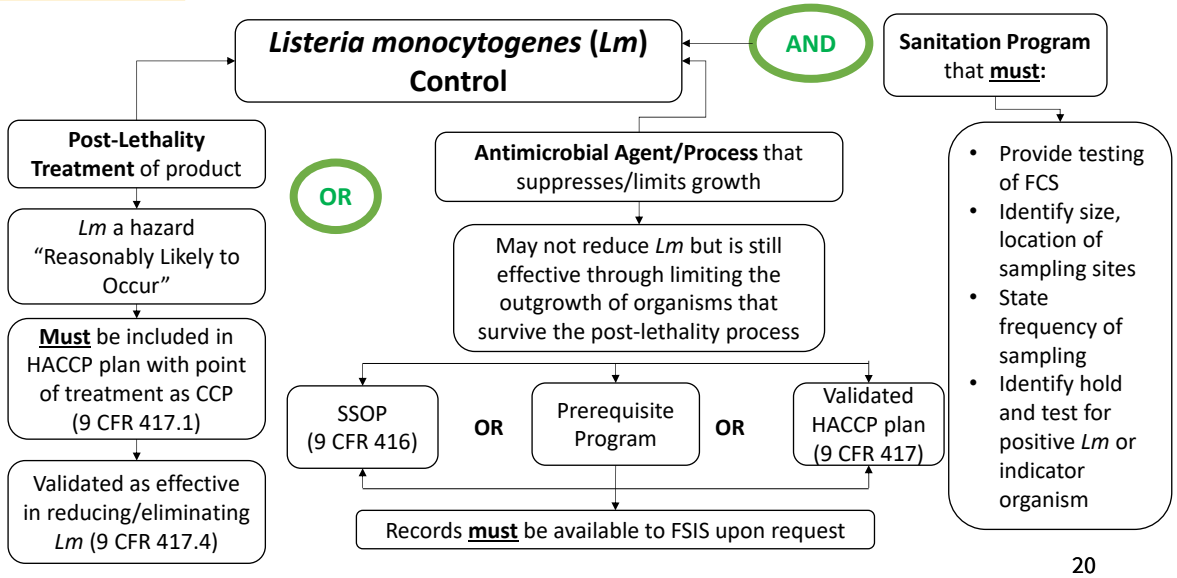
19

Listeria Control Alternative 2 Chart



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Listeria Control Alternative 2 – Table 1

Alternative 2, Choice 1 (Alt. 2a)	The establishment uses a **PLT** to reduce or eliminate *Lm* in the product	• None	• 9 CFR 430.4(b)(2)(i)
Alternative 2, Choice 2 (Alt. 2b)	The establishment uses an **AMAP** to limit or suppress growth of *Lm* in 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)(2)(ii)

21

21

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 time 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

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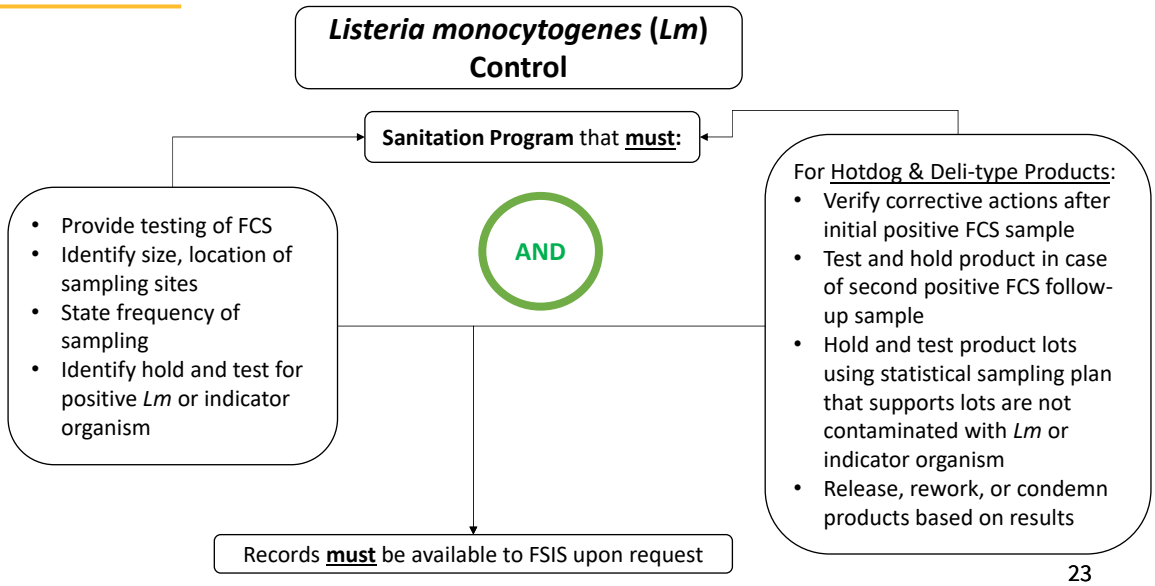
Listeria Control Alternative 3 Chart



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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)(i)

24

24

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 indicator organism control • Hold and test product after a second consecutive FCS (+) for an indicator organism	• 9 CFR 430.4(b)(3)(ii)

25

25

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 time per line per month

26

26

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

27

27

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
- Document all noncompliance in an NR

28

28

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

29

29

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?

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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?

31

31

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?

32

32

Alternative 3 Compliance – Deli Meats, Hotdogs

- Did the 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 follow-up test result?
  - Sample and test product before it entered commerce?
  - Document sampling results?
  - Alternatively, rework any positive product?

33

33

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.

34

34

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).

35

35

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.

36

36

9 CFR 430.4 Noncompliance

- Issue NR for noncompliance with 9 CFR 430 regulations
- Cite appropriate 430 *Lm* regulation and applicable 416 SSOP or 417 HACCP regulations
- Verify establishment corrective actions, follow-up measures, and HACCP plan reassessment, if needed
- Contact DO

37

37

Alternative 1 Noncompliance – Example 1

- **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

38

38

Alternative 1 Noncompliance – Example 2

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

39

39

Alternative 1 Noncompliance – Example 3

• 430.4(b)(1) • 417.5(a)(1), (2)	• 430.4(b)(1) • 417.5(a)(1), (2)	• 430.4(b)(1) • 417.5(a)(2) • 417.4(a)(1)
Establishment PLT included in a HACCP plan but AMAP not in a HACCP plan, SSOP, or PRP	Establishment tests FCS in post-lethality environment but PLT not in a HACCP plan, or AMAP not in a HACCP plan, SSOP, or PRP	Establishment PLT in a HACCP plan but effectiveness not validated

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Alternative 2 Noncompliance – Example 1

- 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

41

41

Alternative 2 Noncompliance – Example 2

- 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)
- 417.5(a)(1), (2)
- 416.13(b)

Alternative 2, Choice 2 only addresses non-FCS testing

42

42

Alternative 2 Noncompliance – Example 3

• 430.4(b)(2) • 417.2 • 417.5(a)(1), (2)	• 430.4(b)(2) • 417.5(a)(1), (2) • 416.13(b)	• 430.4(b)(2) • 417.5(a)(2) • 417.4(a)(1)
Establishment tests FCS but PLT not in a HACCP plan, or AMAP not in a HACCP plan, SSOP, or PRP	Alternative 2, Choice 2 only addresses non-FCS testing	Establishment PLT in a HACCP plan but effectiveness not validated

43

43

Alternative 3 Noncompliance – Example 1

• 430.4(b)(3) • 417.5(a)(1), (2)
Establishment did not address sanitation in a HACCP plan, SSOP, or PRP

44

44

Alternative 3 Noncompliance – Example 2

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

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Alternative 3 Noncompliance – Example 3

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

46

46

Objective Summary

1) Explain why *Listeria monocytogenes* (*Lm*) is a public health concern in post-lethality exposed (PLE) ready-to eat (RTE) meat and poultry products
2) Identify 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

47

47

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Questions?

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48

48