



Food Safety and Inspection Service

U.S. DEPARTMENT OF AGRICULTURE

Listeria monocytogenes Regulations 9 CFR 430



Definitions (9 CFR 430.1)

- RTE product
- Deli product
- Hotdog product



Definitions (9 CFR 430.1)

- Lethality treatment
- Antimicrobial agent
- Antimicrobial process
- Post-lethality treatment



Definitions (9 CFR 430.1)

- Post-lethality processing environment
- Post-lethality exposed product



Definitions (9 CFR 430.1)

- Prerequisite program
- Indicator organism



Verifying Compliance with §430.4

- RTE products that are exposed to the environment after the initial lethality step must comply with §430.4
- If NRTE or not post-lethality exposed the products do not have to meet 430.4
- Examples

Verifying Compliance with §430.4

- Fully Cooked NSS Category Products
 - RTE
 - Receives lethality from a full cook step
 - Some products have standards of identity or customary or usual identity requiring them to be fully cooked
 - Examples

Verifying Compliance with §430.4

- Some establishments may produce fully cooked products that have no standard of identity requirement or customary or usual identity and choose to label it as NRTE.
- Classify these under Heat-Treated Not Fully Cooked – Not Shelf Stable

Verifying Compliance with §430.4

- If required to meet 9 CFR 430 ask management which alternative(s) they have chosen
- Establishment results that demonstrate effectiveness are to be made available
- Use appropriate PHIS tasks to verify compliance

Verifying Compliance with §430.4

- If establishment is subject to 9 CFR 430 and fails to meet these requirements contact DO through supervisory channels



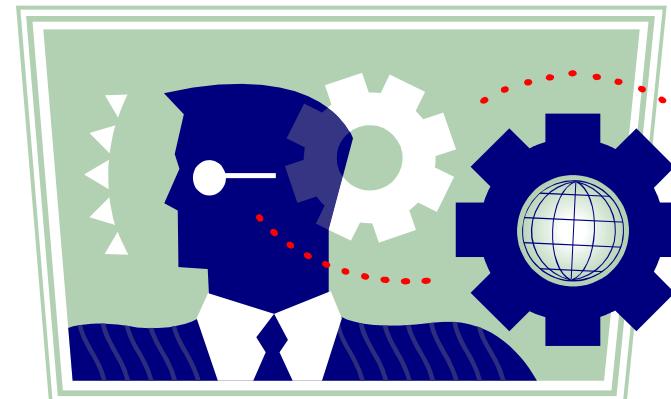
Alternative 1

- 9 CFR 430.4(b)(1)
- Use of a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates (kills) microorganisms on the product **AND** an antimicrobial agent or process that suppresses or limits the growth of LM.

Alternative 1

Thought Process

- Gather information by asking questions
- Assess the information
- Determine compliance



Gather Information by Asking Questions

- Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?
- Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?



Gather Information by Asking Questions

- Is the establishment implementing the post-lethality treatment as described in the HACCP plan?
- Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

Gather Information by Asking Questions

- Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?



Assess the Information

- Review the HACCP plan
- Review validation data
- Review HACCP records
- Review the SSOP and/or prerequisite programs
- Review Sanitation SOP and/or prerequisite program records

Alternative 1

Examples

Determine Compliance

- Compliance
- Noncompliance
 - NR
 - Verify corrective and preventive action



Noncompliance Examples

Alternative 2

- 9 CFR 430.4(b)(2)
- Use of 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 L. monocytogenes

Alternative 2

Alternative 2

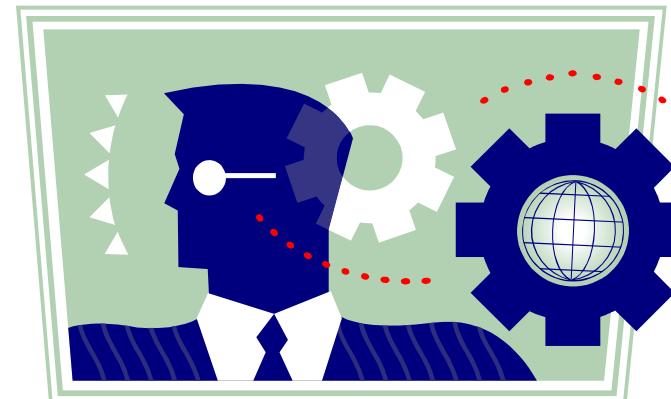
- Choice 1 – post-lethality treatment

OR

- Choice 2 – antimicrobial agent or process and specific sanitation measures

Thought Process

- Gather information by asking questions
- Assess the information
- Determine compliance



Gather Information by Asking Questions

- CHOICE 1
- Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?
- Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?
- Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

Gather Information by Asking Questions

- CHOICE 2
- Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?



Gather Information by Asking Questions

- CHOICE 2
- Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?



Gather Information by Asking Questions

- CHOICE 2
- Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:
 - Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism?

Gather Information by Asking Questions

- CHOICE 2
- Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:
 - Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism?

Gather Information by Asking Questions

- CHOICE 2
- Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:
 - State the frequency with which testing will be done?
 - Identify the size and location of the sites that will be sampled?

Gather Information by Asking Questions

- CHOICE 2
- Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:
 - Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?

Assess the Information

- Review the HACCP plan
- Review validation data
- Review HACCP records
- Review the SSOP and/or prerequisite programs
- Review Sanitation SOP and/or prerequisite program records

Alternative 2 Examples

Determine Compliance

- Compliance
- Noncompliance
 - NR
 - Verify corrective and preventive action



Noncompliance Examples

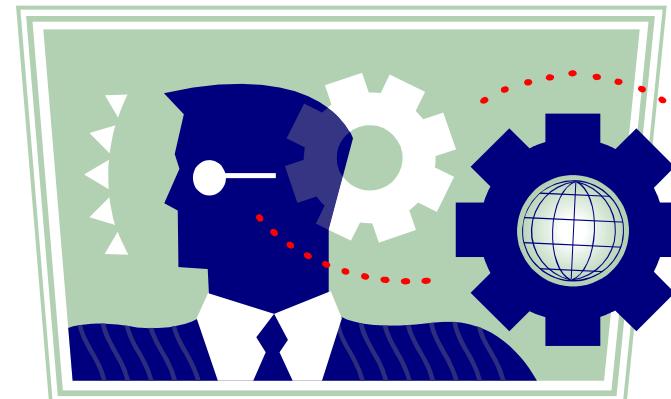
Alternative 3

- 9 CFR 430.4(b)(3)
- *Use of sanitation measures only*

Alternative 3

Thought Process

- Gather information by asking questions
- Assess the information
- Determine compliance



Gather Information by Asking Questions

- Does the establishment have on-going verification testing procedures designed to:
 - Have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program?



Gather Information by Asking Questions

- Does the establishment have on-going verification testing procedures designed to:
 - Test food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism?



Gather Information by Asking Questions

- Does the establishment have on-going verification testing procedures designed to:
 - Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism?



Gather Information by Asking Questions

- Does the establishment have on-going verification testing procedures designed to:
 - State the frequency with which testing will be done?
 - Identify the size and location of the sites that will be sampled?



Gather Information by Asking Questions

- Does the establishment have on-going verification testing procedures designed to:
 - Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?



Gather Information by Asking Questions

- For Deli and Hot Dog products
 - Has the establishment verified corrective action after a positive test for Lm or an indicator organism on a food contact surface and have they implemented follow-up testing?



Gather Information by Asking Questions

- For Deli and Hot Dog products
 - If follow-up testing resulted in a second positive test, did the establishment hold lots of product that may have become contaminated by contacting the food contact surface?



Gather Information by Asking Questions

- For Deli and Hot Dog Products:
 - Did the establishment sample and test product before it entered into commerce?



Gather Information by Asking Questions

- For Deli and Hot Dog Products
 - Has the establishment documented the results of the testing?
 - Did they rework the product?



Assess the Information

- Review the HACCP plan, SSOP and/or prerequisite programs
- Review HACCP records, SSOP records, or the records associated with the prerequisite program

Alternative 3 Examples

Determine Compliance

- Compliance
- Noncompliance
 - NR
 - Verify corrective and preventive action



Noncompliance Examples

Documentation and Enforcement

- Issue NR for noncompliance with 9 CFR 430 regulations
- Cite appropriate 430 regulation and HACCP or SSOP regulation
- Verify establishment actions
- Contact DO if more action needed.

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Rules of Practice Workshop

