UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

10,240.4 | 10/2/03

Verification Procedures for the *Listeria monocytogenes* Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program

PART I -- GENERAL

I. PURPOSE

This directive provides Consumer Safety Inspectors (CSIs) and Consumer Safety Officers (CSOs) with instructions for verifying whether establishments are complying with the regulations in 9 CFR part 430, *Requirements for Specific Classes of Product* (Attachment 5). In addition, this directive includes verification procedures for ready-to-eat (RTE) products other than those applicable to 9 CFR part 430.

NOTE: This document references a number of resources. CSIs and CSOs will receive these resources on a disk. The directive itself, without the resources, contains all the information that CSIs and CSOs need to verify the sections of 9 CFR 430 relating to the control of *Listeria monocytogenes* (*L. monocytogenes*) in post-lethality exposed RTE meat and poultry products.

II. CANCELLATION

FSIS Directive 10,240.3, dated 12/9/02

III. REASON FOR REISSUANCE

To provide verification instructions for 9 CFR Part 430 and to clarify the current sampling instructions.

IV. REFERENCES

FSIS Directive 5000.1, Revision 1, dated 05/21/03
FSIS Directive 5400.5, dated 11/21/97
FSIS Directive 8080.1, Revision 3, dated 1/19/00
FSIS Directive 10,200.1 dated 7/19/01

Title 9 Code of Federal Regulations (CFR) Part 416
Title 9 CFR Part 417
Title 9 CFR Part 430
Title 21 United States Code (U.S.C.) parts 453 and 601

V. BACKGROUND

On June 6, 2003, the Food Safety and Inspection Service (FSIS) published a final rule (68 FR 34207) that amended its regulations to require that official establishments that produce certain RTE meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *L. monocytogenes*. In particular, 9 CFR 430.1 sets out definitions of terms. 9 CFR 430.4(a) states that *L. monocytogenes* is a hazard that an establishment producing a RTE product that is exposed to the environment must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. It also states that RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes.* 9 CFR 430.4(b) sets out three alternatives that establishments producing post-lethality exposed RTE product are to choose from in order to meet the requirements of 9 CFR 430.4(a). CSIs will have verification responsibilities related to the regulatory requirements of 9 CFR 430.4(b).

PART II --- CSI VERIFICATION RESPONSIBILITIES

CHAPTER I CSI Responsibilities for Verifying Compliance with 9 CFR part 430

Upon receipt of this directive, IICs are to hold an awareness meeting with the establishment management and ask them whether they produce an RTE product that is exposed to the environment after the initial lethality step. The establishment is not required to comply with 9 CFR Part 430 if the RTE products produced in the establishment are not exposed to the environment after the lethality step.

If the establishment is producing post-lethality exposed products, the CSI should ask establishment management which alternative they have chosen for each post-lethality exposed RTE product produced by the establishment. Also, the CSI is to inform the establishment management that, as set out in 9 CFR 430.4(b)(7), verification results that demonstrate the effectiveness of the measures the establishment employs are to be made available upon request.

CSIs, using the appropriate 03 procedure, are to verify that the establishment is meeting the requirements of the alternative that it has chosen. If the establishment decides to produce different products using different alternatives, the CSI should verify that the establishment meets the requirements for each of the alternatives selected, for each of the post-lethality exposed RTE products.

If an establishment is producing post-lethality exposed products and has failed to attempt to meet the requirements of **any** of the alternatives, the CSI should contact the District Office (DO) for the issuance of a Notice of Intended Enforcement Action (NOIE).

NOTE: Attachments 1-4 provide flowcharts that set out the requirements of 9 CFR part 430.

A. What are the regulatory requirements of 9 CFR 430.4(b)(1), Alternative 1?

Use of 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 L. monocytogenes.

B. How do CSIs verify compliance with the requirements in Alternative 1?

To verify compliance, CSIs are to follow the methodology from FSIS Directive 5000.1, Revision 1 when seeking answers to questions such as:

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?

2. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?

3. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

4. 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?

NOTE: If CSIs have questions regarding the validation data, they should contact the Technical Service Center (TSC) or a CSO through supervisory channels about the adequacy of the establishment's validation data.

C. How do CSIs document noncompliance?

If the answers to any questions in B. above or similar questions are "no", CSIs are to issue a FSIS form 5400-4, Noncompliance Record (NR) under the appropriate 03 ISP code as described in FSIS Directive 5000.1, Revision 1 and reference 9 CFR 430.4(b)(1) and the appropriate section of 417 (for HACCP and prerequisite programs) or 416.14 (for Sanitation SOP). CSIs are to verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR Part 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative.

D. What are the regulatory requirements of 9 CFR 430.4(b)(2), Alternative 2?

Use of either a post-lethality treatment (which may be an 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

Choice 1 - An establishment that produces post-lethality exposed product that selects this alternative and chooses to use a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product:

OR

Choice 2 - An establishment that produces post-lethality exposed product and that selects this alternative and chooses to use an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes*.

E. How do CSIs verify compliance with the requirements in Alternative 2?

When verifying compliance with Alternative 2, CSIs are to seek answers to the questions from paragraph B. Alternative 2 is based on the same requirements as Alternative 1, **except** that the establishment can choose to just have a post-lethality treatment that meets the requirements of B. 1-3 above (Choice 1), **or** to just use an antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* throughout the shelf life of the product that meets the requirements of B. 4 above (Choice 2). **Also**, if the establishment chooses Choice 2, the CSI should seek answers to the following:

Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:

1. 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?

2. 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?

3. state the frequency with which testing will be done?

4. identify the size and location of the sites that will be sampled?

5. include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?

F. How do CSIs document noncompliance?

If the answers to any of the questions or similar questions are "no", CSIs are to issue a FSIS form 5400-4, Noncompliance Record, NR under the appropriate ISP code as described in FSIS Directive 5000.1, Revision 1 and reference 9 CFR 430.4(b)(2) and, depending where the use of the antimicrobial agent or process is addressed, either the appropriate section of 9 CFR 417 (for HACCP or prerequisite programs) or the appropriate section of 416 (Sanitation SOP). CSIs are to verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR part 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative.

***G. What are the regulatory requirements of 9 CFR 430.4(b)(3),* Alternative 3?**

Use of sanitation measures only

H. How do CSIs verify compliance with the requirements in Alternative 3?

To determine compliance, CSIs are to seek answers to questions such as:

Does the establishment that produces post-lethality exposed product and that selects this alternative have on-going verification testing procedures that are designed to:

1. have sanitation measures incorporated in its HACCP plan, Sanitation SOP, or other prerequisite program?

2. 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?

3. identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of food contact surfaces *for L. monocytogenes* or an indicator organism?

4. state the frequency with which the testing will be done?

5. identify the size and location of the sites that will be sampled?

6. include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes,* or of an indicator organism, is maintained?

Also, does an establishment producing a deli product or a hotdog product:

1. verify that its corrective actions are effective with respect to sanitation after an initial positive in the post-lethality processing environment are effective by follow-up testing that includes a targeted test of the specific site on the food contact surface area as necessary to ensure effectiveness of the corrective actions?

2. hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result, during this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes,* or an indicator organism?

3. sample and test the lots for *L. monocytogenes* 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 *L. monocytogenes,*

in order to be able to release into commerce the lots of product that may have been contaminated with *L. monocytogenes*?

4. document the results of the testing?

5. rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism?

I. How do CSIs document noncompliance?

If the answers to any the questions or similar questions are “no”, CSIs are to issue a FSIS form 5400-4, Noncompliance Record, NR under the appropriate ISP code as described in FSIS Directive 5000.1, Revision 1 and reference 9 CFR 430.4(b)(3) and, depending where the use of the antimicrobial agent or process is addressed, either the appropriate section of 9 CFR 417 (for HACCP or prerequisite programs) or the appropriate section of 416 (Sanitation SOP). CSIs are to verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR Part 430. Such actions may include a reassessment of the HACCP plan to determine whether the decisions made in the hazard analysis regarding the use of the prerequisite program remain valid.

CHAPTER 2 CSIs Responsibilities in Verifying 9 CFR of 430.4(e)

A. What are the regulatory requirements of 9 CFR 430.4(e)?

9 CFR 430.4(e) states: *“An establishment that controls L. monocytogenes by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.”*

B. How do CSIs verify compliance with this regulatory requirement?

The CSI should verify that the establishment has documented that the labeling claim is accurate, that the establishment has data to support the claim, and that the establishment has a sketch label approval on file.

If the CSI has concerns about the validation data supporting the claim, he or she should contact the TSC or a CSO through supervisory channels for technical information. If the establishment does not have data to support the claim, the noncompliance would be documented on an NR using the appropriate HACCP procedure code and reference 430.4(e) and 417.5.

CHAPTER 3 CSIs Responsibilities For Collecting Samples of RTE Product

A. How do CSIs collect samples of RTE Products?

NOTE: The following instructions will apply until FSIS has Alternative and production volume information available to develop the new risk-based RTE sampling program. At that time this directive will be revised and any additional issuance(s) provided.

1. When the Office of Public Health and Science (OPHS) schedules a RTE sample to be taken at an establishment, the CSI receives FSIS Form 10,210-3, "Requested Sample Programs." Once the form is received, the CSI **is to always** collect a RTE product sample.

2. If a specific product is not pre-selected for sampling in Block 18 of the sample request form, the CSI should sample products based on the following priority:

a. Post-Lethality Exposed RTE Products under Alternative 3:

1. Deli meats
2. Hotdogs
3. Deli salads, pate, meat spreads
4. other product

b. If no post-lethality exposed RTE products are produced using Alternative 3 criteria, then sample post-lethality exposed RTE products using Alternative 2 criteria in the following order:

1. Sample product produced using only a growth inhibitor
2. Sample product produced using post-lethality treatment

c. If no post-lethality exposed RTE products are produced using Alternative 3 or 2 criteria, then sample post-lethality exposed RTE products using Alternative 1 criteria.

d. If no post-lethality exposed RTE products are produced, then sample any RTE product that is not produced using an antimicriobial agent or process and likely will be used as a deli-type item, such as a cook-in-bag roast beef.

e. If none of the above is available, select any other RTE product.

Again, most importantly, CSIs are to collect a RTE sample.

3. CSIs are to verify that all product represented by the sample (i.e., the sampled lot) is held by the establishment, should it elect to do so.

4. If possible, **only** collect and mail the samples from the establishment's current day's production that has passed the establishment's pre-shipment record review (see 9 CFR 417.5(c)). If not possible, such as in establishments where production is held off-site before completion of the pre-shipment record review, or the pre-shipment record review is performed at a later date, but there are no additional lethality or other pathogen control steps, collect samples of the current day's production, refrigerate or freeze them, keep them in a secure location, and postpone mailing the samples until the pre-shipment record review is complete, and the product is eligible for shipment. After the establishment completes the pre-shipment record review, CSIs should prepare the samples to be sent to the laboratory on the next available Federal Express pickup day.

5. Complete all requested information in Part II of the FSIS form 10,210-3. The FSIS laboratories will discard any samples with incomplete forms. Record an unscheduled 05B02 on the procedure schedule.

6. CSIs will be provided product sample status information and results through the LEARN System (see FSIS Directive 10,200.1). CSIs should provide this information to establishment management even if the establishment receives e-mail notifications from OPHS.

7. When necessary, program personnel, other than CSIs, collect samples from food contact surfaces.

CHAPTER 4 CSI Responsibilities Regarding Enforcement

FSIS makes the following determinations regarding adulteration based on the circumstances:

A. Pathogen in a product sample.

1. If any RTE product sample collected by FSIS or by the establishment (after pre-shipment review) tests positive for a pathogen of public health concern, product in the sampled lot is adulterated. CSIs are to issue an NR using the appropriate 03 ISP code and FSIS will request a recall if any product in the sampled lot has been shipped.

NOTE: If the positive result is from an establishment test and the establishment held the affected product, CSIs are not to issue an NR unless the establishment fails to comply with 2 - 3 below.

2. CSIs are to verify that establishments implement corrective actions in accordance with 9 CFR 417.3(a) (under HACCP), 9 CFR 416.15 (under

Sanitation SOPs), or 9 CFR 417.4(a)(3) (under prerequisite programs).

3. CSIs are to verify the establishment disposition of the sampled product lot, by verifying that the establishment has documentation to support that potential contamination would be limited to individual production lines and for individual products and by verifying the establishment has destroyed the sampled lot or whether it has reworked the sampled lot with a process that is destructive of *L. monocytogenes*.

B. Pathogen on a food contact surface sample.

1. If a post-lethality exposed RTE food contact surface sample collected by FSIS or by the establishment (after pre-shipment review) tests positive for a pathogen of public health concern, product passing over the surface is adulterated. CSIs are to issue an NR using the appropriate 03 ISP code and FSIS will request a recall if any product in the sampled lot has been shipped.

NOTE: If the positive result is from an establishment test and the establishment held the affected product, CSIs are not to issue an NR unless the establishment fails to comply with 2 - 3 below.

2. CSIs are to verify that establishments implement corrective actions in accordance with 9 CFR 417.3(a) (under HACCP), 9 CFR 416.15 (under Sanitation SOPs), or 9 CFR 417.4(a)(3) (under prerequisite programs).

3. CSIs are to verify the establishment disposition of the sampled product lot, by verifying that the establishment has documentation to support that potential contamination would be limited to individual production lines and for individual products and by verifying the establishment has destroyed the sampled lot or whether it has reworked the sampled lot with a process that is destructive of *L. monocytogenes*.

4. The DO may coordinate scheduling intensified verification sampling through OPHS to verify the establishment's corrective and preventive measures. This sampling should not be initiated until the corrective and preventive measures have been put in place.

NOTE: An establishment may or may not conduct environmental sampling, other than on food contact surfaces, under its HACCP plan, Sanitation SOPs, or a prerequisite program. If the establishment is conducting such sampling, and positive results are received, CSIs are to verify that the establishment takes the appropriate action as outlined in the program under which the sampling is conducted. If the establishment is conducting such sampling, but is not addressing the sampling under HACCP, Sanitation SOPs, or a prerequisite program and CSIs find that such sampling is resulting is persistent positive results, CSIs are to notify the DO. Also, FSIS personnel, other than CSIs, may conduct environmental sampling when necessary and as directed by the DO.

PART III -- CSO Assessment of Compliance with 9 CFR part 430

The CSO should understand the public health risks associated with post-lethality exposed RTE products and processes. Some products and processes pose greater potential risks for *L. monocytogenes* causing human illness and disease in the form of listeriosis than others do. For example, product in alternative 3 likely will present greater risk than product in alternative 2, and product in alternative 2 likely will present greater risk than product in alternative 1. Also, deli product and hotdog product likely will present greater risk than most other product within each alternative. However, other than deli product and hotdog product, deli meat salads and pate/meat spreads likely will present greater risk than other RTE products. Consequently, when considering how to focus verification activity within the establishment when the establishment makes a variety of post-lethality exposed RTE products, more attention should be allotted to the products and processes that present the greatest potential for causing illness and disease.

When CSOs go into an establishment that is producing post-lethality exposed products, they are to conduct a complete comprehensive assessment of the food safety systems in operation. Specifically, CSOs will need to evaluate some design issues relevant only to post-lethality exposed RTE products.

To assess that the establishments have properly addressed the use of a post-lethality step (Alternative 1 or the first choice in Alternative 2), CSOs should review the establishment's HACCP plan and HACCP supporting documentation to verify that post-lethality has been adequately validated so that it prevents, eliminates, or reduces the pathogens of concern on the product to an undetectable level.

If the establishment has based its validation on challenge studies or research articles from scientific publications, the CSOs should assess whether conditions in the establishment, such as ingredients, concentration of antimicrobial agent, pH, moisture, are identical to those found in the challenge studies or research articles from scientific publications. If the conditions are not identical, does the establishment have documentation on file to support that the controls in place are adequate to prevent, eliminate, or reduce to undetectable levels pathogens on the product?

With regard to the use an antimicrobial agent or a process used to suppress or limit the growth of *L. monocytogenes* throughout the shelf life of the product (Alternative 1 or Alternative 2, choice 2), the CSO should assess the documentation in whichever program the use of the antimicrobial agent or process is incorporated (i.e., HACCP, Sanitation SOPs, or prerequisite programs), to determine whether it demonstrates the production of safe product.

With regard to the testing that the establishment is to do if it chooses Alternative 2, choice 2, the CSO should assess the adequacy of how the establishment:

1. tests 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,

2. identifies the conditions under which the establishment will implement hold-and-test procedures following a positive test of food contact surfaces *for L. monocytogenes* or of an indicator organism,

3. establishes and supports the frequency with which the testing will be done,

4. establishes and supports the size and location of the sites that will be sampled,

5. explains and supports why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of an indicator organism is maintained,

6. chooses the sites that are most likely to be locations to find *L. monocytogenes* or an indicator organism,

7. supports the design of the testing to detect *L. monocytogenes* or an indicator organism.

With regard to the testing an establishment has to do if it chooses Alternative 3, CSOs are to assess all the factors for the testing in Alternative 2 as well as in establishments that produce a deli product or a hotdog product, the adequacy of how the establishment:

1. verifies that corrective actions that it took with respect to sanitation after an initial positive test for *L. monocytogenes,* or an indicator organism on a food contact surface in the post-lethality processing environment were effective by follow-up testing that included a targeted test of the specific site on the food contact surface area as was necessary to ensure effectiveness of the corrective actions,

2. holds lots of product that may have become contaminated by contact with the food contact surface during follow-up testing after the establishment obtains a second positive test,

3. samples and tests the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that provided a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes* before releasing into commerce the lots of product that may have been contaminated with *L. monocytogenes,*

4. documents the results of the testing, and

5. reworks held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

When the CSO completes the comprehensive assessment of all of the food safety systems in operation in the establishment, he/she should complete FSIS form 5000-8, Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety System. The findings listed in this report should support the recommendations made by the CSO that the establishment is in compliance, or that further enforcement action is necessary.

The *Compliance Guidelines to Control Listeria Monocytogenes in Ready-to-Eat Poultry Products* will be provided to all CSIs and CSOs on a disk. These guidelines can be used as references for a better understanding of what industry might be doing to control *L. monocytogenes* in post-lethality exposed RTE products.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy and Program Development