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▲ FSIS' Listeria Compliance Guideline Finalized

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FSIS' Listeria Compliance Guideline Finalized

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USDA's Food Safety and Inspection Service (FSIS) finalized its compliance guideline *Controlling Listeria monocytogenes in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products* in January 2014.

FSIS Listeria Guideline January 2014

Attachment 1.1: Control Requirements for *Listeria monocytogenes*

Requirements	Increasing Risk Levels and Frequency of FBS Verification Testing, or			Sanitation and Testing Program	EAT or non-dog product
	ALTERNATIVE 1 Pre-lethality Treatment (MD Antimicrobial Agent or Process)	ALTERNATIVE 2 Post-lethality Treatment (D) Antimicrobial Agent or Process	ALTERNATIVE 3 Choice 1: Pre-lethality Treatment Choice 2: Antimicrobial Agent or Process		
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 5-log reduction in Lm prior to distribution of the product into commerce. Document effectiveness of antimicrobial agent or process. Must be included as part of the establishment's HACCP, Sanitation SOP, or Prerequisite Program and should demonstrate no more than 2-log growth of Lm over the estimated shelf life.	X	X	X		
Sanitation Program Requirements				X	X
Testing food contact surfaces (FCS) in the post-lethality processing environment for Lm 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 Lm or an indicator organism			X	X	X
Identify conditions for Hold-and-Test, when FCS (+) for Lm 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 Lm or an indicator organism. Includes testing of targeted FCS on most likely source and additional testing of the surrounding area.					X
If follow-up testing points to 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 Lm 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 418.	X	X	X	X	X

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The final guideline provides information to processors on how to design or redesign their *Listeria* control programs. The final guideline includes changes that the agency made in response to comments that FSIS received on the draft guidelines that were published in September 2012.

If you're using this document to support the design of your program, be advised there are changes to the recommendations that may cause you to update your previously written food safety programs. We've highlighted in this article what is new in the 2014 guideline.

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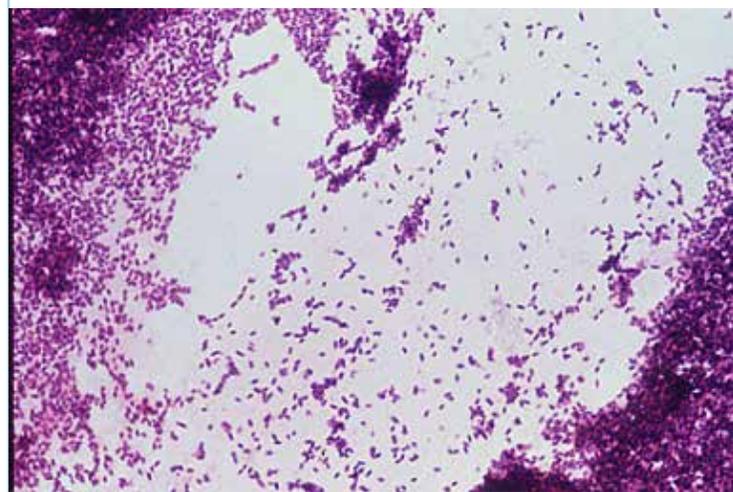
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General Updates and Information

The information in the 2014 guideline has been formatted to be more user friendly and should help you find specific information on the control of *Listeria monocytogenes* (Lm). A glossary has been added at the end of each chapter to provide a better understanding of terminology found in the text. Also, notice that terms in the glossary have been bolded the first time they appear to provide special emphasis.

Separate text boxes have been included to highlight, and give more information about, points made in each chapter. Appendixes have also been added at the end of each section to provide more detailed information regarding



concepts introduced in the text. Lastly, the guideline includes questions and answers to assist you in finding specific information.

Changes from the September 2012 draft guidance include adding the information from the *Federal Register* Notice “Not Applying the Mark of Inspection Pending Certain Test Results” issued December 10, 2012, and subsequent FSIS notices that explain the requirement to hold products -- or not apply the mark of inspection on products tested by FSIS for adulterants -- until acceptable test results are received. Ready-to-eat (RTE) products are covered by this requirement.

Throughout, the new *Listeria* guideline makes clear that the requirements on sanitation, found in Title 9 Code of Federal Regulations (CFR) Part 416, and Hazard Analysis and Critical Control Point (HACCP), found in 9 CFR 417 as well as other applicable regulations, must be met in addition to the requirements of the *Listeria* rule in 9 CFR 430.

To meet the requirements of the *Listeria* rule, an establishment must maintain sanitary conditions and effectively implement its HACCP plan to control the hazards in the system. The guideline provides updated information on the use of a multiple-hurdle approach to control of *Listeria*. For instance, RTE products with added salt, nitrites, and other additives achieve a water activity, pH or moisture-protein ratio that will reduce the level of Lm and other pathogens during processing. These ingredients continue to inhibit the growth of the pathogens during the refrigerated shelf-life. As a result, the added salts and nitrites work together to create multiple hurdles to pathogen growth.

Chapter One - *Listeria* Rule Requirements

Chapter One contains step-by-step instructions to determine whether your product is covered by the *Listeria* rule. The guideline assists in determining whether your products are ready-to-eat and post-lethality exposed, which means products are exposed to the processing environment after lethality treatment (e.g., cooking) and prior to packaging.

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FSIS strongly recommends that you review the information in the compliance guide to ensure that you're in compliance with the regulation.

Appendix 1.2 will help you to determine if your products are classified as RTE or not ready-to-eat (NRTE). For example, there are cases where products receive a full lethality treatment, but are considered NRTE and need to be treated as such. The compliance guide will help you to determine how to characterize your product.

Furthermore, Chapter One also contains clarification on labeling. In particular, Appendix 1.2 contains guidance for product label claims and labeling considerations depending on whether your product is RTE or NRTE.

Chapter Two - FSIS Control Measures for *Listeria*

Chapter Two contains new information regarding the control of reworked product, which is more likely to become contaminated because of increased handling.

FSIS recommends that you take into account your production of returned and reworked product when developing your *Listeria* control programs and determine what products to hold when FSIS samples products or food-contact surfaces for pathogens.

Chapter Two also includes more in-depth information regarding the validation of post-lethality treatments and of antimicrobial agents/processes, which can be found in Appendix 2.1.

The guideline contains descriptions of intensified sampling and intensified sanitation procedures that you may wish to employ in response to positive results for *Listeria*. The reference section has been updated to provide more information about new technologies to control *Listeria*.

Of particular note, Appendix 2.3 includes new information on developing establishment employee training programs for implementing the *Listeria* rule.

Chapter Three - *Listeria* Control: Testing for *Lm* or an Indicator Organism

This chapter provides new and updated information on developing a *Listeria* control program to test for *Listeria monocytogenes* or an indicator organism on food-contact surfaces.

Chapter Three provides updated information on routine testing for *Listeria* species under the three control alternatives, including information on the pros and cons to compositing food-contact surface samples at the laboratory. Although there have been no changes to sampling frequency recommendations for *Listeria* species, this revised chapter provides guidance on meeting the recommended sampling frequencies and the number of samples to collect.



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The revised guideline recommends collecting three to five samples per processing line. By contrast, the previous version of the guideline did not provide any recommendation for sample collection.

Chapter Three provides further clarification regarding FSIS expectations for sample collection and laboratory analysis. Information has also been provided on product and non-food-contact testing (although not required by the *Listeria* rule) to provide you with more information about your products' safety and the sanitary conditions in your food-processing environment.

Chapter Four - Enhanced Sampling Program

Chapter Four updates information on developing enhanced sampling programs for *Listeria* in response to positive results from routine sampling. This chapter contains a new table (Table 4.1) that clarifies timeframes for follow-up and intensified sampling, as well as hold and test of product. The guideline defines intensified sampling to provide more information on how to find and address the source of positive results, including new information on identifying and addressing *Listeria* trends.

In addition, Chapter Four includes updated findings from Food Safety Assessments performed by FSIS to provide "lessons learned" and to increase awareness of common problems associated with *Listeria*.

This chapter also includes the FSIS response to comments received regarding the 2012 draft guideline. Both sections could aid you in the design of a functional *Listeria* control program, specifically by bringing common mistakes to your attention.

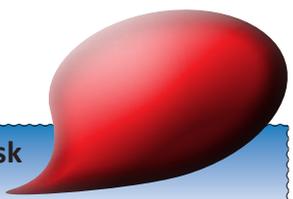
The Lm Summary

In short, this compliance guideline provides information on best practices and on the best science to address *Listeria monocytogenes* in the post-lethality exposed, ready-to-eat environment. The document presents recommendations made by FSIS, not regulatory requirements that must be met.

However, if you follow the recommendations in the guideline, you will not need to provide further support for the procedures you use to address this pathogen.

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If you choose to use the guideline as support for your processes, then you'll need to follow the recommendations in the guideline (e.g., sampling frequency and number of samples to collect).

Remember, it's your responsibility as an operator of a federally inspected facility to support the procedures you conduct to control food safety hazards. If you use this guideline as support, be sure to review the updated document.

If you have any questions, contact FSIS' Small Plant Help Desk toll free at (877) 374-7435 between 8:00 am to 6:00 p.m., ET, or e-mail infosource@fsis.usda.gov.

You can submit your questions by writing to Small Plant News, USDA/FSIS, Patriots Plaza III, Rm. 9-267A, Mailstop 3778, 1400 Independence Ave., SW, Washington, DC 20250. Or e-mail your question to: SmallPlantNews@fsis.usda.gov.