FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products

September 2012

Purpose

This compliance guideline provides specific recommendations that establishments producing post-lethality exposed ready-to-eat (RTE) meat and poultry product may follow to meet the requirements of 9 CFR part 430, the *Listeria* Rule. It also provides information on sanitation, testing for *Listeria monocytogenes* (*Lm*), and prevention of cross contamination of post-lethality exposed, RTE meat and poultry products. This document replaces previous versions of the FSIS *Listeria* Guideline and Q&As.

This document provides **guidance** to assist establishments in meeting FSIS regulations. Guidance represents **best practice** recommendations by FSIS, based on the best scientific and practical considerations, and does not represent **requirements** that must be met.

Comments on the Guideline

FSIS is seeking comments on this guidance document as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products. Comments received will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Summary of Changes

This revised version of the *Listeria* Guideline has been updated as follows.

Chapter 1: This chapter has been revised to provide clear, easy to follow information regarding the **requirements of the *Listeria* Rule**. Although this information has not changed significantly since the May 2006 version of the Compliance Guideline, FSIS recommends that establishments review this information to ensure that they are in compliance with the regulation. The information may be useful to new establishments that are starting production. In the revised version:

- Step-by-step instructions have been provided, to assist establishments in determining whether their product is covered by the *Listeria* Rule.

- The requirements and recommendations for each control alternative are described.

- In addition, a glossary section has been provided with each chapter to further clarify the meaning of the terms used in the guidance and the *Listeria* Rule.

- Resource 1 (Attachment 1.2) has been updated to provide information about products that receive a full lethality that are not considered RTE.

Chapter 2: This chapter provides updated **technical information about establishing control alternatives** under the *Listeria* Rule. In the revised version:

- More in-depth information has been provided in Appendix 2.1 regarding validation of post-lethality treatments and antimicrobial agents.

- In addition, sanitation guidelines have been revised to include a description of intensified sanitation conducted in response to positive results.

- The reference section has been updated to provide more information about new technologies to control *Listeria*.

- New information has been provided in Appendix 2.3 on developing establishment employee training programs for implementing the *Listeria* Rule.

Chapter 3: This chapter provides new and updated information on **developing a *Listeria* Control Program** to test for *Lm* or an indicator organism on food contact surfaces (FCS). In the revised version:

- Updated information on routine testing for *Listeria* under the three control alternatives is provided. Although there have been no changes to sampling frequency recommendations for *Listeria* spp., this revised chapter provides further guidance on meeting the recommended sampling frequencies.

- Also, further clarification has been provided regarding FSIS expectations for sample collection and laboratory analysis of the samples.

- Finally, information has been provided on product and non-food contact testing (although not required by the *Listeria* Rule) to provide establishments with more information about the safety of their products and sanitary conditions in their food-processing environments.

Chapter 4: This chapter provides new and updated information on developing **enhanced sampling programs for *Listeria*** in response to positive results from routine sampling. In the revised version:

- A new table is provided (Table 4.1), clarifying timeframes for follow-up and intensified sampling, as well as hold and test of product.

- Intensified sampling is defined to provide establishments with more information on how to find and address the source of positive results.

- In addition, new information is provided on identifying and addressing *Listeria* trends.

- Findings from Food Safety Assessments (FSA) performed by FSIS in response to *Lm* positives have also been provided to increase awareness of common problems and lessons learned from FSA reviews.

How to Use this Document

The updated information in this revision of the Compliance Guideline should help establishments find specific information on the control of *Lm*, as needed.

- A glossary has been added at the end of each chapter to provide a better understanding of terminology found in the text. Terms in the glossary have been **bolded** the first time they appear in the text.

- Boxes have been provided giving more information about points made in the text.

- Appendices have also been added to the end of each section to provide more detailed information regarding concepts introduced in the text.

- Q&A's have been incorporated into the document to assist establishments in finding specific information.

If the desired information cannot be found within the Compliance Guide, FSIS recommends that users search *Listeria* Q&As in the askFSIS database or submit questions via askFSIS at http://askfsis.custhelp.com. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

Table of Contents

Introduction	Page
Chapter 1: Requirements of the *Listeria* Rule	
1.1 Background	1-1
1.2 How Do I Determine if My Product is Covered by the *Listeria* Rule?	1-3
1.3 The *Listeria* Rule Alternatives	1-3
1.4 Requirements for Establishments Under all Three Alternatives	1-8
1.5 Labeling	1-8
1.6 Glossary	1-8
1.7 References	1-10
Attachments	
1.1 Control Requirements for *Lm*	1-11
1.2 Chart of RTE vs. NRTE Products: Resource 1	1-12
Appendices	
1.1 Product Types	1-14
1.2 Labeling	1-16
Chapter 2: FSIS Control Measures for *Listeria*	
2.1 Post Lethality Treatments (PLT)	2-1
2.2 Antimicrobial Agents (AMA) and Antimicrobial Processes (AMP)	2-4
2.3 Sanitation	2-8
2.4 Expected Levels of Control	2-9
2.5 Training	2-10
2.6 New Technology and New Ingredient Review	2-10
2.7 Glossary	2-11
2.8 References	2-12
Attachments	
2.1 Post-lethality Treatments	2-16
2.2 Antimicrobial Agents or Processes	2-18
Appendices	
2.1 Validation	2-25
2.2 Sanitation	2-38
2.3 Training	2-51
Chapter 3: *Listeria* Control Program: Testing for *Lm* or an Indicator Organism	
3.1 Sampling for *Lm* or an Indicator Organism	3-1
3.2 Design of the *Listeria* Control Program	3-1
3.3 Routine Sampling Program	3-4
3.4 Frequency of Sampling and Explanation of this Frequency	3-6
3.5 Sample Collection and Laboratory Testing Methods	3-9
3.6 Other Routine Sampling	3-12
3.7 Glossary	3-14
3.8 References	3-15
Attachments	
3.1 Possible Food Contact and Non-Food Contact Sites	3-16

Appendices
3.1 FSIS Sampling Programs 3-17
3.2 FSIS Sampling Procedure 3-21
3.3 Sample Collection and Laboratory Testing Methods 3-24

Chapter 4: Enhanced Sampling Program

4.1 Follow-up Sampling 4-1
4.2 Intensified Sampling 4-3
4.3 Hold and Test 4-4
4.4 Reprocessing *Lm* Contaminated Product 4-7
4.5 Determining *Listeria* Trends 4-8
4.6 Glossary 4-9
4.7 References 4-10
Appendices
4.1 Sampling Scenarios by Alternative 4-11
4.2 Hold and Test Scenario 4-14
4.3 *Listeria* Trends Examples 4-20
4.4 Findings from Food Safety Assessments (FSAs) 4-25

Introduction

Listeria monocytogenes (Lm) is a pathogen that can contaminate ready-to-eat (RTE) meat and poultry products and causes the disease listeriosis. Listeriosis is estimated to cause approximately 1,600 foodborne illnesses, 1,500 hospitalizations, and 260 deaths in the U.S. annually (Scallan et al., 2011). In most healthy individuals, **listeriosis** causes flu-like symptoms; however, in highly susceptible populations (e.g., the elderly, pregnant women, and immunocompromised individuals), listeriosis can lead to spontaneous abortion, septicemia, meningitis, and even death. Several outbreaks of listeriosis have been linked to the consumption of ready-to-eat (RTE) meat and poultry products contaminated with *Lm.*

Lm is widely distributed in the environment; it is found in the air, soil, water, dust, and plant material, including silage. As such, *Lm* may enter the environment of processing plants and subsequently contaminate meat or poultry products, as well as other ingredients. *Lm* has ample opportunity to occupy and thrive in various niches in a production facility, such as on floors, in drains, or in standing water. Without proper sanitation and employee hygiene practices, *Lm* can easily cross-contaminate processing equipment, gloves or aprons of employees, and product.

Lm has unique growth characteristics that can make it a formidable pathogen to control in the processing environment. Specifically, *Lm* has the ability to grow in cool damp environments where other pathogens may not and is capable of surviving freezing temperatures. *Listeria* species (*Listeria* spp.) also exhibit heat and salt tolerance. *Lm* is known to form biofilms on FCSs and non-food contact environmental surfaces and, as a result, persists on these surfaces despite aggressive cleaning and sanitizing. Once *Lm* has established a niche, it may persist in the environment for long periods of time until the niche is identified and eliminated.

RTE products are of particular concern for contamination with *Lm* because they may support the growth of the pathogen during refrigerated storage. In addition, since RTE products are often consumed without further cooking, there is a greater possibility of the occurrence of foodborne illness from these products if they become contaminated. Lethality treatments such as cooking meat and poultry products generally eliminate *Lm*; however, RTE products can be re-contaminated by exposure to the environment after the lethality treatment during peeling, slicing, repackaging, and other processing steps. By controlling sanitation in the post-lethality processing environment or implementing interventions in their products, establishments can ensure that their RTE products do not become contaminated with *Lm.*

In 2003, FSIS issued 9 CFR part 430, Control of *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Products (*Listeria* Rule). According to the *Listeria* Rule, RTE products are considered adulterated if they contain *Lm* or come in direct contact with a FCS that is contaminated with *Lm*. Although FSIS testing has shown that levels of *Lm* in RTE meat and poultry products have decreased over the years, the pathogen continues to contaminate RTE products at low levels. Furthermore, illnesses from *Lm*-contaminated RTE products continue to occur, and the infectious dose is thought to be low for highly-susceptible populations. **Therefore FSIS has maintained a "zero tolerance" for the pathogen in RTE products and continues to strengthen programs and recommendations to reduce or eliminate *Lm* from RTE products.**

This guideline provides information that establishments may use to meet the requirements of the *Listeria* Rule. It also provides "safe harbors" that establishments can implement to help ensure that the requirements are met.

Chapter 1

FSIS *Listeria* Guideline: Requirements of the *Listeria* Rule

1.1 Background
1.2 How Do I Determine if My Product is Covered by the *Listeria* Rule?
1.3 The *Listeria* Rule Alternatives
Table 1.1: *Listeria* Control Alternatives
1.4 Requirements for Establishments Under all Three Alternatives
1.5 Labeling
1.6 Glossary
1.7 References
Attachments
1.1 Control Requirements for *Lm*
1.2 Chart of RTE vs. NRTE Products: Resource 1
Appendices
1.1 Product Types
1.2 Labeling

This chapter provides information establishments can use to meet the regulatory requirements of 9 CFR part 430 (the *Listeria* Rule).

1.1 Background

After several large outbreaks of **listeriosis** starting in the 1980s, FSIS and FDA worked together to implement strategies to decrease foodborne illness from ***Listeria monocytogenes* (*Lm*)**. In 2001, FDA and FSIS published the draft "Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods." "The final 2003 version can be found at: (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm). This risk assessment indicated that deli meats and hotdogs posed the greatest per serving risk of illness/death from *Lm*. In February 2002, FSIS initiated the "FSIS Risk Assessment *for Listeria monocytogenes* in Deli Meats*."* The final version can be found at (http://www.fsis.usda.gov/PDF/Lm_Deli_Risk_Assess_Final_2003.pdf. This FSIS risk assessment indicated that the **use of a combination of intervention methods** to control *Lm* in deli meats exposed to the environment after the lethality treatment **has the greatest impact on lowering the risk of illness or death from *Lm*.** The Agency used these risk assessments as resources in developing the regulations to control *Lm* in RTE meat and poultry products.

In 2003, FSIS issued 9 CFR part 430, Control of *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Products (the *Listeria* Rule) http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F.htm. The *Listeria* Rule codified the regulations establishments are required to follow to produce safe RTE products. According to the *Listeria* Rule, *Lm* is a hazard that establishments producing **post-lethality exposed** RTE products must control. Establishments can control *Lm* in the product through their Hazard Analysis and Critical Control Point (HACCP) plans, or prevent *Lm* in the **post-lethality processing environment** through a Sanitation Standard Operating Procedure (SOP), or