BACKGROUND
Final Rule on *Listeria monocytogenes* in RTE Meat & Poultry Products

Quick Summary

On October 6, 2003 a USDA final rule addressing the control of *Listeria monocytogenes* (LM) in ready-to-eat (RTE) products went into effect. This rule took effect in Wisconsin’s state inspected plants on April 1, 2004.

This rule applies only to products which are RTE, and are exposed to the plant’s environment between cooking and packaging. Products which have been determined to be of highest risk are hot dogs and deli meats.

Most plants producing RTE products which are exposed to the environment after cooking will be required to do some micro testing of food contact surfaces associated with RTE product handling and packaging. The amount of testing will be affected by the type of RTE product, and how it is formulated, processed and marketed. For most smaller-scale plants, it is likely that each month at least one food contact surface will need to be tested for LM or *Listeria* species.

Read the information below for more details.

**Background**

On June 6, 2003, the United States Department of Agriculture (USDA) published an interim final rule addressing the control of the disease-causing bacterium *Listeria monocytogenes* (“LM” for short) on ready-to-eat (RTE) meat and poultry products. This rule went into effect October 6, 2003 and will have a major effect on processors of these products. Wisconsin’s state inspected plants must comply with this rule as of April 1, 2004.

**Why is there a new rule?**

Beginning in 1998, multi-state outbreaks of the infection caused by LM were linked to RTE meat products. Several large recalls of RTE meat and poultry products have occurred since then. In 1999, USDA required processors of RTE products to do a HACCP plan reassessment and determine if the hazard of LM was adequately addressed. In the last few days of the Clinton administration, rules were proposed that would require testing of food contact surfaces for LM. These rules were never finalized. Later, a joint Food & Drug Administration (FDA)/USDA Risk Assessment identified certain RTE meat products as moderate to high-risk. The Risk Assessment also stated that combinations of interventions would be more effective than any single intervention at preventing contamination of foods with LM.

These findings led USDA to conclude that LM is a hazard that is “…reasonably likely to occur in all RTE meat and poultry products that are exposed to the environment post-
lethality." The intent of the rule is to encourage processors to take several steps to control LM in RTE products.

**Why is there so much concern about LM?**
Basically, the concerns about LM are 1) it’s very dangerous to society’s most susceptible individuals, 2) it can readily colonize small niches in a processing plant environment, and 3) it can grow at typical refrigerator temperatures.

LM has one of the highest mortality rates (20%) of the food-borne pathogenic bacteria. It can kill an immunocompromised person; in particular, it can cause the spontaneous abortion of a human fetus.

LM is widely found in the environment and can gain entrance into a processing plant by way of raw materials, air, and people. Once in a plant, LM can readily grow in microenvironments throughout the plant. If cooked products touch these microenvironments either directly (slicer blade) or indirectly (condensate, contaminated air, hands), the products can then contain LM. It can be very difficult, expensive, and time-consuming to eliminate LM from harborages in a food processing plant.

Finally, LM can grow at refrigeration temperatures. The greater the number of LM cells on a product when it is eaten, the more likely the product is to cause illness. Increasing shelf-life of RTE products means that LM, if it is present, potentially has more time to grow to dangerous levels.

You may hear the term “Listeria species” and wonder that means. LM is just one species in the genus *Listeria*. The other species do not cause food-borne illness but may inhabit some of the same places as LM.

**What is the purpose of the rule?**
The rule is intended to encourage processors of RTE products to take one or more specific steps to prevent LM contamination of their products. These steps range from focused sanitation steps to adding formulation or processing steps designed to kill or inhibit LM. In most situations, the processor will be required to perform LM testing of food contact surfaces in the environment in which RTE products are handled after cooking. The amount of testing will be related to the types of RTE products made, product ingredients, and how the products are processed and handled.

**What products are covered by the rule?**
The rule only applies to products that are Ready-to-Eat and exposed to the environment after lethality (after cooking). So the first two questions to ask about a meat and poultry product are “Is this product Ready-to-Eat? and “Is this product exposed to environment post-lethality?” Examples of products that could be covered are jerky, beef sticks, frankfurters, bologna, summer sausage ham, and roast beef. The rule also has extra requirements for deli meats (products that are typically sliced and then consumed as part of a sandwich) and hotdogs. These products are most often contaminated with LM.
What are “deli meats”?
A common description would be cold cuts or meats normally sold at a deli counter including: ham, turkey, roast beef, corned beef, bologna, salamis, summer sausages, etc. These products may be pre-sliced, or in log or loaf form that are sliced at the deli. They are RTE and normally eaten without further cooking.

What does the rule require?
The rule requires processors of RTE meat and poultry products to adopt one of three strategies to control LM on their products. The strategies involve varying levels of control and microbiological testing. Before you can understand what the rule requires, there are some terms to understand.

Important Definitions in the Interim Rule on *Listeria monocytogenes* in RTE Meat & Poultry Products

Post-lethality exposure is a term used in the rule to describe a product being exposed to the plant environment between the end of cooking (which killed all non-spore pathogens) until the product is sealed in its final package. The cooler, packaging room, equipment such as peelers, trays, tables, packaging machines, and employee hands and clothing can all contaminate products during this post-lethality exposure time. The most important things to control during post-lethality exposure are food contact surfaces (directly touched by product), but indirect sources of contamination, such as air and condensate, have also been shown to be important. RTE products which are sold in the impervious casing, container or packaging in which they were cooked are not post-lethality exposed, and are not subject to this rule (such as cook in the bag roast beef, or liver sausage chubs stuffed into moisture proof casings).

An antimicrobial agent suppresses or limits LM growth on a product throughout the product’s shelf-life. The antimicrobial agent may be part of the product formulation or added to product post-lethality (after cooking). Examples of antimicrobial agents include sodium or potassium lactate and sodium diacetate added to cured products during formulation. In order to be considered effective, an antimicrobial agent must not allow more than 1 log of LM growth. The effectiveness of lactates and sodium diacetate has been validated for many products in laboratory challenge studies. Also, ongoing studies are looking at incorporating antimicrobial agents into packaging materials. In some cases, the inherent characteristics of a product, such as acidity, may suppress LM growth. Studies are ongoing to evaluate acid formed during fermentation as an acceptable antimicrobial agent. Note: an effective antimicrobial agent may also kill LM or reduce its numbers.

An antimicrobial process physically suppresses or limits LM growth on product throughout shelf life. The antimicrobial process may be performed before, during, or after the cooking. In order to be considered acceptable, an antimicrobial process must not allow more than 1 log of LM growth during shelf life. Examples include drying, freezing, or Modified Atmosphere Packaging.
A post-lethality treatment is a step applied to a product after “post-lethality exposure” that reduces numbers of LM or kills expected populations completely. An example would be post-packaging pasteurization by dipping packaged products in hot water. In order for a treatment to be considered an acceptable post-lethality treatment, it must be strong enough to reduce LM populations by 2 logs.

Processors of RTE products must choose one of the following approaches to preventing LM contamination of the final product:

**ALTERNATIVE 1. Use a post-lethality treatment that reduces or eliminates LM AND an antimicrobial agent or process that suppresses or limits LM growth throughout shelf-life.**

In this approach, the processor destroys any LM that might be present (post-lethality treatment) and prevents growth of LM that might have somehow survived the post-lethality treatment. The post-lethality treatment must be included in the HACCP plan and be validated for effectiveness. The post-lethality treatment would almost certainly be a Critical Control Point (CCP). The antimicrobial agent or process used to suppress growth can be in the HACCP plan, SSOP, or other pre-requisite program. It must be documented as effective. Under Alternative 1, plants are not required to have a microbiological testing program.

**ALTERNATIVE 2. Use either a post-lethality treatment that reduces or eliminates LM OR an antimicrobial agent or process that suppresses or limits LM growth throughout shelf-life.**

Under Alternative 2, the processor uses either a treatment to kill LM (post-lethality treatment) OR uses an antimicrobial agent or process to prevent LM growth. Note that one, but not both options are used. Where Alternative 2 differs is in the consequences of using only an antimicrobial agent OR process to suppress LM growth. If this approach is taken, the plant must have a program of testing food contact surfaces in the post-lethality processing environment for LM or indicator organisms (typically *Listeria* species). The testing plan is part of sanitation program (SSOP or a separate SOP) and must specify what surfaces are tested, how often surfaces are tested, and what action the plant will take if a food contact surface tests positive for LM or *Listeria* spp. Flow chart-based guidance is available to help plants develop their testing plan. Processors should be aware that government regulators will do more verification testing of establishments under Alternative 2 than for those under Alternative 1.

**ALTERNATIVE 3. Use only sanitation measures to prevent LM contamination**

In some situations, processors may be unable or unwilling to choose Alternative 1 or Alternative 2. These processors must then take steps to control LM using only sanitation measures. Because this approach provides the least certainty of success, the processor must have a program of testing food contact surfaces in the post-lethality processing environment for LM or indicator organisms. As for Alternative 2, the testing plan is part of the plant’s sanitation program (SSOP or separate SOP). Under the testing programs required for Alternatives 2 and 3, positive test results must lead to
corrective actions, and follow-up testing to verify that the source of contamination has been eliminated. If follow-up testing of food contact surfaces or products detects LM, then the affected product must re-worked to ensure safety or it must be destroyed. Plants using Alternative 3 will get the most frequent verification testing attention from government regulators.

**What other things does the interim final rule require and allow?**
Processors must provide annual production statistics on RTE products to USDA. Post-lethality treatments, antimicrobial agents, antimicrobial processes may be declared on the label provided the claim is validated.

**What does this rule mean for Wisconsin state-inspected processors of RTE products?**
Wisconsin’s state-inspected plants were required to comply with the rule effective April 1, 2004. Plants should determine if they produce RTE products (most plants do), and which alternative would cover their products. While small plants usually produce a wide variety of products which may be covered by any of the three alternatives, the range of products is usually handled in the same post-lethality (post-cook) environment. Therefore, it is likely that most plants will really be operating under Alternative 3 (sanitation procedures only) because at least one of their products handled on the same equipment is under this alternative.

This means that the plant will be required to test key food contact surfaces in the post-lethality environment for *Listeria* species at some frequency (at least monthly) and have a plan on how to deal with any positive results. This testing will be done by and paid for by processors. The plant’s first line of defense remains effective pre-operational operational sanitation in the post-lethality area. Some processors may decide to add antimicrobial agents to their products to inhibit LM growth. Fermented and/or dried products may already have a composition that achieves inhibition of LM growth.

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