

indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must 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.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes*, the establishment must 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*. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the

decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with § 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with § 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) 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.

Done in Washington, DC: June 2, 2003.

**Garry L. McKee,**  
Administrator.

**Note:** The following appendix will not appear in the Code of Federal Regulations.

## Appendix A

### Final Regulatory Impact Analysis

FSIS is amending its regulations to require that official establishments that produce certain ready-to-eat (RTE) meat and poultry products (MPPs) take measures to prevent product adulteration by *L. monocytogenes* (*Lm*). These amended regulations primarily affect establishments that produce RTE MPPs that are exposed to the environment

following lethality treatment and that support the growth of *Lm*.

The final rule takes into account the differences in the risk of *Lm* contamination by type of RTE MPP product and by the manner in which the pathogen is controlled in the production process. It takes into account these differences by identifying four alternative *Lm* control approaches applying to RTE MPPs that are exposed to the plant environment after undergoing a process that is lethal to the pathogen. Each alternative involves a different level of pathogen control and to each there corresponds a preferred level of monitoring and verification, based on science and the nature of the product.

### Need for the Rule

This action is compelled by recent outbreaks of food borne illness related to the consumption of adulterated RTE meat and poultry products, coupled with information on the pathogenicity of the organism and the findings of the risk assessment and risk ranking conducted by FDA and FSIS. *Lm* contamination is often a result of post processing contamination or growth of the organism after it leaves the Federal establishment. FSIS concluded before beginning this rulemaking that many establishments were not effectively implementing HACCP plans and Sanitation SOPs to prevent *L. monocytogenes* from contaminating the RTE product in the post-lethality processing environment.

Given the pathogenicity of *L. monocytogenes*, the opportunity for it to contaminate RTE product in the post-lethality environment, and the significant consequences that this contamination can have, FSIS is amending its regulations. The Agency is adding provisions that require establishments that produce post-lethality exposed RTE product to include in their HACCP plans or in their Sanitation SOPs or other prerequisite programs measures that prevent product adulteration by *L. monocytogenes*.

**Market Failure.** This final rule addresses a market failure. Market failures occur when resources are misallocated or allocated inefficiently. Markets fail, in the current case, because processors may not always be provided with sufficient incentives to allocate the additional resources and efforts needed to provide effective prevention methods for pathogen contamination in their products. These incentives are lacking because consumers cannot identify (and reward) those firms that produce RTE MPPs and are implementing the desired food safety safeguards. Therefore, consumers are unable to distinguish these products from those produced by lower cost firms that are applying less effective pathogen prevention methods. The lack of information on the safety of the products produced by the establishments in this latter group is a major concern of this rule. The recent FSIS risk assessment clearly indicates that products from establishments that are not taking these precautions can lead to illness or death.

The provisions of this final rule are designed to provide establishments a choice of selected, proven technologies to minimize the presence of *Listeria* in their processing