

VIII. Implementation

Implementation Strategy

FSIS has designed this interim final rule to recognize that there are alternative, effective ways to ensure that post-lethality exposed RTE products do not become contaminated with *L. monocytogenes*. While each approach can be effective in preventing such contamination, Alternatives 1 and 2 present a greater opportunity for mitigating the risk of RTE product contamination than does Alternative 3 because under Alternatives 1 and 2, products are formulated or processed in a manner either to eliminate *L. monocytogenes* or to limit its growth, should it be present.

Hence, in implementing this interim final rule, FSIS plans to conduct verification activities, including testing, that focus most intensively on Alternative 3 establishments and, within that group, on establishments that produce deli meats and hotdogs to verify that the total food safety system under which these products are produced is working properly.

FSIS is aware that the regulated industry is using antimicrobial agents at levels that provide some limitation of growth, that some establishments use these agents at levels that allow no more than 2-log_{10} growth throughout the shelf-life of the product, and that other establishments are using the agents at levels that more severely limit growth. FSIS believes that the majority of products formulated with the higher levels of antimicrobial agents are cured products because they better tolerate the agents, and the products do not have unacceptable organoleptic qualities. For this reason, the FSIS verification testing program for Alternative 2 will cover establishments that produce products formulated with antimicrobial agents but will focus on establishments using lower levels of antimicrobial agents because there is some potential for pathogen growth in the products. However, FSIS does not intend to conduct its verification testing at such establishments at a rate that is any higher than that for establishments in Alternative 3 and certainly not at a rate as high as that for establishments using Alternative 3 and producing deli meats or hotdogs.

FSIS intends to collect information about the RTE products produced by establishments using Alternatives 1 through 3. The information will include estimates of production volume for post-lethality exposed products, so that the Agency can develop annual sampling frequencies for the establishments and the products. FSIS will make the

sampling frequency information available to the establishments so that they will have some indication of how the risk of *L. monocytogenes* contamination is tied to FSIS verification testing.

FSIS is continuing to model scenarios in its risk assessment model and will use this information in determining where to direct its verification testing resources to ensure that such products are not adulterated. In the meantime, FSIS will continue to use currently available production volume figures in directing these resources.

The Agency expects to weight its sample scheduling process so that a large-volume establishment will be targeted more frequently than an establishment with a lower volume of production. Because, under this interim final rule, all establishments must have written programs that address *Listeria* and share their testing results with FSIS, FSIS believes that there will be no need to phase in the implementation of the interim final rule for establishments of different sizes or of different production volume capacity. The effective date will be October 6, 2003, for all establishments. During the 120 days before the interim final rule becomes effective, FSIS will issue a new directive (Directive 10,240.4, discussed below). The Agency is now making available new compliance guidelines that will contain information about the effects of sanitation and testing, as well as the effectiveness of various levels of antimicrobials.

New Directive for FSIS Inspection Program Employees

Through a new directive replacing FSIS Directive 10,240.3 that issued in December 2002, FSIS will conduct a risk-based verification testing program to assess the effectiveness of RTE operations in controlling *L. monocytogenes*. FSIS will identify the general features of the design of its verification testing program. Each fiscal year, FSIS identifies the general number of samples that it expects to collect throughout the year associated with RTE products. In order to implement this interim final rule, FSIS expects to apportion the types of products sampled with an emphasis on deli meats and hotdogs produced under Alternative 3. All RTE products are subject to being tested.

Until FSIS has actual production volume and associated data obtained through the reports required by 9 CFR 430.4(f), FSIS likely will continue sampling in the same manner currently employed by the Agency. FSIS intends to build in the production volume

feature, as soon as possible, in order to ensure that larger volume production is verified more frequently than smaller volume production. In addition, FSIS will continue to assess information about sanitation non-compliances and other plant performance indicators when determining which operations should be tested, but with an emphasis on products that allow for growth of *L. monocytogenes*.

As FSIS obtains information on the effectiveness of establishment process controls for *L. monocytogenes*, the Agency should be able to reduce the intensiveness of verification testing at establishments with more effective controls.

Generally, FSIS expects to collect for *L. monocytogenes* testing just one sample unit of RTE product from a production lot at an establishment selected for sampling. FSIS is considering taking more than one product sample from an establishment that produces product without post-lethality treatments or growth inhibitors, particularly deli meat and hotdog operations. Finally, FSIS expects to collect food contact surface samples and environmental samples mainly from operations that have a history of problems associated with the proper control for *L. monocytogenes*, or that produce RTE products, particularly deli meats and hotdogs, that allow for the growth of *L. monocytogenes*.

IX. Consumer Outreach Effort

Food safety education is one risk management strategy FSIS uses to reduce the incidence of illness associated with *L. monocytogenes* in RTE meat and poultry products. Safe handling, storage and preparation of RTE meat and poultry products can help reduce the risk of illness, particularly for those populations most at risk of contracting listeriosis: pregnant women, newborns, older adults, people with weakened immune systems caused by cancer treatment, AIDS, diabetes, kidney disease, and organ transplants. FSIS reaches these audiences through printed materials, the FSIS Web site, electronic communication, the media, and other information multipliers, in collaboration with other Federal agencies, educators, and healthcare professionals, and through the USDA Meat and Poultry Hotline.

For example, FSIS has worked with the Association of Women's Health, Obstetric and Neonatal Nurses, the International Food Information Council Foundation, FDA, and CDC to produce a patient education sheet, "Listeriosis and Pregnancy: What is Your Risk?" targeted to both pregnant women and