

### *Effectiveness of Industry Controls*

*Comment:* Some commenters stated that the current HACCP and Sanitation SOP requirements are adequate for ensuring control of *Listeria*. Therefore, the need for regulatory change in this area is questionable.

*Response:* It is true that validated HACCP plans and effective Sanitation SOPs should be sufficient to address the *Listeria* hazard. The continuing occurrence of product contamination and of significant outbreaks of illness in which meat and poultry products are implicated, however, suggest that establishments have not appropriately addressed the hazard in their HACCP plans, and that the effectiveness of establishment Sanitation SOPs used to control *L. monocytogenes* contamination is not being ensured. The Agency has therefore concluded that it is necessary to require establishments to take specific steps to control the *Listeria* hazard.

### *Ubiquity of L. monocytogenes and Difficulty of Controlling It*

*Comment:* Several commenters stated that it is important to recognize how ubiquitous *L. monocytogenes* is in the environment and that elimination of *L. monocytogenes* from all food is probably impossible. Thus, the commenters believe, it is not appropriate to require product testing on the basis of a single positive test for *Listeria* spp. on a food contact surface. Some commenters said that environmental testing results should not lead to enforcement actions.

*Response:* While FSIS does not think that the ubiquity of an organism in the environment argues against regulations requiring control of the organism, the Agency agrees that a more flexible approach to *L. monocytogenes* control than that taken in the proposal is warranted and desirable. FSIS is not adopting the proposed requirement to test product after the first positive test on a food contact surface. Although a positive test for *Listeria* species on a food contact surface does not necessarily mean that product is adulterated, or that enforcement action should be taken, such a finding does suggest the need for corrective action. FSIS inspection program personnel are instructed to verify that the establishment takes the corrective actions it has developed, whether as part of a HACCP plan or of a Sanitation SOP or other prerequisite program.

On the other hand, FSIS regards a positive test for *L. monocytogenes* on a food contact surface as evidencing an insanitary condition that may render product injurious to health. RTE

product that comes into contact with the sampled surface at the time it was contaminated with the pathogen and is not subject to any further lethality treatment is adulterated, and FSIS inspection program personnel will take the appropriate action in response to such a finding as set out in Agency directives.

### *Incentives and Disincentives*

*Comment:* The proposed testing requirements are a disincentive to control *L. monocytogenes* and may actually increase risk of foodborne listeriosis. Establishments might test for the organism at a lower rate than they currently do lest positive tests lead to unwarranted enforcement actions by FSIS. Many small and very small establishments have already implemented *L. monocytogenes* control measures (GMPs, Sanitation SOPs, and testing) in excess of the proposed requirements.

*Response:* FSIS agrees that mandating testing at a fixed frequency might discourage some establishments that are making strong efforts at *Listeria* control that include regular testing. This recognition factored into the Agency's decision not to adopt the proposed testing frequencies in this interim final rule.

*Comment:* FSIS should provide incentives for finding harborages, taking corrective actions, and preventing the recurrence of contamination.

*Response:* FSIS agrees with the comment. When the interim final rule becomes effective, FSIS verification testing will be more intensive in establishments where controls are less rigorous. (See discussion of new Directive 10,240.4 below.) Whether FSIS takes an enforcement action will depend on whether establishments are correcting insanitary conditions that may result in product adulteration.

FSIS believes that this interim final rule gives establishments the flexibility to adopt innovative and effective *Listeria* control methods. Moreover, the interim final rule includes a provision enabling establishments to declare on their product labels their use of *Listeria* control measures, provided that the establishments can validate the declarations.

### *HACCP, Sanitation SOPs, Prerequisite Programs, Directives or Performance Standards*

#### *Listeria Controls in HACCP Plans*

*Comment:* Some commenters favored using equipment design, GMPs, and facilities management techniques to control *L. monocytogenes*. They stated

that FSIS should recognize that enhanced and focused sanitation and employee behavior programs can be effective preventive and corrective actions. These commenters argued that contamination occurring in a post-lethality processing area is a sanitation, and not a HACCP, issue.

Others argued, to the contrary, that *L. monocytogenes* should be controlled by CCPs in an establishment's HACCP plan.

*Response:* FSIS is persuaded that *L. monocytogenes* contamination is being prevented in many establishments by Sanitation SOPs and other prerequisite programs. Where these programs are effective, an establishment may conclude in its hazard analysis that *L. monocytogenes* is not a hazard reasonably likely to occur. Of course, in the Agency's view, it is also appropriate to address this hazard in a HACCP plan. Thus, the Agency is allowing establishments the latitude to include *L. monocytogenes* control measures in HACCP plans or to address potential contamination by this pathogen in Sanitation SOPs or other prerequisite programs. It is important to note that if an establishment is applying a post-lethality treatment to an RTE product, the establishment must have concluded that *L. monocytogenes* is a hazard reasonably likely to occur in the product. For this reason, the establishment must include that treatment as a CCP in its HACCP plan.

*Comment:* Since no technology exists to completely eliminate *L. monocytogenes* from products, a CCP for controlling *L. monocytogenes* is infeasible. Establishments should focus their resources on sanitation and plant improvement projects rather than on HACCP CCPs. Allowing plants to develop CCPs instead of testing, they said, would result in decreased consumer protection.

*Response:* FSIS disagrees. A CCP in a HACCP plan is a point, step, or procedure in a food process where the occurrence of an identified hazard can be prevented, eliminated, or reduced to an acceptable level. Various methods are available to prevent, eliminate, or reduce *L. monocytogenes* in the RTE products that are subject to this interim final rule and their effectiveness can be validated. For example, a post-lethality heat treatment of a packaged product can eliminate the pathogen. Thus, establishments that use post-lethality treatments for this purpose should include the treatments in their HACCP plans. But establishments may use other methods, including the addition of antimicrobial agents, that have the effect of limiting or suppressing growth of *L.*