

*monocytogenes* in the products. These methods need not be in the establishments' HACCP plans, so long as the plant is regularly ensuring that these methods are working effectively and is making its records that relate to these methods available to FSIS inspection personnel.

#### *Use of Process Controls and Technologies to Control Listeria*

*Comment:* FSIS should encourage establishments to adopt effective process controls, such as food irradiation and high-pressure processing, rather than imposing testing requirements. Relying solely on Sanitation SOPs or GMPs would fail to control *L. monocytogenes*. Further, products that are subject to an in-package lethality treatment before being shipped should be exempt from both environmental and product testing requirements.

*Response:* FSIS has designed the interim final rule to be sufficiently flexible that establishments will be able to implement a variety of technologies to address *L. monocytogenes*. Of course, before establishments can take advantage of food irradiation for the types of products covered by this interim final rule, FDA approval will be necessary.

FSIS agrees that effective process controls will yield more beneficial results than testing requirements of the kind proposed and that establishments may use various methods to prevent or control *L. monocytogenes* contamination. Therefore, FSIS is not adopting the proposed testing frequency requirements. The Agency is permitting establishments that produce RTE products to implement the type of HACCP or sanitation program that is most appropriate for their production situation and is not imposing uniform testing requirements of the kind proposed. FSIS recognizes that different validation or verification testing regimes are appropriate for different types of products or process control programs, and that a combination of interventions, including post-lethality treatments, sanitation and testing, processing, and the use of growth inhibitors, appears to be most effective in controlling *L. monocytogenes*.

#### *Resource Allocation to Testing or Process Controls*

*Comment:* FSIS has not shown how the proposed, prescriptive, environmental testing will reduce the incidence of *L. monocytogenes* in RTE products. If plants devote resources to environmental testing rather than to effective sanitation activities, consumer

protection would decrease. Also, FSIS should let establishments use prerequisite programs instead of CCPs in the HACCP plan to control *L. monocytogenes*.

*Response:* FSIS acknowledges that testing by itself is insufficient to control *L. monocytogenes* but needs to be a part of a sanitation control program. FSIS regards testing as an essential means of verifying the effectiveness of sanitation procedures to control *L. monocytogenes*, whether the procedures are incorporated in a HACCP plan, a Sanitation SOP, or another prerequisite program. Devoting resources to a testing program developed for this purpose actually supports the control measures.

The proposed *Listeria* testing requirements, which would have mandated specific testing frequencies, were intended for Sanitation SOP verification. Although this interim final rule does not adopt the proposed testing frequency requirements, establishments that do not apply post-lethality treatments to their post-lethality exposed RTE products will have to include at least some food-contact surface testing in their sanitation programs. Such testing is intended to ensure that their measures for controlling, or preventing contamination by, *L. monocytogenes*, whether in HACCP plans or in Sanitation SOPs or other prerequisite programs, are effective.

*Comment:* FSIS should set a performance standard for *L. monocytogenes* as it has for other pathogens of concern. The Agency should also give establishments the flexibility to meet the standard. Thus, the Agency should consider the problem of pathogen growth after processing and give plants maximum flexibility in testing for *L. monocytogenes*.

*Response:* FSIS considered the option of adopting a process performance standard for controlling *L. monocytogenes* but determined that there was insufficient scientific information on which to base such a standard. Nonetheless, the Agency has given the establishments flexibility in deciding how to address this pathogen.

#### *FSIS Directive on Microbial Sampling Procedures for RTE Products*

*Comment:* Some commenters said that the Agency should continue to have its personnel use FSIS Directive 10,240.2, which sets out the procedures to be followed when Agency personnel conduct microbiological sampling in establishments that produce RTE products, rather than issuing new regulations. They said that FSIS could revise the Directive and conduct some

food contact surface testing, either in all establishments that produce RTE products or just in establishments that do not conduct their own sampling.

*Response:* FSIS disagrees with the assertion that a regulation is not necessary to ensure effective control of *L. monocytogenes* in RTE products. As noted, with respect to the risk ranking, there is a significant opportunity for recontamination of RTE products in establishments. Many establishments are not implementing HACCP, Sanitation SOPs, or prerequisite programs in a manner that is effective in eliminating *L. monocytogenes* in RTE products. It should also be noted that FSIS replaced its Directive 10,240.2 in December 2002 with a new directive (10,240.3) with updated inspection verification activities. This new directive will be further revised to reflect the requirements of this interim final rule.

#### *Inspection and Enforcement*

*Comments:* FSIS inspectors should be trained to understand *Listeria* testing and the evaluation of the testing results because the considerations involved are complex. FSIS should make compliance guidance materials available for industry review before final regulations take effect.

*Response:* FSIS will be training its field inspection personnel to ensure that the interim final rule is properly implemented. FSIS's Food Safety Regulatory Essentials training, which addresses RTE products, is being given to all consumer safety inspectors. Regarding guidance materials, FSIS will provide comprehensive guidance to facilitate implementation of this interim final rule by all affected establishments. FSIS will make this guidance material available on its Web site well before this interim final rule takes effect.

#### *Correlation Between Testing and Establishment Size and Production Volume*

*Comments:* There is no evidence that the testing frequencies proposed, which are based on establishment size, will lead to reductions in the rate of listeriosis.

Also, requiring a large establishment to test more frequently than a small one because that establishment manufactured more product is not supportable. The Agency's preliminary economic impact analysis indicated that a small establishment could produce more product than a large establishment because factors other than employees were involved.

*Response:* FSIS agrees that there is no necessary correspondence between