

establishment size and the rate of listeriosis or the degree of risk posed by the products the establishment manufactures. This is one reason why the Agency is not adopting the food contact-surface testing frequencies it proposed. Instead, the Agency is allowing establishments flexibility in designing measures to address *L. monocytogenes*, including appropriate testing and hold-and-test strategies for their products.

FSIS also understands that production volume does not necessarily correspond to establishment size. The Agency has concluded that having better and more comprehensive information about the production volume of RTE products will help it to more efficiently target its resources in verifying establishment *L. monocytogenes* controls.

Hold and Test

Comments: Some commenters stated that requirements for establishments to hold and test product after initial positive tests from environmental sampling would be complicated and likely to result in errors. Such regulation would therefore prove ineffective.

Other commenters insisted that, after an environmental positive, it would be appropriate for an establishment to follow hold-and-test procedures. They said that establishments should regard positive tests for *Listeria* from a non-food contact surface as indicating a sanitation or *Listeria* control problem and that if the positive test were from a food contact surface, all product from the shift represented by the sample should be held and tested before release.

Response: FSIS proposed requirements for food contact-surface testing rather than tests from the general plant environment. In this interim final rule, with the exception of one provision, FSIS is allowing the industry flexibility in designing procedures to be carried out following positive tests for an indicator organism, such as *Listeria* species. However, if a product has been in contact with a food contact surface that has tested positive for *L. monocytogenes*, it is considered adulterated and must be withheld from commerce. FSIS believes that this flexibility should result in the adoption of hold-and-test procedures that are not needlessly complicated and do not result in errors.

Costs and Benefits

Comments: Some commenters stated that the proposed regulations that require establishments to hold and test product after positive environmental test results would impose significant costs that would be especially

burdensome to small businesses. Further, it was asserted that establishments unable to hold product because of customer demand or lack of storage facilities would run the risk of incurring the costs associated with increased product recalls.

Commenters argued that FSIS provided little justification for its *Listeria* testing policies in its proposal. They stated that it is difficult to estimate the number of listeriosis cases that might arise from contamination of meat and poultry products and discrepancies in the Agency's proposal illustrated this fact. For example, there is a significant data gap in the relationship between a product contact surface that tests positive for *Listeria*-like, *Listeria* species, and *L. monocytogenes* and whether the product will be positive and the risk to consumers. Commenters suggested that FSIS estimate the reductions in foodborne illness that would result from the regulation and provide further analysis or quantification of costs and benefits.

Response: FSIS agrees that the proposed testing frequency requirements would not be without cost and is interested in ensuring the accuracy of its estimates. To this end, the Agency has accepted data that were submitted by several commenters on this matter and has used the data in preparing the final regulatory impact analysis.

FSIS agrees that the costs associated with product recalls may far exceed those associated with hold-and-test procedures.

On the effect of *Listeria* control regulations on small businesses, FSIS agrees that a relatively large proportion of small establishments will be affected by this interim final rule. FSIS has prepared compliance guidance for such establishments, including guidance specifically intended to assist them in HACCP plan validation with respect to *L. monocytogenes* control, and is making this guidance available with this interim final rule in the FSIS Docket Room and on the Agency's Web site. Also, FSIS will mail the guidance material to all RTE operations before the effective date of this interim final rule.

FSIS agrees with the comments on the difficulties involved in determining the relationship between listeriosis cases and meat and poultry product contamination and with the suggestion that FSIS estimate the reductions in foodborne illness that could result from the regulation. FSIS initiated a risk assessment of in-plant processing of RTE products to determine the relationship between various food contact surface testing and sanitation

regimes and other pre- and post-packaging interventions in mitigating contamination of RTE products with *L. monocytogenes* and in reducing the subsequent risk of illness or death and has further analyzed the costs and benefits. FSIS considered the results of the risk assessment in developing this interim final rule. In the final regulatory impact analysis, the Agency analyzes the effect of the interim final rule in terms of the reduction of illness and death from listeriosis.

Definition of RTE and Relative Risk of Different RTE Products

Comments: Commenters expressed concern about the terminology that the Agency used in its proposal. These concerns were related to the scope and effects of the regulation. The commenters said that FSIS should more clearly define RTE products. Some of them stated that frozen products ought not to be considered RTE for the purposes of the rule. To include such products in the RTE category, they argued, would be contrary to previous FSIS policy (Agency directives), the FDA's model food code, and the FDA/FSIS risk ranking model for *Listeria* in RTE foods. The commenters argued that another category of products, dried meat and fermented products, also should not be considered RTE for the purposes of the rule, for their water activity (a_w) puts them at low risk as a medium for growth of *L. monocytogenes*.

The commenters suggested that instead FSIS should define RTE products as "refrigerated foods of extended shelf life (>10 days) that can support the growth of *L. monocytogenes* and that will be consumed without further listericidal treatment." The commenters added that FSIS should base *L. monocytogenes* control requirements on risks posed by specific types of products.

Response: The Agency has revised the definition of RTE to be consistent with the definition of RTE used in the 2001 Food Code. FSIS does not believe that frozen foods, as a broad category, can be excluded from the definition of RTE for this rule. Rather, the Agency will continue to follow its existing practice of determining whether foods should be considered RTE because of the manner of processing and the handling instructions provided to consumers. Some instructions direct that the product must receive further preparation for safety purposes.

Several labeling features or statements are used exclusively on RTE products or non-RTE products, but not on both. RTE products often include phrases indicating that they do not require