

meat and poultry products. At this meeting, FSIS requested data relevant to the proposed regulation regarding frequencies of testing for environmental *Listeria* species and the correlation of potential product contamination with production volume.

On November 18, 2002, FSIS held a public meeting to provide a forum for experts from government, academia, industry, and elsewhere to discuss current research and information related to improving the safety of RTE products. The topics discussed included the role of environmental and product testing, decontamination strategies, and consumer behaviors related to RTE foods. At the meeting, FSIS released a new draft directive (Directive 10,240.3, discussed below) on FSIS microbiological testing of RTE products for a number of organisms, including *L. monocytogenes*.

An additional public meeting was held February 26, 2003, to discuss an FSIS draft risk assessment which had been conducted to determine the likelihood that *L. monocytogenes* may contaminate RTE meat and poultry products during production and packaging processes. The Agency's draft risk assessment was released February 14, 2003, and was posted on the FSIS Web site (at <http://www.fsis.usda.gov/OPHS/lmrisk/DraftLm22603.pdf>). Copies also were made available in the FSIS Docket Room. Public and peer reviewer comments on the risk assessment and the Agency's response to the comments also can be viewed in the Docket Room and on the Web site.

#### **V. FSIS Risk Assessment of *L. monocytogenes* in RTE Meat and Poultry Products**

The FSIS risk assessment and the FDA/FSIS risk ranking on *L. monocytogenes* in RTE foods sold at retail provided a framework for evaluation of, and data on, risk mitigation strategies, including in-plant measures, to inform the Agency in this rulemaking as it considered the need to address potential contamination of RTE products by the pathogen.

FSIS initiated its *Listeria* risk assessment in February 2002 in response to public comments on the proposed rule that suggested the need for a stronger scientific basis for provisions requiring the testing of food contact surfaces for *Listeria* species. The risk assessment was developed: (1) To provide insight into the relationship between *Listeria* species on food contact surfaces and *L. monocytogenes* in RTE meat and poultry products exposed to the environment after the lethality treatment (post-lethality exposure); and

(2) to evaluate the effectiveness of food contact surface testing and sanitation regimes, pre- and post-packaging interventions, growth inhibitors, and combinations of these interventions to mitigate contamination of RTE meat and poultry products that are post-lethality exposed, and to reduce the subsequent risk of illness or death from *L. monocytogenes*.

FSIS risk managers asked that the FSIS risk assessors evaluate the effect of various food contact surface testing and sanitation regimes in reducing *L. monocytogenes* contamination of products and the effect of other pre- or post-packaging antimicrobial interventions and of growth inhibitors in reducing such contamination. The risk managers also sought guidance from the risk assessors on testing and sanitation of food contact surfaces for *Listeria* species.

Given the available data and the fact that deli meats comprised about 80 percent of the listeriosis cases associated with ready-to-eat product, the FSIS risk assessment addressed only deli products. In order to evaluate the specific FSIS risk management questions, the risk assessment assumed that all *L. monocytogenes* on RTE product comes from the food contact surfaces and not from inadequate lethality treatment.

Using available data, the FSIS risk assessors developed a dynamic in-plant Monte Carlo simulation model (referred to as the in-plant model) quantitatively characterizing the relationship between *Listeria* species in the in-plant environment and *L. monocytogenes* in a production lot of RTE product at retail.

The outputs of the in-plant model (e.g., concentration of *L. monocytogenes* on deli meats at retail) were used as inputs into the two major components of the FDA/FSIS risk ranking model discussed earlier: the exposure assessment and the associated dose-response relationship for deli meats.

In the FDA/FSIS risk ranking, the retail-to-table exposure assessment for deli meats and the associated dose-response relationship were developed to identify which RTE foods pose the greatest risk for causing listeriosis. Two components of the FDA/FSIS risk ranking model, the exposure assessment for deli meats and the dose-response relationship, were later updated with data and information provided during the public comment period on the draft FDA/FSIS risk ranking. The updated exposure assessment is used to track the level of *L. monocytogenes* in deli meat from retail to table and, using the updated dose-response relationship for *L. monocytogenes*, provides estimates of

the subsequent risk of illness or death from consuming deli meats.

The outputs of the FSIS risk assessment model were calibrated to the *L. monocytogenes* concentration in deli meats at retail in the updated FDA/FSIS exposure assessment. That is, the FSIS output data were statistically compared with standard data on *L. monocytogenes* from a reputable third-party to determine whether the output data deviated from the standard data. Calibration of risk assessment models is intended to ensure the accuracy of risk estimates.

By modeling changes in in-plant practices, such as the frequency of testing and sanitation of food contact surfaces, the FSIS risk assessment model provides insight into the effects of these practices on the annual risk of illness or death from *L. monocytogenes* in RTE meat and poultry products. The risk assessment model was designed to provide numerous outputs that depended on the selection of in-plant practices, such as "test and hold," responding after an initial positive food contact surface sample, or alternatively, after consecutive positive samples, and that were based on various plant characteristics (e.g., plant size or production volume).

The most significant findings of the risk assessment model are: (1) The proposed minimal frequency of testing and sanitation of food contact surfaces (66 FR 12589, February 27, 2001) results in a small reduction in the levels of *L. monocytogenes* on deli meats at retail; and (2) combinations of interventions (e.g., sanitation/testing of food contact surfaces, pre- and post-packaging lethality interventions, and growth inhibitors) appear to be much more effective than any single intervention in mitigating the potential contamination of finished RTE products with *L. monocytogenes* and reducing the subsequent risk of illness or death.

Specific model outputs relating to *L. monocytogenes* concentrations in deli products at retail and the resulting public health impacts of various interventions were developed and were presented at a public meeting on February 26, 2003. FSIS accepted comments on its draft risk assessment at the public meeting and afterward, until March 14, 2003 (68 FR 6109; February 6, 2003). The comments received have been included in the record of this rulemaking proceeding. An analysis of comments and responses is available in the FSIS Docket Clerk's Office and on the FSIS Web site at: <http://www.fsis.usda.gov>.