

## **Executive Summary**

### **2003 FSIS *Listeria* Risk Assessment**

#### **SCOPE AND MANDATE**

This risk assessment was initiated in February 2002 in response to public comments on the Food Safety and Inspection Service (FSIS) proposed rule: *Performance Standards for the Production of Processed Meat and Poultry Products* [66 FR 12589, February 27, 2001]. Several comments indicated a need for a stronger scientific basis for the proposal to require testing and sanitation of food contact surfaces for *Listeria* species. This risk assessment was developed to: 1) provide insight into the relationship between *Listeria* species on food contact surface(s) and *Listeria monocytogenes* in RTE meat and poultry products; and 2) 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 and reduce the subsequent risk of illness or death from *Listeria monocytogenes*.

#### **PUBLIC HEALTH REGULATORY CONTEXT**

*Listeria monocytogenes* is a foodborne pathogen that results in about 2,500 cases of listeriosis annually in the United States. Of these cases, approximately 90% require hospitalization, and 20% progress to death. Those at greatest risk of listeriosis are the elderly, those with suppressed or compromised immune systems (e.g., those who have received a bone marrow transplant, cancer treatment, etc.), and fetuses and newborns.

*Listeria monocytogenes* occurs widely in both agricultural (e.g., soil, water and plants) and food processing environments (e.g., air, drains, floors, machinery). This pathogen grows at low oxygen conditions and refrigeration temperatures, and therefore survives for long periods of time in the environment, on foods, in processing plants, and in household refrigerators. Although frequently present in raw foods (dairy, meat, poultry, fruits, and vegetables), *Listeria monocytogenes* can also be present in ready-to-eat (RTE) foods due to post-processing contamination (i.e., after lethality treatment and before packaging). Of the RTE foods contaminated with *Listeria monocytogenes*, deli meat was identified in a 2001 Food and Drug Administration and FSIS risk ranking evaluation of RTE foods as posing the highest annual risk of listeriosis.

FSIS has taken several steps to reduce contamination, and the subsequent risk of illness or death, from *L. monocytogenes* in RTE meat and poultry products. These include the following: 1) establishment of a “zero tolerance” (e.g., no detectable level of viable pathogens permitted) for *L. monocytogenes* in RTE meat and poultry products; 2) requirement that establishments consider *Listeria monocytogenes* in their HACCP plans and adopt and follow written Sanitation Standard Operating Procedures (Sanitation SOPs) to reduce the likelihood that harmful bacteria will contaminate finished products (e.g., RTE meat and poultry products); 3) development of a proposed regulation [66 FR 12589, February 27, 2001] for establishments that do not have *Listeria monocytogenes* as part of their HACCP plan, to verify, through microbiological testing of food contact surfaces, that the establishment’s Sanitation SOPs are controlling *Listeria* species and the establishment take corrective action when a food contact surface tests positive for *Listeria* species; and 4) initiation of this risk assessment to provide a scientific basis to guide regulations for in-plant interventions (e.g., testing and sanitation of food contact surfaces) to mitigate the risk of listeriosis from RTE meat and poultry products.

#### **RISK MANAGEMENT QUESTIONS**

In the Fall of 2002, FSIS risk managers requested that the risk assessment be designed in order to evaluate the following specific questions:

- 1) How effective are various food contact surface testing and sanitation (corrective action) regimes (e.g., vary the frequency of testing by plant size – large, small, and very small plants) on mitigating *Listeria monocytogenes* in finished RTE product, and reducing the subsequent risk of illness or death?;

- 2) How effective are other interventions (e.g., post-processing interventions or growth inhibiting packaging) in mitigating *Listeria monocytogenes* in finished RTE product, and reducing the subsequent risk of illness or death?; and
- 3) What guidance can be provided on testing and sanitation of food contact surfaces for *Listeria* species (e.g., the confidence of detecting a positive lot of RTE product given a positive food contact surface test result)?

### **LISTERIA RISK ASSESSMENT MODEL**

To address these risk management questions, a dynamic in-plant Monte Carlo 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 was developed using currently available data. The outputs of the in-plant model (e.g., concentration of *Listeria monocytogenes* on deli meats at retail) were used as inputs into specific components of an updated version of the 2001 FDA/FSIS risk ranking model. The 2001 FDA/FSIS risk ranking model (see <http://www.foodsafety.gov/~dms/lmrisk.html>), developed to identify which RTE foods pose the greatest risk of listeriosis, was updated with data and information provided during the public comment period after the release of this model. The outputs of the in-plant model were calibrated to the concentration of *Listeria monocytogenes* in deli meats at retail in the updated version of the 2001 FDA/FSIS risk ranking model. The updated FDA/FSIS risk ranking model then tracks the level of *Listeria monocytogenes* in deli meat from retail to table, and provides estimates of the subsequent risk of illness or death from consuming these products. These two connected models – the in-plant model and the updated 2001 FDA/FSIS risk ranking model – comprise the overall FSIS *Listeria* risk assessment model.

By changing in-plant practices, such as the frequency of testing and sanitation of food contact surfaces, the FSIS risk assessment model can evaluate the impact of these practices in reducing the annual risk of illness or death from *L. monocytogenes* in RTE meat and poultry products.

### **RISK ASSESSMENT OUTPUTS**

Findings from the risk assessment model outputs include the following:

- Food contact surface found to be positive for *Listeria* species greatly increased the likelihood of finding RTE product lots positive for *Listeria monocytogenes*
- Frequency of contamination of food contact surfaces with *Listeria* species appears to encompass a wide timeframe, and the duration of a contamination event lasts approximately a week.
- 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.
- Increased frequency of food contact surface testing and sanitation leads to a proportionally lower risk of listeriosis.
- Combinations of interventions (e.g., testing/sanitation of food contact surfaces, pre- and post-packaging interventions, and growth inhibitors) appear to be much more effective than any single intervention in mitigating the potential contamination of RTE products with *Listeria monocytogenes* and reducing the subsequent risk of illness or death.

Specific model outputs relating to *Listeria monocytogenes* concentrations at retail and the resulting public health impacts of various interventions will be developed and presented at the public meeting on February 26, 2003.