

addressing *L. monocytogenes*. If the reassessment revealed that *L. monocytogenes* was a hazard reasonably likely to occur in an establishment's production process, the establishment would have to address the hazard in its HACCP plan.

The same month, FDA and FSIS announced plans to conduct a quantitative microbial risk assessment to determine the extent of consumer exposure to foodborne *L. monocytogenes* in RTE foods (64 FR 24661; May 7, 1999).

FSIS Action Plan

A May 5, 2000, Presidential directive on *L. monocytogenes* in RTE foods revised the Healthy People 2010 target date for reducing illnesses caused by the pathogen up to 2005 and set other objectives. HHS and USDA responded to this directive with an eight-point action plan providing for consumer, health-care provider, and industry education; redirection of enforcement strategies, including increased microbial sampling; enhanced disease surveillance; coordinated research activities; and proposing new regulations. For its part, FSIS announced its intention to publish a proposed rule that would, among other things, require establishments to conduct environmental testing for *Listeria* species in order to verify the effectiveness of their sanitation standard operating procedures (Sanitation SOPs).

FDA/FSIS Draft Risk Ranking

FDA and FSIS made public a preliminary draft of a risk ranking in January 2001 (66 FR 5515; January 19, 2001). The risk ranking ([see http://www.foodsafety.gov/dms/lmrisk.html](http://www.foodsafety.gov/dms/lmrisk.html)) estimated the relative risks of serious illness and death from listeriosis that may be associated with consumption of different types of RTE foods. The risk ranking did not cover listerial gastroenteritis, a less serious infection with mild flu-like symptoms. The risk ranking (1) estimated the potential level of exposure of three age-based U.S. population groups to *L. monocytogenes* contaminated foods in 20 food categories and (2) related this exposure to public health consequences. The food categories studied included foods with a history of *L. monocytogenes* contamination. The models used in the risk ranking provided a means of predicting the likelihood that severe illness or death will result from consuming foods contaminated with this pathogen. Estimates were made of the relative risks posed by the food categories, but the risk ranking did not predict the precise public health

consequences attributable to any particular contaminated food.

The foods considered in this risk ranking were RTE foods that are generally eaten without being cooked (e.g., cheese) or are typically reheated (e.g., frankfurters) before consumption. The main categories considered were seafood, produce, dairy, meat, and combination foods. The population groups evaluated were: (1) perinatal, including fetuses and neonates from 16 weeks after fertilization to 30 days postpartum. These are pregnancy-associated cases where exposure occurs most often *in utero* as a result of foodborne *L. monocytogenes* infections of the mothers during pregnancy and may result in spontaneous abortions, stillbirths, and neonatal infections; (2) elderly, that is, individuals who are 60 or more years of age; and (3) the intermediate-age group, including the remaining population, both healthy individuals (with very low risk of severe illness or death from *L. monocytogenes*) and certain susceptible population groups.

The population groups included individuals with increased susceptibility to listeriosis, such as acquired immune deficiency syndrome (AIDS) patients or individuals taking drugs that suppress the immune systems (e.g., cancer or transplant drugs). Individuals within these susceptible population groups account for most of the cases of listeriosis within the intermediate-age group. The risk ranking focused on the overall burden of listeriosis on public health and includes the occurrence of both sporadic illnesses (*i.e.*, illnesses not associated with a documented outbreak) and outbreak illnesses.

The results of the risk ranking indicated that certain RTE meat and poultry products presented a relatively moderate to high risk for listeriosis. These included pâtés and meat spreads, deli meats, hotdogs, and deli salads containing meat or poultry products. Further, there was a significant opportunity for recontamination of RTE meat and poultry products in the processing establishment.

IV. Proposed Rule Provisions on *L. monocytogenes*

The Agency concluded that many establishments were not effectively implementing HACCP plans and Sanitation SOPs to prevent *L. monocytogenes* from contaminating the RTE product in the post-lethality processing environment. The Agency therefore resolved to proceed to rulemaking to correct the problem. In February 2001, FSIS issued a proposed

rule that would require that establishments that produce post-lethality exposed RTE meat or poultry products conduct testing of food contact surfaces for *Listeria* species in areas of the establishments into which the products are routed after undergoing lethality treatment and before final product packaging. All establishments would be required to do this unless they had incorporated one or more controls validated to prevent, reduce to an acceptable level, or eliminate the *L. monocytogenes* from their products into their HACCP systems.

The proposed testing was intended to verify that the establishment's Sanitation SOP was preventing direct product contamination by *L. monocytogenes* after the products had undergone a lethality treatment. FSIS recognized that there is a significant risk for RTE meat and poultry products to become re-contaminated by *L. monocytogenes* if they came into contact with the pathogen, and that testing was necessary to verify that the procedures conducted under the Sanitation SOP had killed or eliminated the pathogen.

Under the proposal, if an establishment found that a food contact surface had tested positive for *Listeria* species, the establishment would have to take the corrective action necessary to properly clean the surfaces and to prevent product that may have become contaminated through contact with the surface from entering commerce.

Under the proposal, an establishment that had identified *L. monocytogenes* as a hazard reasonably likely to occur in its HACCP plan, and that had established CCPs for *L. monocytogenes*, was exempt from the proposed mandatory testing frequency requirement because HACCP regulations already require monitoring and verification, including testing frequency, as validated in the HACCP plan. An establishment that did not explicitly identify *L. monocytogenes* as a hazard reasonably likely to occur, but whose HACCP controls for biological hazards effectively prevented, eliminated, or reduced product contamination by the pathogen, would have had to make only minor amendments in its HACCP plan and supporting documentation to reflect that *L. monocytogenes* had been identified as a hazard addressed by the HACCP plan. In any case, if HACCP controls were implemented, the establishment would have to develop and validate the monitoring and verification procedures used to document the on-going effectiveness of the system. FSIS did not specify minimum monitoring and verification requirements for these processors.