

The Agency has made it clear that, in its view, contamination with *L. monocytogenes* is a hazard reasonably likely to occur in all RTE meat and poultry products that are exposed to the processing environment post-lethality. Significant concerns about such contamination underlay the Agency's May 26, 1999, **Federal Register** Notice advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to determine whether the plans were appropriately addressing *L. monocytogenes*. In the proposal, however, the Agency acknowledged that, even though *L. monocytogenes* was a significant concern in RTE products, it may not be necessary to address this pathogen in the HACCP plan itself. FSIS acknowledged that this pathogen may be present but not necessarily likely to occur because the establishment had measures in place, such as Sanitation SOPs, that effectively prevented contamination by the pathogen in the food processing environment. An establishment might have incorporated the controls in its Sanitation SOP and thereby prevented the pathogen from posing a contamination hazard in the processing environment.

Consequently, to verify that such plants were effectively preventing environmental contamination, FSIS proposed to require that establishments without HACCP controls for *L. monocytogenes* test food contact surfaces for *Listeria* species at a frequency that was based on the relative size of the establishments. FSIS proposed that large establishments subject to the requirement conduct at least four such tests per line per month; small establishments at least two per line per month; and very small establishments at least once per line per month. A large establishment was one employing more than 500 employees; a small establishment from 10 to 499 employees; and a very small establishment one employing fewer than 10 employees and grossing less than \$2.5 million in sales. These are the same size criteria the Agency had used in its 1996 final rule on HACCP systems (61 FR 38806).

The Agency solicited information on the proposed rule, including the efficacy of the testing frequencies, their potential cost to industry, the relationship between *Listeria* species on food contact surfaces and *L. monocytogenes* in product, and the various factors that might be important in devising effective testing protocols.

FSIS also proposed that establishments take certain actions after obtaining a positive food contact surface

test result for *Listeria* species. An establishment with such a result would have to take the corrective action defined in its Sanitation SOP. The establishment would have to have in place procedures to determine which lots of product might be affected; to hold, sample, and test that product; and to dispose of affected product appropriately. FSIS acknowledged that some establishments would have to modify their Sanitation SOP corrective actions to include such elements.

FSIS requested comment on whether *Listeria*-positive test results on different food contact surfaces (such as surfaces that had been treated with a bactericide versus those that had not) should be treated differently; whether the Agency should establish more specific requirements on product sampling following a *Listeria*-positive test on a food contact surface; and whether an establishment should have to determine whether a *Listeria*-positive sample is *L. monocytogenes* before having to initiate product testing.

FSIS stated in the preamble of the proposal that if a sampled lot is found to be positive for *L. monocytogenes*, and the product from the lot is already in commerce, the Agency would request that the product be recalled. Further, the Agency stated, if product is found to be positive for *L. monocytogenes*, the establishment that produced it would likely have to establish controls for the pathogen within its HACCP plan.

FSIS noted that the two provisions addressing *Listeria* contamination contained in the proposed rule, HACCP and Sanitation SOPs, required specific daily action to ensure that product is not adulterated. FSIS stated that, as of the time of the proposal, it did not consider programs outside of Sanitation SOPs and HACCP to be sufficient to prevent the hazards associated with post-lethality contamination with *Listeria* in the manufacture of RTE products. For one thing, the Agency noted, documentation of corrective and preventive actions taken in such programs, known as GMPs (good manufacturing practices) or prerequisite programs, generally was not being provided to the Agency.

Compliance guidance: In the proposal, FSIS made a commitment to provide compliance guidance to establishments on testing frequencies and methodologies and appropriate corrective actions to take following positive tests on samples from food contact surfaces. FSIS also said it would publish guidance on available interventions (techniques for killing *L. monocytogenes*) establishments can implement as CCP's. FSIS made the

draft compliance guidance available on its Web site after publication of the proposal.

Opportunity for Public Comment

FSIS provided a 90-day comment period. On April 13, 2001, FSIS published a **Federal Register** notice (66 FR 19102) extending the comment period an additional 30 days, through June 28, 2001, to provide opportunity for the public to comment on issues raised at a technical conference and public meetings that the Agency held May 8–10, 2001, on the proposed regulations. After the extended comment period expired, the Agency announced, in a July 3, 2001, **Federal Register** notice (66 FR 35112), that at the request of a consortium of trade associations, the Agency was reopening the comment period for an additional 30 days, until September 10, 2001. The consortium had said that it needed the additional time to review the large amount of scientific and economic data presented at the May 8–10 meetings, FSIS's draft compliance guidelines, and the draft FDA/FSIS risk ranking on the relationship between foodborne *L. monocytogenes* in RTE foods and human health.

Public Meetings on Listeria

During the development both of the proposal and this interim final rule, FSIS held a series of meetings with constituents and with technical and scientific experts on the problem of *L. monocytogenes* and how to control it. Some meetings were prompted by large-scale product recalls due to contamination with the pathogen or actual outbreaks of listeriosis.

In February 1999, following the late-1998 listeriosis outbreak and a recall of hotdogs and deli meats that had been contaminated with *L. monocytogenes*, FSIS held a public meeting on the food safety issues related to *L. monocytogenes* in meat and poultry products. At the meeting, industry and government procedures were discussed, including sampling programs for RTE products and the best ways to educate "at risk" populations about *Listeria*.

On May 15, 2000, FSIS held a public meeting to discuss current Agency initiatives to prevent human illness from *L. monocytogenes* in RTE meat and poultry products; the use of *Listeria* species as an indicator organism for *L. monocytogenes*; and the efficacy of environmental testing for *Listeria* species.

On May 8, 2001, FSIS held a public meeting to discuss scientific research and new technologies for detecting and controlling *L. monocytogenes* in RTE