

VI. Comments on the Proposal and FSIS Response

On the proposed requirements for controlling *Listeria* in RTE products in the February 27, 2001, **Federal Register** document, FSIS received 28 comments. Comment summaries, grouped by topic, and Agency responses follow.

Support for the Proposal

Comment: Three comments supported the proposed rule and favored even more stringent requirements. They said that manufacturers of RTE products should be required to implement programs for detecting and eliminating *L. monocytogenes* harborages and should perform tests for *L. monocytogenes* and *Listeria* species. All establishments that produce such products should have control programs that include environmental testing. The Agency should require establishments that have CCPs for *L. monocytogenes* to conduct testing. Also, the proposed required sampling frequencies should be increased and the intervals between tests specified. FSIS should mandate specific testing frequencies for product testing to be conducted following an environmental test that is positive for *Listeria*. Two of the commenters suggested that *Listeria* species is an appropriate indicator for *L. monocytogenes*.

The commenters said that FSIS should require even more intensive environmental and product testing than that proposed. Final product testing as well as environmental testing should be required; eventually, continuous product testing should be performed. One commenter opposed the notion of adopting food irradiation as a solution for potential contamination of RTE products.

One commenter said that the Agency should require establishments to test a statistically significant amount of RTE product for *L. monocytogenes*. The establishments also should conduct environmental testing for the organism. If the products are produced by an establishment that does not conduct RTE product testing as part of its HACCP plan, the products should carry warning labels.

Commenters said that FSIS should maintain its “zero tolerance” for *L. monocytogenes* in RTE products rather than setting a minimum colony-forming-unit (CFU) level for the organism in the products, as some have suggested.

A commenter said that official establishments should identify sources of *L. monocytogenes* in their Sanitation SOP.

Response: FSIS agrees with comments that supported establishment use of

effective process controls combined with environmental testing to verify the effectiveness of sanitation programs. The Agency also agrees with the comment that establishments should address sources of *L. monocytogenes* either in their HACCP plans or in their Sanitation SOPs or other appropriate procedures. This interim final rule provides a framework within which establishments must meet this objective and provides flexibility for doing so.

FSIS does not agree that it is necessary to mandate *Listeria* testing for establishments that have a CCP for *L. monocytogenes*. Such establishments are already required to validate and verify the CCP's, and microbiological testing is an important means of validation and verification.

FSIS also believes that, if it mandated a high frequency of environmental or product testing, the Agency would be foreclosing unnecessarily the use of effective control programs or strategies adopted by establishments that might require testing at frequencies different from those mandated. In this interim final rule, FSIS is not adopting the proposed frequency requirements. Instead, the Agency is requiring establishments to adopt one of several alternatives that are appropriate for their products and process controls that are effective in addressing *L. monocytogenes*.

On the question of a “zero tolerance” for *L. monocytogenes* and particularly with respect to RTE products that support growth of the pathogen, FSIS currently regards any amount of the organism as a product adulterant. As stated above, because the product is RTE, it is likely to be consumed without any effort to kill the pathogen, and the presence of the pathogen may render the product injurious to health (21 U.S.C. 601(m)(1), 453(g)(1)) and would cause the product to be unhealthful.

General Comments on the Proposal and Its Scientific Basis

Comment: A number of commenters said that the proposed testing requirements are arbitrary, unsupported by the FDA/FSIS risk ranking, and generally unscientific (*i.e.*, they were not based on the relative risk posed by establishments, products, or processes).

Response: FSIS agrees, in principle, that mandating a testing frequency is not well founded. In this interim final rule, FSIS is not adopting the proposed provisions for testing food contact surfaces at specified frequencies. Under the interim final rule, establishments will have to implement effective controls for *L. monocytogenes*. The interim final rule is based on the

Agency's conclusion that establishments that process post-lethality exposed RTE products must address *L.*

monocytogenes in their food safety systems. Those establishments that rely only on sanitation procedures to control the pathogen should carry out more intensive verification procedures, such as food contact surface testing, to ensure that the procedures are effective, and that products are not contaminated, than establishments that controls the pathogen through their HACCP plans.

Severity of Effects

Comment: In framing the rule, FSIS should consider the relative risk of illness posed by RTE products and the severity of effects.

Response: FSIS has taken into account the relative risk of illness and death posed by the processes and products addressed by this interim final rule as reported in the FDA/FSIS risk ranking of RTE foods sold at retail and the FSIS risk assessment.

Success of Industry Efforts

Comment: The industry has been successful in lowering the incidence of foodborne listeriosis. The industry's efforts will help the country achieve the Department of Health and Human Service's “Healthy People 2010” goals for lowering the incidence of listeriosis in the population within the timeframe established in the May 5, 2000, Presidential directive. Thus, the Agency's proposal to require environmental testing is unjustified, especially in view of the fact that HACCP was intended to obviate the need for this type of prescriptive requirement.

Response: Although it is early to determine whether the “Healthy People 2010” goals for reducing listeriosis (to 0.25 cases per 100,000 population) will be achieved, recent data from CDC indicate that from 1996 to 2002 there was a 38-percent decline in the number of cases per 100,000 population (to .27 overall). Nonetheless, meat and poultry products have been implicated in a substantial proportion (nearly half) of listeriosis cases. FSIS believes that the meat and poultry industry, together with other segments of the food industry, is capable of contributing significantly to the achievement of the Nation's goals for *Listeria* control, particularly by focusing on higher-risk meat and poultry products and on mandatory control procedures—the approach taken in this interim final rule. This interim final rule does not, however, mandate specific testing frequencies.