AMERICAN SOCIETY FOR MICROBIOLOGY

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American Society For
Microbiology

The American Society for Microbiology (ASM) is submitting comments in response to the U.S. Department of Agriculture (USDA) notice requesting comments on the Food Safety and Inspection Service (FSIS) report, "Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule," in the Federal Register, Vol. 69, No. 231 on December 2, 2004, Docket No. 04–032N. The following comments were developed by the ASM Committee on Agriculture and Food Microbiology, of the Public and Scientific Affairs Board.

The ASM is the largest single life science society with more than 42,000 members, including scientists in academic, industrial, clinical, and government institutions, working in areas related to basic and applied research, the prevention and treatment of infectious diseases, laboratory and diagnostic medicine, the environment, and water and food safety. The ASM applauds USDA efforts to reduce the incidence of foodborne illness, including illness caused by *L. monocytogenes,* and to protect the safety of the food supply.

Public Health Team

FSIS Findings

The Public Health team focused on whether it is possible to assess the effects of the rule on public health. The team recognized that it is too early to judge these effects.

FSIS found that more than 87% of the establishments have changed their operations to more effectively control *L. monocytogenes*.

ASM Comments

- We support a sampling program that targets products having the greatest potential for causing human listeriosis. High risk ready-to-eat meat products are those which support the growth of *Listeria monocytogenes* to high numbers during the intended shelf life of the product. Providing baseline surveillance information for the highest risk products enables FSIS to focus its resources on products most likely to cause listeriosis and thereby have the greatest impact on providing public health protection. This is one sound way to determine industry's

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response to the requirements specified in the rule and to assess the potential public health benefits that may be achieved.

Economic Impact Team

FSIS Findings

The Economic Impact team assessed the assumptions that the Agency made in preparing the economic assessment that was part of the interim final rule.

The team considered whether the rule is disproportionately affecting small establishments. Answer: no.

ASM Comments

- FSIS data refute this statement. Table 4 on page 53 shows the percentage of plants in each size category that received LM-related NRs between 10/6/03 and 7/12/04. Note first that this table contains a typographical error. The values provided for large plants should be switched so the number of plants producing RTE products is represented by 119 and the number of individual plants that received LM-related NRs is represented by 17. In any case, the NR rate for very small plants is twice the NR rate for large plants, while the NR rate for small plants is intermediate.

- We strongly support continued efforts to provide training resources to assist small and very small plants. See additional comments throughout.

Labeling and Consumer Education Team

FSIS Findings

The Labeling and Consumer Education Team focused in part on incentive labeling.

The team found that no establishments are using incentive labeling. The team recommended that FSIS use focus group research to help develop statements that would provide flexibility in conveying the fact that RTE product has undergone post-lethality treatment to destroy *Listeria.*

ASM Comments

- We encourage FSIS to consider the potential industry liability concerns regarding incentive labeling.

- We support the use of labeling to advise consumers that products have received either a post-lethality treatment or contain added antimicrobial agents.

- Current consumer research indicates that at risk individuals use their health professionals as a primary source of information. We encourage FSIS to promote the flow of accurate food safety information through health professionals to high risk patients.

- While current consumer focus group research indicates much consumer support for placing food safety messages on product labels, we are concerned that unless the message is displayed prominently on the face of the label, the message may not be received by the consumer.

- Current research indicates that health professionals and at risk individuals alike are highly aware of the importance of discarding out of date foods. Despite this high level of awareness, confusion as to the exact meaning of a package date exists. We encourage the development of a package date labeling plan which is relevant to the risk posed to high-risk individuals and a requirement that date labels be clearly legible when applied to high risk ready-to-eat foods.

- If FSIS moves forward with a consumer education campaign, we encourage the agency to consider education on risks and consumer responsibilities, including advice on proper storage conditions. The recently completed risk assessments led to the conclusion that the risk of listeriosis can be significantly reduced through proper refrigeration of high risk ready-to-eat foods, particularly at retail and in homes. Furthermore, this would have broader benefit toward the risk of reducing foodborne illness from a variety of pathogens.

Sampling Verification Team

FSIS Findings

The Sampling Verification team assessed the *L. monocytogenes* sampling that the Agency performs and determined whether improvements in that sampling are needed.

The team recommended that the Agency complete the development of a risk-based sampling regime, including an intensified sampling program in response to positive findings.

ASM Comments

- We support the modification of the sampling program to provide baseline surveillance information. This is a sound way to determine if progress is being made.

- We support a sampling program that targets the riskiest products. This focuses resources on those products that are most likely to cause listeriosis while also taking into account the special needs of small businesses with respect to production volume.

- We encourage the annual survey of establishments provided that the survey is properly designed and conducted such that it will provide information useful to providing greater public health protection.

- We acknowledge processing plant construction age, building material and design as important risk factors contributing to *Listeria* contamination and encourage consolidation of these factors in any risk-based sampling program.

- We are puzzled by the lack of difference in the prevalence of *L. monocytogenes* in randomly sampled RTE foods (3 of 345 or 0.9%) and targeted sampling of the riskiest products (11 or 1349 or 0.8%). In the future, we encourage FSIS to provide more information on the types of foods tested, to determine *L. monocytogenes* cell numbers in the foods tested, and to collect equal numbers of random and targeted foods before this type of comparison is made.

- In the case of a *L. monocytogenes*-positive sample in a product that supports the growth of the organism, we support the reevaluation of an establishment's HACCP, SSOP or other prerequisite programs to confirm that corrective actions appear reasonable and to ensure that the establishment begins environmental testing. It is important to find and control the source of *L. monocytogenes* in a processing plant to prevent contamination. It also should be noted, that there is a strong need for the development of uniform criteria for HACCP, SSOP and pre-requisite program re-evaluation in the event of a *L. monocytogenes*-positive sample.

Training Team

FSIS Findings

The Training team was responsible for ensuring that the Agency's inspection program personnel are appropriately trained to enforce the interim final rule.

The team recommended that FSIS' Food Safety Regulatory Essentials course be given to all FSIS Consumer Safety Inspectors, and that it be supplemented with compact disc training that focuses on the interim final rule.

ASM Comments

- We support the development of criteria for re-evaluation of HACCP, SSOP and pre-requisite programs in the event of a *L. monocytogenes*-positive sample. Inspectors should be trained in the use of these criteria.

- We encourage the concurrent or joint training of regulatory and industry personnel to promote a common, shared understanding of HACCP, SSOP and pre-requisite programs.

Small Plant Guidance Team

FSIS Findings

The Small Plant Guidance team found that the Agency needs to develop better ways of ensuring that FSIS Compliance Guides reach small and very small establishments.

ASM Comments

- We support the development of criteria for the re-evaluation of HACCP, SSOP and pre-requisite programs in the event of a *L. monocytogenes* positive test result. Small and very small plant employees should receive training in the use of these criteria.

- We encourage the development of training materials to assist small and very small plants in the appropriate use and verification of efficacy of antimicrobial agents in ready-to-eat products.

- We encourage the concurrent or joint training of regulatory and industry personnel (especially for small plants) to promote a common, shared understanding of HACCP, SSOP and pre-requisite programs.

Retail Team

FSIS Findings

Finally, the Retail team focused on possible means of controlling *L. monocytogenes* in RTE products at retail establishments.

This team found that slicing and packaging deli meats at retail establishments represents a significant source of exposure of *L. monocytogenes.* The team suggested two possible strategies for dealing with this problem: (1) education and outreach, and (2) use of antimicrobial agents in products to be sliced and sold at retail establishments.

The team also pointed to efforts already underway in the Agency to compare the risk of listeriosis from product sliced in plants with the risk from those sliced at retail establishments. The results of this assessment will be used by the Agency in developing its strategy for retail establishments.

ASM Comments

- We support the need for additional training for retail staff as an appropriate strategy for reducing *L. monocytogenes* contamination of ready-to-eat products at retail. We also encourage the development of training evaluation measures that track actual behavior changes in addition to knowledge gained.

- We support the use of antimicrobial agents in products at the deli counter as a means to prevent growth of *L. monocytogenes* to high numbers.

- We encourage FSIS to consider prevention of cross-contamination at the deli counter as one critical means to minimizing the transmission of *L. monocytogenes.*

- We encourage FSIS to further investigate the practicality of different practices, such as freezing, that would prevent *L. monocytogenes* growth during transport from the processing plant to the retail store as a means of risk control for high risk ready-to-eat products

- We encourage additional research on the incidence of *L. monocytogenes* on food contact surfaces, as well as research to identify the most likely routes of contamination within delicatessen environments.

ASM appreciates the opportunity to provide these written comments on the FSIS report, "Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule."