

National Advisory Committee on Meat and Poultry Inspection

Issue Paper for consideration by Sub-Committee

***Listeria monocytogenes (Lm)* Interim Final Rule and FSIS's
Preliminary Assessment of its Effects**

Purpose:

The Agency is assessing comments on the *Listeria monocytogenes (Lm)* interim final rule. In this paper, FSIS describes the methodology that the Agency is employing in performing the assessment. The Agency also describes the steps that it intends to follow once the Agency's assessment is complete. The Agency is requesting input from the committee on three questions.

Discussion:

On October 6, 2003, the FSIS interim final rule on *Lm* became effective. In this interim final rule, FSIS found that *Lm* is a hazard that is reasonably likely to occur in the processing of post-lethality exposed ready-to-eat product if not prevented. The Agency therefore required that establishments address *Lm* in their HACCP plans or in their sanitation standard operating procedures (Sanitation SOPs) or other prerequisite programs.

Based on the results of a risk assessment that FSIS conducted with FDA, the Agency identified three alternative approaches to preventing or minimizing post-lethality contamination. Under Alternative 1, establishments would check their HACCP plans and address this hazard through a lethality treatment and incorporate a growth inhibiting agent or process for *Lm* in their products. Under Alternative 2, establishments could employ either a lethality treatment or a growth inhibiting agent or process to address *Lm*. In Alternative 3, the establishment could rely on its Sanitation SOPs to keep the post-processing environment, particularly food contact surfaces, free of *Lm*. The third alternative provides the least amount of control because neither a lethality treatment nor a growth inhibiting agent or process would be employed. The Agency said that its verification testing would be risk-based, based on the alternative that the establishment chose to follow and the volume of products that it produced. The Agency soon will be collecting mandatory information about the production process in order to design and implement the risk-based verification testing program. FSIS also made clear that establishments could highlight the alternative they chose through label statements.

The Agency took a unique additional step. Although the rule was effective in October 2003, making it an interim final rule the Agency made clear that it would assess the effects of the rule and make changes if the assessment demonstrated they are warranted. To gain input for its assessment, the Agency provided an 18-month comment period.

However, the Agency has decided not merely to rely on public comment for this assessment. Seven Agency wide teams were also established to assess and measure the effectiveness of the regulation.

Each is performing a different aspect of the reassessment. The teams include representation from each Agency program area. A list of the teams and their activities follows.

A. Economic Impact Team

The Economic Impact Team will update the assumptions made during the preparation of the economic impact analysis for the interim final rule. This team plans to accomplish the following activities:

- Updating the plant profile, sales, and employment data used in the interim rule and needed for the Final Regulatory Impact Analysis;
- Collecting and analyzing compliance data from establishments subject to the new regulations to determine effectiveness, and thus cost-effectiveness, of regulations;
- Reassessing the assumptions about plant choices among regulatory options using sampling and compliance data, Consumer Safety Officer (CSO) and Enforcement, Investigations, and Analysis Officer (EIAO) reports, available industry surveys, and possibly a new FSIS survey of inspection personnel;
- Collecting and analyzing new and additional data showing direct and indirect costs to industry imposed by the regulations (e.g. purchase by plants of additional storage space for holding product prior to receiving *Lm* test results);
- Working in conjunction with the Public Health team to quantify and possibly put a monetary value on the reduction in illness they identify as resulting from the rule; and
- Determining the number and variety of new technology requests associated with *Lm* as a consequence of the rule and making recommendations to prioritize new technology requests based upon health risks.

B. Labeling/Consumer Education Team

The Labeling/Consumer Education team will focus on the incentive labeling and consumer education. This team plans to accomplish the following activities:

Incentive Labeling

- Continue monitoring of *Lm* incentive labeling claims; and
- Examine how establishments may be redefining their processes to attempt exemption from the rule.

Consumer Education

Activities include:

- Discussions are underway with transplant organizations, community health clinics, geriatric organizations, dialysis centers, and AIDS/HIV care organizations to determine how best to reach these individuals in vulnerable groups. *Lm* informational materials will be distributed as the newly launched Food Safety Education Mobile travels throughout the country;
- Providing education on safe food handling.

- Distributing information to consumers regarding new labels that processors may voluntarily use under this regulation to inform consumers of interventions used to reduce contamination;
- Updating Video News Release and produce Spanish version;
- Publish brochures for “At Risk” groups for 9/04 “Food Safety Month;”
- Arranged Dr. Murano interview and follow-up on “TodoBebe” Hispanic Television show;
- Refining and reevaluating food safety education materials for effectiveness and incorporation of risk assessments/latest available science-based studies; and
- Conducting focus group studies to review *Lm* publications for seniors.

C. Training Team

The Training team will assess the current training delivered to FSIS Inspection personnel relating to ready-to-eat (RTE) products and the Interim Final Rule for *Listeria monocytogenes*; make recommendations for further training needs and methods of delivery; and develop an explicit and well-articulated plan for further evaluation of inspection personnel training. This team plans to accomplish the following activities:

- Evaluate current training materials and delivery methods relating to RTE products and the *Lm* Interim Final Rule, with inclusion of recommendations for future improvements;
- Evaluate current verification and accountability measures that pertain to the training of inspection personnel;
- Evaluate the effectiveness of FSIS training for the *Lm* Interim Final Rule, including suggestions and comments from training participants; and
- Determine the EIAOs mastery of taking food surface contact samples.

D. Sampling Verification Team

The Sampling Verification team will develop both a long-term and short-term assessment of the effectiveness of FSIS’ verification sampling program in targeting inspection resources to reduce the risk of listeriosis from post-lethality exposed RTE meat and poultry products. Specific considerations include: (1) sensitivity to small businesses; (2) focus on high risk products (and processes used to meet requirements of 9 CFR 430.4(b)). This team plans to accomplish the following activities:

- Assess *Lm* sampling program and determine whether modifications are needed;
- Evaluate historical data against data collected since implementation of new rule;
- Determine whether recent data indicate effective implementation of *Lm* Interim Final Rule;
- Evaluate bulk-packed RTE product for retail slicing and the shelf life issues of RTE product;
- Prepare a plan for verification sampling that is risk based and for follow-up sampling that enhances the likelihood of finding a positive product;
- Determine the effectiveness of food surface contact sampling by the EIAO’s; and

- Identify the criteria FSIS will use to determine the effectiveness of the establishment's sanitation program.

E. Small Plant Guidance Team

The Small Plant Guidance team plans to assess the compliance guidelines, which are designed to assist small and very small establishments in meeting the requirements of the *Listeria monocytogenes* Interim Final Rule. This team plans to accomplish the following activities:

- Determine how small and very small plants use and understand the *Lm* Interim Final Rule Compliance Guidelines; and
- Identify specific problems.

F. Retail Team

The Retail team will review the extent of contamination and the possible programs to control the prevalence of *Lm* contamination of RTE meat and products at retail establishments. This team plans to accomplish the following activities:

- Evaluate FSIS and FDA activities that determine the prevalence of *Lm* contamination in retail establishments;
- Evaluate current control programs that retail establishments use for *Lm*; and
- Evaluate FSIS and FDA activities towards developing guidance materials to reduce *Lm* at retail.

G. Public Health Team

The Public Health team plans to develop a short-term and long-term assessment of the impact of the *Listeria monocytogenes* Interim Final Rule on public health. Specific considerations include: (1) identification of data sources for monitoring the burden of illness caused by *Lm* (listeriosis); and (2) accounting for uncertainty in the proportion of listeriosis illnesses that may be caused by FSIS-regulated products. This team plans to accomplish the following activities:

- Collect human listeriosis data, national hazard identification information data from food monitoring systems, and attribution data (if available);
- Evaluate listeriosis data for trends before and after implementation of the *Lm* Rule;
- Analyze trends in listeriosis over time;
- Compare listeriosis data to food adulteration/contamination data (obtained by Sampling Verification Group); and
- Propose further studies for FoodNet as indicated by data needs (e.g. pilot and case control study described above).

Next Steps

Once the assessment teams complete their reports, FSIS plans to take the following actions:

- Conduct an internal Agency review of the report of the results of the assessment;
- Make the report available for public comment; and
- Analyze comments on report in conjunction with the comments on the interim final rule.

Questions:

- 1) What suggestions does the committee have about the assessment?
- 2) Are there issues that the Agency is not addressing in the assessment that it should?
- 3) Do you have any comments or any suggestions for the Agency about additional matters that should be considered by the Agency in deciding on a final rule after the close of the comment period in December of this year?

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