

# National Advisory Committee on Meat and Poultry Inspection

## Update on Assessing the Effectiveness of the “*Listeria monocytogenes*” (Lm) Interim Final Rule

### Background

FSIS made a presentation on the Agency Lm Assessment Team’s activities to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) during the Committee’s June 2004 meeting. NACMPI provided recommendations on each of the issues that the Lm Assessment Team was considering. Each of the *Project Assessment Teams (PAT)* of the Agency Lm Assessment Team considered and responded to the Committee’s suggestions in developing their final reports. NACMPI’s recommendations and the PATs’ responses are summarized in this briefing paper.

### NACMPI’s Advice and Lm Assessment Team Responses

#### *Economic Impact Team Assessment Recommendation*

***NACMPI recommended the following:*** The Committee recommended that the team focus on differences among small, very small and large plants and assess economic impact on very small versus large plants. For example: Has the rule caused companies to go out of business or relinquish their grant of inspection. In addition to the variables included in the “Economic Impact Team” discussion, the team should consider other variables, e.g., product types, frequency of production.

***Economic Impact Assessment Team Response:*** The PAT accepted the NACMPI’s recommendation. The Agency’s economic impact analysis will consider variables such as product types and the frequency of production that focuses on the differences among small, very small, and large plants. The Agency will also review whether the rule has caused firms, particularly small firms, to go out of business.

#### *Labeling/Consumer Education Team Assessment Recommendation*

***NACMPI recommended the following:*** The Committee recommended that FSIS conduct focus groups and other consumer testing to assess various types of informational labeling including safe handling statements, statements addressing particular risk to vulnerable populations for products susceptible to *Lm* contamination and consider NACMCF recommendations on safety-based date labeling. The focus groups are necessary to more closely assess consumer response to labeling, since consumer testing has shown that consumers are frequently confused regarding various labeling statements.

***Labeling/Consumer Education Assessment Team Response:*** The PAT agreed that FSIS should continue to assess the effects of incentive labeling activities and continue to work

with health professionals to disseminate food safety information. However, the PAT stated that the incentive labeling provision should remain in the final version of the *L. monocytogenes* rule as an encouragement to industry to declare that their product has undergone post-lethality treatments or was treated with anti-microbial agents or processes to destroy *L. monocytogenes*. The Agency should further develop *L. monocytogenes* labeling statements by conducting focus group research studies to develop statements that provide flexibility to the industry while still remaining truthful and not misleading.

### **Training Team Assessment Recommendation**

***NACMPI recommended the following:*** The Training Team indicates it is evaluating the effectiveness of *Lm* training and the verification and accountability measures pertaining to the training. Currently, there is a perception that EIAO's and CSO's understand the *Lm* rule while CSI's may not. As part of their evaluation, the Team should review whether the training is equally effective for EIAO's, CSO's, and CSI's and whether the accountability measures are adequate to ensure that those who participate in the training achieve some mastery over the subject.

***Training Assessment Team Response:*** The PAT suggested that the Agency review whether the training is equally effective for EIAOs, CSOs, and CSIs, and whether the accountability measures are adequate to ensure that those who participate in the training achieve some mastery over the subject.

The Team suggested that the current project of training CSIs in FSRE should continue until all current CSIs are trained. Plans should proceed to assure that all new CSIs are also trained in FSRE. Also, the Agency should consider training all in-plant supervisors in FSRE. In addition, CSIs who completed FSRE before October 2003, and employees who have not had the opportunity to attend FSRE updated training, should be provided supplementary training. This may be accomplished by developing an interactive training CD-ROM. When the rule is finalized, this CD-ROM training module should include the full text of the final rule, the associated Agency directives, and the Agency Compliance Guidelines. Additional CD-ROMs should be considered for specific training aspects such as *L. monocytogenes* sampling and guidance when issuing NRs, related to noncompliance of the *L. monocytogenes* requirements.

### **Verification Sampling Team Assessment Recommendation**

***NACMPI Recommendation:*** FSIS' *Lm* verification testing is a critical aspect of the implementation of the rule. FSIS' verification activities will include determining whether establishments are following the correct sampling and testing procedures in compliance with the rule. FSIS should focus on assessment of the three alternatives for risk mitigation to evaluate their effectiveness. Through this process, FSIS can also determine whether the assumptions on product risk made in the FDA/USDA Quantitative Risk Assessment are accurate.

***Verification Sampling Assessment Team Response:*** The Team agreed that the Agency should assess the three alternatives and evaluate their effectiveness for risk mitigation. The Agency is developing a model that can be used for this assessment.

### ***Small Plant Guidance Team Assessment Recommendations***

***NACMPI recommended the following:*** FSIS should recognize that very small plants face special challenges in implementing new requirements. FSIS should include universities in disseminating guidance information to small plants. Representatives of District Offices should be involved to help deliver messages to industry through timely training. FSIS should use available technology to help train FSIS personnel and industry by using remote broadcast and videotapes of the broadcasts through distribution to small plants.

***Small Plant Guidance Assessment Team Response:*** The PAT agrees with NACMPI that the Agency should include universities and the Association of Food and Drug Officials (AFDO) in disseminating guidance information to small plants and involve the District Offices when delivering messages to industry through timely training using available technology such as remote broadcast and videotapes of the broadcasts through distribution to small plants.

The PAT recognized that very small establishments face special challenges when attempting to comply with new requirements. To meet the needs of these establishments, the PAT stated that the Agency should devise ways to disseminate new information in a timely manner. FSIS should explore ways to use available technology when providing information such as remote broadcasting and the distribution of videotapes and videodiscs of these broadcasts. The Agency should examine its current procedures that rely heavily upon the Internet to distribute the Agency's Compliance Guidelines. Most small and very small establishments do not have computers to access documents posted on the Agency's Website. The Agency should also conduct additional workshops targeting small and very small establishments and schedule these workshops well in advance of when the *L. monocytogenes* interim final rule is finalized. The Agency should simplify the Agency's Compliance Guidelines to enable small and very small establishments to easily understand the recommendations. The Agency should also provide establishments with guidance concerning reclassifying their products from RTE to not being RTE.

### ***Retail Team Assessment Recommendations***

***NACMPI recommended the following:*** The Committee recognizes FSIS' expertise in many areas of the manufacturing of meat and poultry products. However, FSIS does not have the same knowledge of retail operations. Other groups, such as FDA, AFDO, State and local agencies, have experience in the operations of retail facilities and should be included in the retail portions of the assessment. This can be accomplished by interviewing the subject experts to fully address all concerns relating to potential contamination of product further processed at retail facilities.

***Retail Assessment Team Response:*** The Agency will continue to work with other groups, such as the Food and Drug Administration (FDA), The Association of Food and Drug Officials (AFDO) and state and local agencies experienced in the operations of retail facilities, when addressing concerns relating to potential contamination of product further processed at retail facilities.

The PAT stated that the Agency should continue to compare the levels of *L. monocytogenes* in RTE product at the establishments producing RTE meat and poultry product with the levels in product of this type after being sliced at retail. The result of this assessment will inform Agency managers regarding the prevalence of *L. monocytogenes* in RTE meat and poultry at retail. This study should include the collection of national and state retail data on the prevalence and level of *L. monocytogenes* in deli meats and associated risk factors such as retail sanitation, product co-mingling, and product formulation. Two possible Agency strategies to mitigate risk in retail establishments are suggested: (1) Food Service and Retail Training: This effort should focus specifically on *L. monocytogenes* issues, particularly with regard to proper sanitation, refrigeration, and products of particular concern (for example, uncured poultry rolls); and, (2) Antimicrobial Agent (AMA) Formulations: Seemingly low-risk deli products containing AMAs may represent a significant hazard in retail deli operations using sub-optimal refrigeration. Even with modest temperature increases, AMAs are far less effective in inhibiting outgrowth. Options for federally inspected establishments in preventing product contamination and outgrowth in retail operations appear to be limited and may not be effective in significantly reducing the likelihood of foodborne listeriosis from deli counter products.

#### **Public Health Team Assessment Recommendations**

***NACMPI recommended the following:*** The Committee believes that it is appropriate that FSIS is evaluating public health data to evaluate the effectiveness of the rule. As with Salmonella, FSIS should conduct molecular sub-typing and attempt to correlate positive product with actual cases of illness.

***Public Health Assessment Team Response:*** The Agency should conduct molecular sub-typing and attempt to correlate positive product with actual cases of illness.

#### **Next Steps**

***NACMPI recommended the following:*** FSIS should publish the report of the assessment and provide sufficient opportunity to comment. Based on the findings in the assessment and the comments, FSIS should make any necessary and appropriate changes to the rule.

**Agency Response:** Agency plans to issue a Federal Register (FR) Notice of Availability summarizing the results of the Assessment of the implementation of the *L. monocytogenes* Interim Final Rule. The Agency's Lm Assessment Team's report will be posted on the Agency's website to coincide with the publication of this FR Notice.

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