FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

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Assessing the Effectiveness of the "Listeria monocytogenes" Interim Final Rule

Summary Report

This report was prepared by the Agency's *Listeria monocytogenes* Assessment Team. Members of this team were Agency employees who served on one or more Project Assessment Teams (PAT's). Each PAT was assigned to one of seven aspects of the assessment. The Summary Report contains an executive summary of major findings and recommendations, as well as the Agency's accomplishments associated with the implementation of the *L. monocytogenes* interim final rule.

Executive Summary

In January 2004, the Food Safety and Inspection Service (FSIS) assembled a team to assess and measure the effectiveness of the new regulation to control *L. monocytogenes* in ready-to-eat (RTE) meat and poultry products. The *Listeria monocytogenes (L. monocytogenes)* Assessment Team (hereafter referred to as the Team) was charged with identifying these measures of effectiveness as well as making recommendations for further evaluations. This report presents the major findings and recommendations of the Team. This information will be considered in finalizing the interim final rule. The Team also began planning for long term Agency initiatives in the areas of retail sampling, RTE shelf life and public health issues.

The 28-member Team represented staff organizations from the Agency. The Team established an overall project plan and assigned members to smaller Project Assessment Teams (PAT). Each PAT designated a project leader, developed its own project assessment plan, and prepared a report of findings and recommendations for its assigned area addressing one of the seven aspects of the rule.

This Summary Report presents the major findings and recommendations as prioritized by the Team. There are additional findings and recommendations with prescriptive suggestions for implementation in each of the PAT's individual reports (attached).

In general, the Team found that the *L. monocytogenes* interim final rule demonstrated a continual positive impact during its short implementation period from October 2003 to June 2004. Sampling based upon risk has begun and a process is in place to improve the scientific basis for sample selection. Plans are underway to continually improve the Agency's efforts to assure that all size establishments and consumers, especially those at risk, are aware of the necessary actions needed to assure RTE products are produced, labeled, and consumed in a safe manner.

Initiatives are continuing to focus on improving the safety of RTE meat and poultry products at retail deli counters. Information sources are being refined to measure the impact of the Agency's policies on the prevalence of *L. monocytogenes* in RTE product and its relationship to public health. The Team also lays the groundwork for future Agency initiatives in retail food handling safety and monitoring the prevalence of *L. monocytogenes* in RTE meat and poultry products to protect the public health.

Establishments are aware of, and responding positively to the new rules. FSIS intends to update the economic impact analysis for the final rule using, among other sources, data from FSIS Form 10,240-1, Production Information on Post-Lethality Exposed Ready-to-Eat Products, which will help measure the capital costs of the alternative compliance approaches. Inspection personnel were trained and are carrying out their responsibilities to ensure compliance. However, additional training needs of inspection personnel are being identified and prioritized.

The Team recommends new initiatives and continued improvement in the Agency's efforts. A new focus on the baseline sampling to support risk analysis is suggested. *L. monocytogenes* labeling statements and a consumer education campaign based upon an analysis of focus group research results is needed. The Team also sees significant potential for the Agency to undertake regulatory and other strategies needed to reduce the prevalence of *L. monocytogenes* at retail deli counters.

To assure that the Agency's regulatory strategies continue to protect the public health, the Team identified three important sources (National Surveillance Data, Outbreak Data, and FoodNet Data) of illness information about the occurrence of listeriosis in the U.S. population and, in some cases, the food vehicle responsible for those illnesses. The Team suggests the need for periodic analysis of this data to create a listeriosis profile and to make recommendations of food safety and public health issues.

Recommendations have been made to address economic impact, training needs, and communications with small businesses. Priorities are listed to provide training to a large number of inspection personnel with ideas on how to expand the Agency's efforts using cost conscious, proven educational technologies such as web-based training to deliver and track progress. Ideas are also presented to improve efforts to reach small businesses, revise the Agency's Compliance Guidelines, and specifically provide assistance on how to assure products are properly classified as RTE.

The Agency provided a briefing on the Team's activities to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) during its June 2004 meeting and obtained its suggestions. The Team's PATs incorporated the Committee's advice into their planned activities and their revised reports that are attached to this document.

Major Findings and Recommendations

The following sections summarize the reports of the seven Project Assessment Teams (PAT). Each section presents the findings and recommendations for the respective PAT.

VERIFICATION SAMPLING

Findings

Current Sampling. The Agency continued its sampling program of RTE meat and poultry products and is currently scheduling randomized samples for all RTE establishments and products regardless of risk. The Agency initiated an additional sampling program at the beginning of the 2004 that targets the riskiest product, at the inspector's discretion, within any given establishment.

Conclusions from available *L. monocytogenes* testing data conducted since January 2004 indicate that the prevalence for both sampling programs is essentially equivalent, less than or approximately 1 percent. Interestingly, some low-risk products have been found to be positive for *L. monocytogenes*.

Risk-Based Sampling. Overall, the relative risk posed by RTE meat and poultry products produced by an establishment varies by the type of product (i.e., deli meat versus dry sausage) and the type of process controls in place after the lethality step.

The Agency's *L. monocytogenes* Risk Assessment (FSIS 2003) indicated that use of both post-lethality interventions and use of growth inhibitors has the greatest impact on lowering the risk of illness/death from *L. monocytogenes* in RTE meat and poultry products. The next category is the use of post-lethality interventions or growth inhibitors, followed by testing and sanitation of food contact surfaces.

Recommendations

Current Sampling. Modifications to the current sampling program should be made to drive sampling toward baseline surveillance. This allows FSIS to gain knowledge of the pattern of occurrence and potential of occurrence in a community. This will enable the Agency to develop ways to control and prevent disease in a community and collect data to accurately track trends and improvements in *L. monocytogenes* prevalence from year to year.

The current Agency sampling program should also be modified to be consistent with the baseline study design using weighted sampling based on production volume or weighted estimate analysis after the fact.

Risk-Based Sampling. Currently, the Agency is working to complete a risk-based sampling scenario that will be used to revise the Agency's Verification Sampling program, as discussed by the *L. monocytogenes* interim final rule. This scenario will take into account the special needs of small businesses with respect to production volume while protecting the public health.

Currently under development is a model that categorizes production into the three alternatives categorized by the *L. monocytogenes* interim final rule. This model is being developed incorporating the risk analysis of the available management interventions such as: testing frequency, number of consecutive positives prior to product testing (test-and-hold), sample size and other factors. This work will develop and incorporate a quantitative risk assessment using the three alternative categories presented in the *L. monocytogenes* interim final rule.

It is likely that other risk factors contributed to *L. monocytogenes* contamination, but the available data precludes this analysis for the present. These factors might include construction at the processing plant, age of the processing plant, building material used in the plant, and degree of separation of incoming product with post lethality treated product.

Other Recommendations. If a sample is found to be positive for *L. monocytogenes* after testing by the Agency, inspection personnel should evaluate the establishment's Hazard Analysis and Critical Control Points (HACCP) plan, Standard Sanitation Operating Procedures (SSOP), and prerequisite programs to confirm that the establishment's proposed corrective actions appear reasonable and insure that the establishment begins environmental testing.

Standardizing the test sampling procedure is inherently difficult. Agency inspection personnel may use discretion when selecting samples and performing sampling techniques. Each plant is a unique environment that affects the development of a standardized and statistically-based approach to sampling procedures and the analysis of sampling results. The introduction of Agency microbiologists in each of the Agency's District Offices should bring additional uniformity to the sampling process and mitigate this problem.

The Agency should conduct Intensified Verification Testing (IVT) of Food Contact Surface (FCS) and Environmental Sampling in response to samples tested positive for *L. monocytogenes*. These test results should not be incorporated into monitoring or baseline data.

IVT should be triggered when product or contact surfaces test positive for *L. monocytogenes* (for all alternatives presented in the *L. monocytogenes* interim final rule). IVT should also begin if continuing sanitation issues are identified by Agency inspection

personnel, or when multiple contact or product positives for *Listeria* spp. or *Listeria*-like organisms occur.

The Agency should conduct an annual survey of establishments to gather information on production volume and the *L. monocytogenes* control alternative presented in the *L. monocytogenes* interim final rule selected by establishments that produce RTE meat and poultry products. This information should be incorporated into the establishment profile captured by the Performance Based Inspection System (PBIS).

The Agency should verify whether growth inhibition ingredients or anti-microbial agents (AMAs) are used appropriately and that product incorporating such ingredients does not provide an opportunity for significant microbial outgrowth. One option to assure compliance may be for inspection personnel to review the establishment's documentation of any AMA validation study conducted, the parameters used and the study's findings.

The Agency should design an audit procedure based upon the Agency's *L. monocytogenes* guidelines. Assuming the Agency adopts such a procedure, the Agency can use its Food Safety Regulatory Essentials (FSRE) training program (FSRE) or other approaches to ensure that effectiveness of an establishment's Standard Sanitation Operating Procedures (SSOP) are adequate to control *L. monocytogenes*.

LABELING/CONSUMER EDUCATION

Findings and Recommendations

Labeling. The industry is not currently using *L. monocytogenes* incentive labeling statements. The incentive labeling provision should remain in the final version of the *L. monocytogenes* interim final 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.

Consumer Education. The Agency actively continues to base its consumer education messages on the latest available science and incorporates social marketing and educational principles to reach their targeted at-risk audiences for *L. monocytogenes*.

The *L. monocytogenes* interim final rule stated that in addition to providing education on safe handling of food, the Agency would provide information to consumers regarding new labels that processors may voluntarily use to inform consumers of interventions used to reduce contamination. By continuing these outreach efforts and conducting focus

group research, the Agency should be able to develop a consumer education campaign on incentive labeling.

RETAIL ASPECTS

Findings

Evidence indicates that slicing and packaging of luncheon meats at retail deli counters presents a significant source of exposure to *L. monocytogenes*. Prevalence reported from these sources ranges from 3 to 5 percent in deli meat sliced at retail. Further studies of this are needed, since the samples that produced these data were insufficient for statistical analysis.

Delicatessen operations present a potential public health concern but are not currently under the active purview of the Agency. Retail delis complied with all Food Code controls 73 percent of the time. Proper holding time and temperature were observed over 43 percent of the time. The opportunity for equipment to become contaminated was seen over 79 percent of the time. These are critical controls for *L. monocytogenes* in RTE food.

Recommendations

The Agency should increase comparisons of the levels of *L. monocytogenes* in RTE meat and poultry products at the establishments producing these products with the levels of *L. monocytogenes* after the products are sliced at retail. The result of this assessment will provide data on 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 risk factors such as retail sanitation, product co-mingling, and product formulation.

Two possible Agency strategies to mitigate risk in retail establishments are suggested:

Food Service and Retail Training. This effort should focus specifically on *L. monocytogenes* issues, pertaining to proper sanitation, refrigeration, and products of concern (for example, uncured poultry rolls).

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

Findings

The Public Health PAT reviewed data on human illness caused by listeriosis and determined that there are three important sources of illness information. Each of these data sources provides useful information about the occurrence of listeriosis in the U.S. population and, in some cases, the food vehicle responsible for those illnesses.

Recommendations

National Surveillance Data. The Center for Disease Control (CDC) issues an annual surveillance summary of nationally reported diseases that represents the national case count of such illnesses. This report contains retrospective data with a two year surveillance lag. The surveillance system provides data on the numbers of cases, incidence rates (cases per population), and demographic profile (age, race, sex, ethnicity, and geography). The Agency should review this data to update listeriosis patient profiles.

Outbreak Data. The CDC also maintains the Electronic Foodborne Outbreak Reporting System (EFORS). This data results from summary reports on outbreaks that were investigated by State public health agencies. Although EFORS data may be incomplete, investigated outbreaks provide the best opportunity to identify the food vehicle associated with illness. As the quality of this data improves, the Agency should match cases with food products. This data along with the information collected from the case interview form for lab-confirmed cases may enable the Agency to correlate changes in its regulations with changes in illness. The Agency should also periodically analyze the EFORS data for other opportunities to construct policy to reduce the levels of listerosis.

FoodNet Data. The Agency should participate in the analysis of FoodNet[1] data. The core activity of FoodNet is to collect all laboratory confirmed cases of foodborne illness, as well as track the trends in such illness. Although FoodNet data may not be nationally representative, it provides a rough estimate of the U.S. burden of illness, specifically, the incidence of laboratory confirmed listeriosis. For example, in 2003 there were 629 cases of listeriosis provisionally reported to CDC (data is not final), yet the FoodNet incidence rate for listeriosis (3.3 cases/1 million) provides an estimate of 951 cases. Thus, FoodNet may provide a more precise measure for monitoring trends in listeriosis. FoodNet also conducts epidemiological studies comparing illness cases to healthy controls. This provides a way of identifying demographic characteristics of food exposures that are associated with illness. Such ongoing studies allow the identification of emerging food vehicles for pathogens that cause foodborne illness, including *L. monocytogenes*.

ECONOMIC IMPACT

Findings

Establishment profile data shows a slight increase in the number of federally inspected establishments producing RTE meat and poultry product since the publishing of the *L. monocytogenes* interim final rule. There are approximately 2,983 federally inspected establishments currently producing RTE meat and poultry products.

Compliance with the *L. monocytogenes* interim final rule, as measured by PBIS noncompliance data indicates that approximately 76 percent of establishments subject to the rule received no Noncompliance Records (NRs) related to *L. monocytogenes* between October 6, 2003 and July 7, 2004. The majority of the *L. monocytogenes*-related NRs (about 53 percent) concern fully-cooked, perishable products.

Approximately 51 percent of all establishments that produce RTE products are classified under the HACCP regulations as very small. About 56 percent of all *L. monocytogenes*-related NRs have occurred in these very small establishments.

FSIS Form 10,240-1, "Production Information on Post-Lethality Exposed Ready-to-Eat Products", will be used to collect data from establishments regarding alternatives they use to control *L. monocytogenes*, the types of RTE products produced, and volumes of the production. This information will enable the Agency to update the initial findings used in preparation of the economic impact analysis of the *L. monocytogenes* interim final rule to determine capital costs of the alternatives available to establishments to control *L. monocytogenes*. This form will be a more reliable source for this type of information than inference from NRs. This data will also enable Agency economists to examine the specific variables suggested by National Advisory Committee on Meat and Poultry Inspection (NACMPI) when estimating cost of compliance.

Recommendation

The Economic Impact PAT was established to support the revision of the Economic Impact Analysis conducted for the *L. monocytogenes* interim final rule. The PAT recommends further data gathering to support that analysis in preparation of the final *L. monocytogenes* regulation.

TRAINING

Findings

Training provided to the Agency inspection workforce to aid in implementation of the *L. monocytogenes* interim final rule included a CD-ROM which focused on the *L. monocytogenes* interim final rule and FSIS Directive 10,240.4, "Verification Procedures for the *Listeria* monocytogenes Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program", dated 10/03/2003. A smaller pool of inspection personnel were provided with more in-depth training including Food Safety Regulatory Essentials (FSRE) classroom training, Intensified Sampling Training, and Enforcement, Investigations, and Analysis Officers (EIAO) training. The Agency plans to provide additional training when the *L. monocytogenes* Final Rule is issued.

In April 2003, the Agency developed and presented a course in College Station, Texas to approximately 35 EAIOs. The course, "Intensified Verification Sampling Training" covered regulations pertaining to *L. monocytogenes*. This course also provided an overview of *L. monocytogenes* and presented techniques used in aseptic sampling that included a sampling practicum, as well as other information related to sampling.

A survey conducted by the Training PAT indicated that the District Managers felt the implementation of the *L. monocytogenes* interim final rule is progressing well. They recommended that the Agency should continue to distribute new information on *L. monocytogenes* as it becomes available. Although the amount of Intensified Sampling conducted by Districts varied, the District Managers felt that the number of trained inspection personnel currently available is adequate to address the sampling needs in their District. District Mangers also informed on *L. monocytogenes* issues by attending the industry workshops, reviewing the video for the industry workshop, reading the directive and attending briefings by members of their District Office staff. Although training within individual districts by the Districts Offices varied, District Managers rely on the FSRE training of the Consumer Safety Inspectors (CSI) to implement the *L. monocytogenes* interim final rule and the associated Agency directives and to train District inspection personnel.

Recommendations

FSRE training should be provided to all CSIs. The Agency should consider training all in-plant supervisors in FSRE. In addition, CSIs who completed FSRE prior to October 2003 and employees who have not had the opportunity to attend FSRE training should attend this course. Training could be facilitated through technologies such as interactive CD-ROM modules. When the rule is finalized, this CD-ROM training module should include the full text of the final rule, related 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 NR related to

noncompliance with the *L. monocytogenes* requirements. One alternative for the delivery of *L. monocytogenes* training to the workforce would be the use of web-based training. This delivery mechanism for training offers an interactive format and delivers the training much like training delivered by CD-ROM, but enhances this method of training by enabling the use of a "Question and Answer" format.

The Agency should establish a certification program in the methodology for performance of intensified and specialized sampling. Certification would require successful mastering of the subject's knowledge and the demonstration of the correct application of sampling techniques and other requirements.

If it is not possible to certify all EIAO inspection personnel, an alternative is to develop a cadre of EIAO's to be certified within each District based upon the number of RTE establishments within the District. Once data is obtained on the alternative selected by establishments producing RTE meat and poultry product as required by the *L. monocytogenes* interim final rule, this information may also provide a means to assure an adequate number of EIAO certified to conduct sampling. Having qualified and certified inspection personnel to serve as experts in intensified sampling would enhance the Agency's ability to conduct enforcement actions if required.

It is recommended that all future training covering *L. monocytogenes* be tracked and mechanisms be put in place to document the successful completion of required training. The Agency currently has such tracking mechanisms in place such as "Aglearn" that may be adapted to track *L. monocytogenes* training.

SMALL PLANT GUIDANCE

Findings

The majority of the small and very small plants did not receive or were unaware of the Agency Compliance Guidelines document associated with the *L. monocytogenes* interim final rule. Of the small and very small establishments that did receive the Agency's Compliance Guidelines, many needed additional guidance to understand the recommendations or experienced difficulty complying with the rule. For example, some of these establishments also needed guidance when considering whether their product met the criteria of RTE and whether the rule pertained to their operations.

Recommendations

FSIS should recognize that very small establishments face special challenges when attempting to comply with new requirements. To meet the needs of these establishments, the Agency should develop outreach to assure that new information is received 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. Some small and very small establishments do not have capability or expertise to access documents posted on the Agency's Website.

The Agency should also conduct additional workshops targeting small and very small establishments. These workshops should be scheduled well in advance of the publication of the final *L. monocytogenes* rule.

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 on how to reclassify their products from RTE to non-RTE products.

Agency Accomplishments

The Team was requested to catalog the significant accomplishments of the Agency during the implementation of the *L. monocytogenes* interim final rule. The accomplishments listed are not exhaustive but representative of the Agency's efforts to assure understanding of inspection personnel and the industry's compliance with the new requirements.

Inspector Survey

The Agency surveyed 1,490 Inspectors-in-Charge (IIC) who cover the over 2,900 establishments that produce RTE meat and poultry products to see if the establishments had made improvements to their *L. monocytogenes* controls since October 6, 2003. Overall, more than 87 percent of these establishments indicated at least one change to their process. In addition, about 59 percent of the establishments in the survey started sampling for *Listeria* or *Listeria*-like organisms on direct food contact surfaces and 27 percent of the establishments in the survey began using an anti-microbial agent or other control process in one or more of the RTE products they produced. Finally the survey indicates that over 17 percent of the establishments initiated the use of a post-lethality treatment in their RTE production process.

Verification Sampling

The Agency's current sampling program of RTE product schedules randomized samples for all establishments producing such product regardless of risk. From January 1, 2004 to June 6, 2004, 345 samples have been tested with three samples testing positive for *L. monocytogenes*.

The Agency also initiated an additional RTE product sampling program at the beginning of the 2004 that targeted the riskiest product, at the inspector's discretion, within any given establishment producing RTE meat and poultry product. As of June 6, 2004, 1,349 of these samples have been tested with 11 samples testing positive for *L. monocytogenes*.

Consumer Education

The Agency actively continues to base its consumer education messages on the latest available science and incorporates social marketing and educational principles to reach their targeted at-risk audiences for *L. monocytogenes*.

The Agency continued to distribute its consumer education messages using multi-media channels; e.g. the Hispanic Radio Network, the USDA Food Safety Mobile, "TodoBebe" (Telemundo Television Network), radio tours, Web sites, and community health fairs.

The Agency assisted in revising "Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health-Care Professionals"[2] to include a major section on *L. monocytogenes*. The Agency also published a Spanish version of "Listeriosis & Pregnancy: What is Your Risk" printed in April 2003 and posted it on the Agency Web site. The Agency updated *L. monocytogenes* information through The Food Safety Educator, EdNet and other e-communications. The Agency's *L. monocytogenes* flyer aimed at pregnant women was developed and revised to reflect the latest *L. monocytogenes* risk assessment.

Agency staff members also participated in a joint effort with FDA and CDC to publish a comprehensive booklet on *L. monocytogenes* aimed at all the at-risk groups. The Agency is developing a series of educational materials for at-risk audiences, beginning with transplant patients, the first to be posted on The Agency Web site in September 2004 for National Food Safety Education Month[SM].

Retail Aspects

FSIS attended the Conference for Food Protection (CFP), presented a summary of the Agency's recent efforts to combat *L. monocytogenes*, and included guidance material based upon recent risk assessments. FSIS employees also served on a CFP committee tasked with developing guidance on the control of *L. monocytogenes* for retail food operations. This guidance will be incorporated into the FDA Food Code, a model set of food regulations that has been adopted by more than 40 states and territories in the United States of America.

Training

The Agency produced and distributed a CD-ROM covering the requirements of the *L. monocytogenes* interim final rule for use by the inspection workforce. The Agency developed and presented a classroom course on intensified verification sampling for *L. monocytogenes* in April 2003 to approximately 35 EIAOs.

The Agency also developed and conducted the Food Safety Regulatory Essentials (FSRE) course that addresses *L. monocytogenes* in RTE meat and poultry products. The course is offered routinely and made available to all CSIs.

Small Plant Guidance

The Agency conducted Workshops targeted for plant operators of small and very small establishments prior to the implementation of the rule. The Agency updated the Agency's Compliance Guidelines to include responses to questions received at the workshops and by Agency staff members at the National Technical Services Center located in Omaha, Nebraska.

The Agency revised FSIS FORM 10,240-1, "Production Information on Post-Lethality Exposed Ready-To-Eat (RTE) Products", based upon comments received from industry groups to assure its ease of proper completion by establishments.

Agency staff members made presentations on the *L. monocytogenes* interim final rule to trade organizations, retail organizations, and at public meetings. The Agency submitted an article to the Conference for Food Protection that was successfully approved and included guidance to revise the Food Code to include methods to control *L. monocytogenes* at retail. The Agency also took steps to assist companies and food processing establishments by sharing information on methods and equipment used in post-lethality treatments, anti-microbial agents, sanitation, and other *L. monocytogenes* control procedures. The Agency also established a method for establishments to present their experiences with new methods and technology and their findings to the Agency.

Endnotes

[1] FoodNet is an inter-Agency collaboration among CDC, FSIS, the Food and Drug Administration (FDA), and 10 State and local health departments.

[2] The Primer was produced collaboratively by the American Medical Association (AMA), the American Nurses Association (ANA), the Centers for Disease Control and Prevention (CDC), the Center for Food Safety and Applied Nutrition-Food and Drug Administration (CFSAN-FDA), and the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture. This primer is intended to provide health care professionals with current and accurate information for the diagnosis, treatment and reporting of foodborne illnesses. The primer also provides health care professionals with patient education materials on prevention of foodborne illness.

Attachments

A. *Listeria* Assessment Aspects
B. Project Assessment Team Reports

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Attachment A

Listeria Assessment Aspects

Purpose: to identify how to assess and measure the effectiveness of the new regulation, Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products; 68 Federal Register, 34208; June 6,2003. The Agency will use this information in finalizing the interim final rule.

Seven Aspects
Verification Sampling • Short term alternative to survey based frame • meets the special needs of small business • focus on high risk products • target large volume establishments
Labeling/Consumer Education • incentive based labeling • consumer education • vulnerable groups
Retail Aspects • potential risk assessment • true prevalence on meat and poultry products at retail
Public Health • the impact of the rule on public health? • what will it take to demonstrate future impact?
Economic Impact • Verification of the assumptions made for the interim rule
Training • An explicit and well-articulated plan to evaluate inspection personnel training
Small Plant Guidance • Are the compliance guidelines assisting small business to meet the requirements

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Attachment B

Project Assessment Team Reports

Sampling Verification

I. Purpose

Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products (1), FSIS Interim final rule, states that FSIS will move toward targeted, risk-based sampling. In this action, the Agency is recognizing differing levels of risk posed by ready-to-eat (RTE) products produced under Alternatives 1, 2, or 3. This PAT was charged with understanding the current sampling scheme, analyzing effectiveness of the Interim Rule, describing the movement of the industry since implementation of the Rule, and making recommendations for Rule and sampling scenario modifications.

The PAT also provides plans for risk analysis that incorporate advice from The National Advisory Committee on Meat and Poultry Inspection (NACMPI) that FSIS should focus on assessment of the three alternatives presented in this report and evaluate their effectiveness for risk mitigation.

II. Major Findings and Recommendations:

A. Current Sampling: Assessment and Suggested Modifications

Current activities:

ALLRTE currently provides a randomized sampling program for all RTE regardless of risk. However, the current implementation does not provide a sound scientific basis for trend analysis because it is not based on relative production volume. Year to date for 2004**,** 345 samples have been tested in ALLRTE, with 3positives.

At the beginning of the 2004, an existing program called "Target" was replaced with a program called "RTERISK1". RTERISK1 targets the riskiest product, at the inspector's discretion, within any given establishment. As such, it provides some focus on public health priorities but is not ideal. Year to date 2004, 1349 samples have been tested in RTERISK 1, with 11 positives.

Conclusions from *Lm* testing data in CY2004- Apparent prevalence for both sampling programs is essentially equivalent, less than or approximately 1%. Interestingly, some low-risk products have been found to be positive for *Lm*. OPHS is still awaiting data on the identity of some of these products.

Issues for consideration with current sampling program:

1. Baseline surveillance is "the systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis, data which is a description of existing conditions to provide a starting point against which progress can be

assessed or comparisons made, for the purpose of gaining knowledge of the pattern of occurrence and potential in a community, in order to control and prevent disease in the community". This is not what the current program provides. Modifications should be made to drive sampling toward this goal.

2. Provide data to accurately track trends and improvements in *Lm* prevalence from year to year. Because prevalence based on relative production volume is more likely to correlate with incidence of illness, the current ALLRTE monitoring program should be modified to be consistent with baseline study design; i.e., weighted sampling based on production volume or weighted estimate analysis after the fact. Redesigning ALLRTE as a baseline is intended to provide Agency management with a reliable tool for tracking progress on product *Lm* prevalence.

3. Sampling should confirm acceptable performance by a given establishment.

4. Surveillance will provide data for refining targeted sampling plans, risk assessments, and regulatory policies.

5. Sampling increases incentive for establishments to implement interventions, to reduce the burden of sampling and to reduce the likelihood of positives in those samples.

A statistically based program (as opposed to random regulatory monitoring) will provide highly reliable annual data on *Lm* prevalence for RTE products as a whole (i.e., all risk groups, cook-in-bag to Alternative 3). Baseline data illustrates a simple picture of a plant on a given day. The composite picture of 2450 plants will provide a movie of reality.

B. Risk Based Sampling: Preliminary Conclusions and Directions

Risk Factors Identified for *L. monocytogenes*

In a prior review of the draft FSIS Directive 10,240.4, several risk factors (e.g., product type, etc.) were identified based on the FSIS *Listeria* risk assessment and the FDA/FSIS risk ranking. These risk factors can be used to support risk-based allocation of inspection resources. Overall, the relative risk posed by RTE meat and poultry products produced by an establishment is due to the type of RTE meat and poultry product produced (i.e., deli meat versus dry sausage) and the type of process controls in place after the lethality step, but not the volume produced by the establishment. [Note: volume is not a risk factor because it would assume that the contamination events, operations, etc. are the same among plants. Instead, these other factors override the issue of volume.]

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The following information was used to support the development of language for Directive 10,240.4 for verification for *L. monocytogenes* in RTE meat and poultry products.

1) Risk Based on Type of Product
The FDA/FSIS Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* (*Lm*) Among Selected Categories of Ready-to-Eat Foods (2002) indicated that deli meats posed the greatest per annum risk of illness/death from *Lm*, followed by frankfurters/hot dogs, pate and meat spreads, and dry/semi-dry fermented sausages. Note: Under this category, the use of growth inhibitors (discussed below) could be also considered (rather than under "processing environment").

2) Risk Based on Processing Environments
The FSIS *Listeria* Risk Assessment (FSIS 2003) indicated that use of post-lethality interventions and use of growth inhibitors has the greatest impact on lowering the risk of illness/death from *Lm* in RTE meat and poultry products, followed by use of post-lethality interventions or growth inhibitors, and testing and sanitation of food contact surfaces (highest to lowest frequency).

The Interim Final Rule categorizes RTE meat and poultry product into three alternatives depending in their use of post lethality processing, antimicrobial agents and targeted sanitation:

Alternative 1 – Employ both a post-lethality treatment and a growth inhibitor for *Listeria* on RTE products. Establishments opting for this alternative will be subject to FSIS verification activity that focuses on the post-lethality treatment effectiveness. Sanitation is important but is built into the degree of lethality necessary for safety as delivered by the post-lethality treatment.

Alternative 2 – Employ either a post-lethality treatment or a growth inhibitor for *Listeria* on RTE products. Establishments opting for this alternative will be subject to more frequent FSIS verification activity than for Alternative 1.

Alternative 3 – Employ sanitation measures only. Establishments opting for this alternative will be targeted with the most frequent level of FSIS verification activity. Within this alternative, FSIS will place increased scrutiny on operations that produce hotdogs and deli meats. In a 2001 risk ranking, FSIS and the Food and Drug Administration identified these products as posing relative high-risk for illness and death.

The current FSIS risk assessment based its categorization on plant size as defined by USDA, which is based on the number of employees. A preliminary analysis was also prepared that categorized plants based upon production volume. Currently under development is a model that categorizes production into these three proposed alternatives. The current scope of work requires the development of such a model along with a risk

analysis of the available management interventions: testing frequency, number of consecutive positives prior to product testing (test-and-hold), sample size, etc.

It is likely that other risk factors are present for *Listeria monocytogenes* contamination, but the available data precludes their analysis for the present. These factors might include construction at the processing plant, age of the processing plant, building material used in the plant, and degree of separation of incoming product with post lethality treated product. This work will develop and analyze a quantitative risk assessment using the three alternative categories. It will build upon the existing FSIS risk assessment model and the FDA/FSIS risk ranking model.

Due in mid-summer 2004, OPHS scientists are working to complete a risk-based sampling scenario, as described here. This scenario will be presented to Agency managers for use in drafting a Verification Sampling program, as called for by the Interim Final Rule. Many of the recommendations presented in this PAT report are in line with the expected outcome of that work. Indeed, the efforts and activities of this PAT will not cease with the submission of this report. Much is left to be done.

III. Continuing Goals of the Verification Sampling PAT

- Refocus sampling on high risk products/as determined by Risk Assessment and Alternatives1, 2, 3.
- Risk-based activity needs to take priority: target large volume establishments/ most potential exposure.
- Outline a method for conducting verification testing until the Survey form clears and is answered.
- Make explicit provisions for avoiding bias in verification testing towards very small production operations: a goal of 10 percent of the verification testing could include high-risk products from this very small production segment.

IV. Background

To protect public health, FSIS is seeking to focus testing and surveillance for *Listeria monocytogenes* in a science-based, risk-prioritized manner, along the requirements outlined in Agency Rules and Directives, to ensure that regulatory controls for *L. monocytogenes* are serving at expected levels of success.

FSIS issued *Directive 10,240.4 Verification Sampling* Verification Procedures for the *Listeria monocytogenes* Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program.
This “Risk-based” sampling is interpreted as stratifying the total population of servings based on the associated risk and public health impact.

The Risk Assessment Division of OPHS is currently working to develop and analyze a quantitative risk assessment using the three alternative categories. It will build upon the existing FSIS risk assessment model and the FDA/FSIS risk ranking model. The results of this Risk Assessment will not be available until mid-summer 2004.

Some historical information to keep in mind when considering a Verification Sampling Program:

Microbiological Testing for Listeria monocytogenes in RTE Meat and Poultry Products. Since 1987, FSIS has randomly sampled and tested RTE meat and poultry products produced in federally inspected establishments for *L. monocytogenes*. Such products testing positive for *L. monocytogenes* are considered "adulterated" under the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA) (21 USC 453(g) or 601(m)). The combination of declaring *L. monocytogenes* in RTE meat and poultry products an adulterant and continued microbiological sampling of these products for *L. monocytogenes* may have contributed to the 44 percent decline from 1989 to 1993 in the rate of illness from *L. monocytogenes*.

FSIS Notice/Listeria monocytogenes in HACCP Plans. In February 1999, during a large outbreak of listeriosis associated with hotdogs and deli meats, FSIS issued a notice advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to ensure that the plans were adequately addressing *L. monocytogenes* (64 FR 27351). FSIS believes that *L. monocytogenes* contamination is reasonably likely to occur in the production of <u>all</u> RTE meat and poultry products.

Environmental Testing for Listeria spp. FSIS acknowledges that there may be certain processing environments in which *L. monocytogenes* is not a hazard reasonably likely to occur and it is therefore not addressed in an establishment's HACCP system. FSIS believes that in such establishments, verification through microbiological testing of food contact surfaces to ensure the establishment's Sanitation SOP in controlling *Listeria spp.* would be necessary, at a minimum. FSIS believes that were an establishment to find *Listeria spp.* on a food contact surface, that finding would be indicative of a sanitation problem that could cause potential adulteration of the product (e.g., cross-contamination). FSIS is also proposing to require that establishments take certain actions after food contact surfaces test positive for *Listeria spp.* (e.g., those defined in its Sanitation SOP according to §416.5).

Proposed RTE Rule. On February 27, 2001 FSIS issued a proposed rule (66 FR 39:12590-12636) to require that all establishments that produce RTE meat and poultry products conduct environmental testing of food contact surfaces for *Listeria spp.* after lethality treatment and before final product packaging. The focus on the non-pathogenic indicator is made because these organisms will be found more frequently in the environment than *L. monocytogenes* and because test results are

available more quickly. Finding *Listeria spp.* would be indicative of a sanitation problem even though the contaminant may not be *L. monocytogenes.* The establishment and FSIS will use the test results to verify the efficacy of the establishment's "Sanitation SOPs" in preventing RTE product contamination by *L. monocytogenes.* FSIS also suggested an increased frequency of *Listeria spp*. testing on food contact surfaces for larger establishments. Since neither the suggested frequency of testing nor the relationship between testing for *Listeria spp.* on food contact surfaces and *L. monocytogenes* on the product was based on published scientific data, the agency requested comment from the public regarding this ruling.

V. Summary Recommendations

A. Suggested **Response to an *Lm*-positive Sample**

If a sample is found to be positive for *L. monocytogenes* by FSIS testing, ideally a set sequence of events should occur. A standardized approach best informs all parties, both regulatory and not, of the expectations, provides the most rapid resolution of the establishment's problem, provides for consistency and fairness, and allows for the most rapid and complete response in protecting the public health.

This response should begin with the CSO for the relevant DO who will evaluate the HACCP, SSOP and prerequisite programs of the establishment. The CSO then confirms proposed corrective actions appear reasonable, consulting OPHS if necessary. CSO takes IVT FCS/environmental samples (total number based on number of relevant lines, i.e., past OPHS guidelines).

For first production lot after corrective actions, FSIS should analyze samples consistent with ICMSF; Case that is consistent with Compliance Guidelines recommendations (e.g., Case 12 for Alternative 3 product distributing to general population).

a. n = # number of samples taken
b. for each sample (product?), one 25-g portion is analyzed by FSIS lab. Up to four samples may be composited (125 g total, Curiale et al.). For Case 12, that would be four 125-g test portions each representing five retail units (i.e., at least 20 packages taken by the inspector).
c. For a second *Lm*-positive finding within a set of 10 subsequent sample tests:
    1. FSA Team would evaluate establishment records, plans and activities.
    2. The establishment would be removed from the applicable targeted testing program above and temporarily placed into the intensified testing program (INTRTE).
        a. One 2-lb sample collected each month for 10 months

b. FSIS lab analyzes each monthly sample according to ICMSF Case consistent with Compliance Guidelines recommendations (see above).
c. Special consideration should be given to circumstances where plant fails again. Extraordinary measures may be required.

B. Suggested Food Contact Surface (FCS) and Environmental Sampling

There is clear value for establishments to conduct FCS and environmental testing to identify possible sources of contamination in the processing environment. FSIS should conduct IVT FCS/environmental testing in response to *Lm*-positive findings, but this testing is not appropriate for monitoring or baseline purposes.

Standardizing the test sample and procedure is inherently difficult. CSOs may introduce bias in choice of sampled area and sampling technique. Each plant is a unique environment, which confounds development of a standardized and statistically based approach to sampling or data analysis. As the number of tested establishments increases, the statistical differences may decrease. The introduction of staff microbiologists in each district would mitigate this problem (more detail to follow).

MLG Chapter 8.03 (i.e., FSIS lab method) may not be ideally suited to this analysis as opposed to product testing. Products are often protective of sublethally injured *Lm*. In contrast, the presence of sanitizer residues in *Lm* sponge samples, even with "neutralizing agents", might be relatively more difficult to detect. Establishment might heavily sanitize surfaces and mask problems easier in the environment than in product. The MLG method provides instruction for sponge analysis but has never been validated for this purpose compared to other potential methods.

What should trigger Intensified Verification Testing (IVTs)?

1. Product or contact surface *Lm* positives (for all alternatives).

2. Continuing sanitation issues identified by CSO (for all alternatives).

3. Multiple contact or product positives for *Listeria* spp. or *Listeria*-like organisms
   A. For Alt. 3: two or more positives in any one year
   B. For Alt. 2: three or more positives in any one year
   C. For Alt. 1: five or more positives in any one year
4. Multiple positive results from an IVT should trigger a Food Safety Assessment.

While the *Listeria* Rule mentions IVTs, it does not specify when they will occur. Further direction from FSIS managers is needed in order to increase the frequency of IVTs. At present, OFO personnel have been tasked with collecting samples for FSIS. This sampling requires increased training, funding, etc and may detract from other regulatory duties of these personnel. As the agency continues to increase the number of samples collected, workload issues could increase. These issues could be solved, in part, by hiring microbiologists in each District. The microbiologists could collect samples, interact with establishment personnel, and analyze in plant data. They could also communicate information to headquarters, and serve as experts on pathogenic organisms and processing interventions. If an outbreak were to occur they could meet with state health officials, and participate in epidemiological investigations of establishments.

C. Annual Survey – criteria and justifications

An FSIS survey of establishments (summer 2004 projected time to be cleared by OMB) is critical to gather information on production volume and the *Lm* control methods used by establishments that produce RTE meat and poultry products. This data will be used to modify the current FSIS *Listeria* risk assessment to evaluate risk-based verification sampling protocols for deli meats. Sensitivity analyses will include consideration of test-and-hold of RTE product, sample size, etc. Since the FSIS survey of establishments is contingent on OMB clearance, development of a modified assessment for verification sampling, one that incorporates this data, will likely be available Fall or Winter 2004[1]. Such information would be useful for updating FSIS risk-based verification sampling protocol, building off ALLRTE and RTERISK1 programs and the recommendations made by this PAT. This will also capture reductions in prevalence as establishment moves toward Alternative 1 or 2, or new processes where product is no longer exposed in the post-process. Risk-based testing programs are dependent on accurate production volume data. FSIS Management should consider regulatory options for mandating and organizing this information as the establishment profile part of PBIS.

D. Verification of growth inhibition ingredients or antimicrobial agents

To verify that validation efforts for antimicrobial agents (AMAs) were appropriate and that product incorporating such ingredients does not provide an opportunity for significant outgrowth, the most cost-effective option and logistically feasible option is review of establishment documentation on validation study parameters and results. This PAT recommends the following plan:

1. OPHS Microbiology Division develops guidance on expectations for proper validations based on NFPA guidelines currently in development.
2. OPHS provides guidance and perhaps training to CSOs on how to review validation data.

[1] OMB approval has been obtained and the survey was conducted after this report was prepared. FSIS is analyzing the survey results.

3. CSOs screen establishment validation documentation for potential issues.
4. Suspect validation documents are submitted to OPHS MD MIB for further scrutiny.

5. If OPHS finds the validation design or results to be suspect, FSIS could send an OPHS Microbiologist on-site to the establishment to verify establishment practices and/or the private contract laboratory that conducted the testing to verify laboratory procedures and methods.

Antimicrobial agents (AMA)

FSIS could consider a requirement or incentive for FSIS-inspected establishments to formulate cook-in-bag or post-lethality treated RTE with AMA to prevent outgrowth while opened product is in use in the retail deli counter. However, it is unclear whether such a policy would provide a cost-effective public health benefit. With regard to certain high-risk products, there are constraints on the effectiveness of current AMAs, particularly for potential use of lactate/diacetate in product formulation. Establishments that produce certain high-risk products complain that only modest, and therefore likely ineffective, levels of lactate are acceptable for incorporation in to their product. Attempting to inhibit *Lm* outgrowth with greater lactate/diacetate combinations and levels alters the palatability and marketability of the product. Antimicrobial packaging or other antimicrobial surface treatments may not be effective protection for products that are eventually sliced at the retail environment. Therefore, current AMA options may not be an effective for reducing listeriosis from certain high-risk products, when much of the contamination is likely to occur in the retail environment. Other seemingly lower-risk deli products containing AMAs may represent a significant risk in retail settings that are using sub-optimal refrigeration; even with modest temperature increases, AMAs are far less effective in inhibiting outgrowth. In short, options for federally inspected establishments in preventing eventual product contamination and outgrowth in retail operations appear to be limited; regulatory strategies that that attempt to project the responsibility onto FSIS-inspected establishments may not be effective in significantly reducing the likelihood of foodborne listeriosis from products later processed in retail environments.

The Potential Use of Formulation Validation

In general, the only truly effective way to verify validation of an AMA is for FSIS laboratories to duplicate conditions of the reported challenge study using inoculated product held through the shelf life. Such a study may require packaging after inoculation and/or special equipment (e.g., pressure treatment system) that is not readily available to FSIS laboratories (i.e., where the testing would have to be conducted). In the event it is possible to duplicate the industry study, FSIS pursuit of such a study would be resource-intensive and is not likely to be cost-effective as routine policy.

FSIS may want to explore quantitative re-testing of products found to be *Lm*-positive from regulatory qualitative testing. Although this would not necessarily address the

validation study conducted by a specific establishment or their laboratory, such a study would provide valuable data for refining risk assessment conclusions in the future.

Furthermore, product found to be positive and quantified could be held until the shelf life date for an additional quantitative test, which could provide some information on the potential for outgrowth in that product under refrigerated storage conditions.

Although such testing would likely have value, data would have to be evaluated with caution. Each of the three tests required above would represent different test portions with potentially different levels of contamination; in fact, it is not uncommon for quantitative follow-up tests of companion samples to be negative due to heterogeneous and sparse levels of *Lm*. Using multiple or larger test portions may reduce the problem to some extent, but a limited amount of product reserve may be available for repeating the tests. Despite these obvious limitations, a policy of testing products that may represent a higher risk for outgrowth may provide useful data for future Agency efforts. OPHS MD/MIB and the FSIS laboratory system could coordinate these testing activities.

In the past (i.e., early 1990s), FSIS investigated potential disparities in prevalence for recently produced product vs. the same product held to the shelf life date. This study was unable to conclude that there was a significant increase in *Lm* prevalence for refrigerated products held to their shelf life date. As the study proposed above, this past study was not intended to address product validation for a specific establishment and product.

E. Assess the effectiveness of Sanitation SSOPs

The Agency requires additional information regarding the status of SSOP programs in plants producing RTE meat and poultry products.

Recommendations: Design an audit for SSOPs. The audit can be used by agency personnel to determine whether an establishment's SSOPs are adequate to control *L. monocytogenes*. The audit can be based on FSIS *L. monocytogenes* Guidelines.

VI. FSIS RTE Verification Sampling, 2004: *A brief overview*

In January 2004, FSIS began two sampling projects, ALLRTE and RTERISK1. All establishments with HACCP process categories 03E, 03F, 03G, or 03I, but not the "No RTE" block checked in their plant profile were put into the sampling frame for each of these projects. There were approximately 2500 establishments meeting these criteria.

In ALLRTE, each establishment has an equal chance of being selected each month. A predetermined number of establishments are selected, and one sample request form sent to the IIC at each selected establishment. On that form, instructions are provided to select randomly a product to sample from among all rte products produced at that establishment, with the exception of the products identified in the exemption list below. The sample is collected and sent to the FSIS laboratory for analysis. All samples are analyzed for the presence of *Salmonella* sp. and *Listeria monocytogenes*; *Escherichia coli* O157:H7 is also analyzed for in dry and semi-dry fermented sausages and fully cooked meat patties.

As of Feb 18, 2004, 129 samples had been analyzed under the ALLRTE project, with 2 (1.55%) positive for *L. monocytogenes*.

In RTERISK1, each establishment has an equal chance of being selected each month. A predetermined number of establishments are selected, and one sample request form sent to the IIC at each establishment. On that form, instructions are provided to select a product to sample according to the priority list outlined in FSIS Directive 10,240.4, page 8. The list is as follows:

If a specific product is not pre-selected for sampling in Block 18 of the sample request form, the CSI should sample products based on the following priority:

a. Post-Lethality Exposed RTE Products under Alternative 3:
   1. Deli meats
   2. Hotdogs
   3. Deli salads, pate, meat spreads
   4. other product

b. If no post-lethality exposed RTE products are produced using Alternative 3 criteria, then sample post-lethality exposed RTE products using Alternative 2 criteria in the following order:
   1. Sample product produced using only a growth inhibitor
   2. Sample product produced using post-lethality treatment

c. If no post-lethality exposed RTE products are produced using Alternative 3 or 2 criteria, then sample post-lethality exposed RTE products using Alternative 1 criteria.

d. If no post-lethality exposed RTE products are produced, then sample any RTE product that is not produced using an antimicrobial agent or process and likely will be used as a deli-type item, such as a cook-in-bag roast beef.

e. If none of the above is available, select any other RTE product.

The sample is collected and sent to the FSIS laboratory for analysis. All samples are analyzed for the presence of *Salmonella* sp. and *Listeria monocytogenes*; *Escherichia coli* O157:H7 is also analyzed for in dry and semi-dry fermented sausages and fully cooked meat patties.

As of Feb 18, 2004, 494 samples had been analyzed under the RTERISK1 project, with 3 (0.61%) positive for *L. monocytogenes*.

Note, the "1" in RTERISK1 does not apply to anything other than it is the first risk-based rte sampling project. It is assumed that the next risk-based rte project would be RTERISK2, etc.

The specific instruction pages for each of these verification sampling projects in FSIS Directive 10,210.1 lists products that FSIS would not be sampling on a regular basis, but would specifically sample if the need were to arise:

> The specific instruction pages for each of these verification sampling projects in FSIS Directive 10,210.1 lists products that FSIS would not be sampling on a regular basis, but would specifically sample if the need were to arise. CSIs are instructed to RANDOMLY select the product to sample from ALL RTE products produced at the establishment, with the exception of the following products: Lard, margarine, lard margarine, mixtures of rendered animal fats, popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, pickled pig's feet, or product labeled "For Further Processing" in which the product is expected to receive a lethality treatment at another federally-inspected establishment. (9CFR430.4 still applies to these products if they are post-lethality exposed)

If a sample from either project is found to be positive for one of the pathogens analyzed for, the District Manager can request follow-up sampling in that establishment. Multiple product, product contact surface, and non-product contact surface, samples can be collected and sent to the FSIS lab for analysis.

Reference:

Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products
http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F.htm

Federal Register: June 6, 2003 (Volume 68, Number 109)][Rules and Regulations][Page 34207-34254] From the Federal Register Online via GPO Access [wais.access.gpo.gov][DOCID:fr06jn03-20]

FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

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FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC
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Listeria monocytogenes Incentive Labeling Assessment

I. Major Finding and Recommendation

The industry is not currently using *Listeria monocytogenes* incentive labeling statements. The incentive labeling provision should remain in the final rule since it provides the industry a means of declaring that their product has undergone post-lethality treatments or was treated with antimicrobial agents or processes to destroy *Lm* and conveys truthful information to the consumer. The Agency should further develop *Lm* labeling statements by conducting focus group research studies to develop statements that would provide flexibility to the industry while still remaining truthful and not misleading.

II. Purpose

To analyze the incentive labeling portion of the interim rule.

III. Goals

To analyze the feasibility of constructing labeling statements that the industry will use and, in conjunction with a consumer education program, will provide accurate useful information.

The PAT also considered advice from The National Advisory Committee on Meat and Poultry Inspection (NACMPI) that FSIS should also assess the effects of incentive labeling activities.

IV. Background

The interim final rule provides for the use of voluntary incentive labeling statements on products that have been treated with an antimicrobial agent or process that eliminates, reduces, suppresses or limits the growth of *Listeria monocytogenes* (Lm) [9 CFR 430.4(e)]. The preamble of the interim rule offered examples of statement that could be made, "Sprayed with a solution of sodium lactate to prevent the growth of *L. monocytogenes*" or "Contains sodium diacetate and sodium lactate to prevent the growth of *Listeria monocytogenes*". Several establishments have submitted labels with *Lm* statements; however, none of the labels used the statements provided as examples and, therefore, were returned for further validation information to substantiate the claims made. To date, the establishments that submitted labels with *Lm* claims have not further pursued label approval. Recently, industry sponsored a survey to evaluate consumer reaction to food safety information statements regarding *Lm.* Industry concluded that the results of the survey show that the use of such statements could be confusing or misinterpreted by consumers. Industry has concerns that these statements could have adverse affects in the marketplace, (e.g., promote

questionable food safety handling practices, drive consumers from food safety enhanced products, or cause a reduction in sales these products).

V. Summary Recommendations

Conduct a two phased focus group research study on food safety labeling statements that would guide the Agency in the development of policy for food safety labeling statements.

Phase I would:

- Assess consumer's perceptions, beliefs, and understanding of meat and poultry labeling features on which they rely for making purchase decisions about the safety of the product, and for food handling/safe preparation, and
- Assess various types of informational labeling that would help consumers choose meat and poultry products that meet their safety concerns and help them understand how to safely handle and prepare the products, including safe handling statements and statements targeting vulnerable populations.

Phase II would:

- Assess the consumer's perceptions of proposed statements and features, and
- Collect views on the extent to which they value or would depend on the specifically designed statements

The research protocol should be developed by the Agency and contracted out, similar to what has been done in the past with RTI for similar research of this type (e.g., conducted in several areas of the country, 4 locations, two groups in each location, one group with a high school education or less and one with individuals that have a college education, include individuals from various age groups, e.g., 8-30, 35-55, and 60 years or older). The LCPS submitted the request for the 2006 budget. If approved, the research would be conducted and completed in 2006.

Findings from the focus group research could be shared with industry or used in an Advanced Notice of Proposed Rulemaking for comment to help guide the development of informative labeling statements that would be useful and valued by consumers. The findings will help the Agency, as NACMPI suggested, to assess the effects of incentive labeling.

VI. Summary Findings

Lm incentive labeling may become a more palatable option for use by the industry if statements could be constructed to provide accurate, non-misleading information in conjunction with promoting the enhanced food safety features of the product.

FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC
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Consumer Education Assessment Report

I. Major Finding and Recommendation

The Agency actively continues to base its consumer education messages on the latest available science and incorporates social marketing and educational principles to reach their targeted at-risk audiences for *Listeria*. The interim final rule also stated that in addition to providing education on safe handling of food, FSIS would provide information to consumers regarding new labels that processors may voluntarily use to inform consumers of interventions used to reduce contamination. Propose to develop a consumer education campaign on incentive labeling following analysis of focus group research results.

II. Purpose

To analyze the consumer education portion of the interim rule.

III. Goals & Accomplishments

To determine if *Listeria* education efforts committed in the interim final rule were carried out.

- Disseminated *Listeria* messages through multi-media channels, e.g. Hispanic Radio Network, USDA Food Safety Mobile, "TodoBebe" (Telemundo Television Network), radio tours, Web sites, local health fairs.
- Completed revision of AMA Primer – with major section on *Listeria* – (made available on April 7, 2004) in cooperation with AMA, ANA, CDC & FDA.
- Spanish version of "Listeriosis & Pregnancy: What is Your Risk" printed in April 2003 and posted on FSIS Web site.
- Updated *Listeria* information through *The Food Safety Educator*, EdNet and other e-communications. (FSIS Web site *Listeria* topics page receives over 3,500 requests each month.)
- Worked on International Life Sciences Institute's (ILSI) risk communication subgroup that developed a blueprint of how to reach key audiences (March 2004.)
- Low literacy *Lm* flyer aimed at pregnant women developed and revised to reflect latest *Listeria* risk assessment.
- Participating in a joint effort with FDA and CDC to publish a comprehensive booklet on *Listeria* aimed at all the at-risk groups (by the end of FY 2004.)
- Beginning with transplant patients, developing a series of educational materials for at-risk audiences, the first to be posted on FSIS Web site in September 2004 for National Food Safety Education Month [SM.]

- The PAT also considered advice from The National Advisory Committee on Meat and Poultry Inspection (NACMPI) that FSIS should continue to work with health professionals to disseminate food safety information.

IV. Background

The interim final rule stated that food safety education is one risk management strategy the Agency uses to reduce the incidence of illness associated with *Lm* in Ready-to-Eat (RTE) meat and poultry products. Safe handling, storage and preparation of RTE meat and poultry products can help reduce the risk of illness, particularly for those populations most at risk of contracting listeriosis: pregnant women, newborns, older adults, people with weakened immune systems caused by cancer treatment, AIDS, diabetes, kidney disease, organ transplants, etc. The Agency reaches these audiences through the USDA Meat & Poultry Hotline, the USDA Food Safety Mobile, the FSIS Website, most recently the Web-based virtual representative (vRep) "Ask Karen," as well as printed material, electronic communication, the media and other information multipliers, in cooperation with other Federal agencies, educators, and healthcare professionals.

V. Summary Recommendations

Continue ongoing targeted consumer outreach beyond FY 2004 that focuses on safe handling, storage and preparation of RTE meat and poultry products for those populations most at risk of contracting listeriosis:

- Continue targeted outreach to at-risk audiences, especially Hispanics and immune compromised individuals, as well as pregnant women, newborns and older adults, through print media, radio, TV, and Web-based and electronic information.
- Continue to develop educational materials using latest scientific information and social marketing principles.
- Continue to explore innovative methods of delivery utilizing the expertise of staff and contractors.
- Continue to provide funding to ensure successful education and outreach programs.
- Continue to leverage resources through partnerships and alliances.
- Focus group research studies to assess effectiveness of *Listeria* messages and impact on consumer behavior(s).
- Continued assessment of effectiveness of delivery methods, and revising/expanding outreach to reach wider target audiences, e.g. through health professionals, health care providers, caregivers, and peer counselors.
- In FY 04, 05 and 06, continue to utilize print media, radio, TV, Web-site, and the USDA Food Safety Mobile in ongoing consumer food safety education and outreach activities.

The success of these consumer education and outreach efforts will be measured by:

- Continued reduction in the incidence of listeriosis cases per CDC Food Net data.
- Monitoring the number of USDA FSIS Web-site hits; questions about *Listeria* to Web-based vRep, "Ask Karen;" electronic mailbox inquiries; publication requests; calls to the USDA Meat & Poultry Hotline, and media tracking reports.

VI. Summary Findings

The *Listeria* consumer education and outreach activities are successfully being carried out as prescribed in the interim final rule.

FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC
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Retail

I. Summary Findings and Recommendations

A. Anecdotal evidence suggests that slicing and packaging of luncheon meats at the retail environment presents a significant source of exposure to *Listeria monocytogenes*. PAT members reviewed the published literature, Gombas et al., as well as unpublished data acquired from New York State. Prevalence reported from these sources ranges from 5-3% in deli meat sliced at retail. Further investigation of this problem is needed, as the sampling frames that resulted in these data were insufficient for statistical analysis.

B. Retail operations are a significant concern for public health but are not currently under the active purview of FSIS. PAT team members reviewed the Database of Foodborne Illness Risk Factors[2], a publication from FDA that present Food Code compliance rates for the critical controls in the retail food setting. The retail delis complied with all Food Code controls only 73% of the time. Proper Holding/Time-Temperature was observed only 43.3% of the time and contaminated Equipment/Protection from Contamination was seen 79.4%. Both of these are critical controls for RTE food. Two possible FSIS strategies to mitigate this problem are presented below:

1. Food Service and Retail Training

Perhaps the most effective strategy for mitigating the problem is offering *Listeria*-specific training to the retail managers, their deli personnel and the state officials that oversee their operations. This effort should focus specifically on *Listeria* issues, particularly with regard to proper sanitation, refrigeration, and products of particular concern (e.g., those products that allow rapid growth of Lm). Including a discussion of liability issues might improve attention of all parties to these issues. It is unclear whether FSIS can facilitate and/or encourage state public health departments to assume more responsibility for these efforts.

2. Antimicrobial Agent (AMA) Formulations

Some in the industry and in the published literature describe AMAs in almost panacea terms. Others, significant other sources, dispute the efficacy of these agents at anything other than unpalatable levels. Furthermore, seemingly low-risk deli products containing AMAs may represent a significant hazard in retail environments using sub-optimal refrigeration; even with modest

[2] Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004) http://vm.cfsan.fda.gov/

temperature increases, AMAs are less effective in inhibiting outgrowth. In short, options for federally inspected establishments in preventing product contamination and outgrowth in retail operations appear to be limited. Regulatory strategies that that attempt to project the responsibility onto FSIS-inspected establishments may not be effective in significantly reducing the likelihood of foodborne listeriosis from deli counter products.

C. PAT members attended the Conference for Food Protection, CFP, and presented a summary of the Agency's recent efforts to combat *L. monocytogenes* and the best guidance gleaned from recent Risk Assessments. PAT members will represent the Agency on a CFP committee tasked with developing guidance on the control of Lm for retail food operations. This guidance will be incorporated into the FDA/FSIS Food Code, a model set of food regulations that has been adopted by more than 40 states and territories in the USA.

II. Purpose

The Retail Aspects PAT was formed to investigate the prevalence of *Lm* in RTE meat and poultry products at retail, to determine the impact of this contaminated product, to describe control programs that may reduce this prevalence and to evaluate and advance FSIS and FDA activities currently underway in these areas.

III. Upcoming Recommendations

Currently underway efforts in OPHS to compare the risk of listeriosis from deli meat sliced in plants versus sliced at retail will continue and the output of this assessment will inform FSIS managers regarding the prevalence of *Lm* in RTE meat and poultry at retail. This may include the collection of national and state retail data on the prevalence and level of *L. monocytogenes* in deli meats and associated risk factors (e.g., retail sanitation, product formulation, etc.). This assessment is projected to be completed in 2006.

The PAT also considered advice from The National Advisory Committee on Meat and Poultry Inspection (NACMPI) that Agencies other than FSIS may have more experts on retail issues. FSIS will continue to work with other groups, such as the Food and Drug Administration (FDA), The Association of Food and Drug Officials (AFDO), the Conference on Food Protection (CFP), 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.

IV. References:

REPORT OF THE FDA RETAIL FOOD PROGRAM DATABASE OF FOODBORNE ILLNESS RISK FACTORS
Prepared by the FDA Retail Food Program Steering Committee

FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC
September28, 2004

Public Health Assessment

I. Major Finding and Recommendation

The Public Health Program Assessment Team, in its review of data on human illness caused by *Listeria monocytogenes* (listeriosis), determined that there are three important sources of illness information, which overlap in their content. Each of the three data sources provides useful information about the occurrence of listeriosis in the U.S. population and, in some cases, the food vehicle responsible for those illnesses.

II. Purpose

This assessment was conducted to determine the available appropriate data sources for measuring the impact on human health (morbidity and mortality) of the Lm Interim Final Rule.

III. Goals

- Identification of potential sources of data on the occurrence of listeriosis in the United States.
- Analysis of the limitations of the identified sources of data.
- Recommendation to FSIS of an approach to monitoring long-term trends in the incidence of listeriosis.
- The PAT also considered advice from The National Advisory Committee on Meat and Poultry Inspection (NACMPI) that, as with *Salmonella*, FSIS should conduct molecular sub-typing and attempt to correlate positive product with actual cases of illness.

IV. Background

Listeria monocytogenes is a relatively rare cause of foodborne illness, estimated to cause about 2500 cases of listeriosis per year in the U.S., although in 2002 (the last year for which final national data is available) only 665 cases were reported by State public health authorities to the Centers for Disease Control and Prevention (CDC). The estimate of 2500 cases of listeriosis includes both those persons with mild illness who do not seek medical care and those who do seek care but are not diagnosed. Although relatively rare, listeriosis is estimated to have a case-fatality rate of 20%, and is unusual among foodborne illnesses in that it can be transmitted from a woman to her fetus and consequently is associated with either spontaneous abortion, stillbirth, or perinatal illness in infants.

Although approximately 99% of the cases of listeriosis are thought due to food exposures, identifying the specific food vehicle for a given case is particularly complicated for this illness. The most common illness presentation is not gastrointestinal, so there may be delay in identifying the illness as foodborne. Also,

listeriosis has an unusually long incubation period (perhaps up to 70 days), so that the exposure that resulted in illness may be difficult to recall. Although most cases are sporadic and isolated, the increasing use of pulsed-field gel electrophoresis (PFGE) to

subtype *Listeria* isolates has resulted in the recognition of clusters or outbreaks, which in turn sometimes results in identification of a common food exposure.

Listeriosis has been associated with meat and poultry products, as well as dairy, produce, and other non-FSIS regulated products. For this reason, it will be difficult to identify the extent to which changes in reported cases of listeriosis are a result of FSIS regulation and the industry compliance with such regulation.

V. Summary Recommendations

- National Surveillance Data. The CDC issues an annual surveillance summary of nationally notifiable diseases, which represents the national case count of such illnesses. The data in this report can be analyzed by FSIS only retrospectively (e.g., the report on 2002 data was just published in May, 2004). The data on listeriosis is characterized by numbers of cases, incidence rates (cases per population), and demographic profile (age, race, sex, ethnicity, and geography). **In the Office of Public Health Science, the Human Health Sciences Division (HHSD) should take the lead on extracting and customizing this data to create a listeriosis profile.**
- Outbreak Data. The CDC maintains the Electronic Foodborne Outbreak Reporting System (EFORS), to which State public health agencies contribute summary information on outbreaks, which they have investigated. Although EFORS data may be incomplete, investigated outbreaks provide the best opportunity to identify the food vehicle associated with illness. As the quality of this data improves, with the use of PFGE to match cases and food products and with the use of an extensive case interview form for all lab-confirmed cases, FSIS will be better able to correlate changes in its regulations with changes in illness. Again, **HHSD should be responsible for periodic analysis of the EFORS data.**
- FoodNet Data. FoodNet is an interagency collaboration between CDC, FSIS, the Food and Drug Administration, and several State health departments. The core activity of FoodNet is to ascertain all lab-confirmed cases of foodborne illness, as well as to track the trends in illness. Although FoodNet data may not be nationally representative, it still provides a rough estimate of the U.S. burden of illness, specifically, the incidence of lab-confirmed listeriosis. As an example, in 2003 there were 629 cases of listeriosis provisionally reported to CDC (data is not final), yet the FoodNet incidence rate for listeriosis (3.3 cases/1 million) provides an estimate of 951 cases. Thus, FoodNet may provide the most precise metric for monitoring trends in listeriosis. **HHSD is the division responsible for leading the FSIS participation in FoodNet and can therefore provide the analysis of this data.**

  FoodNet also conducts epidemiologic studies comparing illness cases to healthy controls, as a way of identifying the food exposures that result in illness. Studies of

this kind, if conducted periodically, will allow identification of novel food vehicles. **HHSD will be responsible for interpreting the results of these studies for FSIS.**

VI. Summary Findings

- FoodNet data may be the best measure of the trend in incidence of listeriosis, though not precisely representative of the U.S. population.
- National surveillance data, though not timely, will permit development of a demographic profile of listeriosis cases.
- Outbreak reports on listeriosis provide the least information on incidence but often the best information on the associated food vehicle.
- Two relatively recent innovations in listeriosis surveillance are likely to increase the precision of our knowledge about listeriosis cases and outbreaks and the exposures responsible for illness:
  - PFGE—this subtyping method allows investigators to link cases to other cases and to food products; it is important to note that all FSIS *Listeria* isolates are subtyped using PFGE and posted to the PulseNet database at CDC, a national database of all human and food isolates submitted by participating Agencies that allows comparison of food and human bacterial isolates.
  - Standardized case interview—use of a standard case interview form has just completed pilot testing in several States; when fully implemented, it will allow public health investigators to obtain detailed exposure information soon after laboratory confirmation of illness.

VII. Summary Discussion of Findings

All of the human health data that FSIS will use to evaluate the effect of the regulatory changes in ready-to-eat processes are best analyzed over a considerable period of time (i.e., years). Short-term, or snapshot, analyses of human illness data are not a reliable measure of such changes. A good example of this recently occurred. The 2003 FoodNet preliminary data showed a slight increase in listeriosis incidence after a 4-year downward trend (Centers for Disease Control and Prevention. *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—Selected Sites, United States, 2003*. MMWR 2004;53:338-343); however, the editorial note in this report omitted discussion of this change, since it is difficult to explain a one-year change in rates without explicit information of other factors that may have contributed to that change. Long-term trends in the incidence of listeriosis reflect changes in regulation, industry practices, food consumption, food safety education, demographics, diagnostic methodologies, and healthcare-seeking behavior. Consequently, the relative impact of the changes in FSIS regulations will be difficult to measure precisely.

It is important that OPHS-HHSD have regular periodic meetings with OPPED to share its analysis of data trends and to respond to specific requests for interpretation of human health data.

VIII. Attachments

Here are links to the most recent year's reports referred to above:

National surveillance data
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5153a1.htm

Outbreak Data
http://www.cdc.gov/foodborneoutbreaks/us_outb/fbo2001/summary01.htm

FoodNet Data
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5316a2.htm

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	Public Health Progam Assessment Team (Public Health PAT)							
	** Data Collection **							
	Data	**Source**	**Usefulness for Evaluating the Public Health Impact of the *Lm* RTE Rule**	**Data Strengths**	**Data Limitations**	**Data Availability for Analysis**		
						Currently Available	**Expected to be Collected**	**Current Data Gap/Proposed Collection**
Human Illness Data	**FoodNet**	MMWR 4/30/04	Compare the incidence of listeriosis in 2003 with the incidence of listeriosis in previous years.	The FoodNet data provides near complete ascertainment of listeriosis cases in the FoodNet sites; rates may be extrapolated to U.S. population with caveats. Introduction of a standardized listeriosis case history form will increase the ability to determine the food vehicle associated with illness.	Since the *Lm* RTE Rule went into effect in October 2003, the requirements of this rule may not be fully implemented and the public healtlh impact not evident until later years (e..g, first quarter listeriosis data for 2005). Listeriosis cases not always attributable to a specific food item, which means that FoodNet data may not have the specificity to directly correlate a reduction in listeriosis to the FSIS *Lm* RTE Rule (e.g., formulation of meat and poultry products with antimicrobial agents, use of post-lethality interventions, etc.)	Yes	Yes	N/A
	National Surveillance of Listeriosis	MMWR Weekly Issues; MMWR Summary of Notifiable Diseases	Each weekly report provides *provisional* data on listeriosis cases from each State, as well as comparison to the previous year's reports of illness for the same time period.	The weekly data provides ability to compare case counts for the current year to the previous year(s) "at-a-glance". The annual reports provide the numbers of cases by month, geography, age, sex, race, and ethnicity, and the incidence rates by age, sex, race, and ethnicity.	Provisional data should not be used to formally evaluate the impact of a regulatory change. The annual summary data is available as historical data	Yes	Yes	
	State Surveillance of Listeriosis	Contact with individual states or their websites	For selected states, data may be available to FSIS more immediately, therefore providing a more current measure of changes in incidence of listeriosis cases	More timely than national summary data.	May require agreements with individual states or via a national organization such as the Council of State and Territorial Epidemiologists.	Yes, but not directly accessible to FSIS.	Yes	
	CDC Listeriosis Outbreak Data	Electronic Foodborne Outbreak Reporting System (EFORS)	Helpful when the food vehicle is identified	Combination of epidemiologic, environmental, and lab data strengthen the identification of a food vehicle.	Many outbreaks are either not attributed to a specific food or else are attributed to mixed foods. Outbreaks convey only part of the picture of foodborne illness.	Yes, but only current through 2001.	Yes, and should be available electronically in a more timely manner in the future.	
	PulseNet	CDC's PFGE database, to which FSIS contributes pulsed-field patterns	This database is useful in identifying or confirming clusters of illness or in matching subtypes from clinical and food/environmental samples.	Standardized method for subtyping bacterial pathogens and subscribed to by CDC, FDA, FSIS and most state labs.	May detect clusters for which the epidemiologic data is insufficient to ascribe cause to a particular food vehicle.	Yes	Yes	
	Note: Linking listeriosis illness to a specific food exposure is especially problematic because of the unusually long incubation period (up to 30 days) in this illness. This results in significant limitations in recalling particular foods that might have resulted in illness. Food histories become food preferences and so are less useful.							
Supporting Data	**Use of FDA/FSIS risk assessment/deli meat pathway**	2003 FDA/FSIS risk ranking model	Provides supporting information on the number of listeriosis cases associated with deli meat sliced and packaged in-plant vs. at retail	Supporting information that may suggest more interventions needed at retail compared to in-plant.	NFPA retail data used in the FDA/FSIS risk ranking came from 2 locations (CA and MD). More retail *Lm* contamination data to be collected for FSIS by a consortium in the next few years to provide more representative data and better estimates of the cases associated with deli meat packaged and sliced at retail vs. in-plant.	FDAFSIS risk rankng model available; NFPA data used; improved retail data not available for a few years	More retail data to be collected.	N/A (has been proposed; in progress)
	1994-1994, 1998 CSFII data	CSFII data set for ready-to-eat products devloped by FDA/CFSAN for FDA/FSIS risk ranking	If further stratified by region (northeast, southeast, etc.), may provide insight regarding cosnumption patterns for ready-to-eat product by regions.	Provide information that may indicate why there is a difference in incidence of listeriosis by FoodNet site (e.g., variation in consumption pattern/expsoure).	FDA/CFSAN has this data set and would have to be willing to provide the analysis of this data set given its complexity. Also, the data cannot be stratified by state (only by region) and therefore cannot be easily correlated to FoodNet listeriosis data. Also, CSFII is no longer a USDA/ARS survey and the last data set is from 1998. Future food consumption surveys will be conducted by DHHS (combined with NHANES) and data is not expected for a few years.	No.	Yes, if FDA is willing to analyze.	No.
	FSIS Environmental Sampling Data	Data from Intensified Verification Testing (IVT) Program	The FSIS Risk Assessment identified environmental contamination as risk factor for illness.	Provides a connection between contamination in the environment, contamination on products, and human illness.	Very little data havebeen collected to date, and the data are only from establishments that are experiencing problems.	Yes.	Yes.	

FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC
September28, 2004

Economic Impact

I. Major Finding and Recommendation

The analysis produced for this PAT was not designed to produce a major finding but to support the RIA. See recommendations for additional analysis below.

II. Purpose

To analyze compliance with the Listeria monocytogenes (Lm) regulations to support assessment of industry costs. Scope of this PAT's work was limited after assigned economist left the Agency.

III. Goals

At a minimum, analysis was intended to update figures used in the interim final RIA and show if implementation of the regulations was having a disparate impact on firms of a certain size and which aspects of compliance firms are finding most difficult. This analysis should support further work estimating the extent and distribution of compliance costs to industry.

The PAT also considered advice from The National Advisory Committee on Meat and Poultry Inspection (NACMPI) and agreed that it should focus on differences among small, very small and large plants and assess economic impact on very small versus large plants, especially whether the rule has caused firms to go out of business. In addition, the assessment will consider other variables such as product types and the frequency of production.

IV. Background

PBIS data was used exclusively for this analysis and the resultant limitations and ambiguities are discussed in the "Supporting Data" section of the full report.

V. Summary Recommendations (list as many as you want)

Because this analysis used data only from plants that have received Lm-related NRs (only 18% of all plants that produce RTE products have received NRs), it reveals nothing about what the majority of plants, presumably compliant, have done to comply. For example, which alternative for Lm control did each choose and how much did it cost to implement? Did these plants have to undertake capital improvements to comply? This data must be collected.

VI. Summary Findings

- *PBIS plant profile data shows a slight increase in the number of official establishments subject to the Lm regulations, with approximately 2,951 Federal plants producing ready-to-eat products (the interim final RIA listed 2,930).*

- *Compliance with the new regulations, as measured by PBIS data, has been very good, with approximately 82% of subject plants receiving no NRs related to Lm between 10/06/04 and 4/15/04.*
- *Continuing compliance is indicated by these figures: roughly 35% of plants receiving Lm-related NRs were cited for not developing plans for controlling Lm and many of the NRs were written shortly after the effective date of the rule. Only 19 of these plants (about 4% of total plants receiving NRs) received additional NRs.*

- *Whether the rule has disproportionately affected very small plants in terms of compliance is uncertain. About 59% of all Lm-related NRs have gone to very small plants, but very small plants represent about 51% of plants that produce RTE products. And of course, this says nothing about the costs incurred by very small RTE plants in compliance.*
- *The majority of the Lm-related NRs (about 53%) concerned fully-cooked, perishable products. Keep in mind, however, that many of these NRs may concern sanitation in general or other processes and may only be coded for this procedure.*
- *Only a small percentage of plants that received Lm-related NRs (about 3%) need to make capital improvements to comply; none of these improvements seem major or costly.*
- *This dataset does not show that in general plants with repeat NRs ultimately needed to make capital improvement to comply (data indicated this in previous economic work on the Lm proposal). However, this dataset is relatively small and extremely limited in detail regarding plant construction, equipment purchases, etc.*
- *Of plants with Lm-control alternatives identifiable from NR narratives, most have chosen Alternative 3. This data is very inconclusive, however, given the number of NRs from which the alternative is not identifiable.*

VII. Summary Discussion of Findings

none

VIII. Accomplishments by the Agency

N/A

IX. Attachments

- **Analysis of Compliance Data**

- **Updated Analysis of Compliance Data**

FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC
September28, 2004

Economic Impact PAT – Analysis of Compliance Data

Introduction

Below is an analysis of compliance with the *Listeria monocytogenes* (*LM*) regulations in 9 CFR 430 since the interim final rule became effective on October 6, 2003 through April 15, 2004. Analysis is intended to show if implementation of the regulations is having a disparate impact on firms of a certain size, which aspects of compliance firms are finding most difficult, how plants are responding to *LM*-related NRs, and other information related to compliance. This analysis should support further work estimating the extent and distribution of compliance costs to industry.

PBIS data was used exclusively for this analysis and the resultant limitations and ambiguities are discussed in the "Supporting Data" section. Further, because this analysis uses data only from plants that have documented noncompliance (only 18% of all plants that produce RTE products have received NRs), it reveals nothing about what the majority of plants, presumably compliant, have done to comply. For example, which alternative for *LM* control did each choose and how much did it cost to implement? Did these plants have to undertake capital improvements to comply? These and other questions are discussed in the "Additional Questions" section at the end of this document.

Findings

- PBIS plant profile data shows a slight increase in the number of official establishments subject to the *LM* regulations, with approximately 2,951 Federal plants[3] producing ready-to-eat products (the interim final RIA listed 2,930).
- Compliance with the new regulations, as measured by PBIS data, has been very good, with approximately 82% of subject plants receiving no NRs related to *LM* between 10/06/04 and 4/15/04.
- Continuing compliance is indicated by these figures: roughly 35% of plants receiving *LM*-related NRs were cited for not developing plans for controlling *LM* and many of the NRs were written shortly after the effective date of the rule. Only 19 of these plants (about 4% of total plants receiving NRs) received additional NRs.
- Whether the rule has disproportionately affected very small plants in terms of compliance is uncertain. About 59% of all *LM*-related NRs have gone to very small plants, but very small plants represent about 51% of plants that produce RTE products. And of course, this says nothing about the costs incurred by very small RTE plants in compliance.
- The majority of the *LM*-related NRs (about 53%) concerned fully-cooked, perishable products. Keep in mind, however, that many of these NRs may

[3] See "Supporting Data" for a breakdown of plants by FSIS size classification.

concern sanitation in general or other processes and may only be coded for this procedure.[4]

- Only a small percentage of plants that received *LM*-related NRs (about 3%) need to make capital improvements to comply; none of these improvements seem major or costly.
- This dataset does not show that in general plants with repeat NRs ultimately needed to make capital improvement to comply (data indicated this in previous economic work on the *LM* proposal). However, this dataset is relatively small and extremely limited in detail regarding plant construction, equipment purchases.
- Of plants with *LM*-control alternatives identifiable from NR narratives, most have chosen Alternative 3. This data is very inconclusive, however, given the number of NRs from which the alternative is not identifiable.

Supporting Data

TABLE 1: Total Number of Plants Producing RTE Products as of 4/15/04

Plant size	# of Plants producing RTE products as of 4/15/04*	% of Total
VS	1510	51%
S	1204	41%
L	118	4%
Unknown ("N" in PBIS)	119	4%
Total	2951	100%

* Approximate because a few of these plants may can product exclusively.

TABLE 2: Individual Plants that Received *LM*-related NRs between 10/6/03 and 4/15/04

* Approximate because a few of these plants may can product exclusively. TABLE 2: Individual Plants that Received *LM*-related NRs between 10/6/03 and 4/15/04 Plant size	Number of individual plants that received *LM*-Related NRs	% of Total
VS	329	62%
S	178	34%
L	15	3%
Unknown ("N" in PBIS)	7	1%
Total	529	100%

[4] I also have yet to count the number of RTE plants that are scheduled for each inspection procedure; it could be that a disproportionate number of RTE plants produce fully-cooked, perishable product.

TABLE 3: Total Number of *LM*-related NRs Issued between 10/6/03 and 4/15/04

Plant size	*LM*-related NR issued	% of Total
VS	419	59%
S	258	36%
L	21	3%
Unknown ("N" in PBIS)	14	2%
Total	712	100%

TABLE 4: Percentage of Plants in Each Size Category that Received *LM*-related NRs between 10/6/03 and 4/15/04

Plant Size	# of Plants producing RTE products as of 4/15/04*	Number of individual plants that received *LM*-Related NRs	% of total plants in size category that received NRs
VS	1510	329	22%
S	1204	178	15%
L	118	15	13%
Unknown	119	7	6%
Total	2951	529	18%

-- An example for interpreting data from TABLES 1 through 4 -- 51% of plants that produce RTE product are very small; 62% of plants that received *LM*-related NRs were very small; 59% of all *LM*-related NRs went to very small plants; 22% of all very small plants received *LM*-related NRs.

TABLE 5: NRs by Procedure Code and Plant Size Issued between 10/6/03 and 4/15/04

Procedure Code	VS	S	L	Unknown	Total
01A01	7	6	1	0	14
01B01	11	10	0	1	22
01B02	12	7	0	0	19
01C01	22	13	0	1	36
01C02	29	25	0	3	57
03A01	23	17	2	0	42
03B*	3	2	0	1	6
03C*	1	1	0	1	3
03F01	29	13	0	0	42
03F02	28	4	0	0	32
03G01	129	79	12	5	225
03G02	96	49	4	0	149
03H01	2	1	0	1	4
03H02	0	1	0	0	1
03I01	3	0	0	0	3
03I02	1	0	0	0	1
04C01	0	1	0	0	1
05A01	0	3	0	0	3
06D01	16	19	2	0	37
06D02	0	1	0	0	1
08S01	1	0	0	0	1
No Code	6	6	0	1	13
Total	419	258	21	14	712

*These NRs, dealing with raw product are either erroneously attributed to the *LM* regulations by inspection personnel or written in such a way that they resulted from the PBIS queries designed for this study.

TABLE 6: Percentages of *LM*-Related NRs by Procedure Element for 10/6/03 to 4/15/04

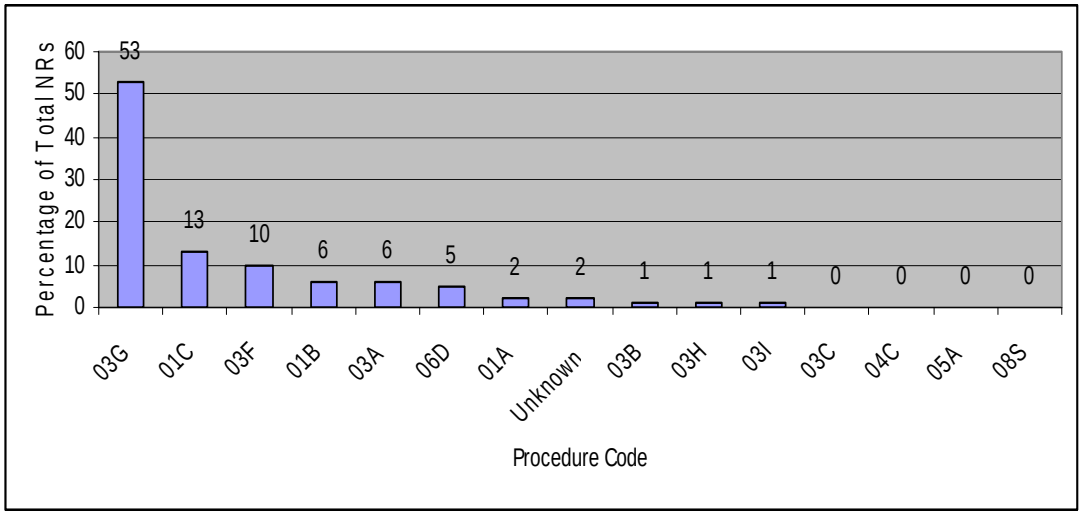

TABLE 7: Repeat *LM*-Related NRs (not necessarily linked) Issued between 10/6/03 and 4/15/04

Plant size	1 NR (no repeat)	2 NRs	3 NRs	4+ NRs
VS	257	57	12	3
S	132	28	8	10
L	10	4	1	0
Unknown (“N”)	5	0	1	1
Total	404	89	22	14

TABLE 8: Needed Improvements to Control *LM* based on NR Issued between 10/6/03 and 4/15/04:

Distribution of Plants by Size, Repeat NRs, and Identified *LM* Control Alternatives

Plant Size	# of NRs	**Need Plan***	**Need Only Changes to Plan Design or Implementation**				**Need Capital Improvements to Control *LM* Despite Plan**				**Other *****
			Alternative Plan 1	Alternative Plan 2	Alternative Plan 3	Plan Unknown **	Alternative Plan 1	Alternative Plan 2	Alternative Plan 3	Plan Unknown	
VS	1	124	2	21	42	44				4	20
	2	13	1	4	19	15			1	3	1
	3	3			8					1	
	4+			1	1	1					
S	1	37	6	4	23	32				4	26
	2	3		3	7	12				1	2
	3		1	1	2	4					
	4+			1	2	6				1	
L	1	1		1		7				1	
	2				1	2				1	
	3				1						
	4+										
Unknown ("N" in PBIS)	1	2				3					
	2										
	3					1					
	4+				1						
Total	1	164	8	26	65	86				9	46
	2	16	1	7	27	29			1	5	3
	3	3	1	1	11	5				1	
	4+			2	4	7				1	
All		183	10	36	107	127			1	16	49

*Plants falling into this category of noncompliance had not yet developed any procedure to address *LM* and so, from analysis of the NR narrative, it is often impossible to determine which alternative they will choose.

** It is impossible to tell from these written NRs which alternative the plant has chosen, although it is clear there is a plan in place.

*** These NRs often reflect positive FSIS tests with no indication of the control alternative chosen or other violations which, in the opinion of the inspector, created a risk of *LM* contamination.

Ambiguity of PBIS Data and Consequent Analysis Problems

Much of the data in TABLE 8 was collected through analysis of NR narratives. In many cases, NR narratives contain ambiguous of insufficient data for determining the exact type of noncompliance recorded, although it is usually clear that noncompliance did occur. For example, one NR narrative in the dataset reads: At 1300 hours as I was performing a review of this establishment prerequisite program for the control of *Listeria monocytogenes* in post lethality RTE product, I observed the following deficiency. The program does not address the hold procedures to be implemented if a test result were to show positive for the presence of *LM* or L species on a product contact zone as per the requirements of CFR 430.4 b 3.The narrative states that the deficiency is with the establishment's prerequisite program. The definition in 430.1 states that a prerequisite

program is "considered by scientific experts to be prerequisite to a HACCP plan." It is not a HACCP plan and may or may not be a Sanitation SOP. Yet, the inspector who recorded this noncompliance coded it as a violation of 9 CFR 417.3 (b), which concerns unforeseen deviations within HACCP, and also of 430.4(b)(3), which concerns the use of sanitation measures *only* to control *Listeria monocytogenes* contamination. So, we can infer that the establishment has chosen alternative 3 from the inspector's citation of 9 CFR 430.4(b)(3), but we cannot tell whether it chose to use sanitation measures as part of a prerequisite program, a Sanitation SOP, or a HACCP plan. This is significant in that we could assign costs to the revision of each of these plans.

Also, it often is impossible to tell from NR narratives which regulatory alternative an establishment has chosen to control *LM*. In many cases, an inspector will describe an incident of noncompliance related to an *LM* control plan or testing, but provide too little information for determining which alternative the establishment has chosen. In other cases, narratives indicate that an establishment has chosen two plans (most often 2 and 3), which is hypothetically possible, but seldom illustrative of what the establishment is actually doing.

Finally, inspection personnel often discuss several types of cited noncompliance in a narrative but can only enter one procedure code. Also, inspection personnel often perform a scheduled procedure, find an incident of noncompliance that would be classified under a different procedure code, but still code the noncompliance with the code of the scheduled procedures. For these reasons, the data in TABLE 5 should be used conservatively – the high level of O3G noncompliance does not necessarily mean that plants are having the most trouble controlling *LM* during the production of perishable, RTE products.

Additional Questions

As stated in the Introduction, this analysis uses data only from plants that have documented noncompliance regarding *LM* since 10/6/03. So, it reveals nothing about the 82% of all plants that produce RTE products and that have received no NRs since then. Numerous questions about these plants and all plants that produce RTE products remain and some are suggested below.

- What is the cost to revise a prerequisite program, Sanitation SOP, or HACCP to control *LM*?
- What is the cost of each of the alternatives and the elements therein (e.g., testing, *LM* growth inhibitors, etc.)? Are there economies of scale associated with each?
- As discussed in the interim final RIA, did plants already with *LM* controls or testing in place change practices because of the rule? Did their practices become more or less rigorous?
- Did plants undertake capital improvements to better comply with the interim final rule?
- Did plants have to purchase or lease additional storage space because of the hold-and-test requirements of the interim final rule?
- Will FSIS of plant testing results cause plants to change alternatives?

Economic Impact PAT – Updated Analysis of Compliance Data

Introduction

Below is an analysis of compliance with the *Listeria monocytogenes* (LM) regulations in 9 CFR 430 from the effective date of the interim final rule on October 6, 2003 through July 12, 2004. This analysis updates the initial analysis conducted using compliance data for the period between October 6, 2003, and May 6, 2004. Analysis of compliance data shows, to some extent, whether implementation of the regulations is having a disparate impact on firms of a certain size, which aspects of compliance firms are finding most difficult, and other information related to compliance. This analysis should support further work estimating the extent and distribution of compliance costs to industry.

PBIS data was used exclusively for this analysis and the resultant limitations and ambiguities are discussed in the original report. Further, because this analysis uses data only from plants that have documented noncompliance (only 24% of all plants that produce RTE products have received NRs so far), it reveals nothing about what the majority of plants, presumably compliant, have done to comply. For example, which alternative for LM control did each choose and how much did it cost to implement? Did these plants have to undertake capital improvements to comply? These and other questions need to be addressed by Agency economists.

Findings

- PBIS plant profile data shows a slight increase in the number of official establishments subject to the LM regulations, with approximately 2,983 Federal plants producing ready-to-eat products (the interim final RIA listed 2,930).

- Compliance with the new regulations, as measured by PBIS data, has been very good, with approximately 76% of subject plants receiving no NRs related to LM between 10/06/04 and 7/12/04. Of course, this data indicates nothing about the cost of compliance, except that it seems to be affordable to a majority of plants.

- Whether the rule has disproportionately affected very small plants in terms of compliance is uncertain. About 56% of all LM-related NRs have gone to very small plants, but very small plants do represent about 51% of all plants that produce RTE products. And of course, this data shows nothing about the costs incurred by very small RTE plants in compliance.

- The majority of the LM-related NRs (about 53%) concern fully-cooked, perishable products. It is likely that a proportionate percentage of RTE products are perishable and fully-cooked (and unlikely that establishments are having a disproportionately high number of problems controlling LM in these products).

The survey data on product type and production volume should better explain this trend in noncompliance.

- We have not updated the initial findings regarding LM-control alternatives selected by plants or regarding capital costs. Forthcoming FSIS Form 10,240-1, *Production Information on Post-Lethality Exposed Ready-to-Eat Products,* will be used to collect data from plants regarding alternatives used, types of RTE products produced, and volumes of production. This survey will be a more reliable source for this type of information than inference from NR narratives (used in the previous report). This survey data also can be used by Agency economists to examine the specific variables suggested by NACMPI for estimating cost of compliance.

Supporting Data

TABLE 1: Total Number of Plants Producing RTE Products as of 7/8/04

Plant size	# of Plants producing RTE products as of 7/8/04*	% of Total
VS	1525	51%
S	1214	41%
L	119	4%
Unknown (“N” in PBIS)	125	4%
Total	2983	100%

* Approximate because a few of these plants may can product exclusively.

TABLE 2: Individual Plants that Received LM-related NRs between 10/6/03 and 7/12/04

Plant size	Number of individual plants that received LM-Related NRs	% of Total
VS	433	60%
S	264	37%
L	17	2%
Unknown (“N” in PBIS)	10	1%
Total	724	100%

TABLE 3: Total Number of LM-related NRs Issued between 10/6/03 and 7/12/04

Plant size	LM-related NRs issued	% of Total
VS	608	56%
S	423	39%
L	34	3%
Unknown ("N" in PBIS)	18	2%
Total	1083	100%

TABLE 4: Percentage of Plants in Each Size Category that Received LM-related NRs between 10/6/03 and 7/12/04

Plant Size	# of Plants producing RTE products as of 7/8/04*	Number of individual plants that received LM-Related NRs	% of total plants in size category that received NRs
VS	1525	433	28%
S	1214	264	22%
L	17	119	14%
Unknown	10	125	8%
Total	724	2983	24%

-- An example for interpreting data from TABLES 1 through 4 -- 51% of plants that produce RTE product are very small; 60% of plants that received LM-related NRs were very small; 56% of all LM-related NRs went to very small plants; 28% of all very small plants received LM-related NRs.

TABLE 5: NRs by Procedure Code and Plant Size Issued between 10/6/03 and 7/12/04

Procedure Code	VS	S	L	Unknown	Total
01A01	7	10	1	0	18
01B01	19	14	2	1	36
01B02	16	11	2	0	29
01C01	35	28	0	1	64
01C02	51	33	0	3	87
03A01	28	27	3	0	58
03B*	3	2	0	1	6
03C*	2	1	0	1	4
03E01	1	5	0	1	7
03E02	5	3	0	0	8
03F01	45	20	0	0	65
03F02	33	7	1	0	41
03G01	190	132	13	6	341
03G02	143	85	4	3	235
03H01	2	1	0	1	4
03H02	2	1	0	0	3
03I01	3	3	0	0	6
03I02	1	0	0	0	1
04B01	1	3	0	0	4
04C01	0	2	0	0	2
05A01	0	3	0	0	3
06D01	21	31	8	0	60
06D02	0	1	0	0	1
08S01	0	0	0	0	0
No Code	0	0	0	0	0
Total	608	423	34	18	1083

*These NRs dealing with raw product are either erroneously attributed to the LM regulations by inspection personnel or written in such a way that they inadvertently resulted from the PBIS queries designed for this study.

Training

I. Major Finding and Recommendation

Training provided to the FSIS inspection workforce to aid in implementation of the *Lm (Listeria monocytogenes)* interim rule has been limited in scope. The training that FSIS has provided is in several different forms, including FSRE classroom training, Intensified-Sampling Training, EIAO training, and the distribution of information in the form of a CD-ROM which focused on the *Lm* interim rule and directive.

The Food Safety Regulatory Essentials (FSRE) course, week 3, Ready-to-Eat/Not Ready-to-Eat (RTE/NRTE) provides training to in-plant Consumer Safety Inspectors (CSIs). FSRE contains an approximately 3 1/2 hour module which explains the *Lm* Directive and Regulation 430 in depth, and focuses on the CSI's inspection verification responsibilities relative to the *Lm* Directive and regulation. Another 3 hour module, RTE Product Sampling, covers the CSI's responsibilities for taking samples, and reacting to positive results. Additionally, a 2 hour module on RTE Sanitation covers the establishment responsibilities for sanitation, including control and prevention of Listeria in RTE products. These modules are part of a three week course which provides the CSI with training in the FSIS Sanitation and HACCP regulatory process. CSIs that successfully complete this course should be prepared to enforce the *Lm* regulations and take RTE product samples.

As of August 26, 2004, 1503 CSIs have completed FSRE training. 1,033 (one thousand thirty-three) students have completed FSRE training (week 3) since the release of the new interim directive in October 2003.

The agency is in the process of providing the FSRE training to all current CSIs. Following completion of this process, all employees promoted from Food Inspector to CSI will be required to complete the FSRE course. New employees hired after May 1, 2004 are required to successfully pass the final exam as a condition of employment, although all students take the exam. Also, all new Public Health Veterinarians (PHVs) are required to successfully complete the FSRE course. Currently, the course is not required for other PHV, or Front-line Supervisors, although Districts are sending some of these current supervisors to the training.

In conjunction with the effective date and implementation of the L*m* Interim rule, FSIS provided a CD-ROM (October 2003) to the field inspection force. The CD contained the documents pertaining to the *Lm* Interim rule and was intended to assist field inspectors who normally use a dial-up connection to access these

documents. The CD-ROM was sent to IICs and may not have reached all the CSIs who needed it. Plans were, at that time, to provide more comprehensive training when the *Lm* final rule is issued.

In April 2003, a group of approximately 35 FSIS employees were trained in Intensified Sampling Procedures. This 3 day course provided these employees the training needed to take product, food contact surface, and environmental samples for the purpose of intensified sampling. This course was held prior to the release of the current *Lm* Directive and Regulation 430. The course was conducted once, in April 2003, and thus there is a limited pool of employees trained in intensified sampling procedures.

The current EIAO (formerly CSO) training includes an overview of the *Lm* Directive and Regulation 430. All EIAOs are required to successfully complete this training, which includes this overview.

II. Purpose

To determine the extent of training information and activities provided to the FSIS inspection workforce in implementation of the *Lm* interim rule. Also, to make a determination of future training needs.

III. Goals

Our goal was to determine the amount of training to provide for implementation of the *Lm* rule, and to describe the adequacy and quality of that training.

The PAT also considered advice from The National Advisory Committee on Meat and Poultry Inspection (NACMPI) and the Team decided to review whether accountability measures are adequate to ensure that those who participate in the training achieve some mastery over the subject.

IV. Background

Data was gathered about the amount of training that was provided to the FSIS inspection workforce, the adequacy and quality of that training. A survey of 5 District Managers was also conducted to determine their views and satisfaction with the training that was provided in conjunction with the release and effective date of the L*m* interim rule.

V. Summary Recommendations

FSRE Training

The current project of training all CSIs in FSRE must continue until completed. Thereafter, all new CSIs must be trained in FSRE. Also, the Agency (FSIS) should consider training all the in-plant supervisors in FSRE. For CSIs who have completed FSRE prior to October 2003, and for employees who have not had the opportunity to attend FSRE yet, CFL will be issuing an interactive training CD-ROM to provide training to inspection personnel that do not attend the classroom training of FSRE (week 3).

Interactive Training CD

To complement the previous training on the *Lm* Interim rule and directive for ready-to-eat (RTE) products, an interactive training CD-ROM will be developed and issued. The CD-ROM training module will include the L*m* Final Rule, associated directive(s), compliance guidelines, and also highlight the main points of these resources. The CD-ROM would be broken up into sections, each section ending with a set of questions to assure subject knowledge.

For long term training, CD-ROMs or web-based training should be developed and used for specific training aspects such as L*m* sampling, NRs relative to *Lm*, and the key elements and specifics of the L*m* rule and directives.

"Certification"

The Agency should establish a "Certification" program in the methodology for performance of intensified and/or specialized sampling. When FSIS personnel are "certified", one option would be to train all EIAOs in sampling and require their "Certification". Certification would require successful completion of the subject knowledge and demonstration of correct application of sampling techniques, etc.

This 'certification' in intensified sampling would require the development of training modules that contain core subject knowledge, methods and techniques of sampling, and demonstration of sampling techniques and proper application.
An alternative to requiring certification for all would be to establish a minimum number of EIAO's with "certification" in each district based upon the number of RTE establishments within the district. Once data is obtained associated with 'Alternative' selection under the L*m* rule, risk may also be a component factored into the equation to determine a minimum/adequate number of certified sampling EIAOs. Also, the potential of qualifying "certified" inspectors, EIAOs, as an expert in the subject of intensified sampling would be beneficial to FSIS in enforcement actions.

Tracking Training

It is recommended that all future training be tracked and mechanisms be put in place to show that an individual has successfully completed the required training. The new "AgLearn" system may possibly be used to track this training. FSIS also has current tracking mechanisms in place that can be used to track all *Lm* training.

Web-based Training

One alternative for the delivery of *Lm* training to the workforce would be the use of web-based training. There are two options for the web-based training. The website could:

(1) Provide training in an interactive web-based format and deliver the training much like training delivered by CD-ROM.
(2) Be designed to deliver training in a "Question and Answer" format.

VI. Summary Findings

- Training provided to the FSIS inspection workforce to aid in implementation of the *Lm* interim rule has been limited. In conjunction with the effective date and implementation of the *Lm* Interim rule, FSIS provided a CD-ROM to the field inspection force. The CD-ROM information was a recap of the *Lm* Interim rule. Plans were, at the time the CD-ROM was issued, to provide much more comprehensive training when the L*m* final rule is issued.
- The third ($3^{rd)}$ week of FSRE (Food Safety Regulatory Essentials) provides training and information relative to control and prevention of *Listeria* in RTE products.
- In April 2003, FSIS developed and presented a course in College Station, Texas to approximately 35 EAIOs. The course subject was "Intensified Verification Sampling Training". This course addressed regulations pertaining to *Listeria monocytogenes*, provided an overview of *Listeria monocytogenes*, taught techniques used in aseptic sampling, and provided a sampling practicum, as well as other information related to sampling.
- A survey of District Managers was conducted to determine perceptions of training and guidance for implementing the *Lm* interim rule. The following questions were asked on the survey. Responses to the survey are included in Attachment 3.

    1. As a District Manager, do you feel that you were provided adequate guidance related to intensified sampling triggers? What type of actions, if any, have you taken subsequent to positive *Listeria monocytogenes* findings (FCS or product)?
    2. What was the specific case or situation in which action was taken? What criteria, if any, are used to initiate these actions?

3. As a District Manager, how did you receive your training associated with the *Lm* interim final rule? Was it adequate?
4. What training was done related to the issuance of the *Lm* Verification Directive in your district for CSIs? Was a district standard set to conduct work unit meetings, individual review of the directive, Q&A sessions? This training is in addition to formal FSRE material delivered by CFL.

5. What tools were used to assess the district's level of understanding by the CSI's related to (about) *Lm?* verification/sampling? Based upon the assessment, how would you best categorize the CSI's knowledge base?
   1) Most CSIs definitely need training
   2) Most CSIs could use training but are performing at an acceptable level (doing okay without it)
   3) Most CSI don't need training
6. As the District Manager, have you assumed that EIAOs are the subject matter experts related to *Lm*? Is additional training required for this job series?
7. Do you have adequate access to employees trained in intensified sampling when you need their specialized skill set for sampling? How many trained individuals are at the District Manager's disposal to initiate intensified sampling?
8. As a District Manager, (related to the question above), are you confident in their abilities based upon observation or repeated, successful performance of this specific skill set (sampling)? Have other individuals (other than those attending the formal training at CFL/Texas) expressed interest in FCS/intensified sampling methodology? If so, were others trained within your District (e.g., train the trainer)?

Summary of District Manager Questionnaire

The Agency should continue to distribute new information on L*m* as it becomes available. The new information can be used by District Office personnel to evaluate triggers for intensified sampling. The amount of Intensified Sampling conducted by Districts varies. One district had not done any Intensified Sampling, another had performed four. The number of individuals trained should be adequate to address the sampling needs in a district. When the District performs Intensified Sampling in an establishment, it is based on several factors including recurring sanitation non-compliances within RTE rooms, major construction, and positive *Lm* product samples.

District Mangers were kept up-to-date on *Lm* material by attending the industry workshops, reviewing the video for the industry workshop, reading the directive and briefings by members of the District staff.

Training within individual districts by the Districts Offices was not consistent. Some individuals used EIAOs to conduct training for FLS and to conduct work unit meetings among CSIs.

District Managers are relying on the FSRE training of the CSIs covering the regulation and directive for training. Since there are many CSIs left to be trained, another faster method of reaching CSIs in the field with the required information may be needed.

VII. Summary Discussion of Findings

FSIS has made progress in providing training and education to the workforce in application of the *Lm* interim rule. Formal training has been provided in the Food Safety Regulatory Essentials (FSRE) week 3, Ready-to-eat, a CD-ROM was issued to the field inspection force to provide information on the implementation of Lm Interim Rule, and a 3 day training course in intensified verification sampling was completed by approximately 35 EIAOs.

VIII. Accomplishments by the Agency

a. FSIS produced and distributed a *Lm* Interim rule CD-ROM for use by the inspection workforce.
b. A classroom course on intensified verification sampling for L*m* was developed and delivered in April 2003 to approximately 35 EIAOs.
c. The Food Safety Regulatory Essentials (FSRE – week 3) course addresses Listeria in ready-to-eat (RTE) products, is taught routinely by the Center for Learning (CFL) and is available to all CSIs.

References

1. FSIS Directive 10,240.4, "Resources and Compliance Guidelines for Controlling *Lm*, CD-ROM, issued October 2003
2. FSRE, Food Safety Regulatory Essentials training manual, week 3, Center for Learning, FSIS

SMALL PLANT GUIDANCE PAT REPORT

I. Major Findings

- Majority of the small and very small plants did not receive or did not know that there is a Compliance Guidelines document for the *Listeria* interim rule.
- Those small and very small establishments that received the Compliance Guidelines need additional guidance in understanding the recommendations and complying with the rule.
- Since the implementation of the *Listeria* interim rule, The Labeling and Consumer Protection Staff (LCPS) has seen an increase in the number of meat and poultry meals, entrees and dinners labeled as not-ready-to-eat (NRTE) although these were historically marketed as ready-to-eat (RTE).

Recommendations

- Develop a system of distributing the Compliance Guidelines to small and very small establishments because most of these establishments do not have computers to access the guidelines on the FSIS web site.
- Conduct more workshops targeting small and very small establishments and schedule workshops earlier prior to implementation.
- Simplify the guidelines to enable small and very small establishments to easily understand the recommendations.
- Guidance should be provided to establishments regarding the appropriate steps to follow in changing the HACCP category of their products from RTE to NRTE.

II. Purpose

- To determine if the Compliance Guidelines are assisting small and very small establishments in meeting the requirements of the *Listeria* Interim Final Rule.
- To determine the establishments' change of HACCP category of their products from RTE to NRTE.

III. Goals

- Gather and analyze sources of information to determine how the Compliance Guidelines helped small and very small establishments; and establishments' change of the HACCP category of their products from RTE to NRTE. Sources of information to be analyzed are the reports on the questions received by FSIS in the *Listeria* interim rule, CSO/EIAO reports, NRs written, report on the workshops, and response to questions sent to University Extension Services, and FSIS offices and staff.
- Provide recommendations to improve distribution of the Compliance Guidelines and its understanding by the small and very small plants.
- Provide guidance for establishments that change the HACCP category of their products from RTE to NRTE.
- The PAT also considered advice from The National Advisory Committee on Meat and Poultry Inspection (NACMPI).

IV. Background

The Compliance Guidelines for the *Listeria* Interim Rule were developed by FSIS in order to help establishments, especially small and very small establishments in complying with the rule. The guidelines were posted on the FSIS web site together with the Directive. As part of the *Listeria* rule assessment, a group was charged to determine if the Compliance Guidelines was indeed helpful to small and very small establishments. An additional charge to the group was to determine establishments' change of the HACCP category of their products from RTE to NRTE.

The Small Plant guidance PAT looked at documents and other sources of information, which may show compliance of small and very small establishments to the rule using the Compliance Guidelines. These documents and other sources of information are:

- Report on the Workshops that FSIS conducted in 5 states prior to October 6, 2004, the implementation date of the rule.
- CSO/EIAO reports from January to February 2004 on establishment compliance to the rule.
- NRs written from 1/22/04 to 3/22/04 to determine the kind of non-compliance to the rule
- Summary of questions received by OPPED, the Technical Service Center and those received at the workshops.
- Response to questions sent to Agricultural Extension Service at 2 universities.
- Response to questions sent to pertinent FSIS offices and staff members

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The Small Plant Guidance PAT met 4 times to report on the findings and discuss possible solutions and recommendations.

V. Summary Recommendations

FSIS should recognize that very small plants face special challenges in implementing new requirements and should devise ways to disseminate new information to small plants in a timely manner. Following are recommendations for distribution, dissemination and simplification of guidance materials.

- Develop a system of distributing the Compliance Guidelines to small and very small establishments.

Suggestions for distribution:
1) Mailing to all small and very small establishments;
2) Send through District Office, or CSO or EIAO;
3) Send through university Agriculture Extension Service;
4) Send through HACCP coordinators in each state program

FSIS should use available technology in training FSIS personnel and industry by using remote broadcast and videotapes of the broadcasts through distribution to

small plants. Suggestions for disseminating information on availability of the Compliance Guidelines, in addition to the web site and the Constituent Update:
1) Agriculture Extension Service live hook-up, phone –in
2) C-Span presentation for government agencies- call-in numbers provided

- Conduct additional workshops that reach small and very small establishments to distribute and explain compliance guidelines
- Conduct workshops at a timely manner to give establishments enough time to prepare to comply with the rule
- Simplify Compliance Guidelines so it is easily understood by small and very small establishments, using easily understood tables, graphs, and flow charts with only 'need to know' information.
  Suggestions for simplifying the compliance guidelines:
  1) Reorganize guidelines such that tables, flow charts, diagrams, scenarios, examples, bulleted/enumerated instructions or step by step instructions to comply with alternatives are in the main body of the guidelines and move the discussions/explanations after the tables/instructions, etc.
  2) Put all tables and instructions in the body of the guidelines and put discussions as attachments.
  3) Trim discussion on sections that may be superfluous.

- Provide guidance to establishment regarding criteria for changing the HACCP category of products from RTE to NRTE.

VI. Summary Findings

- Questions received at OPPED, the Technical Service Center and from the workshops showed aspects of the rule and Compliance Guidelines that need to be clarified.
- Attendees of the Workshops conducted by FSIS prior to implementation of the rule, showed that the Workshops were very helpful to attendees in understanding the rule. Attendees suggested that FSIS conduct more workshops and at earlier time before implementation.
- The CSO/EIAO reports from January to February 2004 period showed that 22 establishments reviewed are not complying with the rule due to various reasons. Most of the very small plants are waiting for the CSOs to talk to them on how they can comply with the rule.
- Analysis of the NRs issued between 1/22/04 to 3/12/04, 3-6 months after implementation of the rule showed requirements of the rule that establishments need to comply with. Examples are hazard analysis, alternatives, sanitation measures, hold and test procedures, food contact surface testing, validation, recordkeeping, and verification.

- Report from a University Extension Service showed that small and very small establishments need help because they may not have the patience and education in understanding the rule and the guidelines. These establishments contact the Agricultural Extension Service or state inspectors for help.
- Report from LCPS estimated that one-fourth of the labels that are submitted to the Agency are for products that were classified as RTE but now may be categorized as NRTE.

VII. Summary Discussion of Findings

A. Questions received by OPPED, Technical Service Center, and at the Workshops

A few of the questions received by FSIS were clearly from small and very small establishments and some from large establishments. However for most of questions, the size of the establishments could not be determined. Some plant management indicated that they were not aware of the compliance Guidelines and the Q and As. Some CSIs were also not aware of these resources accessible via the homepage or the CD format. Very small owners have problems understanding the language in the guidelines such as 'genus' or '*Listeria*-like organisms' and may need simpler language or definitions.
Establishments believe that they can change the HACCP category of their products from RTE to NRTE by just adding cooking instructions so the products are not subject to the rule.

Questions were received on the following subjects: acceptable documentation for validation, validation of jerky, post-lethality treatments, antimicrobial agents, *Listeria* test methods, hold and test procedures, food contact surface testing, lard and tallow, pork rinds, products affected after a positive test, recall procedures, changing Alternatives, temperature control for *L. monocytogenes*, changing HACCP category from RTE to NRTE, deli products, deli salads, among others.

B. FSIS Workshops conducted prior to implementation of the rule

The evaluation sheets showed positive responses to the workshops for content, notebook (hand-outs) and presentation. The attendees commended the Agency for conducting the workshops and suggested that more workshops be held and to hold them much earlier prior to implementation. Most of the attendees said that the workshops were well organized and informative and that they benefited from the workshops. Some attendees suggested that the topics were very general and that more details are needed. The attendees liked them to be able get responses to questions that they asked at the workshops. The report on the Workshops did not show the establishments' size that the attendees represented.

C. Non- Compliance Reports (NR) The NRs were issued from January 22, 2004 to March 12, 2004, about 3 to 6 months after implementation. NRs were issued to 35 meat establishments and 2 poultry establishments. Nineteen (19) of the NRs were written as a result of review of HACCP plan features for completeness in 18 fully cooked not shelf

stable products and in 1 heat treated shelf stable product. Seventeen (17) were cited for verification of HACCP plan implementation to determine if the establishment is following its HACCP plan for heat treated shelf stable products. The NRs showed that the requirements are not being followed in the following: hazard analysis, alternatives, sanitation measures, hold and test procedures, food contact surface testing, validation, monitoring, recordkeeping, and verification. The group looked into these reports to determine how many small and very small establishments were given NRs. However, the size of the establishment receiving NRs was not determined from the report.

D. CSO/EIAO Reports

The CSO/EIAO reports were dated from January to February 2004. Out of 172 reports, 22 were reviewed for compliance to the *Listeria* interim rule. Seven (7) were found to comply with the rule, 15 had deficiencies in complying with the rule, out of which 2 were given NRs, 8 were issued other enforcement action, and 5 had no action taken. Deficiencies found pertain to hazard analysis, alternatives, supporting documentation, food contact surface testing, changing product HACCP category from RTE to NRTE. One very small establishment was identified as waiting CSO to show how to comply to the requirements. These reports were analyzed to determine how many small and very small establishments are visited by the CSOs. The report identified 1 establishment as very small.

E. Report from Agricultural Extension Service

Two professors from university Ag Extension Service were sent questions regarding the Compliance Guidelines for the *Listeria* interim final rule. Response from one University Extension professor indicated that the establishments that they work with were not aware of the Compliance Guidelines until he and his associates talked to them about it in their workshops. He indicated that these establishments would not have the patience nor the education to read the guidelines. These establishments contact them (Extension Service) or state inspectors for questions on the rule. His group conducted 10 half-day workshops in their state (Wisconsin) to explain the rule and the compliance guidelines. He suggested simplifying the guidelines, using easily understood tables, sidebars, and charts with only the “need to know” information.

F. Report from FSIS Offices and Staff

Questions were sent to pertinent FSIS offices and staff regarding the Compliance Guidelines. Responses received: The notebook (hand-out) used in the workshops were mailed to small and very small establishments. Specific work with the guidelines still needs to be done.

G. Report from LCPS on Establishments’ Change of HACCP Category of their Products from RTE to NRTE

LCPS reported an increase in the number of meat and poultry meals, entrees and dinners labeled as NRTE. Although these products were historically marketed as RTE, establishments are now producing these products as NRTE (i.e. produced under a HACCP category that does not have a final lethality step). The establishments producing these products expect the consumer to thoroughly cook the product prior to consumption and thus provide the lethality treatment. They convey this message to the consumers in the product label. It is estimated that products that are historically marketed as RTE and are now marketed as NRTE are produced by large establishments and constitutes one-fourth of the labels submitted to the Agency.

LCPS developed appropriate steps to guide establishments in changing the HACCP category of their products from RTE to NRTE prior to submitting labels to FSIS for approval. FSIS conducted two focus groups to help explore consumers' perception, understanding, and use of these food safety labeling features.

VIII. Accomplishments by the Agency

- Issued/published *Listeria* Interim Final rule, Directive 10,240.4, Compliance Guidelines and Questions and Answers for the control of *L. monocytogenes* in post-lethality exposed RTE meat and poultry products.
- Responded to questions received at OPPED, Technical Service Center and at the Workshops
- Conducted Workshops prior to implementation of the rule to help establishments, especially small and very small ones to comply with the rule.
- Conducted FSRE training for FSIS inspection personnel to train them in enforcing the rule
- Formed a team to assess the *Listeria* interim rule for the finalization.
- Updated the Compliance Guidelines to include responses to questions received and further clarify some sections.
- Revised the production volume form so it is easily understood and answered by establishments.
- Presented talks on the *Listeria* Interim Rule to trade organizations, retail organizations, and in public meetings to disseminate information on the rule and control of *L. monocytogenes*.
- Submitted an issue to the Conference for Food Protection, which was successfully approved, to include guidance to the Food Code for control of *L. monocytogenes* at retail.
- Have companies/establishments with methods and equipment for post-lethality treatments, antimicrobial agents, sanitation, and other *Listeria* control procedures present their findings to FSIS.

IX. Response to Recommendations from NACMPI

NACMPI recommended the following:

1) Include universities in disseminating guidance information to small plant
2) Representatives of District Offices should be involved to help deliver messages to industry through timely training
3) Train FSIS personnel and industry using available technology such as remote broadcast and videotapes of the broadcast for the small plants

Response:

1) Currently FSIS has awarded funding to university extension service so they can help small and very small plants to comply with the rules on meat, poultry and eggs. FSIS will send the guidelines to these and other university extension service for distribution to small and very small establishments.
2) We'll ask the district offices to have representatives (EIAO, CSO, CSI) deliver and disseminate messages to industry.
3) Currently, FSIS is using remote broadcast and videotaping in the training of industry and FSIS for the newest Directive and compliance guidelines.