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Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
300 12th St, SW
Room 102 Cotton Annex
Washington, DC 20250

97-013F, 97-013F-4, AMI, FPA, NCC, NTF

RE: [Docket Nos. 97-013F and 97-013FE] Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products; 68 *FR* 34207; June 6, 2003 and 69 *FR* 70051; December 2, 2004.

[Docket No. 04-032N] Availability of the Food Safety and Inspection Service Report on Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule; 69 *FR* 70051; December 2, 2004

Dear Sir or Madam:

The following comments on the dockets referenced above are being submitted by the American Meat Institute (AMI), the Food Products Association (FPA; formerly the National Food Processors Association), the National Chicken Council (NCC), and the National Turkey Federation (NTF).

AMI is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products in the U.S. Our member companies produce more than 90 percent of meat products available in the United States.

FPA (formerly the National Food Processors Association) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. FPA's scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. FPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

NCC represents integrated chicken producer-processors, the companies that produce, process and market chickens. Member companies of NCC account for approximately 95 percent of the chicken sold in the United States.

NTF is the advocate for all segments of the U.S. turkey industry, representing nearly 100 percent of the industry. NTF is the only national trade association representing the turkey industry exclusively. NTF provides services and conducts activities, which increase demand for its members' products, and protects and enhances the ability to effectively and profitably provide wholesome, high quality, and nutritious turkey products.

I. COMMENTS ON THE INTERIM FINAL RULE: CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT MEAT AND POULTRY PRODUCTS

General Comments

We applaud the Agency for this science-based rulemaking. We applaud the Agency for its very substantial efforts to incorporate into this rulemaking a more risk-based approach grounded in science. The clear focus of the rulemaking on exposed product and the use of appropriate controls verified through selective sampling is right on target. Focusing expectations for industry monitoring for *Listeria monocytogenes* (LM), as well as Agency verification efforts, on products that receive lesser control is a science-based approach that we strongly support.

Considering that LM is normally present in the environment, we believe the results achieved so far clearly indicate the wisdom of a science-based rulemaking that encourages industry to test for, find and eliminate LM where it exists.

We also support risk-based sampling of post-lethality exposed ready-to-eat (RTE) products to verify the effectiveness of environmental controls. We are aware that the Agency is moving in this direction and we encourage expeditious action to implement that desirable policy.

The rule codifies control measures that many firms were already taking to ensure the production and processing of safe products. Many companies were already devoting extensive effort to control LM, including extensive monitoring, before the rule was issued. With implementation of the rule, all companies producing ready-to-eat (RTE) products should now be following industry best practices. Based upon a survey conducted by AMI, FPA, and NTF during the first quarter of 2004, we found that the rule has resulted in an improvement in control of LM. Prior to the interim final rule, roughly 82% of the respondents conducted routine environmental testing of both product contact and non-

product contact surfaces. After the implementation of the rule, 93.5% of the respondents indicated they now conduct both product contact and non-product contact environmental testing. That is an increase of a little more than 11%. Many companies were working on control strategies for antimicrobial processes and treatments prior to publication of the rule. However, as a result of the rule, many companies enhanced their control measures. A summary of the survey is provided as Attachment 1.

We support periodic updates to Compliance Guidance. We support issuance of Compliance Guidance updated in a timely fashion as new knowledge is obtained, as a means for providing flexibility in meeting regulatory requirements while achieving the same level of food safety. The revised Compliance Guidance that was released December 2, 2004 and the revised Q & As provide an excellent reference for both industry and agency personnel.

There is room to further focus the coverage of the rule. We believe there are certain additional changes, as outlined below, that could be made to further focus the rule on products most likely to present a potential public health risk. This is the most effective way to achieve the ultimate goal of both the Agency and the industry – providing the safest food possible.

Specific Comments

Certain RTE Products That Are Not Likely to Cause Illness Should Be Exempt from the Rule.

While the Agency took significant steps to make this rule risk-based, certain categories of products subject to the requirements of the rule pose virtually no risk of contributing to foodborne illness. We believe that the types of products described below should be exempt from the rule so that industry and Agency resources can be focused most efficiently and effectively.

Products receiving sufficient post exposure lethality. The interim final rule applies only to cooked RTE products that are exposed to the environment after a lethal cook has been applied. This is because such exposure offers the potential for the cooked product to be recontaminated by LM. Conversely, products that are cooked, but are not subsequently exposed, are not subject to the rule. This is scientifically appropriate because any pathogens that might have been present initially would be destroyed during the cooking process and there is no subsequent opportunity for the product to become recontaminated. Under the same line of reasoning, we believe that certain products that may be exposed to the environment, but which subsequently receive an adequate, validated lethality (as

described in the next paragraph) in their final package, pose no greater risk of illness than products that are not exposed and therefore also should be exempted from coverage by this regulation.

RTE products may be subjected to many levels of post exposure lethality. The interim final rule recognizes the value of post-lethality treatments by allowing firms that utilize such treatments to operate under Alternative 1 or Alternative 2, with less verification by the firm and by the Agency. However, as noted above, if the post exposure lethality produces, not just an enhanced level of protection, but rather the same level of assurance of product safety as for non-exposed product, then such products should not be required to be produced under Alternative 1 or Alternative 2, they should be exempt from the rule. For example, products validated to achieve probabilities no greater than those in the table below are considered ready to eat and safe for consumption according to the FSIS proposed lethality performance standard (66 *FR* 12590).

Probability of *Salmonella* in 100 grams of finished product				
>0 surviving	>1 surviving	>2 surviving	>3 surviving	>4 surviving
39.4%	9.06%	1.45%	0.177%	0.0174%

FSIS has noted that processes validated to achieve these specific probabilities for destruction of *Salmonella* will also result in destruction of most other pathogens, including *L. monocytogenes*. Products given a post-exposure lethality treatment that meets these probabilities should not be subject to the rule as they should no longer be considered "exposed to the environment post-lethality." Such a policy would be supportive of food safety since it would further encourage firms to apply, wherever possible, substantially lethal processes to their products.

Examples of such products would be products that are cooked, repackaged and then irradiated, thermally processed, or high pressure processed in their final package. We suspect that the final lethal process will be a critical control point for most products. This would be discussed in the firm's hazard analysis and the process would have to be validated.

The fact that there was product exposure during the repackaging operation that followed the initial cook should not subject such a product to the LM control rule. We believe the Agency should clarify this matter in the final rule. Alternatively, this scenario could be clearly explained in revised compliance guidelines. There should be significantly reduced expectations for verification by the establishment and by the Agency for any products that receive a post-lethality treatment sufficient to inactivate levels of LM expected due to recontamination.

Products hot-filled at a lethal temperature. In line with the reasoning presented above, products which remain at lethal temperature until filled into the final package should likewise be exempt from the final regulation. In this case, product is typically heated in a kettle or in a heat exchanger to a lethal temperature for a specified period of time. The product is then conveyed, either in a continuous flow or in batch conveyances to a filler, which dispenses the product into its final package. Unless the operation is conducted aseptically, there will be some exposure of the product to the environment. However, as long as the product is maintained at a lethal temperature until the package is filled and hermetically sealed, any LM that might recontaminate the product will be destroyed by the residual heat. The safety of such product is equivalent to that of product that did not receive post-lethality exposure. Although FSIS has recognized in its response to question 12 in the Questions and Answers for FSIS Form 10,240-1 (Production Information on Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products) that such products need not be considered post-lethality exposed, this should be explicitly stated when the rule is finalized.

Products intended for further processing and appropriately documented as such. FSIS noted in its publication, Questions and Answers for FSIS Form 10,240-1, that "...products intended for further processing and labeled for further processing..." are not subject to the LM control rule 9 CFR 430. We fully concur with this position. The firm's hazard analysis will specify that such product (which might otherwise be considered RTE and subject to the rule) is destined for further processing, either at the same establishment or at a different establishment (owned by the same company or another firm). In this case, the firm will be expected to have documentation that all such product is intended for further processing. Furthermore, the firm will be expected to periodically verify that all product destined for further processing at another establishment is in fact subjected to further processing at that establishment. However, it should be made clear that the documentation envisioned here does not entail the type of lot-by-lot record keeping that may be needed when product known to have tested positive for a pathogen is shipped to another establishment for processing. Rather, periodic verification, perhaps in the form of a report from the second establishment or a quarterly visit to the facility to review records, would be examples of adequate verification.

Products destined for use in another product that meets the FSIS definition for a not-ready-to-eat (NRTE) food. FSIS has noted in several instances, including the Q & A set referenced above, that NRTE products, e.g., products that contain components that have not been fully cooked (even though the meat/poultry component may be fully cooked), are not covered by the rule. By the same reasoning as above, products that otherwise would be considered RTE, but which are shipped to another establishment for use in an NRTE product should not be subject to the rule. Just as noted above, such products would only be exempt from the regulation if the firm specified the end use of the product in its hazard analysis and if it documented and periodically verified that product

useage was in accord with the plan. All finished NRTE products are required to have validated cooking instructions and other appropriate labeling to assure that the product is cooked prior to consumption.

Products with certain product characteristics. In December of 2002, FSIS issued microbial sampling Directive 10,240.3 that included a category of products for non-target verification testing. These products were considered to be a lower risk than "low-risk products," which included the types of products produced under Alternative 1 or 2 of the current regulation. These products included lard, popped pork skins, pork rinds, dried soup bases, concentrated (high salt) soup mixes, pickled pig's feet, and products labeled for further processing. These products will not support the growth of LM and even if exposed to the environment after processing and contaminated with LM, pose no likelihood of causing illness because the organism can not grow to levels capable of causing illness. In many instances, if the product is recontaminated, LM will die off during storage. Thus, while many of these products technically fall under the rule, the public health benefit of applying the rule to these products is negligible. For this reason, we recommend that they be excluded from the final rule.

Establishment Determination of LM Control Alternative Should Take into Account Documented Processes Applied at Another Establishment

As noted above, some firms manufacture RTE products that receive their final processing step at a second establishment, e.g., a product is sent to another establishment to be frozen or otherwise treated. In consideration of the intent of the rule, the Agency should make clear that processes applied at a subsequent establishment may, under certain conditions, be taken into account by an initial establishment when that firm is determining the appropriate LM control alternative under which to operate. An example would be a product manufactured at one establishment using sanitation alone for LM control (Alternative 3) and shipped to a subsequent facility for an antimicrobial process such as freezing (Alternative 2). If the originating establishment adequately documents and periodically verifies that the intended actions are conducted at the subsequent facility, then the initial firm should be allowed to operate as if the product were produced under alternative 2 controls. Again, so long as the application of the antimicrobial process is documented and verified, it makes no difference whether all steps occurred in a single establishment or in two distinct facilities. If the initial establishment's hazard analysis adequately accounts for any potential hazard that may arise due to shipping the product between the facilities, the safety of the finished product is equally well assured in either event.

We Support the Agency Position that Validation Should Take into Account Product Characteristics that Do Not Allow Growth.

Listed on page 13 of the FSIS Updated Compliance Guidelines for the LM control rule is a chart that summarizes certain growth limits for *L. monocytogenes*. The minimum limits specified represent scientific consensus (ICMSF, 1996) as to the temperature, pH, and a_w levels below which *L. monocytogenes* cannot grow. According to the compliance guidelines,

> "Establishments with processes that achieve levels below the minimum limits can use these as their control for the pathogen. Establishments that comply with the levels below the minimum growth parameters need not conduct further validation for their products to prove that growth is inhibited to less than 1-log throughout the shelf-life of the product. The establishment can place the attached reference on file in their control program documentation. However, the establishment should conduct on-going monitoring and verification activities to demonstrate that they are maintaining the conditions for pH, water activity, or temperature."

The minimum conditions from the chart are listed below:

Growth limits for *Listeria monocytogenes* (ICMSF, 1996)

	Minimum
Temperature (°C)	-0.4
pH	4.39
Water activity	0.92

We strongly support this position taken by the Agency.

Guidance on Evaluating the Effectiveness of Post-Lethality Treatments and Antimicrobial Agents and Processes Should Be Made Available.

We believe that the Agency should make available to industry guidance on acceptable procedures for evaluating the effectiveness of new post-lethality treatments and antimicrobial agents or processes. Microbiologists from FPA staff and members, in consultation with FSIS and FDA microbiologists, have developed guidelines for conducting LM challenge studies to validate the effectiveness of lethality treatments and antimicrobial agents. The guidelines are being submitted for publication in a peer reviewed journal. We believe that these guidelines would be suitable for the Agency to provide as an appendix to its Compliance Guidelines. These guidelines have been shared with FSIS and FDA microbiologists. We would be happy to provide the most current version of the guidelines upon request.

FSIS Should Reconsider Its Assumptions about Sanitation Effectiveness.

Industry believes that the FSIS cost-benefit analysis assumption—that sanitation effectiveness is about 85%—is inaccurate. If a manufacturer were only able to manage their sanitation program at 85% efficiency or less, they would not be able to achieve a reasonable shelf life. Rather, sanitation effectiveness greater than 99% is suggested by the fact that *Listeria* species detection rates on contact surfaces among major manufacturers of RTE meat and poultry products subject to the rule are less than 0.2 % and routine Total Plate Count results are generally <10 per square inch.

Industry experience has shown that a *Listeria* positive finding, in many cases, does not indicate an insanitary condition. Thus, it would be inappropriate to consider contamination of products with *L. monocytogenes* by itself to be an indication of inadequate sanitation, given the ubiquitous nature of the organism and the potential for a sporadic, isolated contamination event. *Listeria* can be present in operations and equipment that by all recognized measurements of sanitation efficacy (i.e., favorable pre-operative visual evaluations and microbiological testing) appear to have good, if not excellent, sanitary control. FSIS should consider the result in the context of all other microbiological data available before concluding that sanitation is inadequate.

Labeling Provisions Should Be Rescinded.

The interim final rule 9 CFR 430.4 (e) contains provisions for companies to utilize label claims for products with validated antimicrobial agent or processes:

> (e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

We have submitted comments on this provision in a separate document. We recommend that this provision be deleted when the rule is finalized.

II. COMMENTS ON FSIS REPORT: ASSESSING THE EFFECTIVENESS OF THE *LISTERIA MONOCYTOGENES* INTERIM FINAL RULE

We are submitting the following comments on the FSIS report "Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule," as the findings of the report will likely have an impact on the Agency's deliberations regarding the LM interim final rule.

A. Verification Sampling

Intensified Verification Testing. In the Agency's working group report, the Project Assessment Team (PAT) recommended that FSIS conduct Intensified Verification Testing (IVT) when there are:

> (1) Product or contact surface LM positives (for all alternatives);
> (2) Continuing sanitation issues identified by CSO (for all alternatives); and
> (3) Multiple contact or product positives for *Listeria* spp. or *Listeria*-like organisms (for Alt. 3, two or more positives in any one year; for Alt. 2, three or more positives in any one year; for Alt. 1, five or more positives in any one year).

While we believe that IVT may be appropriate in certain circumstances (e.g., when there are multiple LM positives on product or food contact surfaces, when significant sanitation issues are identified, or when there is a failure to follow a scientific control program as written), we strongly oppose the PAT's recommendation that IVT be performed for "multiple contact or product positives for *Listeria* spp. or *Listeria*-like organisms." It is important that Agency triggers for IVT should consider the nature of positive test results, not just their number. Product contact positives and product positives should be distinguished based on risk and should not all be treated as equal. Clearly, product positives for LM are of greater concern. The likelihood of transfer of *Listeria* cells from a product contact surface to a product will vary based on many factors, including product type, equipment processing surface materials, concentration of organisms on the surface,

etc. Moreover, the likelihood that *Listeria* spp. or *Listeria*-like organisms will be LM varies from plant to plant.

Currently, industry is aggressively looking for *Listeria* in the environment. We believe that IVT for multiple *Listeria* spp. or *Listeria*-like test results could create a disincentive for establishments to continue aggressive *Listeria* monitoring programs designed to detect and eliminate LM. In the final rule, FSIS appropriately determined that establishments should be provided the flexibility to determine their own frequency of *Listeria* testing based on their processes and controls. In other words, IVT could be triggered if it has been established that a company is not following its *Listeria* control programs as written. As part of this assessment, the company should demonstrate that any corrective actions taken are adequate in managing product contact positives. The company's response and follow-up to deficiencies should receive greater attention and focus rather than making an IVT determination based on the arbitrary assignment of positive results against an Alternative category (Bullet 3 above). The working group's proposal is too prescriptive and has no scientific basis.

Although FSIS recommended certain minimum frequencies, the Agency left it up to establishments to determine the number of tests performed on food contact surfaces, provided the frequency is supported. If establishments know that they will be subject to IVT based solely on the number of *Listeria* spp. or *Listeria*-like positives they receive in a given year, they may be less inclined to test aggressively for the organism. Indeed, many establishments simply may choose to adopt the minimum frequencies recommended by the Agency for fear that they will be "penalized" later for having too many *Listeria* spp. or *Listeria*-like positive results in a given year.

In the preamble to the interim final rule, FSIS agreed that the rule should provide incentives for finding harborages, taking corrective actions, and preventing recurrence of contamination. If FSIS truly wishes to meet this goal, the Agency should not penalize establishments for trying to actively detect and eliminate potential harborage areas. When *Listeria* spp. or *Listeria*-like positives are found on food contact surfaces, the Agency should verify that appropriate corrective actions are taken as outlined in the establishment's *Listeria* testing program. If it is determined that the establishment followed its program and took adequate corrective actions, no further action by the Agency is necessary or warranted.

We also question whether the Agency would have the resources necessary to carry out the recommendation of the PAT. Given the ubiquitous nature of *Listeria*, it is not uncommon for RTE establishments to obtain several *Listeria* spp. positives on food contact surfaces in a given year. It is unlikely that FSIS will have the resources to conduct IVT each time an establishment surpasses the arbitrary yearly limits recommended by the PAT. Indeed, even the PAT acknowledged that such a program could create "workload issues" and

"detract from other regulatory duties of [inspection] personnel." Given that the Agency has access to all relevant plant records, if a company is following a scientifically based control program, it may be most appropriate for the Agency to focus its IVT efforts on situations involving suspected illnesses, recalls or serious questions about the adequacy of an establishment's control program.

Response to an FSIS LM-positive sample. The report suggests that if a food sample is found to be positive for LM, a set sequence of events should occur. The response would begin with a CSO evaluation of the establishment's HACCP, SSOP and prerequisite programs. We contend that a complete evaluation may not be needed in all circumstances, depending on the establishment's evaluation of the potential cause and the actions taken by the establishment in response to the positive product. Thus, we propose that the response should begin with the IIC working with the CSO to determine if a CSO evaluation is truly required (e.g., perhaps the plant already has a clear understanding of what led to the product positive, has taken appropriate corrective action, and has established effective preventive measures). If not, a review of the establishment's HACCP, SSOP and/or prerequisite programs would be conducted by the CSO.

The sampling program proposed by the PAT is confusing. We note that the PAT has proposed sampling the first lot after corrective actions have been taken based on ICMSF recommendations as outlined in the Compliance Guidelines. (There is a typographical error in the report that may lead to confusion: up to five (not four) samples may be composited into a single 125-g test portion.) The PAT notes that, for case 12, this is 20 samples that could be composited into four 125-g test portions. The PAT proposes that for a second LM-positive finding within a set of 10 subsequent sample tests, the establishment would be moved into an intensified testing program where one 2-lb sample would be collected each month for 10 months and analyzed "according to ICMSF Case consistent with Compliance Guidelines recommendations." It is not clear what constitutes the "10 subsequent samples" that would lead to intensified testing if there were a second positive. Furthermore, for intensified testing, it would appear that the PAT is suggesting that analysis of four 125-g test portions from the 2-lb sample is consistent with ICMSF case 12. This is not correct, as the plan represents tests of 20 subsamples of a single sample rather than 20 individual samples from a lot. We also question the basis for testing one sample a month for 10 months.

Food contact surface and environmental sampling. The report asserts that "establishments might heavily sanitize surfaces and mask problems easier in the environment than in product." This assertion is not supported by any evidence that such a procedure has ever been used. Moreover, it is unlikely that a plant with a significant LM problem could mask its environmental contamination sufficiently to prevent the detection of *Listeria* by the Agency.

Role of production volume. The report puts considerable emphasis on production volume but the PAT is contradictory in statements about the significance of the risk posed by an establishment based on production volume. The issue of production volume remains a concern to industry because the Agency provides no data to substantiate the report statement that "prevalence based on relative production volume is more likely to correlate with incidence of illness" and that "the current ALLRTE monitoring program should be modified to be consistent with baseline study design, i.e. weighted sampling based on production volume." The report further states that, "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 [type of product and process controls] override the issue of volume." The report suggests that risk models should incorporate production volume along with plant size and other variables. The report includes a reference to a report from the Risk Assessment Division that concludes that plant size is not a significant factor in concentration of contamination, and that the use of production volume as a significant variable is limited by the non-homogeneity of contamination that may be present in the lot. Yet one of the continuing goals of the Verification Sampling PAT is "risk-based activity needs to take priority: target large volume establishments/most potential exposure." We disagree with statements that correlate risk with production volume. The focus should be on the effectiveness of the design and implementation of control programs (including reformulation and post-processing interventions), not on production volume or plant size.

Additionally, the report states that, "FSIS believes that *L. monocytogenes* contamination [in the plant] is reasonably likely to occur in the production of all RTE meat and poultry products." We note that this statement, by itself, fails to recognize the value of post-lethality processing steps, for example. We conclude that the limited data provided in the report suggest that the likelihood of occurrence is more closely linked to Alternative categorization than is suggested by this statement (based on the limited PBIS data, *L. monocytogenes*-related NRs related to Alternative 3, 2, and 1 products were 58%, 20% and 5%, respectively, of the total). In fact, a subsequent paragraph of the report states 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." Thus, this concept is contradictory to that expressed earlier in the report asserting that LM contamination is reasonably likely to occur in all RTE meat and poultry products. Again, we emphasize that verification testing should be determined by the design and implementation of the control programs rather than production volume.

Other. The PAT suggests that FSIS may wish to explore quantitative re-testing of products found to be LM-positive. We support this recommendation. It will provide data to evaluate the true risk of the specific product, as well as generate data for future risk assessments.

B. Labeling/Consumer Education

The report states that the final version of the interim final rule should include the incentive labeling provision 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 report recommends that FSIS develop *L. monocytogenes* labeling statements by conducting a two-phased focus group research study and states that "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." As previously discussed surveys conducted by industry indicate that consumers have difficulty understanding these statements. As such, we oppose such labeling and continue to believe that such labeling may be misleading, and, hence, counterproductive.

C. Retail Aspects

The report states that "slicing and packaging of luncheon meats at retail deli counters present a significant source of exposure to *Listeria monocytogenes*." While we agree that retail handling of luncheon meats is a likely source of LM contamination, we contend that the magnitude of the problem is unknown at this time. Ongoing and proposed studies should elucidate the role of retail in contamination of products at retail. Nevertheless, we agree with the Agency that efforts to control LM contamination at retail are warranted.

Although the report recommends food service and retail training, and continued use of antimicrobial agent formulations to mitigate risks at retail, it states that "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." Further, the report suggests that training of retail managers is likely the most effective strategy to mitigate the problem. Although we strongly support education and training initiatives, we would assert that in addition to training, there must be measurement, monitoring, and enforcement of best practices at retail (e.g., such as those published in the Food Code) to help ensure that such training has been effective in changing behavior.

We agree with the conclusions drawn in the report that "regulatory strategies 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." We recommend that the Agency work with retailers to develop cost-effective measures that will better protect public health.

D. Public Health Assessment

The PAT notes that all of the human health data that FSIS will use to evaluate the effect of the regulatory changes in RTE processes must be analyzed over a considerable period of time (i.e., years). We agree with this assessment and urge the Agency to be cautious in the interpretation of public health data, especially since data from public health agencies linking cases of listeriosis to meat products are very limited. With so few cases of listeriosis identified each year and even fewer of these being linked to a specific food, it will be difficult to develop data to identify trends that can be associated directly with the FSIS LM rule.

E. Training

The report recommends that Food Safety Regulatory Essentials (FSRE) training should be provided to all Consumer Safety Inspectors (CSI) as well as all in-plant supervisors. We agree. The report indicates that currently the course is not required for Front-line Supervisors (FLSs). We strongly recommend that all FLSs be required to take the FSRE course for RTE/NRTE to better understand control measures for LM. We support the development of interactive training via CD-ROM, especially as it can be used effectively for refresher training.

We are particularly concerned about the lack of consistency of training within individual districts, as well as inconsistency in training among districts. The PAT recognized the problem, which is a first step toward correcting it. Ensuring that all CSIs, in-plant supervisors, and FLSs receive FSRE training should help alleviate the problem. Having a reference CD-ROM for inspectors to consult should also help.

The report also states that the Agency should initiate a "certification program" in the methodology for performance of intensified and specialized sampling. We further recommend that FSIS personnel undergo "recertification" as needed considering the evolution of science and regulatory programs. Again we would like to emphasize industry's desire to participate in joint training programs with FSIS personnel when possible.

F. Small Plant Guidance

The PAT noted that the majority of small and very small plants did not receive or did not know about the Compliance Guidance for the LM rule. Since FSIS has an inspector responsible for every plant, we recommend that the District Manager ensure that each plant is aware of all guidance documents, and, where necessary that a copy of these documents be provided to the plant. This can be done at the weekly meeting.

May 5, 2004

Dr. Dan Engeljohn
USDA/FSIS
Room 402/Cotton Annex Bldg.
300 12th Street, SW
Washington, DC 20250-2200

Re: Industry Survey on Implementation of Interim Final RTE Rule

Dr. Engeljohn:

In an effort to gauge industry's reaction to the Food Safety and Inspection Service's (FSIS) interim final rule, *Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products*, the American Meat Institute (AMI), National Food Processors Association (NFPA), and the National Turkey Federation (NTF) collaborated to create and distribute a survey to our members earlier this year. The survey, which was completed and returned by over 60 of our members, provides invaluable insight into the meat and poultry industry's response to the publication of the interim final rule.

We believe this information is not only valuable to industry, but could be extremely valuable to FSIS in its efforts to prepare for publication of a final rule by December 2004. The results show that much of the industry has made significant changes to their testing programs since October 2003.

All of the results received were first blinded by legal counsel. These blinded results and a summary of the data are attached. We hope FSIS will find this information useful. We will further discuss the results of this survey in our written comments to the interim final rule, which will be submitted before the December 2004 deadline.

Please feel free to contact us with any questions.

Thank you,

American Meat Institute
National Food Processors Association
National Turkey Federation

Listeria and the Ready-to-Eat Rule: An Industry Survey

The Survey

The survey was completed by the members of American Meat Institute (AMI), National Food Processors Association (NFPA), and the National Turkey Federation (NTF). Each association mailed the surveys to their members and asked that they be completed and returned to legal counsel for blinding. After data acquisition and entry into Microsoft Excel ® for analysis, the original surveys were destroyed. No establishment identifiers were incorporated into the data file in order to protect confidentiality.

The survey was designed to evaluate industry *Listeria* control activities both before and after the issuance of the FSIS interim final rule on *Listeria* control in post-lethality exposed RTE meat and poultry products.. The survey included sections on:

I. Sampling Program
II. Control Strategies

The Sampling Program section compared the pre-rule versus post-rule status of an establishment training programs, product contact and non product contact surface sampling programs, and actions taken when a positive result is found. The Control Strategies section was designed to estimate how many respondents have already or have plans to reclassify the Alternative categorization of their products. It was also intended to identify which incentives were most effective in encouraging changes to company programs.

Survey Results

Of the surveys mailed, 62 were completed and returned. These responses represented a total to 87 meat and poultry establishments (Table 1).

Table 1. Establishments represented

Number of Establishments Represented by Each Survey Returned	***Responses***
1 to 3 establishments	83.9%
4 to 6 establishments	4.8%
More than 6 establishments	9.7%
No answer provided	1.6%

I. Sampling Program

Of the 62 responses, roughly 82% of the respondents conducted routine environmental testing of both product contact and non-product contact surfaces and 14.5% conducted only non-product contact surface testing prior to the issuance of the final rule. Implementation of the rule resulted in an 11% increase in the number of respondents that conduct both product and non-product contact environmental testing (from 82.3% to 93.5% of respondents) (Table 2).

Table 2. Changes in product contact and non-product contact surface sampling program

Response	*Before Rule (%)*	*After Rule (%)*	*Difference (%)*
Product contact surfaces	1 (1.6)	4 (6.5)	3 (4.8)
Non-product contact surfaces	9 (14.5)	0 (0)	-9 (-14.5)
Both product contact and non-product contact surfaces	51 (82.3)	58 (93.5)	7 (11.3)
Not applicable	1 (1.6)	0 (0)	-1 (-1.6)

When asked about the frequency of product contact and non-contact surface testing for *Listeria* spp. or *Listeria monocytogenes* (Lm), 40% of the respondents indicated that the frequency of product contact surface testing has increased since the implementation of the rule, while 13% of the respondents indicated that the frequency of testing has decreased. Twenty-four percent (24%) of the respondents indicated that the frequency of non-product contact surface testing for *Listeria spp.* or Lm has increased, while 13% indicated that frequency of non-product contact surface testing has decreased.

Respondents were also asked about the frequency of finished product testing. Of the 62 responses, 19.4% indicate that finished product testing has increased while 64.5% suggest their finished product testing has remained the same.

Table 3. Frequency of product contact surface, non-product contact surface and finished product testing

Response	*Contact (%)*	*Non-contact (%)*	*Product (%)*
Increased	25 (40.3)	15 (24.2)	12 (19.4)
Decreased	8 (12.9)	8 (12.9)	5 (8.1)
Stayed the same	29 (46.8)	37 (59.7)	40 (64.5)
No testing	0 (0)	2 (3.2)	5 (8.1)

The survey also examined the availability of on-site establishment technical expertise to handle environmental testing and the source of additional training, if applicable. More than eighty-five percent (85.5%) of respondents indicated that prior to the June 6, 2003 publication of the final rule their establishment did have an individual or a team on-site that had received additional training in environmental testing or techniques to determine root causes of a positive finding.

Only 12.9% of respondents did not have on-site expertise. Approximately eighty-seven percent (87.1%) of respondents indicated that after the rule was published their establishment did have an on-site individual or team, a 1.6% increase.

The respondents were questioned as to the source of additional training they may have received. Results can be seen in Table 4 below.

Table 4. Source of additional training

Source of Additional Training	***Responses****
AMI	31
External consultant	24
Formal education	14
All	2
Other	27
No answer provided	3

* Many respondents selected more than one source.

Corrective Actions for an Initial Listeria spp. *Positive*

Product Contact Surface Testing: Survey respondents were asked if they increased monitoring for *Listeria* spp. in subsequent production shifts if an initial positive is found on a product contact surface. Of the responses, 93.5% indicated that their corrective actions include increased monitoring when they obtain one positive result. Only 2 respondents suggest that they do not increase testing/monitoring when a positive result is obtained. Of those respondents that indicate that they increase monitoring, 55% of them continue increased monitoring for *Listeria* spp. until they obtain more than 2 consecutive negative test results from the product contact surface. While another 13% continue testing until they obtain exactly 2 consecutive negative results from the product contact surface and 27.4% continue increased testing of the product contact surface until they have 1 negative test result.

Non-Product Contact Surface Testing: When asked about increased testing on non-product contact surfaces, 84% of respondents indicated that when they receive a positive test result for *Listeria* spp. on a non-product contact surface, their corrective actions include increased monitoring. A little more than 53% of those respondents continue increased monitoring until they have 2 or more consecutive negative test results from the non-product contact surface. Over thirty percent (30.6%) continue increased testing/monitoring until only 1 negative test result is obtained.

Root Cause Determination: Eighty-eight percent (88%) of respondents indicated that they are able to determine the root cause of multiple consecutive positives on product contact or non-product contact surfaces over 50% of the time. Twelve percent (12%) suggest they are only able to determine the root cause 50% or less of the time (Table 5).

Reponses	Results (%)
≤ 50%	12 (19.4)
> 50 – 75%	16 (25.8)
> 75 – 95%	17 (27.4)
> 95 – 100%	13 (20.9)
No answer provided	2 (3.2)
Not applicable	2 (3.2)

Table 5. Root cause determination

II. Control Strategies

Since implementation of the *Listeria* interim final rule, post-process exposed RTE foods are classified as Alternative 1, 2, or 3 depending on product formulation and controls used during production. Survey respondents were asked if they have implemented additional control measures/formulation changes that allow reclassification of their products from Alternative 3 to Alternative 2 and from Alternative 2 to Alternative 1 (Table 6).

Table 6. Number of respondents reclassifying products from one Alternative to another

Response	Reclassification from	
	Alt 3 to Alt 2 (%)	Alt 2 to Alt 1 (%)
Yes	27 (43.5)	10 (16.1)
No	35 (56.5)	49 (79.0)
No answer	0	3 (4.8)

Over fifty-two percent (52.2%) of the 27 respondents that reclassified product from Alternative 3 to Alternative 2, have reclassified greater than 80% of their products. Forty percent (40%) of the 10 respondents that reclassified product from Alternative 2 to Alternative 1, reclassified more than 80% of their products. (Table7).

Table 7. Percent of products reclassified from one Alternative to another

Percent of products reclassified	Alt 3 to Alt 2 (%)	Alt 2 to Alt 1 (%)
0 – 20	3 (13.0)	2 (20)
21 – 40	3 (13.0)	2 (20)
41 – 60	3 (13.0)	1 (10)
61 – 80	2 (8.7)	1 (10)
81 – 100	12 (52.2)	4 (40)
No answer	4 (14.8)	0

Establishments reclassifying products from Alternative 3 to Alternative 2 were asked how many products were reformulated with antimicrobials. Seventeen (17) of those 27 respondents indicated that they have incorporated antimicrobials into their formulations. Two of the 27 had not used antimicrobials and 8 respondents either did not provide an answer or their answers were unusable in the form submitted. Over thirty-six percent (36.6%) of those who indicated they had implemented additional control strategies have reformulated 20-100 of their products with antimicrobials.

Respondents were also asked how many products now receive a post-packaging lethality treatment. Of the 27 respondents who reclassified products from Alternative 3 to Alternative 2,

22.5% indicated they now apply a post-packaging lethality treatment to more than 10 of their products.

The 27 respondents that indicated they have moved product from Alternative 3 to Alternative 2 were asked, if prior to the final rule publication, how many products fit the Alternative 1 or Alternative 2 classification. Twelve of the respondents indicated they produce products that fit these classifications. Of these twelve respondents, 38% indicate that 10 or more of their products fit the Alternative 1 or Alternative 2 classification.

Of the ten respondents who reclassified products from Alternative 2 to Alternative 1, 66.6% moved the products to Alternative 1 after the final rule publication. 80% of those who have moved from Alternative 2 to Alternative 1 indicated that they have chosen to use thermal processing (i.e., Unitherm, Infrared) for post-packaging lethality.

Of those establishments who either have not moved product from Alternative 3 to Alternative 2 or from Alternative 2 to Alternative 1, 34.8% indicated that they have plans to move to reformulate products with antimicrobials within the next year. Another 34.8% of the respondents are not sure if they will be moving products within the next year. Of those who have not moved products from Alternative 2 to Alternative 1, 21.3% have intentions to incorporate a post-packaging lethality process to move product from Alternative 2 to Alternative 1 within the next year. Another 34.0% are unsure of future plans (Table 8).

Table 8. Future plans to reclassify product from one Alternative to another

Planning to move within	***Alt 3 to Alt 2 or Alt 2 to Alt 1 (%)***	***Alt 2 to Alt 1 (%)***
3 months?	3 (6.9)	1 (2.1)
6 months?	7 (16.3)	2 (4.2)
9 months?	1 (2.3)	2 (4.2)
Year?	4 (9.3)	5 (10.6)
Not sure	15 (34.8)	16 (34.0)
Not planning to move	13 (30.2)	21 (44.7)
No answer given	16	9
Answer not usable	2	0
Not applicable	1	6

The RTE final rule provided incentives for establishments to reclassify products from one alternative to another. The survey attempted to determine which incentives were more attractive to companies. Most respondents (62.5%) indicated that the reduced or eliminated environmental testing by FSIS and/or the reduced or greatly eliminated product testing by FSIS were the most lucrative incentives. The allowance of voluntary food safety labeling claims alone was not enough of a reason to prompt movement (Table 9).

Table 9. Incentives prompting movement from one alternative to another

	Reason	Response (%)
A	Reduced or eliminated environmental testing by FSIS	3 (5.3)
B	Reduced or greatly eliminated product testing by FSIS	10 (17.8)
C	Allowance of voluntary food safety labeling claims	0 (0)
A & B		22 (39.3)
B & C		1 (1.8)
A & C		5 (8.9)
A, B, & C		4 (7.1)
Other -- Customer requirements, corporate requirements, produce safer products, already there – no need to change		11 (19.6)

The survey asked if respondents were concerned about the provision in the rule allowing voluntary food safety labeling claims and, if so, why they were concerned. Out of the 62 total respondents, 54 indicated that the voluntary labeling component was of some concern. 19% of respondents agreed with all of the following statements:

Voluntary food safety labeling claims:

a) may inhibit sharing of best practices for *Listeria* control
b) create a 'good food' vs. 'bad food' perception by consumers
c) mislead consumers into believing products with claims may be handled less safely
d) increase company liability.

14.5% agreed with statements b and c, while 16.1 % agreed with statements b, c and d. Others agreed with either one or many of the statements above.

Table 10. Reasons for concerns with the label claims provision of the RTE Rule

	Statement	Response*
a.	Inhibit sharing of best practices for *Listeria* control?	23
b.	Create "good food" vs. "bad food" perceptions by consumers?	47
c.	Mislead consumers into believing products with claims may be handled less safely?	42
d.	Increase company liability?	30
e.	Don't Know	8

* Many respondents selected more than one statement.

For those respondents that circled more than one answer, they were asked to identify which issue was most problematic. Roughly 23% of those respondents who selected more than one answer believed that the creation of a 'good' vs. 'bad food' perception by consumers was the most troubling (Table 11).

Table 11. Prioritization of concerns

Prioritize statements	***Response (%)***
Highest priority "Inhibit sharing of best practices for Listeria control."	7 (18.4)
Highest priority "Create a 'good food' vs. 'bad food' perception by consumers."	14 (36.8)
Highest priority "Mislead consumers into believing products with claims may be handled less safely."	13 (34.2)
Highest priority "Increase company liability."	4 (10.5)
No answer	7
Not applicable	17