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FSIS Docket Clerk
USDA – FSIS
Room 102, Cotton Annex
300 12th Street, SW.,
Washington DC 20250-3700.

**RE: FSIS Docket Clerk - Docket No. 04-032N
Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule**

The American Association of Meat Processors (AAMP) is pleased to submit the following comments on the USDA-FSIS *Listeria monocytogenes* (*Lm*) Interim Final Rule.

The Association is an international organization whose members include meat and poultry processors, slaughterers, caterers, home food service companies, wholesalers, retailers, suppliers and consultants to the meat and poultry industry. Most of AAMP's members are small, very small and medium-sized businesses, many of them owned by families.

We acknowledge the incidence of *Lm* contamination has declined throughout the years. This information is great for both meat processors and consumers alike. We believe the reasoning behind this decline shouldn't be solely attributed to the Food Safety and Inspection Service (FSIS) or the implementation of new regulations. Many meat processors have educated themselves or received education on *Lm*, the occurrence and the control. The actions of the meat processors also have made a significant impact on the declining numbers of *Lm* contamination. This fact seems to always be avoided when the incident numbers are reported.

Within the executive summary of the *Lm* report, it was mentioned that establishments are aware of and responding positively to the new rules. We would like to know what other option the meat processors had? If meat processors didn't respond to the new *Lm* Interim Final Rule, they would have to stop producing RTE meat products. We will comment on the report according to the sections that have been identified in the report.



Verification Sampling

The Agency's *L. monocytogenes* Risk Assessment (FSIS 2003) indicated that use of both post-lethality inventions 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. Although this may be true, it is not feasibly possible for some products and economically impossible for most small and very small volume meat plants. We recommend that more research be conducted to determine more economically feasible techniques that can be applied. Hot water dipping technology is one such affordable technology that could be utilized, but research to support such technology is not readily available. Furthermore, some FSIS inspection personnel will not recognize such publication as supporting documentation unless every detail of the published materials and methods are followed. For example, we recognize that water temperature is a critical factor, but packaging material is not such a critical factor. This scrutiny is not only discouraging, but also negatively impacts the implementation of such technologies in processing systems when it is not required.

The report brings up the topic of risk-based sampling. We strongly encourage FSIS to move towards implementing a risk-based inspection system. Risk-based inspection would be a better use of FSIS resources than attempting to monitor every RTE product produced. Risk-based inspection would focus FSIS resources towards establishments that produce large volumes of higher risk products (i.e. deli RTE product, frankfurters, etc.) with lengthy distribution chains. When compared to small and very small volume establishments, the other establishments and products are distributed and consumed in a much larger volume and pose a greater risk. We do acknowledge that the large establishments have the economic resources and personnel to use the latest technologies to reduce or eliminate possible *Listeria monocytogenes* in RTE products.

The data collection of other risk factors recommended in this section of the report would be very subjective unless guidelines were established. Construction has not been defined by FSIS and thus would be subjective between data collectors.

Within the other recommendations section, it stated "if a sample is found to be positive for *L. monocytogenes* after testing by the Agency, inspection personnel confirm that the establishment's proposed corrective actions appear reasonable and insure that the establishment begins environmental testing." If the Agency moves forward with this recommendation, we would hope that FSIS inspection personnel would have some consistent protocol to address this procedure. Furthermore, the amount of environmental sampling should be established using statistical techniques rather than the traditional "picking a number" technique. Every establishment does not have a statistician on the payroll and it is highly recommended that the Agency work with the establishments to determine the appropriate amount of testing.

The concept of introducing agency microbiologists in each of the Agency's District Offices is a good concept as long as these microbiologists can work with establishments. Too many times we hear the same comment reiterated from the Agency...it's your HACCP plan and you have to determine how much testing is adequate and support your decision with documentation. If the overall goal is food safety, the Agency should work together with the plants and not take such an antagonistic approach to inspection.

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Microbiologists could provide training videos and materials to both the inspection personnel and establishments, as well as provide guidance on sanitation techniques and materials to reduce the occurrence of *Lm* in establishments.

The topic of Intensified Verification Testing (IVT) gives us the impression that FSIS is returning back to the tried and true method of command and control. It is suggested that IVT be triggered when a product of contact surface tests positive for *L. monocytogenes*. This is a knee-jerk reaction that doesn't seem to follow the Agency's concept of a "science-based" inspection system. Furthermore, we don't believe that the Agency's inspection personnel are educated enough to verify whether growth inhibition ingredients or anti-microbial agents are used appropriately and that product incorporating such ingredients does not provide an opportunity for significant microbial outgrowth.

Labeling/Consumer Education

This section of the report reads as a ploy to force meat processors to add antimicrobials into their RTE meat products. The recommendation to educate the consumer seems to have an ulterior motive. Educate the consumer so that they will expect it in their RTE meat products and will purchase RTE products due to the addition of antimicrobials, thus forcing all meat processors to use antimicrobials to sell their product.

If the Agency moves forward with this recommendation, we would be surprised to see that it has the resources to expend on the marketing of meat products containing antimicrobials, while lacking the time to educate meat processors on the *Lm* Interim Final Rule. After all it is the Food Safety and Inspection Service, not the Food Marketing Service! If a meat company wants to research the use of labeling statements, it should do so at its own expense. FSIS's resources can be better utilized in other ways.

Retail Aspects

The findings of this section reiterate the need for retail and consumer education. Overall it is the same scenario; meat processors can produce the safest product possible, but if the final handler of the product does not understand the importance of food safety, the final goals of a safe product and decreased foodborne illness are unattainable. Although temperature is one of the controlling factors in these types of establishments, the slicers seem to be a harboring site for product contamination. While product temperature is controlled, the slicer sits at room temperature all day, thus enumerating pathogens and contaminating a temperature controlled RTE product.

We strongly agree with the recommendation to educate and train food service and retail establishments, but in most cases this falls outside USDA/FSIS jurisdiction. Furthermore, with FSIS's limited personnel, how would such a task be accomplished? Agencies such as FSIS, USDA, and public health departments need to work together to attain food safety through the entire production, distribution, and retail chain.

Economic Impact

Within this section it was mentioned that about 56 percent of all *L. monocytogenes* related NRs have occurred in very small establishments. This outcome was probably most likely due to the lack of education on the Interim Final Rule published in October of 2003. Although most meat processors realized that it was coming, many of them had no education on how to comply with the Interim Final Rule.

FSIS held five interactive workshops to help small and very small plants prepare for the interim final rule "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products." The provisions of the rule, which were implemented on October 6, 2003, required official establishments that produce certain RTE meat and poultry products to take additional steps to control product adulteration from *Listeria monocytogenes*. The workshops were held on the following dates:

- September 13 - Raleigh, NC
- September 13 - Bridgeport, CT
- September 20 - Kansas City, KS
- October 4 - Albuquerque, NM
- October 4 - Oakland, CA

Although this effort was boasted by the Agency, we concluded that this was a feeble attempt to demonstrate that education was available. Further more, the Agency gave very little time to become educated to the Interim Final Rule prior to the implementation and in some instances this time period was two days. Small and very small volume establishments were set up to fail when the Agency followed such tactics. If it wasn't for some University extension programs, we believe the number of NRs would be much higher. We strongly encourage the Agency to offer more opportunities for small volume meat processors to receive adequate education on upcoming regulations.

Training

We don't believe that the Agency inspection personnel were adequately educated on the *L. monocytogenes* Interim Final Rule. In some instances the inspection personnel was learning about the interim final rule at the same pace as the establishments. This should never be an accepted practice. Agency personnel should be trained and well informed prior to the implementation of any Agency rule. How are establishments expected to comply with a rule when their own inspector is not properly educated? Overall, the Agency needs to extremely improve on this issue. Moreover, the issuance of a CD-ROM to the inspection workforce probably is not the most effective teaching tool.

We would agree with the recommendation that when the rule is finalized, a CD-ROM should be produced. This CD-ROM should be available to inspection personnel as well as all stakeholders (i.e. industry, associations, universities, etc.). Although a majority of the documents can be found on the Internet, a CD-ROM may be much easier for those without Internet service or dial-up connections (since some of the documents are very large in size). Web-based training is one teaching tool that is currently being researched by the Agency, but we would recommend that this method is not the only tool that is used to educate stakeholders.

Small Plant Guidance

We have previously discussed some of the current issues related to small plant guidance in the economic impact section. We strongly reiterate the need to train/educate FSIS inspection personnel prior to any Agency rule implementation. The concept of education prior to implementation should be ritually followed for every Agency rule and should be applied to the FSIS inspection personnel and stakeholders alike.

While some products are easily classified as RTE or NRTE, other traditional products aren't so easily classified. Over the past year we have discouraged establishments from reclassifying their RTE as NRTE. The new October 2004 compliance guidelines make it sound as though this is an achievable task, but past experience has proven otherwise. We have tried to apply the same techniques as described in pages 23-25 of the compliance guidelines, with very little success. Moving a product from a heat-treated, fully cooked HACCP plan to a heat-treated, not fully cooked HACCP plan and the application of appropriate labeling has been extremely discouraged by the Agency since the publication of the guidelines in October of 2003. In fact, most attempts to reclassify RTE products as NRTE have resulted in failure. We would hope that FSIS educates their inspection personnel that this can be done as long as the proper protocol is followed.

Agency Accomplishments

Within this section we are disturbed that the Agency considers the training of 35 EAIOS as an accomplishment. 35 EAIOS were trained, but what is the total number EAIOS employed by the Agency? Furthermore, the Agency considers their workshops that were targeted for plant operators of small and very small establishments prior to the implementation of the rule an accomplishment. We think our previous statements and observations definitely dispute that fact that it was anything but an accomplishment. We do commend the Agency for the improvements they have made since that time and hope the improvements continue in future years.

AAMP appreciates the chance to comment on the Report of Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule. We strongly encourage the Agency to implement further training of FSIS inspection personnel and outreach education for small and very small volume meat processing establishments.

Sincerely,



Jay B. Wenther, Ph.D.
Assistant Executive Director

cc: Scott Cunninham, AAMP President