AMERICAN ASSOCIATION OF MEAT PROCESSORS

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

RE: FSIS Docket Clerk - Docket No. 97-013F
Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products

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.

As for the *Lm* Interim Final Rule itself, we would like to comment on some procedures that were published in the October 2003 version of the *Lm* Compliance Guidelines and remain in the new 2004 version of the *Lm* Compliance Guidelines. We will also comment on the new inserts that have been published in the new 2004 version of the *Lm* Compliance Guidelines.

Sampling Techniques

The guidelines state that "samples should be taken at least 3 hours after the start of operation or an appropriate time period after all parts of the food handling system are operational because the equipment has to be operational for seeding to occur." In some meat or food processing

scenarios this technique is not applicable nor is it feasible. Some processes do not take three hours and doesn't make sense to take samples after other procedures (e.g. packaging of sausage) have begun. Currently USDA/FSIS is stressing the recommendation to hold all tested product until test results are known. The application of this technique of taking samples three hours after operations have begun either forces establishments to hold product or puts the establishment at risk of a possible recall situation. It seems only logical that if the goal is to test food contact surfaces, then the time the tests are taken is irrelevant. Although it states that tests can also be taken at an "appropriate time period after all parts of the food handling system are operational," we have found it extremely difficult to encourage FSIS inspection personnel to deviate from the three hour standard. At this time, the only party that seems to be accountable for anything is the establishment. Occasionally, FSIS inspection personnel refuse to make a decision if they fear that the decision may be questioned or scrutinized.

We strongly recommend that USDA-FSIS implement training of their personnel on proper microbiological sampling techniques. We have received numerous comments from our membership regarding improper sampling techniques. Even if the FSIS inspection personnel are not taking samples, inspection and establishment personnel can work together and help each other in the gathering of samples.

RTE Products not Exposed to the Environment Post-lethality

The new guidelines state "if the product is not exposed to the environment after the lethality treatment and before packaging, then the product is not covered by the *Listeria* rule." This seems perfectly logically, but we recommend that some guidance and training materials be generated by the Agency to educate the final retailers of these types of products. This would include deli operators. Although this product would essentially be completely safe when it arrives at the deli, its safety and wholesomeness can be greatly compromised after the packaging is removed.

Clarification on Whether Control Measures Must be CCPs

Under this section (page 9), the guidelines describe antimicrobial processes that also act as a post-lethality treatment. Under 9 CFR 417.5 a(2)-Records, FSIS requires establishments to have decision-making documents associated with the selection and development of Critical Control Points (CCP's) and Critical Limits (CL). The compliance guidelines state "products with water activity less than 0.85 will not support the growth of *L. monocytogenes* and can sometimes even cause *L. monocytogenes* death." We would like to see what supporting documentation FSIS is using to determine this water activity value. By stating this within the guidelines and not supporting it with scientific documentation, FSIS is setting a dangerous precedent. FSIS inspection personnel will assume that this is the value to control *L. monocytogenes*, when almost every scientific text book has stated that a water activity of 0.92 or less does not support *L. monocytogenes*. We recommend that if FSIS is going to use specific values, they support them with references. FSIS should follow the same rules it applies to meat processors.

Ready-To-Eat (RTE) versus Not Ready-To-Eat (NRTE) &
Reclassification of Certain Ready-To-Eat (RTE) Products as Not Ready-To-Eat (NRTE)

Although this seems like it should be an easy concept to determine, we receive numerous calls regarding this topic. We commend USDA-FSIS for clarifying this issue, but some products don't have a standard of identity and classification is still unclear. For example, although a traditional product such as scrapple has a definition/standard of identity associated with it under 9CFR 318.280, there is very little documentation to determine whether it is RTE or NRTE. Although this product goes through a heat process, the heat process is for quality purposes only to give the product its characteristic texture. The product may reach lethality temperatures, but it is most commonly eaten after it is further cooked. Other ethnic products fall into this same debate. We recommend that USDA-FSIS incorporate a technique to determinate whether the product is RTE or NRTE.

Other products have also sparked debate because they are heat-treated, but not fully cooked. Some FSIS inspection personnel have determined that the consumer can't read the labeling on the package. Even though the packaging has the safe-handling label, cooking instructions, and other instructions such as "cook prior to consumption;" if the product looks cooked, it has been highly recommended that the establishments reach lethality temperatures to make the product a RTE product. Some establishments don't want to make a RTE and are now being essentially forced to produce such a product. We recommend FSIS establish guidelines for its inspection personnel to help them determine how to deal with such products.

Over the past year we have discouraged establishments from reclassifying their RTE as NRTE. The 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, 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.

Controlling Environment During and After Construction

We acknowledge the fact that is has been well documented that construction activities can increase the potential of *L. monocytogenes* contamination. A majority of the points given make good manufacturing sense. The door is opened to debate when the *Lm* compliance guidelines state "construction or maintenance activities that can result in contamination with *L. monocytogenes*." Construction and maintenance are two separate activities in which one is independent of the other. Merriam-Webster has them defined as:

Construct: to make or form by combining or arranging parts or elements (i.e. build)
Maintenance: the upkeep of property or equipment

We recommend that FSIS define these terms more specifically or allow the plants to define them within the document they addressed *L. monocytogenes*. We would consider major structural changes (i.e. the erection or removal of walls, floors, drains, etc.) as construction while minor improvements (i.e. painting, the movement of equipment, etc.) as maintenance.

These minor improvements should be encouraged by the Agency without the implementation of an intensified monitoring of environmental surfaces.

Along with FSIS, we strongly encourage establishments to hold all tested product until test results are known. With the new requirements of the compliance guidelines on page 38 – section 8c, this may cause extreme hardship for establishments. The guidelines state an intensified monitoring of food contact and environmental surfaces until 3 consecutive negative tests on the food contact surfaces for 3 consecutive days. Has the Agency taken into consideration production days versus non-production days? If an establishment follows the recommended test-and-hold guidelines, this may cause a plant not to sell products for possibly over a week (*dependent on when the results are known*).

Furthermore, does this testing take place before production can begin, or is it during production? FSIS needs to expand on this topic with specific details on how tests will be taken and flow diagrams need to be published. Take for example this scenario:

> Construction occurred over the weekend. A food contact surface is tested on Monday, three hours after production (according to previous guidelines mentioned). The establishment stops production and performs a complete clean-up. They go back to packaging the RTE product. On Tuesday, they begin packaging again and a food contact surface is tested three hours after production. If the sample on Tuesday is positive, what is the disposition of the product packaged on Monday after the complete clean-up? We recommend that FSIS still honor the clean-up to clean-up procedures that have been accepted in the past.

Overall, when more testing is recommended we refer FSIS back to the main reason HACCP was implemented. Microbiological testing is seldom an effective means controlling food safety. HACCP addresses food safety through the analysis and control of biological, chemical, and physical hazards throughout production to achieve a wholesome and safe final product. Microbiological testing does play a role in verifying that the overall HACCP system is working, but how much testing is enough and who and why was it decided to be three days?

Hold-and-Test Scenario Flow Chart

The development of the hold-and-test flow chart is a useful tool for meat processors. This may eliminate some of the questions as to how to handle product.

AAMP appreciates the chance to comment on the October 2004 *Lm* Compliance Guidelines. 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,

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Assistant Executive Director

cc: Scott Cunninham, AAMP President