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FSIS Docket Clerk
Food Safety and Inspection Service
United States Department of Agriculture
Room 102 Cotton Annex Building
300 12th Street SW
Washington D.C. 20250-3700

RE: FSIS Docket No. 00-016N *Notice of Public Meeting: Revised Action Plan for the Control of Listeria monocytogenes for the Prevention of the Foodborne Illness Listeriosis*

To whom it may concern:

The American Meat Institute (AMI) is the national organization representing the interests of meat and poultry slaughterers and processors and their suppliers throughout North America. AMI's members produce the majority of meat and poultry products manufactured in the United States. We appreciate the opportunity to comment on the above-captioned docket and other relevant activities.

The processed meat and poultry industry is committed to food safety and has recognized the importance of controlling *Listeria monocytogenes (Lm)* in Ready-to Eat (RTE) meat and poultry products for many years. Food safety systems and practices for RTE meat and poultry product production are designed to protect consumers from listeriosis and other foodborne illnesses. Recent outbreaks of listeriosis point out the need to renew efforts to control *Lm* and to investigate new strategies to protect further consumers from listeriosis. In May 1999, FSIS advised manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to ensure the plans adequately addressed *Lm*. Results of a March 2000 industry survey show that 98 percent of the 277 respondents who answered the question reassessed their HACCP plans with respect to *Lm*. Among the 303 total respondents, 67 percent have an end-product-testing program for *Lm* (88 percent of large plants, 64 percent of small plants and 27 percent of very small plants). More than 90 percent of the respondents conduct some type of

environmental testing (100 percent of large plants, 92 percent of small plants, and 41percent of very small plants).

On May 6, 2000, President Clinton announced during his weekly radio address that he had directed the Food Safety and Inspection Service (FSIS or the agency) and the Food and Drug Administration (FDA) to develop within 120 days an action plan to reduce the number of cases of listeriosis by 50 percent by 2005. Specifically, FSIS has been instructed to publish within that 120-day period proposed "regulations that include any appropriate microbiological testing and other industry measures to: 1) prevent cross-contamination in the processing environment; 2) ensure that the processing of ready-to-eat products meets appropriate standards; and 3) ensure that products are safe throughout their shelf-life."

On May 8, 2000, the FSIS published the above-referenced notice in the *Federal Register* announcing a May 15, 2000, public meeting to discuss and receive comment regarding *Lm*. Specifically, the public meeting's purpose was to discuss the agency's initiatives taken after the February 1999 public meeting regarding *Lm* and future plans to protect further the public from foodborne illness associated with *Lm*. On May 12, 2000, FSIS published the *Food Safety and Inspection Service Revised Action Plan for Control of Listeria monocytogenes for the Prevention of Foodborne Listeriosis* (the action plan) and during the May 15 public meeting the agency reviewed the action plan. The following comments respond to the action plan, as well as other discussions during the public meeting.

Performance standards for RTE meat and poultry products should be based on science and provide manufacturing flexibility.

AMI supports in principle the FSIS plan to establish performance standards for RTE meat and poultry products. The publication of *Performance Standards for the Production of Certain Meat and Poultry Products* required certain cooked meat and poultry products to meet lethality (cooking) and stabilization (cooling) requirements. The RTE meat and poultry products covered by the performance standards (cooked beef, roast beef, and cooked corned beef, certain fully and partially cooked meat patties, and certain fully and partially cooked poultry products) is a small yet traditional portion of the total number of RTE meat and poultry products manufactured. The scope of RTE meat and poultry products not covered by the performance standards is a much larger and more diverse group of products. RTE meat and poultry products not covered by the current performance standards range from traditional RTE meat and poultry products, such as

fully cooked hams and hot dogs, to regional/ethnic RTE meat and poultry products, such as pulled pork barbecue and souse. Many of these RTE meat and poultry products require unique manufacturing techniques to produce the product consumers expect. Therefore, FSIS should ensure that any proposed performance standards for RTE meat and poultry products provide a scientifically based level of consumer protection, while allowing flexible manufacturing techniques.

FSIS should revise Directive 10,240.2 *Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System* (the Directive) to allow for voluntary industry testing.

The RTE meat and poultry industry has repeatedly supported the use of environmental monitoring for indicator organisms such as *Listeria* spp. to reduce the risk of contamination of products with *Lm*. However, it is essential that such programs be designed and implemented in a manner that encourages finding the organism when it is present in the environment. As indicated in the attached *Industry Position On Control Of Listeria monocytogenes, With Emphasis On Meat And Poultry Products,* mandating environmental and equipment monitoring programs may prove counterproductive by requiring a "one-size-fits-all" program that will bring compliance but not necessarily effective control. To address *Lm* effectively and reduce risk to consumers, industry must be allowed the flexibility to design programs that fit the needs of individual operations and to react appropriately to monitoring results. Mandating such programs may inhibit the type of aggressive testing program that can be key in managing the risk to the lowest level possible.

In addition, the 1996 *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) System* final rule requires official establishments to "develop, implement and maintain written standard operating procedures for sanitation (Sanitation SOP's)...." Establishment Sanitation SOP's must "describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s)." Furthermore, these regulations require that establishments routinely evaluate the effectiveness of the Sanitation SOP's and take corrective actions when necessary.

Data from the March 2000 industry survey indicate that, in terms of pounds of product produced, the preponderance of all hot dogs and luncheon meats are manufactured by companies that conduct some environmental or finished product testing to verify effectiveness of their control programs. Of the large and small hot dog

manufacturers responding to the industry survey, 72 percent conduct end product testing and 96 percent conduct environmental testing. Similarly, of the large and small manufacturers of sliced luncheon meats responding to the industry survey, 67 percent conduct end product testing and 96 percent conduct environmental testing. Too few very small manufacturers of such products responded to the survey to provide meaningful statistics. However, it appears that a smaller percentage of these establishments conduct microbiological testing.

AMI proposes an alternative approach to mandatory testing that should result in more effective control of *Lm* by testing finished product or environmental testing, coupled with finished product testing, on a voluntary basis. FSIS should revise the Directive to provide the opportunity for reduced sampling by the agency in establishments conducting product testing or environmental testing, coupled with product testing. Such an approach would allow the agency to focus its resources on those establishments that do not conduct finished product testing or a combination of environmental and finished product testing.

Furthermore, AMI is concerned with the effectiveness of any testing program that closely ties product volume with testing frequency. In our experience, occurrence of contamination of finished product by *Lm* is determined by effectiveness of control programs implemented on each production line and not by production volume. Although ultimately, the extent of risk to the public will be determined by the potential for exposure, it is relatively easy to calculate that a low production volume with a high contamination rate is a relatively high-risk situation. The agency's position seems to be that low-volume processing plants present less risk to the public, and AMI does not agree with that assumption.

Validation of handling instructions and/or open dating must be based on scientific principles.

FSIS plans to propose that establishments "validate the accuracy of the handling/open dating information in their HACCP plans." At the May 15 meeting, FSIS stated that shelf life would be based on safety considerations, and that the agency would expect a product to be pathogen free at the end of its shelf life. With respect to *Lm*, under the current "zero tolerance" policy the organism must be absent (undetectable) in product at all points after processing. Because we know that the organism, if present, will grow in many of these products, it is not clear what type of validation studies would be needed with respect to the shelf-life date for current products.

If products containing growth inhibitors are developed, then the determination of shelf life can be done using challenge tests. Unclear from the agency's statements is whether FSIS intends to force the reformulation of these products to include growth inhibitors in order to meet the shelf life required for marketing purposes. If so, many of today's products likely will disappear from the market place, given the lack of alternatives to reformulation, such as irradiation or post-packaging pasteurization. At the same time, the agency should provide some incentive for companies that reduce greatly the risk of listeriosis through controlling growth of *Lm* in meat and poultry products to be sold refrigerated. Those firms that undertake the expense to reformulate products with compounds that inhibit *Lm* growth over the shelf life of the product should not be held to a rigid interpretation of "zero tolerance" at the time of production. AMI understands that the interagency quantitative risk assessment will prove that growth, not presence or absence of *Lm,* is the chief risk factor by several orders of magnitude. If so, then firms producing such products should be encouraged and rewarded for adopting measures that address growth.

The FSIS testing program should be modified to focus on RTE meat and poultry products that pose the greatest risk.

The action plan indicates that the agency intends to modify its program for sampling and testing RTE meat and poultry products. The revised testing program will expand the range of RTE meat and poultry products subject to testing. AMI agrees that the FSIS testing program should be modified. However, the focus should not be on all RTE meat and poultry products, but rather on those RTE meat and poultry products that pose the greatest risk. Such a program is more likely to reduce the range of products tested rather than expand it.

Although *Lm* is a common organism in the environment, listeriosis is rare. The Centers for Disease Control and Prevention (CDC) estimates there are about 2,500 cases of listeriosis per year in the U.S. Thus, it appears that either relatively high numbers of the organism must be ingested to cause illness or not all strains are pathogenic for humans. The foods involved in outbreaks have been those in which the organism can grow to high numbers. For example, there is no evidence that frozen RTE meat and poultry products, in which the organism cannot grow, present a real public health concern. Clearly, not all RTE meat and poultry products appear to present significant public health problems.

Given the resource limitations, within industry and the government, it seems prudent and practical to focus on products in which the organism can grow. This does not mean that *Lm* control should be ignored for other products. However, the controls, remedial actions and enforcement policies can and should differ for low-risk products without having a negative impact on public health. Thus, we strongly recommend that FSIS revise its testing program to reflect the risk of products based on the ability of the organism to grow in the specific product and the likelihood that the product may be contaminated with the organism. In addition, if the joint risk assessment to be released in July indicates that other foods are only remotely associated with the risk of listeriosis, it is logical to adjust the focus of monitoring programs away from those products in favor of others that pose higher risk.

The interagency risk assessment should be used to develop FSIS policy.

FDA and FSIS are currently undertaking a risk assessment for *Lm* in foods that is expected to be released in July. Based on comments made by FDA's Dr. Robert Buchanan at the May 15 meeting on *Lm*, the risk assessment will indicate that the greatest risk for listeriosis is from products in which the organism can grow. In fact, Dr. Buchanan stated that foods in which the organism cannot grow pose little risk. For this reason, FSIS compliance efforts should not focus on frozen foods (especially if they are heated prior to consumption) or foods with barriers to growth of *Lm* (pH, a_w or additives demonstrated to inhibit growth of the organism in the product). In addition, the agency should not focus on RTE meat and poultry products that are given a listericidal process in the package and shipped without being repackaged, because these items do not present a risk of contamination until after the packages are opened.

Trained subject matter experts should conduct in-depth HACCP Verification Reviews in a uniform manner.

The action plan states that "FSIS plans to use its revised draft protocol for in-depth verification review of the regulatory compliance and scientific validity of a company's HACCP system." The National Advisory Committee on Meat and Poultry Inspection provided recommendations to the agency regarding the in-depth verification draft protocol, procedures used and qualifications of individuals conducting in-depth verifications during the November 4, 1999, meeting (pages 30-48 of the transcript).

Specifically, the committee recommended that FSIS obtain "input and critique from neutral HACCP experts" on its in-depth verification document. The committee was particularly interested in knowing if the appropriate questions were being asked. Furthermore, the committee recommended that the document provide "more feedback to the plant" and that the document be considered a "living document," with the provision that it be finalized prior to its use in the field. The committee further recommended that the revisions to the document be made based on actual document use and with the input of HACCP experts, including those outside the agency, and that it be computerized.

In addition, the committee recommended that the agency look at models used by other regulatory agencies, such as the Health Care Financing Agency. Prior to implementing in-depth reviews, the committee recommended that reviewers be provided formal training/education regarding the auditing process and that the training/education be made available to the industry. The committee also recommended that a standardization/correlation group be formed to ensure uniform application of the review process.

As a final recommendation, the committee outlined a specific process for the in-depth verifications, which should include a notice of the review date and documents for review. On that review date the establishment would make the requested documents available for review and answer questions from the in-depth verification team (the team). After the paperwork review the team would conduct a system review in the establishment. Following the review an exit conference would be held with establishment officials and a preliminary report provided by the team. If the establishment is not meeting regulatory requirements immediate and appropriate regulatory actions should be taken according to part 417. Finally, the agency would provide a formal written report to the establishment within two weeks, with the establishment given 30 days to respond formally in writing to the findings including corrective actions taken. The report and establishment response would not become available until after the 30-day period had expired. District managers would be responsible for follow-up activities.

AMI is unaware that any of these recommendations have been implemented and urges the agency to implement the recommendations prior to any large-scale use of the in-depth verification reviews.

Changes to the United States Department of Agriculture (USDA) commodity food programs specifications should be based on sound science and effective communication messages.

The action plan states that the agency intends to "jump-start" the use of instructional labeling for safe use of RTE meat and poultry products by working with the Agricultural Marketing Service and other USDA agencies. Any instructional or safe use labeling should be tested for effectiveness prior to any changes to specifications. In addition, educational programs should be fully funded, developed, and implemented in conjunction with the specification changes. These educational programs should be focused not only on consumers purchasing these products, but also on those responsible for preparing meals for at-risk groups through the commodity program.

Public messages for at-risk consumers and general consumer education should utilize effective communication messages.

Because listeriosis is extremely serious in certain distinct, vulnerable populations, AMI strongly believes that the government, medical community, and industry should work together to educate at-risk consumers and their healthcare providers about the illness and its prevention. In that regard, AMI, USDA, FDA, CDC, and others have been working through the Partnership for Food Safety Education (the Partnership) to develop effective safe food handling communication messages. The Fight Bac!™ Campaign was launched in October 1997 after being extensively tested through multiple focus groups to ensure that the messages were accurate, understandable, and persuasive.

A new educational product of this cooperative effort, aimed at at-risk consumers for listeriosis, is expected to be available in July 2000. A reproducible patient information flyer to be included in a new physician education module on foodborne illness is the result of collaboration between the American Medical Association, CDC, FDA, and USDA. It is the first of its kind and promises to raise physician awareness of the diagnosis, treatment, and prevention of a host of food and water-borne illnesses.

The agency should work with the Partnership to develop other messages and educational materials for at-risk consumers and the general public. By pooling its resources with the Partnership, the agency will be able to utilize the expertise gained by the Partnership regarding the development and implementation of food safety education efforts.

FSIS should conduct extensive training for headquarters, technical service center and field operations staff regarding *Lm* control.

Before the agency can determine the effectiveness of an establishment's *Lm* control program it must first ensure that FSIS employees, at all levels, understand all aspects of controlling *Lm*. Although the agency has extensive experience with facility design and sanitation, it lacks experience in developing, implementing, and maintaining effective microbial control programs, including data interpretation. Further, the agency has purposefully not trained in-plant field operations personnel on microbial data interpretation (*i.e.* generic *E. coli* testing procedures). However, industry has such expertise. During the May 15 public meeting AMI extended an offer to assist the agency in developing a training program for agency personnel and strongly encouraged the agency to undertake such an effort.

Summary

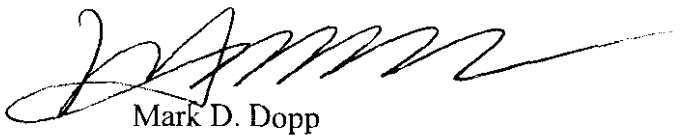
The agency should use the results of the interagency risk assessment to develop future FSIS policy. Based on the risk assessment FSIS should refocus its testing program for RTE meat and poultry products on those products that pose the greatest risk. The agency should propose RTE performance standards that are grounded in science, based on risk, and provide manufacturing flexibility.

The Directive should be revised to allow those establishments conducting finished product testing, or environmental testing coupled with finished product testing, eligibility for reduced agency sampling. FSIS also should identify its expectations of validation of handling instructions or open dating for RTE products prior to proposing regulations.

The agency's in-depth HACCP verification process and tools must be reviewed by HACCP experts and finalized prior to their wide spread use and individuals conducting in-depth HACCP Verifications must be appropriately trained. Changes made to USDA commodity specifications should based on sound science and effective communication messages accompanied by an educational program. Finally, the agency should work in cooperation with the partnership to develop and implement accurate, understandable and persuasive educational messages.

AMI appreciates the opportunity to comment on the action plan and related issues. If you have any question regarding these comments, or anything else affecting this matter, please contact me.

Sincerely,



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