NATIONAL Turkey FEDERATION
60th Anniversary

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Alice L. Johnson

FSIS Docket Clerk,
Docket #00-016N,
Room 102 Cotton Annex,
300 12th Street, SW.,
U.S. Department of Agriculture
Washington, DC 20250-3700

Re: FSIS Revised Action Plan for the Control of *Listeria monocytogenes*

Dear Ms. Moore:

The National Turkey Federation (NTF) respectfully submits these comments in response to the above Notice regarding the Food Safety and Inspection Service's (FSIS) revised action plan to control *Listeria monocytogenes* (*L.m*). NTF is the only national trade association representing the turkey industry exclusively. NTF represents more than 95 percent of the United States turkey industry, including processors, growers, breeders, hatchery owners, and allied industry. Many of our members produce ready-to-eat products and are thus interested in FSIS' policies regarding *L.m.*

As an initial matter, NTF was a signatory to the Joint Industry White Paper presented to the agency at the Listeria Public Meeting last month. The comments below will expound on certain positions in the White Paper in light of the information presented at the Public Meeting.

Moreover, NTF wishes to make clear that it supports the President's initiative to pursue an aggressive action plan so as to reduce the incidence of Listeriosis by 50% in the next five years. We, along with all those in industry, will work with FSIS to make this goal a reality. In this regard, we respectfully make the following comments.

1. FSIS Should Focus on Products Which Pose a Risk of Illness

Given the President's goal is to reduce illness, NTF recommends FSIS focus on those products were there is a demonstrated risk of illness. *L.m.* is ubiquitous in the environment. Yet not all foods present the same degree of risk.

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According to the presentation at the Public Hearing on the Inter-Agency Listeria Risk Assessment, there are four factors which elevate the risk of illness: (1) the food supports the growth of *L.m*; (2) the food has an extended shelf life; (3) there is a high incidence of initial contamination post lethality; and (4) the product is distributed with less than an optimal cold chain. These factors are consistent with the foodborne outbreak incidents discussed by the Centers for Disease Control representative at the public meeting.

We would strongly recommend that FSIS attention and resources be directed almost exclusively to foods with these risk factors. In this regard, we would not support an expansion of agency testing of all ready-to-eat product as mentioned at the public hearing unless the sampling protocol is very heavily weighted towards those products with the above factors.

For example, it would be a waste of resources to focus any appreciable attention on frozen products given *L.m* cannot grow at frozen temperatures. Even during less than optimal distribution, such products do not reach temperatures at which *L.m* could grow. Likewise, refrigerated products containing growth inhibitors will not pose at risk for the same reasons. Finally, items subject to a lethality step in their finished package could not have been contaminated post processing; hence, do not pose a Listeria risk.

2. FSIS Should Work Closely with FDA in Addressing Illness Reduction

We hope FSIS will work closely with its sister agency, the Food and Drug Administration (FDA), in attacking Listeriosis. As the CDC presentation at the public meeting made clear, FDA-regulated products have been implicated in foodborne outbreaks. Thus, action on FSIS regulated products alone may not achieve the President's goal.

3. FSIS Actions Should Foster Listeria Control

We respectfully submit that in determining whether to adopt a particular course of action, FSIS should carefully consider whether the action will have the effect of encouraging or discouraging true Listeria control. In this regard, we strongly recommend that FSIS immediately revise its "Microbial Sampling of Ready-To-Eat Products" Directive (10,240.2) to recognize industry testing of either finished products for *L.m* or environmental/equipment testing for indicator organisms, such as *Listeria* spp., in return for a reduced FSIS sampling frequency. Such a revision will encourage companies to consider and implement Listeria testing programs. As more companies conduct testing, FSIS will have increased resources to test products not otherwise covered by a control program. This would be a win-win situation where companies can tailor their testing programs to their specific needs while the agency expands the total amount of product covered by a testing program.

Although NTF strongly believes an environmental/equipment testing program is generally the most effective current technique to control Listeria in establishments, we

cannot support any FSIS proposed regulation which mandates such programs in all situations. First, in certain situations, this type of testing program may not be the best program to reduce potential Listeria concerns. Second, it may be irrelevant given the absence of environmental contamination, such as with a cook-in bag product. Third, as a regulatory program, there is the tendency to view each test as compliance indicator, with each failure being documented on a Noncompliance Report. As noted below, a single finding is not important, it is what a plant does in response to the finding that is important. Unfortunately, in a regulatory context, the finding is more easily understood and documented than the corrective action.

We wish to emphasize the position in the Joint Industry White Paper and comments made at the Public Hearing -- an effective environmental and equipment testing program is designed to *find* the indicator organism. Accordingly, FSIS should maintain and reaffirm its current policy that an isolated environmental/equipment positive finding triggers corrective action, not product action. It is not the positive finding which is important, it is how a company responds to the finding that FSIS should focus its regulatory attention on.

4. NTF Questions The Agency's Purpose in Conducting a Shelf Life Study

At the Public Hearing, FSIS indicated its intent to conduct a shelf life study to validate the accuracy of the handling and open dating information. Specifically, FSIS indicated it would expect the product to be free of pathogens throughout the shelf life.

We are somewhat uncertain as to the purpose of such a study. If a RTE product is free of a pathogen at time of packaging, there is no pathogen which can grow during distribution and the product cannot mystically become adulterated. If there is a pathogen at time of packaging and there is a zero tolerance for that pathogen, the product is adulterated regardless of whether the pathogen grows or not. Thus, under currently regulatory policy, there is no difference whether a pathogen such as *L.m* grows during the shelf life of the product. Given this, whatever the study establishes will be meaningless.

This study should be more related to the sensitivity of the testing method and the levels of organisms required for detection. NTF feels that the agency should consider a policy focused on preventing the number of *L. monocytogenes* cells from increasing to a level of health significance (a risk-based focus), rather than one based on a total absence of this ubiquitous organism.

To be sure, such a study would be useful if FSIS plans to base its testing priorities on whether *L.m* can grow on the product. It would also be useful in connection with the demonstrating the effectiveness of microbial growth inhibitors. If such is the agency's intent, we request this be made clear. Otherwise, we respectfully submit that there is no benefit to justify the cost of such a study.

Conclusion

We appreciate the opportunity to present our views in this matter and look forward to working with FSIS to achieve the President's food safety goal.

Respectfully submitted,

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INDUSTRY POSITION ON CONTROL OF *LISTERIA MONOCYTOGENES*, WITH EMPHASIS ON MEAT AND POULTRY PRODUCTS

Prepared by the National Food Processors Association
in cooperation with
American Meat Institute, National Turkey Federation, National Chicken Council, North American Meat Processors, National Meat Association, Southwest Meat Association, American Association of Meat Processors

INTRODUCTION

The food industry recognizes that listeriosis is a serious disease that is primarily transmitted through a limited number of foods. Specifically, it appears that foods that support the growth of pathogenic *Listeria monocytogenes* over the shelf life of the product, especially foods given a listericidal process which have become recontaminated, pose the greatest risk to consumers. For these products, the most stringent control measures for *L. monocytogenes* are appropriate. Products that do not support the growth of *L. monocytogenes* (frozen products, products containing inhibitors, etc.) do not pose a similar risk and do not warrant similar focus. This paper explains the basis for this position and sets forth recommendations for industry and regulatory agencies to address further reductions of the risk of listeriosis from consumption of foods.

BACKGROUND

It is widely accepted that *L. monocytogenes* is widespread in the general environment (Ryser and Marth, 1999). It has been found in soil, water, sewage, and decaying vegetation. The organism can be isolated from a variety of animals, including food animals and pets. *L. monocytogenes* has been isolated from a wide variety of foods, including fresh vegetables, meat, poultry, dairy products, and seafood. It has been isolated from food manufacturing plant environments and from the home environment, including dish cloths, refrigerators, and even toothbrushes. It has also been established that *L. monocytogenes* can be routinely isolated from the intestinal tract of healthy humans (Slutsker and Schuchat, 1999). It appears that a carrier state can exist, as is evidenced by shedding for several weeks or even months, without ill effects. Although *L. monocytogenes* has been isolated from a wide variety of food sources, only a few refrigerated food products have been implicated in illness. Those products appear to have common features including:

- intrinsic properties (pH, water activity, etc.) that would permit growth of the organism to significant numbers over their shelf-life;
- stored in a manner that permits growth of the organism;
- opportunity to become recontaminated after administration of a listericidal process.

Despite the wide occurrence of *L. monocytogenes* in the home environment, in retail food establishments, in foods, and in people and pets, the incidence of listeriosis in the U.S. is low. Compared with other disease syndromes, listeriosis has been described as a rare occurrence. Based on FoodNet data, there are an estimated 5 cases/million population, or about 1300 cases per year, in the US; CDC, assuming that only about half the cases are detected, estimates that there are 2500 cases annually. However, mortality for listeriosis is estimated to be 20% or higher, thus justifying the attention being given to this organism. Of these estimated cases, it is reasonable to assume that a portion may be due to the consumption of perishable ready-to-eat (RTE) products contaminated at a manufacturing establishment. However, in our opinion, it is also likely that some of these cases result from food contaminated at retail establishments or in the home.

Since the mid-1980's the food processing industry has been actively seeking and implementing control strategies for *L. monocytogenes* (Bernard and Sveum, 1994; Tompkin et al., 1999). However, control of *L. monocytogenes* has proven to be a difficult challenge in food processing establishments that manufacture RTE products that are not treated in their final package to eliminate this organism. As has already been stated, the organism is widespread in the environment in and around food plants and in homes. Because the organism is pervasive, there is a potential for constant re-introduction into the food plant environment. Extensive efforts to control *L. monocytogenes* can substantially reduce the amount and level of contamination. However, using existing technologies it has not been possible to permanently eradicate it from the processing environment. Thus, it has not been possible to eliminate the potential for contamination of finished products. Despite these challenges, industry efforts to control *L. monocytogenes* apparently were successful in reducing the incidence of listeriosis from 7.3/ million in 1986 to 4.2/million in 1993 in selected surveillance areas (Tappero et al., 1995).

THE CURRENT SITUATION

As a result of an outbreak of listeriosis from hot dogs that caused 101 illnesses, including 21 deaths, in 1998-1999, there has been a renewed focus on *L. monocytogenes*, with particular attention devoted to the meat and poultry industry. USDA FSIS held a public meeting in February of 1999 to address concerns and explore potential solutions. In May of that same year, FSIS released its action plan for addressing *L. monocytogenes*. The plan included three near-term initiatives:

- a notice to establishments to reassess their HACCP plans to ensure that they adequately address *L. monocytogenes*;
- guidance to the industry recommending environmental and end-product testing; and
- educational efforts targeted to "at risk" consumers.

There were also four long-term initiatives:

- research on post-production growth of *L. monocytogenes* in ready-to-eat (RTE) products;

- in-depth verification of HACCP plans for RTE products, particularly for *L. monocytogenes*;
- a risk assessment of *L. monocytogenes* in RTE foods (in conjunction with FDA); and
- food safety standards for RTE products that will address all pathogens, including *L. monocytogenes*.

The agency notice, referred to above, requiring establishments producing RTE meat or poultry products to reassess their HACCP plans, also announced the availability of guidance material on the structure of possible *L. monocytogenes* control programs for industry. The suggested programs were presumably designed to facilitate control programs that included some element of microbiological testing. Industry feels that this guidance has been instructive and facilities that produce the majority of RTE meat and poultry products have adopted the recommended practices in some form. However, no direct linkage was provided to FSIS field activities, as the Microbial Sampling Directive (10,240.2) has not yet been revised and re-issued. Without this modified Directive, and instructions to inspectors on its implementation, industry has been left with no guarantee that results derived from testing programs would be viewed appropriately by inspectors. In addition, inspectors have had little guidance as to their role in industry testing programs.

Subsequent to initiation of FSIS activities, in January, 2000 the Center for Science in the Public Interest submitted a petition to FSIS for regulatory action to require microbial testing for *L. monocytogenes* in RTE meat and poultry products. A letter with a similar request was sent to the Commissioner of FDA.

RECENT INDUSTRY ACTIONS

In 1999 industry reviewed and revised suggested programs designed to minimize the presence/ survival/ multiplication of *L. monocytogenes* in foods. These programs include:

- applying a validated listericidal process where appropriate;
- purchasing from suppliers with a *Listeria* control program;
- minimizing the potential for recontamination;
- adopting new technologies as soon as they are available; and
- implementing an environmental monitoring program for *Listeria* spp. to verify that the control program is effective.

In addition to guidance for RTE meat and poultry products prepared and distributed to trade association members (Joint Industry Task Force, 1999; North American Meat Processors et al., 1999), industry published information on preventing contamination by *L. monocytogenes* in RTE foods for general distribution (Tompkin et al., 1999).

Industry trade associations also recently conducted a survey to determine actions taken in response to the FSIS notice to reassess HACCP plans, and to determine the types of testing programs currently in place. The results show that 98% of the 277 respondents who answered the question (90% of the establishments returning the survey) reassessed

their HACCP plans with respect to *L. monocytogenes*. Among the respondents, 67% have an end-product testing program for *L. monocytogenes* (88% of large plants, 64% of small plants and 27% of very small plants). Over 90% of the respondents conduct some type of environmental testing (100% of large plants, 92% of small plants, and 41% of very small plants).

Industry survey data 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% conduct end-product testing and 96% conduct environmental testing. Similarly, of the large and small manufacturers of sliced luncheon meats responding to the industry survey, 67% conduct end-product testing and 96% 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.

Industry believes that their control programs are having a positive effect. Industry has begun market studies to obtain data on the levels of *L. monocytogenes* in specific products. The data obtained to date, while preliminary, indicate that very few samples of packaged and deli sliced luncheon meats and prepared salads are positive for *L. monocytogenes* and those that are positive contain very low numbers of the organism. (NFPA Research Foundation, unpublished data).

In addition to modifying in-plant practices and upgrading verification programs, many in industry are also seeking long term and more dependable solutions to this problem. Industry is determined to seek unique approaches (such as in-package pasteurization with heat or ionizing radiation) to eliminate *L. monocytogenes* after packaging. Industry has submitted a food additive petition to FDA to permit the use of ionizing radiation for this purpose and is exploring use of other technologies as well. In addition, as risk of listeriosis from foods appears to be proportional to the number of *L. monocytogenes* cells consumed, many firms are taking advantage of recently approved materials to reformulate products to retard/preclude growth of any *L. monocytogenes* that may re-contaminate products.

RECOMMENDATIONS FOR REGULATORS:

The food industry is committed to developing effective programs to control contamination of products by *L. monocytogenes*. However, industry also believes that the shared objective of reducing illnesses from the occurrence of *L. monocytogenes* in RTE foods is best achieved by control of *L. monocytogenes* growth in RTE products. Increased development and implementation of growth-prevention strategies and the resulting reduction in foodborne illness require a modified approach by regulatory agencies.

Focus monitoring by regulatory agencies on high risk products: Since consumption of foods that may contain low levels of *L. monocytogenes* but which do not provide the opportunity for its growth do not appear to pose a health hazard, regulatory agencies should focus compliance efforts and resources on problem products. Products that appear to present greatest risk to consumers are those that have been implicated in listeriosis cases or that have the greatest potential to contain high levels of *L. monocytogenes* at the time of consumption. Compliance efforts should not focus on frozen foods (especially if they are heated prior to consumption), foods with barriers to growth of *L. monocytogenes* (pH, a_w or additives demonstrated to inhibit growth of the organism in the product), or foods that are given a listericidal process in the package and shipped without being repackaged.

Modify application of the zero tolerance policy: FSIS has recently approved new uses or new levels of additives such as sodium lactate that retard the growth of *L. monocytogenes*. Wider use of these compounds and others that may prove effective will markedly reduce, if not eliminate, the risk of listeriosis from consuming ready-to-eat meat or poultry products or other foods that are formulated with such ingredients. However, if the "zero tolerance" policy for *L. monocytogenes* continues to be applied to all RTE products, regardless of the use of these safety enhancing ingredients, this will provide no incentive for industry to reformulate products. If the soon-to-be-released risk assessment confirms that the most important risk factor is growth of this organism, then regulatory policy should be adjusted to reflect this conclusion. A policy focused on preventing the number of *L. monocytogenes* cells from increasing to a level of health significance (a risk-based focus), rather than one based on a total absence of this ubiquitous organism, would promote the use of such ingredients to supplement other controls, with a resulting reduction of risk to consumers.

It is our belief that the risk assessment being conducted jointly by FDA and FSIS will clearly indicate that those foods supporting growth of *L. monocytogenes* over their shelf life compose the category of significant risk to consumers. If true, then the risk of listeriosis can be reduced by a policy change that will promote reformulation to take advantage of these bacteriostatic agents, along with a refocusing of agency monitoring programs.

Moreover, we believe that industry and government resources should not be expended to test products that are produced in a manner whereby *L. monocytogenes* is destroyed and there is no opportunity for product to be recontaminated (such as meat and poultry products cooked in sealed bags or products given a post-packaging listericidal process).

Role of testing programs: Industry believes that the reduction of *L. monocytogenes* in RTE foods in which the organism can grow is best accomplished by rigorous efforts to find and eliminate harborages of this potential pathogen. To this end, agency policies should encourage companies to find the organism in order that appropriate actions can be taken, rather than discouraging efforts to find the organism by overly severe expectations regarding enforcement and compliance.

Industry strongly supports immediate action to revise FSIS Directive 10,240.2, "Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System," to incorporate options for industry testing that is verified by FSIS. For example, establishments that conduct routine testing of RTE product for pathogens of concern and/or environmental testing for indicator organisms such as *Listeria* spp. would be subject to a reduced frequency of product testing by FSIS. Industry and regulatory emphasis should be placed on products known to support the growth of this pathogen at standard refrigeration conditions. These programs would serve to verify that pathogen control measures in the plant are effective.

Issuance of this modified directive should result in firms conducting their own testing as appropriate, significantly increasing the amount of product testing over that currently conducted by FSIS, with FSIS access to product testing results to verify that control is in place. This would also allow the agency to adjust its own sampling program to provide for coverage of those firms who are either reluctant to do their own testing or do not have the facilities or resources to conduct such testing. Moreover, the agency must consider the burden of cost of microbial testing to small operators; directing FSIS resources toward conducting such testing for these establishments would alleviate this cost burden. Industry believes that the revised pathogen testing directive provides the linkage between FSIS and industry to facilitate such a program, while leaving intact the flexibility needed to tailor control and testing programs to accommodate establishment size, equipment/plant design and the variety of products produced by individual establishments. The directive will also serve to clarify FSIS thinking regarding the role of testing in *L. monocytogenes* control programs without the unnecessary delay imposed by notice and comment rule making.

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 *L. monocytogenes*. However, it is essential that such a program be designed and implemented in a manner that encourages finding the organism when it is present in the environment. 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. In order to effectively address *L. monocytogenes* and reduce risk to consumers, industry must be allowed the flexibility to design programs that fit the need 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. Moreover, it is critical that results of environmental testing be interpreted by persons with expertise in the product, the process, and *L. monocytogenes* control programs; the industry strongly believes that regulatory agency personnel who review such programs and the resulting data should have appropriate training and expertise.

Education of the industry: The increased number of recalls of RTE products points out the need to educate processors in best practices to prevent contamination with *L. monocytogenes*. Manufacturers need to know what to look for in equipment design, how to test the environment, remedial actions that can be taken when indicators such as

Listeria spp. are found in the environment, and how to solve a problem when *L. monocytogenes* find a niche in the plant. Industry is willing to work with the International HACCP Alliance, the FSIS Technical Center, and others to establish a workshop and train the trainers to educate processors in how to establish an effective control program for *L. monocytogenes*.

SUMMARY

In conclusion, information that has been collected clearly demonstrates that industry has been responsive to this public health issue. We feel it is time to move to the next phase of addressing the problem of *L. monocytogenes* in RTE foods. We encourage FSIS to finish the work on Directive 10,240.2. Issuance of this modified directive should result in firms conducting their own testing as appropriate, significantly increasing the amount of product testing over that currently conducted by FSIS, with FSIS access to product testing results to verify that control is in place. This would also allow the Agency to adjust its own sampling program to provide for coverage of those firms who are either reluctant to do their own testing or do not have the facilities or resources to conduct such testing.

Regulatory agencies should focus compliance efforts and resources on problem products. Compliance efforts should not focus on frozen foods (especially those heated prior to consumption) foods with barriers to growth of *L. monocytogenes* (pH, a_w or additives demonstrated to inhibit growth of the organism in the product), or foods that are given a listericidal process in the package and shipped without being repackaged. Serious consideration must be given to the results of the joint FDA/USDA risk assessment on *Listeria monocytogenes* in ready-to-eat foods in refocusing the agencies' compliance efforts.

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