

July 18, 2001

FSIS Docket Clerk
Docket No. 00-048N
U. S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

Re: Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan; Docket No. 00-048N , 66 FR 5515.

Dear Sir or Madam:

1. Introduction and General Comments

The *Listeria Monocytogenes* (LM) Working Group appreciates the opportunity to comment on the above-referenced draft risk assessment and joint action plan prepared by the Food and Drug Administration (FDA) and Food Safety and Inspection Service (FSIS) (collectively, the agencies). The LM Working Group is a coalition of trade associations and companies representing the food industry. Since 1994, the LM Working Group has worked with government agencies to foster appropriate, science-based policies for regulation of *Listeria monocytogenes* in ready-to-eat (RTE) foods.

The LM Working Group supports cooperative efforts among government, industry, and consumers to enhance food safety, and advocates prioritization of food safety challenges according to science-based assessments of consumer risk. Accordingly, the LM Working Group applauds the agencies' efforts to evaluate the risks posed by *Listeria monocytogenes* using a science-based analysis.

The LM Working Group firmly supports science-based risk assessments as the most intellectually sound approach to addressing the risks of foodborne illness and encourages the continued use of such assessments by the agencies. We urge the agencies to utilize this important scientific information to dictate future risk management priorities as well as to re-evaluate current regulatory policy.

The Working Group encourages the agencies to update periodically the draft risk assessment as new data become available. We believe that new strategies and controls being implemented by industry, along with effective communication to individuals at risk, will result in a significant reduction in the number of cases of listeriosis.

2. Potential to Support Growth

The LM Working Group believes the most important conclusion of the draft risk assessment is the identification of five factors that affect consumer exposure to *L. monocytogenes* at the time of consumption. The identified factors are:

1. Amount and frequency of consumption of the food;
2. Frequency and levels of *L. monocytogenes* in ready-to-eat food;
3. Potential to support growth of *L. monocytogenes* in food during refrigerated storage;
4. Refrigerated storage temperature; and
5. Duration of refrigerated storage before consumption.

The LM Working Group does not share the agencies' view that these five factors are necessarily additive, or that they are equally relevant in assessing risk. For example, if the organism cannot grow in the food product, refrigerated storage temperature and duration of refrigerated storage before consumption is irrelevant to the potential to cause illness. The food industry understands that regardless of storage temperature or duration of storage, gross contamination should be prevented. However, the LM Working Group submits that refrigerated storage temperature and duration are more properly considered sub-points under the potential for growth during refrigerated conditions.

An example of a food category that does not support the growth of *L. monocytogenes* is ice cream and frozen desserts. The agencies have acknowledged that the pathogen cannot grow in a frozen medium, although it is able to survive. Because the levels of *L. monocytogenes* found in retail surveys were low, and would not increase during distribution, the draft risk assessment characterized ice cream as the product category with the lowest relative risk ranking.

Further refinement of the draft risk assessment and future research should substantiate that "potential to support growth" is THE most important risk factor of those listed in the assessment, given that most scientists agree that the probability of illness is closely associated with the ability of the organism to grow in food and the dose/exposure necessary to cause illness. The LM Working Group submits that growth prevention during processing and distribution is one of many excellent mitigation strategies to reduce the risk of listeriosis. Regulatory officials should recognize the importance of this factor when developing risk management policy.

3. Improvements in Data Should be Considered

The LM Working Group appreciates the hard work and careful thought reflected in the draft risk assessment. The LM Working Group understands that this is a “working” document and that the agencies have always welcomed new data and information that will strengthen the draft risk assessment. In that regard, the LM Working Group appreciated the extension of the comment period so that Novigen Sciences, Inc. could independently evaluate the draft risk assessment. The extension has also permitted other members of the LM Working Group to provide more reinforcing information and data to FDA/FSIS.

The Working Group understands that data gaps currently exist. It is Working Group’s express wish that future research and implementation of the agencies’ action plan creates an environment that will foster generation of new data and information. In that regard, it is imperative that regulatory activity encourage rather than penalize environmental monitoring and strategies aimed at uncovering, understanding, and eradicating sources of *L. monocytogenes*.

The LM Working Group understands, however, the agencies’ need for closure of the risk assessment. It is important that FDA and FSIS complete the *L. monocytogenes* risk assessment so that other important pathogens can be evaluated. However, in recognition of the ongoing study and assessment of this organism, it is imperative that the agencies establish a process to allow sharing of new and important scientific data regarding *L. monocytogenes* developed by the government, academia and industry. We recommend that the current risk assessment be reviewed and updated periodically as new data, scientific understanding and processing methodologies become available. Specifically, the LM Working Group believes that current FDA-funded research will provide additional contamination data and should be incorporated into the risk assessment before the action plan is finalized.

The importance of developing and incorporating new data as it becomes available is underscored by the draft risk assessment's reliance on data that are unrepresentative of the commercial marketplace. For example, information with regard to some small processors and other producers that operate outside the bounds of federal, state and local regulatory oversight may inappropriately skew results. If the agencies intend to use the draft risk assessment to develop sound, meaningful public policy, the LM Working Group strongly believes the assessment must reflect the experience of mainstream commercial food processors and purveyors that recognize federal, state and local jurisdiction over food production.

Accordingly, the LM Working Group recommends that as commercial marketplace data become sufficient for a food category, the agencies should eliminate data that skew results because of activity outside the boundaries of federal, state and local inspection. Because the agencies' eight action areas identified in the "Joint Response to the President" are directed at regulated industry, the risk assessment, and any resulting regulatory actions cannot practically address nor should they reasonably be expected to encompass individuals and companies that operate outside the boundaries of oversight.

4. Specific Improvements Are Needed with Respect to Analysis of the Risks Posed by Frankfurters

The draft risk assessment suggests that frankfurters pose a minimal risk of foodborne listeriosis when reheated but pose a higher risk when not reheated. The LM Working Group believes that while it may be appropriate for the agencies to recognize that consumer handling of frankfurters may play a role in establishing the relative risk of these products, the consumer behavior data used to support that hypothesis are of questionable value.

The agencies relied on a limited, highly variable set of data from a biased source to predict consumption of frankfurters without reheating. These data are poor predictors of consumer behavior. Moreover, the LM Working Group believes that the triangular distribution used was inappropriate; the uniform distribution suggested by FDA would have been a better alternative. Additional, reliable evidence concerning consumer consumption patterns with regard to frankfurters is needed. The LM Working Group encourages the agencies to determine, with scientifically sound estimates, the frequency of consumption of non-reheated frankfurters by that portion of the population that consume the product as packaged. Current industry-generated data will be submitted and should be considered by the agencies before any risk management actions are finalized.

Additional data are also needed with regard to consumer storage practices. The draft risk assessment relies on a single survey designed to determine the duration of frankfurter storage; moreover, the survey looks only at refrigerated storage. The agencies' current survey with regard to consumer storage and consumption of frankfurters should examine the likelihood and duration of both refrigerated and frozen storage of frankfurters by consumers. These data should be incorporated in the draft risk assessment.

5. The Joint Action Plan Should be Updated to Reflect New Information

In response to the release and extension of comments on the draft risk assessment, the agencies should receive substantial amounts of domestic information, data and analysis that address *Listeria monocytogenes* in ready-to-eat foods that are produced under federal and state oversight. The LM Working Group anticipates that this material will address a number of the data gaps in the draft risk assessment. Currently, it is unclear whether and how the agencies plan to incorporate this valuable, new information into their management objectives.

The LM Working Group strongly encourages the agencies to use this new information as a guide, to enhance and strengthen the action plan. Should the action plan remain static, the public will not be served and regulatory resources may not focus on areas that represent the greatest potential risk to public health.

In addition, the LM Working Group notes that the current action plan does not take into account a fundamental conclusion of the draft risk assessment, namely that not all ready-to-eat foods (as currently defined) pose the same risk to consumers. The LM Working Group believes that the action plan should be revised to address the risk, or lack thereof, posed by specific food categories.

6. Prioritizing and Coordinating Research and Training

Objective 8 of the agencies' action plan calls for coordination of research activities to refine the draft risk assessment, enhance preventive controls, and support regulatory enforcement and educational activities. The LM Working Group urges the agencies, in working toward this objective, to ensure that the following critical areas are addressed:

1. Work with industry to prioritize research needs;
2. Foster consistency among responsible federal and state agencies through improved communication;
3. Coordinate training of inspectors between and among federal and state agencies;
4. Re-evaluate the utility and applicability of current inspector training procedures and courses;
5. Institute joint training of industry and agency personnel;
6. Assist states with limited resources through improved federal guidance; and

7. Convert taped training courses for inspectors to web-based delivery systems.

7. Establish Category Specific Action Plan

The LM Working Group strongly believes that, to maximize its usefulness, a significant revision of the joint action plan should be undertaken in order to tailor objectives to the level of risk posed by specific food categories. Objectives that fail to distinguish among the different levels of risk posed by different foods will use valuable resources unproductively and unnecessarily limit the options of at-risk populations.

The LM Working Group understands that the intent of the risk assessment was a “risk ranking” exercise and that in the future the agencies intend to pursue product/pathway risk assessments that will address specific handling practices. In that regard, Objective 2 of the action plan calls for the agencies to provide guidance to processors, retailers, and food service establishments on prevention controls.

The draft risk assessment did not address the potential of cross contamination resulting from distribution handling practices. For certain food categories, these practices affect the level of risk presented; for others, they do not. A category specific action plan, built on a product/pathway risk assessment that incorporates handling information (where relevant), would result in a far more efficient and effective allocation of food safety resources. Accordingly, the LM Working Group urges the agencies to work with industry to identify and fully understand the handling practices to which products are subjected once they leave a manufacturer’s control. Cooperative action of this sort will help facilitate development of action plans specific to food categories that reflect the level of risk posed by the category.

8. Gaps in the Joint Action Plan

The action plan identifies many important areas of focus for the agencies. The action plan is silent, however, with respect to whether and how the agencies will address inconsistencies in their regulatory positions and guidance. The plan also fails to address whether and how the agencies should address regulatory requirements established before completion of the draft risk assessment that are at odds with its findings.

For example, FDA and FSIS define RTE differently. FSIS treats many processed products that contain fully cooked meat or poultry components as RTE although the products require cooking by the consumer prior to consumption. In contrast, FDA does not consider foods that have received a “cook” or other heat treatment step by the processor to be RTE as long as the consumer is instructed to further cook the food prior to consumption.

Listeria regulatory policy should not treat further cooked meat and poultry products, for example, frozen chicken nuggets, in the same manner as deli meats that receive no further cooking by the consumer prior to consumption. Any such policy lacks scientific basis, is not consistent with the conclusions of the draft risk assessment, and should be reconsidered.

To resolve the discrepancy about what constitutes RTE foods, the LM Working Group recommends that the agencies follow the U.S. Public Health Service Food Code definition of RTE. Adopting this definition would ensure consistency among FSIS, FDA, and state and local regulatory agencies. Under the Food Code:

Ready-to-eat food means FOOD that is in a form that is edible without washing, cooking, or additional preparation by the FOOD ESTABLISHMENT or the CONSUMER and that is reasonably expected to be consumed in that form.

The Food Code definition of RTE offers the additional advantages of being consistent with the manner in which RTE is used in the executive summary of the Joint Response to the President, i.e., those foods “that are intended to be eaten as purchased (without additional preparation by the consumer such as cooking, which can kill the bacterium).”

FSIS’s recently proposed performance standards for the production of processed products illustrate the problem of using an imprecise, overly broad definition of RTE. FSIS’s proposed standard would require the same level of *L. monocytogenes* control for products that support growth (e.g., many deli meats), meat and poultry products that prevent growth (e.g., dry fermented sausages and frozen products), and processed meat and poultry products that receive further cooking (e.g., frozen entrees and meals). The results of the draft risk assessment suggest that this type of “one size fits all” approach to *L. monocytogenes* management fails to focus resources on the greatest relative risks. The FSIS performance standard proposal does not recognize that potential for growth of *L. monocytogenes* elevates risk and that consumer cooking reduces it.

Finally, the LM Working Group urges the agencies to structure their action plan to encourage full participation by industry, thereby advancing industry’s continued development of new food safety technologies. Agency policy generally, and the action plan in particular, should act as an incentive for industry to monitor and control *Listeria monocytogenes*. Inflexible regulations that punish companies for monitoring and detecting *Listeria monocytogenes* will only threaten industry and discourage its full participation, impeding progress toward improved food safety.

9. “Use-by Labeling is Not Appropriate

The action plan calls for safety-based “use-by” labeling. This proposed action item suggests using “time” as a means to prevent the pathogen from reaching harmful levels. Yet, under current law, industry is held to a zero tolerance standard for *L. monocytogenes*. The two concepts conflict fundamentally. The LM Working Group believes that safety-based “use-by” labeling is not sound policy for the following reasons:

1. The concept that the food industry should validate a use-by date for a pathogen such as *L. monocytogenes* conflicts with current law, under which ready-to-eat food with detectable levels of the organism is deemed adulterated.
2. If the product does not support growth of the organism and the product meets the current legally applicable zero tolerance standard, the length of time that it is held under refrigeration is not relevant.
3. If growth is possible, the growth rate depends on storage temperature. Manufacturers of RTE products practice tight temperature controls during production and storage to prevent degradation of their products. In many instances, this temperature is at or near the lower limit of organism growth. However, a manufacturer's control of temperature is vastly diminished once the product leaves its control. If the use-by date were calculated by presuming that *L. monocytogenes* were present, and assuming that the lower limit of shelf life would need to be based on the "worst case" distribution scenario provided by manufacturers, distributors, retailers and consumers, the result would be extremely limiting and would not provide a realistic shelf life date.
4. Development of a science-based food safety use-by labeling scheme for these products is not feasible. It simply is not possible to set a date upon which a safe product, one that is not legally adulterated, becomes unsafe due to growth of the pathogen.

10. Consumer Information and Education Efforts

The agencies have developed several consumer messages about *Listeria monocytogenes* based on the results of the draft risk assessment. The messages seek to educate specific population segments to avoid high-risk foods. The messages would be enhanced if they identified those foods that, as

a result of processing, provide built-in safeguards against the risk of Listeriosis.

For example, the draft risk assessment acknowledges that *Listeria monocytogenes* growth does not occur in frozen products or products with extremely low pH like most fruits. In short, vulnerable consumers have numerous food consumption options. They should be told about and understand the full range of options available to them. For example, an additional consumer message could be “Freeze processed meat and poultry products for safer, long term storage.”

Additionally, consumer messages should be re-evaluated and updated to reflect new information that emerges from the draft risk assessment. One example is that Goat, Sheep and Feta cheese were assessed as a low predictive risk due to inherent characteristics associated with these cheeses. Unfortunately, FDA’s consumer food safety messages still suggest, “Do not eat soft cheese such as Feta, Brie, and Camembert cheeses, blue-veined cheeses, and Mexican-style cheeses such as “*queso blanco fresco*.”

11. Conclusion

The LM Working Group appreciates the opportunity to share its views on the draft risk assessment and action plan for the prevention of foodborne listeriosis. The LM Working Group commends FDA and FSIS for fostering and leading the debate on this important public policy issue.

The LM Working Group encourages the continued use of risk assessment as the foundation for managing and communicating the relative risk and benefits of foods to consumers, and we look forward to full participation with the agencies as we continue to develop new food safety strategies and technologies. Moreover, we support the agencies’ use of new information to enhance and strengthen the assessment on a periodic basis, and we hope the Novigen, Inc. review of the agencies’ *L. monocytogenes* draft risk assessment proves valuable to FDA and FSIS.

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The LM Working Group believes that further refinement of the risk assessment should focus on a food's "ability to support growth," and the final product should rely more on data that are representative of the marketplace. It is very important to align the definition of RTE with consumer practices and expectations.

The LM Working Group does not support the concept of validating use-by dates because that approach conflicts fundamentally with the zero tolerance requirement. Moreover, it is not technically possible to set a date upon which a legally safe product becomes unsafe due to the growth of the pathogen.

Finally, agency policy should encourage industry to monitor and control *L. monocytogenes*. The LM Working Group believes if companies are punished for maintaining aggressive monitoring and detection programs, food safety improvements will be impeded.

The LM Working Group looks forward to working with the agencies on the development of scientifically based policies founded on a thorough and complete assessment of the risks posed by *Listeria monocytogenes* in the food supply.

Sincerely,

American Frozen Food Institute
American Meat Institute
Grocery Manufacturers of America
International Dairy Foods Association
National Fisheries Institute
National Food Processors Association
National Frozen Pizza Institute
National Turkey Federation
Snack Food Association
United Fresh Fruit and Vegetable Association