GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

1010 WISCONSIN AVE. NW
NINTH FLOOR
WASHINGTON, DC 20007
PHONE (202) 337-9400
FAX (202)337-4508
www.gmabrands.com

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United States Department of Agriculture
Food Safety and Inspection Service
Room 102; Cotton Annex
300 12th St., SW
Washington, DC 20250-3700

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Susan Ferenc, DVM, Ph.D.

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 Plan; Docket No. 99N-1168; 66 FR 5515

Dear Sir or Madam:

The Grocery Manufacturers of America (GMA) welcomes this opportunity to comment on the above-referenced draft risk assessment and accompanying joint action plan. GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

GMA is pleased that FDA and FSIS have completed the first stage of their joint ***Listeria monocytogenes*** risk assessment and action plan. GMA fully supports science-based assessments of risk as the most efficient, intellectually sound approach to meeting the challenges of foodborne illness. Only by fully exploring and quantifying the risks posed by ***L. monocytogenes*** and other pathogens can the agencies, working cooperatively with industry, hope to develop appropriate, effective control measures.

A Work In Progress

Although publication of the draft risk assessment represents an important milestone, GMA urges the agencies to treat the document as a "work in progress." The draft risk assessment contains a great deal of important information and observations about the hazards of L. ***rnonocytogenes*** contamination in ready-to-eat food products. Yet, additional, relevant data in this regard are continually being developed and made available. These data should be gathered periodically and incorporated into the risk assessment. In this way, the risk assessment will remain a relevant, timely tool for use by government and industry in the development of L. ***rnonocytogenes*** control strategies and procedures.

Confidence and Jncer ty in the Data ar s sults

Control strategies formulated on the basis of a risk assessment, of course, are only as sound as the data that underlie the assessment. FDA and FSIS found that where they had data from numerous studies that were consistent, the degree of uncertainty in the resulting risk estimates were small. In combination with inherent characteristics of the foods themselves, the group of food categories including for example, ice cream and frozen dairy products, were identified as representing substantially less public health risk for individuals and the general population than the other categories of foods. We encourage the agencies to consider these findings with respect to revising current regulatory activities.

Conversely, where available data are scarce or incomplete, as was the case for several food categories, these scarcities and data gaps introduce a significant element of uncertainty into the predicted risk rankings. Novigen concluded in their technical review of the assessment that the large differences in uncertainties likely give disproportionate weight to some risk rankings. Novigen found that the net effect of the identified significant uncertainties is to overestimate the risks of ***L. rnonocytogenes.*** FDA and FSIS acknowledge that reducing these uncertainties is a priority, but do not specify an approach to follow-up on this issue. GMA encourages the agencies to develop a plan to reduce these uncertainties before attempting to devise new regulatory control strategies.

] - ¢ sults of the Risk Assessment

The draft Risk Assessment attempts to incorporate all the factors that have the potential to affect exposure and risk due to L. ***monocytogenes.*** As a result, it is extraordinarily complex. Nevertheless, the draft risk assessment results provide us with critical information. First, in the process of comparing relative risks among food categories, the risk assessment has identified that foods that do not support the growth of ***L. monocytogenes*** do not pose the same level of public health risk as those that do support growth. This should allow the agencies to shift resources away from foods that do not support the growth of ***L. monocytogenes*** under normal use and distribution towards identification of strategies to prevent growth and reduce risk. Second, through the uncertainties, it tells us what we do not yet know about the public health risks of food borne L. ***monocytogenes.*** The significant uncertainties identified by Novigen and FDA/FSIS can serve as a guide for prioritizing the allocation of scarce resources toward

collection of better, relevant data on those foods that pose the greatest risk. We think it would be very informative for FDA-FSIS to re-group these foods and attempt to assess risks according to characteristics of the food and processing and handling techniques that affect the survival and growth of *L. **monocytogenes,*** e.g., the influence of the food matrix characteristics, processing and packaging methods.

The Need for Category Specific Risk Assessments for Risk Management

GMA strongly supports the FDA-USDA position that the risk management plan be firmly linked to the assessment of human health risk from food-borne L. ***monocytogenes.*** Although additional research and data collection along the lines identified above will improve the risk assessment, it will not alter its fundamental purpose. The risk assessment is intended only to rank the risks presented by food categories relative to one another; it does not quantify the risks posed by those categories or evaluate potential reductions in risk offered by specific handling or holding practices. Further, because the approach used was to rank the risks of defined food categories relative to each other, the contribution of specific ready-to-eat foods or food categories, to the risk of food-borne illness cannot be defined adequately by the results. The concept behind establishing relative risk rankings in this assessment is that resources can then be directed toward better characterizing those foods or food categories that pose the greatest risk. This should include the collection of relevant data and the development of specific pathogen/product analyses. GMA believes that product/pathway-specific risk assessments are needed and urges the agencies to follow through with their proposal to conduct these assessments on the foods and food categories posing the greatest risk. Effective risk management interventions for specific foods or food categories can only be assured when risks associated with those foods or categories are individually characterized. Since risks were not characterized on a product-pathway basis, it is extraordinarily difficult to use the results of the draft risk assessment to evaluate the risk reduction impacts of revisions in current regulations, new regulations or the selection of specific targets for inspections or monitoring. As a result, we urge FDA and FSIS to conduct product/pathway analyses prior to further consideration of regulatory control initiatives such as that proposed by FSIS for manufacturers of RTE meat and poultry products. See 66 Fed. Reg. 12590 (February 27,2001).

If product/pathway risk assessments are not undertaken, the agencies will often have no alternative but to structure regulatory actions in a "one size fits all" manner that does not take into consideration important, inherent differences among food categories. ***An*** across-the-board approach of this type can undermine the value of the actions proposed. For example, development and application of a safety-based "use-by" labeling scheme, an item in the agencies' joint action plan, would accomplish no reduction in risk with respect to those products that do not support Listeria growth. For such foods, the length of time until use simply is irrelevant.

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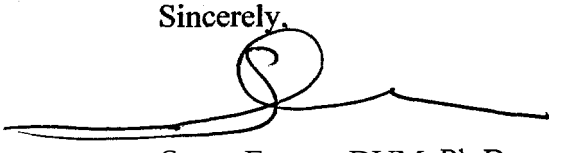
GMA applauds the agencies for their hard work in completing the first stage of the LM risk assessment. Release of the draft assessment is an important first step in the creation of a science-based response to the risks of foodborne listeriosis. GMA urges the agencies to continue to refine the risk assessment as new data become available and looks forward to working with the agencies on this and other Listeria-related initiatives.

Sincerely,



Susan Ferenc, DVM, Ph.D.
Vice President
Scientific and Regulatory Policy