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William H. Sperber
Timothy A. Freier

[Docket No. 99N-1168] 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

Dear Sir or Madam:

Cargill is an international marketer, processor and distributor of agricultural, food, financial and industrial products and services with 87,000 employees in 60 countries. While we have many meat and poultry operations worldwide, in the United States Cargill is one of the top three producers of meat and poultry products, primarily through our Excel Corporation, and North American Turkey Operations.

In January of this year, the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) announced the availability of a draft risk assessment of the relationship of foodborne ***Listeria monocytogenes*** to human health, and asked for comments regarding this document.

Cargill is committed to providing safe, wholesome food to our customers. As part of this commitment, we have actively promoted and initiated food safety programs firmly grounded in science. We believe that the L. monocytogenes risk assessment is a positive step in applying science to the management of this difficult and persistent pathogen, and we applaud the efforts of the FDA and FSIS in producing this draft risk assessment. Therefore, we are grateful for the opportunity to offer comments for your consideration.

It is our understanding that this risk assessment will be used to drive risk management actions by the government, including the development of new regulations, and the targeting of the finite inspection resources to the most significant public health risks.

To a very considerable extent, the results of the predictive modeling in this risk assessment were a foregone conclusion. For more than ten years, in food safety circles there has been no mystery about the types of foods that potentially could be implicated in listeriosis. These are refrigerated, ready-to-eat foods of extended shelf life that will support the growth of ***L. monocytogenes.*** Examples of such foods are soft cheeses, certain cooked meat, poultry and seafood products, meat pates, and smoked fish. In this matter of foodborne listeriosis, the recorded experience around the world has been quite consistent.

We were initially concerned that the several years of effort that were invested in this draft risk assessment, and the likely greater amount of resources that will be necessary to complete the assessment, would potentially impede risk management activities that are necessary to reduce foodborne listeriosis. However, FSIS on February 27,2001, published a proposed rule regarding performance standards for the production of processed meat and poultry products, including new requirements for the control of ***L. monocytogenes.*** Furthermore, for several years, the meat and poultry industry has been moving rapidly to implement additional effective ***L. monocytogenes*** control measures. While these new risk management activities on the part of FSIS and the industry are necessary and commendable, they somewhat beg our initial understanding that the results of this ***L. rnonoctyogenes*** risk assessment would be used to drive the government's risk management proposals.

The point we want to make in the opinion expressed above is that we support the government's and the industry's continued risk management activities, even before the completion of the risk assessment. The expenditure of further resources to complete the risk assessment should not be permitted to impede the continued risk management activities. We are in no way criticizing the fact that the government's ***L. monocytogenes*** risk management activities have gotten far ahead of its ***L. monocytogenes*** risk assessment activities. In the public health perspective, this is a laudable situation.

Given our mutual determination to better protect the public health, we want to offer several additional comments specifically intended to assist the agencies in their continued improvement of the ***L. monocytogenes*** risk assessment model. Further development of the risk assessment will by useful to justify the necessary elimination of the current "zero tolerance" policy for the presence of ***L. rnonocytogenes*** in foods that do not present a risk of listeriosis.

One of our concerns with the draft risk assessment is that it does not clearly delineate high- and low-risk products within the twenty food categories. Our greatest interest is within the category "Deli Meats". This category ranked first in predicted median per annum relative risk for each of the three subpopulations. This ranking will certainly focus intense regulatory activity on RTE meat and poultry products. We do not disagree with the finding that certain RTE meat and poultry products such as sliced deli meats with relatively long refiigerated shelf lives deserve this ranking. However, many other products within this category should have very low risk, because they are frozen, or they have received a validated kill step after final packaging, or they do not support the growth of ***L. monocytogenes.*** We believe that if the risk assessment models were rerun for products that are frozen, receive a post-package kill step, or for some other reason inhibit ***L. rnonocytogenes*** growth, the models would rank these products among the least risky

foods. This reassessment would be very similar to the risk assessors' original separation of ice cream and frozen dairy products from other types of dairy products. As expected, ice cream ranks vastly lower in risk than some other refrigerated dairy products that could support the growth of *L.* monocytogenes after production.

Many questions remain as to how to define the infectious dose for *L.* monocytugenes. However, the findings of the current draft risk assessment clearly indicate an increased risk of infection for those foods that support growth to relatively high levels. The challenge test methodology found in "ANSI/NSF Standard 75 – 2000: Non-Potentially Hazardous Foods" could readily be modified to establish a protocol for determining whether or not a product could support growth of L. monocytogenes to dangerous levels. Our recommended adaptations to Standard 75 would be to focus only on *L.* monocytugenes, hold products at typical refrigeration temperature, and limit the acceptable level of growth to less than two logs within the product's shelf life, or to levels that do not exceed 100 cfu *L. monocytogenes/g* at the time of consumption. This latter recommendation is consistent with regulatory decisions in other countries and with the long-mounting evidence that high levels of *L.* rnonocytogenes are necessary to cause listeriosis, even in susceptible individuals.

As a first step, we strongly suggest that categories such as "Deli Meats" be re-evaluated using current data and risk assessment models in order to further subdivide products into two groups – those that support growth of L. monocytogenes before consumption, and those that do not (i.e., because of freezing or other means of *L.* monocytogenes control). This action will help focus resources on those products that present a true potential risk and will serve to further stimulate industry to develop processes and formulations that would control L. rnonocytogenes, thus enabling progress toward our mutual goal of reducing the incidence of foodbome listeriosis in the United States.

Thank you for your consideration of our comments.

Sincerely,

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c: FSIS Docket Clerk [Docket No. 00-048N]
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