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Rockville, MD 20852

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United States Department of Agriculture
FSIS Docket Room
Docket No. 00-048N
Room 102 Cotton Annex
300 12th St., SW
Washington, DC 20250-3700

00-048N
00-048N-15
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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; Availability
66 Fed. Reg. 5515 (Jan. 19,2001); 66 Fed. Reg. 13545 (Mar. 6,2001)

COMMENT ON DRAFT RISK ASSESSMENT

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the draft risk assessment for *Listeria rnonocytogenes* published by the Food and Drug Administration (FDA) (Docket No. 99N-1168) and Food Safety and Inspection Service (FSIS) (Docket No. 00-048N). CSPI is a nonprofit consumer group that focuses primarily on nutrition and food-safety issues. CSPI is based in Washington, D.C., and has more than 800,000 members/subscribers to its Nutrition Action Healthletter. These comments are endorsed by the

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following members of the Safe Food Coalition: the American Public Health Association, the Consumer Federation of America, the National Consumers League and Safe Tables Our Priority.

CSPI applauds the members of the risk assessment team for their efforts in preparing this ***Draft Assessment of the Relative Risk to Public Health from Foodborne*** Listeria monocytogenes ***Among Selected Categories of Ready-to-Eat Foods*** (risk assessment). More than two years have passed since the Bil Mar outbreak—the most deadly food-safety epidemic in 15 years—brought national attention to the inadequacies of the government's response to *L. **monocytogenes*** in ready-to-eat foods. Since then, other outbreaks have occurred. For instance, in December 2000, deli turkey meat produced by Cargill was linked to four deaths, three miscarriages/stillbirths and 22 illnesses from listeriosis in ten states. The actual numbers are most likely far higher, since typically only very seriously ill people seek medical attention. Although further revisions to the draft risk assessment will occur in response to public comments, we encourage FDA and FSIS to act promptly in finalizing this document. Consumers cannot afford for this process to be stalled.

In addition, CSPI strongly urges FDA and FSIS not to suspend risk management decisionmaking while the final risk assessment document is being prepared. Such delays would be unwarranted, because the draft risk assessment does not present a significant amount of new information and does not challenge the prevalent thinking on this pathogen. The agencies should use the information currently available to begin designing and implementing risk management strategies expeditiously.

As to our comments on the draft risk assessment, we recognize that the data available to the risk assessors were not perfect. To that end, the comments we offer are an effort to assist the team in strengthening the document.

I. The Risk Assessment Should Use Assumptions That Are More Protective of Public Health.

The *L. monocytogenes* risk assessment uses assumptions that are not sufficiently protective of public health. If anything, the agencies should err on the side of caution when making assumptions about this pathogen, particularly since it can grow during refrigeration and is more resistant than most other microorganisms to control measures.

Specifically, we urge the agencies to revise the assumptions relating to the number of bacteria likely to be found in food, the likely contamination level of unpasteurized fluid milk at retail and, for frankfurters and deli meats, the likely length of storage.

A. Presence/Absence Data Should Be Quantified Using the Average or Mean Level of Contamination from Enumeration Data.

The risk assessment underestimates the number of bacteria likely to be found in food because data measuring the presence/absence of *L. monocytogenes* were assumed to represent quantitatively the lowest detectable level of contamination, or 0.04 organisms per gram of food. Because the numbers for likely contamination levels in ready-to-eat foods were understated and because the modeling relied far more on converted qualitative data than on quantitative studies, the conclusions reached about the probability that an exposure will cause an adverse health effect were quite low. Specifically, 85 percent of the sampling data (and 77 percent of the studies) on contamination levels were qualitative and thus converted to quantitative data based on a lower than average contamination rate. It is critical that these calculations be revised by assigning to the data from presence/absence studies a mean or average level of contamination (rather than the lowest level of contamination).

The mean or average level of contamination can be drawn from the studies containing quantitative (enumeration) data.

B. The Predicted Contamination Level at Retail of Unpasteurized Fluid Milk Should Not Be Assumed to Drop From the Time of Production to the Time of Sale at Retail.

The contamination level of unpasteurized fluid milk at retail is likely underestimated in the risk assessment. Raw milk is only one of two food categories whose contamination levels, the assessors predicted, drop fiom time of production to time of sale. The explanations given in the "Exposure Assessment" and "Risk Characterization" fail to provide an adequate basis for the "low" predicted contamination level for raw milk at retail.

The risk assessment states that the initial frequency of contamination of unpasteurized milk is "moderate"--one order of magnitude larger than the contamination frequency of pasteurized milk (4 percent and 0.4 percent, respectively). However, the "predicted contamination" of raw milk at time of sale is characterized as "low." The assessors concede that they have based their decision on "limited data" and that "[h]igher median levels of contamination with *L. monocytogenes* might be expected in unpasteurized milk [at retail]." They buttress their categorization by citing an untested hypothesis that "competition fiom more numerous spoilage microorganisms present in Unpasteurized Fluid Milk may slow the growth rate of *L. rnonocytogenes* and also reduce the maximum growth."

We encourage the assessors to base their assumptions relating to contamination of raw milk at retail on data relating to pasteurized milk at retail (with an adjustment upward to reflect the higher

contamination frequency and lack of listericidal treatment) and correlated with the "limited data" they have on raw milk. This approach would not be unprecedented. For example, the assessors used the pasteurized milk data for the median serving size and median sampling size for unpasteurized fluid milk.

C. The Most Likely Storage Times for Frankfurters and Deli Meats Should Be Adjusted.

The risk assessment also probably underestimates the "Most Likely Storage Times" for **hot** dogs and deli meats, because it assumes that they will be consumed between within a "moderate" time frame (between three and six to ten days).' This estimate is inconsistent with "use-by" date labeling practices of most manufacturers of packaged frankfurters and deli meats. Since many consumers meet or exceed the "use-by" dates on ready-to-eat foods, frankfurters and deli meats should be categorized as having "long" storage times.

Unlike the remaining categories of ready-to-eat foods, the storage times for hot dogs and deli meats were based on preliminary data from a survey of **73** people and the responses of 136 callers to the FSIS Meat and Poultry Hot Line. We believe that this information is inadequate to represent the storage practices of consumers across the nation, for two reasons: First, the Georgetown University survey provided only preliminary data. We believe that the final data will offer good insights and that the preliminary data should not be used to inform the risk assessment process. However, we believe that more support is needed than these data currently can offer. Second, the information gathered from callers to the **FSIS** Meat and Poultry Hot Line does not reflect the

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[1] Food and Drug Administration and Food Safety and Inspection Service, ***Interpretive Summary: Draft Assessment of the Relative Risk to Public Health From Foodborne*** Listeria monocytogenes ***Among Selected Categories of Ready-to-Eat Foods,*** (Jan. **2001),** p. 6, Table 1.

practices of average consumers. Those who call FSIS are more informed and/or more concerned about food-safety than most consumers. Therefore, we believe these people are less likely to keep and consume ready-to-eat foods beyond their "use-by" dates. Data needs to be compiled from a more representative sampling of consumers. In addition, because the category of deli meats encompasses both deli counter meats and prepackaged deli meats, the risk assessment needs to account for the date labeling on prepackaged meats, Most of them have "use-by" date labels that extend far beyond the length of the "moderate" storage period category applied to deli meats in the risk assessment.

At the very least, the information from the Georgetown University survey and the Hot Line callers (209 total) needs to be adjusted to reflect both the "expert judgments" of those who estimated the storage periods of other ready-to-eat foods, as well as the average or mean "expiration" dates of prepackaged deli meats.

11. The Risk Assessment Should Characterize All Frankfurters As High Risk.

In the "Interpretations and Conclusions" section of the risk assessment, ready-to-eat foods are assigned to four categories: those that warrant identification of new approaches for reducing potential contamination, those that have a high degree of variability or uncertainty, those that have a potentially low risk, and those that have a low predicted risk. Frankfurters that have not been adequately reheated are not assigned to any of the four categories. Hot dogs that have been reheated are considered to be "potentially low risk." The Bil Mar outbreak calls both these conclusions into question. Frankfurters are high-risk products, even if they are reheated, because L. ***monocytogenes***-tainted frankfurters introduce this hazard into the kitchen. Once present, the pathogen can spread

through hand-to-mouth transmission, when consumers don't wash their hands after touching the frankfurters, or through cross-contamination, when the juices from the hot dog package drip onto other ready-to-eat foods. Adequate reheating of the frankfurters will not prevent illnesses from these practices; therefore, all hot dogs should be included in the category of those that warrant identification of new approaches for reducing potential contamination.

111. The Risk Assessment Should Include Labeling As a New *L. monocytogenes* Strategy.

The "Interpretations and Conclusions" section of the risk assessment calls for "increased awareness of the potentially important role refiigerated storage conditions and shelf-life have on the risks associated with products that support the growth of *L. **monocytogenes.**''* While the risk assessment lists a series of new strategies to achieve that goal, it fails to include labeling as a means to alert high-risk consumers about the potential **risk.** As FSIS advised consumers in the wake of the Bil Mar outbreak, ready-to-eat products are not truly ready-to-eat for people who are especially vulnerable to foodborne illness. Labeling gives consumers important information both at the point-of-purchase and when preparing the food. For this reason, CSPI petitioned **FSIS** to require labels with safe-handling instructions on all ready-to-eat meat and poultry products until such time as the entire industry is required to test for the presence of *L. **rnonocytogenes*** in plants and end products. Labeling continues to be a valuable approach to informing consumers about food-safety risks when government regulations are unable to ensure that foods are not adulterated.

Conclusion

We applaud the FDA and the FSIS for their efforts in preparing this joint *L. moncytogenes* action plan. However, the federal government has long been aware of the danger posed by *L. **monocytogenes*** in ready-to-eat products. Consumers should not have to wait another three years to see progress on controlling this severe public-health threat.

Sincerely,

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On Behalf Of:

American Public Health Association
Center for Science in the Public Interest
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