Request for Comment and Information

This is a draft *Listeria monocytogenes* risk assessment. The conduct of a risk assessment is a process by which available data are arrayed in a systematic manner in order to consider factors that influence the risk of an adverse event (i.e., listeriosis). The data available to conduct a risk assessment are never "perfect." When data deficiencies were encountered, this risk assessment used assumption-based expert judgement of the science underlying the area in question.

In developing this risk assessment, the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) made a series of assumptions that have been identified in the body of the document. In making these assumptions the agencies actively sought data and advice, including formally seeking comments from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Interagency Risk Assessment Consortium (RAC).

The agencies' goal is to use the best science available to develop this risk assessment. Therefore, public comment is sought on this draft risk assessment. A comment period has been established during which comments, suggestions, and additional data may be submitted. Written comments should be submitted as indicated in the Federal Register Notice of Availability for this document (FDA Docket No. 99N-1168 or FSIS Docket No. 00-048N). Submit comments to the Dockets Management Branch (HFA-305), Docket No. 99N-1168, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, or to the 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.

In particular, comments are requested for four main topics and in response to specific questions.

Main Topics:

1. Assumptions and surrogate data sources used when specific data were unavailable.
2. Modeling approaches and techniques used in developing the exposure assessment, hazard characterization, and risk characterization.
3. Adequacy of the data sets used in developing the exposure assessments.
4. Transparency of the risk assessment document.

Specific Questions:

1. Foods were grouped into 20 categories in part because of the lack of adequate contamination (particularly enumeration data) and growth rate data to model the specific contamination concentration distributions of individual foods at consumption.

    a. Is it appropriate to group the foods for modeling purposes? Are current groupings of foods into the different food categories adequate, and if not, on what basis should the foods be grouped?

    b. Would pooling of all data on contamination levels to develop a single distribution for *L. monocytogenes* contamination levels in ready-to-eat foods be an effective means of describing and modeling the pattern of *L. monocytogenes* contamination?

    c. Can you provide any additional growth/survival data at refrigeration temperatures for any of the food categories that would significantly improve the model?

Request for Comment and Information (continued)

d. Storage times for foods in the home before consumption were estimated (using USDA recommended practices as a guide) because no specific data were available on the minimum, most likely, and maximum storage times. Are there data on storage times or other factors that should be included?

2. Current and Quantitative Contamination Data: This risk assessment primarily relied on published studies. In some cases, the studies were conducted more than 10 years ago and may not reflect current practices. However, all available data were generally used in the contamination databases even though the quality, study protocols, level of peer review, or any specific documentation of potential biases or quality factors were at times unknown.

a. Can you provide any more recent contaminant level (enumeration) data?
b. Do you have data to support or modify the assumptions used to model reheating for the Frankfurter food category?
c. Can you provide any additional growth/survival data at refrigeration temperatures for any of the food categories that would significantly improve the model?

3. Issues concerning the model and modeling techniques:

a. Can you suggest alternative approaches for modeling of pre- and post-retail growth and/or survival?
b. Cross contamination of *L. monocytogenes* from one food to another via cutting boards, utensils or storage in opened packages was not considered because of a lack of quantitative data on the frequency and extent of this occurring. How might we approach including possible cross contamination in the model if it is considered necessary to account for this mechanism of food contamination?
c. The dose-response models relied on animal studies to describe the range of variability in *L. monocytogenes* virulence and host susceptibility. The relationships developed were then anchored to relate the resulting distributions to human surveillance reports. Is there an alternative approach we should consider for modeling the dose response? Do you know of additional studies that address strain virulence and host susceptibility factors?
d. Three U.S. subpopulations (elderly, perinatal, and intermediate-age) were considered in the model based on availability of FoodNet and food consumption survey data. Is it advisable to determine the dose-response relationship for additional groups in the U.S. population? Are data available to allow the development of additional dose-response relationships?

4. Is there additional information that could be provided that would better describe the conduct of this assessment? How might the results be better presented?

Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods

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