

SUMMARY OF PUBLIC COMMENTS AND FDA/FSIS REVISIONS TO RISK ASSESSMENT

A notice of availability of a draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health, and a proposed risk management action plan was published in the Federal Register of January 19, 2001 (66 FR 5515) by the Food and Drug Administration (FDA), in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC). As part of a peer evaluation of the draft risk assessment, FDA/FSIS requested comments on the technical aspects of the draft risk assessment in the following areas: (1) the assumptions made; (2) the modeling techniques; (3) the data used; and (4) the transparency of the document. Comments were solicited for a 60-day period, ending March 20, 2001. Extensions were granted to comment on the risk assessment, extending the comment period to July 18, 2001.

We received 20 submissions of public comments. Submissions to the docket were received from: consumer groups; industry; trade associations representing the food industry, restaurants, food processors, manufacturers, distributors, marketers; consumer groups; manufacturer of food processing equipment; expert risk assessors and modelers; food retailer; educational and scientific society; and marketer, processor and distributor of agricultural and food products. The specific comments and the corresponding FDA/FSIS action/response for each topic area are described in Appendix 2.

We wish to both acknowledge and express our appreciation to those who provided comments to us. We considered the specific public comments in preparing this revised risk assessment. On the basis of the comments received, we determined that certain modifications should be included in the revised risk assessment. These modifications include the following.

1. Revision of the Food Categories

- The cheese categories have been reorganized into six categories based on moisture content.
- The Miscellaneous Dairy Products have been split into two categories: Cultured Milk Products (includes the low pH dairy foods manufactured with lactic acid fermentation) and High Fat and Other Dairy Products (includes the remainder of the dairy products that generally support growth).
- The frankfurter category was separated into reheated and not reheated frankfurter categories.
- Vegetable and fruit salads with salad dressing (including cole slaw and potato salad) were moved to the Deli-type Salad food category.
- Canned fruits and nuts were removed.
- Pickled, dried, and processed vegetables were removed.
- The number of food categories was increased from 20 to 23.

2. Modifications to the Contamination Data

- Newly available published and unpublished contamination data (approximately 40 studies) were included.
- Contamination data were weighted according to geographical location, year collected, and study size and an adjustment factor was used for food categories that had no new data.
- Food category-specific generalizations were made for the shape of the *Listeria monocytogenes* concentration distributions based on enumeration studies.

3. Modifications to the Growth Data

- Newly available data on growth of *Listeria monocytogenes* in various foods and post-retail storage times (frankfurters and deli meats) were included.
- For the Deli-type Salad food category, salads were segregated into growth and non-growth salads (and included consideration of the use of preservatives in salads made for bulk distribution to retail stores).
- For non-growth foods, the rates of inactivation were estimated from the research literature.
- The percentage of Frankfurters frozen before consumption were excluded from the growth model.

4. Incorporated Key New Data:

- American Meat Institute (AMI) consumer survey on how long (on average) deli meats and frankfurters were stored prior to consumption.
- National Food Processors Association (NFPA)/ Joint Institute for Food Safety and Applied Nutrition (JIFSAN) retail study, detailing the frequency and prevalence of *Listeria monocytogenes* in deli meats, deli salads, bagged fresh vegetables, seafood salads, smoked seafood, soft cheeses, and Hispanic-style cheeses.
- FDA/CFSAN study on the growth of *Listeria monocytogenes* in deli salads.
- International Dairy Foods Association (IDFA) data on cheese and ice cream.
- Refrigerated Foods Association study in growth of *Listeria monocytogenes* in deli salads.

5. Dose-Response and Other Model Modifications

- An additional year of FoodNet data (2000) was incorporated, which slightly reduced the total number of predicted cases.
- Separate mortality to hospitalization ratios were calculated for each sub-population.
- A 'scaling factor' was selected to adjust each uncertainty distribution of the predicted number of cases to the FoodNet estimates. As a result the 'scaling factor' is a distribution; but the total number of predicted cases for each population is not.
- The model was rewritten in Visual Basic for Applications to speed up the computation time required for each run of the model and to facilitate review.

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

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