Appendix 11:

RESEARCH NEEDS

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An important benefit of conducting a risk assessment is the identification of knowledge and data gaps. In the course of collecting and evaluating the data for the 2001 draft version of risk assessment, it became apparent that additional data could enhance the certainty and reduce variability in the risk assessment results. Consequently, new data were generated specifically for this risk assessment and data were obtained from the published literature on levels *of L. monocytogenes* in food, growth in Deli Salads, home storage times, and other data. The additional data are listed at the beginning of this document in the section titled "Summary of Public Comments and FDA/FSIS Revisions to the Risk Assessment." These new data significantly improved the predicted risk estimates and reduce the amount of uncertainty associated with those estimates. New data and information would also facilitate the development of commodity- or product-specific risk assessments. Continuing research is needed to continue filling existing gaps and to facilitate future *L. monocytogenes* risk assessment work.

Food Consumption

The two food consumption surveys used in this risk assessment were designed primarily for nutritional purposes, not for a microbiological exposure assessment. The surveys were not designed to collect information on aspects of food consumption related to food safety questions, such as whether a cheese was made from unpasteurized fluid milk; whether the milk or juice that was consumed was pasteurized or unpasteurized; whether smoked seafood is hot or cold smoked; whether peas put into a pasta salad were freshly cooked, frozen, or canned; whether luncheon meat was prepackaged or sliced in a deli; or whether steamed shrimp or crabs and fried chicken were eaten freshly cooked or allowed to cool before eating. To be more useful in future microbial risk assessments, food consumption surveys could include such information.

Specific dietary information was limited or lacking for many of the susceptible subpopulations. Food consumption information was available for women of childbearing

age and the elderly subpopulation not in an institution. In the future, the *L. monocytogenes* risk assessment might also include data from the CDC Pregnancy Nutrition Surveillance Survey. Additional studies specifically comparing diets of pregnant women to women of childbearing age would also be helpful. It is also unclear whether consumption by the elderly has been adequately represented in the food consumption surveys: data are not available to characterize the consumption by elderly living in nursing homes or other forms of assisted living out of the home. In addition, better information is needed about the health status of consumers to better identify the size and characteristics of immunocompromised subpopulations and to better characterize the consumption patterns of all susceptible subpopulations.

Information related to food preparation, storage, and eating practices is needed. Data on consumer food preparation and eating practices are limited. A survey on home storage times for Deli Meats and Frankfurters was conducted (AMI, 2001), but additional information is needed for other food categories. Because *L. monocytogenes* can grow during refrigerated storage, the storage time and temperature are major factors in the degree of hazard. Related factors include the time after opening the original package (particularly if it is a vacuum or modified atmosphere package), and likely cross-contamination at the retail level such as sales, or in the home refrigerator or kitchen.

Food Contamination and *L. monocytogenes* Growth

There were no systematic, quantitative surveys of the U. S. food supply specifically for *L. monocytogenes*. The majority of studies from the published literature determined the presence/absence of *L. monocytogenes* in foods, typically at the sensitivity of 0.04 cfu/g. Quantitative data are necessary to understand the range of contamination levels that occur and to estimate exposure levels. Surveys by industry and trade organizations (NFPA, 2002; Frye, 2000) provided the best information ever obtained on several of the food categories; similar surveys are needed for the other foods included in this risk assessment.

Additional inoculated pack studies are needed on selected foods to determine the growth rates and the maximum growth in the presence of normal spoilage flora. Essential information from these studies include the physical properties (such as pH or salt content) of the food studied and the identity of the *L. monocytogenes* strain used. It is further recommended that these studies be conducted using a group of well-characterized *L. monocytogenes* strains, to allow for both direct comparison across foods and information on the diversity of strain responses. There are an adequate number of these types of studies for use in assessing risk associated with some foods but additional studies are needed.

Epidemiology

The source food associated with most cases of listeriosis is never identified. Increased routine analysis by pulse field gel electrophoresis (PFGE), ribotyping, or other strain identification techniques would allow increased identification of links between cases and food isolates.

Enhanced investigative techniques and expanded efforts in both surveillance and outbreak investigation would provide better, more accurate information. Among the types of information needed are: the frequency and amount of suspect food consumed by both symptomatic and asymptomatic individuals, the number of *L. monocytogenes* in the food; information about the total number of individuals exposed to the suspect food in order to calculate the attack rate; and relevant characteristics of cases and exposed individuals.

Dose-Response

The immunological defense mechanisms of an individual are critical factors in determining whether an exposure to *L. monocytogenes* will result in clinical signs of

illness. Objective measures of the immune status of symptomatic and asymptomatic individuals would lead to better assessment of an individual's vulnerability to listeriosis. Knowledge of the role of the immune system in preventing listeriosis is also limited. Most of the information on resistance to *L. monocytogenes* infection comes from animal (primarily mouse) studies. The relevance of these studies to immune mechanisms important in human infection, particularly in pregnancy, should be investigated more thoroughly.

There is at least a 5-log range in virulence between *L. monocytogenes* strains. The current serotyping system (1/2a, 4b, etc) is not related to or based on specific virulence mechanisms. Development of methodologies to rapidly quantify the virulence of strains would allow more effective assessment of the public health threat of *L. monocytogenes* found in foods.

The effect of the food matrix and factors such as stomach acidity, achlorhydria, and use of antacids on the rate of listeriosis is not known and would be useful in understanding differential susceptibility in humans.

A collection of attack rates and consumption of *L. monocytogenes* could lead to better dose-response models. For example, more complete epidemiological investigation of outbreaks at the local, state, and federal levels will provide individual data points on the susceptibility of humans to listeriosis. Animal and biochemical tests need to be correlated to the epidemiological data to enable assessment of new *L. monocytogenes* isolates and to establish relevant biomarkers of human susceptibility.