VI. RESEARCH NEEDS

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 this risk assessment, it became apparent that additional data could enhance the certainty and reduce variability in the risk assessment results. New data and information would also facilitate the development of commodity- or product-specific risk assessments. Research needed to fill existing gaps and to facilitate future *L. monocytogenes* risk assessment work is discussed below.

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 collected no information, for example, on aspects of food consumption as they 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.

It has also been determined that 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. In addition, no information was found in the published literature on storage times for the foods included in the risk assessment. 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. Information about reheating practices for frankfurters and deli meats before consumption is needed.

Food Contamination and *L. monocytogenes* Growth

There is no systematic, quantitative survey 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. New data that reflect contamination levels closer to actual levels may indicate that the available contamination data used for some of the food categories may be overstating current contamination frequencies and levels.

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 single, well-characterized *L. monocytogenes* strain, to allow direct comparison across foods. There are an adequate number of these types of studies for use in assessing risk associated with some foods but many more 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 identification of links between cases and food isolates in more instances.

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 each case and 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. Understanding the immunity process would lead to better assessment of an individual's vulnerability to listeriosis and provide information for the development of methods to detect virulent strains. 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. However, the current serotyping system (1/2a, 4b, etc) is not related to or based on specific virulence mechanisms. Development of methodologies to rapidly identify high vs. low virulence 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.

More intensive 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.

Microbial dose-response modeling should be further explored to develop consensus among the scientific community on the best modeling approach for *L. monocytogenes*. Extrapolation to low doses remains highly uncertain.

Assuming that the preceding research and data acquisition is successful, future changes to the *L. monocytogenes* risk assessment that could be realized are summarized in the table below.

Table VI-1. Proposed Future Changes to the *Listeria monocytogenes* Risk Assessment

Issue	Modification
1) Because the Intermediate Age population represents highly immunocompromised persons as well as healthy persons, the listeriosis predictions are not optimally reflective of the susceptible population.	1-a) Separate the Intermediate Age into multiple groups, such as immunocompromised and non-immunocompromised Intermediate Age groups. Or, 1-b) Insert "placeholders" in the model that will allow predictions for particular populations (e.g. diabetics) to be rapidly conducted when an illness rate and population size are identified.
2) It is difficult to predict what effect additional contamination data for a food category will have on the prediction of listeriosis from that food category. Uncertainty is underreported in the contamination models, allowing them to be greatly influenced by additional data.	2) Additional approaches will be developed.
3) It is unclear from FoodNet data whether prenatal deaths are captured in surveillance efforts. A correction has been applied using California State Health Department data. This risk assessment currently develops a neonatal dose response curve and then adjusts for unreported prenatal deaths.	3) Alternative approaches will be developed.
4) The same serving size is used for each of the three populations.	4) Model meal size separately for each population of interest to account for differences in consumption.
5) Contamination study quality is uneven. Data were accepted at face value from all published studies.	5) Consider developing criteria for inclusion or exclusion of individual studies.