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This risk assessment included analysis of the available scientific information and data in the development of exposure assessment and dose-response models to predict the relative public health impact of foodborne *L. monocytogenes* from 20 food categories. The assessment focuses on predicting the comparative risk among ready-to-eat foods that have a history of either *L. monocytogenes* contamination or were implicated epidemiologically. The risk assessment focuses on the predicted relative risk associated with these foods in relation to the overall incidence of listeriosis including both apparently sporadic illnesses and illnesses associated with outbreaks. Illnesses attributed to documented outbreaks are a small proportion of the total estimated annual cases of listeriosis. Outbreaks frequently represent a breakdown in the food safety controls that have been established to prevent such occurrences. For example, outbreaks of listeriosis have been linked to failure to protect a frankfurter processing line from environmental contamination caused by plant renovations (1998-99), use of defective processing equipment in the production of chocolate milk (1994), and inadequate pasteurization of milk used to make fresh soft Mexican-style cheese (1987). Therefore, maintenance of food safety control systems and either initiating new or strengthening existing controls will contribute to reduction of the incidence of listeriosis.

The scientific evaluations and the mathematical models developed during the risk assessment, provide a systematic assessment of the scientific knowledge needed to assist both in reviewing the effectiveness of current policies, programs, and practices, and identifying new strategies to minimize the public health impact of foodborne *L. monocytogenes*. This systematic assessment provides a foundation to assist in future evaluations of the potential effectiveness of new strategies for controlling foodborne listeriosis. The risk assessment provides a means of comparing the relative risks associated with these foods on a per serving and a per annum basis. However, considering only the simple ranking of the relative risk associated with the various food categories is not sufficient. As discussed above the results must also be evaluated in relation to the degree of variability and uncertainty inherent in the predicted relative risk,

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and interpreted in relation to available scientific knowledge pertaining to the production, marketing, and consumption of the various food categories.

The following conclusions are provided as an integration of the results derived from the models, the evaluation of the variability and uncertainty underlying the results, and the impact that the various qualitative factors identified in the hazard identification, exposure assessment, and hazard characterization have on the interpretation of the risk assessment.

- The risk assessment reinforces past epidemiological conclusions that foodborne listeriosis is a moderately rare although severe disease. Although the exposure assessment suggests that U.S. consumers are exposed to low levels of *L. monocytogenes* on a regular basis, the likelihood of acquiring listeriosis is very small.
- The risk assessment also supports the findings of epidemiological investigations of both sporadic illness and outbreaks of listeriosis that certain foods, e.g., pâté, soft cheeses, smoked seafood, frankfurters, and some foods from delicatessen counters, are potential vehicles of listeriosis for susceptible populations.
- New case control studies are needed to reflect changes in food processing, distribution patterns, preparation, and consumption practices.
- From the exposure models, it is apparent that five factors affect consumer exposure to *L. monocytogenes* at the time of food consumption.
 1. Amounts and frequency of consumption of a food
 2. Frequency and levels of *L. monocytogenes* in ready-to-eat food
 3. Potential to support growth of *L. monocytogenes* in food during refrigerated storage
 4. Refrigerated storage temperature
 5. Duration of refrigerated storage before consumption

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Any of these factors can affect potential exposure to *L. monocytogenes* from a food category. These factors are “additive;” food categories in which more than one of these factors affects the food favor a greater risk of higher levels of *L. monocytogenes* contamination and are the foods more likely to increase consumers’ risk of listeriosis.

- Three dose-response models were developed that predict the number of deaths that are likely to be caused by exposure to different levels of *L. monocytogenes* in three age-based subpopulations; perinatal (fetuses and newborns), the elderly, and intermediate-age. These models are used to describe the relationship between levels of *L. monocytogenes* ingested and the incidence of serious listeriosis. From this hazard characterization, it is concluded that the dose of *L. monocytogenes* necessary to cause listeriosis depends greatly upon the immune status of the individual.
 1. Susceptible subpopulations (the elderly and perinatal) are more likely to contract listeriosis from a specific exposure to *L. monocytogenes* than the intermediate-age group (general population).
 2. Within the intermediate-age group, almost all cases of listeriosis are associated with specific subgroups with increased susceptibility (e.g., individuals with chronic illnesses, individuals taking immunosuppressive medication).
 3. The strong association of foodborne listeriosis with specific groups suggests that reducing the public health impact of this pathogen would benefit from strategies targeted to susceptible subpopulations, i.e., perinatal (pregnant women), elderly, and susceptible individuals of the intermediate-age group.
- The dose-response models developed for this risk assessment considered, for the first time, the range of virulence of different isolates of *L. monocytogenes*. In addition to more accurately describing the likelihood of *L. monocytogenes* causing disease, the dose-response curves suggest that the relative risk of contracting listeriosis from low exposures is less than previously calculated.

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- The risk characterization combines the exposure and dose-response models to predict the relative risk of illness attributable to each food category. Although a substantial degree of variability and uncertainty exists around the models' predictions, the results provide a means of comparing the relative risks among the different food categories and subpopulations considered in the assessment and should be useful in focusing control strategies.
- Extensive research has demonstrated that for products that receive a treatment that inactivates *L. monocytogenes*, the risk of listeriosis is determined to a large extent by the potential for recontamination. There is a need for increased awareness of the potentially important role refrigerated storage conditions and shelf-life have on the risks associated with products that support the growth of *L. monocytogenes*.
 1. New strategies are needed (a) to decrease the rates of recontamination during the manufacturing and marketing of ready-to-eat foods, (b) to estimate the impact of storage times and temperatures on the potential levels of *L. monocytogenes* when the microorganism is present, and (c) to ensure adequate information related to storage conditions and safe handling practices is available.
 2. Industry and regulatory agencies should identify the key aspects of sanitation standard operating practices, good manufacturing practices, and other process control and process verification systems, such as HACCP, that prevent the recontamination of ready-to-eat foods, particularly those that support the growth of *L. monocytogenes* at refrigerator temperatures.
 3. New strategies are needed to ensure that consumers receive sufficient product safety information about the storage and shelf-life of refrigerated products, so that consumers can store them properly and use or discard when the shelf-life expires.
 4. New strategies are needed to educate consumers to pay strict attention to manufacturer safety information about the storage and shelf-life of

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refrigerated products, storing them properly and using or discarding when the shelf-life expires.

- The following food categories warrant identification of new approaches for reducing the potential for *L. monocytogenes* contamination:

Pâté and Meat Spreads; Fresh Soft Cheese, such as queso fresco (particularly those made with unpasteurized milk); Smoked Seafood; Deli Meats; and Deli Salads. Unpasteurized Fluid Milk is also included in this group because in addition to being a moderate relative risk from direct consumption, it is also a primary ingredient in products that have a higher degree of relative risk or that have been epidemiologically linked to listeriosis (e.g., Fresh Soft Cheese).

- This risk assessment indicated that a number of the food categories have either a high degree of variability associated with their potential to contribute to foodborne listeriosis or a higher degree of uncertainty associated with their predicted relative risk ranking. These food categories need to be examined on an individual basis to determine if the appropriate means for reducing their predicted relative risk is through the establishment of control strategies (variability) or whether ranking will be affected by acquisition of additional data (uncertainty). Food categories that require such an evaluation are:

Preserved Fish; Dry/Semi-Dry Fermented Sausages; Cooked Ready-to-Eat Crustaceans; Miscellaneous Dairy Products; and Vegetables.

- Some food categories have a potentially low relative risk due to the inclusion of a “listericidal treatment” in the manufacturing or preparation of the foods. Over 15 years of scientific investigations have indicated that the primary determining factor affecting the presence of *L. monocytogenes* in these products is the likelihood that they will be recontaminated. Thus, the low relative risk associated with these foods is dependent on manufacturers', distributors', food service and retailers', and consumers' continued vigilance in producing, preparing, and storing these products. The importance of this continuing vigilance is emphasized by the fact that several of these foods have been implicated in outbreaks of listeriosis. This group of food categories is:

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Frankfurters (when adequately reheated); Heat-Treated Natural Cheese and Processed Cheese; Pasteurized Fluid Milk; and Soft Mold-Ripened and Blue-Veined Cheese.

- Some food categories have low predicted relative risk due to inherent characteristics associated with the food. In addition this group of food categories appears to represent substantially less relative risk in terms of either cases or outbreaks of foodborne listeriosis. This group of food categories is:

Ice Cream and Frozen Dairy Products; Aged Cheese; Fruits; Goat, Sheep, and Feta Cheese; and Raw Seafood.

The models generated as the basis for this risk assessment can be used in the future to further evaluate the impact of listeriosis on the public health. It is anticipated that additional risk assessments on individual foods within specific food categories will be conducted to help answer specific questions about how individual steps in their production and processing impact public health, including the likely effectiveness of different preventive strategies. The models may be used to evaluate the expected public health impact of preventive controls such as storage limits, sanitation improvements, or new processing technologies. Sources of contamination during food production and retail conditions can also be added to the model to provide more detailed examination of factors contributing to the risk of listeriosis from the final product.

The results of this *L. monocytogenes* risk assessment are influenced by the assumptions and data sets that were used to develop the exposure assessment and hazard characterization. The results of this draft risk assessment, particularly the predicted relative risk ranking values, could change as a result of the DHHS/FDA and USDA/FSIS actively seeking new information, scientific opinions, or data during the public comment period.

This risk assessment significantly advances our ability to describe our current state of knowledge about this important foodborne pathogen, while simultaneously providing a framework for integrating and evaluating the impact of new scientific knowledge on enhancing public health.