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

Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services

Food Safety and Inspection Service
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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.

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EXECUTIVE SUMMARY

Background

The U.S. Department of Health and Human Service, Food and Drug Administration's Center for Food Safety and Applied Nutrition (DHHS/FDA/CFSAN) conducted this risk assessment in collaboration with the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) and in consultation with the DHHS Centers for Disease Control and Prevention (CDC). The purpose of the assessment is to examine systematically the available scientific data and information to estimate the relative risks of serious illness and death associated with consumption of different types of ready-to-eat (RTE) foods that may be contaminated with *Listeria monocytogenes*. This examination of the current science and the models developed from it are among the tools that food safety regulatory agencies will consider when evaluating the effectiveness of current and future policies, programs, and regulatory practices to minimize the public health impact of this pathogen.

The Healthy People 2010 goals for national health promotion and disease prevention called on federal food safety agencies to reduce foodborne listeriosis by 50% by the end of the year 2005. Preliminary FoodNet data on the incidence of foodborne illnesses for the United States in 2001 indicated that the incidence of infection from *Listeria monocytogenes* decreased between 1996 and 2001 from 0.5 to 0.3 cases per 100,000 people per year. The level then reached a plateau. In order to reduce further the incidence to a level of 0.25 cases per 100,000 people by the end of 2005, it became evident that additional targeted measures were needed. The *Listeria monocytogenes* risk assessment was initiated as an evaluation tool in support of this goal.

Listeria monocytogenes is a bacterium that occurs widely in both agricultural (soil, plants and water) and food processing environments. Ingestion of *Listeria monocytogenes* can cause listeriosis, which can be a life-threatening human illness. In 2000, the CDC reported that of all the foodborne pathogens tracked by CDC, *Listeria monocytogenes* had the second highest case fatality rate (21%) and the highest hospitalization rate (90.5%). Serious illness almost always occurs in people considered to be at higher risk, such as the elderly and those who have a pre-existing illness that reduces the effectiveness of their immune system. Perinatal listeriosis results from foodborne exposure of the pregnant mother leading to *in utero* exposure of the fetus, resulting in fetal infection that leads to fetal death, premature birth, or neonatal illness and death. *Listeria monocytogenes* also causes listerial gastroenteritis, a syndrome typically associated with mild gastrointestinal symptoms in healthy individuals. This risk assessment focuses on the severe public health consequences.

Scope and General Approach

This risk assessment provides analyses and models that (1) estimate the potential level of exposure of three age-based population groups and the total United States population to *Listeria monocytogenes* contaminated foods for 23 food categories and (2) relate this exposure to public health consequences. The food categories consist of foods with a documented history of *Listeria monocytogenes* contamination. The models provide a means of predicting the likelihood that severe illness or death will result from consuming foods contaminated with this pathogen. These predictions are interpreted and used to estimate the relative risks among the food categories. The foods considered in this risk assessment are ready-to-eat foods that are eaten without being cooked or reheated just prior to consumption. One food, frankfurters, may or may not be reheated prior to consumption and was considered as two separate food categories. The working assumption is that all the cases of listeriosis are attributed to the foods in 23 categories, so that the risk assessment could be 'anchored' to the United States public health statistics. However, it is recognized that additional foods or cross-contamination from raw foods before cooking to other RTE foods may also contribute to additional cases.

The published scientific literature, government food intake surveys, health statistics, epidemiological information, unpublished food product surveys acquired from state and federal public health officials and trade associations, and surveys specifically designed to augment the data available for the risk assessment are the primary sources of data used in this document. Expert advice on scientific assumptions was actively sought from leading scientists from academia, industry, and government. This included two formal reviews of the underlying model structure and assumptions by the United States National Advisory Committee on Microbiological Criteria for Foods. In addition, the risk assessment was initially published in draft form and public comments sought for six months.

While the risk assessment purposely did not look into the pathways for the manufacture of individual foods, the risk assessment model developed can be used to estimate the likely impact of control strategies by changing one or more input parameters and measuring the change in the model outputs. This process, referred to as conducting 'what-if' scenarios, can be used to explore how the components of a complex model interact. Several 'what-if' scenarios are detailed within the risk assessment to evaluate the impact of refrigerator temperature, storage times, and reduction of the number of organisms in foods at before it is sold, and reduction in the contamination levels in foods that support growth.

Results

The relative risk rankings, along with the corresponding risk estimates expressed in terms of both the predicted number of cases per serving and per annum, are provided in Summary Table 1. Both measures are important in understanding and interpreting the risks associated with foodborne listeriosis. The per serving value can be considered the inherent risk associated with the manufacturing, distribution, marketing, and use of the food category, and is reflective of the degree of *Listeria monocytogenes* control achieved. Examples of factors that influence the 'per serving' risk include the frequency of contamination, the extent of that contamination, the ability of the food category to support the growth of *Listeria monocytogenes*, the duration and temperature of refrigerated storage, and the size of the serving. The predicted relative risk per serving can be viewed as the relative risk faced by individual consumers when he/she consume a single serving of the various foods considered in this risk assessment. The 'per serving' risk is typically the value upon which risk management decisions related to a specific product are based.

Summary Table 1. Relative Risk Ranking and Predicted Median Cases of Listeriosis for the Total United States Population on a per Serving and per Annum Basis

Relative Risk Ranking	Predicted Median Cases of Listeriosis for 23 Food Categories					
	Per Serving Basis[a]			Per Annum Basis[b]		
		Food	Cases		Food	Cases
1	High Risk	Deli Meats	7.7×10^{-8}	Very High	Deli Meats	1598.7
2	High Risk	Frankfurters, not reheated	6.5×10^{-8}	High Risk	Pasteurized Fluid Milk	90.8
3	High Risk	Pâté and Meat Spreads	3.2×10^{-8}	High Risk	High Fat and Other Dairy Products	56.4
4	High Risk	Unpasteurized Fluid Milk	7.1×10^{-9}	High Risk	Frankfurters, not reheated	30.5
5	High Risk	Smoked Seafood	6.2×10^{-9}	Moderate Risk	Soft Unripened Cheese	7.7
6	High Risk	Cooked Ready-to-Eat Crustaceans	5.1×10^{-9}	Moderate Risk	Pâté and Meat Spreads	3.8
7	Moderate Risk	High Fat and Other Dairy Products	2.7×10^{-9}	Moderate Risk	Unpasteurized Fluid Milk	3.1
8	Moderate Risk	Soft Unripened Cheese	1.8×10^{-9}	Moderate Risk	Cooked Ready-to-Eat Crustaceans	2.8
9	Moderate Risk	Pasteurized Fluid Milk	1.0×10^{-9}	Moderate Risk	Smoked Seafood	1.3
10	Low Risk	Fresh Soft Cheese	1.7×10^{-10}	Low Risk	Fruits	0.9
11	Low Risk	Frankfurters, reheated	6.3×10^{-11}	Low Risk	Frankfurters, reheated	0.4
12	Low Risk	Preserved Fish	2.3×10^{-11}	Low Risk	Vegetables	0.2
13	Low Risk	Raw Seafood	2.0×10^{-11}	Low Risk	Dry/Semi-dry Fermented Sausages	<0.1
14	Low Risk	Fruits	1.9×10^{-11}	Low Risk	Fresh Soft Cheese	<0.1
15	Low Risk	Dry/Semi-dry Fermented Sausages	1.7×10^{-11}	Low Risk	Semi-soft Cheese	<0.1
16	Low Risk	Semi-soft Cheese	6.5×10^{-12}	Low Risk	Soft Ripened Cheese	<0.1
17	Low Risk	Soft Ripened Cheese	5.1×10^{-12}	Low Risk	Deli-type Salads	<0.1
18	Low Risk	Vegetables	2.8×10^{-12}	Low Risk	Raw Seafood	<0.1
19	Low Risk	Deli-type Salads	5.6×10^{-13}	Low Risk	Preserved Fish	<0.1
20	Low Risk	Ice Cream and Other Frozen Dairy Products	4.9×10^{-14}	Low Risk	Ice Cream and Other Frozen Dairy Products	<0.1
21	Low Risk	Processed Cheese	4.2×10^{-14}	Low Risk	Processed Cheese	<0.1
22	Low Risk	Cultured Milk Products	3.2×10^{-14}	Low Risk	Cultured Milk Products	<0.1
23	Low Risk	Hard Cheese	4.5×10^{-15}	Low Risk	Hard Cheese	<0.1

[a]Food categories were classified as high risk (>5 cases per billion servings), moderate risk (<5 but ≥1 case per billion servings), and low risk (<1 case per billion servings).

[b]Food categories were classified as very high risk (>100 cases per annum), high risk (>10 to 100 cases per annum), moderate risk (≥1 to 10 cases per annum), and low risk (<1 cases per annum).

The second measure, the 'per annum risk,' is the predicted number of fatal infections per year in the United States for each food category. This value takes into account the number of servings of the food category that are consumed. The predicted per annum risk of serious illnesses for each food category can be thought of as the predicted relative total public health impact for each food category. Since the 'per annum' risk is derived from the 'per serving' risk, there is generally a higher degree of uncertainty associated with the former. The predicted per serving and per annum relative risks are used to develop risk rankings to compare the various food categories. In addition to presenting the 'most likely' relative risk rankings for the different population groups and food categories, the risk assessment provides the inherent variability and the uncertainty associated with these rankings.

Evaluation and Interpretation

The overall interpretation of the risk assessment requires more than just a simple consideration of the relative risk rankings associated with the various food categories. First, the interpretation of the results requires an appreciation of the fact that the values being compared are the median values of distributions that may be highly skewed (i.e., not evenly distributed). The use of median values was selected as being the appropriate method for comparing the overall relative risks among the different food categories. The quantitative results must be considered in relation to the associated variability and uncertainty (i.e., the confidence intervals surrounding the median) and interpreted in the context of both the epidemiologic record and how the food categories are manufactured, marketed, and consumed. A detailed consideration of the quantitative and qualitative findings for each food category is provided in the risk assessment and its appendices.

A number of methods for objectively grouping the results were evaluated, and are discussed in detail within the risk assessment. One approach is cluster analysis. When performed at the 90% confidence level, this analysis groups the per serving rankings into four clusters and the per annum rankings into five. These clusters are used, in turn, to develop a two-dimensional matrix of per serving vs. per annum rankings of the food categories (Summary Figure 1). In this approach, the 'per serving' clusters are arrayed against the 'per annum' clusters. The matrix is then used to depict five risk designations: Very High, High, Moderate, Low, and Very Low.

The risk characterization combines the exposure and dose-response models to predict the relative risk of illness attributable to each food category. While the risk characterization must be interpreted in light of both the inherent variability and uncertainty associated with the extent of contamination of ready-to-eat foods with *Listeria monocytogenes* and the ability of the microorganism to cause disease, the results provide a means of comparing the relative risks among the different food categories and population groups considered in the assessment and should prove to be a useful tool in focusing control strategies and ultimately improving public health through effective risk management. As described above, cluster analysis techniques are employed as a means of discussing the food categories within a risk analysis framework. The food categories are divided into five overall risk designations (see Summary Figure 1), which are likely to require different approaches to controlling foodborne listeriosis.

Decreased Risk per Annum →

Decreased Risk per Serving ↓

	Clusters A and B	Clusters C and D	Cluster E
Cluster 1	**Very High Risk (Clusters 1-A, 1-B)** Deli Meats Frankfurters (not reheated)	**High Risk (Clusters 1-C, 1-D)** Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	**Moderate Risk (Cluster 1-E)** No food categories
Cluster 2	**High Risk (Clusters 2-A, 2-B)** High Fat and Other Dairy Products Pasteurized Fluid Milk Soft Unripened Cheese	**Moderate Risk (Clusters 2-C, 2-D)** Cooked RTE Crustaceans	**Moderate Risk (Cluster 2-E)** No food categories
Cluster 3	**Moderate Risk (Clusters 3-A, 3-B)** No food categories	**Moderate Risk (Clusters 3-C, 3-D)** Deli-type Salads Dry/Semi-dry Fermented Sausages Frankfurters (reheated) Fresh Soft Cheese Fruits Semi-soft Cheese Soft Ripened Cheese Vegetables	**Low Risk (Cluster 3-E)** Preserved Fish Raw Seafood
Cluster 4	**Moderate Risk (Clusters 4-A, 4-B)** No food categories	**Low Risk (Clusters 4-C, 4-D)** No food categories	**Very Low Risk (Cluster 4-E)** Cultured Milk Products Hard Cheese Ice Cream and Other Frozen Dairy Products Processed Cheese

Summary Figure 1. Two-Dimensional Matrix of Food Categories Based on Cluster Analysis of Predicted per Serving and per Annum Relative Rankings

[The matrix was formed by the interception of the four per serving clusters vs. the per annum clusters A and B, C and D, and E. For example, Cluster 3-E (Low Risk) refers to the food categories that are in both Cluster level 3 for the risk per serving and Cluster level E for the risk per annum.]

<u>Risk Designation Very High</u>. This designation includes two food categories, Deli Meats and Frankfurters, Not Reheated. These are food categories that have high predicted relative risk rankings on both a per serving and per annum basis, reflecting the fact that they have relatively high rates of contamination, support the relatively rapid growth of *Listeria monocytogenes* under

refrigerated storage, are stored for extended periods, and are consumed extensively. These products have also been directly linked to outbreaks of listeriosis. This risk designation is one that is consistent with the need for immediate attention in relation to the national goal for reducing the incidence of foodborne listeriosis. Likely activities include the development of new control strategies and/or consumer education programs suitable for these products.

Risk Designation High. This designation includes six food categories, High Fat and Other Dairy Products, Pasteurized Fluid Milk, Pâté and Meat Spreads, Soft Unripened Cheeses, Smoked Seafood, and Unpasteurized Fluid Milk. These food categories all have in common the ability to support the growth of *Listeria monocytogenes* during extended refrigerated storage. However, the foods within this risk designation appear to fall into two distinct groups based on their rates of contamination and frequencies of consumption.

- Pâté and Meat Spreads, Smoked Seafood, and Unpasteurized Fluid Milk have relatively high rates of contamination and thus high predicted per serving relative risks. However, these products are generally consumed only occasionally in small quantities and/or are eaten by a relatively small portion of the population, which lowers the per annum risk. All three products have been associated with outbreaks or sporadic cases, at least internationally.

  These foods appear to be priority candidates for new control measures (i.e., Smoked Seafood, Pâté and Meat Spreads) or continued avoidance (i.e., Unpasteurized Fluid Milk).

- High Fat and Other Dairy Products, Pasteurized Fluid Milk, and Soft Unripened Cheeses have low rates of contamination and corresponding relatively low predicted per serving relative risks. However, these products are consumed often by a large percentage of the population, resulting in elevated predicted per annum relative risks. In general, the predicted per annum risk is not matched with an equivalent United States epidemiologic record. However, the low frequency of recontamination of individual servings of these products in combination with their broad consumption makes it likely that these products are primarily associated with sporadic cases and normal case control studies would be unlikely to lead to the identification of an association between these products and cases of listeriosis.

  These products (High Fat and Other Dairy Products, Pasteurized Fluid Milk, and Soft Unripened Cheeses) appear to be priority candidates for advanced epidemiologic and scientific investigations to either confirm the predictions of the risk assessment or identify the factors not captured by the current models that would reduce the predicted relative risk.

Risk Designation Moderate. This risk designation includes nine food categories (Cooked Ready-to-Eat Crustaceans, Deli Salads, Fermented Sausages, Frankfurters-Reheated, Fresh Soft Cheese, Fruits, Semi-soft Cheese, Soft Ripened Cheese, and Vegetables) that encompass a range of contamination rates and consumption profiles. A number of these foods include effective bactericidal treatments in their manufacture or preparation (e.g., Cooked Ready-to-Eat Crustaceans, Frankfurters-Reheated, Semi-soft Cheese) or commonly employ conditions or compounds that inhibit the growth of *Listeria monocytogenes* (e.g., Deli Salads, Dry/Semi-dry Fermented Sausages). The risks associated with these products appear to be primarily associated with product recontamination, which in turn, is dependent on continued, vigilant application of proven control measures.

Risk Designation Low. This risk designation includes two food categories, Preserved Fish and Raw Seafood. Both products have moderate contamination rates but include conditions (e.g., acidification) or consumption characteristics (e.g., short shelf-life) that limit *Listeria monocytogenes* growth and thus limit predicted per serving risks. The products are generally consumed in small quantities by a small portion of the population on an infrequent basis, which results in low predicted per annum relative risks. Exposure data for these products are limited so there is substantial uncertainty in the findings. However, the current results predict that these products, when manufactured consistent with current good manufacturing practices, are not likely to be a major source of foodborne listeriosis.

Risk Designation Very Low. This risk designation includes four food categories, Cultured Milk Products, Hard Cheese, Ice Cream and Other Frozen Dairy Products, and Processed Cheese. These products all have in common the characteristics of being subjected to a bactericidal treatment, having very low contamination rates, and possessing an inherent characteristic that either inactivates *Listeria monocytogenes* (e.g., Cultured Milk Products, Hard Cheese) or prevents its growth (e.g., Ice Cream and Other Frozen Dairy Products, Processed Cheese). This results in a very low predicted per serving relative risks. The predicted per annum relative risks are also low despite the fact that these products are among the more commonly consumed ready-to-eat products considered by the risk assessment. The results of the risk assessment predict that unless there was a gross error in their manufacture, these products are highly unlikely to be a significant source of foodborne listeriosis.

Conclusions

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. United States consumers are exposed to low to moderate levels of *Listeria monocytogenes* on a regular basis.

- The risk assessment supports the findings of epidemiological investigations of both sporadic illness and outbreaks of listeriosis that certain foods are more likely to be vehicles for *Listeria monocytogenes*.

- Three dose-response models were developed that relate the exposure to different levels of *Listeria monocytogenes* in three age-based subpopulations [i.e., perinatal (fetuses and newborns), elderly, and intermediate-age] with the predicted number of fatalities. These models were used to describe the relationship between levels of *Listeria monocytogenes* ingested and the incidence of listeriosis. The dose of *Listeria monocytogenes* necessary to cause listeriosis depends greatly upon the immune status of the individual.

    1. Susceptible subpopulations (such as the elderly and perinatal) are more likely to contract listeriosis than the general population.

2. Within the intermediate-age subpopulation group, almost all cases of listeriosis are associated with specific subpopulation groups with increased susceptibility (e.g., individuals with chronic illnesses, individuals taking immunosuppressive medication).

3. The strong association of foodborne listeriosis with specific population groups suggests that strategies targeted to these susceptible population groups, i.e., perinatal (pregnant women), elderly, and susceptible individuals within the intermediate-age group, would result in the greatest reduction in the public health impact of this pathogen.

- The dose-response models developed for this risk assessment considered, for the first time, the range of virulence observed among different isolates of *Listeria monocytogenes*. The dose-response curves suggest that the relative risk of contracting listeriosis from low dose exposures could be less than previously estimated.

- The exposure models and the accompanying 'what-if' scenarios identify five broad factors that affect consumer exposure to *Listeria monocytogenes* at the time of food consumption.

  1. Amounts and frequency of consumption of a ready-to-eat food

  2. Frequency and levels of *Listeria monocytogenes* in a ready-to-eat food

  3. Potential of the food to support growth of *Listeria monocytogenes* during refrigerated storage

  4. Refrigerated storage temperature

  5. Duration of refrigerated storage before consumption

Any of these factors can affect potential exposure to *Listeria monocytogenes* from a food category. These factors are 'additive' in the sense that foods where multiple factors favor high levels of *Listeria monocytogenes* at the time of consumption are typically more likely to be riskier than foods where a single factor is high. These factors also suggest several broad control strategies that could reduce the risk of foodborne listeriosis such as reformulation of products to reduce their ability to support the growth of *Listeria monocytogenes* or encouraging consumers to keep refrigerator temperatures at or below 40 ºF and reduce refrigerated storage times. For example, the 'what-if' scenarios using Deli Meats predicts that consumer education and other strategies aimed at maintaining home refrigerator temperatures at 40 ºF could substantially reduce the risks associated with this food category. Combining this with pre-retail treatments that decrease the contamination levels in Deli Meats would be expected to reduce the risk even further.

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 public health enhancement.

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

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ABBREVIATIONS AND ACRONYMS

Abbreviation/ Acronym	Definition
ARS:	USDA's Agricultural Research Service
CDC:	Centers for Disease Control and Prevention
CFSAN:	FDA's Center for Food Safety and Applied Nutrition
CFU:	Colony forming unit
CSFII:	USDA's Continuing Survey of Food Intakes by Individuals
EGR:	Exponential Growth Rate
FDA:	US DHHS's Food and Drug Administration
FSIS:	USDA's Food Safety and Inspection Service
GMP:	Good Manufacturing Practice
GSD:	Geometric Standard Deviation
HACCP:	Hazard Analysis Critical Control Point
IP:	Intraperitoneal
LD_{50}:	The 50 % Lethal Dose (See Glossary)
LLO:	Listeriolysin O (see Glossary)
NACMCF:	National Advisory Committee on Microbiological Criteria for Foods
NAS:	National Academy of Sciences
NFS:	Not further specified; a term used by CSFII
NHANES III:	Third National Health and Nutrition Examination Survey
PFGE:	Pulsed Field Gel Electrophoresis
RAC:	The interagency Risk Assessment Consortium
RTE:	Ready-to-Eat
SSOP:	Sanitation Standard Operating Procedure
UHT:	Ultra high temperature
US DHHS:	United States Department of Health and Human Services
USDA:	United States Department of Agriculture
WHO:	World Health Organization

GLOSSARY

Term	Definition
Antibody Titer:	A measure of the activity of an antibody solution.
Antibody:	A protein capable of specifically reacting with a particular antigen.
Antigen:	A substance capable of eliciting the formation of an antibody.
Asymptomatic:	Without symptoms, or not exhibiting symptoms.
Attack Rate:	The numbers of people at risk who develop a disease out of the total number of people at risk. The attack rate is useful in comparing the risk of disease in groups with different exposures.
Colony Forming Unit:	A cell or cluster of two or more attached sister cells capable of multiplying to form a macroscopic colony of cells.
Cumulative Distribution:	A representation of a distribution where the values are arranged in ascending or descending order.
Distribution:	A series of values or a mathematical equation describing a series of values.
Dose:	The amount or number of a pathogen that is ingested or interacts with an organism (host).
Dose-response Assessment:	The determination of the relationship between the magnitude of exposure and the magnitude and/or frequency of adverse effects.
Elderly:	United States population 60 years of age and older.
Empirical Distribution:	A series of observed values or data.
Exposure Assessment:	A component of a risk assessment that characterizes the source and magnitude of human exposure to the pathogen.
Fetus:	The term used to refer to an unborn child from 16 weeks after fertilization to birth.
Foodborne Pathogen:	A microorganism (bacteria, virus, protozoa) that is capable of causing disease and is transmitted by food.
Food Code:	A number representing a food in the food consumption surveys; each food has its own food code.
Food Matrix:	The food environment that a pathogen is in. It includes the food's fat levels, acidity, salt level and other characteristics of the food that affect the pathogen's ability to cause disease.
FoodNet:	Foodborne Diseases Active Surveillance Network. A surveillance system led by the Centers for Disease Control and Prevention for compiling epidemiological data on the incidences of foodborne illness (also see Appendix 4).
Frequency Distribution:	A distribution describing the rate or frequency of occurrence of a value in a series or population.

Term	Definition
Gene Knock Out Model:	An animal host which is specifically used because it has a known genetic defect or gene disruption in order to determine the role of the missing gene in a biological process such as resistance to infection.
Intermediate-age Subpopulation:	Total United States population excluding elderly and pregnancy-associated groups, and including susceptible populations such as cancer patients, AIDS patients, and transplant patients.
Hazard Health Effect:	A biological, chemical or physical agent in, or property of, food that may have an adverse health effect.
Hazard Identification:	The identification of known or potential health effects associated with a particular agent.
Hazard Characterization:	The qualitative or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents that may be present in food.
Incidence:	The number of new cases of a disease that occur during a specified period of time in a population at risk for developing the disease.
Infection:	When a microorganism or other pathogen becomes established in the host; this includes invasion, multiplication, and transmission.
Iteration:	A single calculation among a series of calculations (e.g. a Monte-Carlo simulation).
Intraperitoneal:	Route of introduction of an inoculum (pathogen) by a needle or syringe into the peritoneal cavity (abdomen) of the host.
Intragastrical:	The route of introducing an inoculum in which the material is injected into the stomach of the host by a tube that bypasses the mouth and esophagus. The normal route of invasion of a foodborne pathogen is through ingestion, survival in the stomach and invasion through the gastrointestinal system.
Immunosuppression:	An agent or condition that decreases a person's ability to resist infection.
LD_{50}:	The dose resulting in 50 % lethality in a population.
Listerial Gastroenteritis:	Mild, flu-like symptoms caused by *Listeria monocytogenes* infection: chills, diarrhea, headache, abdominal pain and cramps, nausea, vomiting, fatigue, and myalgia.
Listeriolysin O:	A protein produced by *Listeria monocytogenes* that disrupts red blood cells in the host.
Listeriosis:	The disease caused by infection with *Listeria monocytogenes.*

Term	Definition
Modeling (mathematical):	Attempting to predict aspects of the behavior of some system by creating an approximate (mathematical) model of it. Mathematical models contribute to the understanding of complex systems and their predicted behavior within the scope of the model.
Meat or Poultry Spreads:	A ready-to-eat product that generally is cooked and contains meat or poultry, fat, and other ingredients to result in a paste-like consistency (e.g., "Ham Spread" or "Tongue Spread"). Meat or poultry spreads differ from pâté in that the primary meat product or poultry product is liver.
Monte-Carlo Simulation:	A process for making repeated calculations with minor variations of the same mathematical equation, usually with the use of a computer. May be used to integrate variability in the predicted results for a population or the uncertainty of a predicted result. A two dimensional Monte-Carlo in simulation may be used to do both.
Neonate:	A newborn from birth to 30 days of age.
Outbreak:	The occurrence of two or more cases of similar illness resulting from the ingestion of a common food (See Sporadic).
Perinatal:	As used in this risk assessment, refers to the susceptible population that includes fetuses and neonates from 16 weeks after fertilization to 30 days after birth.
Prenatal:	As used in this risk assessment, a fetus over 16 weeks gestation.
Prevalence:	In epidemiology, the number of affected persons present in the population at a specific point in time divided by the number of persons in the population at that time.
Probability:	As used in this risk assessment, probability denotes uncertainty. The term is also sometimes used to denote frequency.
Ready-To-Eat:	Foods that may be eaten as purchased without further preparation by the consumer, particularly without additional cooking.
Relative Risk:	As used in this risk assessment, the term refers to the comparisons and rankings of the risks per serving and cases per annum of listeriosis attributed to each of 23 food categories. The food categories are ranked from 1 (highest risk) to 23 (lowest risk) based on the model predictions for the median number of cases of listeriosis. An implicate assumption is that virtually all cases of foodborne listeriosis reported by CDC can be attributed to the foods in these 23 food categories.

Term	Definition
Ribotype:	A subtype of a bacterial strain more detailed than the species or serotype level; determination of a ribotype is based on analysis of patterns formed by DNA fragments.
Risk:	The likelihood of the occurrence and the magnitude of the consequences of exposure to a hazard on human health.
Risk Analysis:	The process consisting of three components: risk assessment, risk management, and risk communication.
Risk Assessment:	The scientific evaluation of known or potential adverse health effects resulting from human exposure to hazards. The process consists of the following steps: hazard identification, exposure assessment, hazard characterization (dose-response), and risk characterization.
Risk Characterization:	Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.
Serotype:	A group of related microbes distinguished by its composition of antigens.
Serving Size:	The amount of food eaten per eating occasion. [In this risk assessment, it does not refer to the amount customarily consumed per eating occasion, as defined by FDA in the Code of Federal Regulations.]
Sporadic Case:	When a single individual becomes ill; an isolated event not documented as an outbreak.
Susceptible Population:	A group of people at increased risk for infection and illness from a pathogen, often caused by a decrease in the effectiveness of the person's immune system.
Susceptibility:	The degree that a host is vulnerable to infection; includes the ability of the host to defend itself.
T lymphocytes:	A subset of lymphocytes (white blood cells) defined by their development in the thymus gland. They are involved in most aspects of adaptive immunity including antibody production (via interaction with B-lymphocytes) and inflammation.
Uncertainty:	An expression of the lack of knowledge, usually given as a range or group of plausible alternatives.
Uncertainty Distribution:	A description of the range of plausible values for a prediction.
Variability:	A description of differences among the individual members of a series or population.
Virulence:	The capacity of a microbial pathogen to invade and/or produce illness in the host. Mediated by the presence of specific genes and their protein products that interact with the host.

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

I. INTRODUCTION

The United States DHHS Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA/CFSAN) conducted this risk assessment in collaboration with the United States Department of Agriculture's Food Safety and Inspection Service (FSIS), and in consultation with the Centers for Disease Control and Prevention (CDC). The purpose of this assessment is to systematically examine available scientific data and information in order to estimate the predicted relative risk of serious illness and death that may be associated with consumption of different types of ready-to-eat foods that may be contaminated with *Listeria monocytogenes*. This examination of current science and the models developed are among the tools that food safety regulatory agencies will use to evaluate the effectiveness of current policies, programs and regulatory practices that will minimize the public health impact of this pathogenic microorganism. This work provides a comprehensive assessment, building on and improving upon previously published assessments that related foodborne exposure to human listeriosis (Lindquist and Westöö, 2000, Buchanan *et al*., 1997; Farber *et al*., 1996; Haas *et al*., 1999; Hitchins, 1995 and 1996; and Teufel and Bendzulla, 1993).

DHHS/FDA and USDA/FSIS announced their intent to conduct a risk assessment of the public health impact of *Listeria monocytogenes* from food in the *Federal Register* (US DHHS, 1999a). At that time, the public was invited to comment on the planned assessment and submit scientific data and information for use in the assessment. The advice and recommendations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) were sought on the assumptions and the risk assessment model structure to be used (US DHHS, 1999b, 1999c). During the conduct of this risk assessment, FDA and FSIS solicited the technical advice and opinions of scientific experts in various disciplines. In addition, critical review of this risk assessment model and a draft document was solicited and received from members of the Interagency Risk Assessment Consortium and other government employees.

This risk assessment was preceded by the Draft Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* among Selected Categories of Ready-To-Eat Foods (DHHS/USDA, 2001). In January 2001, FDA and FSIS invited comments on the draft risk assessment. These comments, additional new data, and improved modeling techniques are incorporated into this revised version. A chronology of the technical and scientific review involved in the development of this *Listeria monocytogenes* risk assessment is provided in Appendix 1. A summary of the public comments submitted in response to the January 2001 draft risk assessment and our responses to these comments is provided in Appendix 2.

An international risk assessment on *Listeria monocytogenes* is concurrently being conducted by WHO/FAO for the Codex Alimantarius, Codex Committee on Food Hygiene (WHO/FAO, 2003). This FDA/FSIS risk assessment was conducted simultaneously with but independent of the WHO/FAO effort. The latter explored the dose-response relationship in more detail but determined the risks for only four representative foods. The conclusions reached in the WHO/FAO risk assessment are compatible with those reached in this FDA/FSIS risk assessment.

This risk assessment estimates the potential levels of consumer exposure to foodborne *Listeria monocytogenes* from different types of ready-to-eat (RTE) foods (including seafood, vegetables, fruit, dairy products, and meats), and characterizes the likely impact of this exposure on public health. Included is an evaluation of the impact of foodborne *Listeria monocytogenes* on the health of three age-based subpopulations, two of which are vulnerable groups that were distinguished based on FoodNet surveillance data.

- Perinatal: This subpopulation includes fetuses and neonates from 16 weeks after fertilization to 30 days postpartum. The neonatal cases are assumed to be pregnancy-associated cases where exposure occurs *in utero* as a result of foodborne *Listeria monocytogenes* infections of the mothers during pregnancy. Manifestations of listeriosis for this subpopulation group include spontaneous abortions, stillbirths, and neonatal infections.

- Elderly: This subpopulation includes individuals who are 60 or more years of age. This group is considered to have increased susceptibility to listeriosis due, in part, to physiological changes associated with the natural aging process.
- Intermediate-Age: Because there are insufficient data to separate the remaining population into discrete subpopulations, this group includes the remaining population, both healthy individuals (with very low risk of severe illness or death from *Listeria monocytogenes*) and certain susceptible subpopulations. The subpopulations include individuals with increased susceptibility to listeriosis; such as AIDS patients or individuals taking drugs that suppress the immune systems (*e. g*., cancer or transplant drugs). Individuals within these subpopulations account for most of the cases of listeriosis within the intermediate-age group.

In addition, the number of predicted cases of listeriosis for the total United States population was estimated on a per serving and per annum basis for each food category.

Background

A series of illness outbreaks associated with the consumption of coleslaw, pasteurized milk, and fresh soft cheese in the early 1980s led to the recognition of *Listeria monocytogenes* as a foodborne pathogen.

In 1991, the NACMCF presented its analysis of the emerging problem and its recommendations to FSIS, FDA and other United States government agencies (NACMCF, 1991). The NACMCF recommended control strategies to minimize the presence, survival, and multiplication of *Listeria monocytogenes* in foods. These control strategies included the development of an effective surveillance system for listeriosis, targeted efforts on specific foods, and the use of HACCP-based (Hazard Analysis and Critical Control Points) programs to ensure the safety of foods from processing to consumption.

Major efforts by industry and regulatory agencies during the early 1990s reduced the incidence of listeriosis by approximately 50%. However, further reductions in illness are increasingly difficult, in part because of the unique challenges associated with controlling this pathogen. Several barriers to its control include:

- The microorganism is commonly found in the environment, including food processing, distribution, and retail environments, in foods, and in the home.
- It primarily affects a small segment of the population that has heightened susceptibility.
- It can grow slowly in many foods during refrigerated storage.
- It is more resistant than most bacteria to the conditions and treatments used to control foodborne pathogens.

Current Policies

Based on the known characteristics of this microorganism and the disease, FDA maintains a policy of "zero-tolerance" for *Listeria monocytogenes* in ready-to-eat foods (i.e., products that may be consumed without any further cooking or reheating). This means that the detection of any *Listeria monocytogenes* in either of two 25-gram samples of a food renders the food adulterated as defined by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a)(1) (Shank *et al*., 1996). This policy was affirmed in the 1995 United States District court decision, United States v. Union Cheese Co. (Anonymous, 1995).

FSIS's "zero-tolerance" policy applies to the detection of *Listeria monocytogenes* in ready-to-eat products. If meat or poultry products are contaminated with *Listeria monocytogenes*, the products are adulterated under the provisions of the Federal Meat Inspection Act and the Poultry Inspection Act, 21 U.S.C. 601(m) or 453 (g), respectively (Anonymous, 1994).

Other countries, including some major trading partners of the United States, have different policies for dealing with *Listeria monocytogenes* contamination. Countries such as Canada and Denmark have a "non-zero tolerance" for *Listeria monocytogenes* for some classes of foods (Health Canada, 1994). For example, in Canada, ready-to-eat (RTE) foods that have not been associated with an outbreak and do not allow any growth of *Listeria monocytogenes* during a 10-day period of refrigerated storage, may contain up to 100 *Listeria monocytogenes* organisms per gram of food (Health Canada, 1994). Denmark has six classes of foods with various criteria for *Listeria monocytogenes*. In raw RTE foods, for example, two of five samples can contain between 10 and 100 organisms per gram, but no sample can exceed 100 organisms per gram.

There is no epidemiological evidence that demonstrates whether a zero or non-zero tolerance policy leads to a greater rate of listeriosis. Estimates of disease rates between different countries must be considered with caution because of different surveillance and reporting systems but the comparable overall rates of listeriosis for ranges from 0.1 to 11.3 cases per million persons per year in Europe, 3.4 to 4.4 cases per million people per year in the United States, and 3 cases per million per year in Australia (WHO/FAO, 2003).

Healthy People 2010 Initiative

The commitment of FDA, FSIS, and CDC to reduce foodborne listeriosis was formally reaffirmed as a national public health goal in the Healthy People 2010 initiative coordinated by the United States Department of Health and Human Services (US DHHS). The federal government established a goal of working with industry, public health, and research communities to achieve an additional 50% reduction in listeriosis by 2010. "Healthy People" is a national health promotion and disease prevention initiative that brings together national, state, and local government agencies; nonprofit, voluntary, and professional organizations; and businesses, communities, and individuals to improve the health of all Americans, eliminate disparities in health, and improve years and quality of healthy life (US DHHS, 2000).

Preliminary FoodNet data on the incidence of foodborne illnesses for the United States in 2001 indicated that the incidence of infection from *Listeria monocytogenes* decreased between 1996 and 2001 from 0.5 to 0.3 cases per 100,000 people per year. The level then reached a plateau. In order to reduce further the incidence to a level of 0.25 cases per 100,000 people by the end of 2005, it became evident that additional targeted measures were needed. The *Listeria monocytogenes* risk assessment was initiated as an evaluation tool in support of this goal.

Risk Assessment Overview

This risk assessment follows the risk assessment structure of the Joint Food and Agriculture Organization/World Health Organization Expert Consultation on the Application of Risk Analysis to Food Standards Issues (Joint FAO/WHO, 1995). The structure consists of four components: (1) hazard identification, (2) exposure assessment, (3) hazard characterization, and (4) risk characterization. Hazard identification is defined by the Joint FAO/WHO Consultation as the identification of known or potential health effects associated with a particular biological, chemical, or physical agent. Exposure assessment is the qualitative and/or quantitative evaluation of the degree of intake likely to occur. Hazard characterization is the qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents that may be present in food. Finally, risk characterization is the integration of hazard identification, hazard characterization, and exposure assessment into an estimation of the adverse effects likely to occur in a given subpopulation, including attendant uncertainties.

Microbiological risk assessments generally use the same conceptual framework developed for chemical risk assessments (ICMSF, 1994). However, while there are many similarities between chemical and microbial risk assessments, there are also differences. At this time, the major concern with microbiological hazards is an acute illness from a single exposure, rather than illness from a low level, chronic exposure. Even so, sequelae and other long-term effects are beginning to be recognized for some microorganisms, but knowledge is still limited in this area. In this microbial risk assessment, the infectious unit is a single microorganism. Low levels of microorganisms (rather than low concentrations of a chemical substance) characterize the frequent exposure with higher levels of exposure occurring only occasionally. While the likelihood of disease increases with increasing numbers of pathogenic microorganisms consumed, the potential for low levels of infectious agents to cause disease cannot be dismissed. Another difference between microbial and chemical hazards is that the level of a microorganism in a food can change, while chemical concentrations usually remain constant. This change in microbial levels should be accounted for in a microbial risk assessment's model. Human exposure levels to a pathogen in a food can rapidly increase by a million-fold within even a relatively short period of temperature abuse. Conversely, heating food immediately before consumption can reduce pathogen levels to a negligible risk. These biological characteristics of bacteria require the inclusion of detailed modeling steps in the exposure assessment. There is usually little question as to the hazard of microbial pathogens, although the dose-response relationships may not be easily described.

Figure I-1 shows the organization of this report including the main components of each chapter such as types of data and modeling techniques described. Additional details concerning the structure and modeling techniques used in this risk assessment are provided in Appendix 3.

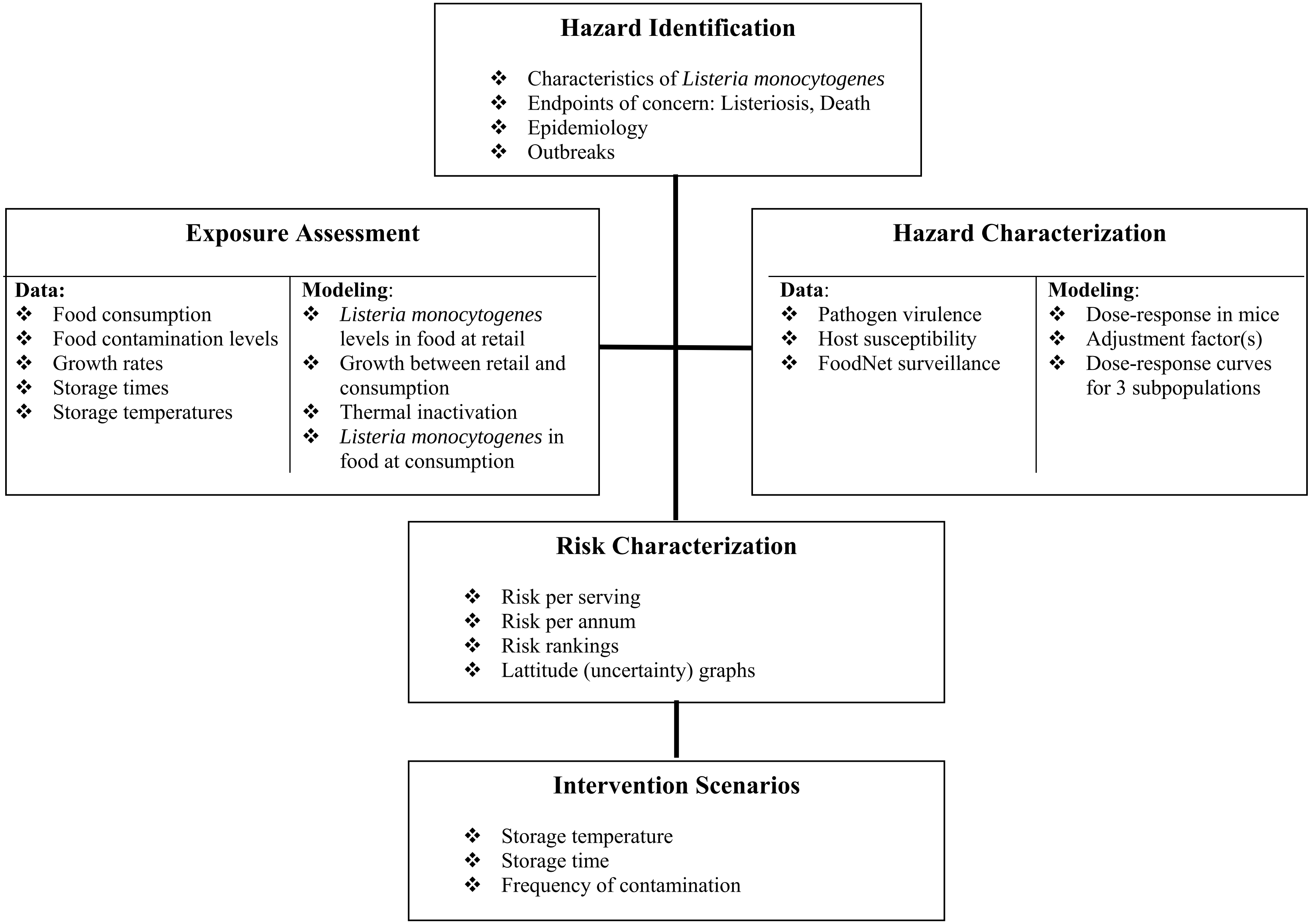


Figure I-1. Overview of *Listeria monocytogenes* Risk Assessment Document

II. HAZARD IDENTIFICATION

In the hazard identification, the known or potential health effects associated with *Listeria monocytogenes* are identified by establishing the general relationship between the pathogen, its presence in foods, and the adverse outcome (illness or death) associated with consumption of foods contaminated with *Listeria monocytogenes*. While the negative health impact of a hazard must be recognized for a risk assessment to be undertaken, the nature of the impact must be clearly defined, and specific endpoints, or health outcomes of interest, identified. Common endpoints for infectious agents are infection, disease (morbidity), death, and chronic sequelae (long-term after-effects). This risk assessment is concerned with the endpoints of serious illness and death.

Listeria monocytogenes

Listeria are short (0.5 µm in diameter by 1 to 2 µm long) gram positive, non-spore-forming rods. *Listeria monocytogenes* is one of six species are currently recognized within the genus (Rocourt, 1999). It can be isolated from numerous species of domestic and wild animals, as well as from soil, silage, and other environmental sources. *Listeria monocytogenes* can be classified into a number of subtypes using several methods. The most common is based upon recognition of antigens on the surface of the bacterium by specific antisera (Graves *et al*., 1999). Thirteen of these serotypes are associated with *Listeria monocytogenes* (1/2a, 1/2b, 1/2c, 3a, 3b, 3c, 4a, 4ab, 4b, 4c, 4d, 4e, 7). Some of these serotypes are also associated with other species of *Listeria* (1/2b, 4ab, 4c, 4d). The numbers and letters refer to specific combinations of bacterial antigens used for serotyping (Seeliger and Höhne, 1979). Serotyping is often used as a first step to type strains associated with human listeriosis, but it has relatively low discriminating power compared to molecular methods such as ribotyping or pulse field gel electrophoresis (PFGE). Ribotyping relies on separation and analysis of specific well-conserved DNA fragments and this method is often used in combination with serotyping to identify and trace a specific strain of *Listeria monocytogenes* associated with illness to a food source or to link seemingly unrelated illnesses. On the basis of ribotyping and PCR-restriction fragment length polymorphism of three virulence genes (hly, actA, and inlA), Wiedmann *et al*. (1997) separated *Listeria monocytogenes* into three lineages, which appear to have distinctive pathogenicities. Several reviews and books have summarized the ecology, characteristics, presence in foods, and public health effects of *Listeria* (Farber *et al*., 1996; Farber and Peterkin, 1991; Ryser, 1999a; Slutsker and Schuchat, 1999).

Listeriosis

Listeria monocytogenes is a well-known hazard for which there is extensive surveillance and outbreak data. Although rare when compared to many other foodborne diseases (Table II-1), listeriosis often leads to severe consequences, particularly in susceptible subpopulations. In 2000, *Listeria monocytogenes* caused higher rates of hospitalization than any other pathogen and caused over one-third of the reported deaths. Because listeriosis so often results in medical care, CDC believes that its surveillance system (FoodNet) misses only half of all cases, compared with 97% of missed cases for other pathogens (Mead *et al*., 1999). A description of the Foodborne Diseases Active Surveillance Network (FoodNet) is provided in Appendix 4. *Listeria monocytogenes* usually causes only flu-like symptoms in healthy people. For the purposes of this risk assessment, a distinction is made between non-invasive listeriosis with mild, flu-like symptoms (referred to as listerial gastroenteritis) and invasive listeriosis that is severe and sometimes life-threatening (referred to as listeriosis in the risk assessment).

Table II-1. Incidence of Foodborne Pathogens in the United States

Pathogen	Infections (Cases per 1,000,000 population[a])
Cyclospora	0.7
Vibrio	2.1
Listeria	3.4
Yersinia	4.4
E. coli 0157:H7	21
Shigella	79
Salmonella	144
Campylobacter	157
Total Pathogens	411.6

[a] FoodNet sites include CT, MN, GA, OR, and selected counties in CA, MD, NY, TN; Total population 30.5 million. FoodNet is the Foodborne Diseases Active Surveillance Network. (CDC, 2000a)

Invasive Listeriosis

Invasive listeriosis typically has a 2 to 3 week incubation time, but can sometimes extend up to three months (Gellin and Broome, 1989). Serious conditions caused by *Listeria monocytogenes* in adults can include septicema, meningitis, enceplalitis, abortion, or stillbirth (Shelef, 1989a). Invasive diseases in nonpregenant adults can include a variety of other clinical manifestations. Endocarditis can occur in patients with underlying cardiac lesions. Cutaneous infections have been reported in persons handling animals and those exposed by accidental exposure while working in laboratories. Focal infections are rare but can include endophthalmitis, septic arthritis, osteomyelitis, pleural infection and peritonitis (Slutsker and Schuchat, 1999).

Most information on the pathogenesis of *Listeria monocytogenes* comes from studies in mice or cell biology studies using tissue culture cells (Kuhn and Goebel, 1999). When ingested, *Listeria monocytogenes* penetrates the intestinal tissue and is exposed to phagocytic cells of the immune system that function to kill microbial invaders. A portion of invading *Listeria monocytogenes* can evade the killing mechanisms, survive, and multiply within host phagocytes (macrophages). Protected within, or having escaped from these host cells, *Listeria monocytogenes* moves throughout the host via blood or lymphatic circulation to various tissues. Once in a tissue it can invade cells, multiply within them, and then use cytoskeletal acting filaments to spread to adjacent cells, without risk of exposure to humoral components of the immune system. The probability of tissue invasion depends upon the number of organisms consumed, host susceptibility, and virulence of the strain (Gellin and Broome, 1989). Most cases of listeriosis occur in fetuses or neonates and individuals with a predisposing condition that impairs the immune system (Slutsker and Schuchat, 1999).

Although *Listeria monocytogenes* is generally known to cause severe illness, there have been outbreaks in which the majority of patients only developed mild symptoms such as diarrhea, fever, headache, and myalgia (Dalton *et al.*, 1997; Salamina *et al.*, 1996; Riedo *et al.*, 1994; Aureli *et al*., 2000). The frequency of these types of outbreaks is unknown because most cases of listerial gastroenteritis are not reported to public health officials. For this reason, this risk assessment is restricted to severe cases of listeriosis.

High Risk Individuals

Two high risk (susceptible) subpopulations are considered in this risk assessment: elderly and perinatal. Persons at high risk for developing listeriosis often have deficient or immature immune systems (immunocompromised). Actual numbers of susceptible individuals are difficult to determine because these individuals belong to diverse groups including the elderly, cancer and transplant patients, and persons with immunosuppressive diseases such as AIDS (Morris and Potter, 1997). In addition, the description of an immunocompromised state is often based on qualitative or circumstantial criteria that may apply to some, but not all members of a particular group.

Susceptible subpopulations are not homogeneous with regard to susceptibility, both within and between groups. High-risk subpopulations can be separated into non-perinatal and perinatal groups. A non-pregnancy related case is a person other than a pregnant woman or her child in whom *Listeria monocytogenes* organisms are cultured from a normally sterile site. Of the non-perinatal groups, the elderly constitute the largest and most well characterized subpopulation. A case-control study revealed that of 98 cases of non-perinatal sporadic listeriosis in the United States, 98% had at least one underlying medical condition. Most (69%) of these were associated with probable immunosuppression (Schuchat *et al.,* 1992). The next largest group (33%) was associated with heart disease. Many individuals fell under more than one category. In people over the age of 60, the disease is often present with sepsis or meningitis (Schuchat *et al.*, 1991; Shelef, 1989a; Linnan *et al.*, 1988; WHO Work Group, 1988).

A perinatal infection occurs primarily as the result of transplacental transmission to the fetus following infection of the mother. The perinatal group includes fetuses or neonates from whom *Listeria monocytogenes* organisms are isolated from a normally sterile body site. Perinatal infections can occur before or after birth and outcomes include live birth of an infected neonate, stillbirth, or premature termination of pregnancy. Neonates (newborns) are defined by the American Medical Association as newborn infants from birth to one month of age. In this risk assessment, neonates are considered to be between 0-30 days of age. The term fetus is used to refer to an unborn child from 16 weeks after fertilization to birth.

Women may become infected with *Listeria monocytogenes* at any time during pregnancy, but most cases of listeriosis are reported in the third trimester (Slutsker and Schuchat, 1999). Usually three to seven days after the onset of symptoms, a woman may abort the fetus or have premature delivery (Gellin and Broome, 1989). In the first trimester, listeriosis may result in spontaneous abortion. In later stages of pregnancy, the result may be stillbirth or birth of a critically ill newborn. Listeriosis is rarely life threatening to the mother and is not known to cause increased risk in subsequent pregnancies (Skidmore, 1981; Farber and Peterkin, 1991).

Neonates may present with an early-onset or late-onset form of listeriosis. Approximately 45 to 70% of newborn cases are early-onset (Slutsker and Schuchat, 1999). Early-onset listeriosis often presents with sepsis and may progress to a syndrome known as granulomatosis infantisepticum (Gellin and Broome, 1989). This syndrome is often characterized by widely disseminated granulomas, premature birth, respiratory distress, and circulatory failure. Late-onset is defined as listeriosis in a newborn between 8 to 30 days of life. Usually late-onset neonates are born apparently healthy and at full-term. Meningitis rather than sepsis is more common in late-onset neonates (Farber, 1991a). The mothers of late-onset neonates usually have an uneventful pregnancy without illness. *Listeria monocytogenes* is rarely isolated from the mother and the source of listeriosis is often not identified in late-onset cases (Farber and Peterkin, 1991; Slutsker and Schuchat, 1999).

Non-Invasive Listeriosis (Listerial Gastroenteritis)

Gastrointestinal illness (listerial gastroenteritis) from *Listeria monocytogenes* has only recently been recognized as a distinct entity (Dalton *et al*., 1997). Typical signs and symptoms associated with the mild form of *Listeria monocytogenes* infection are primarily those associated with gastrointestinal illness: chills, diarrhea, headache, abdominal pain and cramps, nausea, vomiting, fatigue, and myalgia. A variety of foods have been implicated as the vehicle of infection. Because symptoms are mild, there is a high potential for underreporting of listerial gastroenteritis. Data are currently unavailable through foodborne surveillance mechanisms such as FoodNet to capture the incidence of listerial gastroenteritis since routine stool cultures do not include evaluation for *Listeria monocytogenes*.

Nevertheless, outbreaks of listerial gastroenteritis have been identified. Table II-2 shows reported events where most of the cases reported mild symptoms (Heitmann *et al.*, 1997; Dalton *et al.*, 1997; Salamina *et al.*, 1996; Riedo *et al.*, 1994; Aureli *et al.*, 2000). In the vast majority of these cases, there was no evidence for invasive disease beyond the intestine. Gastrointestinal and other mild symptoms were reported in individuals with no known underlying predisposition. In two of these reports, there was evidence of very high levels of food contamination. These facts suggest that, in normal individuals, listerial gastroenteritis may be associated with exposure to high levels of *Listeria monocytogenes*. It is possible that this manifestation of *Listeria monocytogenes* infection is a different disease compared to invasive and more severe listeriosis. Because modeling in this risk assessment depends on case reporting and non-invasive gastroenteritis is not likely to be reported, listerial gastroenteritis was not considered in the risk assessment model. However, the outbreaks do provide important observations related to the exposure of populations to extremely high levels of the microorganisms without identifiable cases of invasive listeriosis.

Table II-2. Reports of Outbreaks of Listerial Gastroenteritis

Location	Year	Number of Cases	Vehicle	Reference
Northern Italy	1997	1566	Tuna/Corn Salad	Aureli *et al.*, 2000
Denmark	1996	3	Unknown	Heitmann *et al.*, 1997
United States	1994	45	Chocolate Milk	Dalton *et al.*, 1997
Northern Italy	1993	18	Rice Salad	Salamina *et al.*, 1996
United States	1989	10	Shrimp	Riedo *et al.*, 1994

Asymptomatic Carriage

The large intestine may be a reservoir for *Listeria monocytogenes* in humans. Estimates of fecal carriage in various populations of healthy adults range from <1% to 21%. It has been suggested that stress can undermine resistance in fecal carriers, and may trigger listeriosis in the carrier. Several studies have looked at fecal carriage to gain insight into listeriosis. However, it is unknown how fecal carriage relates to length of incubation or occurrence of invasive disease (Skidmore 1981; Slutsker and Schuchat, 1999; Mascola *et al.,* 1992; and Schuchat *et al.,* 1991).

Approximately 1 to 5% of normal asymptomatic carriers shed *Listeria monocytogenes* bacteria in the feces (Hof, 2001). *Listeria monocytogenes* was isolated from 2 of 100 colon biopsy specimens from patients with colon cancer; however, neither patient exhibited signs of listeriosis (Hof, 2001).

In a retrospective study of the outbreak in 1985 that was linked to Hispanic-style fresh soft cheese, outbreak-related listeriosis patients and matched controls were asked to participate in a study of stool carriage of *Listeria monocytogenes* (Mascola *et al*., 1992). Fecal carriage incidence was also determined for employees of the cheese plant and their household contacts. Stool specimens from 8% of those tested were positive for *Listeria monocytogenes*. The highest rate of recovery of the organism from stool samples was from employees of the cheese plant and their household contacts. It was found that the occurrence of listerial gastroenteritis or listeriosis was not associated with fecal carriage of *Listeria monocytogenes,* and was actually more common for persons with negative stool samples.

Between January 1990 and December 1991, as part of a multistate active surveillance project on sporadic listeriosis, a study was conducted to evaluate the fecal carriage of *Listeria monocytogenes* among household contacts of patients with invasive listeriosis (Schuchat *et al*., 1993). The authors determined that the rates of carriage did not vary significantly by sex but were significantly higher in younger persons. The organism was isolated from 32% of those <30 years of age, compared to 7% from older persons. Nearly 20% of household contacts of patients with sporadic listeriosis had asymptomatic carriage of the strain associated with illness. The authors suggested that carriage of *Listeria monocytogenes* is more common in persons that have been in contact with listeriosis patients and that it was difficult to compare the fecal carriage rate in this study group to the population at large.

Epidemiological Patterns of Listeriosis: Sporadic versus Outbreak-Associated Cases

The Centers for Disease Control and Prevention (CDC) has estimated that approximately 2,500 cases of listeriosis occur annually in the United States (Mead *et al*., 1999). The overall annual incidence of listeriosis in the United States has been estimated to range from 3.4 per million (CDC, 2000) to 4.4 per million (Tappero *et al*., 1995). The incidence of listeriosis reported from other countries vary substantially, for example 3.5 per million persons in Bristol, England; 1.8 per million persons in England, Wales and Northern Ireland; and 6 to 7 per million persons in Denmark (Slutsker and Schuchat, 1999).

Most cases of human listeriosis occur sporadically although much of what is known about the epidemiology of the disease has been derived from outbreak-associated cases. However, it is unclear what percentage of sporadic cases may actually represent unrecognized, temporally or geographically diffuse outbreaks. Case-control studies are often used to elucidate risk factors for both outbreak-associated and sporadic cases. Investigations of outbreaks have provided much of our knowledge of the etiology of this disease organism, particularly in relation to isolation of *Listeria monocytogenes* from both the case patient and the implicated food. Investigation of sporadic cases of listeriosis often does not lead to this direct product isolate-human isolate link. Therefore, studies of sporadic cases are more likely to identify a food group, such as soft cheese, as a risk factor rather than a specific brand of soft cheese, the latter to be more likely in an outbreak investigation. Also, outbreaks of listeriosis are often associated with a processing or production failure (Slutsker and Schuchat, 1999) whereas this has been less evident among sporadic cases (Barnes *et al*., 1989).

Sporadic Listeriosis

In 1988, a microwave reheated turkey frank, consumed by an immunocompromised woman, was among the first microbiological food isolates from an RTE product associated with sporadic clinical listeriosis in the United States. Food isolates of *Listeria monocytogenes*, of the same serotype with the same electrophoretic enzyme type as the clinical isolate, were identified from both opened and unopened turkey franks from the same manufacturer (Barnes *et al*., 1989).

Likely dietary risk factors for sporadic cases of listeriosis have been identified through two case-control studies conducted by the CDC. Case-patients were identified through active surveillance conducted by CDC, and controls were selected and matched on age, geographic location, socioeconomic status, and underlying health conditions. The first case-control study of sporadic cases of listeriosis enrolled 82 patients and 239 controls from 1986 to 1987. Non-reheated frankfurters and undercooked chicken were found to have an attributable risk of 15% and 6%, respectively. These were the only foods that were statistically significantly associated with sporadic cases of listeriosis. In the subsequent and larger case-control study conducted by CDC from 1988 to 1990, 165 patients and 376 controls were enrolled in the study of sporadic listeriosis cases. This study also included a microbial assessment of patient-consumed foods.

Case-patients were significantly more likely to have consumed foods bought at a deli or to have eaten soft cheeses (Schuchat, *et al.*, 1992). Food samples were collected from 123 (75%) of patients' refrigerators and assayed for presence of *Listeria monocytogenes*. The organism was isolated from at least 1 food item in 64% of refrigerators. *Listeria monocytogenes* was found in 7.6% of ready-to-eat samples including processed meats, leftovers, cheeses, and raw vegetables. These ready-to-eat food items, as well as other food samples containing the 4b serovar of the organism, were significantly more likely to be associated with disease (Pinner *et al*., 1992). The contamination rates, by type of food are presented in Table II-3.

The FoodNet Listeria Case-Control Study was initiated in 2000 and will be completed in 2003 (Varma, 2003). The goal of the case-control study is to further characterize established risk factors and identify other potential risk factors for *Listeria* infection. Nine FoodNet sites have enrolled cases and controls and interviewed subjects with a standardized questionnaire that explores more than 400 different dietary, behavioral, and environmental risk factors.

Table II-3. Isolation of *Listeria Monocytogenes* In Food Specimens Collected from the Refrigerators of Patients with Listeriosis

	Number of Samples	
Type of Food	**Positive samples**	**Total tested**
Beef	50	140
Poultry	33	108
Pork	26	95
Deli Meats	18	98
Seafood	7	57
Vegetables	72	683
Fruit	5	155
Dairy	9	533
Other[b]	6	144
Total	226	2,013

[a]Source: Pinner *et al*., 1992.
[b]Included bread, pasta, eggs, lamb, and miscellaneous mixtures of food.

Outbreak-Associated Listeriosis

Reported outbreak-associated listeriosis cases represent a small proportion of the annual number of listeriosis cases estimated to occur in the United States (Mead *et al*., 1999). However, data collected during outbreak investigations provide important information about both the vehicle of transmission and the mechanism by which the food contamination occurred. Published and unpublished outbreak investigation reports for the period 1970 through 2000 were reviewed. Seventeen (32.7%) of the outbreaks occurred in the United States, with the remaining 37 outbreaks occurring outside the United States. Of the 17 domestic outbreaks, one or more contaminated food vehicles were identified in 13 (76.5%) outbreaks; in the remaining four outbreaks the source of the outbreak was not identified. In two (13.3%) outbreaks, the majority of cases were classified as having listerial gastroenteritis. Of the 37 international outbreaks, one or more vehicles were identified in 22 (59.5%) outbreaks. In all but one of the outbreaks in which no vehicle was identified, the events occurred prior to 1988. In four (10.8%) outbreaks, the majority of cases were classified as having listerial gastroenteritis.

Outbreaks in the United States. A total of 466 cases of listeriosis occurred during 12 severe listeriosis outbreaks in the United States between 1970 and 2002 (Table II-4). The mean number of cases per outbreak was 39 (median, 24.5; range 2 to 142 cases). Only two outbreaks had more than 100 associated cases, and these occurred over an extended time period. Eleven of the outbreaks involved RTE products and an outbreak of two cases involved raw eggs. Mexican-style soft cheese was the identified vehicle for the largest reported outbreak of 142 cases of which 93 (65.5%) were perinatal cases. A total of 48 perinatal and non-perinatal deaths (37.5%) were attributed to this outbreak. The second largest outbreak of 101 cases (with 21 deaths) involved two products, frankfurters and deli meats, both of which were produced by the same manufacturing establishment. During the course of the outbreak, the plant was noted to have widespread environmental disruption (with major construction being done), a known risk factor for post-kill-step recontamination of RTE products (Mead, 1999).

Among the eight outbreaks for which mortality data were available, there were 121 deaths among 466 cases (26 %) and ranged within the outbreaks from 11.1 to 44.4 %. A total of 130 (36.9%) of 352 cases occurred in a fetus or neonate (perinatal listeriosis), in nine outbreaks for which perinatal infection data were available. The serotype was reported for eight outbreaks, of which serotype 4b was responsible for seven (87.5%) outbreaks (Table II-4).

A total of four food categories were implicated in the 12 outbreaks of listeriosis listed in Table II-4. Nine outbreaks were associated with only one type of food vehicle each. A dairy product was implicated in four outbreaks, meat was implicated in three, and one outbreak each was attributed to eggs and vegetables. The specific food vehicles included pasteurized milk, Mexican-style cheese, butter, eggs (raw), deli turkey meat, pâté, and vegetables. Considering only those outbreaks in which a single vehicle was identified, the numbers of cases by food vehicle were dairy, 309 (63.75%); meat, 103 (33.3%); vegetables, 7 (2.3%); and eggs, 2 (0.6%). More than one vehicle was implicated in three outbreaks involving a total of 157 cases. The largest outbreak involved RTE meats produced in the same processing establishment.

Table II-4. Outbreaks of Listeriosis in the United States (1970-2002) with Known Food Vehicle(s)

Year	Food Vehicle	State	Cases	Perinatal cases (% of total)	Deaths (% of total)	Serotype	Reference
1979	Raw vegetables or cheese	MA	20	0 (0)	3 (15.0)	4b	Ho, 1986
1983	Pasteurized fluid milk	MA	32	7 (21.9)	14 (43.8)	4b	Fleming, 1985
1985	Mexican-style cheese (raw milk)	CA	142	93 (65.5)	48 (33.8)	4b	Linnan, 1988
1986-1987	Ice cream, salami, brie cheese	PA	36	4 (11.1)	16 (44.4)	4b,1/2b, 1/2a	Schwartz, et al., 1989
1986-1987	Raw eggs	CA	2	Unknown	Unknown	4b	Schwartz, et al., 1988
1987	Butter	CA	11	Unknown	Unknown	Unknown	Ryser, 1999a
Not specified	Frozen vegetables	TX	7	3 (42.9)	Unknown	4b	Simpson, 1996
1998-1999	Hot dogs, deli meats	22 states	101	Unknown	21 (20.8)	4b	Mead, 1999
1999	Pâté	CT, MD, NY	11	2 (18.2)	unknown	1/2a	Carter, 2000
2000	Deli turkey meat	10 states	29	8 (27.6)	7 (24.1)	unknown	CDC, 2000b
2000-2001	Homemade Mexican-style cheese (raw milk)	NC	12	10 (83.3)	5 (41.7)	unknown	CDC, 2001
2002	Deli turkey meat, sliceable	8 North Eastern states	63	3 (4.8)	7 (11.1)	unknown	CDC, 2002b
Total			466				

Outbreaks outside the United States. A total of 1,058 listeriosis cases occurred during 18 listeriosis outbreaks outside the United States between 1970 and 2000 (Table II-5). The mean number of cases per outbreak was 59 (median, 24; range 4-355 cases). All of the reported outbreaks outside the United States in which a vehicle was identified occurred in so-called “developed” countries. Five (27.8%) outbreaks occurred in France, five (27.8%) in Oceania (Australia and New Zealand), two (11.1%) in England, and one (5.6%) each in Austria, Canada, Denmark, Finland, Sweden, and Switzerland.

Information on the number of deaths was available for 18 outbreaks. A total of 257 (24.3%) of 1,058 persons who were ill died. The number of hospitalized cases was available for five outbreaks; 91 (42.9%) of 212 cases were hospitalized. Thirteen reports contained information about the number of perinatal cases; 477 (49.1%) of 972 cases were perinatal. The serotype was reported for 15 outbreaks, of which, 9 (60.0%) were caused by serotype 4b (Table II-5).

A single food vehicle was identified in 17 outbreaks involving 1,030 cases. Dairy products were implicated in six (35.3%) outbreaks, meat products in five (29.4%) outbreaks, seafood products in four (23.5%) outbreaks, and vegetables in two (11.8%) outbreaks. The specific food items included cheese (four outbreaks), two outbreaks each for pâté, pork tongue, and smoked mussels, one outbreak each for cold-smoked trout, pasteurized cream, butter, rillettes (a RTE product made of ham cooked with fat), raw fish, cabbage, and raw vegetables. Considering only those outbreaks in which a single food vehicle was identified, the number of cases by food group were: meat, 710 (68.9%); dairy, 228 (22.1%); vegetables, 53 (5.1%); and fish, 39 (3.8%). In one outbreak in Austria in 1978, multiple food vehicles were identified during the epidemiologic investigation (unpasteurized milk, vegetables).

Examples of using outbreak information in developing dose-response curves is presented in Appendix 9 using the 1985 Mexican-style cheese outbreak and Finish butter outbreak.

Table II-5. Outbreaks of Listeriosis Outside the United States (1970-2000) with Known Food Vehicle

Year	Food Vehicle	Country	Cases	Perinatal cases (% of total)	Deaths (% of total)	Serotype	Reference
1978-1979	Vegetables (raw)	Australia	12	Unknown	0 (0)	Unknown	Le Souëf and Walters, 1981
1980	Raw seafood (finfish and mollusks)	New Zealand	22	22 (100.0)	6 (27.3)	1b	Lennon *et al.*, 1984
1981	Miscellaneous Dairy Products	England	11	Unknown	5 (45.5)	1/2a	Ryser, 1999a
1981	Vegetables (raw)	Canada	41	34 (82.9)	17 (41.5)	4b	Schlech, *et al.*, 1983
1983 - 1987	Vacherin Mont d'Or cheese	Switzer-land	122	65 (53.3)	31 (25.4)	4b	Bille, 1990; Bula *et al.*, 1995
1986	Unpasteurized milk, organic vegetables	Austria	28	24 (85.7)	5 (17.9)	Unknown	Allerberger and Guggenbichler 1989
1987-1989	Pâté and meat spreads	England	355	185 (52.1)	94 (26.5)	4b	McLaughlin *et al.,* 1991
1989 - 1990	Semi-soft Cheese (blue)	Denmark	23	Unknown	0 (0)	4b	Jensen, 1994
1990	Pâté and meat spreads	Australia	11	11 (100.0)	6 (54.5)	1/2a	Ryser, 1999a
1991	Smoked mussels	Tasmania, Australia	4	0 (0)	0 (0)	1/2a	Mitchell, 1991; Misrachi *et al.*, 1991
1992	Smoked mussels	New Zealand	4	0 (0)	0 (0)	1/2	Brett, *et al.*, 1998
1992	Pork tongue in jelly	France	280	93 (33.2)	63 (22.5)	4b	Jacquet *et al.*, 1995
1993	Rillettes	France	38	31 (81.6)	11 (28.9)	4b	Goulet, 1998
1994-1995	Smoked Seafood (finfish and mollusks)	Sweden	9	3 (33.3)	2 (22.2)	4b	Ericsson *et al.*, 1997
1995	Soft Ripened Cheese, >50% moisture (brie, camembert, feta, mozzarella)	France	33	9 (45.0)	4 (20.0)	4b	Goulet *et al.*, 1995; Jacquet *et al.*, 1995
1997	Pon l'Eveque cheese	France	14	Unknown	0 (0)	4b	Ryser, 1999a
1998-1999	Butter	Finland	25	0 (0)	6 (0)	3a	Lyytikainen *et al.*, 2000
1999-2000	Pigs tongue in aspic	France	26	Unknown	7 (0)	Unknown	Dorozynski, 2000
Total			1058				

<u>All outbreaks combined.</u> Data from outbreaks from within and outside the United States were collectively summed by number of outbreaks and number of cases and each food group was ranked accordingly (Table II-6). When ranked by number of associated outbreaks, dairy

products ranked highest, followed by meat products, then seafood and finally, produce. When number of outbreak-associated cases are ranked, meat products were first and dairy products were second. Contaminated meat and dairy products were responsible for more than 90% of cases. In addition, dairy and meat products were implicated in three other outbreaks with multiple food vehicles. Serotype 4b was found in 16 (72.7%) of 22 outbreaks; 1/2a was found in four (18.0%) outbreaks (Tables II-4 and II-5).

Table II-6. A Comparative Ranking of Types of Food Vehicles by Outbreaks and Cases with Combined United States and International Outbreak Data

Type of Food Vehicle	Ranking Order by the Number of Outbreaks or Cases	
	Outbreaks	Cases
Dairy	1	2
Meat	2	1
Seafood	4	4
Produce	3	3

Dairy and RTE meat products were most often implicated in domestic and international outbreaks. The most commonly implicated dairy product was soft (fresh and mold-ripened) cheese. A variety of meat products have been involved in listeriosis outbreaks including all RTE meats, such as frankfurters, deli meat, pâté and pork tongue. These findings are similar to those from case-control studies of sporadic listeriosis, in which un-reheated frankfurters, undercooked chicken, soft cheeses and foods purchased at a deli counter were associated with listeriosis (Schwartz *et al*., 1988; Schuchat *et al*., 1992). "Foods purchased at a deli counter" as a food group is not specific, but a subset of case-patients identified RTE meats as the only item they had purchased at a deli counter prior to becoming ill with listeriosis. The results of this case-control study were corroborated by Pinner *et al.* (1992), who found that the foods most likely to cause listeriosis were RTE foods, foods with a high concentration of *Listeria monocytogenes*, and foods from which serotype 4b was isolated. In this analysis of outbreaks, serotype 4b was found in almost 70% of the outbreaks.

The proportion of fatal cases was similar for domestic (26%) and foreign (24%) outbreaks and agreed with other sources (Slutsker and Schuchat, 1999). A somewhat lower fatality rate has been reported (i.e., 20%) when sporadic outbreak cases were considered (Mead *et al*., 1999).

The proportion of outbreak associated perinatal (prenatal and neonatal) cases was approximately similar (40 to 50%) between outbreaks in the United States and outside the United States. In many reports, information about the number of perinatal cases and hospitalized cases was incomplete; therefore, the proportion of perinatal cases and hospitalized cases reported are probably underestimated. For international outbreaks 42.9% of cases were reportedly hospitalized. This proportion substantially underestimates the findings reported by Mead *et al*. (1999), in which 92.2% of persons with culture confirmed listeriosis required hospitalization.

The epidemiology of listeriosis outbreaks occurring within the United States appears to be similar to outbreaks occurring outside the United States. Outbreaks appear to have disproportionately higher frequency of serotype 4b. The reported median number of cases per outbreak are 24.5 and 24, respectively; however, the means are not similar. The proportion of fatal cases (26% and 24.3%), and the food groups implicated in causing outbreaks are also similar. Therefore, it appears valid to generalize the results from international (developed countries) listeriosis outbreaks to the United States.

Outbreaks due to dairy products were most often the result of raw milk being present in a product such as soft (fresh and mold-ripened) cheese, or from post-pasteurization contamination. Dairy products were incriminated in nine outbreaks, including five due to contaminated soft (fresh and mold-ripened) cheese. Post-processing contamination of butter was blamed for an outbreak in Finland (Lyytikainen *et al*., 2000). A 1983 outbreak in Massachusetts was epidemiologically linked to pasteurized milk, suggesting that *Listeria monocytogenes* can survive the pasteurization process (Fleming *et al*., 1985); however, Ryser (1999c) has raised doubts about this conclusion, citing studies that have shown *Listeria monocytogenes* is unlikely to survive pasteurization. Schuchat and colleagues (1992) proposed that contamination of the implicated milk have occurred post-pasteurization. The source of contamination implicated in this outbreak has been frequently debated without a definitive conclusion. A Danish case-control study found unpasteurized milk to be a risk factor for sporadic listeriosis (Jensen *et al*., 1994). Additional foods associated with sporadic cases of listeriosis are discussed in earlier in this chapter in the section titled 'Sporadic Listeriosis.'

III. EXPOSURE ASSESSMENT

Exposure is a function of the quantity of a food consumed and the level of contamination in that food. While the contamination level in food at consumption is the important parameter in evaluating public health, most of the available contamination data pertain to foods sampled at retail stores. Hence, it was necessary to develop estimates of the frequency and amount of each serving of the contaminated foods likely to be consumed in the United States, as well as the *Listeria monocytogenes* levels in those foods. Limitations inherent in food consumption data and the paucity of contamination data for certain foods made certain assumptions necessary to develop the estimates. These limitations and assumptions are discussed later in this chapter.

The goal of this risk assessment was to provide information needed to focus risk management strategies among a variety of foods that could be potentially contaminated with *Listeria monocytogenes*, the purpose of the exposure assessment is to estimate the contamination and consumption of foods that have a potential for *Listeria monocytogenes* contamination. Therefore, this risk assessment modeled growth of *Listeria monocytogenes* in foods during post-retail storage and reduction of levels during home cooking or reheating of frankfurters. Growth was also modeled for some contamination data that were collected pre-retail to account for possible growth between manufacture and retail.

Foods that were included in the risk assessment were identified through a comprehensive review of the recall, microbiological and epidemiological literature. Each food was placed in one of 23 food categories. Using distributions of contamination and consumption data, estimates of exposure to *Listeria monocytogenes* in the various foods were derived. The components of the exposure assessment are provided in Figure III-1, and specific modeling details are provided in Appendix 3.

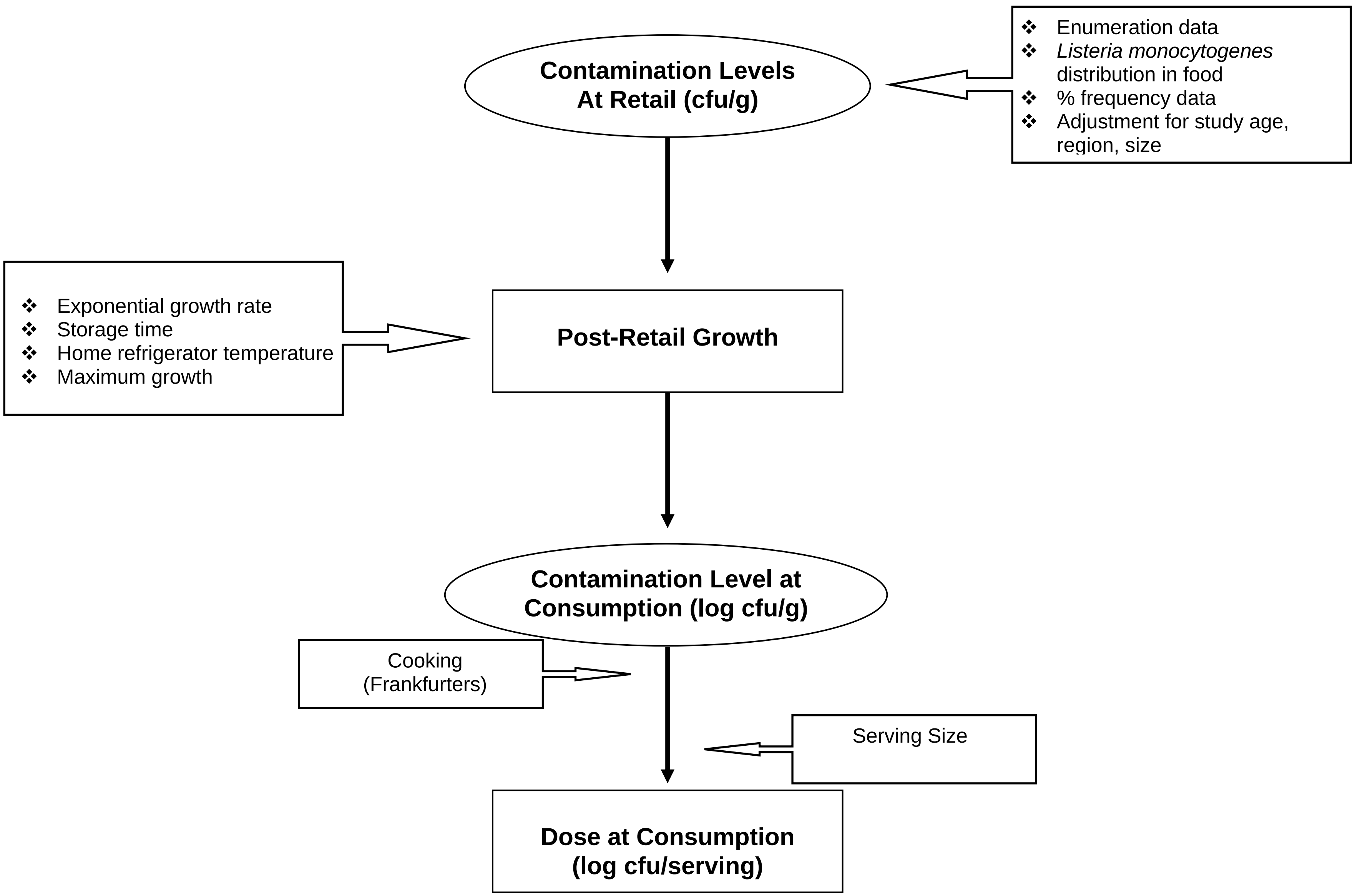


Figure III-1. Components of the Exposure Assessment Model

Food Category Identification

The first step in the exposure assessment was to consider appropriate foods to include in the risk assessment model. As the risk assessment progressed, foods and food categories were continually reevaluated and modifications were made based on new information, such as the results of growth models or new microbiological or epidemiological literature. Foods that have a significant potential for *Listeria monocytogenes* contamination were identified. They represent a subset of foods that comprise an individual's total diet. Foods that have not been linked to *Listeria monocytogenes* contamination were not included, for example, grain products (*e. g.,* bread, cookies, cakes), soft drinks, canned fruits, and cooked mixed dishes (*e. g.,* lasagna, soups). Furthermore, foods that have limited association with *Listeria monocytogenes* contamination (*e. g.,* cream-filled pastries) were not included because neither contamination level data nor appropriate data to serve as a substitute were available. It was also presumed that some foods that are cooked just prior to consumption (*e. g*., most meats and seafoods) present a very low likelihood of containing *Listeria monocytogenes* when consumed and were not included in this risk assessment. Eggs are an example of a food category that was not included in the risk assessment, but could be a vehicle for listeriosis. Although eggs have been implicated in one outbreak with two cases (Schwartz *et al*., 1988), *Listeria monocytogenes* has not been isolated from intact eggs and eggs products are typically cooked before consumption (Ryser and Marth, 1999).

A review of the literature was conducted to identify foods that have a significant potential for *Listeria monocytogenes* contamination. The review concentrated on the following:

- Outbreaks
- Sporadic cases, i.e. individual cases not reported as part of a documented outbreak
- Recalls and regulatory actions
- Literature related to prevalence and incidence of *Listeria monocytogenes* through analytical testing in North America (the United States and Canada)
- Literature on outbreaks, sporadic cases, and prevalence and incidence studies of *Listeria monocytogenes* in other countries

The next step in selecting foods for the risk assessment was a review of the available data on contamination and the ability of the food to support growth of *Listeria monocytogenes*. Food contamination data were compared with the available food consumption data to create food categories.

Foods that are ready-to-eat (RTE) were ultimately selected. Some RTE foods are raw and others receive some processing prior to sale. Still other RTE foods are fully cooked before sale but may be subjected to subsequent handling and storage, thereby increasing the possibility of recontamination.

The identified foods were further sorted into categories based upon food characteristics, use, and the potential for growth of *Listeria monocytogenes*. For example, Dry/Semi-dry Fermented Sausages were differentiated from other deli meats such as bologna, sliced turkey, and ham. The Cooked RTE Crustaceans food category contains peel-and-eat shrimp, steamed and boiled shrimp, and steamed crabs – foods that may be refrigerated and eaten chilled or allowed to cool after cooking, thus allowing for re-contamination and growth. The Vegetable food category includes many raw vegetables, as well as mixed vegetables such as bagged salads (without salad dressings). Similarly, the Fruits food category includes many raw and dried fruits and mixed fruits such as fruit salads (without salad dressings). In this updated risk assessment, the vegetable and fruit salads with salad dressings are included in the Deli-type Salad food category. While there is a single Deli-type Salad food category for reporting purposes, to model growth of *Listeria monocytogenes*, salads were segregated into growth and non-growth salads and considered the use of preservatives in salads made in bulk for distribution to retail stores.

In this updated risk assessment, the cheese categories have been reorganized into six categories based on moisture content. Another update to the categories included splitting the Miscellaneous Dairy Products into two categories. The Cultured Milk Products category includes the low pH dairy foods manufactured with lactic acid fermentation. Of this category, yogurt is the most frequently consumed food, followed by sour cream and buttermilk. The High Fat and Other Dairy Products category includes the remainder of the dairy products that generally support growth (including powdered products when reconstituted). Butter, cream and half and half are the most prominent foods in this category, but shakes and chocolate milk made with cocoa or syrup are also included. The frankfurter category has been divided into reheated and not reheated frankfurters to distinguish the impact that reheating before consumption can have on the predicted risk. The number of unreheated frankfurters was represented by a triangular distribution with a minimum of 4%, most likely of 7%, and maximum of 10% of the total frankfurters consumed without reheating. These values were based on surveys conducted by USDA and American Meat Institute.

Table III-1 lists the 23 food categories that were used in this risk assessment. The food categories fall into five general groups: Seafood, Produce, Dairy, Meat, and Combination Foods. (See Appendix 5 for a detailed listing of the foods included in each food category.)

Table III-1. Food Categories Used in this Listeria monocytogenes Risk Assessment

SEAFOOD
Smoked Seafood (i.e., finfish and mollusks)
Raw Seafood (i.e., finfish and mollusks)
Preserved Fish (i.e., dried, pickled, and marinated finfish)
Cooked Ready-to-Eat Crustaceans (i.e., shrimp and crab)
PRODUCE
Vegetables (raw)
Fruits (raw and dried)
DAIRY
Fresh Soft Cheese (i.e., Queso Fresco, Queso de Creama, and Queso de Puna)
Soft Unripened Cheese, >50% moisture (i.e., cottage cheese, cream cheese, and ricotta)
Soft Ripened Cheese, >50% moisture (i.e., brie, camembert, feta, and mozzarella)
Semi-soft Cheese, 39-50% moisture (i.e., blue, brick, monterey, and muenster)
Hard Cheese, <39% moisture (i.e., cheddar, colby, and parmesan)
Processed Cheese (i.e., cheese foods, spreads, and slices)
Pasteurized Fluid Milk
Unpasteurized Fluid Milk
Ice Cream and Frozen Dairy Products
Cultured Milk Products (i.e., yogurt, sour cream and buttermilk)
High Fat and Other Dairy Products (i.e., butter, cream, other miscellaneous dairy products)
MEAT
Frankfurters (reheated)
Frankfurters (not reheated)
Dry/Semi-dry Fermented Sausages
Deli Meats (cooked, ready-to-eat)
Pâté and Meat Spreads
COMBINATION FOODS
Deli-type Salads (i.e., fruit, vegetable, meat, pasta, egg, or seafood salads with dressing)

Food Consumption Data

Data from two large-scale, nationwide food consumption surveys were used to provide estimates of exposure to *Listeria monocytogenes* via distributions of food consumption. The first survey is the Continuing Survey of Food Intakes by Individuals (CSFII 1994-96). This is the latest survey of consumers of all ages conducted by USDA's Agricultural Research Service (USDA/ARS, 1998a, 1998b). The survey consists of the following:

- Two 24-hour recalls of foods eaten during two nonconsecutive days (with the interview for the second day conducted 3 to 10 days after the interview for the first day, but not on the same day of the week).
- Sample weights for weighting the data so that they will more closely reflect consumption by the non-institutionalized United States population.
- A sample of 16,103 respondents, including:

Pregnant and/or lactating women	(n = 123)
Children under 4 years	(n = 2,284)
People 60 years and older	(n = 2,315)

- Over sampling of low income, young children, and the elderly (USDA ARS, 1998a).
- A Population Parameter of 261,897,280, appropriate for 1994-1996.

The second nationwide survey of food consumption is the Third National Health and Nutrition Examination Survey (NHANES III), which was conducted in 1988 to 1994 (US DHHS, 1998). NHANES was conducted by the National Center for Health Statistics in the Center for Disease Control and Prevention (CDC/NCHS), DHHS. The survey consists of the following:

- One 24-hour recall of foods eaten.
- Sample weights for weighting the data so that they will more closely reflect consumption by the non-institutionalized United States population.
- A sample of 30,818 respondents, including:

Pregnant and/or lactating women	(n = 399)
Children under 4 years	(n = 3,979)
People 60 years and older	(n = 3,919)

- Over sampling of young children, older persons, black persons, and Mexican Americans.
- A United States Population Parameter of 251,097,003, appropriate for 1988-1994.

Consumption data from the CSFII 94-96 survey were used for 21 of the 23 food categories. CSFII data were used preferentially because they are newer and account for up to two days of eating per respondent. Data for unpasteurized fluid milk and unreheated frankfurters were modeled based on CSFII data for pasteurized milk and all frankfurters consumed. NHANES III data were used for two food categories (Raw Seafood and Preserved Fish) for which there are fewer than 30 eating occasions (servings) in the CSFII survey.

The surveys contain consumption data for many foods and each food has an associated food code. Over 640 food codes for RTE foods were matched to one of the 23 food categories. The following information was extracted from the databases for each food category:

- Weighted descriptives (*e. g.,* mean amount eaten in grams, median amount eaten in grams, number of servings) that characterize all eating occasions in two nonconsecutive days of eating (one day for NHANES III).
- Distributions of the amount of food (in grams) eaten in all servings over two days (one day for NHANES III).
- Distributions of the amount of food (in grams) eaten in all servings, expressed as weighted percentiles.
- Weighted descriptives to describe the amount of the food (in grams) eaten per person per day, as well as the number of eaters.
- Per capita estimates of food eaten.

Several limitations of the food consumption surveys had an impact on their use for risk assessment purposes. For some foods, it was a challenge to determine consumption. Surveys listed some particular foods under several food codes, such as ham consumed alone or ham in a ham sandwich. The proportion of a particular food (such as ham) in a mixed ingredient product (such as a ham sandwich) was determined using a generic recipe provided by the survey. The gram amount of the food (ham) consumed was then calculated and added to the intake derived from other food codes for the specific food (ham). For this risk assessment, sandwiches were broken down into individual ingredients. Specifically, for frankfurters, dry semi/dry fermented sausages, deli meats, pâté and meat spreads, and deli salads, the actual consumption of meat or deli salad product consumed alone, as well as the proportion used in sandwiches, was used. In the case of vegetable and fruit salads (in which fruits and vegetables were the major component) and deli-type salads (not included in a sandwich), however, the entire salad was used, rather than the component ingredients.

The consumption surveys do not collect information from consumers to determine whether the milk they drank was pasteurized or unpasteurized (raw). Although federal law requires milk in interstate commerce to be pasteurized, some states allow unpasteurized milk to be sold and consumed within the state. Results of a 1995 FDA/CDC survey of all 50 states, Puerto Rico, and the District of Columbia, showed that 28 states (54%) permit the sale of unpasteurized fluid milk. However, it is estimated that unpasteurized milk accounts for less than 1% of the total volume of milk sold in these states (Headrick *et al.*, 1998). Because consumption surveys did not list "drinking occasions" (servings) of unpasteurized fluid milk, the consumption of this food category was modeled by estimating it as 0.5% of the amount consumed per serving of pasteurized milk (54% x 1%). The consumption surveys did not provide any information on the storage and heating of frankfurters. Estimates for the fraction of frankfurters stored frozen before consumption and those eaten without reheating were obtained from other surveys.

Another limitation of food consumption surveys used is that some food categories have a small number of servings. Estimates based upon small sample sizes may be less statistically reliable than estimates based on larger sample sizes (USDA/ARS, 1998a). Although weighted food consumption data provide a better representation of the United States population, weighting small samples does not provide better reliability. In addition, the surveys do not provide corrections to account for underreporting and over reporting of the amount of a food eaten by consumers.

The food consumption surveys did not collect demographic information delineating consumers who are immunocompromised. Furthermore, the surveys did not measure consumption by the elderly who are living in nursing homes or other forms of assisted living outside of the home, nor did they contain a large enough sample of pregnant women to generalize consumption to all pregnant women. Thus, the available consumption data did not allow the determination of comprehensive estimates of food consumption for each individual susceptible subpopulation. Consumption between the subpopulations was compared. Specifically, nonparametric statistical analyses were conducted to determine if there were significant differences between the distributions of the amount eaten in each serving (expressed as weighted percentiles) for the elderly and the intermediate-age population. Seventeen food categories had sufficient consumption data to permit these analyses. There were no statistically significant differences in consumption patterns for 14 of the examined 17 food categories. Thus, for the purpose of estimating the distribution of serving sizes, the food consumption data representing all eaters were used.

Note: Starting in 2002, CFSII and the dietary component of NHANES were merged into NHANES. The integrated survey will provide two 24-hour recalls of food consumption for 5,000 individuals a year and characterize "What We Eat in America."

Annual Number of Servings of Foods

In order to estimate the number of servings of the foods in each food category eaten in a year, some key data assumptions were necessary. First, it was assumed that the weighted number of servings for one (NHANES III) or two days (CSFII) of consumption of the foods in a specific food category could be extrapolated to the number of servings of those foods eaten by the population on an annual basis. Second, it was assumed that the weighted number of eaters of a food per day would represent the number of eaters of the food over 365 days. Obviously, there are some foods that individuals are more likely to eat each day (*e. g.,* vegetables, milk) and others that they eat frequently (*e. g*., fruits, deli meats) or occasionally (*e. g*., frankfurters, cottage cheese). Some foods are seasonal and are not available year round (*e. g*., some fruits and vegetables), and people may not be likely to purchase more costly items (*e. g*., shrimp, crabmeat) for regular consumption. Thus, it is important to note that when estimating the consumption of foods on an annual basis, all foods reported in food consumption surveys during a one- or two-day period are not likely to be eaten in the same frequency by the same people over an entire year. To estimate the number of annual servings for each food category, we divided the weighted number of serving consumed in two days by 2 (one-day basis) and then multiplied that value by 365 (annual basis). Table III-2 provides the annual number of servings of food consumed in the United States for each of the 23 food categories.

The annual number of servings associated with the pregnancy exposures resulting in neonatal deaths were estimated using the number of servings in the intermediate-aged group multiplied by the birth rate (1.74%) and a fractional exposure period. A triangular distribution with a minimum of 1 day, a most likely value of 7 days, and a maximum value of 30 days was used to represent the uncertainty in the exposure period. In order to estimate the number of servings in the neonatal group, the annual number of servings in the intermediate-age group was multiplied by the exposure period (triangle distribution) and divided by 365 days to estimate the number of per annum servings consumed by pregnant women. Because the perinatal exposure period is longer than neonatal (the total number of deaths includes prenatal, i.e., stillbirth, cases occurring in the last trimester), perinatal per serving death rates from listeriosis were estimated using an exposure period of 90 days (3/12 yr = 0.25) and a pregnancy rate (2.77%) rather than birth rate.

Serving Size Distributions

Empirical distributions were used to describe the serving sizes (grams of food eaten per serving) in the 23 food categories. These distributions are expressed as a series of population percentiles of the amount of food eaten per serving, weighted to reflect the consumption survey demographics. There were no uncertainties presented for these food categories because empirical distributions were used. The uncertainties associated with the serving size distributions would be relatively small, compared to other uncertainty distributions in this risk assessment for three reasons. First, even the smallest data sets used to characterize the serving size distributions are large relative to other parts of the *Listeria monocytogenes* risk model. Second, although the data may not be completely representative of the current behavior of the United States population, the data come from surveys that were explicitly designed for that purpose. Third, the variability (range) in serving sizes covers a smaller range (two logs) than many other parts of the model.

Table III-3 shows the 50th (median), 75th, 95th and 99th percentiles of the weighted distributions of serving size. For example, these percentiles for Smoked Seafood are 57, 75, 136 and 142 g/serving, respectively. This distribution indicates that half of the servings were less than 57 g and 95% of the servings were less than 136 g.

Table III-2. Estimates of the Total Number of Annual Servings of Foods Consumed in the United States by Population and Food Category

Food Category[a]	Intermediate-Age Population	Perinatal Population[b]	Elderly Population	Total Population[c]
SEAFOOD				
Smoked Seafood	1.6×10^{8}	1.1×10^{6}	4.1×10^{7}	2.0×10^{8}
Raw Seafood	1.8×10^{8}	1.3×10^{6}	5.7×10^{5}	1.8×10^{8}
Preserved Fish	8.3×10^{7}	5.7×10^{5}	2.2×10^{7}	1.1×10^{8}
Cooked Ready-to-Eat Crustaceans	4.7×10^{8}	3.3×10^{6}	8.1×10^{7}	5.5×10^{8}
PRODUCE				
Vegetables	6.8×10^{10}	4.7×10^{8}	1.7×10^{10}	8.5×10^{10}
Fruits	3.7×10^{10}	2.5×10^{8}	1.2×10^{10}	4.9×10^{10}
DAIRY				
Fresh Soft Cheese	6.9×10^{7}	4.8×10^{5}	1.3×10^{6}	7.1×10^{7}
Soft Unripened Cheese	3.4×10^{9}	2.3×10^{7}	1.0×10^{9}	4.4×10^{9}
Soft Ripened Cheese	1.7×10^{9}	1.2×10^{7}	1.8×10^{8}	1.9×10^{9}
Semi-soft Cheese	1.6×10^{9}	1.1×10^{7}	1.5×10^{8}	1.8×10^{9}
Hard Cheese	7.8×10^{9}	5.4×10^{7}	1.3×10^{9}	9.0×10^{9}
Processed Cheese	1.1×10^{10}	7.6×10^{7}	1.6×10^{9}	1.2×10^{10}
Pasteurized Fluid Milk[d]	7.2×10^{10}	5.0×10^{8}	1.5×10^{10}	8.7×10^{10}
Unpasteurized Fluid Milk[d]	3.6×10^{8}	2.5×10^{6}	7.5×10^{7}	4.4×10^{8}
Ice Cream and Frozen Dairy Products	1.2×10^{10}	8.2×10^{7}	3.1×10^{9}	1.5×10^{10}
Cultured Milk Products	6.1×10^{9}	4.2×10^{7}	1.2×10^{9}	7.2×10^{9}
High Fat and Other Dairy Products	1.6×10^{10}	1.1×10^{8}	4.3×10^{9}	2.1×10^{10}
MEAT				
Frankfurters, reheated[e]	5.5×10^{9}	3.8×10^{7}	5.8×10^{8}	6.1×10^{9}
Frankfurters, not reheated[e]	4.2×10^{8}	2.9×10^{6}	4.4×10^{7}	4.7×10^{8}
Dry/Semi-dry Fermented Sausages	1.5×10^{9}	1.1×10^{7}	2.5×10^{8}	1.8×10^{9}
Deli Meats	1.8×10^{10}	1.2×10^{8}	2.8×10^{9}	2.1×10^{10}
Pâté and Meat Spreads	9.7×10^{7}	6.7×10^{5}	2.1×10^{7}	1.2×10^{8}
COMBINATION FOODS				
Deli-type Salads	1.0×10^{10}	7.0×10^{7}	3.1×10^{9}	1.3×10^{10}

[a] Serving size data based on CSFII 94-96 extrapolated from two days of eating to an annual basis, except data for Raw Seafood and Preserved Fish from NHANES III were extrapolated from one day of eating. Servings denote variable amounts consumed and not a standard serving size that represents the amount customarily consumed per eating occasion.

[b] For the purposes of estimating rates of listeriosis per serving, the values for the perinatal group were calculated by adjusting the number of annual servings for the intermediate-aged group for the annual pregnancy rate: The annual pregnancy rate (2.77%) was multiplied by the number of servings for the intermediate-aged population and 0.25 (0.25 = 3/12, to estimate the number of pregnant women in the last 3 months of pregnancy).

[c] The annual number of servings for the total population was calculated by summing the values for the elderly and intermediate-aged populations. The perinatal group was not included because the servings for this population are a subset of the intermediate-aged group.

[d] Consumption of Pasteurized Fluid Milk is based on 99.5% of total milk consumption and consumption of Unpasteurized Fluid Milk is based on 0.5% of total fluid milk consumption.

[e] Consumption of not reheated frankfurters is a distribution based on an uncertainty range of 4 to 10% of the consumption of frankfurters. The value in the table is the mean of the distribution. The value for reheated frankfurters is the difference between the total frankfurters consumption and the value for not reheated frankfurters.

Table III-3. Percentiles of Serving Size Distributions for Each Food Category

Food Categories	Weighted Percentiles (grams per serving)[a]			
	50th	75th	95th	
Seafood				
Smoked Seafood	57	75	136	142
Raw Seafood	16	28	77	136
Preserved Fish	70	125	130	250
Cooked Ready-to-Eat Crustaceans	50	96	256	345
Produce				
Vegetables	28	55	123	220
Fruits	118	138	272	570
Dairy				
Fresh Soft Cheese	31	85	246	246
Soft Unripened Cheese	29	105	226	420
Soft Ripened Cheese	28	48	85	168
Semi-soft cheese	28	57	142	227
Hard Cheese	28	38	85	122
Processed Cheese	21	42	84	130
Pasteurized Fluid Milk	244	245	488	732
Unpasteurized Fluid Milk	244	245	488	732
Ice Cream and Frozen Dairy Products	132	186	330	454
Cultured Milk Products	114	227	245	490
High Fat and Other Dairy Products	13	30	312	510
Meats				
Frankfurters (reheated and not reheated)	57	114	171	285
Dry/Semi-dry Fermented Sausages	46	69	161	161
Deli Meats	56	75	113	196
Pâté and Meat Spreads	57	85	128	454
COMBINATION FOODS				
Deli-type Salads	97	177	301	464

[a] There are no uncertainties presented for these food categories because empirical distributions were used.
Note: Serving size denotes variable amount consumed and are not a standard serving size that represents the amount customarily consumed per eating occasion.

Food Contamination Data

Over the last fifteen years, numerous studies have been published that report on foods contaminated with *Listeria monocytogenes* in a variety of countries and locations. Contamination data included in this risk assessment were reported from the United States and other countries on six continents. Most of the studies were from the industrialized countries of North America and Western Europe. Many studies did not identify the sampling of imported foods or indicate whether imports were excluded from the study. Contaminant serotype information was not considered because the food contamination studies did not usually identify the serotypes.

Data sources included the published scientific literature, published and unpublished official government documents, and data obtained from the private sector. All data and references are available in the docket established for this risk assessment. Two types of data describing the levels of *Listeria monocytogenes* contamination in food were identified.

- Presence/absence (qualitative) data (i.e., the number of positive samples relative to the total sample collection).
- Enumeration (quantitative) data (i.e., the number of colony forming units (cfu) of *Listeria monocytogenes* that were measured from a sample). It is conventionally assumed that one cfu is equivalent to one organism.

Both qualitative and quantitative studies were used in the assessment (Table III-4; Appendix 7). Data from presence/absence studies (qualitative data) were converted to numerical data and included in the model by assigning the lowest possible contamination level that can be detected by the laboratory method. For a method that uses a 25-g sample, the lowest detectable level is 0.04 cfu/g of food. Consequently, the qualitative data could be used along with the quantitative data in the construction of the cumulative distribution curves of *Listeria monocytogenes* levels in food.

Because each food category usually includes many related types of foods, data were collected to represent all the foods in a designated food category. For example, the deli meats include, in part, ham, bologna, and sliced chicken. These deli meats have diverse microbial characteristics and there are relatively few existing studies for each of these foods. Hence, all data available on these products were used with the assumption that the summation of the collected data represented the diverse compositional, geographic, seasonal, home vs. away-from-home, relative frequency of consumption, and other factors that affect the exposure from *Listeria monocytogenes* in these foods. Where methodologies or designations varied among multiple data sources, the original data were often regrouped or recalculated (particularly for the growth modeling work).

Table III-4. *Listeria monocytogenes* Contamination: Numbers of Qualitative and Quantitative Studies and Samples

Food Category	Number of Studies[a]				Number of Samples[b]	Percent of Positive Samples[c]
	Total	United States	Total Quant-itative	United States Quant-itative		
SEAFOOD						
Smoked Seafood	30	6	10	2	7,855	12.9
Raw Seafood	46	11	4	1	15,650	7.0
Preserved Fish	18	1	5	0	1,495	9.8
Cooked Ready-to-Eat Crustaceans	11	4	3	2	4,004	2.8
PRODUCE						
Vegetables	32	5	8	1	9,223	3.6
Fruits	4	2	0	0	254	11.8
DAIRY						
Fresh Soft Cheese	8	3	1	1	4,866	1.4
Soft Unripened Cheese	8	2	3	0	814	3.9
Soft Ripened Cheese	17	3	5	1	3,109	3.8
Semi-soft Cheese	11	3	3	1	2,615	3.1
Hard Cheese	12	2	2	0	973	1.4
Processed Cheese	4	1	1	0	325	0.9
Pasteurized Fluid Milk	30	3	3	1	12,407	0.4
Unpasteurized Fluid Milk	45	10	3	0	19,080	4.1
Ice Cream and Frozen Dairy Products	22	5	2	0	170,787	0.2
Cultured Milk Products	6	1	1	0	490	0.8
High Fat and Other Dairy Products	12	4	2	0	18,169	1.3
MEAT						
Frankfurters	9	6	2	2	3,763	4.8
Dry/Semi-dry Fermented Sausages	14	3	3	0	3,357	6.4
Deli Meats	19	4	3	1	33,824	1.9
Pâté and Meat Spreads	12	3	7	0	5,665	6.5
COMBINATION FOODS						
Deli-type Salads	16	6	5	1	17,915	3.8

[a] See Appendix 5 for the reference citation for each study. [b] Total number of samples equals qualitative plus quantitative samples for each category. [c] The percent of positive samples was calculated using the total positive samples in a food category. The value in the table is an unweighted percentage (i.e., does not reflect the weighting done to represent study reliability for predicting current *Listeria monocytogenes* levels in the United States).

Pairing consumption data with the appropriate contamination data was often imperfect. Dietary intake data were highly specific as to the type of food consumed (*e. g.*, smoked mussels). In contrast, the contamination data reported in the literature were often more generic (*e. g.*, samples may only be described as shellfish).

The analytical methods used in the food contamination studies to determine the presence of *Listeria monocytogenes* were generally well known and were approximately equal in sensitivity at about 1 cfu per 25 g sample (0.04 cfu/g). However, for enumeration methods of analysis, the sample size was usually less than 25 g and was not as sensitive (typically 20 to 50 cfu/g). Typically, the samples obtained for analysis were from non-composited samples of food. An exception, however, was unpasteurized fluid milk obtained from bulk tanks.

Contamination levels at consumption were modeled with the assumption that contamination distributions for a given food in the United States do not vary significantly from those in other countries, especially Western Europe and other developed countries. Similarly, it was assumed that all foods within a category have a similar pattern of contamination. Furthermore, all *Listeria monocytogenes* food isolates were accepted as having the potential to cause human illness. No differences in ability to grow or other characteristics between food and clinical isolates were assumed. As will be discussed later, the impact of these assumptions was considered in the uncertainty associated with relative risk determinations.

The available data on *Listeria monocytogenes* levels had some limitations that affected the distributions for levels of *Listeria monocytogenes* in foods. First, there are relatively few data points above the limit of detection (0.04 cfu/g). This is because the occurrence of detectable levels of *Listeria monocytogenes* in food is rare and because most surveys of the occurrence of *Listeria monocytogenes* in food did not quantify the levels in positive samples. Second, some of the data are not from the United States and this data may not always be representative of food and processing procedures in the United States. To create an estimate of the current United States distribution, the data sets were weighted by the number of samples in the data set, likelihood of the food in that country to be imported to the United States food supply, and the recency of the data. Third, there was a wide degree of variation between studies in the occurrence of high levels of *Listeria monocytogenes*. The extent to which this variation reflects true variation in a particular food, is not known.

Many of the studies found in the published literature were conducted in the late 1980s and early 1990s. The extent that improved sanitation and other control measures implemented by the food industry have reduced the frequency and level of contamination since 1993 (when the earlier research was conducted) is difficult to determine from published literature. It was felt that some allowance should be made for the age of data and therefore, all data were used but the more recent data were given greater weight (details below). Because some food categories had little data, which would result in a biased estimate, the overall trend in contamination for all the food categories from before 1993 to after 1998 was obtained and applied to these data sets.

The length of time a food was held at retail before it was obtained for microbial sampling was not recorded in the survey studies. It was therefore necessary to assume that foods were sampled without bias and would represent the entire range of post-production and pre-sale conditions for that food.

Growth Data

Growth of *Listeria monocytogenes* in food is a function of the storage time, storage condition, and rate of growth in specific foods. The storage times were multiplied by the rate of growth to provide an estimate of the amount of *Listeria monocytogenes* growth occurring between retail purchase of the food and its consumption. The model includes consideration of the interaction of storage time and temperature and maximum growth that specific foods support.

Storage time

Some foods are consumed on the day of purchase whereas others remain in the home refrigerator for lengthy periods of time. This is a major source of variability in the estimate of growth and ultimately, in the numbers of *Listeria monocytogenes* consumed. Except for frankfurters and deli meats, no data were found on the storage of foods in the home; therefore, storage time, including variation and uncertainty, were estimated based on the expert judgment of the risk assessment team in consideration of recommendations developed by the Food Marketing

Institute (2002) and other individuals familiar with the production and use of the various foods. It is recognized that foods may be kept beyond the recommended storage times. This risk assessment modeled estimated consumer food practices, not necessarily the recommended practices. The values were developed by consensus of the risk assessment team and vetted by government subject matter experts and other scientific reviewers including those who submitted comments following the release of the draft risk assessment. The minimum, most likely and maximum storage times used to develop the distribution of storage times for the food categories are presented in Table III-5. These are skewed distributions with relatively few servings at the maximum storage time. For Smoked Seafood, as an example, over 90% of the servings are stored for less than 13 days.

Table III-5. Variation in Post-Retail Storage Times Assigned to the Food Categories

Food Categories	Storage time (days)[a]		
	Minimum	Most Likely	Maximum
SEAFOOD			
Smoked Seafood	0.5	3 to 5	15 to 30
Raw Seafood	0.5	1 to 2	10 to 20
Preserved Fish		[Not Applicable][b]	
Cooked Ready-to-Eat Crustaceans	0.5	1 to 2	10 to 20
PRODUCE			
Vegetables	0.5	3 to 4	8 to 12
Fruits	0.5	3 to 4	8 to 12
DAIRY			
Fresh Soft Cheese	0.5	1 to 5	15 to 30
Soft Unripened Cheese	0.5	6 to 10	15 to 45
Soft Ripened Cheese	0.5	6 to 10	15 to 45
Semi-Soft Cheese	0.5	6 to 10	15 to 45
Hard Cheese	0.5	6 to 10	90 to 180
Processed Cheese	0.5	6 to 10	45 to 90
Pasteurized Fluid Milk	0.5	3 to 5	10 to 15
Unpasteurized Fluid Milk	0.5	2 to 3	7 to 10
Ice Cream and Frozen Dairy Products		[Not Applicable][b]	
Cultured Milk Products	0.5	6 to 10	15 to 45
High Fat and Other Dairy Products	0.5	6 to 10	15 to 45
MEATS			
Frankfurters		[Not applicable][c]	
Dry/Semi-Dry Fermented Sausages	0.5	6 to 10	45 to 90
Deli Meats		[Not applicable][c]	
Pâté and Meat Spreads	0.5	6 to 10	15 to 45
COMBINATION FOODS			
Deli-type Salads	0.5	3 to 4	8 to 12

[a]For the food categories a BertPert distribution with these minimum, most likely and maximum parameters were used.
[b] Not applicable because this is a food category that does not support growth.
[c] Emperical data was used (see Table III-6).

Estimating duration of post-retail storage for Frankfurters and Deli Meats

Preliminary data from a study being conducted for FSIS by Georgetown University (Wachsmuth, 2000) provided information for frankfurters and deli meats used in the draft risk assessment. For frankfurters, 3 of 73 respondents gave 21 days storage and 3 gave 30 days as the maximum time. For deli meats, 2 of 81 respondents gave 21 days of storage, and 2 gave 30 days as the maximum time. FSIS also questioned people who called in to their telephone Meat and Poultry Hot Line about their frankfurter storage and cooking or reheating practices. Of 136 callers, one had kept frankfurters 90 days and one for 180 days (Wachsmuth, 2000).

In response to the need for more comprehensive information on consumer practices for frankfurters and deli meats, the American Meat Institute (AMI) commissioned a consumer survey that asked how long, on average, deli meats and frankfurters were stored before consumption (American Meat Institute, 2001). The responses are shown in Table III-6. These data were used to model storage times for frankfurters and deli meats as described in section "Modeling: Growth Between Retail and Consumption."

Table III-6. Refrigerated Storage Times for Frankfurters and Deli Meats in the Home

Average Storage Time	Distribution (Fraction) of Responders[a]	
	Pre-packaged deli meats and frankfurters	Custom sliced deli meats
1 to 3 days	0.32	0.39
4 to 7 days	0.37	0.36
8 to 10 days	0.06	0.03
11 to 14 days	0.04	0.01
15 to 21 days	0.01	0
22 to 30 days	0.01	0
31 to 60 days	0.01	0
61 days or more	0	0
Always freeze	0.03	0.01
Don't eat	0.13	0.17
Don't know/refused	0.02	0.02

[a]Source: American Meat Institute, 2001

Refrigeration Storage temperature

Data for home refrigerator temperatures were obtained from a 1999 survey conducted by Audits International (Audits International, 1999). Nine hundred thirty nine refrigerators in the United

States were included in the survey. Approximately 26% of the refrigerators exceeded 41°F (5°C) and 1.4% exceeded 50°F (10°C) (Table III-7). The refrigeration temperatures were modeled with a discrete distribution where temperature values were randomly sampled from the data provided by Audits International.

Table III-7. Frequency Distribution of Home Refrigerator Temperatures

Refrigerator Temperature (°F)	Frequency (%)
< 32	9
33 - 35	10
36 - 38	25
39 - 41	29
42 - 44	18
45 - 47	5
48 - 50	3
51 - 53	0.4
54 - 56	0.5
57 - 59	0.4
60 - 63	0.1

Total number of refrigerators in survey = 939 (Audits International, 1999)

Growth Rate

A summary of the growth rate data is presented in Table III-8 and a complete list of the literature data can be found in Appendix 8. Significant differences in composition and processes are present within many of the food categories. Within the Smoked Seafood food category, for example, there were hot and cold smoked fish, various salt levels, both aerobic and vacuum packaging, and different fish species. The modeling process used a cumulative table of the actual data points, not the means and standard deviations presented in Table III-8.

Table III-8. Mean Exponential *Listeria monocytogenes* Growth Rates and Total Number of Samples From Growth Rate Studies for Each Food Category

Food Categories	Growth Rate at 5 °C		Number of Samples[b]
	Mean ($\log_{10}$ cfu/g per day)[a]	Standard Deviation	
SEAFOOD			
Smoked Seafood	0.150	0.096	27
Raw Seafood	0.152	0.126	5
Preserved Fish		**No Growth**	
Cooked Ready-to-Eat Crustaceans	0.384	0.110	3
PRODUCE			
Vegetables	0.072	0.114	26
Fruits	0.046	0.047	5
DAIRY			
Fresh Soft Cheese	0.082	0.138	10
Soft Unripened Cheese	0.090	0.286	29
Soft Ripened Cheese	- 0.013[a]	0.133	17
Semi-soft cheese	- 0.043[a]	0.032	10
Hard Cheese	- 0.053[a]	0.065	11
Processed Cheese	- 0.045[a]	0.055	6
Pasteurized Fluid Milk[c]	0.257[c]	0.105	11
Unpasteurized Fluid Milk[c]	0.257[c]	0.105	11
Ice Cream and Frozen Dairy Products		**No Growth**	
Cultured Milk Products	- 0.168[a]	0.142	5
High Fat and Other Dairy Products	0.114	0.118	6
MEATS			
Frankfurters	0.131	0.051	5
Dry/Semi-dry Fermented Sausage	- 0.016[a]	0.016	4
Deli Meats	0.282	0.196	23
Pâté and Meat Spreads	0.252	0.154	2
COMBINATION FOODS			
Deli-type Salads (growth)	0.122	0.030	2
Deli-type Salads (non-growth)	-0.143	0.134	19

[a]Negative values indicate a decline in population for the mean growth rate.
[b] See Appendix 8 for more details about the studies.
[c]Pasteurized and unpasteurized milk were combined for analysis of exponential growth rate of fluid milk.

Modeling: *Listeria monocytogenes* Levels in Food at Retail

The majority of the data collected on the contamination of foods only determined whether or not a sample, typically 25 g, contains *Listeria monocytogenes*. Compared to the amount of qualitative data on the presence or absence of *Listeria monocytogenes* in foods, there is relatively little recent quantitative data available. This is due to the additional laboratory effort necessary to enumerate samples, the low frequency of detecting positive samples, the need to test a large number of samples, and regulatory requirements that do not require enumerative data. Therefore, the approach taken was to develop a generic contamination model to describe the distribution of *Listeria monocytogenes* in food.

A three-step process was used to model levels of *Listeria monocytogenes* in food at retail.

- Step 1: Characterize the distribution of *Listeria monocytogenes* across food categories using the contamination data reported in selected quantitative data sets (i.e., create a generic distribution).
- Step 2: Characterize the uncertainty distribution for the frequency of detectable contamination for each food category using prevalence data adjusted to account for study size, age, and country of origin.
- Step 3: Integrate the quantitative data from generic distributions (step 1) with the adjusted prevalence data, specific for each food category (step 2).

The general approach was to assume that the contaminated samples are detectable contaminations arising from a continuous log normal distribution of contamination. The minimum detectable level from presence/absence tests is typically 1 organism in 25 g or 0.04 organisms per gram. A low percentage of samples has contamination at or above this level and the remainder has non-detectable levels (i.e., <0.04 organisms/g). There may be no detectable *Listeria monocytogenes* in a specific sample (a 25.0 g package), but if 1000 packages from that lot are analyzed *Listeria monocytogenes* might be found. The average contamination could be one organism in 1000 packages (or a level of 0.00004 organisms per gram), far below the detectable level of 0.04 organisms/g. Therefore, what is observable with the presence/absence and quantitative tests is only the upper tail of the distribution. As shown in Figure III-2, the model fits a curve to the log cfu/g data and the mean and standard deviation are calculated. This curve represents a food category with approximately 10% of the samples positive for *Listeria monocytogenes*. It also shows that 3.1% of the samples have more than 100 cfu/g.

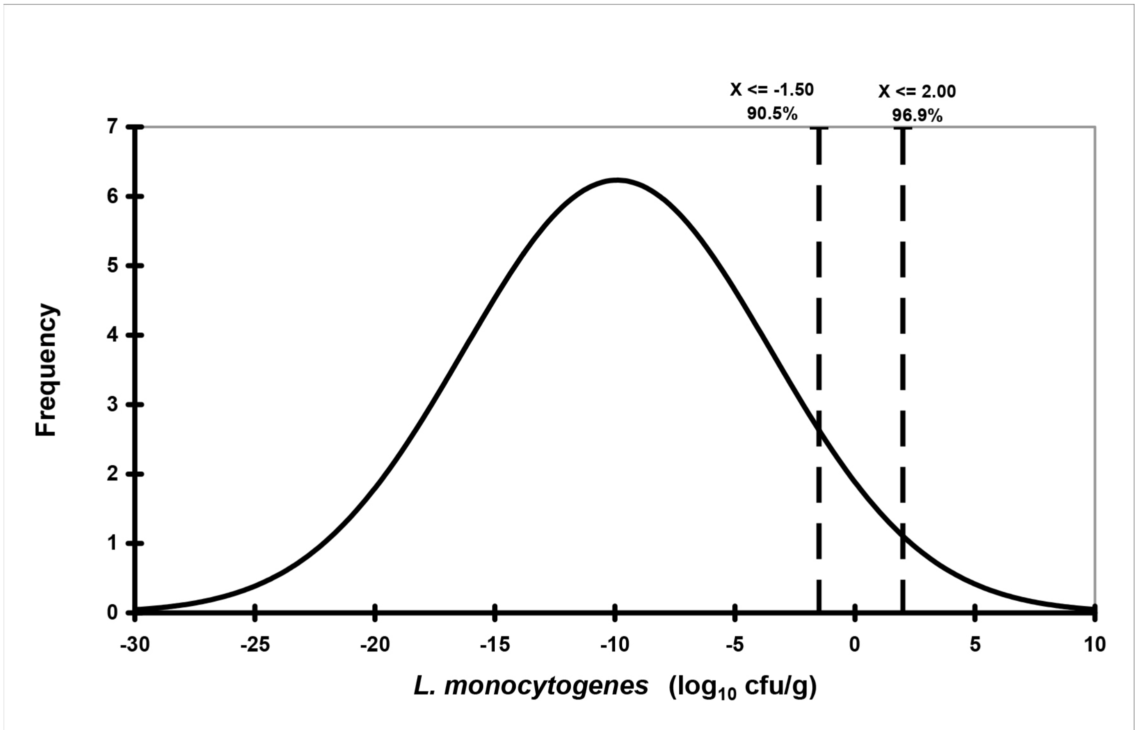


Figure III-2. Example of the Contamination Curve for a Typical Food Category Showing Frequencies of Detectable and Nondetectable Samples

Studies with enumerated samples were selected and fitted to a normal distribution. The standard deviations from each of these studies were used to estimate the uncertainty in the distribution. The presence/absence data for each food category were then used to create a frequency distribution of contamination at the 0.04 cfu/g level. A normal curve with the appropriate standard deviation was then fit to the presence/absence data by "sliding" the mean until the percentage of positive samples corresponded to the presence/absence data. A normal curve for the log cfu/g was chosen because studies enumerating spoilage flora that are at sufficiently high levels to observe the curve showed that this distribution was appropriate (Kilsby and Pugh, 1981; Gill *et al*., 1996).

Step 1: Characterize the distribution of *Listeria monocytogenes* across food categories

Seventeen studies were selected for quantitative analysis (Table III-9). All of these studies had at least ten samples with enumerated values. The levels of *Listeria monocytogenes* in the samples were transformed to log scale and the data for each study were fit using a normal distribution (Figure III-3). The mean level of *Listeria monocytogenes* (log cfu/g) and the standard deviation of the contamination data sets were calculated. This process was repeated for the 17 studies with adequate enumeration data.

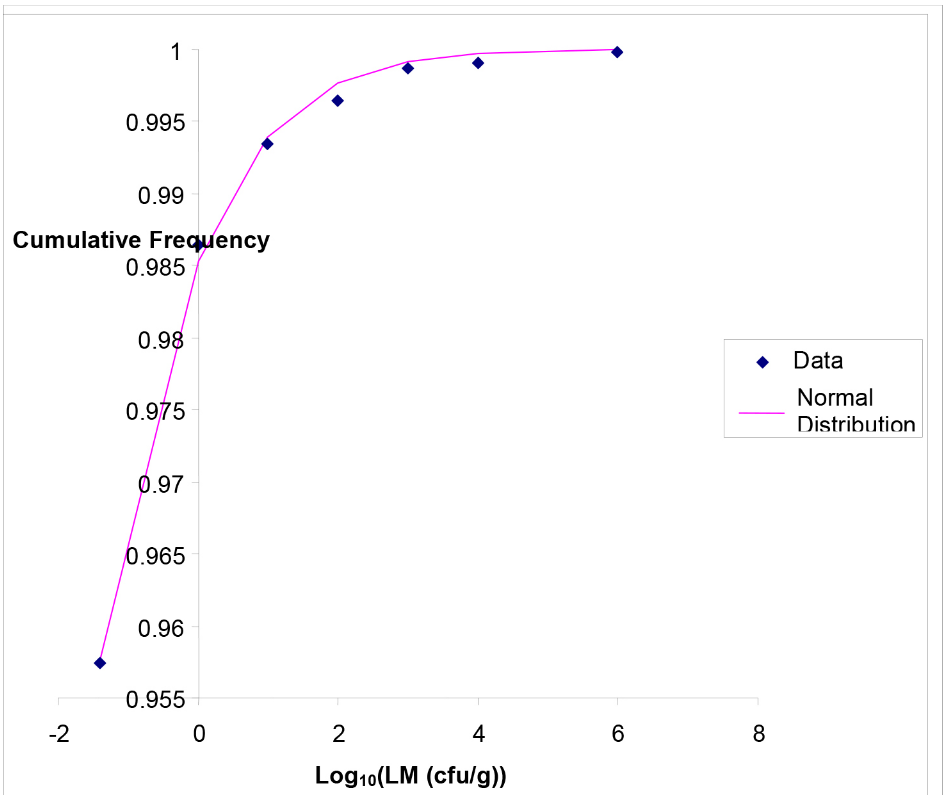


Figure III-3. A Lognormal Distribution for *Listeria monocytogenes* in Smoked Seafood

The standard deviations and mean levels of *Listeria monocytogenes* (log cfu/g) are summarized in Table III-9**.** The standard deviations of the distribution for each study ranged from 1.1 to 10.7 although most were less than 5.0.

Table III-9. Selected Studies Used to Characterize the Distribution of *Listeria monocytogenes* in Food at Retail

Study Reference[a]	Food Category	Number of Samples		Calculated Mean Level LM[a] (log cfu/g)	Estimated Standard Deviation[b]
		Total Tested	Total Positive		
Rawles, 1995	Cooked RTE Crustaceans	126	10	-9.9	6.4
NFPA, 2002	Deli Meat (CA)	4600	28	-12.2	4.3
NFPA, 2002	Deli Meat (MD)	4599	54	-7.7	2.8
WNYJWG, 1991	Deli-type Salad	149	21	-12.5	10.7
NFPA, 2002	Deli-type Salad (CA)	5504	126	-4.2	1.4
NFPA, 2002	Deli-type Salad (MD)	5606	191	-4.3	1.6
Hayes, *et al*., 1992	Frankfurter	40	12	-1.9	1.1
Morris and Ribeiro, 1991	Pâté	73	37	-1.2	4.0
Morris and Ribeiro, 1992	Pâté	216	75	-2.9	3.9
Jørgensen and Huss, 1998	Preserved Fish	91	23	-4.6	5.3
NFPA, 2002	Semi-soft Cheese	1623	23	-5.6	1.9
Cortesi, *et al*., 1997	Smoked Seafood	165	32	-4.4	3.5
Jørgensen and Huss, 1998	Smoked Seafood	420	163	-2.1	2.8
Dominguez *et al*., 2001	Smoked Seafood	170	38	-4.8	4.6
NFPA, 2002	Smoked Seafood	2687	114	-6.7	3.1
Loncarevic *et al*., 1995	Soft Ripened Cheese	31	13	-2.0	3.9
NFPA, 2002	Vegetables	2963	22	-8.9	3.1

[a]NFPA = National Food Processors Association; WNYJWG = West and North Yorkshire Joint Working Group; LM = *Listeria monocytogenes.*
[b]Standard Deviation of the log data.

These standard deviations were used to characterize the variation and uncertainty of the distribution of *Listeria monocytogenes* concentration in the food categories. The ranges of standard deviations used are given in Table III-10. A default range of 2 to 5 standard deviations was used for all food categories unless additional information was available to refine the uncertainty. Refined standard deviation ranges were used for four food categories (smoked seafood, pâté and meat spreads, deli meats, and deli-type salads) based on information as described in Table III-10. For example, the range of standard deviations assigned to Smoked

Seafood is narrower than the default range based on consideration of the standard deviations from four enumeration studies for this food category.

Table III-10. Standard Deviation Ranges for Each Food Category

Food Category	Standard	Comment
Default	2 to 5	This range was used as a default for all food categories (except Smoked Seafood, Pâté and Meat Spreads, Deli Meats, and Deli-type Salads) for which there was little or no empirical basis for estimating a distribution.
Smoked Seafood	2.8 to 4.6	This range encompasses the range for the four enumeration studies of smoked seafood samples.
Pâté and Meat Spreads	3.8 to 4.8	The standard deviation values for these products fit in a relatively narrow range and were generally higher than for other food categories.
Deli Meats	3.8 to 4.8	The standard deviation values for these meat products fit in a relatively narrow range and were generally higher than for other food categories
Deli-type Salads	1.5 to 2.5	The standard deviations for Deli Salads from the 2002 NFPA study were low (1.4; 1.6) in samples collected from both California and Maryland. A much higher value (10.7) was indicated by West Yorkshire study conducted 20 years ago in the U.K. Since the latter study is probably less representative of the current United States food supply, it was acknowledged by slightly raising the maximum range indicated by the NFPA study.

<u>Step 2: Characterize the Uncertainty Distribution</u>

The set of presence/absence studies for each food category was used to generate a discrete uncertainty distribution (a histogram) for the frequency of detectable contamination. First, the presence/absence data were used to generate a single estimate of the fraction of positive samples (i.e., a rate-concentration estimate) for each study. The concentration level was equal to the detection limit of the analysis (typically 0.04 cfu/g; based on 1 organism per 25 g sample). Next, the individual studies were adjusted (weighted) to account for sample size, geographic region of food origin, and date of collection. In addition, some data sets were obtained by sampling at the manufacturer instead of at retail. These data sets were adjusted to allow for growth between manufacture and retail. With this adjustment the data collected at manufacture would then have the same percentage of positive samples but they were assigned higher cfu/g values.

Adjust for sample size, geographic location, and study date

The relevance of a particular contamination data set to represent current United States retail foods for the purposes of this risk assessment was a difficult judgment. If abundant, quantitative, recent and United States data were available, only this data would be used in the risk assessment. However, for most food categories these data were not available. Therefore, all data sources were used and weights were assigned to each data set so that the more relevant sets were given greater importance in this risk assessment. These weights were obtained from a panel comprised of government subject matter experts (Carrington and Dennis, 2001).

The individual studies were weighted by sample size, geographic region, and study date as follows in Equation 1.

$$\text{Study Weight} = n * gw * dw \qquad \text{Equation [1]}$$

Where:

n is the total number of samples in the study. A larger study would provide a better estimate of the percentage of positive samples than a small study.

gw is the geographic weight. A value of 1 was used unless the study was conducted in a region and food category for which there is little or no contribution (importation) to the United States food supply, in which case a value of 0.3 was used.

dw is the weight for the date of the study. Evidence exists that improved sanitation and HACCP programs have reduced the contamination of foods since the recognition of the public health problem from *Listeria monocytogenes* in the 1980's. A value of 1 was used for studies published within the past three years, a value of 0.7 was used for studies published between 1993 and 1999, while a value of 0.4 was used for studies published before 1993.

The width of the probability interval assigned to each study was proportional its relative weight as shown in Equation 2.

$$\text{Study Probability} = \text{Study Weight} / \text{Total Weight} \qquad \text{Equation [2]}$$

where Total Weight is the sum of all the Study Weights for the food category.

Adjustment of older data for food categories without large recent studies

About half of the food categories had large studies that were conducted within the past three years. As a result of the weighting scheme used to weight the studies, these recent studies usually received at least half the probability interval, dominating the analysis. Ten food categories had only older studies and those studies tended to have higher prevalence rates. The higher prevalence ranges may result from higher actual contamination levels or non-representative sampling. In either case, the data may tend to overestimate current *Listeria monocytogenes* concentrations, thereby biasing these categories compared to categories with recent data. To represent the uncertainty of this bias, the impact of large new studies on prevalence of *Listeria monocytogenes* was evaluated (Table III-11). Ratios were calculated by dividing the weighted pooled prevalence of 1999 and earlier data (percentage positive samples) by the weighted pooled prevalence of data for all years. A ratio less than 1 indicates that the prevalence of contaminated samples is currently higher than in the past. The reduction ratio values were used to adjust the food categories for which recent, large studies were not available. Specifically, the set of values in Table III-11 were used as an uncertainty distribution to reduce the number of positive values from older studies in categories without newer data. The food categories adjusted with the ratios to account for the lack of newer data include: Preserved Fish, Cooked RTE Crustaceans, Fruits, Hard Cheese, Processed Cheese, and Cultured Milk Products.

Table III-11. Prevalence Reduction Ratios for *Listeria monocytogenes* Using Study Age

Food Category	Prevalence Reduction Ratio[a]
High Fat and Other Dairy Products	0.9
Raw Seafood	1.0
Fluid Milk, Unpasteurized	1.0
Soft Ripened Cheese	1.8
Semi-soft Cheese	1.8
Vegetables	2.1
Deli-type Salads	2.3
Fluid Milk, pasteurized	2.6
Deli Meats	3.4
Fresh Soft Cheese	8.7
Frankfurters	9.7
Ice Cream and Frozen Dairy Products	31.3

[a]Prevalence reduction ratio = percentage of positive samples from data collected prior to 1999 divided by the total data set for each food category.

Adjustment for growth between production and retail for samples taken at manufacturing/ production

Some studies collected samples at manufacturing/ production prior to the point of retail (see Appendix 7). Since growth can be anticipated between production and purchase, the prevalence of positive samples for those data sets from sampling at manufacture were adjusted with estimates derived from the growth models (see section, "Modeling: Exponential Growth Rates").

The temperature ranges and storage times for the food categories are presented in Table III-12. These values were estimated as likely to be encountered between manufacture and retail. Because the distributions are narrow, rectangular distributions were used for storage time and for the temperature range. The median value from the growth models were used to adjust the contamination level but not the frequency of the presence/absence data. If, for example, the estimated growth was 0.5 logs prior to retail, a study with 5% positive at 0.04 cfu/g (-1.394 log) at manufacture would become 5% positive at 0.13 cfu/g (-0.884 log) at retail [0.5 log + -1.394 log = -0.894 log]. The contamination level was therefore increased from 0.04 cfu/g to 0.13 cfu/g to account for the possible growth of *Listeria monocytogenes* in food between production and retail.

Table III-12. Estimated Storage Temperature and Duration Between Manufacture and Retail and Predicted Median Growth

Food Category	Temperature Range[a] (°C)	Storage Time[a, b] (days) Minimum	Storage Time[a, b] (days) Maximum	Median Growth [c] (log cfu)
SEAFOOD				
Smoked Seafood	1 to 5	10	30	1.08
Raw Seafood	1 to 5	1	3	0.11
Preserved Fish		**Not applicable[b]**		
Cooked RTE Crustaceans	1 to 5	1	3	0.28
PRODUCE				
Vegetables	1 to 5	1	10	0.10
Fruits		**Not applicable[b]**		
DAIRY				
Fresh Soft Cheese		**Not applicable[b]**		
Soft Unripened Cheese		**Not applicable[b]**		
Soft Ripened Cheese	1 to 5	10	30	0.04
Semi-Soft Cheese		**Not applicable[b]**		
Hard Cheese	1 to 5	10	45	-0.94
Processed Cheese		**Not applicable[b]**		
Pasteurized Fluid Milk	1 to 5	1	3	0.20
Unpasteurized Fluid Milk		**Not applicable[b]**		
Ice Cream and Frozen Dairy Products		**Not applicable[b]**		
Cultured Milk Products		**Not applicable[b]**		
High Fat and Other Dairy Products	1 to 5	3	10	0.24
MEATS				
Frankfurters	1 to 5	10	30	1.03
Dry/ Semi-dry Fermented Sausage		**Not applicable[b]**		
Deli Meats	1 to 5	10	30	1.86
Pâté and Meat Spreads	1 to 5	1	7	0.34
COMBINATION FOODS				
Deli-type Salads		**Not applicable[b]**		

[a] Rectangular distributions were used for both the temperature range and storage times.
[b] Not applicable because none of the samples were collected at manufacture so growth between manufacture and retail was not calculated for these food categories.
[c]Median growth (log cfu) is calculated by multiplying the storage times and the exponential growth rates (see Section "Modeling: Growth Between Retail and Consumption").

Step 3: Integration of Prevalence Data and Quantitative Analysis

Frequency distributions for *Listeria monocytogenes* concentration for each food category were generated by integrating the standard deviation estimates with the rate estimates for detectable *Listeria monocytogenes*. This was accomplished with a 300 iteration simulation in which pairs of values were randomly selected from a uniform distribution of the standard deviations (Table III-10) and the weighted collection of the presence/absence data sets for each food category (including those at 0.04 cfu/g at retail and those adjusted for pre-retail growth). For each of the 300 pairs of values, a mean of the log cfu/g value was calculated (using the Excel Goal Seek procedure) to find the geometric mean that matches the cumulative frequency of positive samples at the detection limit of the assay (0.04 cfu/g or the adjusted value) with the selected standard deviation. Therefore, for each food category, 300 contamination curves were generated. The average frequency for each contamination level was determined to create the variability of contamination levels. The standard deviation of the frequencies for each contamination level became the uncertainty of the distribution for the contamination data.

Example of the Modeling for *Listeria monocytogenes* in Food at Retail Using Smoked Seafood

Step 1. Characterize the distribution of *Listeria monocytogenes* across food categories

Data from NFPA (2002) for Smoked Seafood is used to illustrate this step. As shown in Figure III-3, at the 0.04 cfu/g (-1.4 on log scale) contamination value, 0.958 (95.8%) of the samples (2573/2687) contain less than or equal to that contamination level. Sixty-seven more samples had levels < 0.1 cfu/g and eleven samples were contaminated at less than or equal to 1 cfu/g (0.0 on log scale). Therefore the fraction of negative samples is 0.986 [(2573 + 67 + 11)/2687]. This procedure is repeated for the samples that had higher levels of contamination. A normal curve was fitted to the data points by least-squares and the mean and standard deviation were estimated as –6.7 and 3.1, respectively. This process was repeated for the 17 selected enumeration studies and the resulting means and standard deviations are summarized in Table III-9.

Step 2. Characterize the uncertainty distribution for the frequency of detectable contamination

- Adjust for sample size, geographic location, and study date. The study weight and study probability are calculated as described by Equations 1 and 2 using the total number of samples in the study (n), the geographic weight (gw), and the weight for the date of the study (dw). These values are shown for Smoked Seafood in Table III-13. For example for the Aguado *et al*., 2001 study, the study weight is 52 (52 x 1 x 1) and the study probability is 0.009 (52/6034.7).

- Adjustment of older data for food categories without large recent studies. This step is not applicable for smoked seafood as recent large studies were available. However an adjustment was made using the range of prevelance ratios given in Table III-11 for Preserved Fish, Cooked RTE Crustaceans, Fruits, Hard Cheese, Processed Cheese, and Cultured Milk Products.

Adjustment for growth between production and retail for samples taken at manufacturing. In Table III-13 the 'collection' column indicates which studies were collected at manufacturing/ product and at retail. For the studies collected prior to retail, the level of *Listeria monocytogenes* was increased to account for anticipated growth between manufacturing and retail. From Table III-12, the mean exponential growth for smoked seafood of 0.15 logs/day at 5°C was multiplied by a uniform distribution (minimum of 1 day, most frequent of 10 days, and maximum of 30 days of storage) and the median of this resulting distribution was 1.08 logs. The fraction of positive samples (0.04 cfu/g or -1.4 log cfu/g) at manufacture was increased to a fraction of positive samples with a value of 0.48 cfu/g (-0.32 log cfu/g) at retail (-1.4 log + 1.08 log = -0.32 log cfu/g). In Step 3 described below, the procedure for the fitting of the contamination distribution the fraction of positive samples remained the same but the contamination level was now represented by a value of –0.32 log cfu/g for these studies.

Table III-13. Prevalence Studies of *Listeria monocytogenes* in Smoked Seafood

Study Reference	n[a]	# neg[b]	gw[c]	dw[d]	Collection[e]	Study	Cumulative	LM%
Aguado *et al*., 2001	52	36	1	1	R	52	0.009	0.69
Baek *et al*., 2000	68	65	1	1	R	68	0.020	0.96
Cortesi *et al*., 1997	165	133	1	0.7	R	115.5	0.039	0.81
Dauphin *et al*., 2001	36	20	1	1	R	36	0.045	0.56
Dillon *et al*., 1994	258	246	1	0.7	R	180.6	0.075	0.95
Dominguez *et al*., 2001	170	132	1	1	R	170	0.103	0.78
Eklund *et al*., 1995	61	13	1	0.7	P	42.7	0.110	0.21
Ericsson *et al*., 1997	9	6	1	0.7	R	6.3	0.111	0.67
Farber, 1991b	32	22	1	0.4	P	12.8	0.113	0.69
Garland, 1995	285	284	1	0.7	P	199.5	0.146	1.00
NFPA, 2002	2687	2573	1	1	R	2687	0.592	0.96
Guyer and Jemmi, 1990	64	60	1	0.4	P	25.6	0.596	0.94
Hartemink and Georgsson, 1991	31	30	1	0.4	R	12.4	0.598	0.97
Heinitz and Johnson, 1998	1080	929	1	0.7	P	432	0.669	0.86
Hudson *et al*., 1992	26	13	1	0.4	R	10.4	0.671	0.50
Inoue *et al*., 2000	92	87	1	1	R	92	0.686	0.95
Jemmi, 1990	820	732	1	0.4	R	328	0.741	0.89
Jørgensen and Huss, 1998	420	257	1	0.7	R	294	0.790	0.61
Maija *et al*., 2001	232	222	1	1	R	232	0.828	0.96
Miettinen, *et al*., 2001	25	22	1	1	R	25	0.832	0.88
Ng and Seah, 1995	2	1	1	0.7	R	1.4	0.832	0.50
Norton *et al*., 2000	38	32	1	1	P	38	0.839	0.84
Norton *et al*., 2001	96	85	1	1	P	96	0.855	0.89
Oregon State Dept of Agriculture, 2001	168	167	1	1	R	168	0.882	0.99
Scoglio *et al*., 2000	21	18	1	1	R	21	0.886	0.86
Teufel and Bendzulla, 1993	380	353	1	0.4	R	152	0.911	0.93
Vogel *et al*., 2001a	324	231	1	1	P	324	0.965	0.71
Vogel *et al*., 2001b	200	65	1	1	P	200	0.998	0.33
Yamazak *et al*., 2000	13	10	1	1	R	13	1.000	0.77
TOTAL						6034.7		

[a] n = total number of samples in the study
[b] # neg= total number of non-detectable samples in the study (i.e., <0.04 cfu/g)
[c]gw= geographic weight. A value of 1 was used unless the study was conducted in a region and food category for which there is little or no contribution (importation) to the United States food supply, in which case a value of 0.3 was used.
[d]dw= weight for the date of the study. A value of 1 was used for studies published within the past three years; a value of 0.7 was used for studies published between 1993 and 1999; and a value of 0.4 was used for studies published before 1993.
[e]Collecction. R= sample collected at retail; and P = sample collected at production/ manufacturing
[f] Study weight = n x gw x dw
[g] Cumulative probability.
[h] LM% negative = percentage of *Listeria monocytogenes* below the method of detection (i.e., <0.04 cfu/g)

Step 3: Integration of Prevalence Data and Quantitative Analysis

The *Listeria monocytogenes* concentration model for Smoked Seafood is presented in Figure III-4. The model estimates are compared to the prevalence studies and the enumeration data. The median (50th percentile), lower (5th percentile) and upper (95th percentiles) bounds reflect the *Listeria monocytogenes* concentration model (i.e., the set of Lognormal disitribution parameter values). Each data point in the "Prevalence Studies" data set represents an individual study (weighted for sample size and other study characteristics as described in Step 2). The data points in the "Enumeration Studies" data set are pooled from four different studies as noted in Table III-5. The prevelance studies at the –0.32 log cfu/g level represent the studies collected at manufacturing/ production and were adjusted for potential growth between production and retail.

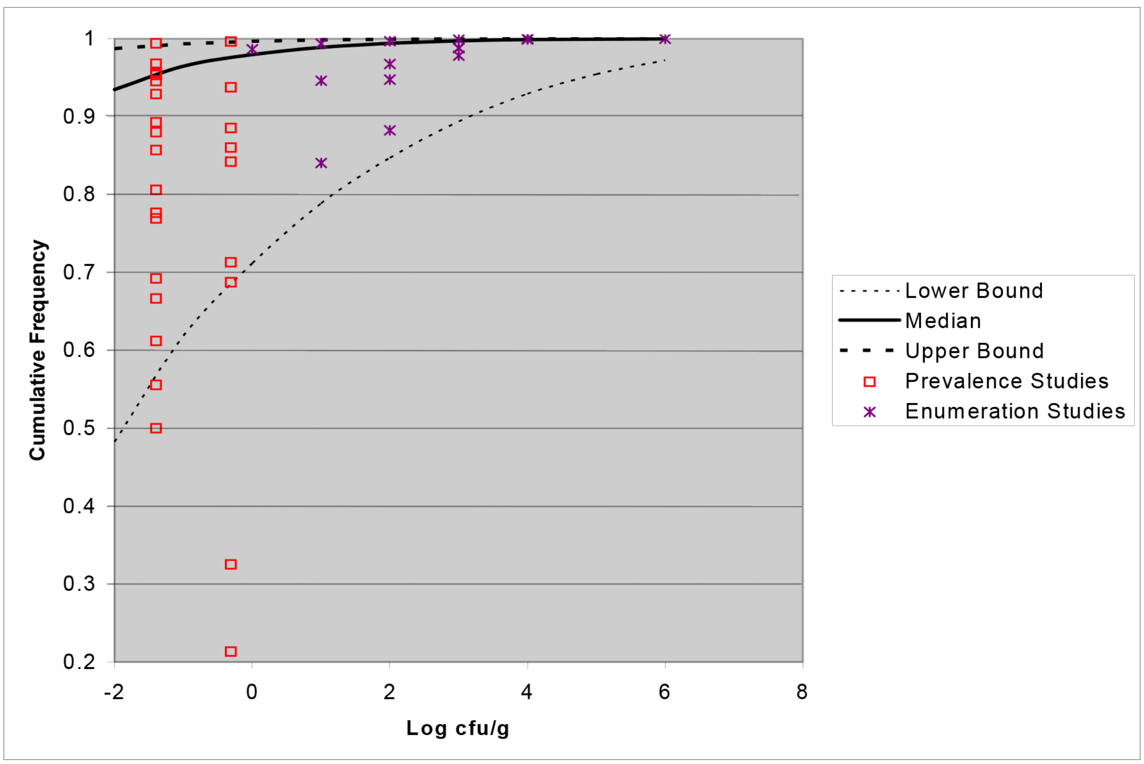


Figure III-4. Modeled Contamination Data for Smoked Seafood Food Category

Results: Modeled Contamination at Retail

Table III-14 shows the modeled distributions for *Listeria monocytogenes* contamination for the 23 food categories at retail. The first column of data in Table III-14 provides the median percentage of servings with less than one organism per serving, this estimate is not the same as undetectable values (<0.04 cfu/g) because different foods have different serving sizes. The predicted median of the servings having less than one organism of *Listeria monocytogenes* per serving ranged from 91.3 to 99.9% for the various food categories. In other words, less than 0.1 to 8.7% of the servings had one or more *Listeria monocytogenes* per serving, depending on the food category. The 5th and 95th percentiles provide information to estimate the uncertainty distributions for each of these median values. Although some servings of all food categories are likely to be contaminated at the retail level, servings of certain food categories (*e. g.,* Smoked Seafood, Raw Seafood, Deli Meats, Dry/Semi-Dry Fermented Sausages, and Deli Salads) were the most likely to be contaminated. Other columns in Table III-14 provide the percentage of servings with higher levels of contamination. Most frequently, the food categories are contaminated with 1 to 1000 cfu/serving. The calculations in the risk assessment model used 0.5 log intervals (referred to as bins) instead of the 3 log intervals shown in Table III-14.

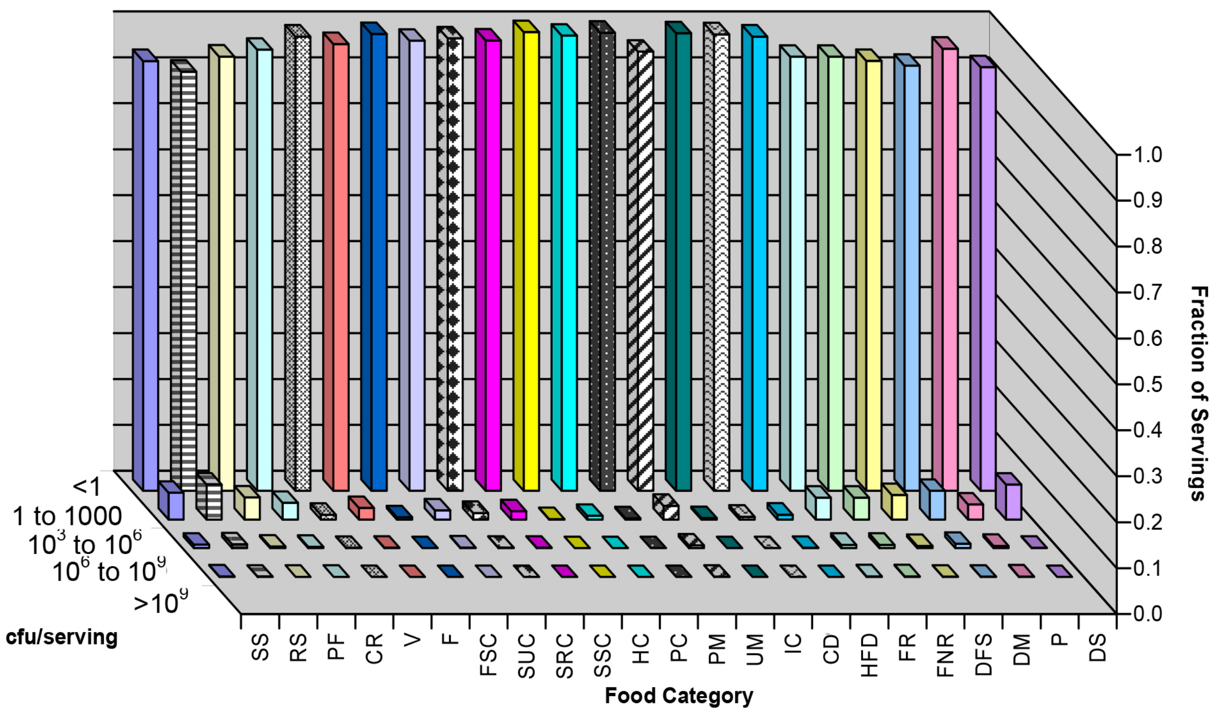
The bar chart in Figure III-5 provides a graphic depiction of the modeled distributions. Most of the servings for each food category are in the <1 cfu/serving level (back row of bars). As the level of contamination per serving rises (moving into the front rows of bars), the fraction of servings decreases markedly for most of the food categories.

Thus, for the Smoked Seafood category, the fraction of servings at <1, 1 to 10^3, 10^3 to 10^6, 10^6 to 10^9, and >10^9 cfu/serving are about 93.6, 5.8, 0.8, 0.1, and 0.0% of servings, respectively. The sum of the fractions of servings for a food category do not necessarily equal 100% because of rounding and because adding medians is not mathematically correct.

Table III-14. Modeled Percentage Distribution of Food Servings Contaminated with *Listeria monocytogenes* at Retail

Food Category	Median Percentage of Servings Contaminated at Different Levels									
	<1 cfu/serving		1 - 1000 cfu/serving		10^3 - 10^6 cfu/serving		10^6 - 10^9 cfu/serving		> 10^9 cfu/serving	
	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]
Seafood										
Smoked Seafood	93.6	(51.6, 98.7)	5.8	(0.9, 28.5)	0.8	(0.1, 12.8)	0.1	(<0.1, 5.9)	<0.1	(<0.1, 0.1)
Raw Seafood	91.3	(87.2, 98.6)	7.6	(1.3, 11.4)	0.8	(0.1, 1.7)	<0.1	(<0.1, 0.3)	<0.1	(<0.1, <0.1)
Preserved Fish	94.5	(70.8, 99.8)	4.8	(0.2, 20.4)	0.4	(<0.1, 4.1)	<0.1	(<0.1, 0.8)	<0.1	(<0.1, <0.1)
Cooked Ready-to-Eat Crustaceans	96.0	(93.9, 97.0)	3.6	(2.7, 6.0)	0.3	(0.1, 0.6)	<0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)
Produce										
Vegetables	98.9	(98.7, 99.0)	1.1	(0.9, 1.3)	0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Fruits	97.3	(70.4, 99.8)	2.5	(0.2, 22.0)	0.1	(<0.1, 6.8)	<0.1	(<0.1, 1.3)	<0.1	(<0.1, <0.1)
Dairy										
Fresh Soft Cheese	99.5	(95.1, 99.7)	0.5	(0.3, 4.8)	<0.1	(<0.1, 0.5)	<0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)
Soft Unripened Cheese,	98.0	(90.0, 99.9)	2.0	(0.1, 8.6)	0.2	(<0.1, 3.3)	<0.1	(<0.1, 0.7)	<0.1	(<0.1, <0.1)
Soft Ripened Cheese	98.5	(83.4, 99.9)	1.4	(0.1, 13.4)	0.1	(<0.1, 2.9)	<0.1	(<0.1, 0.4)	<0.1	(<0.1, <0.1)
Semi-soft Cheese	98.0	(90.8, 98.6)	1.8	(1.2, 7.2)	0.1	(<0.1, 1.5)	<0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)
Hard Cheese	99.9	(97.8, 100.0)	0.1	(<0.1, 2.0)	<0.1	(<0.1, 0.2)	<0.1	(<0.1,< 0.1)	<0.1	(<0.1, <0.1)
Processed Cheese	99.1	(97.5, 99.9)	0.8	(0.1, 2.4)	<0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Pasteurized Fluid Milk	99.7	(97.8, 99.9)	0.3	(0.1, 2.0)	<0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Unpasteurized Fluid Milk	96.1	(90.0, 100.0)	3.3	(<0.1, 8.5)	0.3	(<0.1, 4.0)	<0.1	(<0.1, 0.9)	<0.1	(<0.1, 0.1)
Ice Cream and Frozen Dairy Products	99.6	(99.3, 99.8)	0.4	(0.2, 0.6)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Cultured Milk Products	99.4	(94.0, 99.9)	0.6	(0.1, 5.5)	<0.1	(<0.1, 0.5)	<0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)
High Fat and Other Dairy Products	98.9	(98.3, 99.1)	1.1	(0.7, 1.7)	0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Meats										
Frankfurters (reheated)	94.5	(88.5, 95.5)	4.8	(3.6, 9.4)	0.7	(0.7, 2.0)	0.1	(0.1, 0.5)	<0.1	(<0.1, <0.1)
Frankfurter (not reheated)	94.5	(88.5, 95.5)	4.8	(3.6, 9.4)	0.7	(0.7, 2.0)	0.1	(0.1, 0.5)	0.1	(<0.1, <0.1)
Dry/Semi-dry Fermented Sausages	93.6	(77.7, 97.6)	5.4	(2.1, 19.7)	0.5	(<0.1, 4.1)	<0.1	(<0.1, 1.1)	<0.1	(<0.1, <0.1)
Deli Meats	92.5	(87.8, 99.3)	6.3	(0.7,11.1)	1.0	(<0.1, 1.3)	<0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)
Pâté and Meat Spreads	96.2	(79.7, 98.0)	3.3	(1.8, 14.9)	0.5	(0.2, 4.5)	0.1	(<0.1, 1.2)	<0.1	(<0.1, <0.1)
Combination Foods										
Deli-type Salads	92.2	(86.5, 97.7)	7.6	(2.3, 13.3)	0.1	(<0.1, 0.4)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)

[a] The 5 th and 95th percentiles uncertainty levels, respectively.



LEGEND			
SS =	Smoked Seafood	PC =	Processed Cheese
RS =	Raw Seafood	PM =	Pasteurized Fluid Milk
PF =	Preserved Fish	UM =	Unpasteurized Fluid Milk
CR =	Cooked Ready-To-Eat Crustaceans	IC =	Ice Cream and Frozen Dairy Products
V =	Vegetables	CD=	Cultured Milk Products
F =	Fruits	HFD	High Fat and Other Dairy Products
FSC =	Fresh Soft Cheese	FR =	Frankfurters (reheated)
SUC =	Soft Unripened Cheese	FNR =	Frankfurters (not reheated)
SRC =	Soft Ripened Cheese	DFS =	Dry/Semi-Dry Fermented Sausages
SSC =	Semi-soft Cheese	DM =	Deli Meats
HC =	Hard Cheese	P =	Pâté and Meat Spreads
		DS =	Deli Salads

Figure III-5. Modeled Distribution of *Listeria monocytogenes* Contamination Levels in Food Servings at Time of Retail

Modeling: Growth Between Retail and Consumption

Most of the contamination data used in this risk assessment were from samples collected at retail. Because *Listeria monocytogenes* can grow slowly at refrigeration temperatures, a growth module was incorporated into the exposure assessment to account for the potential growth of the organism in the food during storage in the home, prior to consumption. The growth model provides an estimate of the numbers of *Listeria monocytogenes* in the food at the time of consumption.

The growth model included the initial level of *Listeria monocytogenes* in the foods at retail where the food is purchased, the storage temperature in the home refrigerator, the exponential growth rate of *Listeria monocytogenes* in a food stored at a specific temperature, the storage time in the home and the maximum growth (stationary phase). Inoculated food studies, where growth of *Listeria monocytogenes* inoculated into a food was measured, showed that maximum growth at low refrigeration temperatures (<5°C) was often less than growth in the same foods at higher temperatures. It was also concluded that refrigeration temperature and storage time are not independent factors. High storage temperatures and long storage times would not be likely to occur because this combination would lead to obvious spoilage and the food would not be consumed. The output from the growth model was a frequency distribution of the log cfu/g for each food category at the time of consumption.

Exponential Growth Rates

The square root model for exponential growth rate (EGR) was chosen because of its simplicity and general acceptance as indicated by the documented use in the microbiology literature (Ratkowsky *et al.*, 1982). A straight line results when the square root of the EGR is graphed for different growth temperatures. The equation for the model is:

$$\sqrt{EGR} = a(T - T_0) \qquad \text{Equation [3]}$$

where **EGR** is the exponential growth rate ($\log_{10}$ cfu/day), **T** is the growth temperature (°C), $\mathbf{T_0}$ is the extrapolated minimum notational growth temperature (°C), and **a** is the slope parameter for *Listeria monocytogenes* in the specific food. T_0 values were estimated from four sources (Alavi *et al*., 1999; Duh and Schaffner, 1993; USDA, 1997 Pathogen Modeling Program; Wijtzes *et al*., 1993) and an average of these values (-1.18°C) was used in the model.

Different storage temperatures were used in the studies from the published literature that reported growth of *Listeria monocytogenes* in various foods. Therefore, using the data from these studies, equivalent EGRs ($\log_{10}$ cfu/day) at 5°C were calculated. The equation, presented as Equation 4, is a ratio and rearrangement of Equation 3. The slope factor (a) is a constant and cancels out in the equation.

$$\frac{EGR_5}{EGR_{lit}} = \left[\frac{a(T_5 + 1.18)}{a(T_{lit} + 1.18)}\right]^2 = \left[\frac{6.18}{(T_{lit} + 1.18)}\right]^2 \qquad \text{Equation [4]}$$

where:

$\mathbf{EGR_5}$ is the converted growth rate at 5°C,

$\mathbf{EGR_{lit}}$ is the growth rate from the inoculated pack study,

$\mathbf{T_5}$ is set to 5°C to standardize the EGRs, and

$\mathbf{T_{lit}}$ is the temperature used in the literature.

If a category had five or more data points, variation was modeled by fitting statistical distributions to the resulting values (using the software program ParamFit). Paramfit employs ten different distribution models: Beta, Cauchy, Exponential, Gamma, Logistic, Lognormal, Normal, Rectangular (Uniform), Triangular, and Weibull. There is no theoretical support for any one distribution to be more appropriate than any other distribution. Therefore, the range of values generated by each of the ten statistical distributions reflects the uncertainty.

The 10 distribution models are used to construct a probability tree for the predictive model. Within an iterative simulation, the frequency of use of each model is allocated according to its relative model weight which is calculated as follows:

$$\text{Model Weight} = (((1 + n / Pn)^{O}) \times ((1 - gof)^{H}) \qquad \text{Equation [5]}$$

where
n = number of observations
Pn = number of model parameters
gof = Goodness-of-Fit
O = an arbitrary constant to describe parameter penalty, a value of 19 was used
H = An arbitrary constant to modify and provide a better fit, a value of 141 was used

ParamFit uses least residual squares for the predicted percentiles as the optimization criteria. The ratio of the sum of residual squares to the sum of total squares for the predicted percentile is used as a goodness-of-fit statistic. This approach fits the middle of the distribution, so that outliers have less impact on the shape of the distribution.

In some food categories (such as Dry/Semi-dry fermented sausages and Deli-type Salads), the *Listeria monocytogenes* levels decline at a slow rate. The rate of decline was modeled with the same square root model (Equation 3) as for growth with a negative slope (**a**) and a negative EGR. Negative EGR values from the literature were combined with positive data to create one distribution, which was fitted to the growth models as explained earlier. The rate of decline was adjusted for temperature, after being converted to a positive value, by the same ratio method of Equation 4. Increasing the storage temperature above 5°C increases the rate of decline and conversely temperature decreases below 5°C decrease the rate of decline. This approach agrees with the USDA Pathogen Modeling Program (USDA, 1997), which predicts faster rates of decline at higher storage temperatures. This relatively simple approach to modeling growth versus decline (survival) sufficiently accounted for the relatively slow rates of declines encountered in this risk assessment.

If all of the growth values were positive, the data were fit with all ten distributions and the four with the highest weights were used in the probability tree. If some of the growth values were negative (reflecting a possible decline in *Listeria monocytogenes* numbers), then the data were only fit with the Beta, Cauchy, Normal, Triangular, and Rectangular distributions as these are the only distributions of the ten that will accept negative values. Of these five distributions those with the three highest weights were used.

Several of the food categories had only two or three data points. Under this circumstance, probability trees were constructed with equiprobable rectangular or normal distribution. The maximum and minimum values were used as the parameters for the rectangular distribution. A standard algebraic formula was used to calculate the mean and standard deviation of the normal distribution.

Details on the variations and uncertainties used in the risk assessment for each food category are provided in Appendix 5. A value of zero for the EGR at all refrigeration temperatures is assigned to food categories that did not support growth (such as ice cream) and in which the pathogen levels remained stable over an extended period.

As an example, data from the Smoked Seafood food category (see Appendix 5) will be used to illustrate how the exponential growth rate of *Listeria monocytogenes* was calculated. Briefly, the data sets of EGR values at 5 °C are placed in order of ascending magnitude. Figure A5.1.2 (see Appendix 5) titled 'Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C,' is a cumulative frequency graph where the x-axis is the EGR in $\log_{10}$ cfu/day and the y-axis is the fraction of data points from the literature with that value or lower (values are from Appendix 8). Different statistical distributions are fitted to the cumulative frequency distribution with the residual sums of squares for each frequency distribution used to weight the distributions. The probability column from Table A5.1.6 (see Appendix 5) indicates the weights for the four best-fitting distributions. In this example, the Lognormal and Gamma distributions have 40 and 31% of the weight, respectively. The Beta and triangular distributions had poorer fits and carried relatively little weight (16 and 13%, respectively). The probability of each growth model dictates the frequency of selection of each distribution for use in each uncertainty iteration during a Monte Carlo simulation (Cassin, *et al*., 1998; Vose, 1998). The variation predominantly reflects the shape(s) of the most heavily weighted statistical distribution.

Post-Retail Storage Times

The distribution of storage times were multiplied by the EGR to provide an estimate of the amount of *Listeria monocytogenes* growth occurring between retail purchase of the food and its consumption. Some foods are consumed on the day of purchase whereas others remain in the home refrigerator for lengthy periods of time. This is a major source of variability in the estimate of growth and ultimately, in the numbers of *Listeria monocytogenes* consumed. The variation in storage time was described using a modified BetaPert distribution (Figure III-6). A BetaPert distribution is defined by minimum, most likely, and maximum values. The distribution was modified by increasing the weight for the central value from 4 to 7. This modification reduced the frequency of values in the extended tails. The storage times were not used in the modeling for foods where *Listeria monocytogenes* does not grow. The uncertainty was described using a ±20% uniform distribution for the most frequent value and a ±50% uniform distribution for the maximum value, with a 100% correlation between the two distributions.

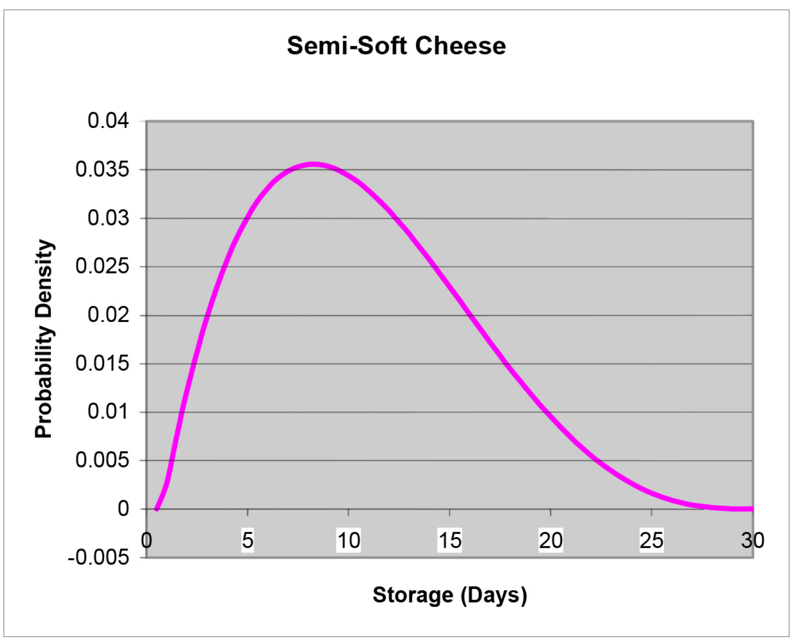


Figure III-6. Example of a Modified BetaPert Distribution

Frankfurters and Deli Meats

The survey sponsored by the American Meat Institute (AMI, 2001) asked for the average time consumers keep frankfurters and deli meats in the refrigerator. For example, 4% of the survey responders indicated that they stored frankfurters for an average of 11 to 14 days (Table III-6). This means that those responders consumed some individual servings of frankfurters after shorter storage times and others were kept longer than 14 days. While this is helpful information, what was needed for the model was the likely distribution of storage times for individual servings of frankfurters and deli meats. Thus, AMI data estimates inter-household variation. To get information on intra-household variation, consumers could be asked how long they stored the product the last time it was consumed. In order to introduce intra-household variation to the AMI data set, a log normal distribution was applied to the empirical AMI data points. The magnitude of the intra household variation, expressed as the Geometric Standard Deviation (GSD), ranged from 0.4 to 0.6 to be consistent with the data from the USDA/FSIS hotline study. The USDA hotline study asked for the 'last storage time' (Wachsmuth, 2000).

Figure III-7 shows a comparison of the USDA/FSIS hotline data (used in the draft risk assessment) and the AMI survey (indicated in the figure as 'individual average' data). The uncertainty bounds (GSD 0.2 to 0.6) are also shown in Figure III-7.

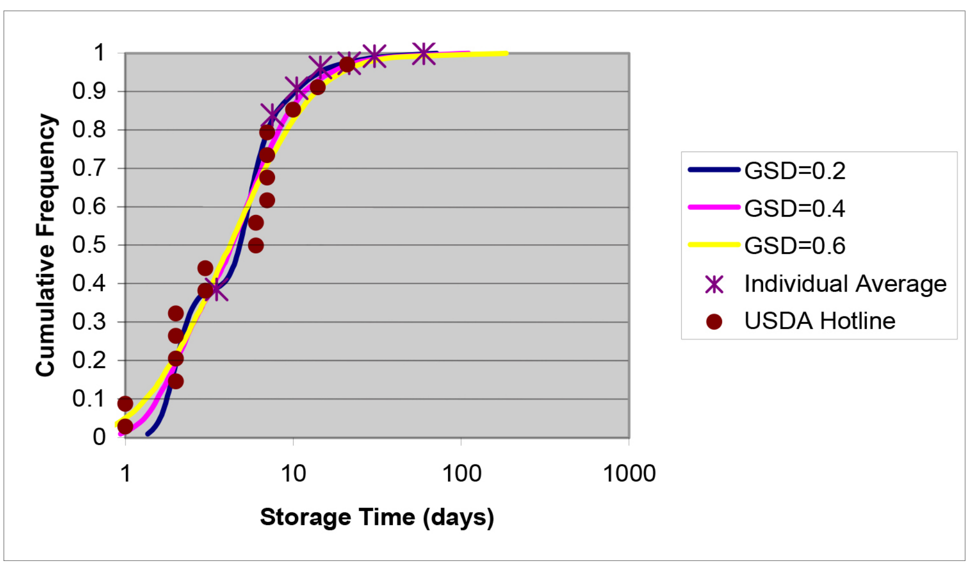


Figure III-7. Storage Time Distribution for Frankfurters and Deli Meats

Deli-type Salads

The data and assumptions behind growth estimates in deli salads were reexamined after the 2001 draft risk assessment. Data provided by Johnson (1993) and studies conducted in FDA's laboratories (Eblen, 2002a) showed that *Listeria monocytogenes* populations decline during the refrigerated storage of most deli foods. This is a consequence of processor-made salads having sufficient acidity and other preservatives to prevent growth. Locally- or store-made salads may not have these ingredients. The FDA studies indicated that growth only occurred in the shrimp and crab seafood salads. With the assistance of industry production data (Mitchell, 2001) the split between store-made and processor-made salads was estimated to be 15:85. It was also estimated that shrimp and crab salad are less than 10% of the total salad sales. Therefore, a triangular distribution of (1, 1.5, 3) was used to represent the fraction of deli salads that support growth and the uncertainty in that estimate. The growth rate at 5°C averaged 0.122 logs/day in the salads that supported growth and the declining rate averaged 0.143 logs/day in the majority of salads that did not support growth.

Modeling: Interaction of Storage Times and Temperatures

Increases in the levels of *Listeria monocytogenes* were calculated as the product of the EGR (which is dependent on the refrigeration temperature) and storage time. The Monte Carlo simulation program randomly selects different values from each calculated distribution. Both temperature and time distributions are concentrated toward the center of their ranges, 4°C and 8 days, respectively for Smoked Seafood. As a result, the most frequent estimates of growth would reflect these conditions. The simulation process would also select, at a lower frequency, the combination of low refrigeration temperatures and short storage times. Such combinations would result in relatively little growth. Similarly, the process could select high refrigeration temperatures and long storage times, 10°C and 45 days, which would result in extensive growth. However, this combination of temperatures and times would likely result in the food showing obvious spoilage and hence would not be consumed. Modeling the refrigeration temperature and storage time distributions as independent distributions was not believed to be appropriate. Therefore, the uncertainties in the mode and maximum storage times were negatively correlated to the temperature. For example, for Smoked Seafood, this means the mode ranged from 6 to 10 days. When refrigeration temperature was 10°C, the time was 6 days and when the temperature was 0°C the time was 10 days. The maximum storage time similarly ranged from 15 to 45 days for 10°C and 0°C storage, respectively. This means that at higher temperatures the distribution for storage times is much compressed relative to the distribution at lower temperatures.

Maximum Growth Levels

Growth is the product of the EGR (at a specific temperature) and the storage time. For each iteration of the Monte Carlo simulation, the logarithm of growth estimated during storage was added to a contamination level at retail. No lag phase was calculated; it was assumed that the *Listeria monocytogenes* cells were already in the food and adjusted to the food's environment during the period before retail purchase. The only change made from retail to storage was to a new refrigerator temperature. This relatively small change would take several hours for a packaged food and the cells would effectively adjust as the temperature changes.

The populations for the stationary phases of *Listeria monocytogenes* in foods were obtained from the published literature and were used to establish limits for the maximum calculated growth levels for each food category (Appendix 8). If the calculated level for *Listeria monocytogenes* exceeded the maximum level, the maximum value was used. The literature also indicated that the maximum growth level is dependent upon the storage temperature. However, there were only a few studies in the literature that provided for the growth in a food to the stationary phase at more than one temperature to permit accurate estimation of this behavior.

Duffes *et al.* (1999) showed maximum levels (cfu/g) in smoked salmon to be less than 10^5 at 4°C and $10^{8.1}$ at 8°C. Pelroy *et al.* (1994a) found maximum levels in smoked salmon to be 10^5 and $10^{6.5}$ at 5 and 10°C, respectively. Maximum populations were reported in cream as 10^7 and $10^{7.5}$ at 4 and 8°C, respectively (Rosenow and Marth, 1987); in butter it was reported as $10^{5.5}$ and 10^6 at 4 to 6 and 13°C, respectively (Olsen *et al*, 1988); and in lettuce it was reported as 10^5 to $10^{5.5}$ and $10^{6.5}$ to $10^{7.5}$ at 5 and 10°C, respectively (Beuchat and Brackett, 1990b). In addition to direct comparisons, a collection of individual growth studies also showed this tendency to grow to higher population levels at higher temperatures.

The maximum growth levels (cfu/g) used were applied across all food categories with 10^5, $10^{6.5}$ and 10^8 used as maximums for temperatures of <5, 5 to 7 and >7°C, respectively. For milk, sufficient data were found in the literature for growth levels of 10^7, $10^{7.5}$ and 10^8, to use as the maximums for the three temperatures, respectively. A uniform range of one logarithm was used to represent the uncertainty for each of the maximum growth levels. The calculated growth levels were added to the retail contamination levels during each iteration of the model, and these new levels of *Listeria monocytogenes* contamination in food were compared to the maximum growth level. If the calculated growth level exceeded the maximum growth level in any iteration, the amount of growth was reduced to the maximum growth level.

Modeling: Thermal Inactivation

Frankfurters have been implicated in outbreaks of listeriosis although they are generally reheated before serving. Because they are precooked during manufacturing, frankfurters are considered to be a RTE food. Reheating will kill *Listeria monocytogenes* in food. Frankfurters are usually, but not always, reheated before consumption. Therefore, a thermal inactivation step was included in the model for frankfurters. The frequency of insufficient reheating and the extent of inactivation of *Listeria monocytogenes* when not properly reheated were estimated in this step of the model.

No data describing the prevalence or extent of under-reheating of frankfurters has been published. However, the Georgetown survey (n=90) found approximately 1% of the respondents did not reheat their frankfurters (Wachsmuth, 2000). In an FSIS Hotline survey, 14% of the respondents indicated that at least one household member has eaten frankfurters directly from the package (Wachsmuth, 2000).

Some frankfurters are frozen by the consumer when they are brought home from the retail store. Information on the proportion of frozen frankfurters from the AMI survey and FDA Food Safety survey (Lando, 2003) led the risk assessment team to assign a uniform distribution from 3.0 to 8.7 % to represent this proportion and its uncertainty. To the frozen portion of frankfurters, the growth of *Listeria monocytogenes* would be set to zero, that is, the bacteria don't grow or die during the frozen storage. The time of storage would be irrelevant. It was assumed that all of the frozen frankfurters would be reheated before consumption. Therefore, the distribution of *Listeria monocytogenes* inactivation used for part of the non-frozen frankfurters was applied to all of the frozen frankfurters.

The final distribution of *Listeria monocytogenes* consumed per serving in reheated frankfurters is the summation of the respective proportions of the frankfurters stored frozen and reheated and the frankfurters stored refrigerated and reheated. The number of cases per annum was calculated from the total number of frankfurter servings and the proportion of the total in these two groups. The distribution of *Listeria monocytogenes* consumed per serving in non-reheated frankfurters represents the remaining proportion, represented by a triangular distribution of (4, 7, 10) percent of the non-frozen frankfurter servings (uncertainty distribution).

It was recognized that frankfurters are reheated in boiling water and microwave ovens more frequently than grilling, and that frankfurters are more likely to be contaminated on the surface than the interior. The Georgetown survey showed that 20% of the frankfurters were microwaved; the percentage of all responses for the FSIS Hotline was 19.4% with 4.7% microwaved less than 1 minute (Wachsmuth, 2000). In a preliminary experiment conducted by FDA/CFSAN, the heating of frankfurters by microwave ovens was measured with low (600 W) and high (1,100 W) powered microwave ovens (Buchanan, 2000). Four types were tested, including chicken frankfurters, low salt frankfurters, and two different size diameter frankfurters. Using various combinations of the two microwave power settings and four types of frankfurters, it was shown that the surface temperature increased faster than the center temperature. Heating for 25 seconds in the high power oven (1,100 W) and 40 seconds in the lower power oven (600 W) raised the surface temperature to at least 59 °C and, in some cases, raised the surface temperatures to over 70 °C. There is no information on what combinations of heating times and temperatures are actually realized by consumers, but this preliminary experiment suggests that microwave heating is likely to be sufficient to cause substantial inactivation of any *Listeria monocytogenes* that might be present.

Inadequate data were found with which to directly model thermal inactivation in the frankfurters that receive some heating by microwaving, boiling, frying, grilling, broiling or other means. Therefore, data from inactivation of *E. coli* O157:H7 in hamburgers were adapted (Juneja *et al.,* 1997). These authors determined that survival of *E. coli* O157:H7 after cooking to maximum temperatures ranging from 54 to 77ºC (129 to 171 ºF) may be estimated by this equation:

$$\log_{10} \text{survivors} = 20.53 - 0.12\ T \qquad \text{Equation [6]}$$

The maximum cooking temperature to calculate the decrease (T) is in degrees Fahrenheit. Because the initial contamination was 6.6 logs, the equation can be rearranged to calculate the decrease in contamination and applied to any initial level of contamination. The temperature was also converted into degrees Celsius:

$$\log_{10} \text{reduction} = 0.216\ (T - 46.4) \qquad \text{Equation [7]}$$

A standard deviation of 0.5 logs was used to represent the uncertainty in the estimated reduction. This value reflects the sampling error from a similar experiment with *E. coli* O157:H7 (Jackson *et al*., 1996) where a 4.1 $\log_{10}$ reduction was observed after cooking to 68.3ºC.

Reductions in *Listeria monocytogenes* levels were calculated by estimating a distribution of cooking temperatures with a triangular distribution having a minimum of 54 ºC, most frequent temperature in the range of 69 to 73 ºC, and a maximum of 77 ºC. The four-degree range for the most frequent temperature represents uncertainty in the cooking temperature distribution. Table III-15 contains the resulting cumulative distribution in log reductions for the frankfurters that were given some reheating. The remainder had no reduction in *Listeria monocytogenes* after the growth modeling.

Table III-15. Cumulative Distribution of the Reduction ($\log_{10}$) of *Listeria monocytogenes* in Reheated Frankfurters

Percentile	Median Reduction, $\log_{10}$ cfu/g [a]
1st	0.00 (0.00, 0.00)
5th	2.09 (1.90, 2.29)
10th	2.63 (2.52, 2.77)
25th	3.50 (3.38, 3.62)
50th	4.49 (4.32, 4.63)
75th	5.30 (5.13, 5.45)
90th	5.89 (5.78, 6.01)
95th	6.18 (6.05, 6.29)
99th	6.68 (6.57, 6.77)

[a] Values in parentheses are the 5th and 95th uncertainty levels.

Results: Modeled *Listeria monocytogenes* Levels in Food at Consumption

The estimated levels of *Listeria monocytogenes* at consumption are presented on Table III-16. This table has the same format as the table for *Listeria monocytogenes* contamination at retail (Table III-5), and may be directly compared to it to observe the shift in levels of *Listeria monocytogenes* after storage and/or heating. The median percentage of servings that fall within designated ranges of *Listeria monocytogenes* levels per serving are presented. The actual simulation modeling was at narrower levels (every logarithm and half-logarithm cfu/serving). The 5 and 95% values for the distributions for *Listeria monocytogenes* levels in each food are also given. These distributions indicate the uncertainty in the value for each median. The distribution observed with the values across a row gives the variation in *Listeria monocytogenes* levels expected for each food category. Because these medians are from skewed uncertainty distributions and because of rounding errors, a row may not sum to exactly 1.00.

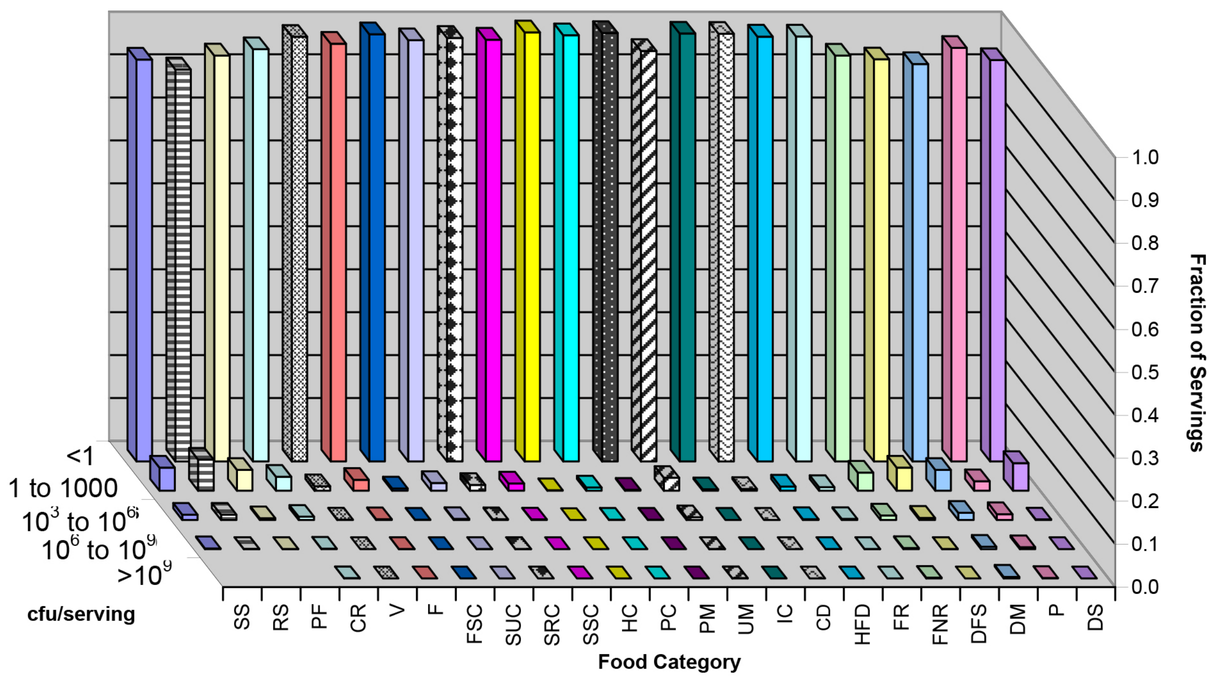
As shown previously with the retail contamination estimates, every food category has some fraction of servings with at least 1 cfu/serving. The food categories range from 0.1% in hard cheeses to 8.7% in raw seafood. The column in Table III-16 showing 10^6 to 10^9 *Listeria monocytogenes* per serving is the level where the occurrence of listeriosis would be expected to be most likely. Smoked Seafood, Cooked RTE Crustaceans, Frankfurters not reheated, Deli Meats, and Pâté and Meat Spreads categories comprise a group of foods estimated to have the greatest likelihood of containing 10^6 to 10^9 *Listeria monocytogenes* per serving. These levels are illustrated in Figure III-8. The row in the rear represents the fraction of servings with <1.0 cfu *Listeria monocytogenes*. All of the food categories have more than 90% of their servings in this contamination range. The rows have increasing levels of contamination toward the front of the figure.

Comparing corresponding values in Tables III-14 and III-16 shows the predicted effect of storage on the levels of *Listeria monocytogenes* at consumption. Cooked RTE Crustaceans, Frankfurters (not reheated), Deli Meats, and Pâté and Meat Spreads have some of the most dramatic changes. For example, at retail, 1.0% of Deli Meat servings would be in the 10^3 to 10^6 cfu/serving group. This increases to 1.6% at the time of consumption. In addition, the reduction in *Listeria monocytogenes* from reheating frankfurters is evident by comparing the <1, 1-1000 and 10^3 to 10^6 cfu/serving groups in Table III-16. The levels of *Listeria monocytogenes* in foods that do not permit growth, such as ice cream, do not show a change in comparing the values in Table III-14 (at retail levels) and Table III-16 (at consumption levels).

Table III-16. Modeled Percentage Distribution of Food Servings Contaminated with *Listeria monocytogenes* at Time of Consumption

Food Category	Median Percentage of Servings Contaminated at Different Levels[a]									
	<1 cfu/serving		1 - 1000 cfu/serving		10^3 - 10^6 cfu/serving		10^6 - 10^9 cfu/serving		> 10^9 cfu/serving	
	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]
Seafood										
Smoked Seafood	93.6	(51.6, 98.7)	5.3	(0.8, 24.6)	1.2	(0.2, 15.0)	0.2	(<0.1, 8.2)	<0.1	(<0.1, 0.5)
Raw Seafood	91.3	(87.3, 98.6)	7.2	(1.2, 10.8)	1.2	(0.1, 2.2)	<0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)
Preserved Fish	94.5	(70.8, 99.8)	4.8	(0.2, 20.4)	0.4	(<0.1, 4.1)	<0.1	(<0.1, 0.8)	<0.1	(<0.1, <0.1)
Cooked Ready-to-Eat Crustaceans	96.0	(93.9, 97.0)	3.2	(2.5, 5.5)	0.7	(0.4, 1.0)	0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)
Produce										
Vegetables	98.9	(98.7, 99.0)	1.0	(0.9, 1.3)	0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Fruits	97.3	(70.4, 99.8)	2.5	(0.2, 21.4)	0.2	(<0.1, 7.5)	<0.1	(<0.1, 1.4)	<0.1	(<0.1, <0.1)
Dairy										
Fresh Soft Cheese	99.5	(95.2, 99.7)	0.5	(0.3, 4.5)	<0.1	(<0.1, 0.7)	<0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)
Soft Unripened Cheese	98.1	(90.1, 99.9)	1.8	(0.1, 7.5)	0.2	(<0.1, 3.7)	<0.1	(<0.1, 1.0)	<0.1	(<0.1, <0.1)
Soft Ripened Cheese	98.6	(84.0, 99.9)	1.3	(0.1, 12.8)	0.1	(<0.1, 3.0)	<0.1	(<0.1, 0.4)	<0.1	(<0.1, <0.1)
Semi-soft Cheese	98.2	(91.4, 98.8)	1.7	(1.1, 6.9)	0.1	(<0.1, 1.3)	<0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)
Hard Cheese	99.9	(98.3, 100.0)	0.1	(<0.1, 1.6)	<0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Processed Cheese	99.2	(97.8, 99.9)	0.7	(0.1, 2.1)	<0.1	(<0.1, 0.2)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Pasteurized Fluid Milk	99.7	(97.8, 99.9)	0.2	(0.1, 1.8)	<0.1	(<0.1, 0.4)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Unpasteurized Fluid Milk	95.6	(90.0, 99.6)	3.0	(0.4, 7.6)	0.6	(<0.1, 5.1)	<0.1	(<0.1, 1.3)	<0.1	(<0.1, 0.2)
Ice Cream/Frozen Dairy Products	99.6	(99.3, 99.8)	0.4	(0.2, 0.6)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
Cultured Milk Products	99.6	(95.8, 99.9)	0.4	(0.1, 3.8)	<0.1	(<0.1, 0.3)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)
High Fat and Other Dairy Products	98.9	(98.3, 99.2)	0.9	(0.6, 1.5)	0.2	(0.1, 0.4)	0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)
Meats										
Frankfurters (reheated)	98.9	(97.3, 99.1)	0.8	(0.7, 2.1)	0.2	(0.2, 0.5)	0.1	(<0.1, 0.1)	<0.1	(<0.1, <0.1)
Frankfurters (not reheated)	94.5	(88.5, 95.5)	4.2	(3.1, 8.1)	1.0	(1.0, 2.5)	0.3	(0.2, 0.8)	0.1	(0.1, 0.3)
Dry/Semi-dry Fermented Sausages	93.6	(77.7, 97.6)	5.4	(2.1, 19.7)	0.5	(<0.1, 4.1)	<0.1	(<0.1, 1.1)	<0.1	(<0.1, <0.1)
Deli Meats	92.5	(87.8, 99.3)	4.8	(0.5, 8.6)	1.6	(0.1, 2.4)	0.5	(<0.1, 0.7)	0.3	(<0.1, 0.6)
Pâté and Meat Spreads	96.3	(79.8, 98.0)	2.2	(1.2, 8.6)	1.3	(0.6, 7.8)	0.4	(0.2, 3.8)	0.1	(<0.1, 0.6)
Combination Foods										
Deli-type Salads	93.5	(88.7, 98.2)	6.4	(1.8, 11.1)	0.1	(<0.1, 0.3)	<0.1	(<0.1, <0.1)	<0.1	(<0.1, <0.1)

[a] The 5th and 95th percentiles uncertainty levels, respectively.



LEGEND			
SS =	Smoked Seafood	PM =	Pasteurized Fluid Milk
RS =	Raw Seafood	UM =	Unpasteurized Fluid Milk
PF =	Preserved Fish	IC =	Ice Cream and Frozen Dairy Products
CR =	Cooked Ready-To-Eat Crustaceans	CD=	Cultured Milk Products
V =	Vegetables	HFD	High Fat and Other Dairy Products
F =	Fruits	FR =	Frankfurters (reheated)
FSC =	Fresh Soft Cheese	FNR=	Frankfurters (not reheated)
SUC =	Soft Unripened Cheese	DFS =	Dry/Semi-Dry Fermented Sausages
SRC =	Soft Ripened Cheese	DM =	Deli Meats
SSC =	Semi-soft Cheese	P =	Pâté and Meat Spreads
HC =	Hard Cheese	DS =	Deli-type Salads
PC =	Processed Cheese		

Figure III-8. Three Dimensional Graph of the Modeled Distribution of *Listeria monocytogenes* Levels of Contamination at the Time of Consumption for the Food Categories

An approximation of the overall frequency of consumption of *Listeria monocytogenes* by the United States population can be made by multiplying the fraction of servings in each food category-dose bin (Table III-16) by the annual number of servings in each food category (Table III-2). The numbers of servings are then summed for each dose for all of the food categories. Table III-17 shows that most of the servings have less than one *Listeria monocytogenes* and the number of contaminated servings decreases with increasing levels of contamination. If the number of contaminated servings is divided by the United States population (2.6×10^8), an approximation of how frequently the "average person" would encounter these levels of *Listeria monocytogenes* each year can be calculated. This "average" person would consume a serving with 10^3 to 10^6 microorganisms 2.4 times per year, 10^6 to 10^9 microorganisms once every two years and more than 10^9 microorganisms once every three years.

Table III-17. Number of Servings of Food per Year Containing Various Levels of *Listeria monocytogenes*

***Listeria monocytogenes* Levels in Food (per serving)**	**Number of Servings (per year in the United States)**	**Number of Servings (per person per year)**
0	3.3×10^{11}	1300
1 to 1000	4.9×10^9	19
1×10^3 to 1×10^6	6.2×10^8	2.4
1×10^6 to 1×10^9	1.3×10^8	0.5
$> 1 \times 10^9$	7.3×10^7	0.3

IV. HAZARD CHARACTERIZATION

Hazard characterization describes the adverse effects of a particular substance, organism, or other entity. The relationship between the exposure level (dose) and frequency of illness or other adverse effect (response) is estimated and the severity of the health effects is also evaluated, often by considering multiple biological endpoints (e.g., infection, morbidity, fatalities, sequelae). In the case of *Listeria monocytogenes*, the overall incidence of illness, its severity, and the differential risk to immunocompromised subpopulations are well characterized (see section titled "II: Hazard Identification"). In contrast, the relationship between the amount of *Listeria monocytogenes* consumed (the dose) and the likelihood or severity of illness resulting from that dose (the response) is not well understood. This part of the *Listeria monocytogenes* risk assessment focuses on characterization of the dose-response relationship.

Three factors, often called the disease triangle, affect the dose-response relationship: the environment (in this case, the food matrix), the pathogen (virulence characteristics or factors), and the host (susceptibility or immune status factors). Data may be obtained from humans (outbreaks, case reports, case-controlled studies, volunteer feeding trials), animals (mice, rats, primates, and other species), or *in vitro* (e.g., tissue culture) studies. For this risk assessment, surveillance data were used to describe the magnitude and the incidence of severe disease. This human data from surveillance studies was combined with data from surrogate studies using animals to establish the dose-response relationship for the subpopulations.

Based upon the available information and the objectives of this risk assessment, the total population was separated into three groups: the elderly (60 years and older), pregnancy related cases (perinatal), and the remaining population (designated the intermediate–aged). Perinatal deaths result from foodborne infection of a pregnant woman that is transmitted to the fetus before birth. Neonatal death rates from surveillance data were adjusted to include prenatal infections that resulted in very early termination of pregnancy (i.e., miscarriages). Distinct disease surveillance data on prenatal deaths were not consistently reported and had to be estimated based on neonatal death rates. The intermediate-aged group contains both individuals with fully competent immune systems and individuals with decreased immune function that are at greater risk of listeriosis.

In this revised FDA/FSIS risk assessment, adjustment ('dose-response scaling') factors were used to account for the variability of the many parameters (e.g., host susceptibility and *Listeria monocytogenes* strain virulence) that influence the relationship between the level of the dose and the severity of illness. For example, variability in the effect of host susceptibility on the level of a lethal dose was determined using mortality data from animal studies that compare normal mice with those having various forms of immune suppression. Animal studies were also used to characterize the range of *Listeria monocytogenes* strain virulences.

The WHO/FAO Risk Assessment of *Listeria monocytogenes* in Ready-To-Eat Foods (WHO/FAO, 2002) contains estimations for the risk of listeriosis for individuals with a range of medical conditions. This degree of detail was not undertaken in the current risk assessment since it would not improve the primary objective of this revised risk assessment, i.e., to compare the risk of different foods. Without food consumption information on the frequency and serving size of smoked seafood for diabetic and cancer patients, for example, it is not possible to provide additional insight from that already in the WHO/FAO document. We would also need information on the number of cases of listeriosis in the immunocompromised groups.

In the Hazard Characterization that follows, the relevant background for each component of the hazard characterization dose-response model is discussed, followed by a description of how specific related information was used for probabilistic modeling and any model outputs. The background sections describe the type of data available, including its strengths and limitations for use in this risk assessment. A diagram showing the main components of the Dose-Response model is provided in Figure IV-1.

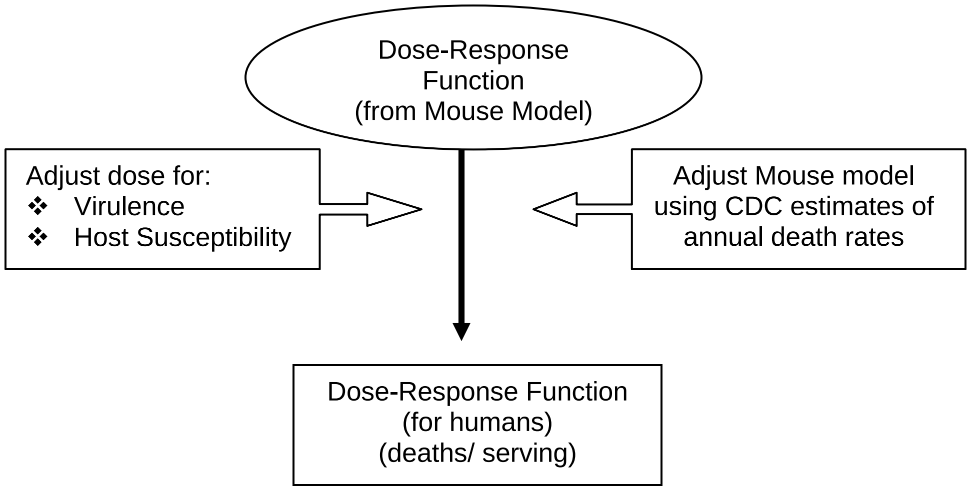


Figure IV-1. Components of the Dose-Response Model

Dose-Response Modeling

The primary variables involved in constructing dose-response models for *Listeria monocytogenes* are pathogen virulence (the ability of the pathogen to produce illness), host susceptibility (the capacity of the host to defend against the pathogen), and the effect of the food matrix (the relationship between the physico-chemical nature of *Listeria monocytogenes*-contaminated food and the fate of the organism following ingestion). Because of variability in host susceptibility and food matrix effects, there is no single infectious dose for *Listeria monocytogenes*, or any other pathogen that can be used for all individuals.

The food matrix has been theorized to affect the ability of a pathogen to survive gastric acidity or to interact with intestinal mucosa, changing the likelihood of infection. While *Listeria monocytogenes* has been found in many environments, human listeriosis has often been associated with high salt, low pH, or high fat foods (Juntilla and Brander, 1989; McLauchlin, 1996; Linnan *et al.*, 1988; Dalton *et al.*, 1997; Barnes *et al.*, 1989). While these findings are circumstantial in nature, adaptation of *Listeria monocytogenes* to acidic or high salt environments may also increase its ability to survive the stomach acid barrier or within host cells (O'Driscoll *et al.*, 1996). Similarly, high fat content in foods may protect *Listeria* *monocytogenes* from gastric acid, or possibly enhance uptake and survival in host cells via interaction with cell membrane lipids (Coleman and Marks, 1998). At present, there are only limited studies in animal surrogates that assess the effects of food matrix on dose-response (Sprong *et al*., 1999), so incorporation of this parameter into the dose-response model awaits further research.

Pathogen virulence studies with different strains and serotypes of *Listeria monocytogenes* have been conducted with experimental animals (Pine *et al.*, 1990; Pine *et al.*, 1991; Stelma *et al.,* 1987). Studies have also been performed that attempt to quantify the relationship between immune function and lethal dose (Czuprynski *et al*., 1996; Czuprynski and Brown, 1986; Golnazarian *et al*., 1989). These types of studies were used to develop the relative extremes of dosages that affect lethality in laboratory animals with respect to susceptibility.

There are no human clinical trials with *Listeria monocytogenes.* Human data to anchor animal ranges (*i.e.,* relate effects observed in surrogate animals with those in humans) are limited to outbreak, case-control, and surveillance studies. Although numerous epidemiological investigations have been conducted for *Listeria monocytogenes*, the emphasis of these investigations has not been quantification of the number of organisms consumed by both ill and exposed (but not ill) subjects. However, two outbreak investigations did occur that provided quantitative data. The use of outbreak data to create a dose-response curve is described in Appendix 9.

Comparison of the FDA/FSIS Revised Dose-Response Model to Other Dose-Response Models for *Listeria monocytogenes*

Previously published risk assessments for *Listeria monocytogenes* included dose-response models (Farber *et al*., 1996; Buchanan *et al.*, 1997; Haas *et al*., 1999; Lindqvist and Westöö, 2000; WHO/FAO, 2002). These efforts share some similarities with the dose-response evaluation used in this FDA/FSIS revised risk assessment, but there are significant differences as well. In Table IV-1, several aspects of the models are compared: empirical basis for the estimates, health endpoints modeled, consideration of susceptible subpopulation, consideration of strain virulence, and models employed.

The earlier dose-response assessments each used a single mathematical model, and the model was different in each case. Farber *et al*. (1996) used a three-parameter Weibull-Gamma model, Buchanan *et al.* (1997) used a single parameter exponential model, and Haas *et al*. (1999) used a beta-Poisson model after rejecting the exponential model for lack of fit. Lindquist and Westoo (2000) used exponential and Weibull-Gamma models. The FDA/FSIS revised risk assessment used an initial battery of eight models. All the models that appeared to provide a reasonably close fit (described in Appendix 6) were used to characterize the uncertainty in the prediction arising from model selection using a probability tree.

Both Farber *et al*. (1996) and Buchanan *et al.* (1997) sought to predict cases of listeriosis, which they defined as infections serious enough to require clinical attention and generate a public health record. The endpoint modeled by Haas *et al*. (1999) was infection in mice (i.e., presence of the microorganism in the liver or spleen of mice), which does not necessarily correlate with a clinical outcome in humans (e.g., illness). The dose-response model for the revised FDA/FSIS risk assessment uses mortality as the outcome because it represents a comparable endpoint for both the human epidemiology record and experimental mouse data. The total number of listeriosis cases is estimated with a multiple for each population based on CDC epidemiological data.

The dose-response analysis by Farber *et al*. (1996) began with a presumption of the doses corresponding to illness rates of 10% and 90%. Although there may have been some empirical basis for these estimates, the basis was not specified. The dose-response model developed by Buchanan *et al.* (1997) relied on exposure and public health data collected in Germany. Haas *et al.* (1999) based their model on data collected from a study with controlled exposures of mice to *Listeria monocytogenes*. The dose-response model in the revised FDA/FSIS risk assessment uses one of the studies also employed by Haas *et al*. (1999), but also accounted for the difference in susceptibility between mice and humans using public health data collected in the United States.

Both Farber *et al*. (1996) and this revised FDA/FSIS risk assessment generate separate equations for different population groups. Farber *et al.* (1996) employed a Weibull-Gamma model with a different set of parameters for two groups designated as susceptible and non-susceptible. The revised FDA/FSIS risk assessment includes a scaling factor that adjusts the effective dose to match the dose-response model with the surveillance data. The analysis by Buchanan *et al.* (1997) did not explicitly model susceptible subpopulations. However, the variation in host susceptibility is implicitly an integral part of the total variability represented by the equation. The dose-response model of Haas *et al*. (1999) reflected the variation of the population in the study with inbred mice in a highly controlled environment. It did not attempt to address the greater variation that might be expected in a human population.

Farber *et al*. (1996) did not specify the empirical basis of their estimate, so the extent to which strain virulence was considered is not apparent. The estimate by Haas *et al*. (1999) was based on a study with a single strain and it clearly did not address strain virulence. Although Buchanan *et al.* (1997) did not model strain variability, the variation in strain virulence was implicitly an integral part of the total variability represented by the equation because it was based upon statistics for the entire population.

The WHO/FAO (2002) risk assessment used a combination of the models from Buchanan *et al*. (1997), Lindqvist and Westöö (2000), and the draft US HHS/USDA (2001) risk assessments for its hazard characterization. The first two studies, Buchanan *et al*. (1997), Lindqvist and Westöö (2000), reported an r-value derived from the exponential dose-response curve. A third r-value was calculated from the dose-response graph reported in the draft US HHS/USDA (2001) risk assessment; this r-value was smaller than the other two. The difference in the r-values resulted from the assumption about the highest *Listeria monocytogenes* doses that would be encountered in the rare servings that were most likely to lead to illness. The draft US HHS/USDA (2001) estimated higher numbers of *Listeria monocytogenes* would be consumed resulting in a lower calculated r-value (i.e., consumption of higher cell numbers means that a cell has a lower probability of causing illness). The WHO/FAO (2002) risk assessment tested some of the consequences of this assumption, but in this comparative risk assessment, the same assumptions regarding maximum growth levels that are used to derive the dose-response model are then used to calculate the risks for the different food categories.

Table IV-1. Characteristics of This *Listeria monocytogenes* Risk Assessment (FDA/FSIS) and Previously Conducted *Listeria monocytogenes* Risk Assessments that Contain Dose-Response Models for Listeriosis

Study	Empirical Basis	Endpoint	Models Examined	Model Used	Host Susceptibility	Strain Virulence
Farber *et al*. (1996)	Subjective	Illness (including lethality)	Weibull-Gamma	Weibull-Gamma	Explicit	Unknown
Buchanan *et al.* (1997)	Epidemiology	Illness (including lethality)	Exponential	Exponential	Implicit	Implicit
Haas *et al*. (1999)	Mouse	Infection	Beta-Poisson Exponential	Beta-Poisson	Mice = Men	Not Addressed
Lindquist and Westoo, 2000	Epidemiology	Illness	Exponential and Weibull-Gamma	Exponential	Implicit	Implicit
FDA/FSIS draft risk assessment (US HHS/ USDA, 2001)	Mouse, Epidemiology	Lethality and Infection	Multiple	Multiple	Explicit	Explicit
WHO/FAO, 2002	Epidemiology	Morbidity, Mortality	Multiple	Exponential	Explicit	Implicit
FDA/FSIS Risk Assessment (revised, current document)	Mouse, Epidemiology	Lethality and Infection	Multiple	Multiple	Explicit	Explicit

Dose-Response in Animal Surrogates

Data Collected from Animal Studies

The virulence factors of *Listeria monocytogenes* and their interaction with the host's defense systems help determine the infectious dose of listeriosis. However, because of the potential for fatal outcomes in human listeriosis, clinical studies involving human subjects have not been conducted. Experimental dose-response data are therefore derived exclusively from studies using animal and *in vitro* surrogates.

Extrapolation from animal to human infection involves the interaction of several factors related to the inherent differences between surrogates (e.g., mice) and humans. The relationship of infective dose to body mass, for example, if treated in a classic chemical toxicology approach, suggests that mouse doses may be equivalent to a 50- or 500-fold higher dose in humans, depending on age. It is not known whether this approach is directly applicable to microbial dose-response. For this reason, no explicit body weight dose adjustment factor was included.

The difference in lifetime daily exposure patterns between humans and animal surrogates is also significant. Dose-response studies in surrogates, such as mice, generally use animals that are immunologically naïve (i.e., previously unexposed) to *Listeria monocytogenes* but with normal immune systems. In humans, both food contamination data and fecal carriage studies suggest that exposure to *Listeria monocytogenes* is relatively common among humans. Most of the surveys of fecal carriage are based on point prevalence rather than cumulative exposure (Slutsker and Schuchat, 1999). Unless fecal carriage is monitored over time in the same individuals, it cannot be determined what proportions of positive isolates of *Listeria monocytogenes* represent transient passage of the organism versus asymptomatic or mildly symptomatic carrier status.

The exact relationship between fecal carriage and immunological exposure and sensitization is not clear. Prolonged exposure, such as colonization of intestinal tissues, would likely result in immune sensitization. In an outbreak involving a high infective dose in chocolate milk, in which the major symptom was gastroenteritis, the severity of symptoms correlated with subsequent higher antibody titers against the antigen listeriolysin O (Dalton *et al.,* 1997). Another study reported that T lymphocytes that were reactive to *Listeria monocytogenes* antigens were present in the peripheral blood of 50 normal, healthy adults surveyed (Munk and Kaufmann, 1988).

This suggests that exposure and subsequent immune sensitization may commonly occur. This observation also suggests that such exposure may result in increased resistance because T lymphocytes have been shown to be an important component of resistance to *Listeria monocytogenes* in mice (Kuhn and Goebel, 1999, Unanue, 1997b). Comparison of dose-response in a normal population of mice versus a "normal" population of humans therefore results in additional uncertainty. The surrogates (mice) are uniformly immunologically naïve while the human population probably encompasses various degrees of immune sensitization resulting from an individual's response to frequent dietary exposure to *Listeria monocytogenes*.

In laboratory dose-response studies with mice, two methods of administering *Listeria monocytogenes* have been employed. One model uses oral infection of mice as a surrogate for human foodborne exposure. A great deal of additional data for mice are available from studies using the intraperitoneal (IP) infection route. Comparative studies have shown a similar dose-response for oral and IP infections in mice (Golnazarian *et al.*, 1989; Pine *et al.*, 1990). Endpoints in studies with animal surrogates are usually infection or death. Values for these endpoints are usually expressed as median infective dose (ID_{50}) and median lethal dose (LD_{50}). The infective dose in surrogate animals is determined by isolation of the organism from normally sterile sites, typically liver and spleen. It is not known whether this is directly comparable to serious illness in humans; however, this is an implicit assumption when surrogate animal data for this biological endpoint are used. The ID_{50} is influenced by the degree of sensitivity of the isolation method.

One study determined both endpoints (ID_{50} and LD_{50}) following oral dosing of inbred mice (Golnazarian *et al.*, 1989). This approach is useful for determining the relationship between these endpoints. The *Listeria monocytogenes* strain used, F5817, was a human patient isolate, serotype 4b. In this study, ID_{50} was determined by a sensitive 48-hour enrichment method, as well as by culturing directly from tissues. This tends to result in a lower ID_{50} than one determined by direct plating alone.

No dose-response studies of *Listeria monocytogenes* in animal surrogates were found that used gastrointestinal illness as an endpoint or that relied on biomarkers such as fever, neurological, or immune parameters. Therefore, the gastrointestinal endpoint of listeriosis in humans (Dalton *et al.,* 1997) was not included in the dose-response model. Development of quantitative biomarkers of exposure would be useful for establishing comparable endpoints in animals and humans. Although useful in establishing a general dose-response model for severe or lethal listeriosis, attempts to use the mouse model to establish the dose-response for neonatal listeriosis have not produced stillbirth or neonatal infection in mice. This is perhaps related to the differences between rodent and primate placental structure (Golnazarian *et al.,* 1989), and indicates a need to look for more appropriate surrogates. Recently, a primate model of oral infection has been developed (Smith et al., 2003). This model uses stillbirth following oral infection in pregnant Rhesus monkeys as an endpoint, and is currently being used to develop dose-response information. Other oral dose-response studies involving rats (Schlech *et al.*, 1993) and primates (Farber *et al.*, 1991) have also been conducted, but these systems are not as developed as the mouse system. They also lack the extensive genetic and immunological tools that are available in the mouse model.

The recent development of a transgenic mouse model expressing the human form of E-cadherin (an adhesion molecule) on the intestinal mucosa has demonstrated an increase in susceptibility following oral infection (Lecuit *et al*., 2001). This increased susceptibility is apparently based on the enhanced ability of the *Listeria monocytogenes* virulence factor, internalin A, to interact with human E-cadherin versus the normal mouse molecule. This difference is attributable to a single amino acid change in this otherwise highly conserved molecule (i.e., the molecule is similar across a broad range of different species). If these results are replicated with other strains of *Listeria monocytogenes*, it may lead to significant improvement in the mouse model and point the way to development of other "humanized" transgenic models.

Modeling: Dose-Response in Mice

The relationship between the number of *Listeria monocytogenes* consumed and the occurrence of death (mortality) was modeled by using data obtained from mice with a single strain of *Listeria monocytogenes* (F5817) (Golnazarian *et al*., 1989). In this risk assessment, the effective dose was modified to account for strain variation, host susceptibility surveillance statistics, and differences in susceptibility of laboratory mice in a controlled environment and humans in an uncontrolled environment. Therefore, the mouse model is primarily used to establish the breadth of the range of doses that can cause illness and death. This can be seen in the shape or steepness of the dose-response curve. The animal data were not used to establish the actual doses that cause human illness, which is seen in the scale or relative position of the dose-response curve on the dose axis. As will be described below, actual doses were derived using human health statistics.

For mortality in mice (Figure IV-2), the data came from three different experiments using the same strain (F5817) with comparable results. The data were fit with six different models using the Dose Frequency curve-fitting procedure (see Appendix 6). The best five models (Probit, Exponential, Logistic, Multihit, and Gompertz-Log) were used to characterize the uncertainty in the shape of the dose-response curve. The parameters used for these models are provided in Table IV-2. The exponential model provided the best fit and received the most weight (Figure IV-2).

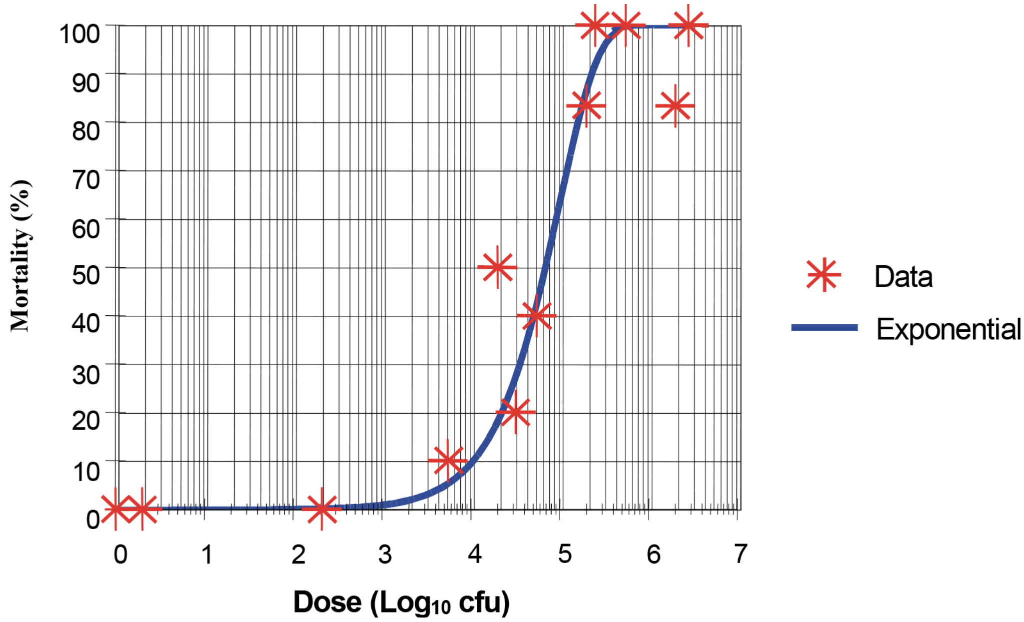


Figure IV-2. *Listeria monocytogenes* Dose vs. Mortality in Mice

Table IV-2. Parameters for the Statistical Distribution Models Used in the Probability Tree for the Mouse Dose-Frequency Relationship

Model	Parameter 1[a]	Parameter 2[a]	RSQ[b]	N[c]	CP[d]
Logistic	-14.7	1.34	0.159	2	0.14
Exponential	0.000011		0.140	2	0.50
Gompertz-Log	-10.47	0.91	0.134	2	0.68
Probit	-8.73	0.80	0.159		0.82
Multihit	0.000008	82	0.132	2	1.00

[a]See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).
[b]RSQ = Residual Sum of Squares
[c]N = number of parameters
[d]CP = Cumulative Probability

Dose-Response Curves for Infection and Serious Illness

Infection in humans was not modeled in the FDA/FSIS revised risk assessment and serious illness was predicted from dose-response mortality curves. However, for illustrative purposes only, a dose-response curve for infection was developed using mouse data. The data were taken from Golnazarian *et al*. (1989), who described the results of experiments in which mice were infected by the oral route. The data were fit with six different distribution models using the Dose Frequency curve-fitting procedure. (See Appendix 6 for information about this procedure and more details about modeling and software.) Five distribution models with the best fit (Beta-Poisson, Logistic, Gompertz-Log, and Gompertz-Power, and Gamma-Weibull) were used to characterize the uncertainty in the shape of the dose-response curve; the exponential model was discarded for lack of fit based on visual inspection. The Gompertz-Log model provided the best fit and received the most weight (Figure IV-3). The shape of the curve for infection is very shallow and rises gradually, whereas the curve for lethality (Figure IV-2) rises very sharply. Serious illness and mortality are subsets of infection that primarily correspond to the upper (higher dose) portion of the infection curve. The infection endpoint in mice was based on the detection of viable *Listeria monocytogenes* in one or more internal organs using sensitive methods that cannot be routinely applied to human infections. In human infection, it is not known how the presence of a small number of *Listeria monocytogenes* in tissues correlates with clinical illness. Therefore, because the relationship between infection in mice and the spectrum of clinical illness in humans (invasive, non-invasive, or asymptomatic) is not understood, especially at lower doses, this risk assessment used mortality rather than infection as the endpoint to model human dose-response.

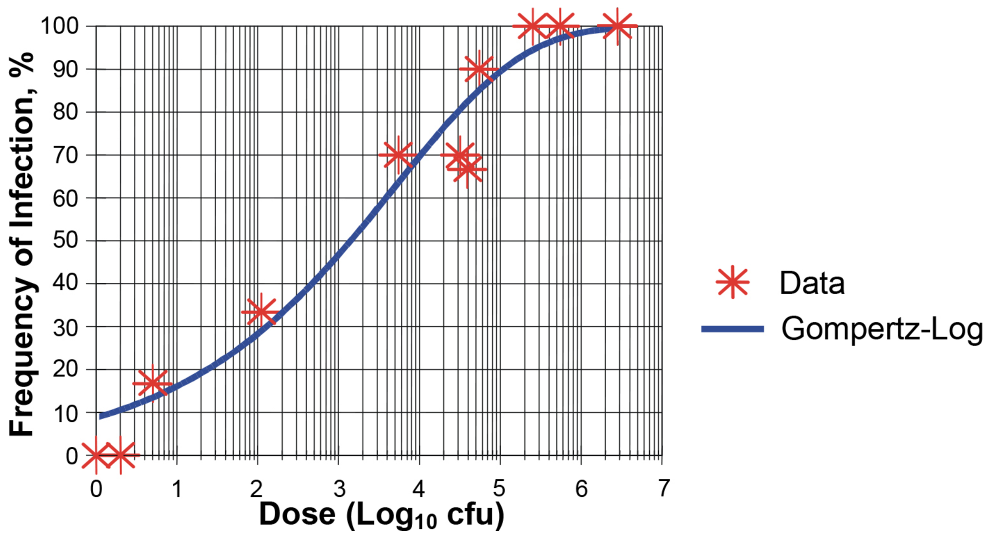


Figure IV-3. Dose vs. Frequency of Infection in Mice

Variability in Virulence

Available Data

Variation in virulence is demonstrable among *Listeria monocytogenes* strains. This variability influences the number of organisms required to produce illness and possibly the severity or manifestations of illness. From a mechanistic perspective, this problem has been extensively investigated, and a large number of virulence components of *Listeria monocytogenes* have been discovered. Studies on *Listeria monocytogenes* virulence have, of necessity, been conducted using well-characterized strains of *Listeria monocytogenes*, selected for the presence or absence of the specific virulence gene of interest. Where animal studies are involved, genetically inbred mouse strains are commonly used. While the use of tightly defined systems (clonal bacteria and genetically identical hosts) is necessary to solve the questions associated with virulence mechanisms, they are not likely to reflect the range of virulence profiles found among naturally occurring, foodborne *Listeria monocytogenes*.

There is also epidemiological evidence for variability in virulence among foodborne isolates of *Listeria monocytogenes*. Most illnesses are associated with a restricted number of serotypes, primarily 1/2a, 1/2b, and 4b. Serotype 4b occurs most frequently in outbreaks (Farber and Peterkin, 1991). In sporadic cases, the same serotypes predominate; however, the frequencies are somewhat different with 1/2a and 1/2b accounting for a higher proportion of cases than 4b (Slutsker and Schuchat, 1999). However, the frequency with which these serotypes are isolated from foods does not parallel the disease distribution. For example, while the 4b and 1/2a serotypes are most frequently associated with foodborne illness, they are not the strains most commonly isolated from foods (Pinner *et al*., 1992). In addition to serotyping, ribotyping has also been used to identify three lineages or groupings of *Listeria monocytogenes* primarily associated with large outbreaks, sporadic cases, or animal disease (Wiedman *et al.*, 1997).

With the complete sequencing of the genome of both *Listeria monocytogenes* and *L. innocua*, tools are now available to completely discover all of the relevant virulence genes in *Listeria monocytogenes* (Glaser *et al*., 2001). Approximately 270 genes were found to be unique to *Listeria monocytogenes*, and many of these are similar structurally to already discovered virulence factors (Cabanes *et al*., 2002). This information has the potential as the basis for development of genetic tools such as microarrays to further characterize variability in virulence.

Animal surrogate studies also show a range of virulence among food isolates of *Listeria monocytogenes*. Del Corral *et al.* (1990) demonstrated a three-log LD_{50} range of virulence among 13 food isolates (all serotype 1) in immunocompromised mice following intraperitoneal inoculation. In two surveys involving multiple serotypes, Pine *et al*. (1990) and Stelma *et al.* (1987) used oral dosing with normal mice to demonstrate a range of virulence. These studies included clinical isolates, as well as strains lacking known virulence genes (*e. g*., listeriolysin O (LLO)). Major reductions in mouse lethality were seen with strains lacking LLO, but clinical strains did not prove to be consistently more virulent than food isolates with no known human disease association. Where multiple serotypes or ribotypes were compared, there was not a consistent pattern of increased virulence associated with any subtype(s) in animal (Pine *et al*., 1990, Stelma *et al*., 1987) or *in vitro* studies (Pine *et al*., 1991, Weidman *et al.*, 1997). Thus, while serotype, phagetype, and ribotype data are valuable epidemiological tools for identifying and tracking outbreaks, they are not mechanistically related to virulence. The predominance of certain subtypes identified in outbreaks may not be related to the presence or absence of known virulence factors. It is possible that allelic differences in virulence genes occur that account for variability in virulence properties (Weidman *et al.*, 1997), or that there are as yet unidentified virulence factors. Another consideration is the effect of pathogen adaptation to various ecological niches on the survival and virulence of certain illness-associated subtypes in foods (Boerlin and Piffaretti, 1993).

Finally, while strong circumstantial evidence exists for a predominant role of certain subtypes in human disease, there is demonstrable variation in virulence within these subtypes in animal studies and all serotypes have been associated with at least some human illness. Therefore, animal data were used to model a range of variability in virulence among

Listeria monocytogenes isolates, but neither animal nor human outbreak data were used to assign virulence rankings based on sub-types.

Modeling: Variability in Strain Virulence

The extent of the variation in the ability of different *Listeria monocytogenes* strains to cause human disease was based on comparisons made in mice. Specifically, the range of LD_{50} values observed in mice was also used to characterize the range of variation expected in humans. Since the strain used to establish the overall dose-response relationship was not used in any of the studies of strain variability, the model assumes that the shape of the population dose-response function is the same for all strains.

Table IV-3 describes the LD_{50} values from three studies in which *Listeria monocytogenes* was administered to healthy, immunocompetent mice by intraperitoneal injection. The data were used to develop the distributions for the range of strain virulence. Although some of the strains were obtained directly from food, most of the strains tested were clinical isolates. Since members of the latter set were identified because they resulted in disease, the set of strains represented in the sample may be biased towards strains that are more virulent. Virulence in mice ranged over seven logs; however, there were no large or obvious trends in the LD_{50} values relative to either serotype or strain source.

It is possible that the conditions under which strains are held in the laboratory can affect strain virulence. The Scott A strain, one of the clinical strains tested and found to have relatively low virulence, has been cultured for use in laboratory studies for many years. This may have allowed the accumulation of new and different mutations in the laboratory strain, which would not have occurred in the strain in nature, creating differences in virulence in the laboratory and environmental strains. Other strains may have also been altered in this way. In this instance, the effect would be to bias the set of strains represented in the sample toward strains that are less virulent.

Table IV-3. LD_{50} Values for Various *Listeria monocytogenes* Strains Following Intraperitoneal Injection in Normal Mice

Strain	Serotype	Source	LD_{50} (Log_{10} cfu)[a]	Reference
G9599	4	clinical	2.57[a]	Pine *et al*., 1990
G1032	4	clinical	2.69[a]	Pine *et al*., 1990
G2618	1/2a	food	2.89[a]	Pine *et al*., 1991
F4244	4b	clinical	3.62	Pine *et al*., 1991
F5738	1/2a	clinical	3.67	Pine *et al*., 1990
F6646	1/2a	clinical	4.49	Pine *et al*., 1990
15U	4b	clinical	4.56	Pine *et al*., 1991
F4246S	1/2a	clinical	4.57	Pine *et al*., 1991
F7208	3a	clinical	4.61	Pine *et al*., 1990
G2228	1/2a	clinical	4.66[a]	Pine *et al*., 1990
F2381	4b	food	4.73	Pine *et al*., 1991
G2261	1/2b	food	4.95[a]	Pine *et al*., 1991
F2380	4b	food	4.96[a]	Pine *et al*., 1990
F2392	1/2a	clinical	5.08	Pine *et al*., 1990
NCTC 7973	1/2a	clinical	5.47[a]	Pine *et al*., 1991
F7243	4b	clinical	5.75[a]	Pine *et al*., 1990
F7245	4b	clinical	5.91[a]	Pine *et al*., 1990
SLCC 5764	1/2a	clinical	6.00	Pine *et al*., 1991
V37 CE		food	6.04	Stelma *et al*., 1987
F7191	1b	clinical	6.23	Pine *et al*., 1991
V7		food	6.80	Stelma *et al*., 1987
Brie 1		food	7.28	Stelma *et al*., 1987
Murray B		clinical	7.30	Stelma *et al*., 1987
Scott A	4b	clinical	7.54	Stelma *et al*., 1987
G970	1/2a	clinical	8.88	Pine *et al*., 1991
NCTC 5101	3a	clinical	9.70	Pine *et al*., 1991

[a] These LD_{50} (50% of the lethal dose) values are averages from multiple experiments.

Table IV-4 presents the results of a study by Pine *et al*. (1990) in which *Listeria monocytogenes* was administered by intraperitoneal injection and intragastric gavage. For some strains, the intraperitoneal route was more effective (lower LD_{50}), and for other strains, the intragastric route was more effective. To facilitate comparison, the log_{10} of the ratio of the intragastric LD_{50}/ intraperitoneal LD_{50} was calculated. The median value for the log_{10} ratios was positive, indicating that the IP values may slightly overestimate intragastric LD_{50} by approximately a half log_{10}.

Table IV-4. Effect of Route of *Listeria monocytogenes* Administration (Intragastric vs. Intraperitoneal) on Mouse LD_{50}

Strain	Serotype	Source	Log_{10} ratio [a] (intragastric/intraperitoneal)
F2380	4b	food	-1.81
F7243	4b	clinical	-0.75
F7245	4b	clinical	-0.47
G2228	1/2a	clinical	0.00
G2261	1/2b	food	0.00
NCTC 7973	1/2a	food	0.04
F6646	1/2a	clinical	0.21
F2380	4b	food	0.71
G9599	4	clinical	0.96
G1032	4	clinical	1.60
F5738	1/2a	clinical	1.81
G2618	1/2a	food	2.00

[a] All data from Pine *et al*., 1990. A Log_{10} ratio of 0 indicates that the LD_{50} by the two routes were identical. A negative number indicates a lower LD_{50} (50% of the lethal dose) by the intragastric route, while a positive number indicates a greater LD_{50} by the intraperitoneal route.

Data shown in Table IV-3 were modeled by fitting nine distributions with ParamFit (see Appendix 6). Figure IV-4 displays all nine distributions. The best four models (Triangular, Gramma, and Lognormal) were used to characterize the dose-response model uncertainty associated with the distribution. The parameters used for these models are provided in Table IV-5. Output from the resulting function is given in Table IV-6 and describes the extent of virulence variability in determining dose-response. Since the virulence estimated from the distribution was from intraperitoneal doses, the estimated LD_{50} was increased by 0 to1 logs (uncertainty range) to produce an estimated intragastric LD_{50}.

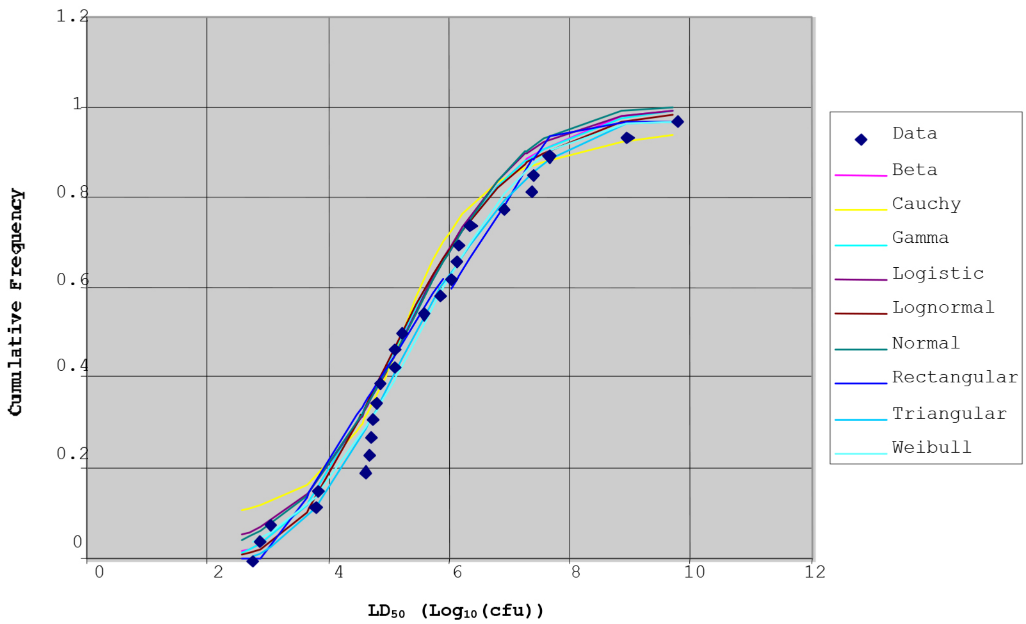


Figure IV-4. Variation (Cumulative Frequency) of *Listeria monocytogenes* Strain Virulences: Nine Distributions

Table IV-5. Parameters for the Statistical Distribution Models Used in the Probability Tree for Variation in Strain Virulence

Model	Parameter 1[a]	Parameter 2[a]	Parameter 3[a]	RSQ[b]	N[c]	CP[d]
Triangular	2.09	4.80	9.19	0.037	2	0.30
Gamma	12.0	0.440		0.037	2	0.58
Lognormal	1.65	0.289		0.038	2	0.83
Logistic	5.29	0.92		0.041	2	1.00

[a]See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models)
[b]RSQ = Residual Sum of Squares
[c]N = number of parameters
[d]CP = Cumulative Probability

Table IV-6. Model Output for *Listeria monocytogenes* Strain Virulence

Variation Percentile	LD_{50} Log_{10}(cfu)[a]		
	Median	5th Percentile	95th Percentile
1st	2.55	0.97	2.80
5th	3.12	2.47	3.32
10th	3.53	3.18	3.66
25th	4.28	4.20	4.39
Median	5.25	5.15	5.34
75th	6.35	6.23	6.48
90th	7.45	7.25	7.67
95th	8.06	7.84	8.54
99th	9.47	8.52	10.59

[a] LD_{50} is the dose with a 50% mortality.

Host Susceptibility

Available Data

Susceptibility in Humans and Animal Surrogates

Variation in susceptibility to listeriosis among people exists. This influences the number of organisms required to produce illness and the type of illness produced. Information on susceptibility for this risk assessment was taken from epidemiology and case reports of conditions that predispose to infection, as well as studies with animal surrogates on the role of host defense components in susceptibility to *Listeria monocytogenes* infection.

Immunosuppression in Humans and Animal Surrogates

With respect to immune function, dose-response information related to susceptibility in humans must be gleaned from surveillance and other epidemiological data. Again, animals are potentially useful surrogates. The approach used was to identify biomarkers of susceptibility that reflect defects in immune mechanisms in both human populations and in animal surrogates. This approach is based on the premise that human and animal resistance mechanisms are similar. The mouse *Listeria monocytogenes* animal model was characterized with respect to the role of many specific immune defects. Host resistance mechanisms to *Listeria monocytogenes* have been studied using a variety of immune-compromised mouse models. These animal models include "gene knockout animals" in which genes for specific immune functions are disrupted. Other surrogate animal models involve depletion of cytokines or immune cells with monoclonal antibodies, and mouse strains with genetic defects related to macrophage-mediated killing of *Listeria monocytogenes* (Czuprynski and Brown, 1986; Cheers and McKenzie, 1978, Unanue, 1997a).

In mouse models of *Listeria* infection, certain inbred mouse strains exhibit increased susceptibility. Mouse strains C57BL10 and BL6 are relatively more resistant than Balb/c and A/J. The genetic basis of this resistance is distinct from *Nramp I* and involves2 loci on chromosomes 5 and 13, and possibly other loci as well (Kramnik and Boyartchuk, 2002). The exact mechanism is unknown, but appears to involve a defect in the ability of susceptible strains to form granulomas around foci of infection in the liver (Boyartchuk *et* *al*., 2001). In addition, mapping has revealed distinct T cell epitopes recognized by Balb/c and C57BL strains (Geginat *et al*., 2001). It is probable that similar differences exist among the genetically diverse human population.

Pregnant Women. Within some susceptible human populations, immune system defects or alterations that correlate with resistance in mouse models have been identified. In pregnancy, there is a characteristic inhibition of natural killer (NK) cell activity in the placenta (Schwartz, 1999). In the mouse, these NK cells, stimulated by Interleukin 12, are the primary source of interferon, which is a key component of resistance (Unanue, 1997a; Tripp et al, 1994). Pregnancy is also associated with development of a T-helper cell type 2 (Th-2) cytokine environment which favors the production of Interleukins 4 (IL-4) and 10 (IL-10) (Schwartz, 1999). Immune defects in the mouse, which simulate immune status alterations occurring in pregnancy impact negatively on resistance (Nakane *et al.,* 1996; Genovese *et al.,* 1999). Cytokines characteristic of a T-helper cell Type 1 (Th-1) response (*e. g*., interferon) are critical for resistance (Unanue, 1997a, 1997b; Tripp *et al*., 1994; Huang *et al.,* 1993). Listeriosis symptoms in pregnancy are often mild (Slutsker and Schuchat, 1999) suggesting that pregnancy may not predispose mothers to more severe illness. However, it is possible that immunosuppression as a consequence of pregnancy results in increased likelihood that even small numbers of *Listeria monocytogenes* in the circulation can colonize placental tissues, increasing the chances of fetal exposure. Because the fetus has a poorly developed immune system and is immunologically naïve with respect to *Listeria monocytogenes*, the consequences of fetal exposure are severe, often resulting in stillbirth or neonatal infection.

Elderly and Neonates. At the extremes of age, (neonates and the elderly), changes in both innate and acquired immunity have been observed. Numerous biomarkers of immune responsiveness have been measured in the elderly including decreased γ-interferon production, NK cell activity, and increased IL-4 and IL-10 production (Rink *et al.,* 1998; Mbawuike *et al.,* 1997; Di Lorenzo *et al.,* 1999). The effects on IL-4 and IL-10 are suggestive of a predominant Th-2 vs. Th-1 response. A similar imbalance, characterized by decreased interferon production and increased production of IL-10 may occur in neonates

(Lewis *et al.,* 1986; Genovese *et al.,* 1999). Thus, in the elderly and during pregnancy, as well as in neonatal immune systems, biomarkers can be documented that correlate with decreased resistance in mouse models having the same immune defect(s). Relatively few mouse studies investigate dose-response in an oral infection model in immunocompromised mice (Czuprynski *et al.,* 1996; Golnazarian *et al.,* 1989).

Cancer, Transplant, and AIDS Patients. As with pregnant women, neonates, and the elderly, there are immune defects that occur in AIDS patients, cancer patients, and organ transplant recipients. These may involve not only depletion of T-lymphocytes, but also neutropenia (depletion of neutrophils) as a result of immunosuppressive medications (Morris and Potter, 1997). Severe neutropenia would be expected to result in greatly increased susceptibility as has been demonstrated in mouse studies in which neutrophils are experimentally depleted (Czuyprynski *et al*., 1996).

Because the experimental studies all involve highly controlled manipulation of the immune system, it is very difficult to translate their results to a highly variable, uncontrolled human population. However, because relative change in susceptibility could be determined, these compromised mouse studies were used in aggregate to set limits or bounds for a maximal degree of increased susceptibility due to immunosuppression. The validity of this approach is based upon the concept that host-resistance mechanisms targeted in animal studies are connected with human biomarkers of exposure and susceptibility. It is important to note, however, that knockout mice or treatment with monoclonal antibodies both reflect a near complete abrogation of the immune parameter in question, which is probably not the case in most humans. In addition, most of these targeted immunocompromised animal model systems have not been tried with oral infection.

Non-Immune Factors Affecting Susceptibility

While susceptibility in these groups is thought to be related primarily to impaired immune function, another physiologic parameter thought to be relevant to susceptibility is a reduced level of gastric acidity. Reduced gastric acidity (achlorhydria) may be associated with aging or with drug treatment for gastric hyperacidity. Another factor responsible for reduction in gastric acidity in humans is infection with another bacterium, *Helicobacter pylori (*Feldman *et al*., 1999*).* Two dose-response studies dealing with this issue involved treatment of mice or rats with the acid suppressor, Cimetidine, concurrent with oral infection with *Listeria monocytogenes*. The mouse study showed no significant effect with drug treatment (Golnazarian *et al*., 1989), while the rat study showed increased infectivity of *Listeria monocytogenes* at the lowest dose (Schlech *et al*., 1993). Because of the conflicting nature of these reports, and lack of additional information, no dose modification factor was included for gastric acidity.

Modeling: Host Susceptibility

Variation in host susceptibility was represented with triangular distributions that modified the effective dose for individual servings. In order to represent populations with different ranges of susceptibility, three alternative triangular distributions were applied to generate three different effective dose estimates. The distributions all had a minimum value of -1 and a median value of 0, so that the net effect of the host susceptibility adjustment was to broaden the distribution of effective doses without greatly altering the midpoint. The maximum values were 1.5, 3.0, and 4.5 $\log_{10}$ cfu for the Low, Medium, and High Variability distributions, respectively (see Table IV-7). In addition, the uncertainty in the tails of the frequency distributions were assigned uncertainty ranges using rectangular distributions, so that there was overlap in the uncertainty ranges of the three frequency distributions. A single random number was used to select the values for the tails, so that a low uncertainty percentile selects a narrow distribution, while a large uncertainty percentile results in a wide distribution.

Table IV-7. Parameters for Variability Distributions for Host Susceptibility for Listeriosis

Distribution	Minimum	Most Frequent	Maximum
Low Variability	-1 to 0	0	0 to 1.5
Medium Variability	-1 to 0	0	1 to 3
High Variability	-1 to 0	0	2.5 to 4.5

The three distributions encompass the range of susceptibility that has been observed in animal studies (see section titled 'Modeling: Dose-Response in Surrogates'). In conjunction with a population-specific dose-response scaling factor (see section titled "Dose-Response Scaling Factor"), these distributions may be used to create a unique dose-response function for a particular subpopulation. The selection of one of the three distributions for a particular population will depend on the relative homogeneity of the population being modeled. If the population is thought to be nearly as homogeneous as a population of laboratory mice, the Low Variability adjustment would be the most appropriate (one tail of the uncertainty distribution gives an overall modification of 0, implying that the population is as homogeneous as a population of laboratory mice). A population thought to include both highly susceptible and individuals displaying a normal degree of resistance, but still within the ranges documented in the animal studies would mandate the Medium Variability adjustment. Speculation that the range of susceptibility may exceed ranges in the animal studies may be expressed by using the High Variability adjustment.

Dose-response functions for specific subpopulations were developed by altering the dose-response scaling factor by 0.25 $\log_{10}$ increments so that the median estimate roughly predicted the number of annual cases estimated from surveillance data, given the number of servings consumed for each food category, and distribution estimates of effective dose in either the Low, Medium, or High Variability populations. The model output for the host susceptibility, showing the distributions for the low, medium, and high variability adjustments is provided in Table IV-8.

Table IV-8. Model Output for Variability Adjustment Factors for Host Susceptibility to Listeriosis

Percentiles	Low Variability Adjustment[a] (Log_{10} cfu)	Medium Variability Adjustment[a] (Log_{10} cfu)	High Variability Adjustment[a] (Log_{10}cfu)
1st	-0.4 (-0.8, -0.1)	-0.4 (-0.8, 0.0)	-0.4 (-0.7, 0.0)
5th	-0.3 (-0.6, 0.0)	-0.3 (-0.5, 0.0)	-0.2 (-0.4, 0.0)
10th	-0.3 (-0.5, 0.0)	-0.1 (-0.3, 0.0)	-0.1 (-0.2, 0.1)
25th	-0.1 (-0.2, 0.0)	0.1 (0.0, 0.1)	0.3 (0.2, 0.3)
Median	0.1 (0.0, 0.1)	0.4 (0.3, 0.5)	0.9 (0.7, 1.0)
75th	0.3 (0.0, 0.5)	0.9 (0.5, 1.2)	1.6 (1.3, 2.0)
90th	0.4 (0.0, 0.8)	1.3 (0.7, 1.8)	2.3 (1.8, 2.9)
95th	0.5 (0.1, 1.0)	1.5 (0.8, 2.2)	2.7 (2.0, 3.3)
99th	0.7 (0.1, 1.2)	1.8 (1.0, 2.6)	3.1 (2.3, 3.9)

[a] The median value is presented. The 5th and 95th uncertainty values are given in parenthesis.

High variability host susceptibility distributions were used for the intermediate-age and elderly subpopulations since the members of these subpopulations most probably exceed the range of physiological states characterized by the animal research. Because the susceptibilities of individuals within the elderly subpopulation or immunocompromised individuals within the intermediate-aged subpopulation may be varied, wider ranges are assigned to these groups. The neonatal dose-response functions were based on the medium variability distributions since the basis of categorization does not occur as a matter of degree. Because the adjustments were somewhat dose-response model-dependent, the adjustment is expressed as a range.

Dose-Response Scaling Factor

The relationship between dose and response (or cause and effect) is often complex and is often influenced by many different parameters. Some of these parameters (or causative factors), such as virulence variability, have quantitative data that can be incorporated into the model. However, there are a variety of host and food matrix factors that could potentially influence *Listeria monocytogenes* dose-response, but these have either not been identified or no data are available. As a result, a single additional parameter, the dose-response scaling factor, was used to account for these influences, and thus bridge the relationship between the response in humans versus surrogate animals. Without this adjustment, the mouse dose-response model, when coupled with the exposure assessment model, greatly overestimates the incidence of lethal infections in humans from *Listeria monocytogenes*.

The dose-response curve derived from the mouse study estimates that the LD_{50} is about 4.26 logs or 20,000 cfu. The food contamination data indicate that human exposure to this number of *Listeria monocytogenes* is relatively frequent. If the mouse dose-response model were directly applicable to humans, the dose-response model would overestimate the number of human deaths due to listeriosis by a factor of over one million. This indicates that normal human beings are much less susceptible to *Listeria monocytogenes* than laboratory mice. There are a number of factors that may be responsible for the difference in susceptibility between humans and mice, any or all of which may contribute:

- <u>Inherent differences between mice and humans</u>: Factors, such as body mass, metabolic rate, body temperature, or gastrointestinal physiology may contribute to differences.
- <u>Immunity</u>: Humans are more likely to have had prior exposure to low levels of *Listeria monocytogenes* that may serve to develop immunity to challenges with larger numbers.
- <u>Route of exposure</u>: The *Listeria monocytogenes* dosing in the animal studies was not introduced by the dietary consumption route. The consumption of *Listeria monocytogenes* in food may reduce its ability to penetrate the intestine.
- <u>Strain bias</u>: The strains surveyed in mice may be more virulent than those typically encountered in food.
- <u>Food matrix effects</u>: The physico-chemical nature of a *Listeria monocytogenes*-contaminated food may vary depending on fat content or other factors.
- <u>Exposure</u>: Some fraction of the dose-response scaling factor may result from overestimate of the occurrence and growth of *Listeria monocytogenes* in the exposure assessment. This occurs because the development of a dose-response scaling factor includes using the exposure assessment result as an estimate of dose along with the epidemiological incidence.

Since there are no available quantitative data related to *Listeria monocytogenes* for the factors listed above, a dose-response scaling factor (referred to as a scaling factor) was developed to correct the mouse-derived model so that it was applicable to humans. The size of this factor is determined by surveillance data reported to FoodNet for each of the three subpopulations modeled in this risk assessment. Differences among subpopulations may mainly be attributed to the first two factors listed above (i.e., inherent differences between mice and humans, and immunity). Thus, while the shape of the dose-response curve is initially derived from mice, the scale is determined by the human epidemiology. The range of dose-response scaling factors for each of the three subpopulations is provided in Table IV-9.

Table IV-9. Model-Dependence of the *Listeria monocytogenes* Dose-Response Scaling Factor Ranges for the Three Subpopulations

Subpopulation	Dose-Response Scaling Factor (Log_{10} cfu)		
	Median	5th Percentile	95th Percentile
Intermediate-Age	12.8	11.1	15.9
Neonatal[a]	9.0	7.9	11.6
Elderly	11.4	10.1	14.3

[a] An adjustment to account for total perinatal deaths (prenatal and neonatal) is described in the risk characterization section.

This single dose-response scaling factor is used to account for all of the factors listed above, as well as any others not yet identified. In the future, it may be possible to give specific attribution to particular influences such as the food matrix or the development of immunity. Because the dose-response scaling factor was selected to ensure that the dose-response model, combined with the exposure assessment, is consistent with available public health data, new information about initial *Listeria monocytogenes* contamination levels, growth rates, strain virulence, host susceptibility, or the annual number of reported cases would affect the magnitude of the scaling factor. A demonstration of this effect can be found in the hazard characterization section entitled 'Modeling: Outbreak Data."

Estimating Listeriosis Rates in Susceptible Subpopulations

FoodNet surveillance data from the CDC were used to help determine the relative susceptibility of sensitive subpopulations. Figure IV-5 shows listeriosis incidence by age using 1999 FoodNet data (CDC, 2000a) and Table IV-10 shows the number of listeriosis isolates by age and the total number of *Listeria monocytogenes* isolates per year from FoodNet from 1997 to 2000 (CDC, 1998a, 1999a, 2000a; Wong, 2000; Lay, 2001).

Mead *et al.* (1999), adjusting for underreporting, estimated that there were 2,493 cases including 499 deaths due to foodborne listeriosis using 1996-97 surveillance data and extrapolating to the 1997 total United States population. This estimate of the total foodborne illness was made by adjusting the number of reported cases to account for underreporting and estimating the proportion of illnesses specifically attributed to foodborne transmission. To calculate for underreporting (the difference between the number of reported cases and the number of cases that actually occur in the community), a multiplier of two was used based on the assumption that *Listeria monocytogenes* typically causes severe illness and one out of every two cases would come to medical attention. More information about FoodNet is available in Appendix 4.

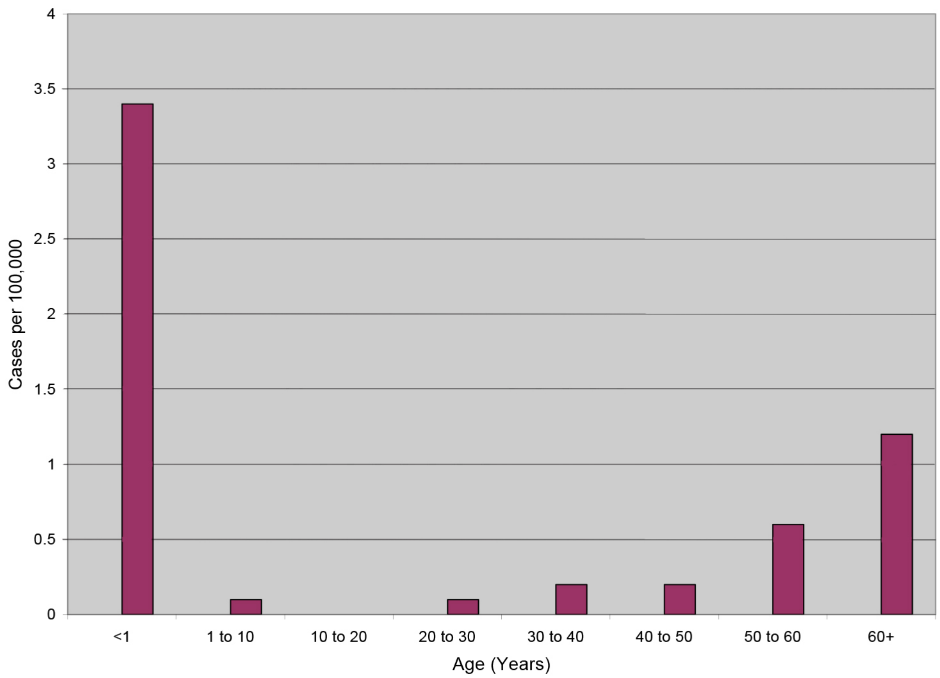


Figure IV-5. 1999 FoodNet Estimates of Listeriosis Incidence, by Age

Table IV-10. Number of *Listeria monocytogenes* Isolates by Patient Age and Year of Occurrence

Patient Age	Number of *Listeria monocytogenes* isolates			
	1997[a]	1998[b]	1999[c]	2000[d]
< 1 year old[e]	5	10	12	13
1 to 9 years old	2	1	3	2
10 to 19 years old	1	2	1	4
20 to 29 years old	3	6	5	2
30 to 39 years old	9	13	7	10
40 to 49 years old	6	6	8	8
50 to 59 years old	9	13	16	4
≥ 60 years old	42	61	48	62
Unknown age	0	0	14	0
Total	77	112	114	105

[a] CDC, 1998a (from five states).
[b] CDC, 1999a (from seven states).
[c] CDC, 2000a,d (from seven states) and Wong, 2000 (Unpublished data).
[d] Lay, 2001
[e] All of these cases were less than 30 days old.

Illness-Mortality Ratios

FoodNet data was used to estimate the numbers of serious illness relative to the number of deaths. The illness-mortality ratio was population specific (Table IV-11), and was used to estimate the number of serious illnesses (including deaths) in the Risk Characterization section. Because this conversion factor is applied after the final step in the modeling process, it affects the absolute number of listeriosis cases attributable to a given food category, but not the relative risk ranking of the food categories. The use of a conversion factor to estimate serious illness, rather than modeling illness as an endpoint is confounded by at least two recognized problems: 1) The steepness of the infectious dose-response curve in mice is much less than that for mortality so that the factor in humans may be different at various doses, and 2) if the variation in susceptibility among the three age-based groups is assumed to be different, the ratio of serious illness to mortality may also be different among these groups. Nevertheless, because the conversion factor used is based on surveillance data, it implicitly incorporates these and other uncertainties and reflects the overall relationship between serious illness and mortality across the entire dose range.

Table IV-11. Reported and National Annual Projections for Severe Listeriosis, Based of FoodNet Reports

Sub-Population	National Projected Annual[a]		FoodNet Reported 4-Year Total[b]		Illness: Mortality Ratio[c]
	Cases of Listeriosis[d]	Deaths	Cases of Listeriosis[d]	Deaths	
Neonatal	216	16[e]	38	3	12.7
Intermediate	702	67	113	10	11.3
Elderly	1159	307	194	52	3.7
TOTAL	**2078**	**390**	**345**	**65**	

[a]Adjusted cases and deaths for the total population (average of 4 years FoodNet data).
[b]Reported total cases and deaths for the FoodNet catchment areas (4 year total)
[c]The mortality: illness ratio is calculated using the reported cases and deaths in the FoodNet catchment area, i.e., deaths divided by cases.
[d] Serious cases of listeriosis requiring hospitalization.
[e] Perinatal deaths = 40. Deaths for the perinatal group are calculated by multiplying the death for neonatal by 2.5 to account for abortions and stillbirths not reported in FoodNet surveillance reports. See description of the neonatal dose-response curve below.

The estimates of cases of listeriosis and deaths shown in Table IV-11 are based on the average number of reported cases from CDC's FoodNet surveillance from 1997 to 2000. The projections are corrected for the percentage of the nation covered by FoodNet (6 to 11%) and include a factor of 2 to account for underreporting so that it is consistent with the CDC estimates.

Results: Dose-Response Curves for Three Population Groups

Intermediate-Age Dose-Response Curve

After applying the virulence distribution (Table IV-2) to the mouse dose-response mortality curve (Figure IV-2), the dose-response scaling factor is used to shift the curve towards higher doses necessary for lethality estimates similar to surveillance data. Figure IV-6 depicts the results of applying this factor to the intermediate-age subpopulation. It describes the dose required to produce death from a series of servings contaminated with different (or variable) *Listeria monocytogenes* strains. The range of values (indicated by the lower and upper bound lines) accounts for the uncertainty from three primary sources: 1) variation in the virulence of different strains; 2) uncertainty in the host susceptibility among individuals within this population; and 3) uncertainty in the exposure to *Listeria monocytogenes*.

An example of how the dose-response curve relates exposure to public health impact can be examined using Figure IV-6 as an example. By selecting a dose from the x-axis, an estimated death rate can be read off the y-axis. For example, at a dose of 1 x 10^{10} cfu/serving, the dose-response model predicts a median death rate of 1 in 769,231 servings. The uncertainty results in a lower bound prediction of 1 death in 40 trillion servings and an upper bound prediction of 1 in approximately 6,667 servings. Similar predictions can be made for any other dose. At higher predicted mortality rates, the number of bacteria necessary to attain that level of mortality is above the practical upper limit that would be encountered in foods. For example, doses greater than 10^9 to 10^{10} cfu/serving exceed the populations of *Listeria monocytogenes* attainable in food.

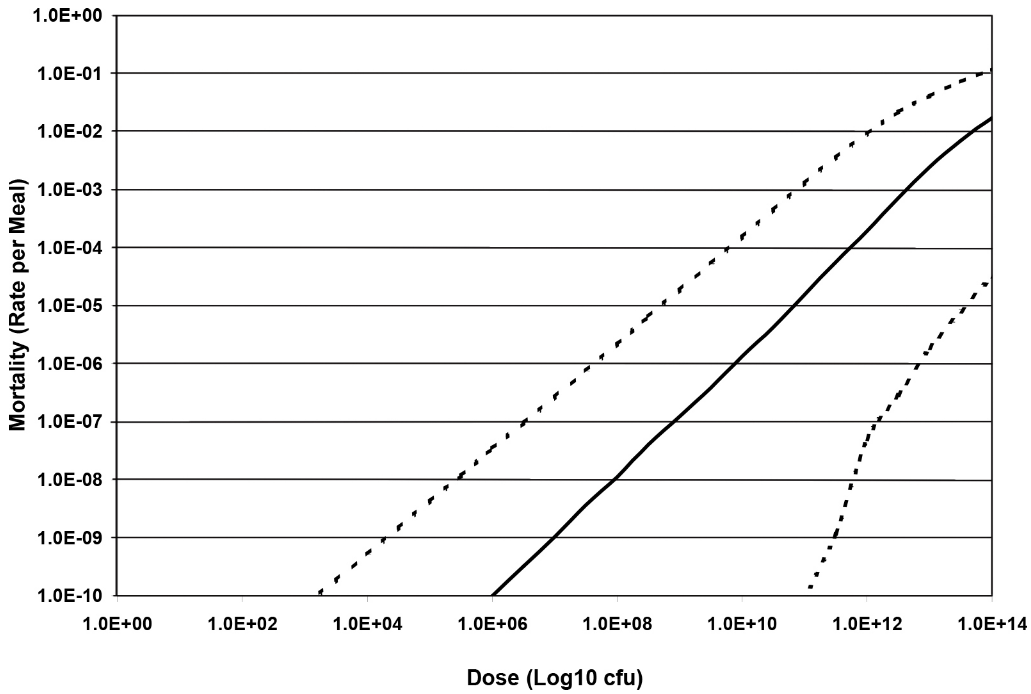


Figure IV-6. ***Listeria monocytogenes*** **Dose-Response for Mortality with Variable Strain Virulence for the Intermediate-Age Subpopulation**

Neonatal/Perinatal Dose-Response Curve

Figure IV-7 depicts the neonatal subpopulation dose-response curve. It describes the dose required to produce death from a series of servings, consumed maternally, that are contaminated with different (or variable) *Listeria monocytogenes* strains. The distribution (indicated by the lower and upper bound lines) accounts for the uncertainty from three primary sources: 1) variation in the virulence of different strains;
2) uncertainty in the host susceptibility among pregnant women; and 3) uncertainty in the exposure to *Listeria monocytogenes*.

By selecting a dose from the x-axis, the expected death rate can be read off the y-axis. For example, at a dose of 1 x 10^{10} cfu/serving, the dose-response model predicts a median death rate of 1 in 667 servings. However, the uncertainty introduced by the variability in virulence and in host susceptibility results in a lower bound prediction of 1 death in 303,030 servings and an upper bound prediction of 1 death in approximately 37 servings. Similar predictions can be made for any dose.

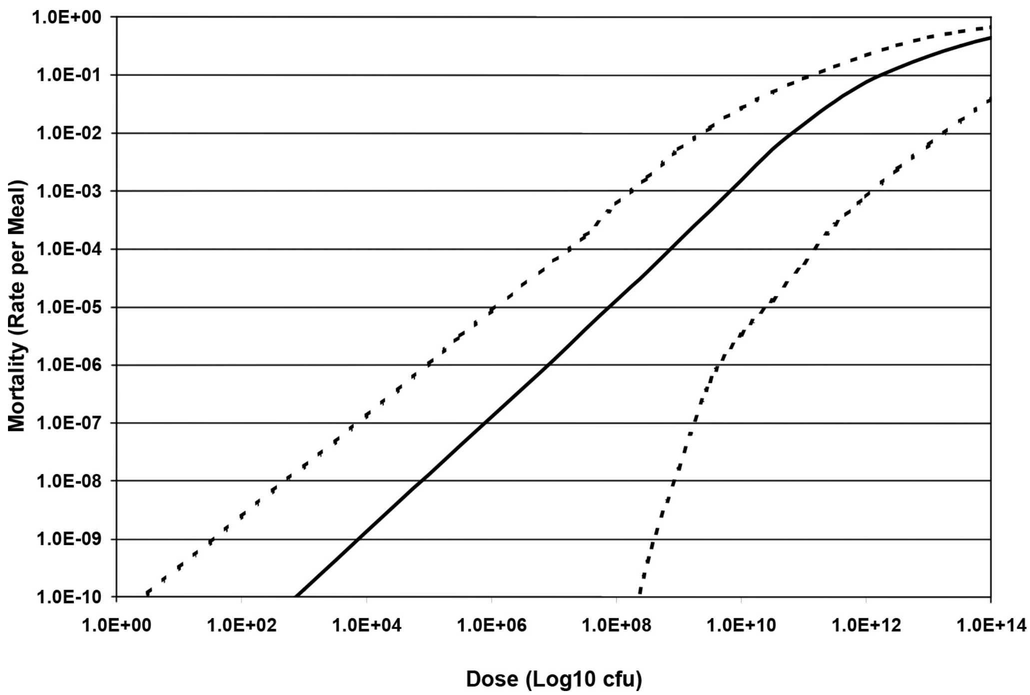


Figure IV-7. *Listeria monocytogenes* Dose-Response for Mortality with Variable Strain Virulence for the Neonatal Subpopulation

Data reported to FoodNet are the only national data available for estimating cases of neonatal infection and death but these data do not consistently record fetal deaths. To compensate for underreporting of death rates, data from the County of Los Angeles Department of Health Services mandatory listeriosis reporting system were used to estimate the proportion of prenatal infections that resulted in premature termination of pregnancy. These data provided detailed patient information concerning *Listeria monocytogenes* isolates from clinical laboratories indicating that the combined prenatal and neonatal deaths (perinatal deaths) were 2.5 times the neonatal deaths (Buchholz, 2000). Therefore, the number of perinatal deaths was calculated by multiplying the neonatal deaths by 2.5. [Note: The perinatal deaths include both prenatal and neonatal.] However, because non-lethal infections do not result in prenatal hospitalizations, this multiplier was not used to estimate the number of perinatal cases of listeriosis.

Elderly Dose-Response Curve

Figure IV-8 depicts the elderly subpopulation dose-response curve. It is intended to describe the dose (in colony forming units) required to produce death from a series of servings that are contaminated with different (or variable) *Listeria monocytogenes* strains. The range of values (indicated by the lower and upper bound lines) accounts for the uncertainty from three primary sources: 1) variation in the virulence of different strains; 2) uncertainty in the host susceptibility among individuals within this population; and 3) uncertainty in the exposure to *Listeria monocytogenes*.

By selecting a dose from the x-axis, the expected death rate can be read off the y-axis. For example, at a dose of 1 x 10^{10} cfu/serving, the dose-response model predicts a median death rate of 1 in 25,641 servings. However, the uncertainty results in a lower bound prediction of 1 death in 1.7 billion servings and an upper bound prediction of 1 death in approximately 588 servings.

Table IV-12 provides a summary of the data presented in the preceding figures for the intermediate-aged, neonatal, and elderly subpopulations. The death rate per serving is presented as the median and the upper (95^{th}) and lower (5^{th}) boundaries of the uncertainty. The data in Table IV-12 show a 20-fold decrease in the dose necessary to cause death from listeriosis for the elderly subpopulation compared to the intermediate-aged population. The intermediate-aged population does contain individuals with immunocompromising diseases or treatments. The neonatal population is approximately 10,000-fold more sensitive than the intermediate-aged population.

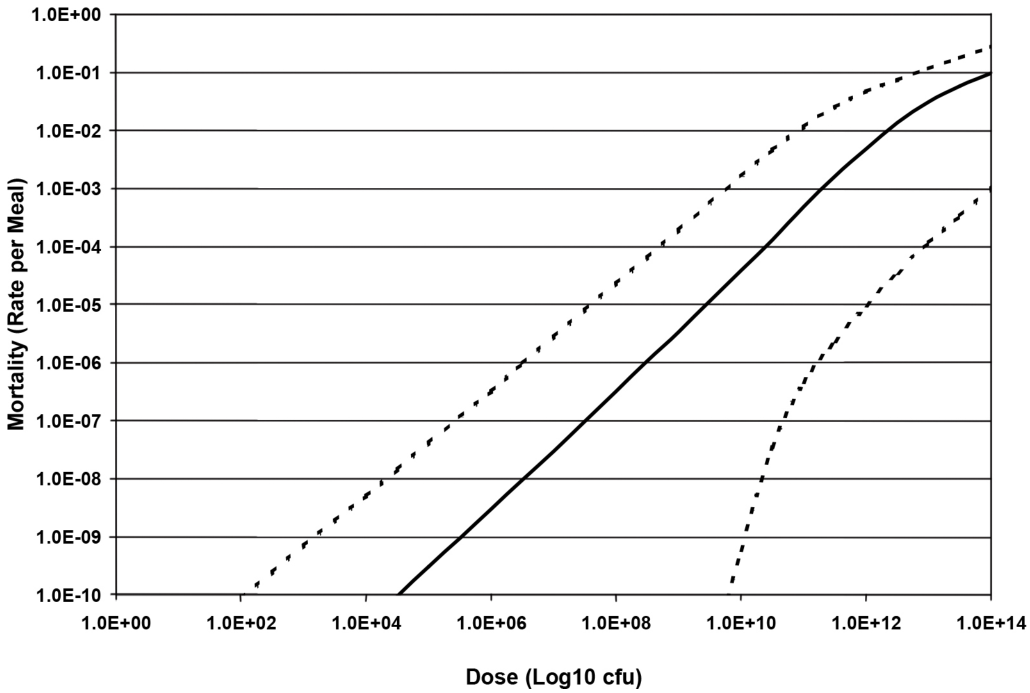


Figure IV-8. *Listeria monocytogenes* Dose-Response for Mortality with Variable Strain Virulence for the Elderly

Table IV-12. Dose-Response with Variable *Listeria monocytogenes* Strain Virulence for Three Age-Based Subpopulations

	Median Mortality Rate per Serving[a]		
Dose (cfu/serving)	**Intermediate-Age**	**Neonatal[b]**	**Elderly**
1	$1.5x10^{-16}$ ($1.2x10^{-146}$, $1.9x10^{-13}$)	$1.6x10^{-13}$ ($1.2x10^{-99}$, $4.0x10^{-11}$)	$4.0x10^{-15}$ ($6.3x10^{-124}$, $1.8x10^{-12}$)
10^3	$1.2x10^{-13}$ ($5.4x10^{-92}$, $6.8x10^{-11}$)	$1.3x10^{-10}$ ($4.3x10^{-56}$, $1.7x10^{-8}$)	$3.6x10^{-12}$ ($2.2x10^{-74}$, $7.2x10^{-10}$)
10^6	$1.0x10^{-10}$ ($1.9x10^{-50}$, $3.5x10^{-8}$)	$1.3x10^{-7}$ ($1.2x10^{-25}$, $8.6x10^{-6}$)	$3.1x10^{-9}$ ($5.7x10^{-38}$, $3.3x10^{-7}$)
10^9	$1.2x10^{-7}$ ($6.0x10^{-22}$, $1.9x10^{-5}$)	$1.4x10^{-4}$ ($1.6x10^{-8}$, $5.1x10^{-3}$)	$3.4x10^{-6}$ ($1.3x10^{-14}$, $1.9x10^{-4}$)
10^{10}	$1.3x10^{-6}$ ($2.5x10^{-15}$, $1.5x10^{-4}$)[c]	$1.5x10^{-3}$ ($3.3x10^{-6}$, $2.7x10^{-2}$)	$3.9x10^{-5}$ ($6.0x10^{-10}$, $1.7x10^{-3}$)
10^{12}	$1.9x10^{-4}$ ($4.9x10^{-8}$, $9.2x10^{-3}$)	$7.4x10^{-2}$ ($7.8x10^{-4}$, $2.2x10^{-1}$)	$4.9x10^{-3}$ ($9.8x10^{-6}$, $4.8x10^{-2}$)

[a] The 5^{th} and 95^{th} percentiles from the uncertainty are in parenthesis.
[b] An adjustment to account for total perinatal deaths (prenatal and neonatal) is in the risk characterization section.
[c]The median mortality rate per serving of $1.3x10^{-6}$ for the intermediate-age subpopulation at the 10^{10} cfu/serving dose level, corresponds to 1 death in approximately 769,231 servings ($1/1.3x10^{-6}$).

Dose-Response for an Epidemic with an Unknown Strain

Figure IV-9 represents the dose-response relationship for an epidemic with a single strain of unknown virulence. This simulation treated the strain virulence as a source of uncertainty, rather than as a source of variability that contributed to the rate. This is because a single strain has a single virulence rate (therefore, no variation); however, it is not known what that the actual rate is (therefore, there is uncertainty). As a result the slope is somewhat steeper and the uncertainty bounds wider (i.e., compared to Figure IV-7).

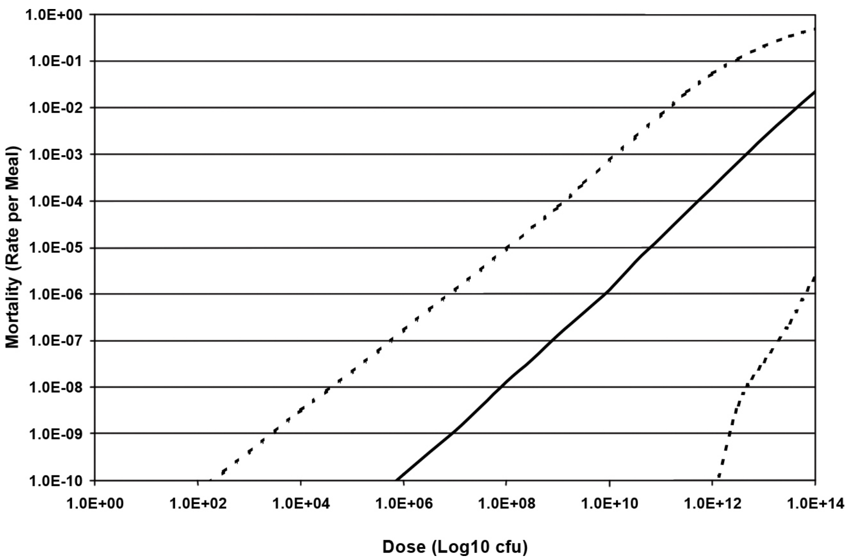


Figure IV-9. Dose Frequency Function for Elderly Population with a Single Strain of Unknown Virulence

V. RISK CHARACTERIZATION

Risk characterization integrates information and data acquired during the hazard identification, hazard characterization, and exposure assessment into an estimate of the adverse effects likely to occur in a given population. In this risk assessment, the risk characterization links the probability of exposure to *Listeria monocytogenes* from consumption of foods with the adverse health outcomes. The primary focus is on the prediction of the relative probability of contracting listeriosis from consumption of a single serving of food in one of the 23 food categories. Additional predictions also consider the extent of annual consumption of the various foods and the predicted contribution of each of the individual food categories to the number of listeriosis cases nationally.

This risk assessment is based on contaminated foods at the retail level. The risk characterization of the overall burden of listeriosis on public health includes both sporadic (i.e., illnesses not associated with a documented outbreak) and outbreak illnesses. Illnesses attributed to documented outbreaks are a small proportion of the total estimated annual cases of listeriosis. At this time it is not possible to separate the risk attributable to specific foods to sporadic and outbreak cases. Outbreaks frequently represent a breakdown in food production, manufacturing, or distribution systems instituted to prevent *Listeria monocytogenes* contamination. Assessing the likelihood that these systems will fail requires detailed information about the manufacture of individual foods that is beyond the scope of this assessment. However, an important benefit of conducting a risk assessment is the identification of knowledge and data gaps. Continuing research is needed to facilitate future *Listeria monocytogenes* risk assessment work (see Appendix 11: Reseach Needs).

Simulation Modeling

The model is comprised of two major components—exposure and dose-response. These models are integrated for the risk characterization simulations as shown in Figure V-1.

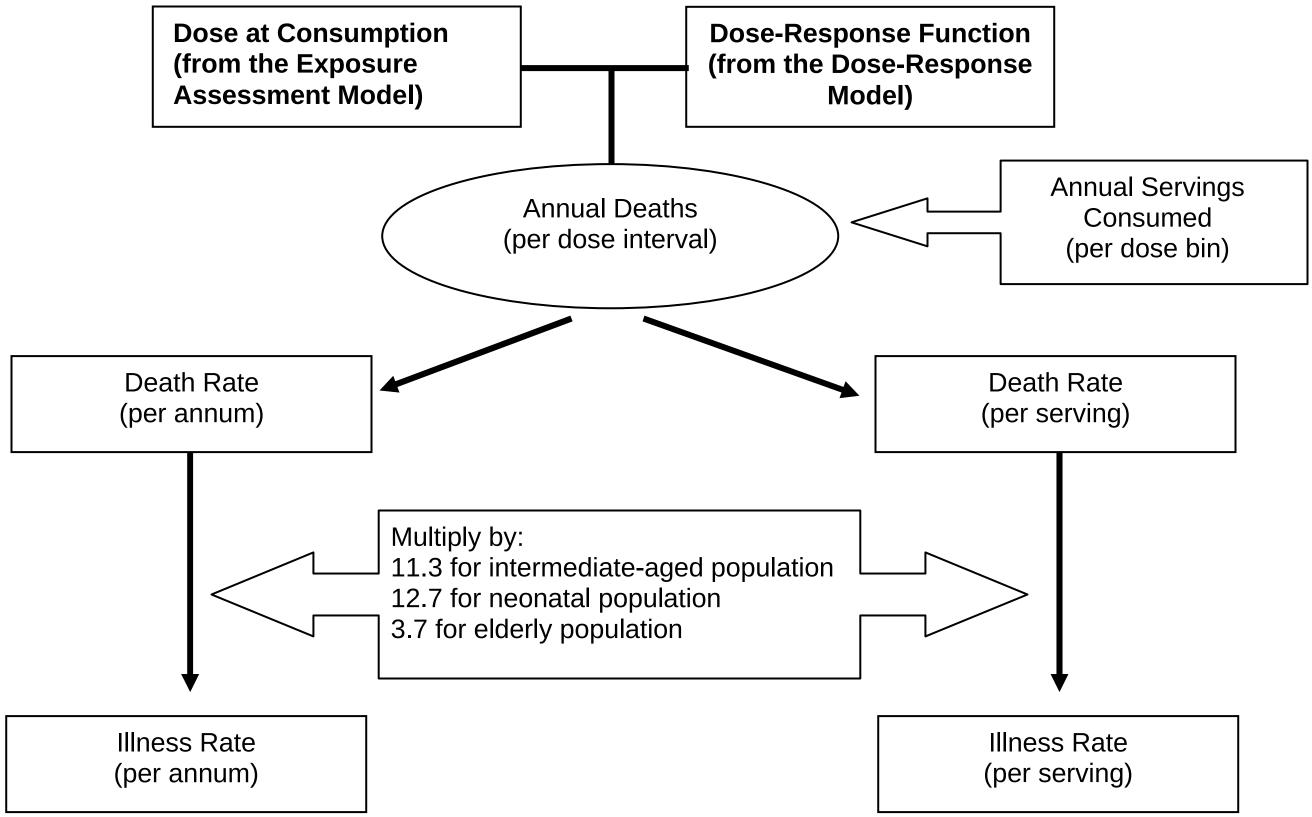


Figure V-1. Components of the Risk Characterization Model

A separate exposure simulation was constructed for each food category. Results from all the food categories were then carried forward to the dose-response simulations, where a separate simulation was constructed for each of the three subpopulation groups. Details of the various modeling steps are provided in Appendix 3.

The exposure assessment modeled the effect of various factors (e.g., frequency and extent of contamination at retail, consumption patterns, the growth potential of *Listeria monocytogenes* in foods, length of refrigerated storage, and refrigeration temperatures) that might affect levels of *Listeria monocytogenes* contamination in a food at the time of consumption. For the exposure assessment, a two-dimensional Monte-Carlo simulation (100,000 variability and 300 uncertainty iterations; total of 30,000,000 iterations) was used to integrate the components of the exposure model for each of the food categories. The result of each exposure simulation is the fraction of servings that occur at designated dose levels (broken out into half-$\log_{10}$ intervals), which are referred to as dose bins. The conversion to dose bins was necessary in order to integrate the exposure simulation, (which evaluated the exposure from individual servings) with the dose-response model (which predicted the number of cases at a population level). The exposure simulations produce 300 distributions (sets of dose bins) of predicted doses for each food category.

The dose-response simulation was carried out in several steps. First, the two-dimensional Monte-Carlo simulation (100,000 variability and 300 uncertainty iterations) was used to integrate the variability and uncertainty of the strain-virulence and host susceptibility functions for each of the subpopulations to provide dose-adjustment factors. The variability dimension for these combined dose-adjustment factors were then grouped into half-$\log_{10}$ bins, which ranged from -5 to +10 logs. Second, a one-dimensional (4,000 uncertainty iterations) dose-response simulation was run for each food category by selecting one of the 300 sets of dose bins from the exposure assessment.

These two sets of distributions (exposure dose bins for each food category and dose-response scaling factors for each subpopulation) consist of a relatively small set of finite values and were combined algebraically by adding the arrays. Although some resolution was lost through the creation of the bins for the distribution, avoidance of the use of random numbers provides greater precision at the tails of the summed distribution. In order to calculate the annual rates of cases of listeriosis, the number of deaths per year were multiplied by factors of 11.3 for intermediate-aged population, 12.7 for neonatal, and 3.7 for the elderly population. To calculate the number of perinatal deaths per year, the neonatal death estimate was multiplied by a factor of 2.5. The 2.5 is the approximate ratio of perinatal (106) to neonatal (41) deaths from the County of Los Angeles Department of Health Services (Buchholz, 2000).

The dose-response scaling factor was adjusted so that the sum of the dose-response function (derived from the mouse model) times the exposure assessment doses equaled the CDC estimates for the annual number of cases of listeriosis. This procedure anchors the overall predicted incidence of listeriosis with the actual incidence of listeriosis. An implicit assumption is that the foods encompassed by the 23 food categories account for all cases of foodborne listeriosis.

The medians of the 4,000 iterations of predicted deaths (per serving) for each food category and each subpopulation were reported. These predictions were ranked from highest to lowest. Because of the variability incorporated into the model (i.e., from differences in consumption of the foods in each categories, pathogen virulence, host susceptibility, and inherent uncertainty), the predicted relative ranking of food categories changes with each of the 4,000 iterations (in some cases significantly). To illustrate the degree of uncertainty associated with the relative risk ranking, the results of each set of the 4,000 iterations was ranked and compared. To this end, the ranking of each food category from 1st to 23rd was determined for each set of the 4,000 uncertainty iterations. The number of times each food category was observed to be ranked at each specific position was determined. These data were compiled and presented graphically (see the latitude graphs, Figures V-4a to V-26b in the section below titled "Summaries of the Food Categories").

For a more detailed explanation of two-dimensional Monte-Carlo and the dose-binning process, see Appendix 3.

Results

The results of this risk assessment, the predicted relative risks of listeriosis associated with each food category, are presented first as an initial overview followed by a more detailed consideration of the individual food categories. The individual food category discussions further interpret the meaning and significance of the analyses in relation to the goal of the risk assessment, as well as discuss factors contributing to the variability and uncertainty associated with the predictions.

A significant difference between the FDA/FSIS risk assessment (the 2001 draft and this revised version) approach and prior attempts to evaluate the risks associated with ready-to-eat foods is the complexity of factors considered in the hazard characterization (Lindquist and Westöö, 2000, Buchanan *et al*., 1997; Farber *et al*., 1996; Haas *et al*., 1999; Hitchins, 1995 and 1996; and Teufel and Bendzulla, 1993). In addition to establishing a general dose-response relation, models were developed for three distinct age-based subpopulations and for assessing the full range of virulence potential that is likely to occur among *Listeria monocytogenes* isolates. It also emphasizes the fact that most exposures to *Listeria monocytogenes* seldom lead to listeriosis, even among highly susceptible segments of the population.

Medians (the value with 50% of the values above and 50% of the values below) are used to represent the "expected" (central tendency) of the estimated risk values. We used medians rather than means because the distributions have long "tails" (high uncertainty and skewed distributions). Medians are less influenced by these extreme values in the distribution but still allow us to represent the central tendency of the distribution with a single value. For other purposes, such as summing the food categories or additional calculations, the mean values are provided in Appendix 10.

<u>Risk Per Serving</u>

A key value used to assess the predicted relative risk among the 23 food categories is the "per serving" likelihood that consumption of a food will lead to listeriosis. This can be viewed as the risk that individual consumers face when they eat a serving of a food. The risk assessment results indicate that listeriosis could potentially be caused by foods in any of the food categories; that is, no food category is risk-free because almost any food could become contaminated with *Listeria monocytogenes.* It is equally apparent that there are substantial differences in risk among the different food categories.

As anticipated from the review of the scientific literature that was conducted in conjunction with this risk assessment, five factors have a large influence on the results of the exposure assessment and thus, the characterization of the predicted relative risk. These factors include the following.

- Frequency and extent of *Listeria monocytogenes* in the food
- Amounts and frequency of food consumption
- Potential for growth of *Listeria monocytogenes* in food during refrigerated storage
- Duration of refrigerated storage before consumption
- Temperature at which the food was held during refrigerated storage

Any of these factors alone affects the potential contamination level at consumption. Those food categories in which one or more of these factors produce a greater risk of exposure to higher levels of *Listeria monocytogenes* contamination are more likely to increase consumers' risk of listeriosis. Examination of the food categories shows that certain factors may have a larger role in driving the predictions of higher risk. Food categories that contained foods that have a high growth potential, based on moderate or high growth rates, coupled with moderate or long storage times, were often the categories that had higher predicted relative risk values. These results have to be interpreted being cognizant of the fact that data on actual consumer storage practices were generally not available, so storage times were estimated based on expert judgment and USDA recommended practices. It is likely that the actual consumer storage times of food are longer than USDA recommendations.

As previously indicated in the description of the exposure assessment, other assumptions related to factors that could affect the frequency or extent of contamination could have a significant impact on the predicted relative risk per serving associated with individual food categories. These, in turn, could affect the predicted relative risk rankings of other food categories. For example, during manufacturing frankfurters are fully cooked to temperatures that are lethal for *Listeria monocytogenes.* However, subsequent recontamination prior to packaging may occur followed by growth of the pathogen. Although frankfurters are usually reheated prior to consumption, a portion of the population consumes them without reheating. To estimate the proportion of frankfurters consumed unreheated, a triangular distribution was used with a minimum of 4%, most likely of 7% and maximum of 10%. The impact of these types of assumptions on the predicted relative risk is considered in the discussion of the individual food categories.

Predicted Cases of Listeriosis per Serving. The results are summarized in Table V-1 as the median number of cases of listeriosis per serving for each of the three age-based subpopulations and the total United States population. Figure V-2 also shows the differential in median predicted risk per serving (the median values on a log scale are represented in the graph as a box) for the total United States population. The figure illustrates the point that elimination of *Listeria monocytogenes* from any single food will not eliminate foodborne listeriosis; control of listeriosis will require consideration of a variety of foods. However, some foods represent a substantially greater risk per serving and are likely to warrant additional attention from industry and regulators.

In addition to the median values, the 5th and 95th percentile values were also calculated for each of the subpopulations and the total United States population (Table V-1). These lower and upper bound values provide a method of estimating the uncertainty associated with the predictions. Figure V-2 shows these lower and upper bounds for the total United States population. In order to more easily present the data in a graph, the cases of listeriosis for each of the food categories is presented in Figure V-2 on a log scale. It is apparent that for some foods, the range covered was substantial. This was largely the result of exposure distributions where either a small percentage of the foods were predicted to have elevated levels of the pathogen or a high degree of uncertainty had to be assumed due to limitations in available data. The predicted relative risk values must be evaluated in relation to observed variability and uncertainty when using them to determine the best course of action for each of the different food categories. This interpretation of the results is discussed in greater depth for each of the individual food categories later in this chapter.

Table V-1. Estimated Number of Cases of Listeriosis per Serving for Each Food Category and Subpopulation

Food Category	Number of Cases of Listeriosis per Serving[a]											
	Intermediate-Age [b]			Elderly			Perinatal[c]			Total		
	Percentiles			Percentiles			Percentiles			Percentiles		
	Median	5th	95th	Median	5th	95th	Median	5th	95th	Median	5th	95th
SEAFOOD												
Smoked Seafood	2.1×10^{-9}	8.8×10^{-11}	1.2×10^{-7}	1.9×10^{-8}	9.7×10^{-10}	1.0×10^{-6}	8.4×10^{-7}	4.3×10^{-8}	4.6×10^{-5}	6.2×10^{-9}	3.0×10^{-10}	3.3×10^{-7}
Raw Seafood	1.3×10^{-11}	1.1×10^{-17}	2.9×10^{-10}	1.3×10^{-10}	1.7×10^{-14}	2.9×10^{-9}	6.7×10^{-9}	7.4×10^{-12}	2.0×10^{-7}	2.0×10^{-11}	7.4×10^{-15}	4.6×10^{-10}
Preserved Fish	6.4×10^{-12}	5.5×10^{-20}	2.6×10^{-9}	6.7×10^{-11}	3.9×10^{-17}	2.2×10^{-8}	4.1×10^{-9}	2.1×10^{-14}	9.9×10^{-7}	2.3×10^{-11}	6.9×10^{-17}	7.5×10^{-9}
Cooked RTE Crustaceans	2.2×10^{-9}	2.5×10^{-10}	2.1×10^{-8}	1.9×10^{-8}	2.4×10^{-9}	1.6×10^{-7}	7.4×10^{-7}	9.7×10^{-8}	6.1×10^{-6}	5.1×10^{-9}	6.5×10^{-10}	4.6×10^{-8}
PRODUCE												
Vegetables	8.4×10^{-13}	1.5×10^{-19}	6.3×10^{-11}	8.2×10^{-12}	3.7×10^{-16}	5.7×10^{-10}	4.8×10^{-10}	1.4×10^{-13}	3.1×10^{-8}	2.8×10^{-12}	2.8×10^{-16}	1.9×10^{-10}
Fruits	5.0×10^{-12}	6.0×10^{-20}	9.6×10^{-9}	5.1×10^{-11}	5.3×10^{-17}	5.7×10^{-8}	2.8×10^{-9}	1.3×10^{-14}	3.0×10^{-6}	1.9×10^{-11}	4.5×10^{-17}	2.3×10^{-8}
DAIRY												
Fresh Soft Cheese	1.2×10^{-10}	4.6×10^{-13}	2.1×10^{-9}	1.0×10^{-9}	5.0×10^{-12}	1.7×10^{-8}	4.2×10^{-8}	2.6×10^{-10}	7.0×10^{-7}	1.7×10^{-10}	8.0×10^{-13}	2.9×10^{-9}
Soft Unripened Cheese	5.8×10^{-10}	8.4×10^{-14}	1.6×10^{-8}	4.9×10^{-9}	7.2×10^{-13}	1.2×10^{-7}	2.0×10^{-7}	4.8×10^{-11}	5.3×10^{-6}	1.8×10^{-9}	2.8×10^{-13}	4.4×10^{-8}
Soft Ripened Cheese	2.1×10^{-12}	1.8×10^{-21}	1.3×10^{-9}	2.2×10^{-11}	3.3×10^{-18}	1.1×10^{-8}	1.3×10^{-9}	3.5×10^{-15}	5.2×10^{-7}	5.1×10^{-12}	7.9×10^{-18}	2.6×10^{-9}
Semi-soft Cheese	2.9×10^{-12}	9.3×10^{-17}	2.9×10^{-10}	3.0×10^{-11}	5.5×10^{-15}	2.7×10^{-9}	1.6×10^{-9}	9.2×10^{-13}	1.4×10^{-7}	6.5×10^{-12}	2.5×10^{-15}	5.8×10^{-10}
Hard Cheese	3.4×10^{-15}	5.3×10^{-47}	1.9×10^{-12}	9.2×10^{-15}	5.8×10^{-39}	1.9×10^{-11}	8.1×10^{-13}	3.4×10^{-32}	1.3×10^{-9}	4.5×10^{-15}	2.5×10^{-35}	5.5×10^{-12}
Processed Cheese	1.4×10^{-14}	3.2×10^{-30}	2.3×10^{-12}	9.3×10^{-14}	8.8×10^{-25}	2.2×10^{-11}	6.7×10^{-12}	6.6×10^{-20}	1.4×10^{-9}	4.2×10^{-14}	5.4×10^{-23}	6.0×10^{-12}
Pasteurized Fluid Milk	4.4×10^{-10}	2.8×10^{-11}	5.7×10^{-9}	3.4×10^{-9}	2.5×10^{-10}	3.9×10^{-8}	1.5×10^{-7}	1.2×10^{-8}	1.7×10^{-6}	1.0×10^{-9}	7.5×10^{-11}	1.3×10^{-8}
Unpasteurized Fluid Milk	2.9×10^{-9}	3.5×10^{-11}	6.8×10^{-8}	2.2×10^{-8}	3.4×10^{-10}	5.1×10^{-7}	9.9×10^{-7}	1.7×10^{-8}	2.3×10^{-5}	7.1×10^{-9}	9.7×10^{-11}	1.6×10^{-7}
Ice Cream/Frozen Dairy Products	1.3×10^{-14}	2.7×10^{-35}	1.8×10^{-12}	9.2×10^{-14}	1.4×10^{-28}	1.9×10^{-11}	6.5×10^{-12}	2.7×10^{-23}	1.3×10^{-9}	4.9×10^{-14}	1.7×10^{-26}	6.3×10^{-12}
Cultured Milk Products	9.5×10^{-15}	2.4×10^{-40}	1.7×10^{-11}	5.6×10^{-14}	6.5×10^{-33}	1.7×10^{-10}	4.7×10^{-12}	5.1×10^{-26}	9.9×10^{-9}	3.2×10^{-14}	3.3×10^{-29}	4.9×10^{-11}
High Fat and Other Dairy Products	1.0×10^{-9}	1.0×10^{-10}	8.2×10^{-9}	8.3×10^{-9}	8.9×10^{-10}	5.7×10^{-8}	3.2×10^{-7}	3.7×10^{-8}	2.0×10^{-6}	2.7×10^{-9}	2.9×10^{-10}	1.9×10^{-8}
MEATS												
Frankfurters (reheated)	2.7×10^{-11}	4.2×10^{-15}	3.4×10^{-10}	2.7×10^{-10}	8.6×10^{-13}	3.4×10^{-9}	1.6×10^{-8}	2.1×10^{-10}	2.6×10^{-7}	6.3×10^{-11}	2.7×10^{-13}	8.0×10^{-10}
Frankfurters (not reheated)	3.3×10^{-8}	3.1×10^{-9}	2.8×10^{-7}	2.9×10^{-7}	3.2×10^{-8}	2.3×10^{-6}	1.1×10^{-5}	1.3×10^{-6}	8.3×10^{-5}	6.5×10^{-8}	7.1×10^{-9}	5.2×10^{-7}
Dry/Semi-Dry Fermented Sausages	6.0×10^{-12}	6.8×10^{-20}	2.7×10^{-9}	6.2×10^{-11}	2.0×10^{-16}	2.4×10^{-8}	3.7×10^{-9}	5.1×10^{-14}	1.1×10^{-6}	1.7×10^{-11}	1.5×10^{-16}	6.3×10^{-9}
Deli Meats	3.3×10^{-8}	6.8×10^{-9}	4.1×10^{-8}	3.0×10^{-7}	5.8×10^{-8}	3.9×10^{-7}	1.2×10^{-5}	3.2×10^{-6}	1.4×10^{-5}	7.7×10^{-8}	1.7×10^{-8}	9.9×10^{-8}
Pâté and Meat Spreads	1.2×10^{-8}	1.0×10^{-9}	1.4×10^{-7}	1.1×10^{-7}	1.1×10^{-8}	1.1×10^{-6}	4.5×10^{-6}	4.7×10^{-7}	4.5×10^{-5}	3.2×10^{-8}	3.1×10^{-9}	3.3×10^{-7}
COMBINATION FOODS												
Deli-type Salads	1.7×10^{-13}	1.8×10^{-31}	1.3×10^{-10}	1.4×10^{-12}	3.3×10^{-25}	1.2×10^{-9}	8.8×10^{-11}	9.3×10^{-20}	5.5×10^{-8}	5.6×10^{-13}	8.0×10^{-23}	4.1×10^{-10}

[a]This table provides estimates of the rate of listeriosis per serving and the confidence intervals about that estimate. For example, for the perinatal group in the Smoked Seafood category, the risk assessment estimates that there is only a 5% probability that the rate of listeriosis is less than 4.3×10^{-8} and a 95% probability that it is less than 4.6×10^{-5} (or a 5% probability that it is greater). The median risk estimate has a 50% probability of being greater or smaller than the rate of listeriosis. [b]The Intermediate-age population includes susceptible populations not captured in the other groups, such as cancer, AIDS, and transplant patients, for whom there are insufficient data to consider as a separate population. [c]The Perinatal population is a susceptible population that includes fetuses and neonates. Exposure occurs *in utero* from contaminated food eaten by the pregnant woman. The predicted cases are predominately neonatal, therefore to estimate the perinatal cases presented in this table, an exposure period of 10 days was used. The value of 10 approximately corresponds to the mean of the triangle distribution (1, 7, 30) used in the simulation.

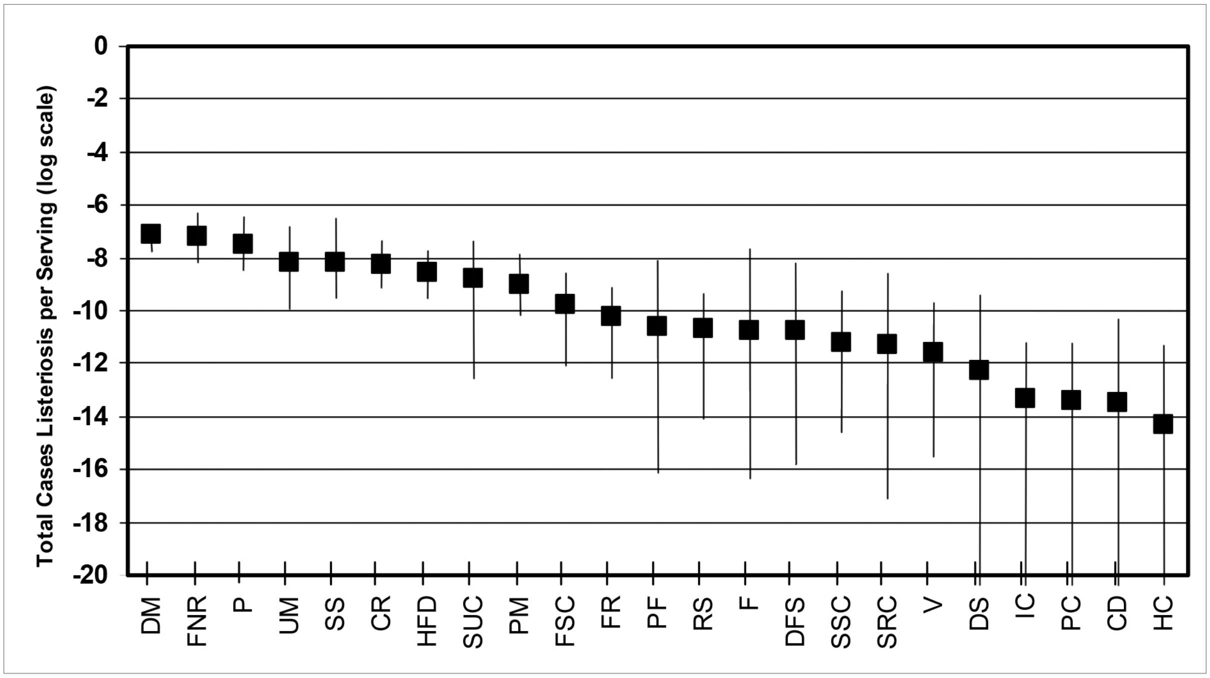


Figure V-2. Predicted Cases of Listeriosis (log scale) Associated with Food Categories for the Total United States Population on a per Serving Basis

[The box indicates the median predicted number of cases of listeriosis (log scale) and the bar indicates the lower and upper bounds (i.e., the 5^{th} and 95^{th} percentiles). The y-axis values are presented on a log scale. For example a log of –6 is equivalent to 1 in a million.]

DM = Deli meats; FNR = Frankfurters (not reheated); P= Pâté and Meat Spreads; UM= Unpasteurized Fluid Milk; SS= Smoked Seafood; CR = Cooked Ready-To-Eat Crustaceans; HFD = High Fat and Other Dairy Products; SUC = Soft Unripened Cheese; PM = Pasteurized Fluid Milk; FSC = Fresh Soft Cheese; FR = Frankfurters (reheated); PF = Preserved Fish; RS = Raw Seafood; F = Fruits; DFS= Dry/Semi-dry Fermented Sausages; SSC = Semi-soft Cheese; SRC = Soft Ripened Cheese; V = Vegetables; DS = Deli-type Salads; IC= Ice Cream and Frozen Dairy Products; PC = Processed Cheese; CD = Cultured Milk Products; HC = Hard Cheese.

<u>Predicted Risk Ranking</u>. The predicted median values for the cases of listeriosis on a per serving basis were used to develop predicted relative risk ranks. The median predicted relative risk ranking among the different food categories is summarized for the three subpopulations and the total United States population in Table V-2. It is apparent that the predicted relative risk rankings of the food categories are similar for the three subpopulations, but not identical.

The uncertainty associated with the risk ranking is described in the latitude ranking graphs that are presented as part of the discussion of each of the individual food categories (see Figures V-4a to V-26b). It is important to note that in a number of instances there are only minor differences separating the rankings of various food categories.

Although the number of iterations in the ranking process was very high (4,000), analysis of variance techniques were used to provide an indication of the statistical certainty of the rankings. Nonparametric analysis of variance technique (i.e. Kruskal-Wallis Test), followed by a multiple comparison procedure, was used to evaluate the differences in the median rankings of risk per serving for the total United States population. The analyses were performed using NCSS (NCSS, 2001) to determine which of the median rankings were not significantly different based on the number of simulation samples (iterations) and an alpha level of 0.05 for the family-wide error rate with respect to all pairwise comparisons of the 23 food categories. The results are shown in Table V-2.

Table V-2. Predicted Relative Risk Rankings for Listeriosis Among Food Categories for Three Age-Based Subpopulations and the United States Total Population Using Median Estimates of Predicted Relative Risks for Listeriosis on a per Serving Basis

Food Categories[a]	Subpopulation			
	Intermediate Age[b]	Elderly[b]	Perinatal[b]	Total [b, c]
SEAFOOD				
Smoked Seafood	6	5	5	5b
Raw Seafood	12	12	12	13d
Preserved Fish	13	13	13	12d,e
Cooked Ready-to-Eat Crustaceans	5	6	6	6b
PRODUCE				
Vegetables	18	18	18	18
Fruits	15	15	15	14e
DAIRY				
Fresh Soft Cheese	10	10	10	10
Soft Unripened Cheese, >50% moisture	8	8	8	8c
Soft Ripened Cheese, >50% moisture	17	17	17	17f
Semi-soft Cheese, 39-50% moisture	16	16	16	16f
Hard Cheese, <39% moisture	23	23	23	23
Processed Cheese	20	20	20	21g
Pasteurized Fluid Milk	9	9	9	9c
Unpasteurized Fluid Milk	4	4	4	4b
Ice Cream and Frozen Dairy Products	21	21	21	20g
Cultured Milk Products	22	22	22	22g
High Fat and Other Dairy Products	7	7	7	7
MEATS				
Frankfurters, reheated	11	11	11	11
Frankfurters, not reheated	2	2	2	2a
Dry/Semi-Dry Fermented Sausages	14	14	14	15d
Deli Meats	1	1	1	1a
Pâté and Meat Spreads	3	3	3	3
COMBINATION FOODS				
Deli-type Salads	19	19	19	19

[a] Food categories are grouped by type of food but are not in any particular order.
[b] A ranking of 1 indicates the food category with the greatest predicted relative risk per serving of causing listeriosis and a ranking of 23 indicates the lowest predicted relative risk of causing listeriosis.
[c] Ranks with the same letter are not significantly different based on the Bonferroni Multiple Comparison Test (alpha = 0.05).

Risk per Annum

A full picture of listeriosis risk requires consideration of the number of servings consumed, as well as the risk per serving. These data were considered for each of the food categories and used to calculate the predicted cases of listeriosis on a per annum basis. If the "risk per serving" is considered the predicted relative risk faced by each consumer, then the "risk per annum" is a measure of the predicted relative risk faced by the country. The risk per annum is greatly affected by the number of servings per year. Thus, a food that has a relatively high risk on a per serving basis but is seldom consumed may have a relatively low per annum risk. Conversely, a food with a relatively low risk on a per serving basis that is consumed extensively is likely to have a higher risk on a per annum basis. Table III-2 shows the wide range in number of annual servings among the food categories. The per annum relative risks inherently have a greater degree of uncertainty than the corresponding per serving relative risk because of the additional uncertainty associated with the number of annual servings. Another factor that affects predicted relative risk on a per annum basis is the size of the subpopulations, in proportion to the total population. They are substantially different, i.e., perinatal, elderly, and intermediate-age groups, represent approximately 2%, 13%, and 85% of the total population, respectively.

The results were generated in a manner similar to that described above for the predicted relative risk per serving. Table V-3 provides the predicted median number of cases of listeriosis on a per annum basis for each of the age-based populations. The upper and lower bounds (5th and 95th percentile values) are also provided in Table V-3 to show the range of variability and uncertainty of the estimates. The range in the predicted number of cases of listeriosis is depicted in Figure V-3 for the total United States population.

The predicted relative risk ranking is presented in Table V-4. The uncertainty associated with the ranking is also described using individual latitude ranking graphs based on the rankings for the total United States population (see Figures V-4a to V-26b). These graphs are provided in the discussions of individual food categories. It is important to note that the differences among several of the food categories were very small, so differences between adjacent or closely occurring ranks must only be considered in conjunction with the estimates of uncertainty which are provided as part of the discussion of the individual food categories.

In most instances, the food categories that had high predicted relative risk rankings on a per serving basis also had a high predicted relative risk ranking on a per annum basis. However, there were instances where foods with lower risk per serving rankings had higher risk per annum values and vice versa. For example, Pâté and Meat Spreads had a higher predicted relative risk on a per serving basis than on a per annum basis. This reflects the fact that foods in this category are eaten relatively infrequently and in relatively small amounts. Conversely, Vegetables and Pasteurized Fluid Milk are products where a predicted low or moderate per serving relative risk was elevated on a per annum basis. In these examples, this appears to be a function of two factors. The first is the variability in the data sets available on a worldwide basis (see discussion of individual foods in the section titled "Overview and Discussion of Food Categories"). A wide degree of variability increases the number of predicted exposure values in the "tails" of the distribution. To a large extent, it is these extremes of the distributions that determine the per annum risk. The second is that the numbers of servings consumed annually for Vegetables and Pasteurized Fluid Milk are several orders of magnitude higher than other food categories. Again, this strongly influences the per annum predicted relative ranking for these foods. With both of these food categories, the results of the risk assessment must be interpreted in relation to the uncertainty estimates. The best interpretation may be the need to assure continued vigilance. However, these data do demonstrate how a risk assessment can provide a means of systematically examining risks from different vantage points. The results clearly point out that a relatively low predicted relative risk per serving associated with foods that are consumed extensively (such as Pasteurized Fluid Milk or Vegetables) could lead to a potentially greater impact on the relative risk of listeriosis per annum.

Table V-3. Estimated Number of Cases of Listeriosis per Annum for Each Food Category and Subpopulation

Food Category	Number of Cases of Listeriosis per Annum[a]											
	Intermediate-Age[b]			Elderly			Perinatal[c]			Total		
	Percentiles			Percentiles			Percentiles			Percentiles		
	Median	5th	95th	Median	5th	95th	Median	5th	95th	Median	5th	95th
SEAFOOD												
Smoked Seafood	0.3	<0.1	19.4	0.8	<0.1	43.2	0.1	<0.1	5.8	1.3	0.1	68.1
Raw Seafood	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Preserved Fish	<0.1	<0.1	0.2	<0.1	<0.1	0.5	<0.1	<0.1	0.1	<0.1	<0.1	0.8
Cooked Ready-to-Eat Crustaceans	1.0	0.1	10.0	1.5	0.2	13.2	0.3	<0.1	2.2	2.8	0.4	25.7
PRODUCE												
Vegetables	0.1	<0.1	4.3	0.1	<0.1	9.7	<0.1	<0.1	1.6	0.2	<0.1	15.7
Fruits	0.2	<0.1	351.4	0.6	<0.1	680.4	0.1	<0.1	85.4	0.9	<0.1	1127.7
DAIRY												
Fresh Soft Cheese	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.2
Soft Unripened Cheese	2.0	<0.1	52.3	5.1	<0.1	128.8	0.5	<0.1	13.6	7.7	<0.1	193.5
Soft Ripened Cheese	<0.1	<0.1	2.1	<0.1	<0.1	2.1	<0.1	<0.1	0.7	<0.1	<0.1	4.9
Semi-soft Cheese	<0.1	<0.1	0.5	<0.1	<0.1	0.4	<0.1	<0.1	0.2	<0.1	<0.1	1.1
Hard Cheese	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Processed Cheese	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Pasteurized Fluid Milk	31.4	2.0	410.1	49.8	3.7	584.4	8.0	0.7	95.8	90.8	6.5	1084.6
Unpasteurized Fluid Milk	1.1	<0.1	24.7	1.7	<0.1	38.3	0.3	<0.1	6.5	3.1	<0.1	69.2
Ice Cream/Frozen Dairy Products	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	0.0	<0.1	<0.1	<0.1	<0.1	0.1
Cultured Milk Products	<0.1	<0.1	0.1	<0.1	<0.1	0.2	0.0	<0.1	<0.1	<0.1	<0.1	0.4
High Fat and Other Dairy Products	17.0	1.7	135.0	35.1	3.8	241.3	4.0	0.5	25.3	56.4	6.0	398.9
MEATS												
Frankfurters (reheated)	0.1	<0.1	1.9	0.2	<0.1	2.0	0.1	<0.1	1.1	0.4	<0.1	4.9
Frankfurters (not reheated)	13.8	1.3	119.4	13.0	1.4	103.0	3.6	0.4	26.9	30.5	3.3	245.4
Dry/Semi-Dry Fermented Sausages	<0.1	<0.1	4.1	<0.1	<0.1	6.0	<0.1	<0.1	1.3	<0.1	<0.1	11.2
Deli Meats	589.1	120.6	736.4	849.6	164.6	1106.2	161.2	44.5	197.0	1598.7	341.2	2038.2
Pâté and Meat Spreads	1.2	0.1	13.2	2.2	0.2	23.5	0.3	<0.1	3.4	3.7	0.4	39.5
COMBINATION FOODS												
Deli-type Salads	<0.1	<0.1	1.3	<0.1	<0.1	3.8	<0.1	<0.1	0.4	<0.1	<0.1	5.4

[a]This table provides estimates of the rate of listeriosis per annum and the confidence intervals about that estimate. [b]The Intermediate-age group includes susceptible populations not captured in other groups, such as cancer, AIDS, and transplant patients, for whom there are insufficient data to consider as a separate population. [c]The Perinatal population is a susceptible population that includes fetuses and neonates. Exposure occurs most often in utero from contaminated food eaten by the pregnant woman.

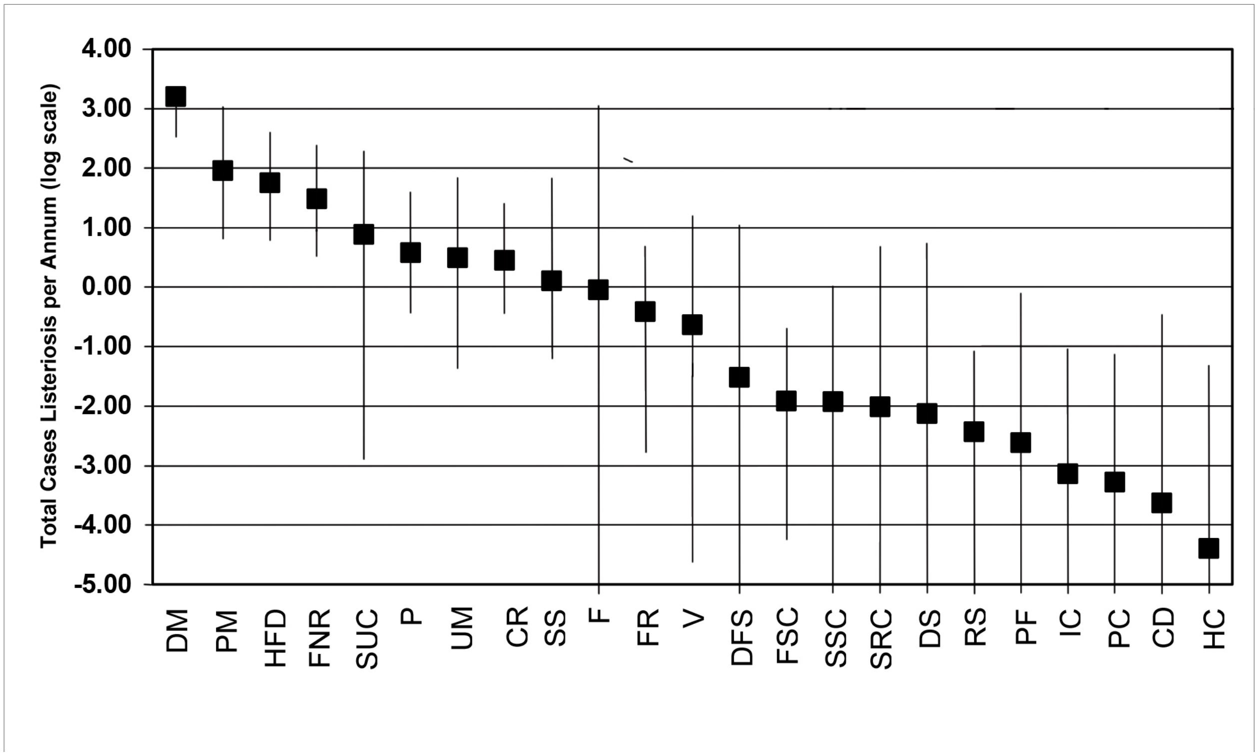


Figure V-3. Predicted Cases of Listeriosis (log scale) Associated with Food Categories for the Total United States Population on a per Annum Basis

[The box indicates the median predicted number of cases of listeriosis (log scale) and the bar indicates the lower and upper bounds (i.e., the 5th and 95th percentiles. The y-axis values are presented on a log scale. For example a log of –3 is equivalent to 1 in a thousand.]

DM = Deli meats; PM = Pasteurized Fluid Milk; HFD = High Fat and Other Dairy Products; FNR = Frankfurters (not reheated); SUC = Soft Unripened Cheese; P= Pâté and Meat Spreads; CR = Cooked Ready-To-Eat Crustaceans; UM= Unpasteurized Fluid Milk; SS= Smoked Seafood; F = Fruits; FR = Frankfurters (reheated); V = Vegetables; DFS= Dry/Semi-dry Fermented Sausages; FSC = Fresh Soft Cheese; SSC = Semi-soft Cheese; SRC = Soft Ripened Cheese; DS = Deli-type Salads; RS = Raw Seafood; PF = Preserved Fish; IC= Ice Cream and Frozen Dairy Products; PC = Processed Cheese; CD = Cultured Milk Products; HC = Hard Cheese.

Table V-4. Predicted Relative Risk Rankings for Listeriosis Among Food Categories for Three Age-Based Subpopulations and the United States Total Population Using Median Estimates of Relative Predicted Risks for Listeriosis on a per Annum Basis

Food Categories[a]	Subpopulation			
	Intermediate	Elderly[b]	Perinatal[b]	Total [b, c]
SEAFOOD				
Smoked Seafood	9	9	9	9
Raw Seafood	17	21	17	18g
Preserved Fish	19	17	19	19g
Cooked Ready-to-Eat Crustaceans	8	8	8	8b,d,e
PRODUCE				
Vegetables	12	12	12	12
Fruits	10	10	10	10
DAIRY				
Fresh Soft Cheese	14	18	14	14f
Soft Unripened Cheese, >50% moisture	5	5	5	5b,c
Soft Ripened Cheese, >50% moisture	16	16	16	16f
Semi-soft Cheese, 39-50% moisture	15	15	15	15f
Hard Cheese, <39% moisture	23	23	23	23
Processed Cheese	20	20	21	21h
Pasteurized Fluid Milk	2	2	2	2a
Unpasteurized Fluid Milk	7	7	7	7d,e
Ice Cream and Frozen Dairy Products	21	19	20	20h
Cultured Milk Products	22	22	22	22h
High Fat and Other Dairy Products	3	3	3	3a
MEATS				
Frankfurters, reheated	11	11	11	11
Frankfurters, not reheated	4	4	4	4
Dry/Semi-Dry Fermented Sausages	13	13	13	13
Deli Meats	1	1	1	1
Pâté and Meat Spreads	6	6	6	6b,c,d
COMBINATION FOODS				
Deli-type Salads	18	14	18	17f

[a] Food categories are grouped by type of food but are not in any particular order.
[b] A ranking of 1 indicates the food category with the greatest predicted relative risk of causing listeriosis and a ranking of 23 indicates the lowest predicted relative risk of causing listeriosis.
[c] Ranks with the same letter are not significantly different based on the Bonferroni Multiple Comparison Test (alpha=0.05).

Overview and Discussion of Food Categories

Because *Listeria monocytogenes* is ubiquitous in foods and the food-processing environment, a large number of foods needed to be considered in this risk assessment. In order to have a practicable number of food groupings, 23 categories were formed from the more than 640 ready-to-eat foods in the consumption surveys. These categories are sometimes broadly defined to include several distinct but similar classes of food, while in other instances they are quite small and specific. The foods included in this risk assessment are primarily organized into categories based on primary origin of the foods (e.g., seafood, vegetable, dairy, meat), composition and processing (moisture content, raw vs. cooked, pH, salt level), contamination with *Listeria monocytogenes,* and association with listeriosis. Although generally similar, some characteristics of foods within a single category may vary. For example, within a single food category, consumption may be greater for one food, contamination higher in another, and average rate of growth in a third food. In the future, if further investigations of an individual food category or a particular food within a category are conducted, the model developed in the current risk assessment could be modified to provide a more detailed analysis.

Consumption

Consumption estimates on a per serving basis were determined, as well as the amount of food eaten per person per day. Data indicate that, for the one or two days of the consumption surveys, there were 1.8×10^9 servings consumed of the foods identified in the 23 categories. Extrapolated to an annual basis, there were 3.4×10^{11} servings consumed in a year. The vast majority (96.3% or 2.5×10^8 individuals) of the population reported eating the foods included in this risk assessment. There were a relatively low number of eaters for some of the food categories (e.g., Smoked Seafood, Fresh Soft Cheese, Pâté and Meat Spreads), while other food categories are consumed widely and often (e.g., Pasteurized Milk, Vegetables). Consumption information for each food category is included in the discussion below.

Contamination

Contamination levels at retail ranged from less than 0.04 cfu/g to more than 10^6 cfu/g in the food data considered in this analysis. The highest levels reported for specifically identified food products were in the range of 10^5 to 10^6 cfu/g, although the results of laboratory investigations indicate that contamination levels greater than 10^6 cfu/g can occur. Studies that were limited to the determination of presence or absence were assigned a contamination value commensurate with the lowest limit of detection possible: 0.04 cfu/g. The highest frequency of contaminated samples was 12.9 % (Smoked Seafood). All food categories demonstrated some contamination, with a range of positive samples from 0.2 % to 12.9 % (see Table III-4). The frequency of occurrence of contaminated samples was lower at higher contamination levels. The contamination studies used in this study were published over a period of seventeen years (1985-2002). Because there was a major effort worldwide to control foodborne listeriosis, the incidence of contamination was evaluated for differences in data published pre-1993, 1993 to 1998, and post-1998. To estimate the current variation in contamination, studies were weighted by number of samples, country, and date of publication as explained in Chapter II: Exposure Assessment. Food categories with no recent data were adjusted by a factor relative to the other food categories.

Growth of *Listeria monocytogenes*

To predict possible growth between retail sampling and consumption, a growth model was created, based on growth rates from studies of various foods inoculated with *Listeria monocytogenes* under laboratory conditions. These studies were conducted at a number of temperatures. The reported growth rates were adjusted to give the equivalent growth rate at 5°C. Within each food category, the adjusted Exponential Growth Rate (EGR) from individual studies was used to develop a distribution of growth rate values. As previously mentioned, little data were available that adequately described the distribution of storage times (except for frankfurters and deli meats). Therefore, a modified BetaPert distribution was created for each food category, with minimum, most likely and maximum times (days) to account for the variation in storage times. The minimum time for all food categories (0.5 day) represents food consumed within 24 hours of purchase. For each specific food category, the most likely and maximum values were given an uncertainty range. For frankfurters and deli meats, an empirical data set was used (AMI, 2001). For each iteration of the growth simulation, the model selected a refrigeration storage temperature (that varied from 1 to 11°C) and calculated the EGR ($\log_{10}$ cfu/day) at that temperature. The EGR was multiplied by the storage time to estimate growth from retail to consumption and the estimated growth was added to the initial number of *Listeria* *monocytogenes* to calculate the total *Listeria monocytogenes.* The projected growth was limited by temperature-dependent maximum growth values (stationary phase). The maximum growth was greater at higher storage temperatures than at lower temperatures. In addition, the model contained a negative correlation between storage temperature and storage times. This minimized combinations of long storage times and high temperatures that would most likely result in detectable spoilage from other microorganisms and disposal of the food rather than consumption.

Summaries of the Food Categories

Because the risk assessment model is based on many parameters and an extensive amount of both qualitative and quantitative data, it can be difficult to determine the impact of each of the factors considered. Accordingly, sets of qualitative descriptors were developed to aid in the discussion and comparison of these parameters in the food categories. The criteria used to characterize data among food categories as low/moderate/high or short/moderate/long for each parameter are presented in Table V-5a. Table V-5b provides a characterization of each of the parameters for each food category. See Appendices 5, 7 and 8 for the supporting data.

An overview of each of the 23 food categories is provided in this chapter including information for each food category on cases of listeriosis, consumption, contamination, and growth of *Listeria monocytogenes*, and a summary of the designated parameter levels based on the criteria listed in Table V-5a. In addition, the latitude graphs (Figures V-4a to V-26b) show the uncertainty associated with the predicted relative risk rankings on both a per serving and per annum basis for each food category. These graphs show how frequently a food category ranked 1st, 2nd , and so on to 23rd. A food category that primarily ranked 1st or 2nd should be considered a higher risk than a food category that primarily ranked 22nd or 23rd. The distribution of rankings shown for a food category is an indication of the certainty of its ranking. The narrower the range, the greater is the certainty associated with the relative risk ranking.

As an initial means of categorizing the results of the risk assessment in order to relate them to the characteristics of the different food categories, the relative predicted risk on a per serving basis was classified as high, moderate, or low. The following criteria was used: high = >5 predicted cases of listeriosis per billion servings; moderate = <5 but ≥ 1 predicted case per billion servings, and low = <1 predicted case per billion servings. Based on these criteria, five of the foods were considered to be high risk, four were in the moderate risk group, and the remaining foods fell into the low risk per serving category (Table V-6). The number of predicted cases per annum in the United States for the total population was classified as low (less than 1 case per annum), moderate (>1 to 10 cases per annum), high (>10 to 100 cases), and very high (>100 cases). Based on these criteria, one food category was considered very high, three food categories were considered to cause a high number of cases and five food categories a moderate number of cases, with the remaining considered low. Additional means of grouping the results are considered later in the document (see the cluster analysis in Chapter VII).

Table V-5a. Criteria Used to Designate Parameter Ranges for *Listeria monocytogenes* Among the Food Categories

Parameter	Designated Parameter Level		
	Low/Short	Moderate	High/Long
Number of Annual Servings	$\leq 1 \times 10^9$	$> 1 \times 10^9$ to $< 1 \times 10^{10}$	$\geq 1 \times 10^{10}$
Median Amount Consumed per Serving (g)	≤ 40 g	> 40 g to < 90 g	≥ 90 g
Contamination Frequency (%)	≤ 2%	> 2% to < 5%	≥ 5%
Contamination at Retail—Predicted Servings at 10^3 to 10^6 cfu (%)	≤ 0.1%	>0.1% to < 0.6%	≥ 0.6%
Exponential Growth Rate at 5 °C ($\log_{10}$ cfu/day)	≤ 0.1	> 0.1 to < 0.2	≥ 0.2
Most Likely Storage Time (days)	≤ 2 days	> 2 to 5 days	≥ 6 to 10 days

Table V-5b. Summary of Data Used to Model *Listeria monocytogenes* Exposure for Each Food Relative to Other Food Categories

Food Category	Number of Annual Servings	Median Amount Consumed	Contamination Frequency	Contamination Level at Retail	Growth Rate During Storage	Storage Time
SEAFOOD						
Smoked Seafood	Low	Moderate	High	High	Moderate	Moderate
Raw Seafood	Low	Low	High	High	Moderate	Short
Preserved Fish	Low	Moderate	High	Moderate	—[a]	—[a]
Cooked Ready-to-Eat Crustaceans	Low	Moderate	Moderate	Moderate	High	Short
PRODUCE						
Vegetables	High	Low	Moderate	Low	Low	Moderate
Fruits	High	High	High	Low	Low	Moderate
DAIRY						
Fresh soft cheese	Low	Low	Low	Low	Low	Moderate
Soft Unripened Cheese, >50% moisture	Moderate	Low	Moderate	Moderate	Low[b]	Long
Soft Ripened Cheese, >50% moisture	Moderate	Low	Moderate	Low	Low[b]	Long
Semi-soft cheese, 39-50% moisture	Moderate	Low	Moderate	Low	Low[b]	Long
Hard Cheese, <39% moisture	Moderate	Low	Low	Low	Low[b]	Long
Processed Cheese	High	Low	Low	Low	Low[b]	Long
Pasteurized Fluid Milk	High	High	Low	Low	High	Moderate
Unpasteurized Fluid Milk	Low	High	Moderate	Moderate	High	Moderate
Ice Cream and Frozen Dairy Products	High	High	Low	Low	—[a]	—[a]
Cultured Milk Products	Moderate	High	Low	Low	Low[b]	Long
High Fat and Other Dairy Products	High	Low	Low	Low	Moderate	Long
MEATS						
Frankfurters, reheated	Moderate	Moderate	Moderate	High	Moderate	Moderate
Frankfurters, not reheated	Low	Moderate	Moderate	High	Moderate	Moderate
Dry/Semi-Dry Fermented Sausages	Moderate	Moderate	High	Moderate	Low[b]	Long
Deli Meats	High	Moderate	Moderate	High	High	Long
Pâté and Meat Spreads	Low	Moderate	High	Moderate	High	Long
COMBINATION FOODS						
Deli-type Salads	High	High	Moderate	Low	Low[c]	Moderate

[a] A non-growth food category; growth rates and storage times are not applicable. [b] Includes probabilities that *Listeria monocytogenes* numbers will decline during storage. [c]Overall *Listeria monocytogenes* declines in deli salads, but it can grow at a moderate rate in a small fraction of salads.

Table V-6. Relative Risk Ranking and Predicted Median Cases of Listeriosis for the Total United States Population on a per Serving and Per Annum Basis

Relative Risk Ranking	Predicted Median Cases of Listeriosis for 23 Food Categories					
	Per Serving Basis[a]			Per Annum Basis[b]		
		Food	Cases		Food	Cases
1	High Risk	Deli Meats	7.7×10^{-8}	Very High	Deli Meats	1598.7
2	High Risk	Frankfurters, not reheated	6.5×10^{-8}	High Risk	Pasteurized Fluid Milk	90.8
3	High Risk	Pâté and Meat Spreads	3.2×10^{-8}	High Risk	High Fat and Other Dairy Products	56.4
4	High Risk	Unpasteurized Fluid Milk	7.1×10^{-9}	High Risk	Frankfurters, not reheated	30.5
5	High Risk	Smoked Seafood	6.2×10^{-9}	Moderate Risk	Soft Unripened Cheese	7.7
6	High Risk	Cooked Ready-to-Eat Crustaceans	5.1×10^{-9}	Moderate Risk	Pâté and Meat Spreads	3.8
7	Moderate Risk	High Fat and Other Dairy Products	2.7×10^{-9}	Moderate Risk	Unpasteurized Fluid Milk	3.1
8	Moderate Risk	Soft Unripened Cheese	1.8×10^{-9}	Moderate Risk	Cooked Ready-to-Eat Crustaceans	2.8
9	Moderate Risk	Pasteurized Fluid Milk	1.0×10^{-9}	Moderate Risk	Smoked Seafood	1.3
10	Low Risk	Fresh Soft Cheese	1.7×10^{-10}	Low Risk	Fruits	0.9
11	Low Risk	Frankfurters, reheated	6.3×10^{-11}	Low Risk	Frankfurters, reheated	0.4
12	Low Risk	Preserved Fish	2.3×10^{-11}	Low Risk	Vegetables	0.2
13	Low Risk	Raw Seafood	2.0×10^{-11}	Low Risk	Dry/Semi-dry Fermented Sausages	<0.1
14	Low Risk	Fruits	1.9×10^{-11}	Low Risk	Fresh Soft Cheese	<0.1
15	Low Risk	Dry/Semi-dry Fermented Sausages	1.7×10^{-11}	Low Risk	Semi-Soft Cheese	<0.1
16	Low Risk	Semi-soft Cheese	6.5×10^{-12}	Low Risk	Soft Ripened Cheese	<0.1
17	Low Risk	Soft Ripened Cheese	5.1×10^{-12}	Low Risk	Deli-type Salads	<0.1
18	Low Risk	Vegetables	2.8×10^{-12}	Low Risk	Raw Seafood	<0.1
19	Low Risk	Deli-type Salads	5.6×10^{-13}	Low Risk	Preserved Fish	<0.1
20	Low Risk	Ice Cream and Other Frozen Dairy Products	4.9×10^{-14}	Low Risk	Ice Cream and Other Frozen Dairy Products	<0.1
21	Low Risk	Processed Cheese	4.2×10^{-14}	Low Risk	Processed Cheese	<0.1
22	Low Risk	Cultured Milk Products	3.2×10^{-14}	Low Risk	Cultured Milk Products	<0.1
23	Low Risk	Hard Cheese	4.5×10^{-15}	Low Risk	Hard Cheese	<0.1

[a]Food categories were classified as high risk (>5 cases per billion servings), moderate risk (<5 but >1 case per billion servings), and low risk (<1 case per billion servings).

[b]Food categories were classified as very high risk (>100 cases per annum), high risk (>10 to 100 cases per annum), moderate risk (>1 to 10 cases per annum), and low risk (≤1 cases per annum).

Food Category: Smoked Seafood

The foods in the Smoked Seafood category had a high predicted relative risk of causing listeriosis on a per serving basis. This reflects the fact that Smoked Seafood has a high frequency of contamination; high levels of contamination at retail, supports a moderate rate of growth; and is often stored for moderate lengths of time (and occasionally long periods of time). This is offset somewhat by the moderate serving sizes and the low number of servings associated with this food category. These combine to make Smoked Seafood a moderate contributor to the total number of predicted cases of listeriosis per year.

The predicted relative risk per serving for Smoked Seafood is consistent with various smoked seafoods having been associated with listeriosis. Smoked mussels have been linked to outbreaks of listeriosis in Australia and New Zealand, cold smoked rainbow trout to an outbreak in Sweden, smoked salmon to sporadic cases in Australia, and smoked cod roe to sporadic cases in Denmark (Ryser, 1999a; Brett *et al.*, 1998; Ericsson *et al.*, 1997). Contaminated retail packages are regularly identified by regulatory surveillance programs (Ryser and Marth, 1999a). However, the small volume of most production lots and a low number of servings consumed means that outbreaks are unlikely from a contaminated product; sporadic cases would be expected to be the typical consequences of *Listeria monocytogenes* in this food category.

Foods included in this category from the consumption databases are smoked salmon, trout, herring, oysters, and other smoked fish not identified as to species. Both hot and cold smoked products are included in this category, in part because the consumption databases do not distinguish between these two processes. The predicted median amount consumed per serving for this category is 57.0 g (approximately 2 ounces), and the annual total number of servings in the United States is only 2.0×10^8 (i.e., less than 1 serving per person per annum, on average).

Data from 30 smoked seafood studies provided the contamination data used for this category. Only six of these studies were conducted in the United States. Quantitative data were available in 10 studies. The contamination database included samples from both hot and cold smoking, but the process or the species was not always specified. Salmon was the most frequent product tested but other finfish and mussels were represented. The smoking process for this category, when specified, was usually cold smoking. The impact of different smoking methods on contamination is not known, but available literature suggests that inactivation resulting from hot smoking is often lost due to recontamination. Cold smoking has no significant effect on *Listeria monocytogenes*. The percentage of retail samples with detectable contamination was high, about 13% overall. In a few cases, the observed level of *Listeria monocytogenes* in the enumerated samples was very high. For example, the NFPA (2002) study (Gombas et al., 2003) collected 2,686 samples at retail and found 113 positive for *Listeria monocytogenes*. Two of these samples were between 10^5 and 10^6 cfu/g.

The growth rate data for this category came from 10 studies containing a total of 25 individual growth rates for hot- and cold-smoked salmon, trout, and cod. The average exponential growth rate adjusted to 5°C was a moderate 0.15 logs/day. Home storage times tend to be moderate in most instances but occasionally samples are stored for lengthy periods. The most likely and maximum storage times used were 3 to 5 days and 15 to 30 days, respectively. The estimated number of *Listeria monocytogenes* consumed per serving was high. The median estimate was 6.7% of servings exceeded 1 x 10^3 cfu/serving and 0.2% of the servings exceeded 1×10^6 cfu/serving.

The predicted median number of cases of listeriosis per serving for Smoked Seafood was 6.2×10^{-9}. This corresponds to a relative risk ranking of fifth for the Smoked Seafood category for the total United States population. The range for the per serving ranking distribution for Smoked Seafood is clustered in the higher ranks, with a normal distribution with a single mode (Figure V-4a). The level of uncertainty was typical of that observed with most food category rankings. The predicted median per annum relative risk rankings were ninth for the total United States population. The median predicted number of cases per annum of 1.3 for the total United States population was moderate. The relative ranking distribution for the per annum value (Figure V-4b) was shifted slightly to the lower risk ranks, reflecting the lower number of servings per year of foods in this category. Although the uncertainty for the cases per annum was greater than for the per serving value, the uncertainty associated with the per annum value was still typical for those observed with most food categories.

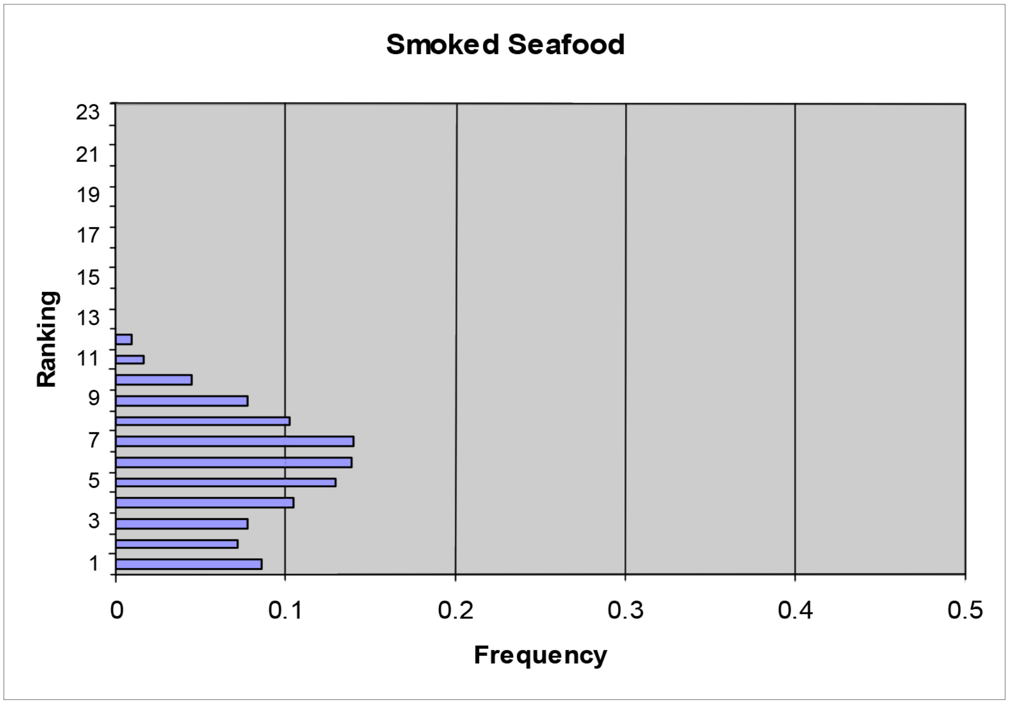


Figure V-4a. Rankings of Total Predicted Listeriosis Cases per Serving for Smoked Seafood

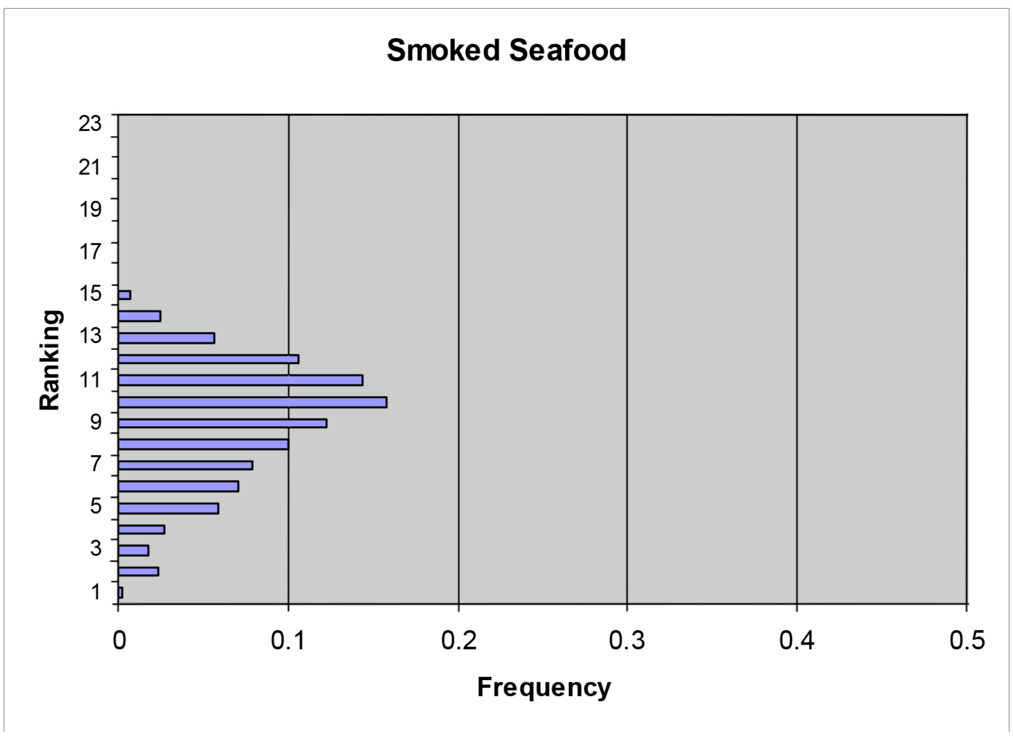


Figure V-4b. Rankings of Total Predicted Listeriosis Cases per Annum for Smoked Seafood

Food Category: Raw Seafood

Raw Seafood has a low predicted relative risk per serving of causing listeriosis in the United States. The foods in this category generally were characterized by a low annual number of servings, a low percent of the population consuming the food, and small serving sizes. However, the contamination levels at retail were high and *Listeria* can grow in these foods at moderate rates. As perishable foods, storage times are typically short which effectively limits the growth and the numbers of organisms likely to be consumed. This combination of factors made the predicted estimates of exposure and illness low. Though the Raw Seafood category has a low predicted relative risk of causing listeriosis in the United States, products in this category have been linked to an outbreak in New Zealand and to a sporadic case in Italy (Farber and Peterkin, 1991).

This category is fairly heterogeneous. Foods for which there were consumption data were flounder, pompano, tuna, sturgeon roe, squid, oysters, and sushi. The median amount consumed per serving is 16.0 g (approximately 0.5 ounce), and the annual total number of servings is low at 1.8 $x10^8$.

Forty-six contamination studies (including 11 from the United States) analyzed over 15,500 samples of uncooked seafood and seafood products, primarily to determine the presence or absence of *Listeria monocytogenes*. Four studies provided quantitative data.

Contamination data were mainly for fresh or frozen whole animals, but products such as cakes, fingers, minces, sushi, and unspecified fish parts are also included. These can be categorized as finfish and non-finfish. Finfish, when specified, included butterfish, catfish, red snapper, trout, and tuna. Both wild caught and aquaculture-reared fish were included. Non-finfish included shellfish and crustaceans. Among the specified foods were lobster, squid, langostino, oyster, shrimp, mussel, clams, and scallops. The percentage of samples with detectable contamination was high (7.0%). Pathogen levels were predicted to be in the high range for the percentage of servings with 10^3 to 10^6 cfu at retail.

Six papers provided *Listeria monocytogenes* growth rates in these foods. Individual foods were trout, catfish, shrimp, and oysters. The growth rates averaged 0.15 logs per day at 5°C. Storage times were relatively short for these foods; the most likely storage time was 1 to 2 days, and the maximum time was 10 to 20 days.

The predicted median risk per serving for the Raw Seafood category was $2.0\text{x}10^{-11}$ and ranked 13th for the total United States population. The range for the per serving ranking distribution (Figure V-5a) is relatively narrow and concentrated in the lower risk ranks. This indicates that there is little uncertainty associated with the predicted per serving relative risk ranking for the Raw Seafood category. The predicted median per annum relative risk ranking was 18th for the total United States population. The range for the per annum ranking distribution (Figure V-5b) was narrow, indicating that there is also little uncertainty associated with the per annum predicted relative risk for Raw Seafood. This decrease in the per annum ranking compared to the per serving ranking is consistent with the small number of servings consumed per year.

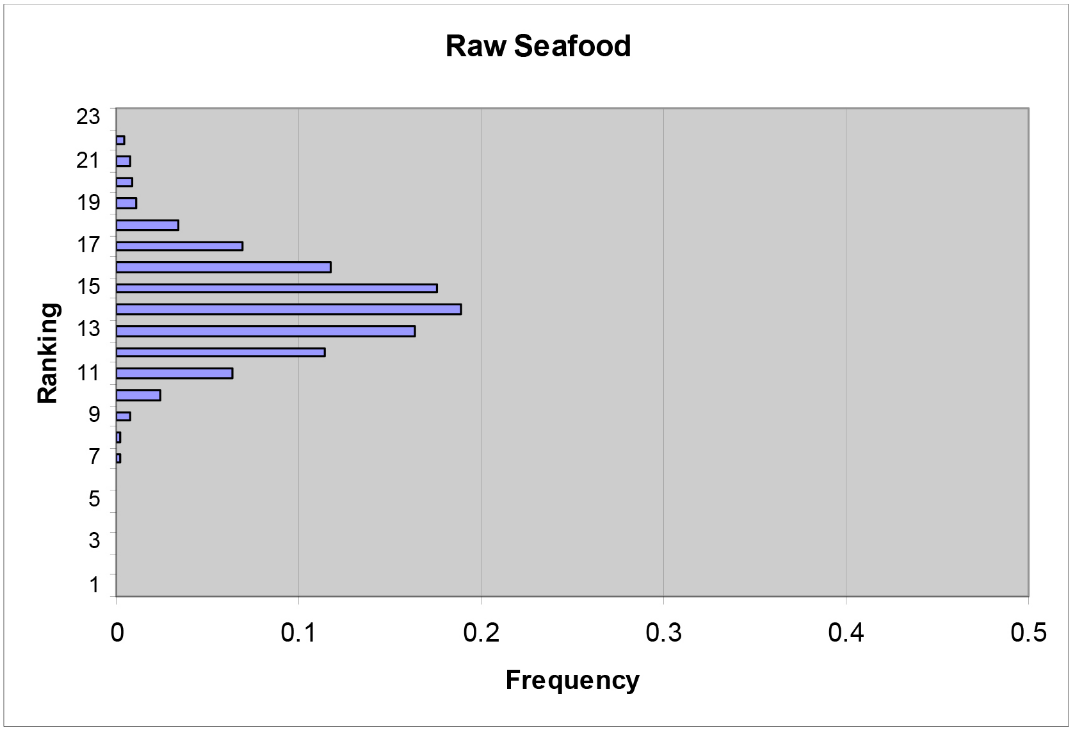


Figure V-5a. Rankings of Total Predicted Listeriosis Cases per Serving for Raw Seafood

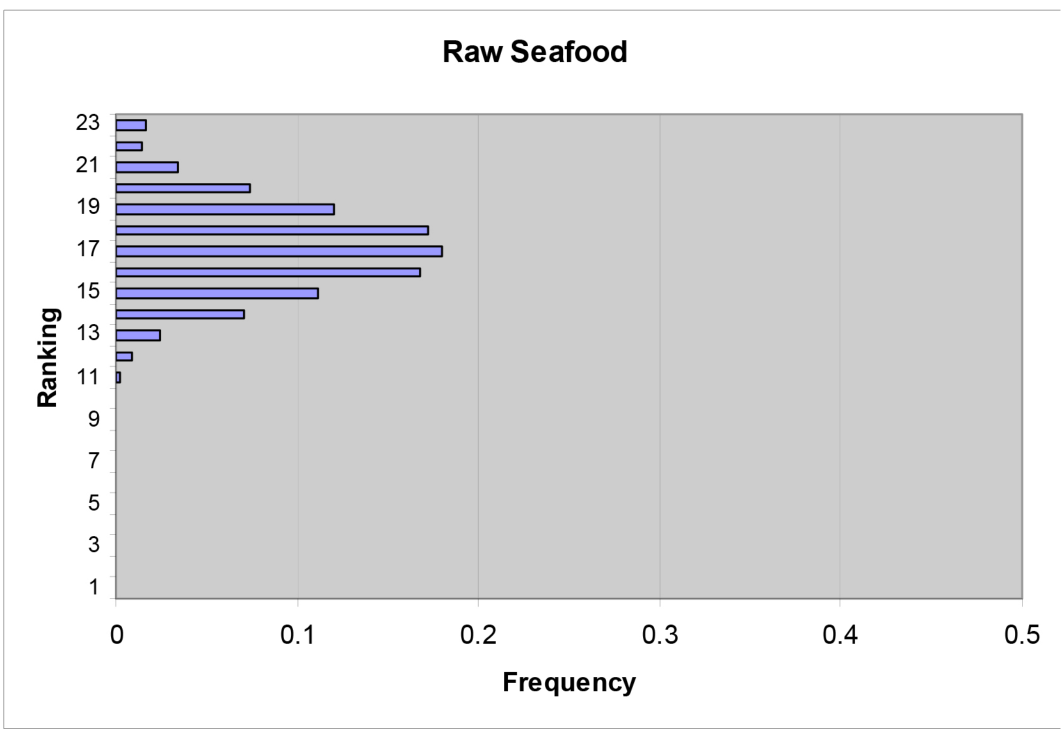


Figure V-5b. Rankings of Total Predicted Listeriosis Cases per Annum for Raw Seafood

Food Category: Preserved Fish

Preserved Fish, including pickled, marinated, or dried products, had a low predicted relative risk of causing listeriosis on a per serving basis and a low predicted contribution to the total number of cases on a per annum basis. The foods in this category had a low annual number of servings and a low percent of the population consuming the food, but had moderate serving sizes, high frequency of contamination, and moderate contamination levels at retail. Growth was not modeled for this category, since preserved fish do not support growth. Typically, the inability of a food category to support the growth of *Listeria monocytogenes* results in a low per serving relative risk. However, in this instance the lack of growth appears to be offset by the frequency of contamination at retail. Moderate level contamination likely occurs because foods in the Preserved Fish category are often prepared using traditional techniques, which require long processing times and occasionally may not meet stringent sanitary standards. This creates the potential for substantial growth of *Listeria monocytogenes* during initial production steps (e.g., brining) before the product equilibrates to the salt and pH levels that are the basis of preservation. Gravad rainbow trout has been linked to an outbreak of listeriosis in Sweden (Ericsson *et. al.*, 1997).

The Preserved Fish category includes consumption data for pickled or marinated fish, such as ceviche and pickled herring, dried and salted cod, and non-specified dried fish. The median amount consumed per serving for this category is 70 g (approximately 2.5 ounces), and the annual total number of servings is 1.1×10^8.

Contamination data for this food category was from 18 studies. Haddock, gravad trout, ceviche, and unspecified finfish that were pickled, smoked, dried, salted, or preserved were included. Of these studies only one was from the United States. Five studies contained quantitative data. The percentage of samples with detectable contamination was 9.8%, higher than for Raw Seafood, but just slightly less than Smoked Seafood. The predicted percentage of servings contaminated with 10^3 to 10^6 cfu at retail was moderate.

Because these products do not allow growth of *Listeria monocytogenes,* storage times are not a factor in the levels of *Listeria monocytogenes* present at the time of consumption. Although not a factor, storage times were also believed to be somewhat shorter than those for Smoked Seafood. The high salt and acidity present in the final products prevent growth of *Listeria monocytogenes*. However, the microorganism is known to survive these conditions, particularly if held at refrigeration temperatures.

The predicted median risk per serving for the Preserved Fish category was 2.3×10^{-11}, which corresponds to a relative risk rankings of twelfth for the total United States population. The range for the per serving relative ranking distribution is relatively broad (Figure V-6a) with a bimodal distribution. The wide spread indicates a high degree of uncertainty which likely is due to a combination of the limited quantitative data and broad variability in conditions under which these products are produced. The bimodal distribution may indicate that there are differences among different foods within this food category, and may require that the category be subdivided if additional data become available in the future in order to achieve a more accurate measure of the relative risks associated with the different foods. The predicted median per annum relative risk ranking was low, at less than one case per annum and ranked nineteenth for the total United States population. The range for the per annum ranking distribution was also a bimodal distribution (Figure V-6b), again indicating a substantial degree of uncertainty or variability. Overall this food category is not predicted to make a substantial contribution to the cases of listeriosis in the United States, however, the uncertainty in the risk per serving indicates that it may be a concern for the small population that consumes these products.

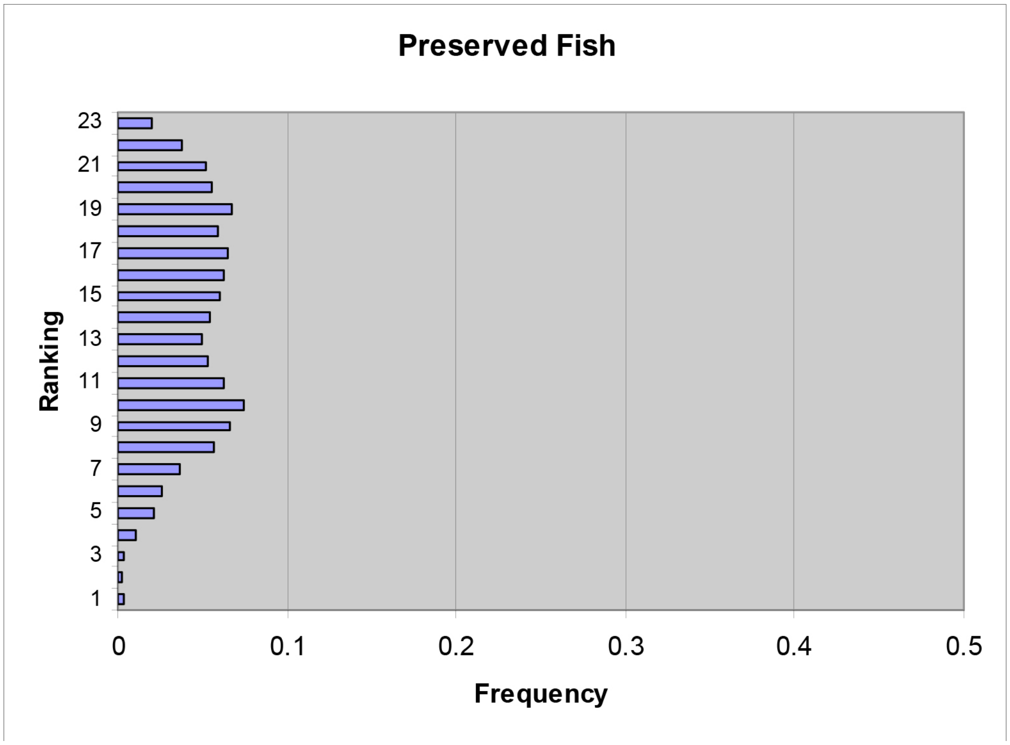


Figure V-6a. Rankings of Total Predicted Listeriosis Cases per Serving for Preserved Fish

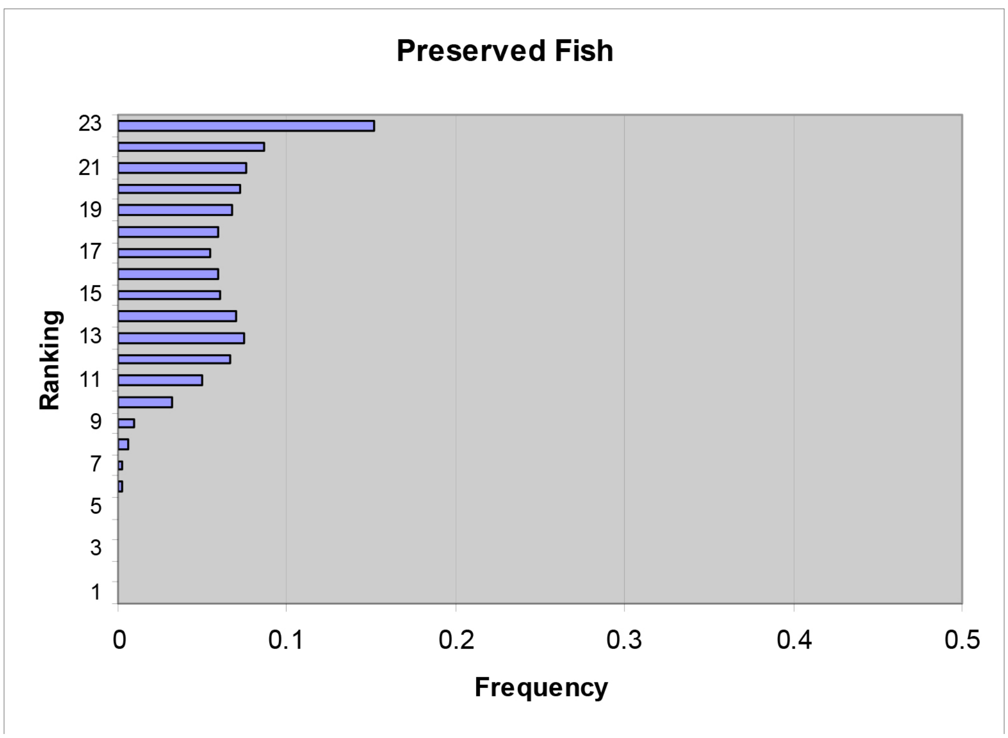


Figure V-6b. Rankings of Total Predicted Listeriosis Cases per Annum for Preserved Fish

Food Category: Cooked Ready-to-Eat Crustaceans

Cooked Ready-to-Eat (RTE) Crustaceans (crab and shrimp) had a high predicted relative risk of causing listeriosis in the United States on a per serving basis. The foods in this category generally were consumed at a low frequency and with moderate serving sizes. The relatively high growth rate of *Listeria monocytogenes* in these foods, one of the usual factors that drives listeriosis risk in food, was offset by relatively short storage times. It would be expected that the cooking step in the preparation of these foods would eliminate *Listeria monocytogenes*. However, foods in this category may often be stored refrigerated after cooking, allowing for recontamination and growth.

Imitation crabmeat has been linked to an outbreak of listeriosis in Canada and shrimp was epidemiologically linked to an outbreak in the United States. (Ryser, 1999a; Riedo *et al.*, 1994). The FDA has also monitored recalls for cooked shrimp and crab.

The Cooked RTE Crustaceans category includes consumption data for steamed, hard shell crab; steamed or boiled shrimp; and cocktail shrimp. The median serving size for this category was 50 g (approximately 1.8 ounces), and the annual total number of servings was 5.5×10^{8}.

Eleven contamination studies provided data mainly from cooked crab and shrimp. Four studies were for product in the United States. Two studies, both from the United States, provided quantitative data. The percentage of contaminated samples was moderate at 2.8%. A small number of samples with high contamination levels (greater than 10^{3} cfu/g) have been reported. The predicted percentage of servings with 10^{3} to 10^{6} cfu/serving at retail was moderate. Only three papers were found that reported growth rates for pasteurized crab and for cooked shrimp and lobster. This category had the fastest reported growth rates of any food category, averaging 0.38 logs/day at 5° C. Storage times were estimated to be relatively short; the most likely storage time was only 1 to 2 days, and the maximum time was 10 to 20 days.

The predicted median risk per serving for the Cooked RTE Crustaceans category of 5.1×10^{-9} corresponded to a relative risk ranking of sixth for the total United States population. The range for the per serving ranking distribution for Cooked RTE Crustaceans (Figure V-7a) is narrow and concentrated in the lower risk rankings (i.e., a higher risk food). This indicates that there is little uncertainty associated with the predicted per serving relative risk for the Cooked RTE Crustaceans category. The predicted median per annum risk is approximately three cases of listeriosis per annum and a relative risk ranking of eighth for the total United States population. The range for the per annum ranking distribution is narrow and generally normally distributed (Figure V-7b), suggesting relatively little variability or uncertainty in the extent to which this food category is consumed.

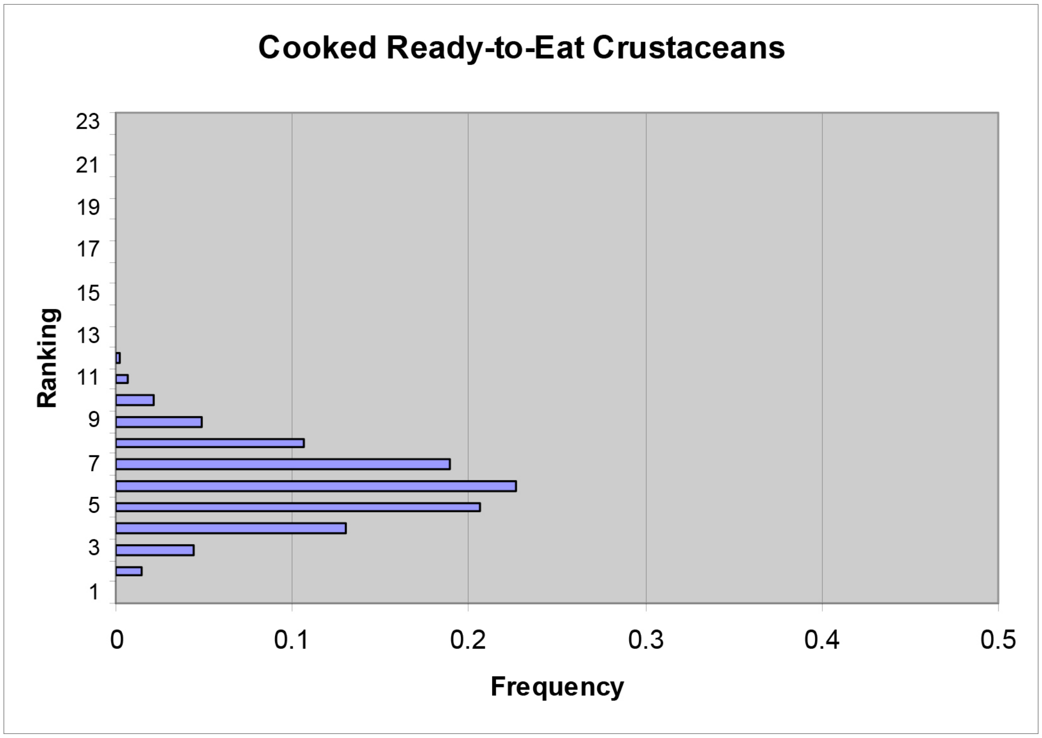


Figure V-7a. Rankings of Total Predicted Listeriosis Cases per Serving for Cooked Ready-to-Eat Crustaceans

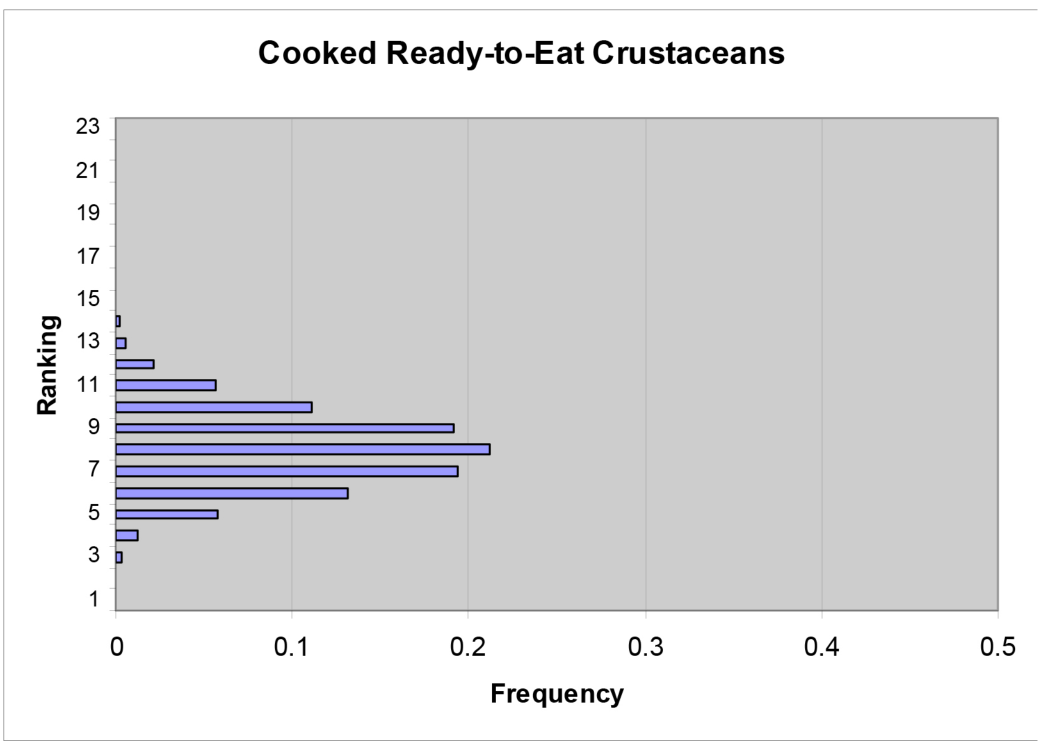


Figure V-7b. Rankings of Total Predicted Listeriosis Cases per Annum for Cooked Ready-to-Eat Crustaceans

Food Category: Vegetables

Foods in the Vegetables category had a low predicted relative risk of causing listeriosis in the United States on a per serving basis. The Vegetables category is difficult to characterize because it encompasses a diverse set of products that are typically consumed without cooking. The annual number of servings of Vegetables is high, while the median serving size, contamination level, and growth rate are low. The storage time and the contamination frequency are moderate.

Both raw and processed vegetables have been implicated in outbreaks. Raw vegetables have been linked to outbreaks of listeriosis in Austria and Western Australia; frozen broccoli, cauliflower, celery, tomatoes, and lettuce in the United States (Ryser, 1999a; Simpson, 1996; Riedo *et al.*, 1994; Farber and Peterkin, 1991; Allerberger and Guggenbichler, 1989). In addition, raw vegetables have been linked to sporadic cases in Australia, the U.K. (English lettuce, vegetable rennet), and Finland (salted mushrooms) (Ryser, 1999a; Farber and Peterkin, 1991).

Foods included in the Vegetables category are raw as well as mixed vegetable salads that contain raw vegetables but not salad dressing. In addition to vegetables typically consumed raw (e.g., spinach, carrots, tomatoes, celery, lettuce, onions), this category includes less frequently consumed vegetables such as artichokes, sprouts, and raw seaweed. However, salads such as cole slaw and potato salads are included in the Deli-type Salads food category because of the creamy dressing base and frequent handling in the retail deli. The median amount consumed per serving for this category is 28 g (i.e., ~ 1 ounce), and the annual total number of servings is 8.5×10^{10}. The low median serving size most likely reflects the consumption patterns associated with the wide span of vegetable types included in the analysis, though certain vegetables may be eaten in substantially larger amounts (e.g., tomatoes).

Thirty-two contamination studies were found that examined individual raw vegetables or mixed vegetables (without dressing). Of these studies, five were from the United States and eight contained quantitative data. The vegetables analyzed included raw bean sprouts, broccoli, cabbage, carrot, celery, cilantro, cress, cucumber, fennel, legumes, lettuce, mushrooms, parsley, green peppers, onions, radish, scallion, tomato, and watercress. The NPFA (2002) survey collected 2,963 samples of bagged, precut leafy salads and found 2.3% positive, with one sample containing between 10^2 and 10^3 cfu/g. Overall, the percentage of samples with detectable contamination was a moderate 3.6%. The predicted percentage of servings with high contamination levels was low.

Nine papers provided 26 estimates of growth rates for *Listeria monocytogenes* on vegetables. The vegetables included in these studies were lettuce, cabbage, broccoli, cauliflower, asparagus, tomatoes, and carrots. The average growth rate of Vegetables was slow, 0.07 logs/day at 5°C. Moderate storage times were assumed with the most likely 3 to 4 days and the maximum of 8 to 12 days.

The predicted median risk per serving for the Vegetables category was $2.8x10^{-12}$ and the relative risk ranking was eighteenth for the total United States population. The range for per serving distribution for Vegetables (Figure V-8a) is similar to what was observed with most food categories and clustered in the lower risk rankings. This indicates that there is relatively little uncertainty associated with the predicted per serving relative risk for the Vegetables category. The predicted median per annum risk was less than one case and the corresponding relative risk ranking was twelfth for the total population. The per annum ranking distribution (Figure V-8b) had a relatively broad range, indicating substantial uncertainty. The distribution was shifted to the higher risk ranks compared to the per serving distribution. These results presumably reflect the large number of servings of Vegetables consumed, as well as the variability in the products encompassed in this highly diverse category. The broad range suggests that this food category and its ranking could benefit from additional investigations and the possible subdivision of the food category into several smaller groupings.

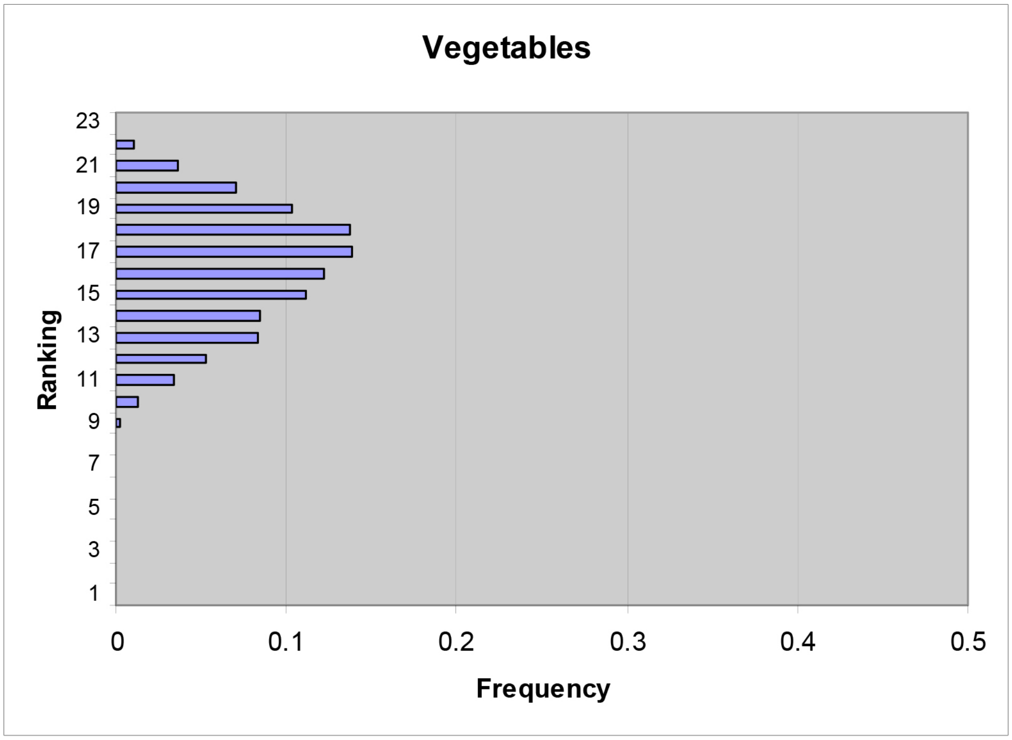


Figure V-8a. Rankings of Total Predicted Listeriosis Cases per Serving for Vegetables

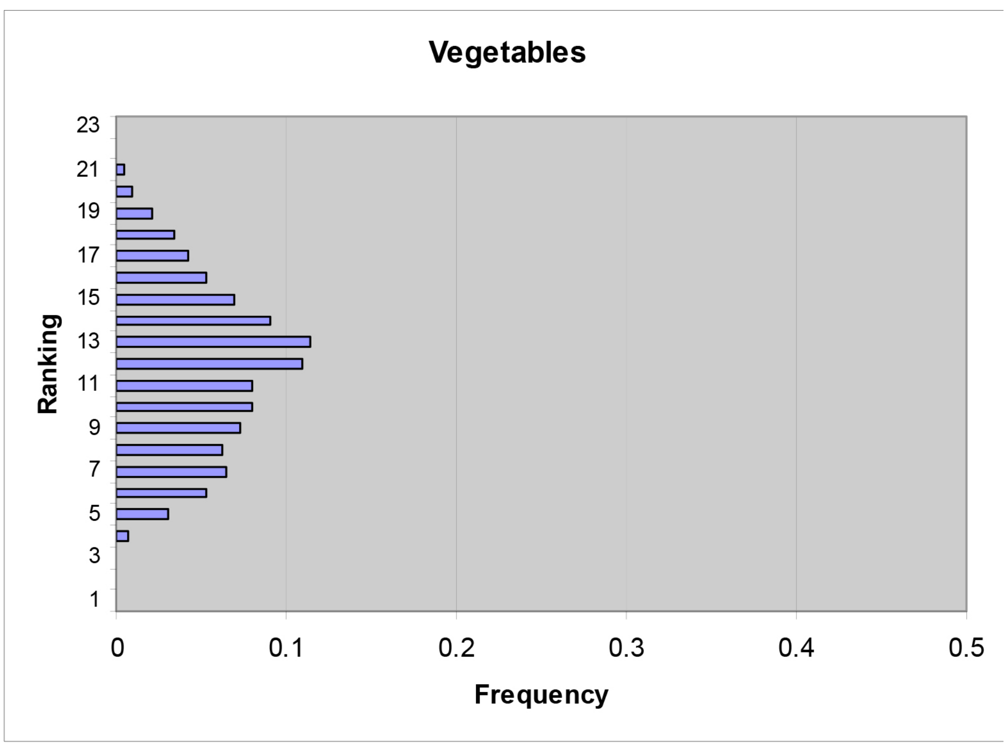


Figure V-8b. Rankings of Total Predicted Listeriosis Cases per Annum for Vegetables

Food Category: Fruits

Foods in the Fruits category had a low predicted relative risk of causing listeriosis on a per serving basis. Fruits have not been linked to outbreaks or sporadic cases of listeriosis, and this might explain why there is little contamination data in the published literature available for this category. The annual number of servings, median serving size and contamination frequency of Fruits are high. These factors lead to a high risk for fruits on a per annum basis even though the growth of *Listeria monocytogenes* during storage would be low. The high level of uncertainty indicates a need for more information and data for this food category. This is a diverse food category that includes acidic fruits (such as pineapples) and pH neutral fruits (such as cantaloupes).

The Fruits category includes consumption data for many types of raw and dried fruits, as well as fruit salads (with fruits as the main ingredient without salad dressing). This category is simplified from the 2001 draft risk assessment in that fruit salads containing salad dressing were moved to the Deli-type Salad food category. The median amount consumed per serving for this category is 118 g (i.e., slightly over 4 ounces), and the annual total number of servings is 4.9×10^{10}.

Only four contamination studies, two of which were from the United States were available. None of these studies included quantitative data. Fruits specified in these studies included apples, blueberries, cantaloupes, pears, pineapples, and fruit products. The percentage of samples with detectable contamination was 11.8%, a high contamination frequency. The contamination levels were estimated from the presence/absence data assuming the standard deviation of the frequencies of contamination levels. The high frequency of contamination would indicate that high levels of contamination could also occur.

Two studies (orange juice and fresh apple slices) were found that characterized the rate of *Listeria monocytogenes* growth in fruits. When the pH was less than 4.8, *Listeria monocytogenes* did not grow. At pH 5.0, growth was slow, at 0.05 logs/day. Moderate storage times were assigned for this category, with a most likely time of 3 to 4 and a maximum time of 8 to 12 days.

The predicted median risk per serving for the Fruits category was 1.9×10^{-11} which corresponds to a relative risk ranking of fourteenth for the total United States population. The range for the ranking distribution for Fruits (Figure V-9a) is broad. The predicted median risk per annum is approximately 1 case per year and the relative risk ranking is tenth for the total United States population (Figure V-9b). This increase in relative risk compared to the per serving value reflects the large number of servings consumed annually. The range for the ranking distribution was broad indicating substantial uncertainty in the predicted relative risk ranking. This likely reflects the limited data available, the diversity of the products that fall within this food category, and the variability in the frequency and extent of contamination rates among the data that were evaluated. The bimodal nature of the distribution suggests that the food category may need to be subdivided when additional data become available. Overall, the Fruits category is a broad category with varied consumption and contamination, and few data were available to characterize this category. Thus, there is a high degree of uncertainty associated with this category.

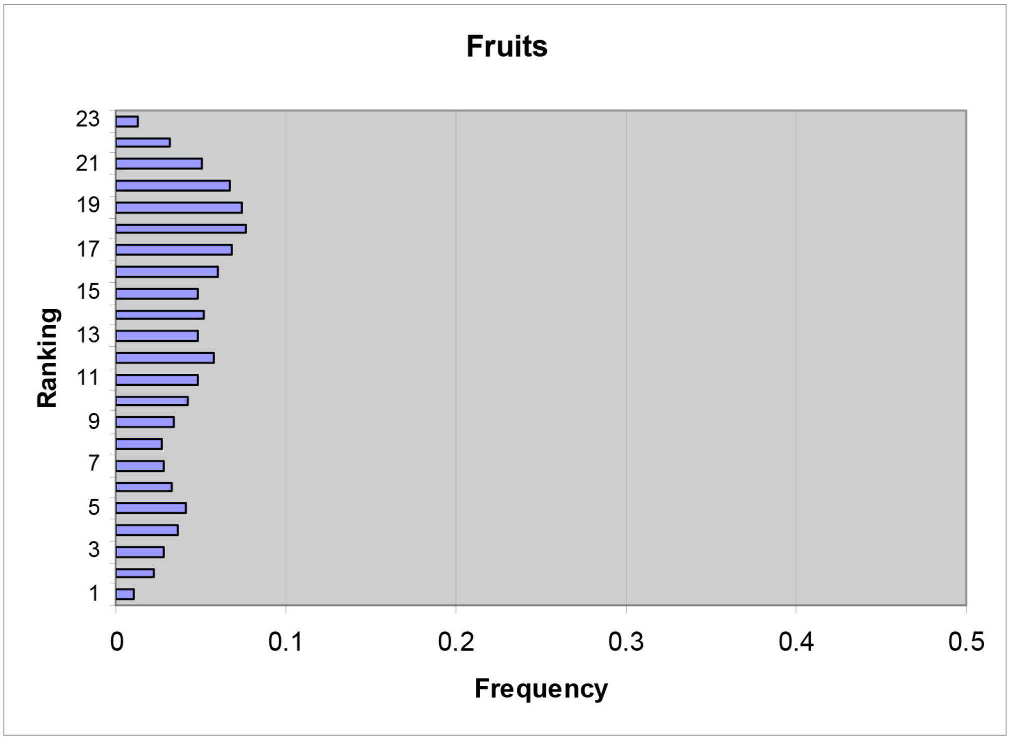


Figure V-9a. Rankings of Total Predicted Listeriosis Cases per Serving for Fruits

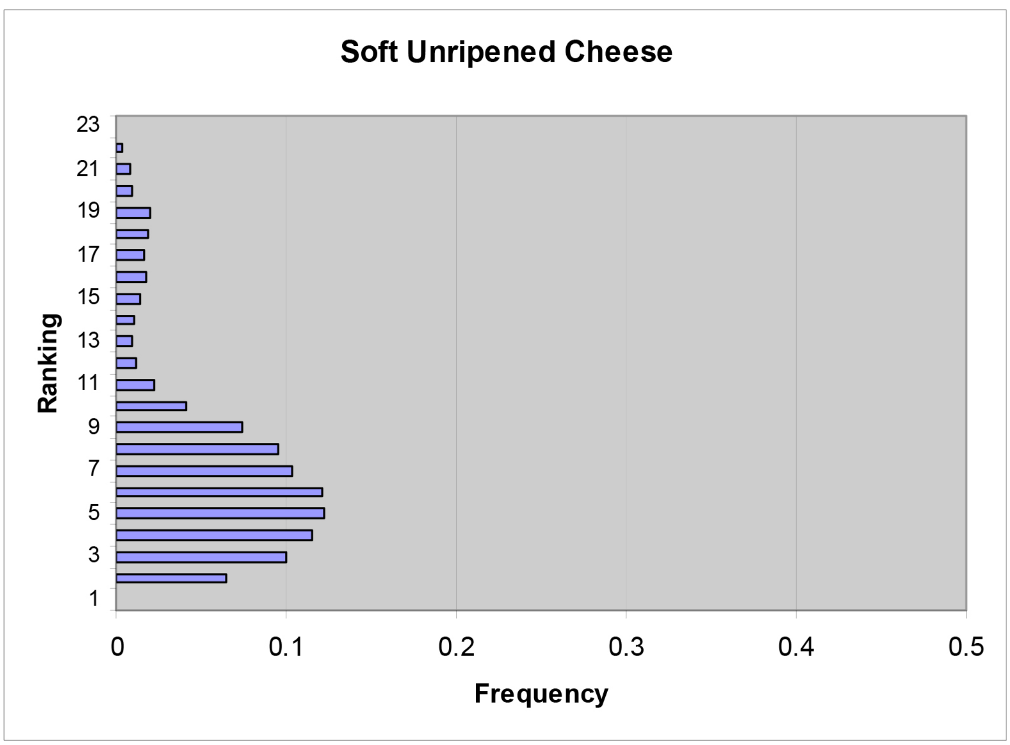


Figure V-9b. Rankings of Total Predicted Listeriosis Cases per Annum for Fruits

Food Category: Fresh Soft Cheese

Fresh Soft Cheese had a low predicted relative risk of causing listeriosis on a per serving basis. These cheeses are high moisture (>50%) fresh cheeses consumed shortly after manufacture. This category includes traditional Hispanic-style soft cheese (sometimes made from raw, unpasteurized fluid milk) such as panela, Queso de Crema, Queso Fresco,and Queso de Puna. The 2001 draft risk assessment included Queso Chihuahia and Queso Asadero attributed to this category, but these cheeses were moved from this category because they are not fresh, high moisture cheeses. The contamination level at retail, contamination frequency, growth rate during storage, and the annual number of servings are all low.

Fresh Soft Cheese (suspected to be made from unpasteurized milk) has been linked to both outbreaks and sporadic cases of listeriosis in the United States (Ryser, 1999a; Linnan *et al.*, 1988; CDC, 2001), including an outbreak in Los Angeles in 1985 and one in North Carolina in 2001. The 1985 outbreak in Los Angeles was the incident that convincingly established *Listeria moncytogenes* as an important serious foodborne pathogen. In 2000/2001, an outbreak in the Carolinas associated with homemade cheese made from unpasterurized milk resulted in 12 cases of serious listeroisis.

Consumption data was only available for one type of Fresh Soft Cheese, Queso fresco. The median amount consumed per serving for this category is 31 g (just over 1 ounce), and the annual number of servings is 7.1×10^7. Data are not available to estimate the proportion of Fresh Soft Cheese that is consumed in the United States made from unpasteurized milk; however, since the initial outbreak there has been a concerted effort to reduce the consumption of soft fresh cheeses made from unpasteurized milk. Fresh soft cheese made from unpasteurized milk does not meet FDA standards for interstate commerce.

Data from eight contamination studies were used to model the frequency of contamination for the Fresh Soft Cheese category. Cheeses in these studies were described as Hispanic-style, Queso Fresco, panela, requesoy, and fresh cow and goat milk cheeses. The most recent study was the NFPA (2002) survey and the contamination levels found in this study were much lower than those previously observed. In that study, 5 contaminated samples out of 2,936 total samples were positive, all at a level of less than 100 cfu/g. The samples from the NFPA study were collected in retail stores and were most likely made from pasteurized milk. Products made outside the retail system (including those made from unpasteurized milk) were not reflected in the NFPA survey. A ‘what if’ scenerio test was conducted to allow a comparison of the expected estimate of the risk per serving for fresh soft cheese made from pasteurized vs. raw, unpasteurized milk (see below).

Only one growth rate study with these cheeses was available. That study reported a low growth rate of 0.082 logs/day when adjusted to 5° C. The assumed storage times for Fresh Soft Cheese were 1 to 5 days and 15 to 30 days for most likely and maximum times, respectively.

The median risk per serving for the Fresh Soft Cheese category of $1.7x10^{-10}$ corresponds to a relative predicted risk ranking of tenth for the total United States population. The range for the predicted per serving risk ranking distribution for Fresh Soft Cheese (Figure V-10a) is relatively narrow and concentrated in the middle of the risk rankings. This indicates that there is little uncertainty associated with the per serving predicted relative risk for the Fresh Soft Cheese category. The predicted median per annum risk was less than one case per year and the relative risk ranking was fourteenth for the total United States population. The range for the per annum ranking distribution is concentrated in the higher risk rankings (Figure V-10b) indicating a lower risk. The breadth of the range indicates that there was somewhat more uncertainty associated with the per annum predicted relative risk ranking for the Fresh Soft Cheese category. This is likely associated with variability in the number of servings and the serving sizes.

An area of uncertainty associated with this food category that is not captured in this risk assessment is the consumption of “homemade” soft cheeses made from raw, unpasteurized milk. Raw milk soft cheeses are not produced and marketed through typical commercial means and have in the past been illegally brought into the United States. Data on such cheeses are not captured in the contamination data base used to develop this risk assessment. However, we recognize that a substantial portion of soft cheeses consumed in the United States may be made from unpasteurized milk.

Scenario Testing: Fresh Soft Cheese Made From Contaminated Unpasteurized Milk

Unlike the 2001 draft risk assessment, the revised risk assessment indicates that the risk from Fresh Soft Cheese is low. This change is largely attributable to the inclusion of additional new data indicating a very low prevalence rate in this food category. However, in the past there has been a strong epidemiological correlation between Hispanic-style fresh soft cheese (Queso Fresco) and listeriosis. A likely explanation for this discrepancy is that the data collected for this category is not representative of the cheese linked to the disease (i.e., fresh soft cheese made from raw, unpasteurized milk). In particular, although most commercial sources of fresh soft cheese are manufactured from pasteurized milk, some sources of queso fresco are made from raw milk. Many of these sources appear to be restricted to specific local areas and have not had the benefit of FDA oversight.

To characterize the risk from highly contaminated queso fresco an exposure model was constructed using the same analog as in the 2001 draft risk assessment – soft unripened cheese made from raw milk (Loncarevik, *et al*., 1995), where 50% of the samples tested were positive. The tested 'high prevalence' scenario increased the predicted risk on a per serving basis approximately 40-fold for the perinatal and elderly subpopulations. (For additional details, see Chapter VI 'What-If' Scenarios.)

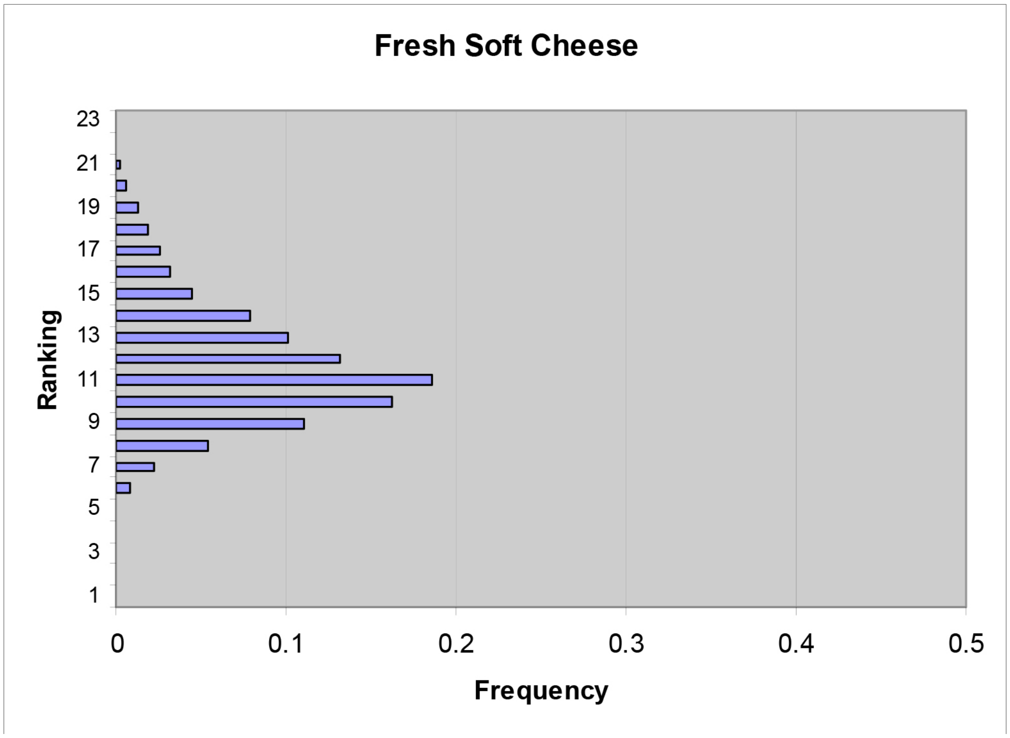


Figure V-10a. Rankings of Total Predicted Listeriosis Cases per Serving for Fresh Soft Cheese

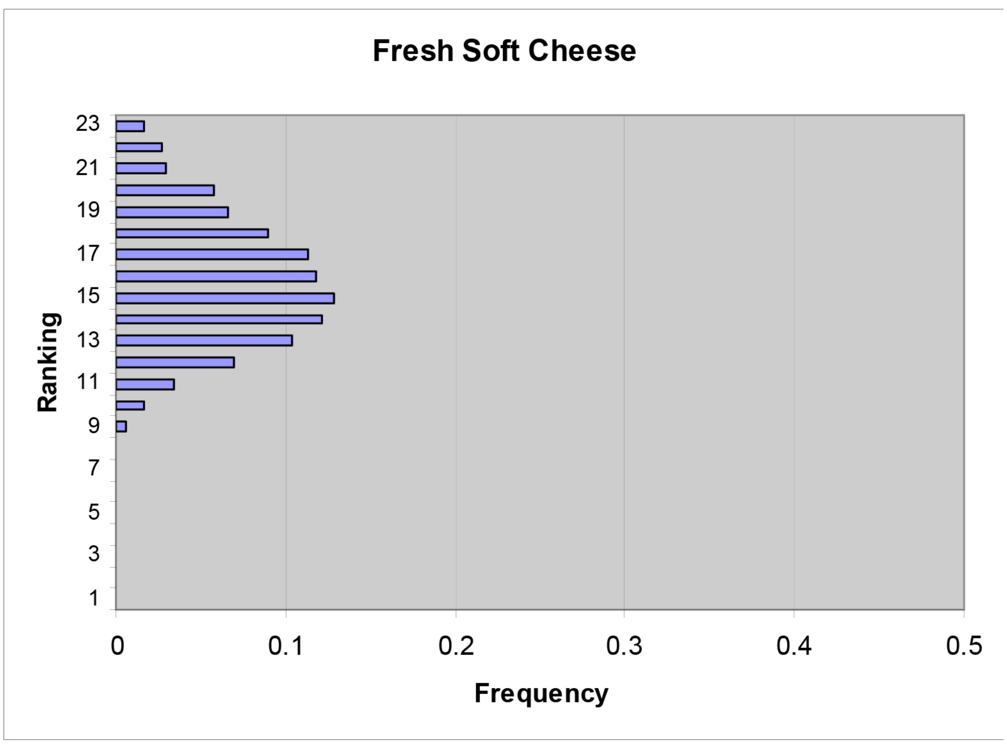


Figure V-10b. Rankings of Total Predicted Listeriosis Cases per Annum for Fresh Soft Cheese

Food Category: Soft Unripened Cheese

The Soft Unripened Cheese category has a moderate predicted relative risk of causing listeriosis on a per serving basis. The cheeses in this category have moderate frequency and levels of contamination and can have a long storage time. However, they support only a low rate of growth. Serving sizes are typically low, whereas the annual number of servings and contamination levels at retail are moderate. There was a sporadic listeriosis case in the United States linked to the consumption of a highly contaminated ricotta cheese (Ryser, 1999a). There are no reported cases of listeriosis associated with consumption of cottage and cream cheese, but there have been FDA recalls of cream cheese products.

The category represents high moisture (>50%), white curd varieties such as cottage cheese, baker's cream, and American-type Neufchatel cheese. Milk to be manufactured into soft unripened cheese is coagulated through the production of acid by the starter culture (or by direct acidification of milk) rather then by addition of a coagulant. Unlike fresh soft cheese, the refrigerated shelf-life is typically up to 60 days.

Consumption data available were available for cottage, cream, and ricotta cheeses. The median amount consumed per serving for this category is 29 g (about 1 ounce), and the annual total number of servings is 4.4×10^9.

There were eight studies with contamination data for these cheeses, with two from the United States. Three quantitative studies provided quantitative data. Cheeses in the contamination database included Anari, Halloumi, farmer, gournay, Quark, and cottage cheese. Of the 32 positive samples, four samples contained over 500 cfu/g and four samples over 10^6 cfu/g. The percentage of positive samples was 3.9%.

Twenty-nine data sets provided data on the growth or survival of *Listeria monocytogenes* in these cheeses. Nine of these studies showed a decline in levels over time. The research literature indicates that growth or decline of *Listeria monocytogenes* in these low salt cheeses is largely dependent upon pH. For example, ricotta cheese (pH=5.9 to 6.1) permitted rapid growth, whereas declines were observed in some cream cheeses (pH=4.8). The growth rates were standardized to 5 °C and a distribution fitted to the data to allow growth or decline (i.e., negative growth) in proportion to the available data. The average growth rate was 0.09 logs/day. Storage times were relative long, with the most likely 6 to 10 days and the maximum 15 to 45 days.

The median risk per serving for the Soft Unripened Cheese category of 1.8×10^{-9} corresponds to a relative predicted risk ranking of eighth for the total United States population. The range for the predicted per serving risk rankings for Soft Unripened Cheese (Figure V-11a) is bimodal but concentrated in the higher risk rankings. This indicates some uncertainty associated with the per serving predicted relative risk for this category. The median per annum risk was predicted as approximately 8 cases per year and the relative risk ranking was fifth for the total United States population. The range for the per annum ranking distribution is concentrated in the lower risk rankings, which corresponds to a higher risk (Figure V-11b). However, the broad ranges in uncertainty likely result from the differences of the products in this food category to support growth or cause a decline in levels of *Listeria monocytogenes*. Based on these results, this food category could benefit from subdivision.

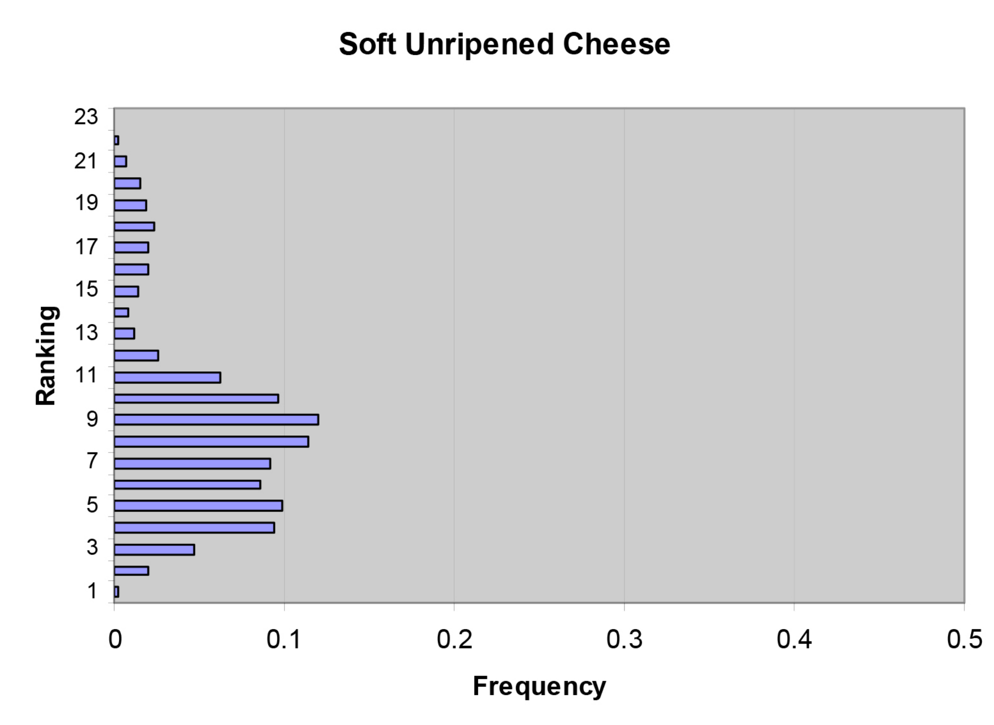


Figure V-11a. Rankings of Total Predicted Listeriosis Cases per Serving for Soft Unripened Cheese

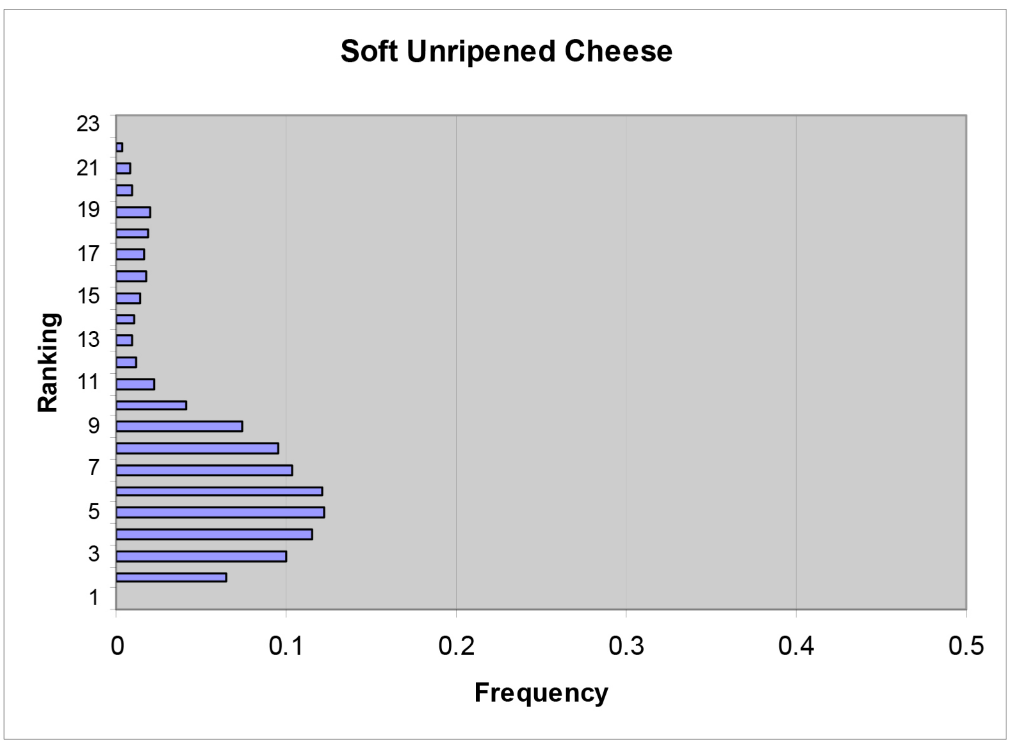


Figure V-11b. Rankings of Total Predicted Listeriosis Cases per Annum for Soft Unripened Cheese

Food Category: Soft Ripened Cheese

The cheeses in the Soft Ripened Cheese food category had a low predicted relative risk of causing listeriosis in the United States on a per serving basis. This food category includes high moisture (>50%), ripened cheeses such as mold surface-ripened cheeses (Brie, Camembert), pickled (white brined) cheeses, feta, and soft Italian-style cheeses (mozzarella). There are a moderate number of annual servings and small serving sizes. Growth rates were low but, contamination frequencies and levels at retail were moderate and storage times were long. Soft Ripened Cheeses including mold-ripened cheeses have been linked to outbreaks of listeriosis in Denmark, France and Switzerland and linked to sporadic cases in Belgium, Canada, and the U.K (Ryser, 1999a; Riedo *et al*., 1994; Art and Andre, 1991; Farber and Peterkin, 1991). There have not been any confirmed reports of sporadic cases or outbreaks associated with these cheeses in the United States.

The median amount consumed per serving for this category is 28 g (~1 ounce) and the annual number of servings is 1.9×10^9. Data are not available on the proportion of United States or imported cheese that is made from unpasteurized fluid milk. Market data indicate that the United States imports approximately 50% of the Camembert and Brie Cheese and 20% of the feta cheese sold in the United States (National Cheese Institute, 1998).

Contamination data was obtained for 17 studies with three being from the United States. Five studies provided quantitative data. Brie, Camembert, Feta, and Taleggio are some of the cheeses represented in the contamination data. Of the 17 studies, 6 contained quantitative contamination data. In the 2001 NFPA study, two samples were positive for *Listeria monocytogenes* with levels less than 10 cfu/g. The frequency of contamination was 3.8%.

Listeria monocytogenes populations were reported in the research literature to both increase and decrease in these cheeses. Of 17 studies, 7 showed declines, one no change, and 9 indicated growth. Therefore, the growth rate distribution used with this food category (–0.013 logs/day) included both growth and decline, with the ‘average’ response being a slow rate of decline. Storage times for this food category were long, with a maximum of 15 to 45 days.

The median risk per serving for the Soft Ripened Cheese category of $5.1x10^{-12}$ corresponds to a relative predicted risk ranking of seventeenth for the total United States population. The range for the predicted per serving risk ranking distribution for this category (Figure V-12a) is broad but concentrated in the higher risk rankings (low predicted risk). This indicates substantial uncertainty associated with the per serving predicted relative risk for this category resulting from the ability of some of these cheeses to support growth of *Listeria monocytogenes* and other cheeses to cause a decline. The median per annum risk was predicted as less than one case of listeriosis per year and the relative risk ranking was sixteenth for the total United States population. With the wide range for the per serving rankings, the resulting range for the per annum ranking distribution is quite broad (Figure V-12b) indicating high uncertainty associated with the per annum predicted relative risk ranking.

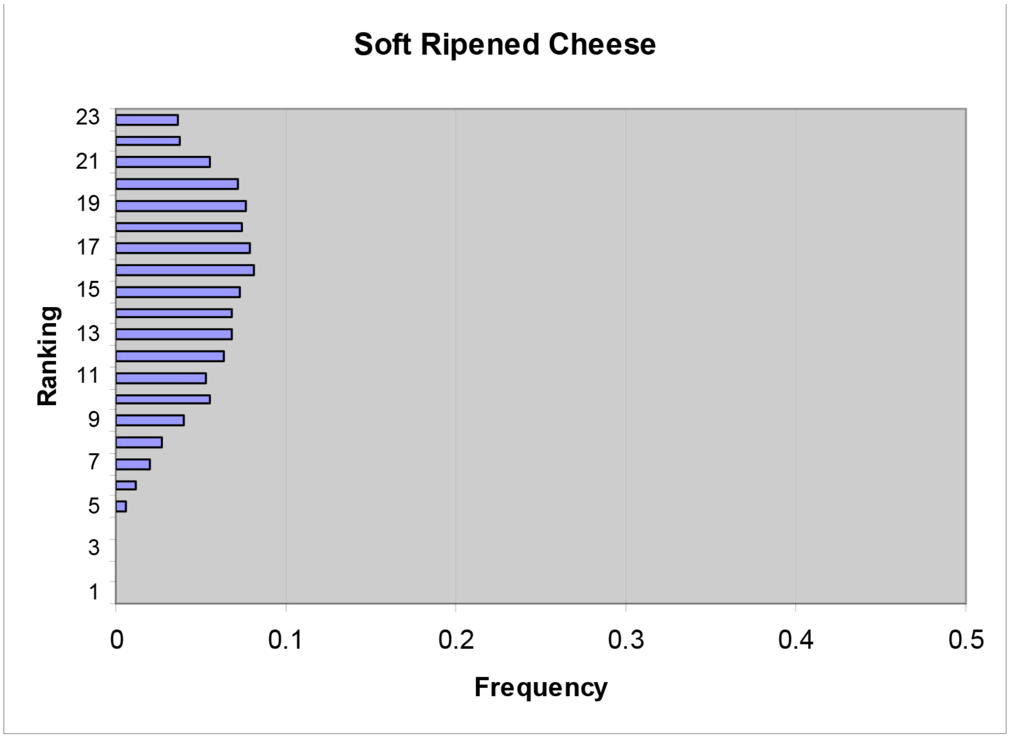


Figure V-12a. Rankings of Total Predicted Listeriosis Cases per Serving for Soft Ripened Cheese

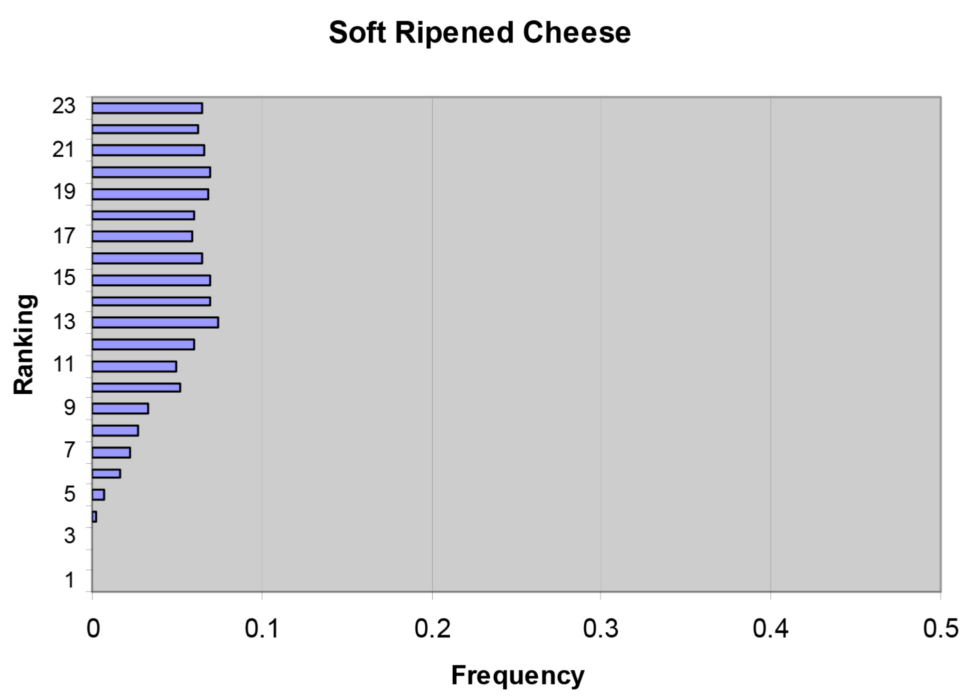


Figure V-12b. Rankings of Total Predicted Listeriosis Cases per Annum for Soft Ripened Cheese

Food Category: Semi-soft Cheese

The Semi-soft Cheese food category has a low predicted relative risk of causing listeriosis on a per serving basis. Semi-soft Cheese has a moisture content that ranges between 39% and 50%. The cheeses in this food category include blue, brick, Edam, Gouda, havarti, Limburger, Monterrey jack, Muenster, and provolone. The serving sizes are small, the annual number of servings, and contamination frequency are moderate, and the levels at retail are low. Although the storage times are long, the growth rates are low. Blue cheese has been linked to an outbreak of listeriosis in Denmark (Jensen *et al*., 1994) and Monterrey jack cheese made from raw milk to a sporadic case in the United States (Ryser, 1999a). FDA has monitored recalls of several semi-soft cheeses because of the presence of *Listeria monocytogenes*.

The median amount consumed per serving for this category is 28 g (1 ounce), and the annual number of servings is 1.8×10^9. Data are not available to describe the proportion of United States or imported cheese that is made from unpasteurized fluid milk. Market data indicate that the United States imports approximately 20% of the blue cheese (including Gorgonzola) sold in the United States (National Cheese Institute, 1998).

There were eleven studies with contamination data, including three from the United States. Three studies provided quantitative data. The average frequency of contamination from these studies was 3.1%. The recent NFPA survey (NFPA, 2002) collected 1,623 samples of semi-soft cheeses, of which 23 were positive. The highest contamination observed was less than 100 cfu/g.

Semi-Soft Cheeses do not generally permit growth of *Listeria monocytogenes*. Of the 10 data sets found in the literature, levels declined in eight studies and the mean exponential growth rate was –0.043 logs/day at 5 °C. The storage times were long with a maximum of 15 to 45 days.

The median risk per serving for the Semi-soft Cheese category of 6.5×10^{-12} corresponds to a relative predicted risk ranking of sixteenth for the total United States population. The range for the predicted per serving risk ranking distributions for this category (Figure V-13a) is relatively narrow and concentrated in the higher risk rankings (low predicted risk). This indicates relatively little uncertainty associated with the per serving predicted relative risk for this category. The median per annum risk was predicted as less than one case of listeriosis per year and the relative risk ranking was fifteenth for the total United States population. As with the range for the per serving rankings, the range for the per annum ranking distribution is similar to that typical of most food categories (Figure V-13b) indicating relatively little uncertainty associated with the per annum predicted relative risk ranking.

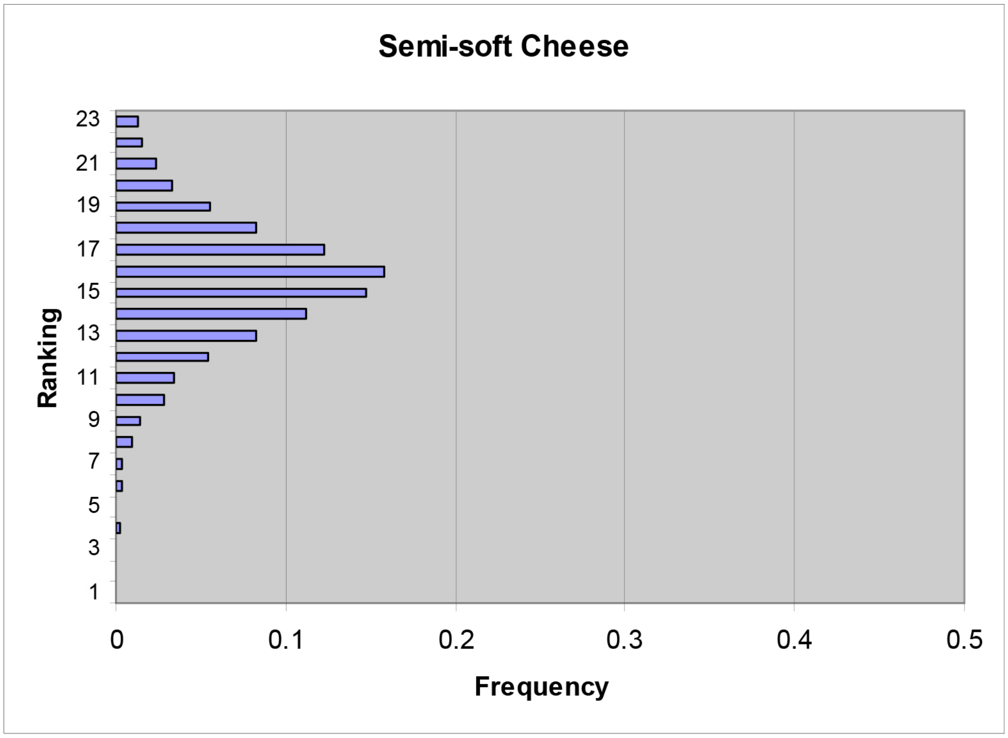


Figure V-13a. Rankings of Total Predicted Listeriosis Cases per Serving for Semi-soft Cheese

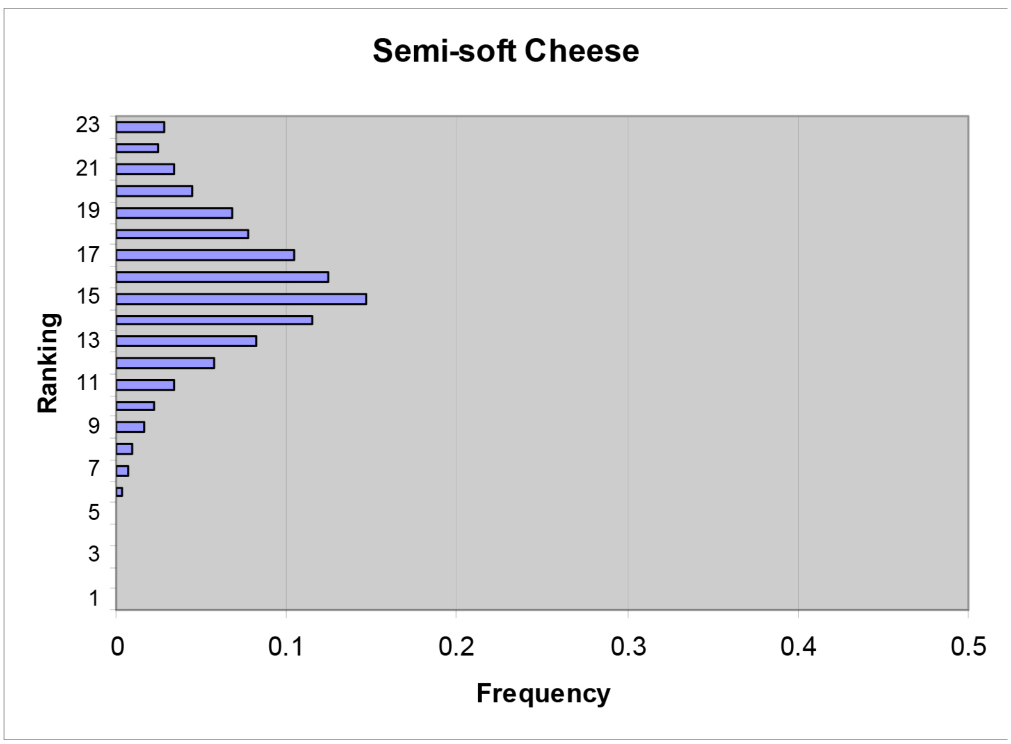


Figure V-13b. Rankings of Total Predicted Listeriosis Cases per Annum for Semi-soft Cheese

Food Category: Hard Cheese

The Hard Cheese food category had a low predicted relative risk of causing listeriosis on a per serving basis. The low relative risk can be attributed to the small amount consumed, low contamination level at retail, and little, if any, growth during storage, despite the long storage times, and a moderate annual number of servings. Hard Cheeses have less than 39% moisture and include cheddar, Emmemtaler, Gruyere, parmesan, Queso Chihuahua, romano, silton, and Swiss. These types of cheeses typically have a high salt content, which limits the growth of *Listeria monocytogenes*. There are no recognized outbreaks or illnesses traced to Hard Cheese.

This cheese category includes consumption data for a variety of cheese types, including Swiss, cheddar, and parmesan. The median amount consumed per serving for this category is 28 g (~1 ounce) and the annual number of servings is 9.0×10^9.

Twelve studies, including two from the United States, provided contamination data for this category. Two studies provided quantitative data. Some of the data were collected from 2000 and later but the majority of the data was collected before 1993. The quantititive data were from the U.K, in 1990 and 1991. The frequency of contamination was only 1.4%, a low rate.

Seven studies provided data on the growth and survival of *Listeria monocytogenes* in hard cheeses. Of the 11 data points available, 10 indicated declines in *Listeria monocytogenes* populations, with an average of –0.053 logs/day at 5 °C. Storage times for this category of cheese were longer than other cheese categories. The most likely storage time was 6 to 10 days and the maximum was 90 to 180 days.

The median per serving and per annum predicted relative risk ranking for the Hard Cheese category were both last (23rd) for the total United States population. The range of the per serving ranking distribution (Figure V-14a) was moderately narrow and strongly concentrated in the higher rankings (low risk). The per annum ranking distribution (Figure V-14b) is similar to the per serving distribution. This indicated that there was little uncertainty with the predicted rankings.

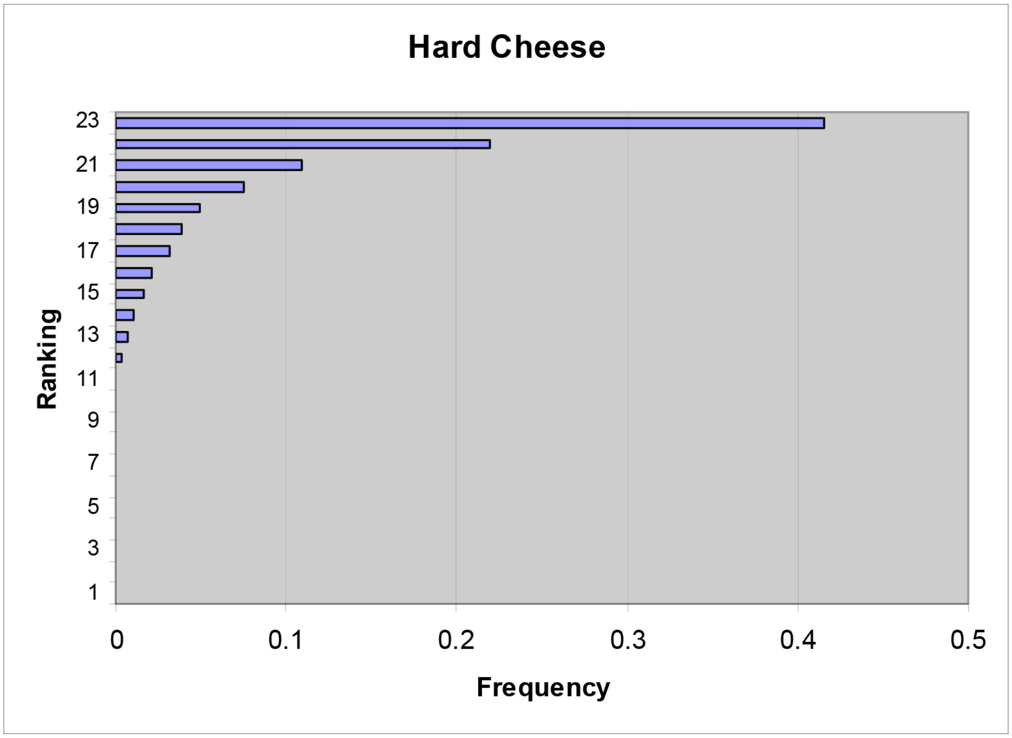


Figure V-14a. Rankings of Total Predicted Listeriosis Cases per Serving for Hard Cheese

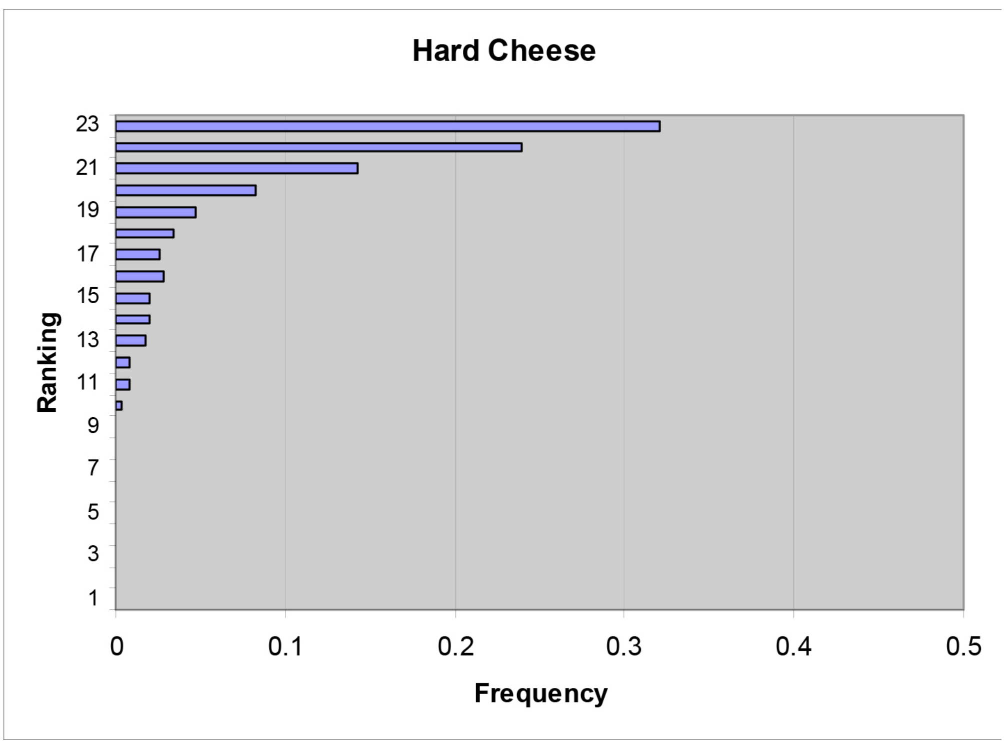


Figure V-14b. Rankings of Total Predicted Listeriosis Cases per Annum for Hard Cheese

Food Category: Processed Cheese

The Processed Cheese category had a low predicted relative risk of causing listeriosis on a per serving basis. This category has a high annual number of servings and a long storage time, but a low growth rate during storage and low contamination frequency. The median amount consumed per serving is 21 g (about 0.75 ounce), and the annual total number of servings is 1.2×10^{10}.

Processed cheeses are made with natural cheese, dairy ingredients, and emulsifying salts. These cooked (pasteurized) and packaged cheeses include cheese food, cheese spreads, cheese sauces, and cheese slices. Processed cheeses from this category have not been linked to outbreaks or sporadic cases of listeriosis, but FDA has monitored recalls of cheese foods and cheese spreads because of the presence of *Listeria monocytogenes*.

There were four contamination studies available for this category, of which one was from the United States. A total of 325 samples were analyzed with only 0.9% found to contain *Listeria monocytogenes*. In two of these studies, the three positive samples were enumerated with the highest level being less than 100 cfu/g. In two recent studies, the 49 collected samples were negative for *Listeria monocytogenes*. The predicted percentage of servings with 10^3 to 10^6 cfu at retail was low.

Six data points for the survival of *Listeria monocytogenes* in Processed Cheese were found in the literature. All showed decreasing numbers during storage. Overall, a survival rate of -0.045 logs/day at 5°C was used. Storage times were long for this category; the assumed most likely time was 6 to 10 days and the maximum time was 45 to 90 days.

The median risk per serving for the Processed Cheese category of 4.2×10^{-14} corresponds to a relative predicted risk ranking of twenty-one for the total United States population. The predicted median per annum relative risk rankings was also twenty-first for the total United States population, with less than one case per year predicted for this food category. Both ranking distributions for Processed Cheese (Figures V-15a and V-15b) are moderately wide and concentrated in the higher rankings (i.e., a lower risk). The degree of uncertainty was slightly greater for the per annum rankings. Overall, there was a moderate degree of uncertainty in both the predicted per serving and per annum predicted relative risk rankings for the Processed Cheese category. This reflects the fact that there was only limited data that were available for this food category.

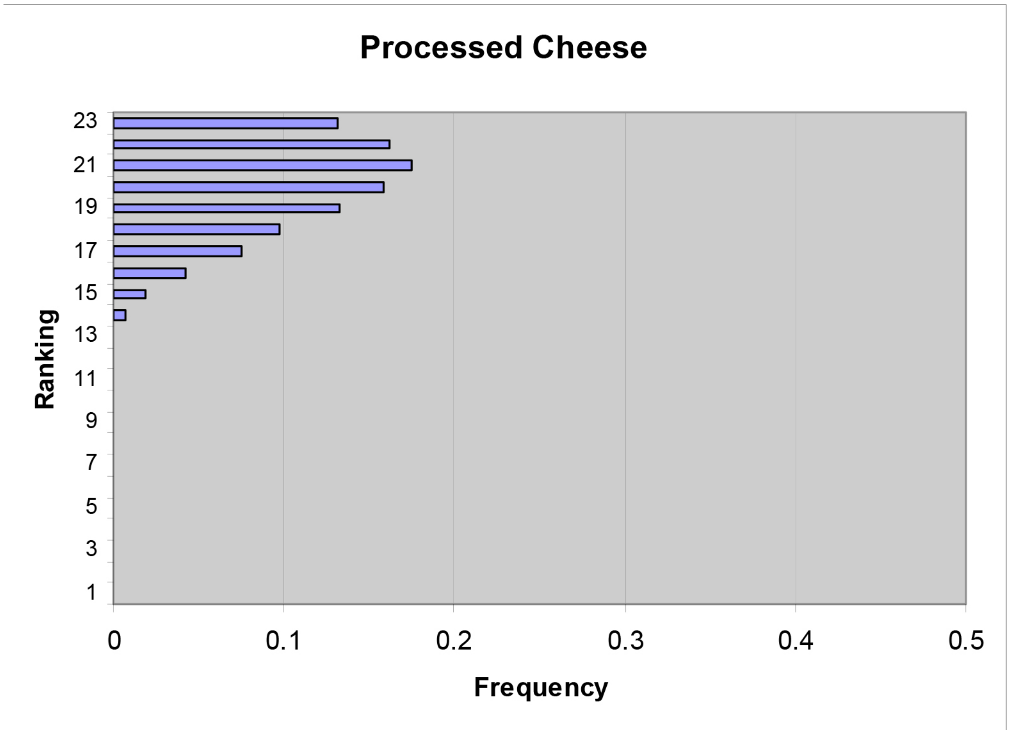


Figure V-15a. Rankings of Total Predicted Listeriosis Cases per Serving for Processed Cheese

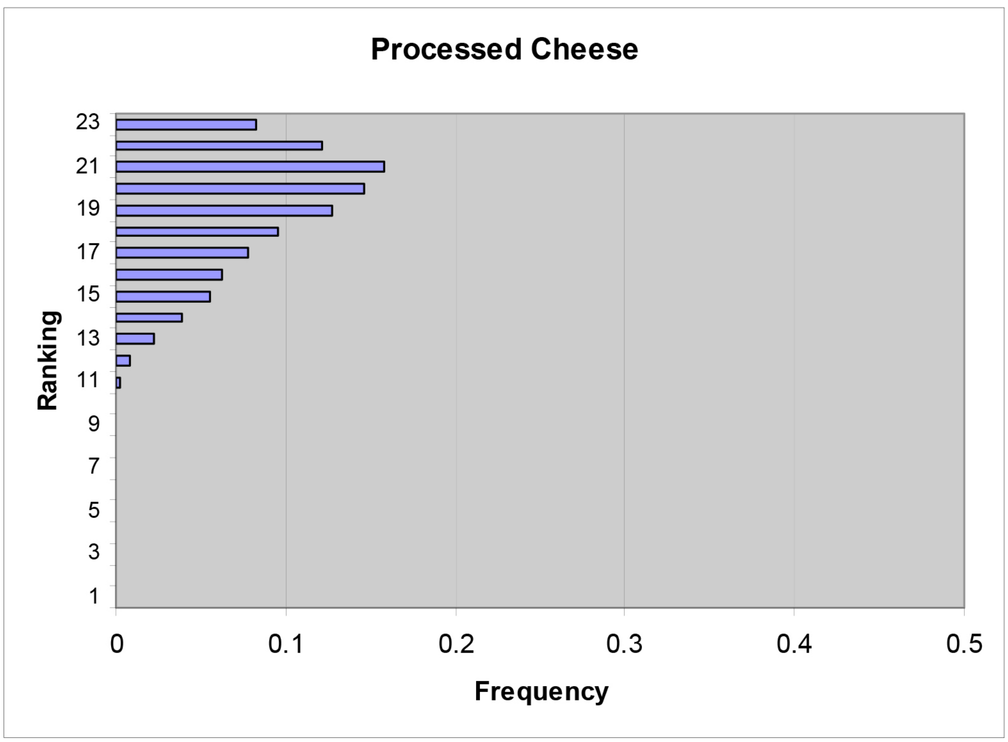


Figure V-15b. Rankings of Total Predicted Listeriosis Cases per Annum for Processed Cheese

Food Category: Pasteurized Fluid Milk

Pasteurized Fluid Milk had a moderate predicted relative risk of causing listeriosis on a per serving basis. The Pasteurized fluid milk category includes cow and goat milk, chocolate milk, other flavored milk, and malted milk. This is the most commonly consumed food category. Products in this category are eaten 4 to 100 times more often than foods in most other categories. Powdered milk and other dairy products that are reconstituted by the food preparer and milk shakes were included in the High Fat and Other Dairy Products food category.

Contamination frequency at retail for this category is low (average of 0.4%) due to pathogen inactivation during pasteurization. However, this is offset somewhat by the large serving sizes associated with this product and high potential for growth of *Listeria monocytogenes* in the product during storage. The median amount consumed per serving is 244 g (approximately 8 ounces), which is substantially larger than the serving sizes of most other foods considered in this risk assessment. The frequency of serving (8.7×10^{10}) is also the highest among the food categories.

It is generally assumed that contamination of Pasteurized Fluid Milk is the result of post-pasteurization recontamination, since normal pasteurization will effectively eliminate the microorganism. One of the most likely sites is during filling which would lead to the occasional recontamination of individual cartons. Accordingly, control of recontamination is likely to be a key factor in further risk reduction. Experimental studies have demonstrated that pasteurized milk will support growth of *Listeria monocytogenes* to high levels at refrigeration temperatures within the normal shelf-life of the food.

An outbreak of listeriosis has been associated with post-pasteurization recontamination of pasteurized chocolate milk (Dalton, *et al.*, 1997). A second outbreak was epidemiologically linked to pasteurized whole or 2% milk; however, this could not be confirmed by laboratory analyses (Ryser, 1999a; Fleming *et al.*, 1985). Such outbreaks likely represent a significant loss of control whereas the sporadic recontamination of individual contains would be likely to be

expected to produce sporadic cases. Sporadic cases would be difficult to identify using traditional case control studies due to the high rate of consumption of this food.
Over 12,400 samples from 30 studies were available to provide data on the frequency of detectable contamination. Most of these studies were from samples collected outside of the United States. Approximately 0.03% of the milk consumed in the United States is imported (Frye and IDFA, 2000a). Two reports (Kozak *et al*., 1996; Frye and IDFA, 2000b) of surveys conducted in the United States and one survey from Canada were available to estimate the frequency of contamination in North America. The overall frequency of contamination was low at 0.4%. The survey conducted in the United States by the International Dairy Foods Association (Frye and IDFA, 2000b) observed only one positive sample in 4,552 collected samples and the level in that sample was below quantitation (<1 cfu/g). The other studies with enumeration data (conducted in Germany and the U.K.) analyzed a total of 1,559 samples of which only 4 were positive.

Five laboratory investigations of the growth rate of *Listeria monocytogenes* in pasteurized, unpasteurized, Ultra High Temperature (UHT), skim, and chocolate milks were found. The mean exponential growth rate was 0.26 logs/day, a relatively rapid rate of growth compared with other food categories. In contrast to the other food categories, the literature indicated that milk supported higher maximum levels of *Listeria monocytogenes* and that the storage temperatures did not affect as much the maximum growth potential in fluid milk. The storage intervals used in the model for storage ranged from 0.5 to 15 days, with 3 to 5 days as the most likely storage time.

The median per serving predicted relative risk rankings for the Pasteurized Fluid Milk category were ninth for the total United States population. The range for per serving ranking distribution for Pasteurized Fluid Milk was moderately broad. The distribution of rankings was normally distributed, and similar to that observed with other food categories (Figure V-16a). Thus, the predicted per serving relative risk ranking was considered to have a moderate degree of uncertainty. The number of servings predicted to contain 10^3 to 10^6 cfu/g after refrigerated storage is low. Furthermore, the number of servings associated with the limited quantitative data required the use of a broad distribution for post storage contamination levels. This, in turn, may lead to an overestimation of the relative risk associated with this product.

The median per annum predicted risk was approximately 91 cases per year which corresponds to a relative risk ranking for Pasteurized Fluid Milk of second for the total United States population. The increase in the predicted per annum relative risk ranking compared to the per serving ranking reflects the frequency of consumption. Pasteurized milk is the most extensively consumed food category both in terms of frequency of consumption and serving sizes. These factors, in combination with the uncertainty associated with the lack of quantitative data for the levels of *Listeria monocytogenes* in contaminated pasteurized milk results in a small percentage of contaminated servings being assigned a high level of contamination. These few, highly contaminated servings predicted by the model drive the risk estimates.

While the per annum ranking distribution is relatively narrow (Figure V-16b), it is strongly influenced by the highly uncertainty values in the “tails” of the broad distributions that had to be incorporated into the models. Definitive interpretation of the per annum risk and its ranking will have to await the acquisition of additional quantitative data and possibly more sophisticated epidemiologic investigations that could shed more light on the differences between the epidemiologic record and the risk predicted by the current model.

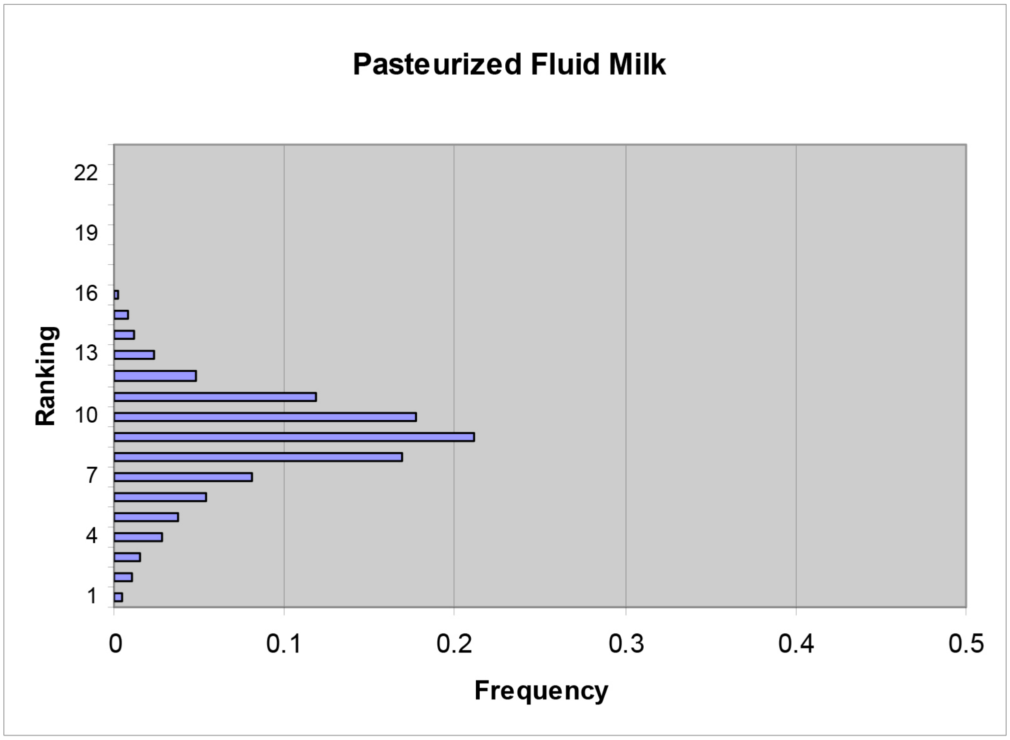


Figure V-16a. Rankings of Total Predicted Listeriosis Cases per Serving for Pasteurized Fluid Milk

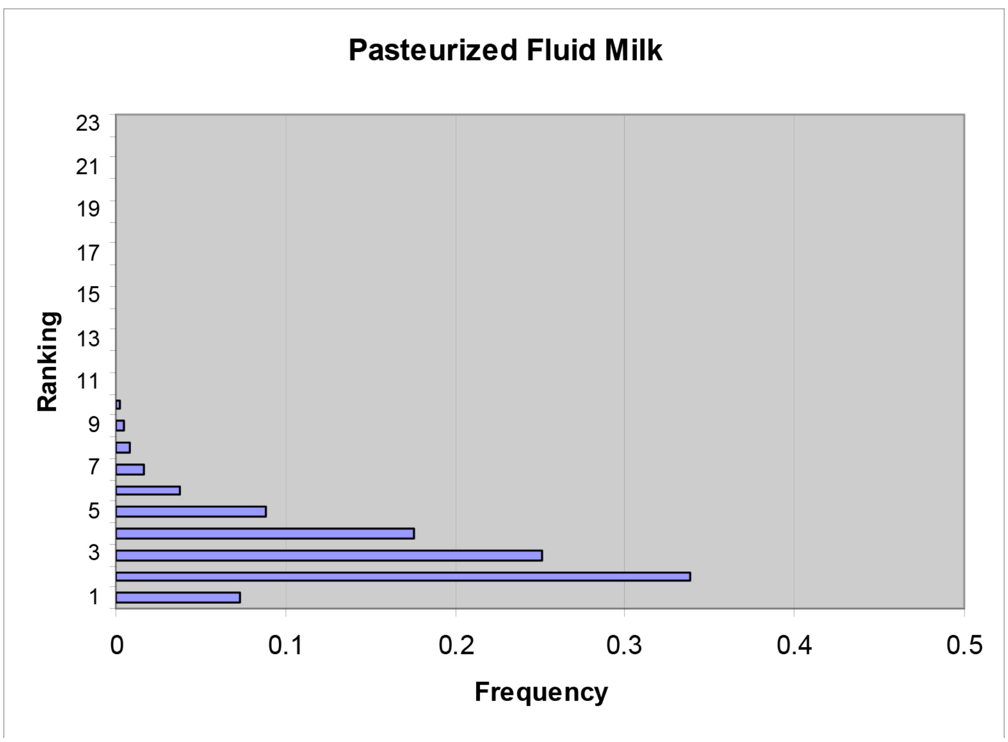


Figure V-16b. Rankings of Total Predicted Listeriosis Cases per Annum for Pasteurized Fluid Milk

Food Category: Unpasteurized Fluid Milk

Unpasteurized Fluid Milk had a high predicted relative risk of causing listeriosis on a per serving basis. Although consumption of unpasteurized fluid milk is infrequent, relatively large serving sizes and a moderate frequency of contamination, coupled with a significant (high) potential for growth during its refrigerated shelf-life affect the relative risk for this category. The annual number of servings consumed of Unpasteurized Fluid Milk was estimated to be low, 4.4×10^8 servings (0.5% of pasteurized fluid milk). The median serving size (244 g, or approximately 8 ounces) was assumed to be the same as for pasteurized fluid milk.

Although federal law requires milk in interstate commerce to be pasteurized, some states allow milk consumed within the state to be sold and drunk as unpasteurized milk. Results of a 1995 FDA/CDC survey of all 50 states, Puerto Rico, and the District of Columbia showed that 28 states (54%) permit the sale of unpasteurized milk. In the states where the sale of unpasteurized milk is legal, the estimated volume of unpasteurized milk sold, as a percentage of total milk sold, was less than 1% by volume (or weight) (Headrick *et al.*, 1998). Several studies have shown that *Listeria monocytogenes* is present in 1 to 6% of unpasteurized milk samples on a worldwide basis. There has been an outbreak linked to unpasteurized milk in Austria and a sporadic case of listeriosis was linked to unpasteurized milk in Denmark (Jensen *et al.*, 1994; Allerberger and Guggenbichler, 1989). The use of unpasteurized milk to manufacture other dairy products has also been linked to outbreaks and sporadic cases of listeriosis.

There were 45 contamination studies, including 10 from the United States. Three studies (all non-United States) provided quantitative data. Almost all of the samples were cow's milk but a small portion was goat or other non-bovine milk. The contamination frequency was moderate at 4.1%. The three recent studies from the United States found a contamination frequency of 1.6%, i.e., 20 positive samples out of 1,263 total samples (Abou-Eleinin *et al.*, 2000; Frye and IDFA, 2000b; and Oregon Dept of Agriculture, 2001).

In general, the initial frequency of contamination is greater in unpasteurized milk than in pasteurized milk, 4.1% vs. 0.4%, respectively. Although the prevalence of low level contamination is much higher in unpasteurized milk than for pasteurized milk, the calculated relative risk per serving is only slightly higher. This appears to be due to two factors. The first is that higher contamination rates are offset somewhat by the shorter storage time assumed for unpasteurized milk. The storage times used in the analysis were 0.5 to 10 days with a most likely time of 2 to 3 days. Because of the presence of a more extensive spoilage microflora, the product tends to be held for a shorter time period than pasteurized milk. The second factor that influenced the predicted per serving relative risk associated with Unpasteurized Fluid Milk is the small degree of variability in the frequency and levels of contamination reported in a large number of studies. This availability of substantially more quantitative data led to a substantially narrower range of contamination values and eliminated the distribution "tails" that increased the uncertainty discussed in the preceding section on Pasteurized Fluid Milk. This emphasizes the impact that the degree of uncertainty has on the calculation of risk.

The predicted percentage of servings contaminated with 10^6 to 10^9 cfu/serving at retail was low. Unpasteurized Fluid Milk would be characterized by frequent contamination at low levels. This is in contrast to Pasteurized Fluid Milk, which would have infrequently contaminated cartons. Because unpasteurized milk does not receive any treatment that would reduce *Listeria monocytogenes* levels, several of the studies used were of bulk tank milk instead of milk in retail containers. The extent to which this might affect the estimated exposure is unclear. Higher median levels of contamination with *Listeria monocytogenes* might be expected in unpasteurized milk; however, the limited data do not support this.

It has been hypothesized that competition from more numerous spoilage microorganisms present in Unpasteurized Fluid Milk may slow the growth rate of *Listeria monocytogenes* and also reduce the maximum growth. However, no data were available to allow this to be factored into the risk assessment. There were two growth studies using unpasteurized fluid milk. They did not indicate any clear difference in growth rates compared to pasteurized fluid milk. Therefore, the growth characteristics of the Pasteurized Fluid Milk category were assumed for Unpasteurized Fluid Milk. As indicated previously, while storage times for unpasteurized milk were moderate, the values used were shorter than those for pasteurized milk. If this assumption is not correct, this would lead to a degree of understating the relative risk due to the food category.

The median per serving predicted relative risk rankings for the Unpasteurized Fluid Milk category was fourth for the total United States population (Figure V-17a). The range of the ranking distribution for Unpasteurized Fluid Milk was similar to those observed with the other food categories (Figures V-17a and V-17b) and tended to the lower relative risk rankings (i.e., higher risk). This indicates that there was moderate uncertainty associated with the relative ranking for the Unpasteurized Fluid Milk category. This uncertainty is likely due to the variability in the frequencies and extents of contamination among the different studies. The median per annum predicted relative risk ranking was seventh for the total United States population (Figure V-17b). This decrease in predicted relative risk in comparison to the per serving values reflects the relatively few servings consumed annually. The distribution of per annum rankings was moderately broad and nearly normally distributed, indicating a moderate but typical degree of uncertainty associated with the predicted per annum risk ranking.

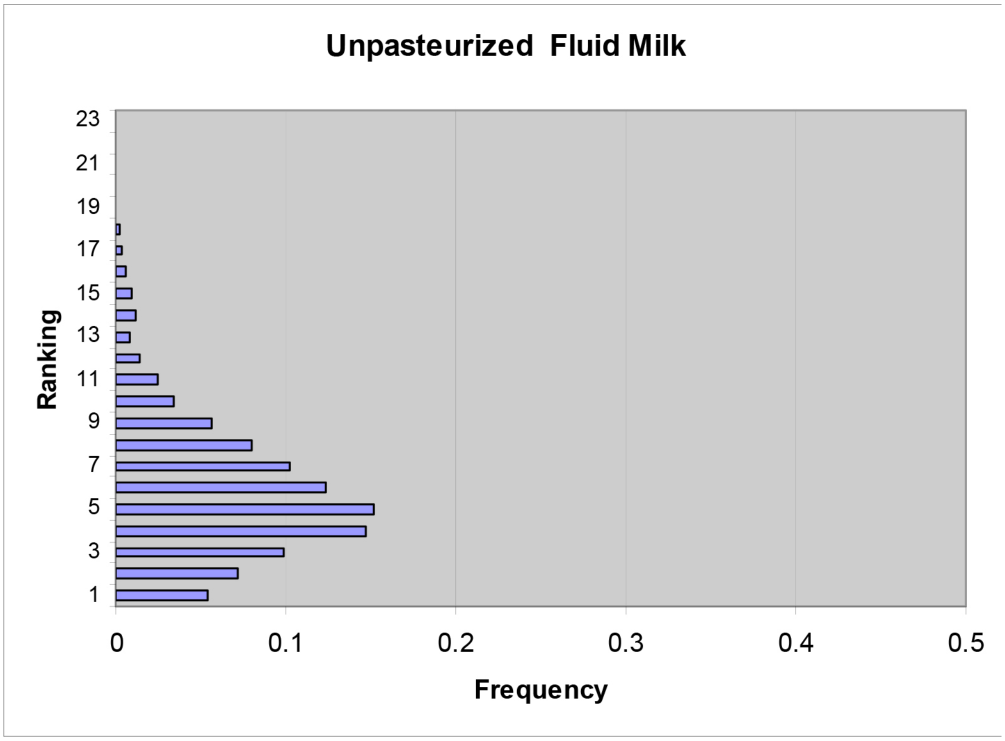


Figure V-17a. Rankings of Total Predicted Listeriosis Cases per Serving for Unpasteurized Fluid Milk

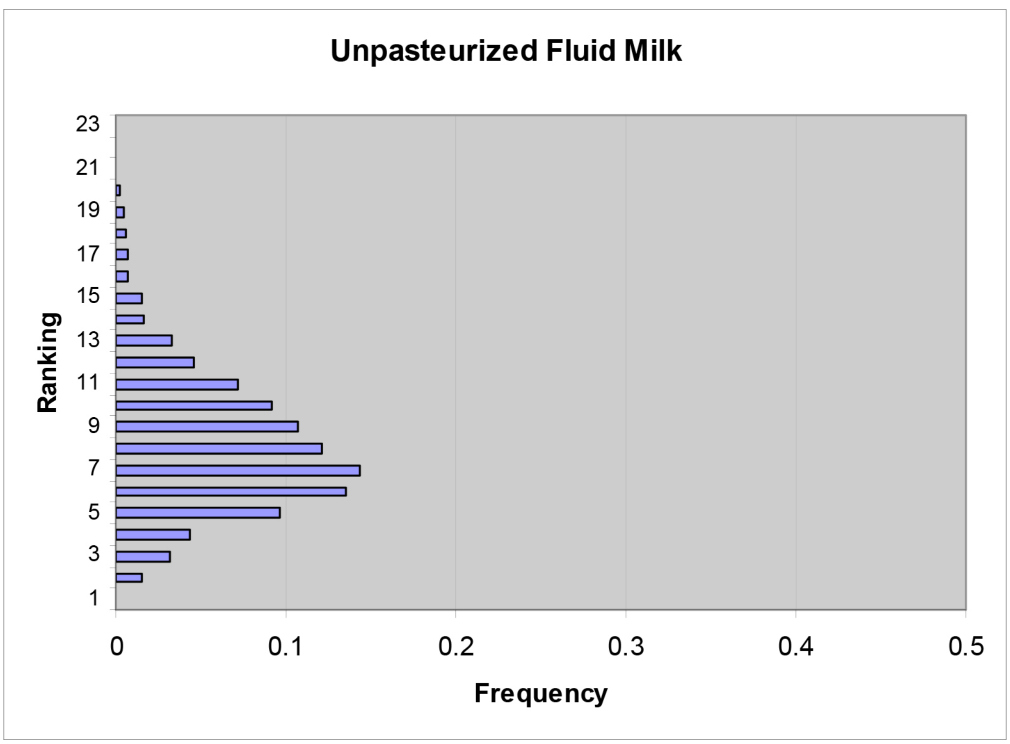


Figure V-17b. Rankings of Total Predicted Listeriosis Cases per Annum for Unpasteurized Fluid Milk

Food Category: Ice Cream and Other Frozen Dairy Products

Ice Cream and Frozen Dairy Products had a low predicted relative risk of listeriosis on both a per serving and per annum basis. While ice cream and frozen dairy products are consumed frequently and the median serving size is large, contamination frequency is low and is usually at low levels. Growth is not supported at freezer temperatures. The only association between listeriosis and ice cream or other frozen dairy products was a sporadic case in Belgium, which was linked to commercially prepared ice cream made from contaminated cream (Ryser, 1999a). Like Pasteurized Fluid Milk, contamination of Ice Cream and Other Frozen Dairy Products appears to be largely the result of occasional post-pasteurization recontamination of individual cartons, which would be more consistent with sporadic cases that outbreaks.

Consumption data included many types of ice cream and frozen dairy products. The median amount consumed per serving for this category is 132 g (approximately 4.7 ounces) and the annual number of servings consumed is 1.5×10^{10}.

Twenty-two studies provided contamination data. Five were conducted in the United States and two studies (none from the United States) provided quantitative data. Tested products included ice cream, frozen yogurt, ice milk, ice cream mix, and novelty ice cream products. The percentage of positive samples was low (0.12%). A recent, large quantitative study from Germany (Hartun, 2001) observed only two positive from a total of 1,696 samples and both of these samples contained less than 100 cfu/g of *Listeria monocytogenes*.

Although *Listeria monocytogenes* cannot grow at freezer temperatures, it is able to survive. If temperature abuse occurs that permits changes in the texture of these products (i.e., warming and refreezing), the product does not become warm enough to permit *Listeria monocytogenes* growth. More drastic temperature abuse, of the kind that would allow growth, results in an inedible product. The levels of *Listeria monocytogenes* found in the retail surveys of ice cream and frozen dairy products would not increase prior to consumption.

The predicted median per serving and per annum relative risk rankings for the Ice Cream and Frozen Dairy Products category were both twentieth for the total United States population. The ranges for both predicted ranking distributions for ice cream and frozen dairy products are clustered in the high rankings (low risk) (Figures V-18a and V-18b). The uncertainty was similar to that observed with other food categories. The extensive database available and the characteristics of the food category provide significant confidence in the relative rankings for the Ice Cream and Other Frozen Dairy Products category.

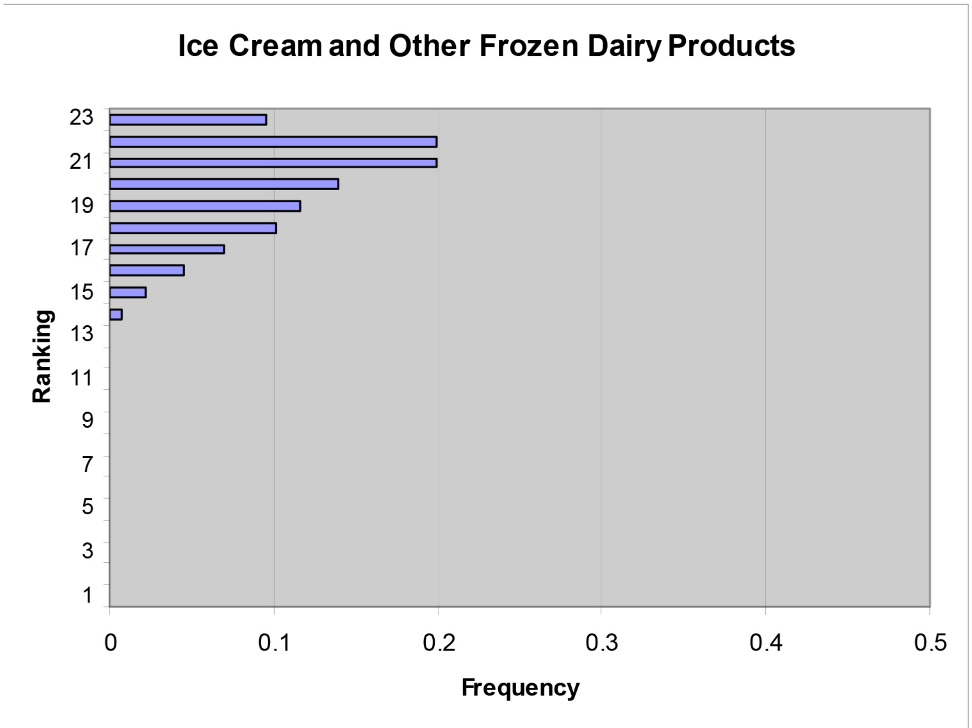


Figure V-18a. Rankings of Total Predicted Listeriosis Cases per Serving for Ice Cream and Frozen Dairy Products

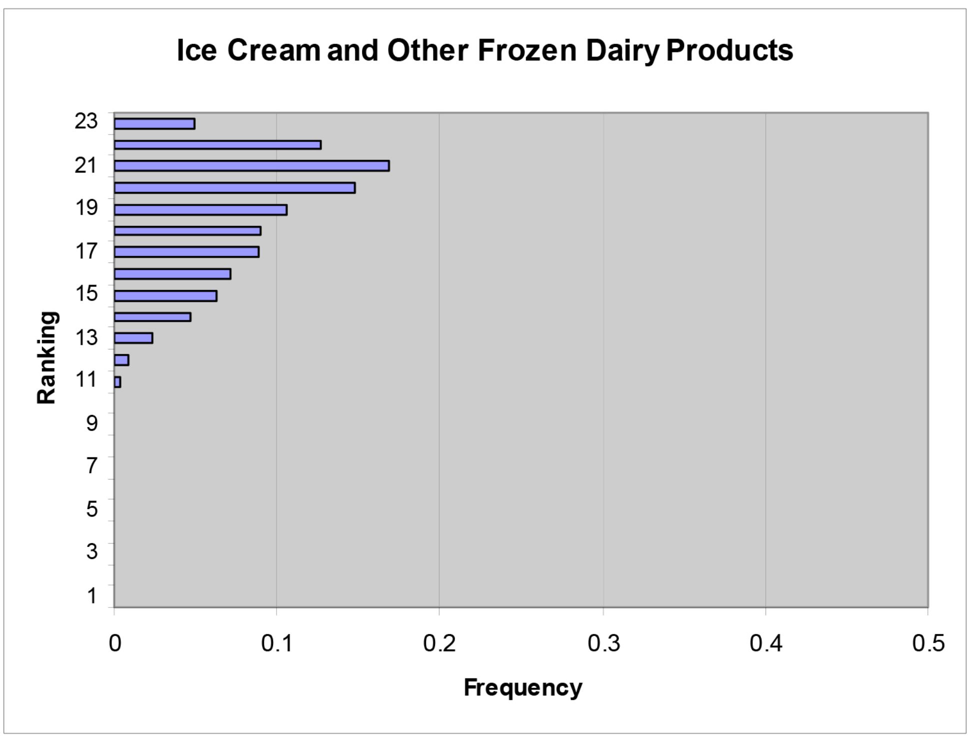


Figure V-18b. Rankings of Total Predicted Listeriosis Cases per Annum for Ice Cream and Frozen Dairy Products

Food Category: Cultured Milk Products

Cultured Milk Products had a low predicted relative risk of listeriosis on both a per serving and per annum basis. The Cultured Milk Products category had a relatively low contamination frequency and levels of contamination. Because of the breadth of the category, there were a moderate number of servings annually, high amounts consumed, and the proportion of the population eating products from this category was high.

The Cultured Milk Products category includes low pH dairy foods manufactured with lactic acid fermentation. Of these foods, yogurt is the most frequently consumed food. Others include buttermilk and sour cream. These products had previously been grouped with High Fat Dairy Products (referred to as the Miscellaneous Dairy Products) in the 2001 draft risk assessment. In this revised risk assessment, the cultured milk products and high fat milk products have been separated into two food categories based on product characteristics. No illnesses have been linked to Cultured Dairy Products.

Consumption data for Cultured Milk Products include many types of dairy products such as buttermilk, yogurt, and sour cream. The median amount consumed per serving for this category is 114 g (slightly over 4 ounces), and the annual number of servings is 7.2×10^9.

Six contamination studies were available, with the single study conducted in the United States collected only 14 samples. A 1991 study conducted in the U.K. observed four positive samples, one of which was enumerated and contained 10^3 to 10^4 cfu/g. The contamination frequency for these studies was low at 0.8%.

Inoculated pack studies showed that *Listeria monocytogenes* does not grow in these foods. Five data sets for yogurt and buttermilk were averaged and indicate an inactivation rate of –0.17 logs/day. The storage times for these products are relatively long and range from 0.5 to 45 days with the most likely storage time between 6 and 10 days.

With a low frequency of contamination and declining *Listeria monocytogenes* numbers during a potentially lengthy storage, this food category is predicted to pose a low risk per serving and a low contribution to the total cases per annum. The predicted median per serving and per annum relative risk rankings for the Cultured Milk Products were twenty-second for the total United States population. The ranges for both predicted ranking distributions are broad but clustered in the high rankings (low risk) (Figures V-19a and V-19b). There was more uncertainty for this food category than for other dairy products (such as ice cream), with more iterations having lower rankings. This is largely attributed to the limited data available.

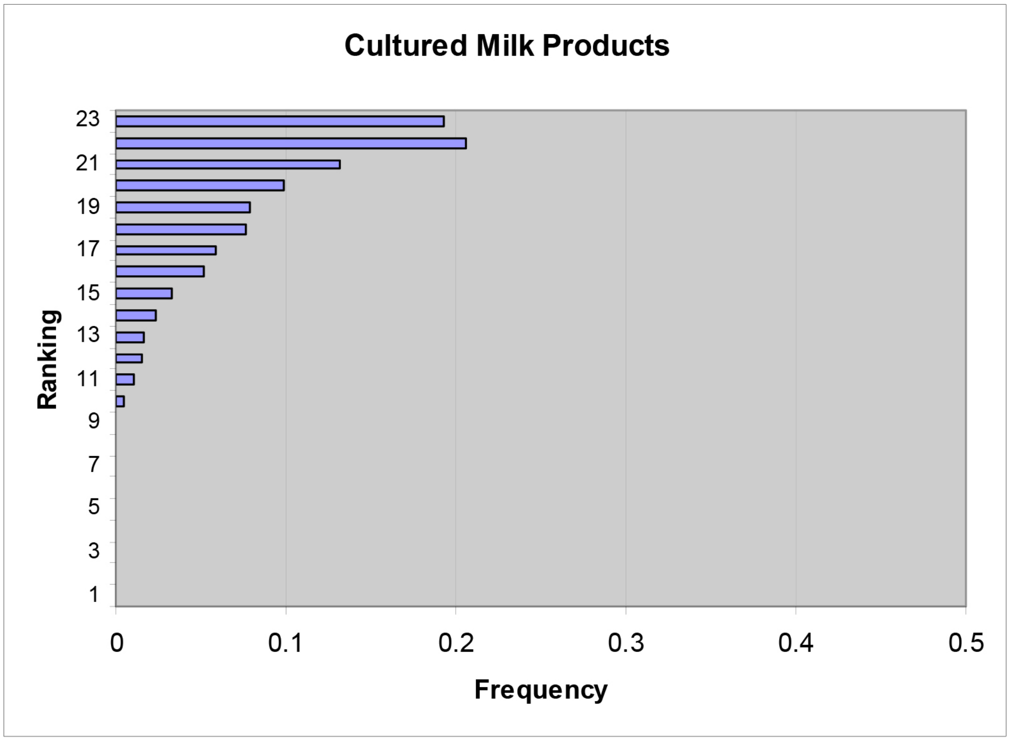


Figure V-19a. Rankings of Total Predicted Listeriosis Cases per Serving for Cultured Milk Products

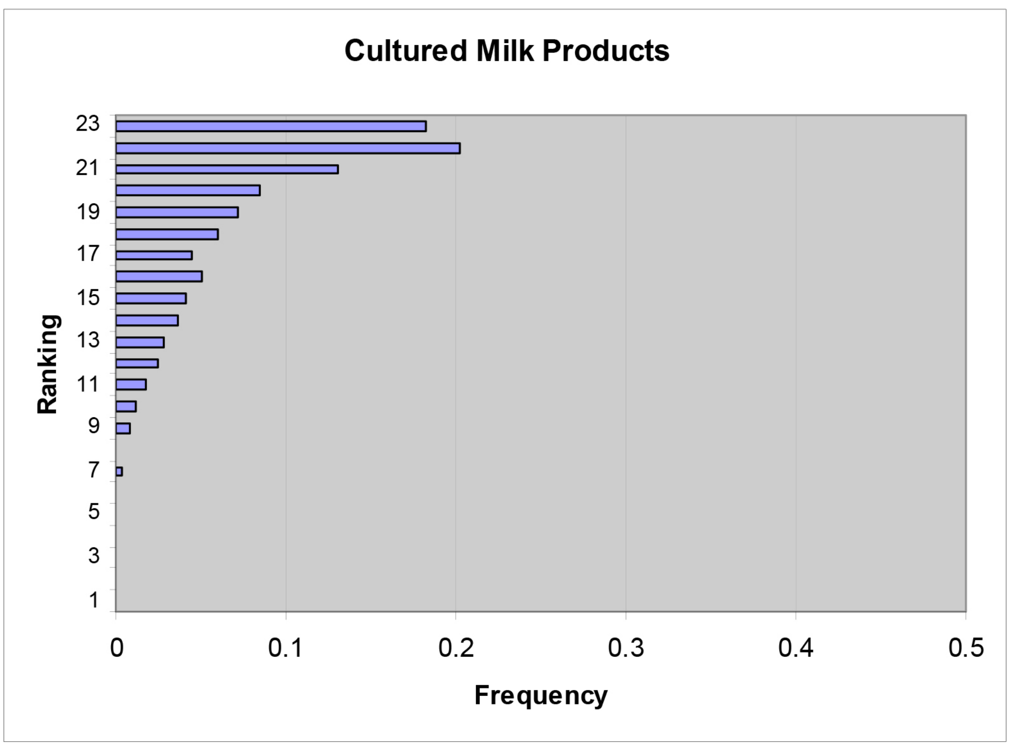


Figure V-19b. Rankings of Total Predicted Listeriosis Cases per Annum for Cultured Milk Products

Food Category: High Fat and Other Dairy Products

The High Fat and Other Dairy Products food category had a moderate predicted relative risk of listeriosis on a per serving basis. Although the High Fat and Other Dairy Products category had a relatively low contamination frequency and levels of contamination, *Listeria* can grow in these products and storage times are typically long. Because of the breadth of the category, there were a high number of servings annually, and the proportion of the population eating products from this category was high. This is offset to a degree by the low amount consumed per serving. These factors resulted in a high predicted relative risk on a per annum basis. Two products, pasteurized cream (in the U.K.) and butter (in the United States and Finland), have been linked to outbreaks of listeriosis (Ryser, 1999a; Lyytikäinen *et al.*, 2000).

The High Fat and Other Dairy Products category consists of high fat dairy products such as butter, cream, half and half, and other dairy products including shakes. These products had previously been grouped with Cultured Milk Products (referred to as the Miscellaneous Dairy Products) in the 2001 draft risk assessment. In this revised risk assessment, the cultured milk products and high fat milk products have been separated into two food categories based on product characteristics. Even with the removal of cultured dairy products from this group, the High Fat and Other Dairy Products category remains a relatively diverse group. Acquisition of additional data to address product-specific questions and subdivision of this category into smaller product groupings may be warranted in the future.

Consumption data for the High Fat and Other Dairy Products include many types of dairy products (milk shakes, cream, and butter). The median amount consumed per serving for this category is 13 g (a little less than 0.5 ounce), and the annual number of eating occasions is 2.1×10^{10}.

Twelve contamination data sets were available for this category, including four from the United States. Two studies (not from the United States) provided quantitative data. The studies comprised 18,169 samples of all types of dairy products, including some unspecified products. The specified products were butter and cream, primarily. It was not typically indicated whether these products, which generally have high water activity, were made from pasteurized or unpasteurized milk. One set of cream samples was reported as being unpasteurized. Microbial analysis of dry milk products, casein, non-fat dried milk, and dry infant formula in their dry state were excluded. Over 40% of the samples were analyzed quantitatively. The percentage of samples with detectable contamination was about 1.3%, a low contamination rate, but the contamination levels were moderate.

Most of the foods in the High Fat and Other Dairy Products category support growth of *Listeria monocytogenes*. The six data sets ranged from –0.02 to 0.26 logs/day with an average of 0.11 logs/day, a moderate growth rate. The storage times for this category were long. The assumed distribution had a most likely time of 6 to 10 days and a maximum time of 15 to 45 days. The risk assessment did not attempt to estimate the fraction of butter servings left at room temperature; this practice could increase the predicted risks for this food category.

The median risk per serving for the High Fat and Other Dairy Product category of 2.7×10^{-9} corresponds to a predicted relative risk ranking of seventh for the total United States population. The per serving rankings for High Fat and Other Dairy Products was normally distributed and the range of the distribution was relatively narrow (Figure V-20a), indicating that there is a reasonable degree of certainty associated with the per serving ranking despite the broad range of foods in the category. The predicted median per annum relative risk ranking for the High Fat and Other Dairy Products category was third for the total United States population, representing a median of approximately 56 predicted cases of listeriosis for the total United States population. The range for the per annum ranking distribution is somewhat narrower (Figure V-20b) and shifted to the lower ranks (i.e., higher risk levels). This indicates that there was also a fair amount of certainty associated with the per annum predicted relative risk ranking for the High Fat and Other Dairy Products category. However, the degree of uncertainty associated with this food category must be considered in light of the category's diversity. If additional data became available, uncertainty would likely be reduced further if this food category was subdivided.

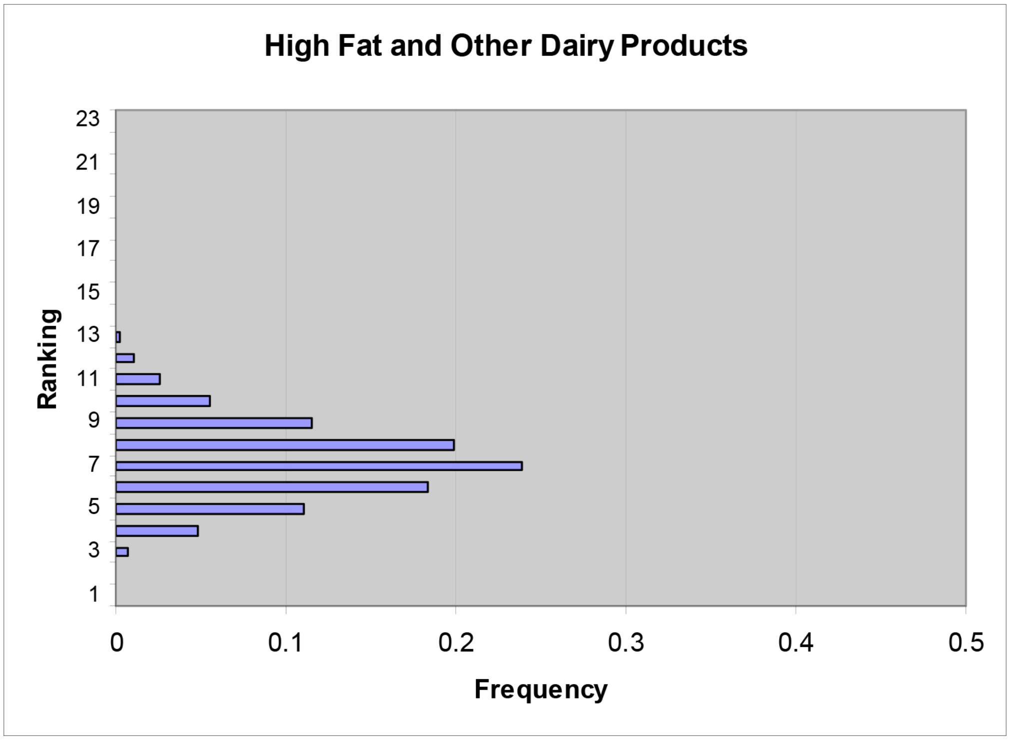


Figure V-20a. Rankings of Total Predicted Listeriosis Cases per Serving for High Fat and Other Dairy Products

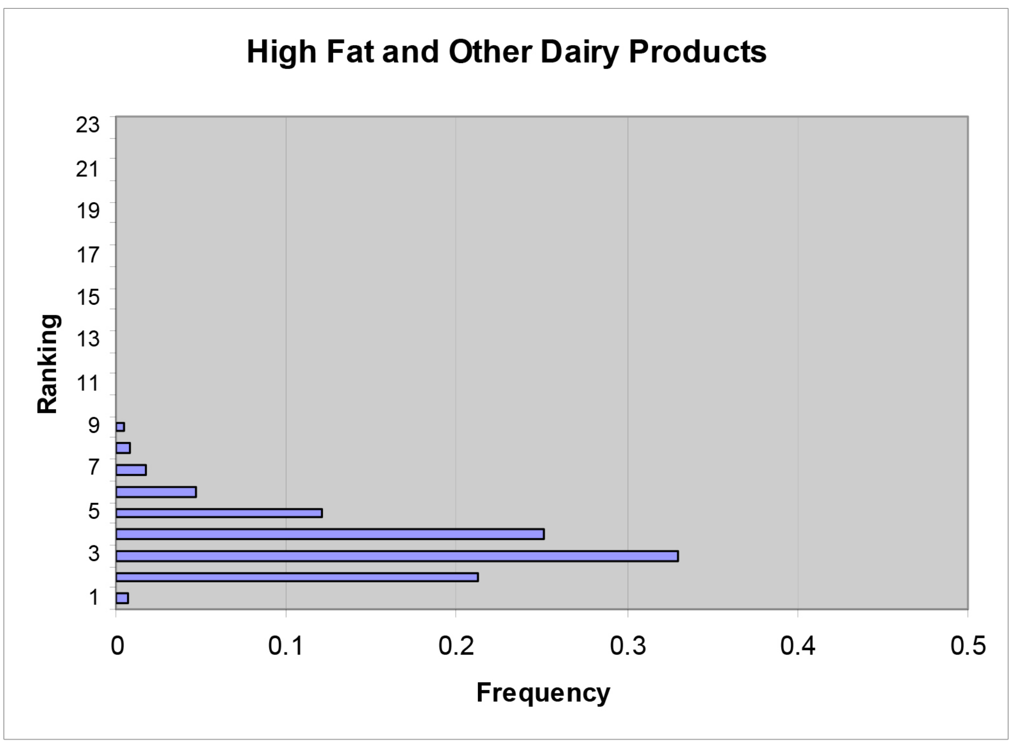


Figure V-20b. Rankings of Total Predicted Listeriosis Cases per Annum for High Fat and Other Dairy Products

Food Category: Frankfurters (Reheated)

Reheated Frankfurters had a low predicted relative risk of causing listeriosis in the United States on a per serving basis and per annum basis. The initial cooking of frankfurters during manufacture is sufficient to eliminate *Listeria monocytogenes* so contamination is associated with the post-processing recontamination of the product. Reheating the product just prior to consumption would be expected to produce a significant reduction in contamination. There is potential for frankfurters to serve as a source for cross contamination prior to reheating, however, there were no data available upon which this could be modeled in the current risk assessment. The number of annual servings, median amount consumed per serving, contamination frequency, and growth rate were moderate for reheated frankfurters.

In this risk assessment, the risk for frankfurters reheated before consumption was calculated separately from those eaten without reheating. Up to 7% of frankfurters are frozen by the consumer before reheating (AMI, 2001). The model assumed that growth would not occur in these frozen frankfurters. It was also assumed (based on survey data) that between 1 and 10% of the frankfurters are consumed without reheating (i.e., 90 to 99% are reheated). To account for the reduction of levels of *Listeria monocytogenes* in adequately reheated frankfurters, a thermal inactivation step was included in the risk assessment model. There have been two outbreaks in the United States of listeriosis linked to consumption of frankfurters or microwaved turkey franks (Ryser, 1999a; CDC, 1998a, 1999b; Farber and Peterkin, 1991). These were likely the results of breakdowns in food safety controls within the processing plant. The factor that has the greatest effect on the predicted health impact of frankfurters is the extent of post-retail reheating by the consumer.

Consumption data for the frankfurter category include the meat portion of various types of frankfurters. This excludes the bun, relish, and other condiments. Frankfurters made with chicken, turkey, all beef, and beef-pork products are included. Bologna, which is processed similarly to frankfurters, but has different retail and home handling practices, is included in the Deli Meat food category. The median amount consumed per serving for this category is 57 g (approximately 2 ounces, the typical weight a single frankfurter), and the annual total number of servings is $6.1x10^9$.

There were nine contamination studies with a total of about 3,763 samples for this food category. Six of the studies were conducted in the United States. One of the largest data sets used to develop the exposure rates for this food category was the result of the recent FSIS analyses of product taken soon after manufacture. These results were modified to take into account the likely increase in *Listeria monocytogenes* levels that would have resulted from storage conditions and times that would have been likely to have occurred between manufacture and purchase. The large size of this data set had a substantial influence on the overall calculated relative risk.

As introduced above, two underlying assumptions used in estimating the relative risk associated with this product are that *Listeria monocytogenes* was transmitted via the direct consumption of frankfurters, and that reheating of the product just prior to consumption is a generally effective means of eliminating the microorganism. Thus, to a large extent the primary factor controlling the risk is the percentage of individuals that do not adequately reheat the product. Nevertheless, if a substantial portion of frankfurter-associated listeriosis cases were the result of the product cross-contaminating other foods prior to reheating or if certain types of reheating were not fully effective in eliminating the pathogen, this would significantly alter the relative risk associated with the product. In such a case, the relative risk would be more accurately estimated by increasing the percentage of frankfurters consumed without adequate reheating. These possibilities are supported by the results of outbreak investigations where the victims reported reheating the product prior to consumption.

In general, the literature references did not indicate whether the frankfurters were made from beef or poultry meats. The percentage of samples with detectable contamination was a moderate 4.8%. The highest levels of *Listeria monocytogenes* were less than 100 cfu/g.

Five studies reported growth rates for *Listeria monocytogenes* in frankfurters, including beef/pork, turkey, and chicken frankfurters. The average growth rate at 5°C was 0.13 logs/day. As with most foods, the maximum growth was related to storage temperature. Based, in part, on a survey sponsored by the American Meat Institute (AMI, 2001), the distribution of home storage times assumed that 91% of the frankfurters were consumed within 9 days and 99% were consumed within 26 days.

The predicted median per serving and per annum relative risk rankings for the Frankfurters (reheated) category were both eleventh for the total United States population. The range for the per serving ranking distribution for Frankfurters is moderately narrow (Figure V-21a) and the range for the per annum is similar and normally distributed (Figure V-21b). This indicates that there was a relatively low degree of uncertainty associated with the predicted relative risk ranking for the Frankfurters (reheated) category.

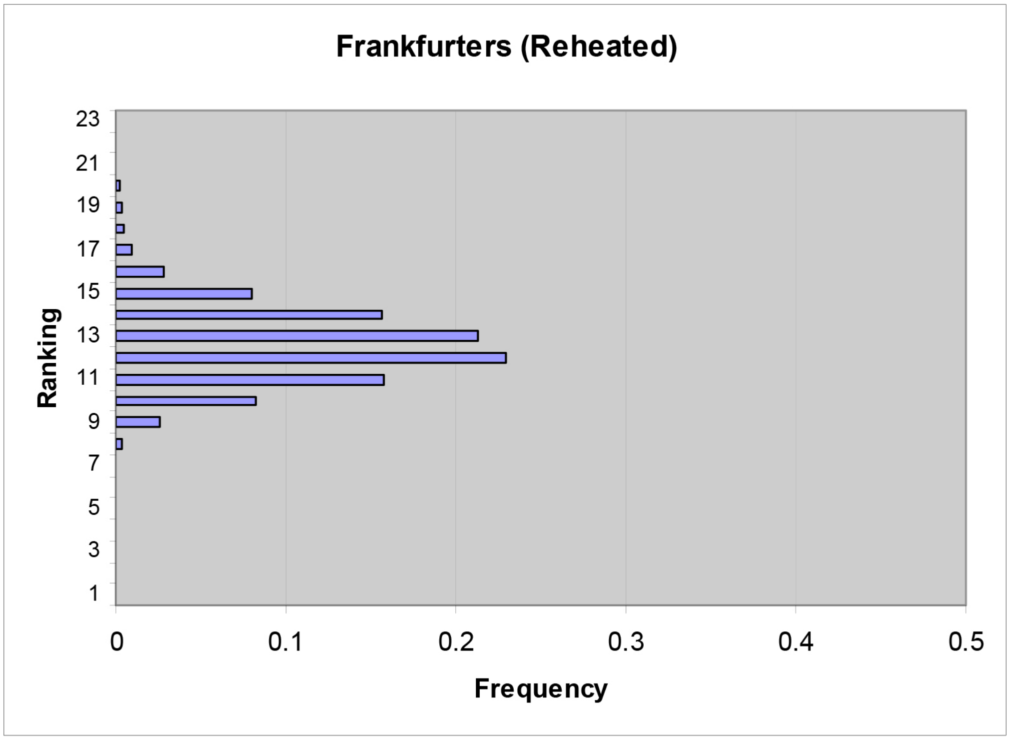


Figure V-21a. Rankings of Total Predicted Listeriosis Cases per Serving for Frankfurters (Reheated)

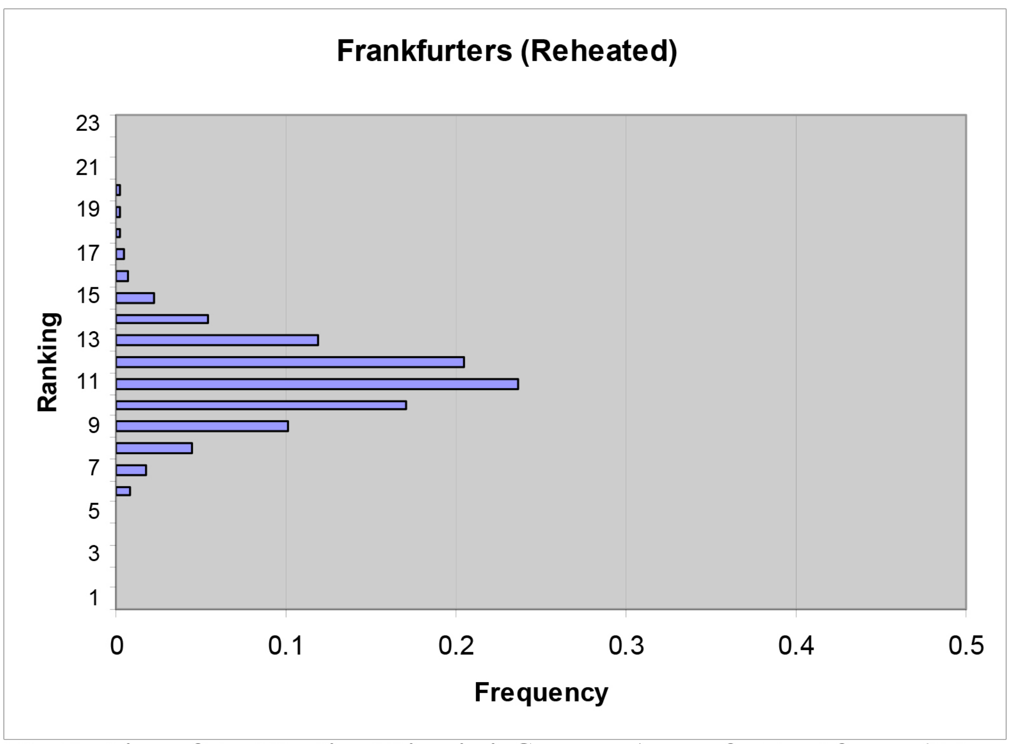


Figure V-21b. Rankings of Total Predicted Listeriosis Cases per Annum for Frankfurters (Reheated)

Food Category: Frankfurters (Not Reheated)

Frankfurters (not reheated) had a high predicted relative risk of causing listeriosis in the United States on a per serving basis. Comparison of the Frankfurter (reheated) and Frankfurter (not reheated) food categories indicates that post-retail reheating by the consumer significantly reduces contamination levels and the resulting predicted risk to public health.

In this risk assessment the risk for frankfurters reheated before consumption was calculated separately from frankfurters eaten without reheating. In the 2001 draft risk assessment the risk of frankfurters eaten without reheating was determined only on a per serving basis. This category includes the 1 to 10% of frankfurters that are stored in the refrigerator (not frozen) and consumed without reheating (i.e., no thermal inactivation step).

The Frankfurters (not reheated) and the Frankfurter (reheated) categories share the same contamination frequency, contamination levels, growth rates and storage times. See the section above for Frankfurters (reheated) for a discussion of these data. Consumption for the Frankfurter (not reheated) category is a proportion of the total frankfurters. The mean number of annual servings of not reheated frankfurters was 4.7×10^{8} for the total United States population. Without the decrease in *Listeria monocytogenes* levels from heating, the frequency of contamination at consumption was high with 1.0% of the servings containing 10^{3} to 10^{6} cfu. This is in contrast to the reheated frankfurters, which had a comparative frequency of only 0.5%.

The predicted median per serving risk for Frankfurters (not reheated) category was 6.5×10^{-8} which corresponds to a relative risk ranking of second for the total United States population. This ranking is based on the assumption that 1% to 10% of frankfurters are consumed without reheating. The predicted median per annum relative risk ranking was fourth, representing a median prediction of 31 cases of listeriosis per year for the total United States population. The range for the per serving and per annum ranking distributions for Frankfurters are narrow (Figures V-22a and V-22b) and concentrated toward the lower ranks (higher risk). This indicates that there was a relatively low degree of uncertainty associated with the predicted relative risk ranking for the Frankfurters (not reheated) category.

Scenario testing: Reduction of the Estimated Consumption of Unreheated Frankfurters

Cooking is a post-retail intervention. Because cooking is an effective method of killing *Listeria monocytogenes*, the risk from unreheated frankfurters is much greater than from adequately reheated frankfurters. A simulation was run in order to simulate the consequence of an intervention that reduces the number of frankfurters consumed without adequate reheating. Reducing the number of frankfurters consumed without adequate reheating reduced the predicted median number of cases of listeriosis. (For additional details, see Chapter VI 'What-If' Scenarios.)

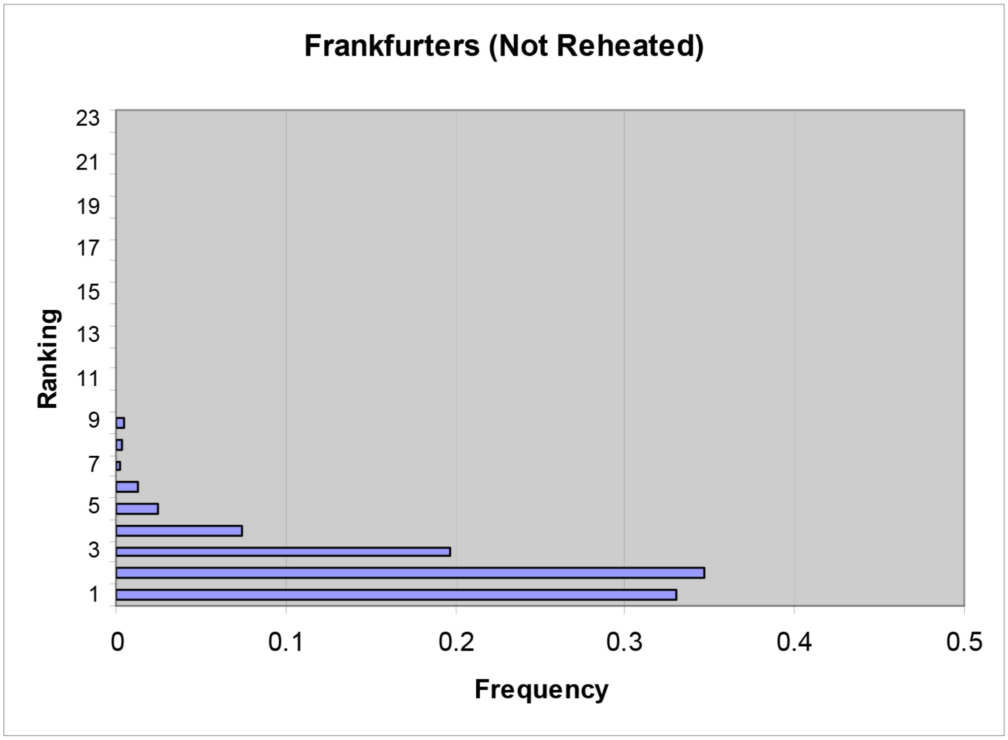


Figure V-22a. Rankings of Total Predicted Listeriosis Cases per Serving for Frankfurters (Not Reheated)

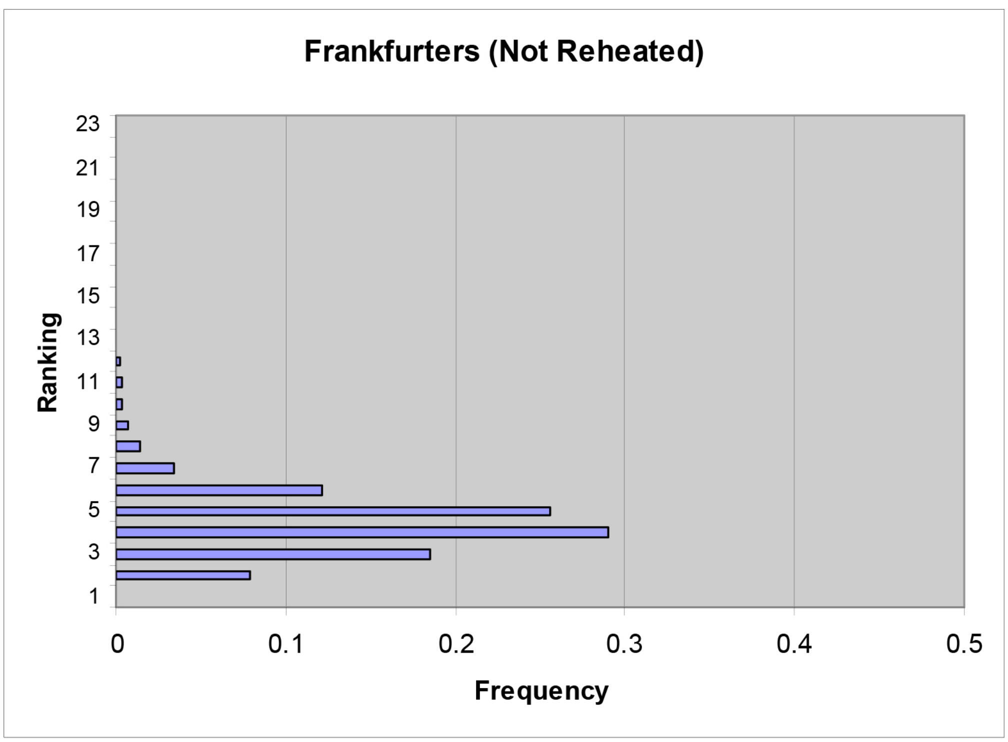


Figure V-22b. Rankings of Total Predicted Listeriosis Cases per Annum for Frankfurters (Not Reheated)

Food Category: Dry/Semi-Dry Fermented Sausages

The Dry/Semi-dry Fermented Sausages food category had a low predicted relative risk of causing listeriosis in the United States on a per serving basis. This reflects the fact that this is a food category that does not support growth, despite all other factors except contamination frequency storage time are at a moderate level. This food category included foods such as Lebanon bologna, mortadella, pepperoni, and salami. One outbreak and one sporadic case of listeriosis in the United States have been linked to the consumption of salami (Ryser, 1999a; Farber and Peterkin, 1991).

Consumption data for this category included samples of smoked beef sausage, Lebanon bologna, pepperoni, salami, and Thuringer sausage. The median amount consumed per serving for this category is 46 g (i.e., just over 1.5 ounces), and the total annual number of servings is $1.8x10^9$. Both of these values are considered moderate.

There were 14 contamination studies, including 3 studies from the United States. Three studies provided quantitative data. Products tested included salami, cured chorizo, pepperoni, beef stick, and unspecified fermented, dry and other sausages. Two of the United States studies were from FSIS and included 1208 samples with 32 positives (2.6%). This contamination frequency is lower then the overall frequency for this food category (6.4%) and is a source of uncertainty. The quantitative data are from Europe, with 3 of the 41 positive samples containing 10^2 to 10^4 cfu/g.

Inoculated pack studies show *Listeria monocytogenes* decreases several logs during the manufacture of these meat products and then slowly declines with additional storage. The organism can grow during the early phase of the fermentation or if there has been a fermentation failure. Fermentation failures also have been linked to outbreaks caused by *Staphylococcus aureus* and *Salmonella* in products associated with this food category. Four data sets were used to model the rate of decline of *Listeria monocytogenes* in these foods during storage; the range was 0.0 to -0.036 logs decline/day. The length of storage is long, ranging from 0.5 to 90 days with the most likely 6 to 10 days.

The predicted median per serving relative risk rankings for the Dry/Semi-Dry Fermented Sausages category was fifteenth for the total United States population. The range for the per serving ranking distribution for Dry/Semi-Dry Fermented Sausages is broad (Figure V-23a) and concentrated in the middle ranks (moderate risk). This indicates that there was a high degree of uncertainty associated with the per serving predicted relative risk ranking for Dry/Semi-Dry Fermented Sausages category. The predicted median per annum relative risk ranking was thirteenth for the total United States population. The range of the per annum ranking distribution was broad (FigureV-23b), indicating substantial uncertainty associated with the per annum predicted relative risk ranking. The uncertainty may reflect the variability in the consumption patterns for this food category.

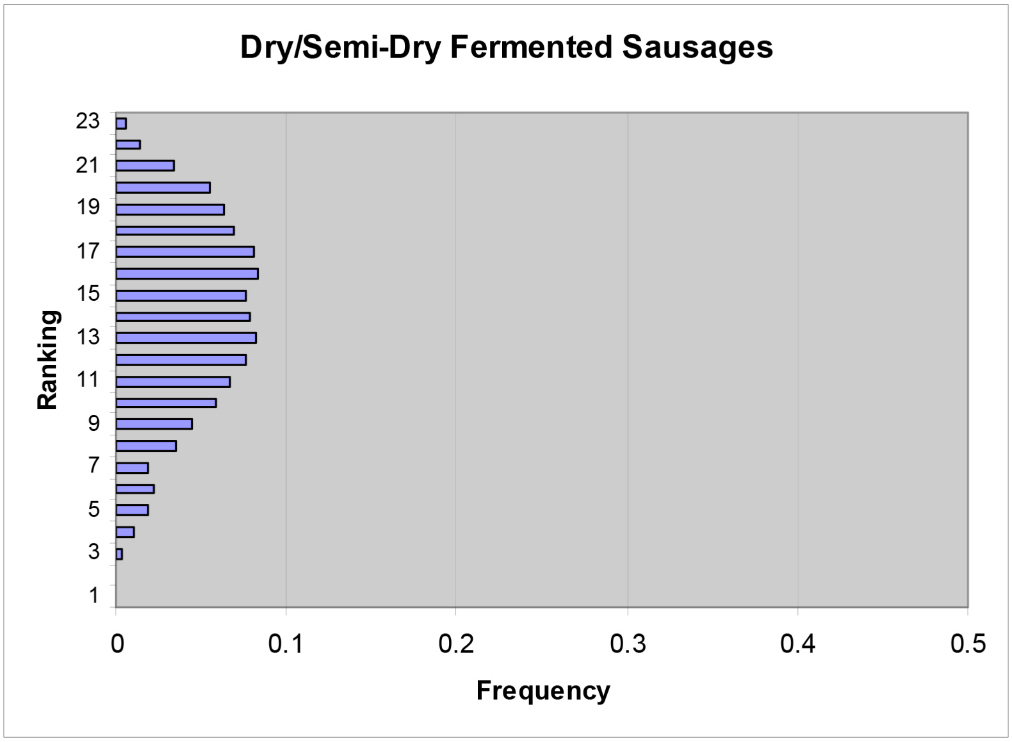


Figure V-23a. Rankings of Total Predicted Listeriosis Cases per Serving for Dry/Semi-Dry Fermented Sausages

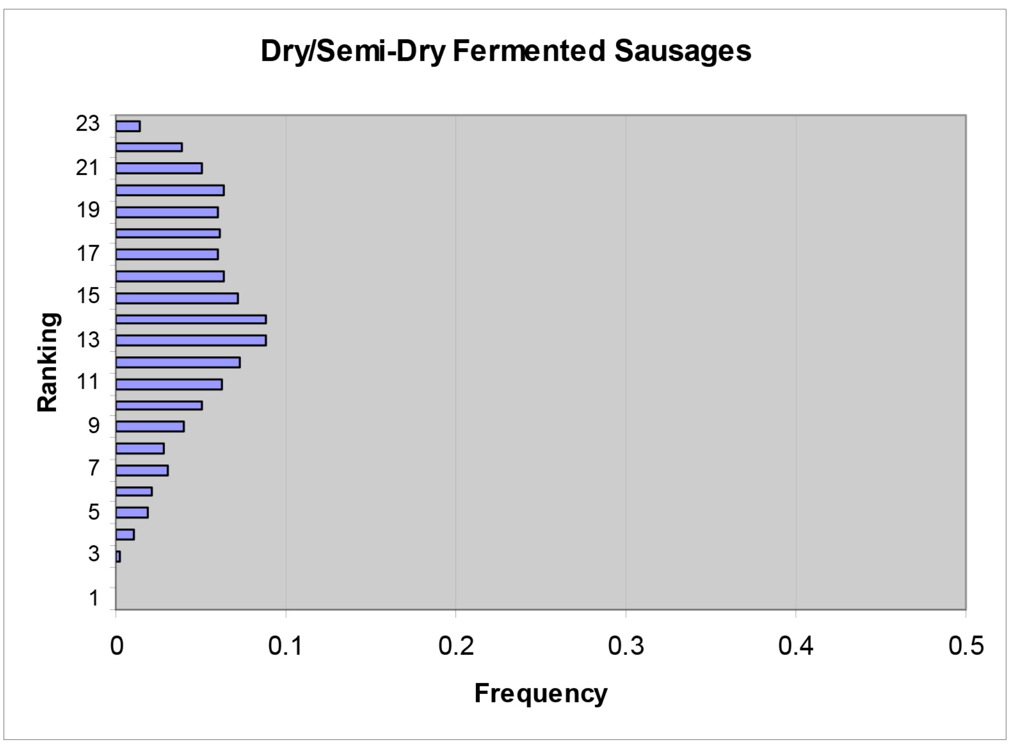


Figure V-23b. Rankings of Total Predicted Listeriosis Cases per Annum for Dry/Semi-Dry Fermented Sausages

Food Category: Deli Meats

Deli Meats had the highest predicted relative risk of causing listeriosis in the United States on both per serving basis and per annum basis. Though this category had a moderate contamination frequency with high contamination levels, there were a high number of servings consumed and a high growth rate, two of the primary factors that drive listeriosis risk in foods. Deli meats have been implicated in two United States outbreaks: a 1998-99 outbreak that was primarily linked to frankfurters but contaminated luncheon meats were also found, and a 2002 outbreak in the Northeastern United States which was linked to poultry products. There have been two outbreaks of listeriosis in France linked to pork tongue in jelly, and an outbreak in Western Australia linked to processed meats (Ryser, 1999a; CDC, 1998a, 1999b).

Consumption data were available for a number of deli meats, such as bologna, ham, turkey, roast beef, chicken, and the meat portion of sandwiches. Consumption databases (and most contamination studies) did not distinguish between pre-packaged and sliced deli products. The median amount consumed per serving for this category is 56 g (i.e., ~ 2 ounces), and the total annual number of servings is estimated to be $2.1x10^{10}$.

This category of products encompasses a variety of processes and formulations that can affect contamination and growth. There were 19 contamination studies, including four from the United States. Three studies provided enumeration data. The overall percentage of positive samples from these 19 studies was 1.9%. The 2000 and 2001 surveys conducted by USDA/FSIS observed 2.1% positive samples (395 of 18,506) from collection at manufacturing, however, the 2002 NFPA survey observed a lower frequency of positive samples of only 0.8% from collection of 9,199 samples at the retail level.

The cooking steps that are used to produce Deli Meats are assumed to kill any *Listeria monocytogenes* present. It is generally assumed that *Listeria monocytogenes* present in the finished product is the result of recontamination. This is often associated with specific processing steps, such as slicing. Sliced Deli Meats are available in two forms: those that are sliced and then packaged for consumer purchase, and those that are produced in bulk and then sliced in retail stores. It is generally assumed that the latter group of products is more likely to be recontaminated, but would also have a shorter storage time. The NPFA survey showed a prevalence rate of 1.2% for in-store packaged but only 0.4% for manufacturer packaged deli meats (Gombas *et al*., 2003). Nevertheless, insufficient data were available to allow these two approaches to the marketing of Deli Meats to be distinguished in the risk assessment.

The Deli Meats were differentiated from the Dry/ Semi-dry Fermented Sausages category by higher pH values and water activities that allowed growth. There were nine growth studies conducted on a variety of deli meats including bologna, corned beef, ham, roast beef, poultry loaf, and breaded chicken fillets. Growth rates varied with product composition (e.g., salt, pH) and packaging (e.g., aerobic, vacuum). The average growth rate was 0.28 logs/day at 5°C, a rapid rate of growth. Storage times were relatively long compared with the other food categories. Storage times were based on the survey sponsored by the American Meat Institute (AMI, 2001).

The predicted median cases per serving (77×10^{-9}) and per annum (1,599) risks both correspond to relative risk rankings for the Deli Meats category of first (highest risk) for the total United States population. The ranges for the per serving and per annum ranking distributions for Deli Meats are narrow (Figures V-24a and V-24b). This suggests a low degree of uncertainty associated with the predicted relative risk rankings for this food category. Deli Meats are clearly the highest risk food category of those considered in this risk assessment.

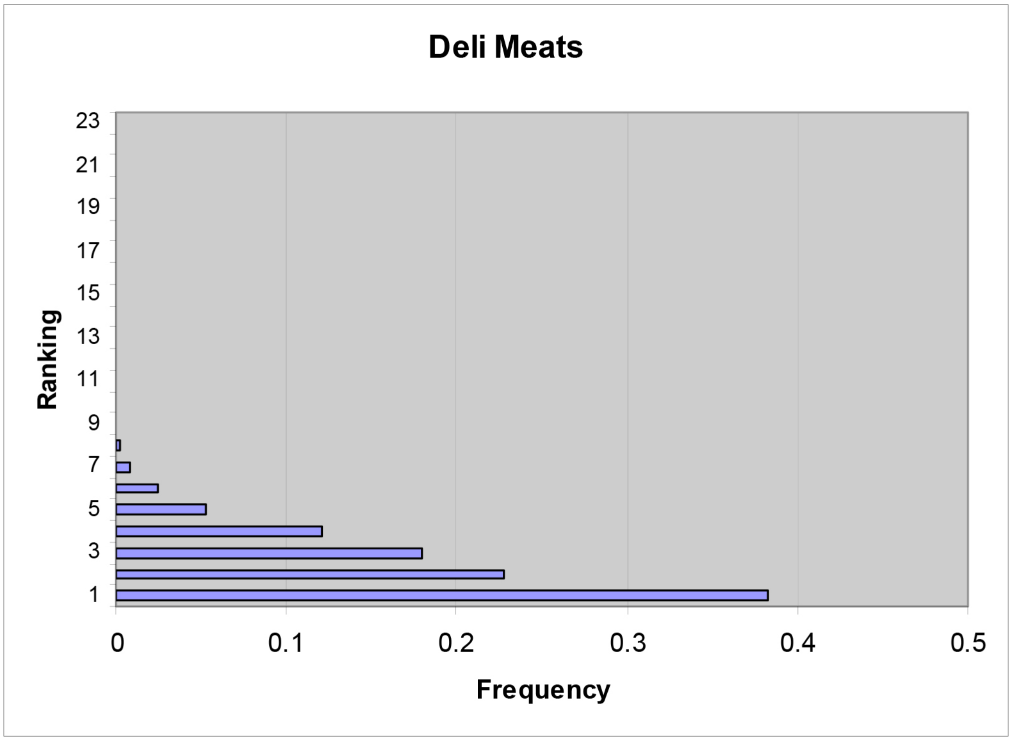


Figure V-24a. Rankings of Total Predicted Listeriosis Cases per Serving for Deli Meats

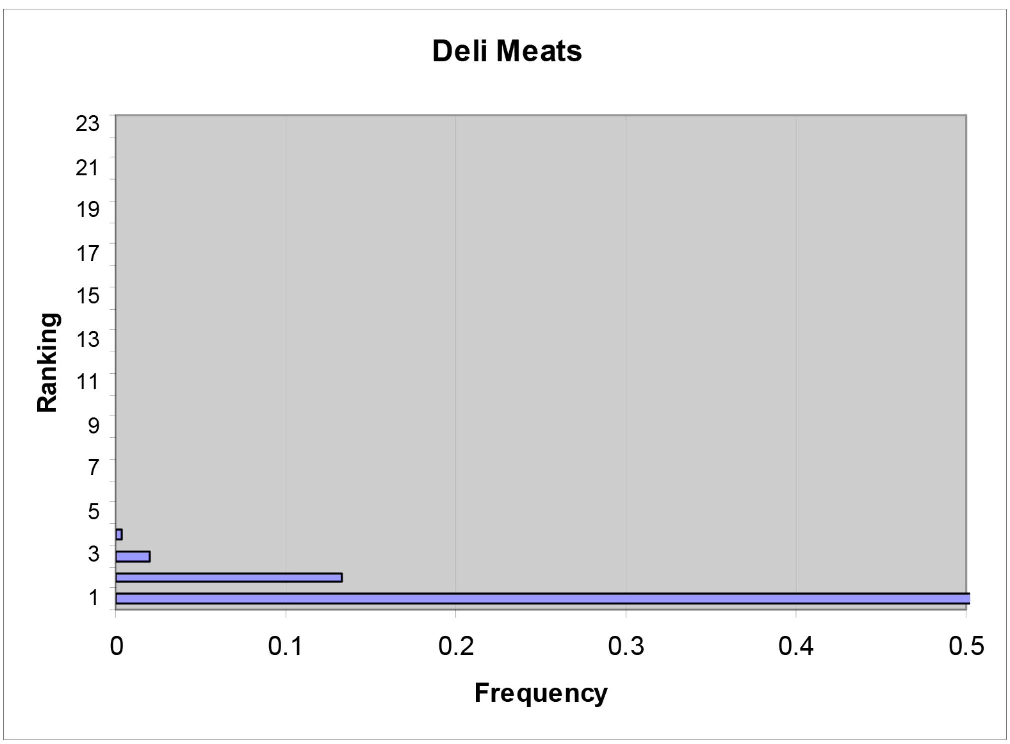


Figure V-24b. Rankings of Total Predicted Listeriosis Cases per Annum for Deli Meats

Food Category: Pâté and Meat Spreads

Foods in the Pâté and Meat Spreads category had a high predicted relative risk of causing listeriosis in the United States on a per serving basis. Foods in this category generally were consumed on an infrequent basis, with moderate serving sizes. The contamination frequency and the growth rates are high and the storage times long. Outbreaks in the U. K., France, and Western Australia have been linked to consumption of pâté (Ryser, 1999a; Goulet *et al.*, 1998).

Contamination data for this category included pâté (e. g., liver pâté) and meat spreads**.** The percentage of samples with detectable contamination was about 6.5%, which is in the moderate contamination range. Three of the twelve contamination studies were conducted in the United States, including the USDA/FSIS surveys conducted in 2001 and 2002 where 17 of the 721 samples were positive. In total, there were 208 positive enumerated samples (most from the U.K.) with high contamination levels including 3 samples greater than 10^5 cfu/g and 3 samples greater than 10^6 cfu/g. The modeled median amount consumed per serving for this category is 57 g (approximately 2 ounces) and the total annual number of servings is 1.2×10^8.

Pâté and Meat Spreads are known to support growth of *Listeria monocytogenes* and the two available studies reported high rates of growth (0.14 and 0.36 logs/day). Storage times were long, ranging from 0.5 to 45 days, with the most likely 6 to 10 days. The predicted percentage of servings with 10^3 to 10^6 cfu at retail was moderate. Post-retail levels are likely to increase prior to consumption due to a significant predicted post-retail growth.

The predicted median risk per serving for the Pâté and Meat Spreads category was 3.2×10^{-8} cases of listeriosis per serving which corresponds to a relative risk ranking of third for the total United States population. The range for the per serving ranking distribution for Pâté and Meat Spreads is relatively narrow (Figure V-25a) and concentrated in the lower ranks (higher risk). This indicates that the extent of variability and uncertainty affecting the predicted relative risk ranking for the Pâté and Meat Spreads category is minimal. The predicted median per annum relative risk rankings was sixth (approximately 4 cases of listeriosis per year) for the total United States population. The range of the per annum ranking distribution was normally distributed but slightly broader than for the per serving distribution, indicating increased uncertainty associated with the predicted per annum ranking (Figure V-25b). The broadening of the distribution of the per annum rankings reflects the variability and uncertainty associated with the annual consumption of this food category.

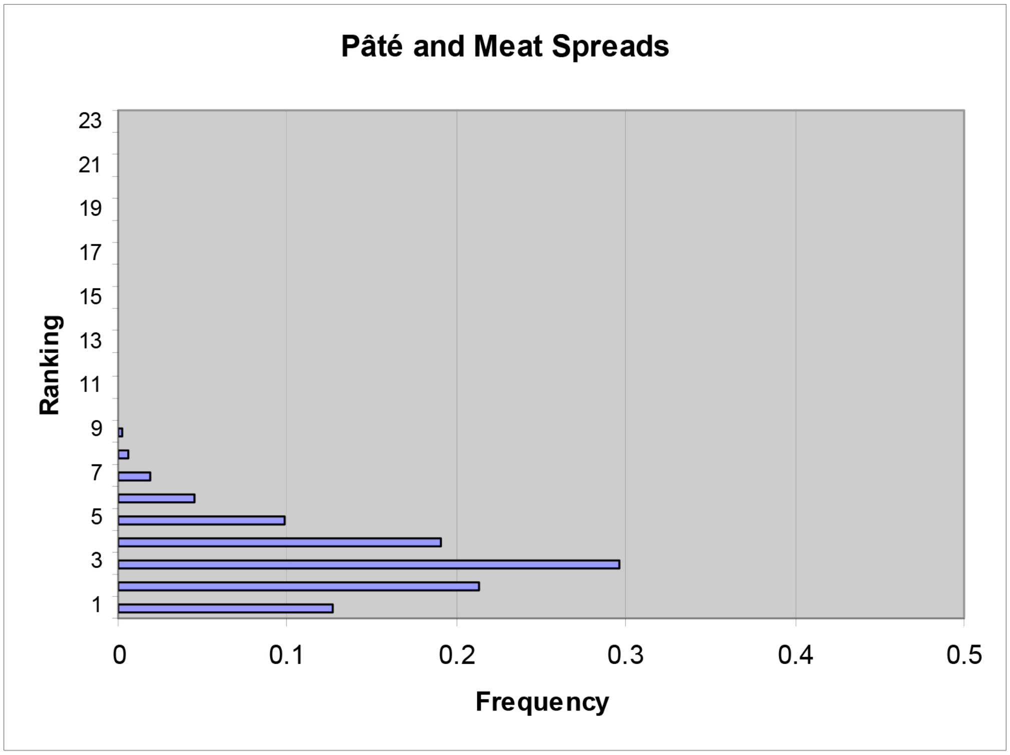


Figure V-25a. Rankings of Total Predicted Listeriosis Cases per Serving for Pâté and Meat Spreads

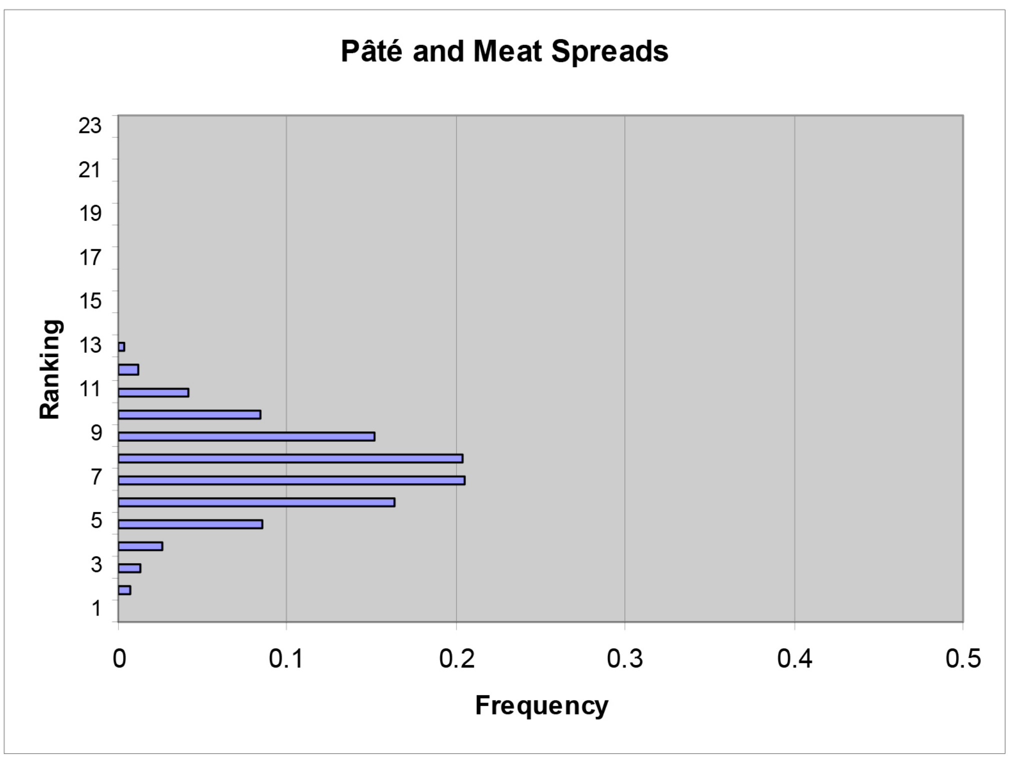


Figure V-25b. Rankings of Total Predicted Listeriosis Cases per Annum for Pâté and Meat Spreads

Food Category: Deli-type Salads

Foods in the Deli-type Salads category has a low predicted relative risk of causing listeriosis in the United States on a per serving basis. The predicted risk for this food category is much lower than the predication of risk in the 2001 draft risk assessment. Based on public comments and newly available data, there were two major changes to the Deli-type Salad food category for this revised risk assessment. First, the vegetable and fruit salads made with dressing were moved from the Vegetables and Fruits categories to the Deli-type Salads category. Secondly, new growth rate information (Johnson *et al*., 1993; Eblen, 2002a) indicated that levels of *Listeria monocytogenes* actually decrease in most types of Deli Salads during storage instead of growing (as assumed in the 2001 risk assessment). The meat, seafood, eggs, and pasta salads from this category have not been linked to outbreaks or sporadic cases of listeriosis, but FDA has monitored recalls of seafood and egg salads because of the presence of *Listeria monocytogenes*. On the other hand, deli-type salads that are predominately composed of vegetables, have been linked to outbreaks. For example, coleslaw has been linked to an outbreak of listeriosis in Canada, potato salad in the United States and Australia, and sweet corn and rice salad in Italy (Ryser, 1999a).

Although the annual number of servings and median amount consumed are high, the levels of *Listeria monocytogenes* at retail are low and the storage times are short. Of most importance is that the *Listeria monocytogenes* has a low growth rate or declines in most of the foods in this category.

This category includes consumption data for a wide variety of meat, seafood, egg, and pasta salads, vegetable and fruit salads with salad dressing, as well as the salad portion of sandwiches. The median amount consumed per serving is 97 g (i.e., about 3.5 ounces, which is considered a high amount) and the total annual number of servings is 1.3×10^{10}.

Changes in *Listeria monocytogenes* populations were modeled using the newly available data (Johnson *et al*., 1993; Eblen, 2002a). Decreases in *Listeria monocytogenes* populations are particularly evident in deli salads made by food processors where sufficient acidity and the addition of preservatives (e.g., sorbate, benzoates) create an inhospitable environment for *Listeria monocytogenes*. In contrast, Deli-type Salads made fresh in the retail establishment typically were not made with preservatives, and could support growth. FDA research (Eblen, 2002a) showed that retail-made seafood-containing salads permitted growth. It is estimated that 85% of the deli-type salads are manufactured by food processors and do not support growth, and that shrimp and crab salads represent less than 10% of the total deli salad sales (Mitchell, 2001). Storage times were relatively moderate and ranged from 0.5 to 12 days with a most likely range of 3 to 4 days.

Sixteen studies, including six conducted in the United States provided contamination data for this food category. The NFPA (2002) survey, which analyzed 11,236 samples, observed that 3.9% were positive (443 positive samples). The contamination frequency was higher for seafood salads (4.5%) vs. non-seafood deli-type salads (2.4%). Of the positive samples, two contained between 100 and 1000 cfu/g and one contained between 10^3 and 10^4 cfu/g. The overall contamination rate for 16 studies in this food category was moderate at 3.8%.

The predicted median per serving relative risk ranking for the Deli-type Salads category was nineteenth for the total United States population. The range for the per serving ranking distribution for Deli Salads was broad (Figure V-26a) but clustered in the higher rankings (i.e., lower risk). The predicted median per annum relative risk rankings was seventeenth for the total United States population. The range for the per annum ranking distribution for Deli-type Salads was slightly wider (Figure V-26b) compared with the per serving ranking distribution. Overall, there was a relatively high degree of uncertainty associated with both the predicted per serving and per annum rankings. This likely reflects that fact that this category includes deli-type salads that do and do not support the growth of *Listeria monocytogenes*. If additional data become available, uncertainty would likely be reduced if this food category was subdivided.

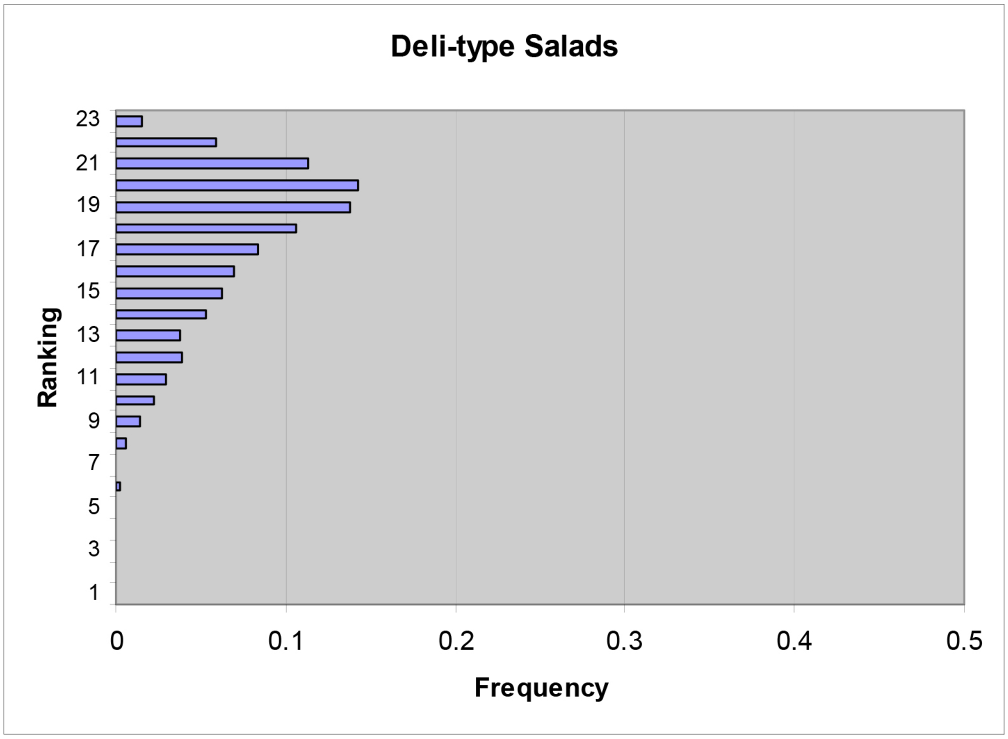


Figure V-26a. Rankings of Total Predicted Listeriosis Cases per Serving for Deli-type Salads

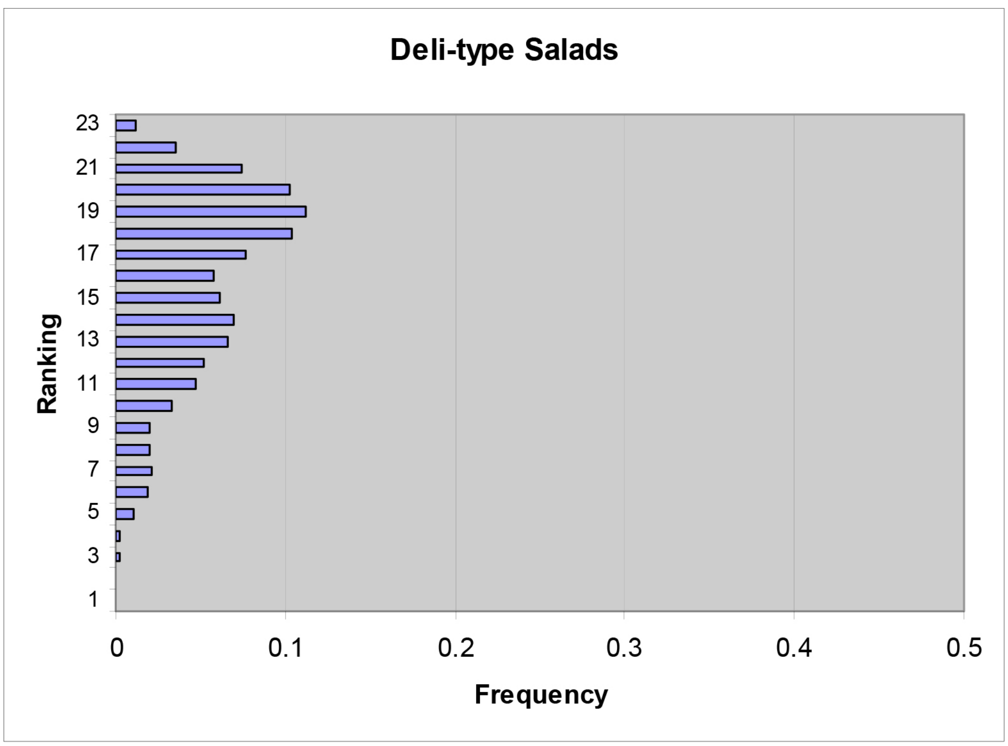


Figure V-26b. Rankings of Total Predicted Listeriosis Cases per Annum for Deli-type Salads

VI. 'WHAT IF' SCENARIOS

The revised FDA/FSIS *Listeria monocytogenes* risk assessment model, taken in its entirety, describes the current status of knowledge about listeriosis and provides predications of disease incidence based on *Listeria monocytogenes* concentration in foods at retail, frequency of consumption, serving size, the microorganism's growth/survival characteristics, and storage conditions. This risk assessment model can be used to estimate the likely impact of intervention strategies by changing one or more input parameters and measuring the change in the model outputs. These changes to the model, which are commonly referred to as 'what if' scenarios, can be used to test the likely impact of new or different processing parameters or regulatory actions. These 'what if' scenarios can also be hypothetical, not necessarily reflecting achievable changes but designed instead to show how different components of the complex model interact. Modeling specific scenarios can assist in the interpretation of a complex risk assessment model by allowing a comparison of baseline calculations to new situations. The following scenarios are intended to simulate the consequence of a putative regulatory policy (i.e., a possible intervention strategy) that alter one or more of the input distributions. Post-retail, at retail and pre-retail interventions were evaluated.

Several simulations were constructed to illustrate the relationship between concentration at consumption or at retail and predicted disease rate. These simulations used exposure models with a range of fixed concentrations. Because a separate simulation was required for each concentration point at the range, a few selected food category/ subpopulation pairs were selected to serve as examples.

Post-Retail Interventions

This risk assessment indicates that most cases of listeriosis result from consuming high levels of *Listeria monocytogenes* from foods that permit growth. For a specific food, the growth is dependent on the characteristics of the food matrix and on the temperature and time allowed for growth. Microbial growth is exponential with time (e.g., linear when plotted on a logarithmic scale) until the stationary phase is approached. The levels of a microorganism after a period of growth also depend upon the initial levels. The following scenarios show how refrigeration temperature and storage time are interrelated using selected food categories and subpopulations.

The relationships demonstrated with these examples would generally apply to other foods and to the other subpopulations. Cooking is another post-retail intervention. The impact of consumers adequately cooking foods was evaluated to measure the impact of reducing the number of frankfurters consumed without adequate reheating on the predicted number of illnesses. The rate of illness as a function of the concentration levels of *Listeria monocytogenes* in food at the time of consumption was also examined.

Refrigerator Temperature Scenarios

These scenarios evaluate the impact of controlling refrigerators to eliminate temperature above various limits. The baseline model used the full empirical distribution of refrigerator temperatures reported by Audits International (1999). Two types of scenarios were run:

- Limit range of refrigeration temperatures for two food categories. The baseline model for Deli Meats and Pasteurized Fluid Milk were modified by limiting the range of refrigeration temperature values to a maximum of 4 to 16 ºC (39 to 53 ºF) and calculating the resulting annual mortality.
- Truncate refrigeration temperatures for all food categories. The baseline model for all 23 food categories was modified by truncating the refrigeration temperature at 5 ºC and 7 ºC (41 and 45 ºF). This scenario allows a comparison of the impact of total cases of listeriosis if the maximum refrigerator temperatures could be regulated at these two specific temperatures.

Figures VI-1 and VI-2 show the estimated annual predicted mortality rate in the elderly subpopulation as a function of maximum temperature for Deli Meats and Pasteurized Fluid Milk, respectively. The median number of annual cases of listeriosis predicated by the baseline assumption (includes all refrigeration temperatures up to a maximum of 16 °C) is 228 for Deli Meats and 13 for Pasteurized Fluid Milk. As the refrigerators that have higher temperatures are removed from the distribution (i.e., moving from the right to the left on the curve) the number of predicted cases declines. This is a consequence of removing the higher temperature refrigerators where the fastest growth of *Listeria monocytogenes* would occur. The number of refrigerators with temperatures between 12 and 16 °C represent about 1% of the refrigerators from the Audits International survey, however, these refrigerators account for approximately 10% of the deaths from consumption of deli meats. At 7 °C, the removal of 12.2% of the refrigerators reduces the median mortality from deli meat consumption to 71 cases (68.9% reduction). For milk, the decrease in mortality is more linear than for deli meats and occurs at higher limits than for deli meats. Removal of refrigerators above 7 °C reduces the predicted median number of cases from milk consumption from 13 to only 2 cases (84.6% reduction). It should be noted that the relationship between maximum temperature and case rate varies among food categories. However, both examples indicate that eliminating the minority of refrigerators operating above 7 °C would greatly reduce the incidences of listeriosis. The impact on the predicated total number of cases of listeriosis from all 23 food categories and total United States population by eliminating the refrigerators operating above 5 and 7 °C is shown in Table VI-1. By limiting the refrigerator temperature at 7 °C, the number of cases of listeriosis is reduced 69% from 2105 to 656 and limiting the refrigerator temperature at 5 °C further reduces the number of cases to 28 per year (>98% reduction). These scenarios indicate that controlling refrigerator temperature is a potentially effective means to reduce listeriosis.

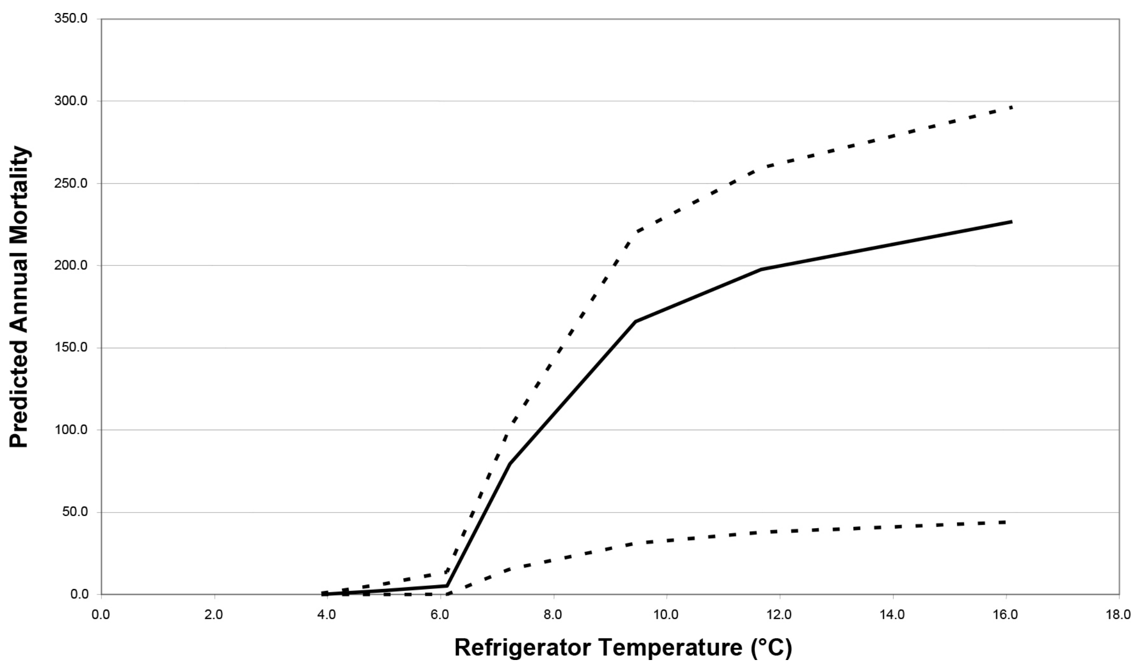


Figure VI-1. Predicted Annual Mortality in the Elderly Population Attributable to Deli Meat as a Function of Maximum Storage Temperaure
[The solid line represents the median estimate. The dotted lines represent the 5th and 95th percentiles of the uncertainty distribution.]

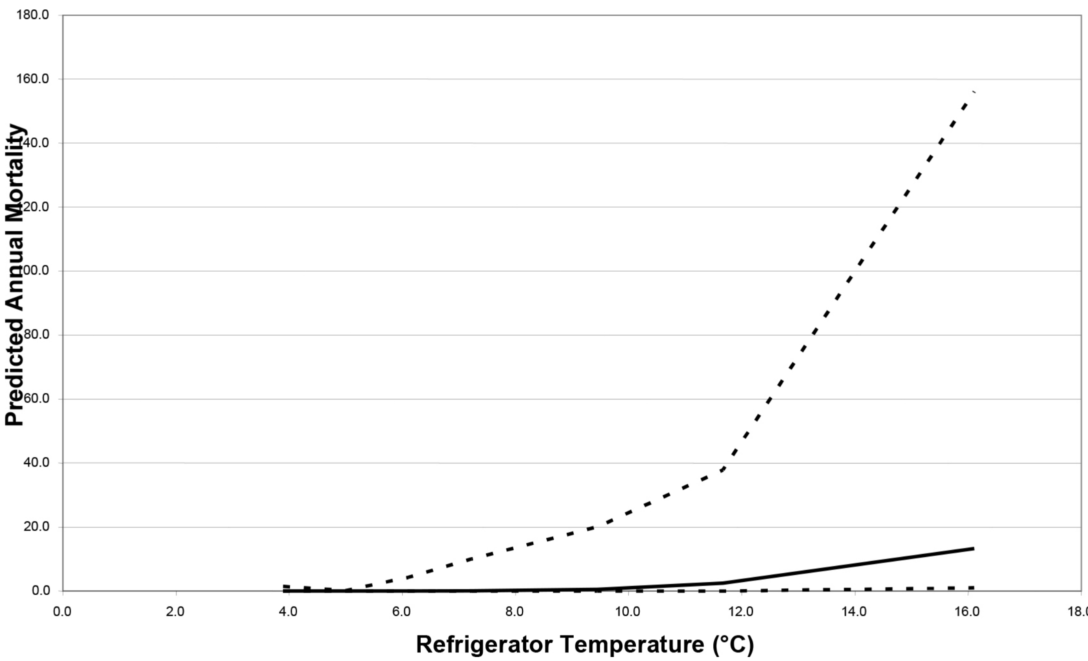


Figure VI-2. Predicted Annual Mortality in the Elderly Population Attributable to Pasteurized Milk as a Function of Maximum Storage Temperaure

[The solid line represents the median estimate. The dotted lines represent the 5th and 95th percentiles of the uncertainty distribution.]

Table VI-1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures

Maximum Refrigerator Temperature	Cases of Listeriosis[a]		
	Median	5th Percentile	95th Percentile
Baseline[b]	2105	—[c]	—[c]
7 ˚C (45 ˚F) maximum	656	331	761
5 ˚C (41 ˚F) maximum	28	1	126

[a]Values for the median, upper and lower uncertainty levels.
[b]The baseline uses the full empirical distribution of refrigerator temperatures from the Audits International (1999) survey.
[c]The baseline number of cases of listeriosis is fixed based on CDC surveillance data.

Storage Time Scenarios

These scenarios evaluate the impact of changing the maximum storage time (e.g., by labeling food with "consume-by" dates). In two scenarios using Deli Meats and Pasteurized Fluid Milk, the baseline model was modified by truncating the storage time at various maximum limits. In another scenario using Smoked Seafood, the impact of extending shelf life on the predicted risks was explored. The baseline distributions were modified BetaPert distributions defined by minimum, most likely and maximum times.

Limited Storage Times. In these scenarios, when a simulation chose a storage time longer than desired, that simulation was assigned the maximum storage time for that scenario. These simulations assume that the food is consumed during storage up to the maximum scenario storage time and the food is not discarded. Simulations were run for Deli Meats and Pasteurized Fluid Milk and the predicted annual mortality rate attributable to the group was calculated for the elderly subpopulation. The scenarios tested included seven maximum storage times for deli meats of 4, 7, 10, 14, 17, 21, and 28 days and four maximum storage times for milk of 4, 7, 10, and 14 days. The baseline maximum storage time is 28 days for deli meats and 14 days for milk.

Results from the simulations are presented in Figure VI-3 and Figure VI -4. The baseline risk assessment is shown on the right of the curve (28 days for deli meats and 14 days for milk). Limiting the storage time for deli meat from the 28 day baseline to 14 days reduces the median number of cases of listeriosis in the elderly population from 228 to 197 (13.6%) and shortening storage time to 10 days further reduces the cases to 154 (32.5%). For milk, reducing the maximum storage time from the 14 day baseline to 4 days reduced the annual number of listeriosis cases from 13.3 to 7.5 (43.6%). The dependence of predicted risk on storage time varies across food categories. Reducing maximum storage time appears to be less effective at reducing risk than reducing the refrigerator temperature for the deli meat and milk examples. Other storage time scenarios with other food categories would produce different results, for example, the reduction in cases of listeriosis might be greater if foods stored beyond the maximum scenario storage time are discarded instead of consumed on the last day.

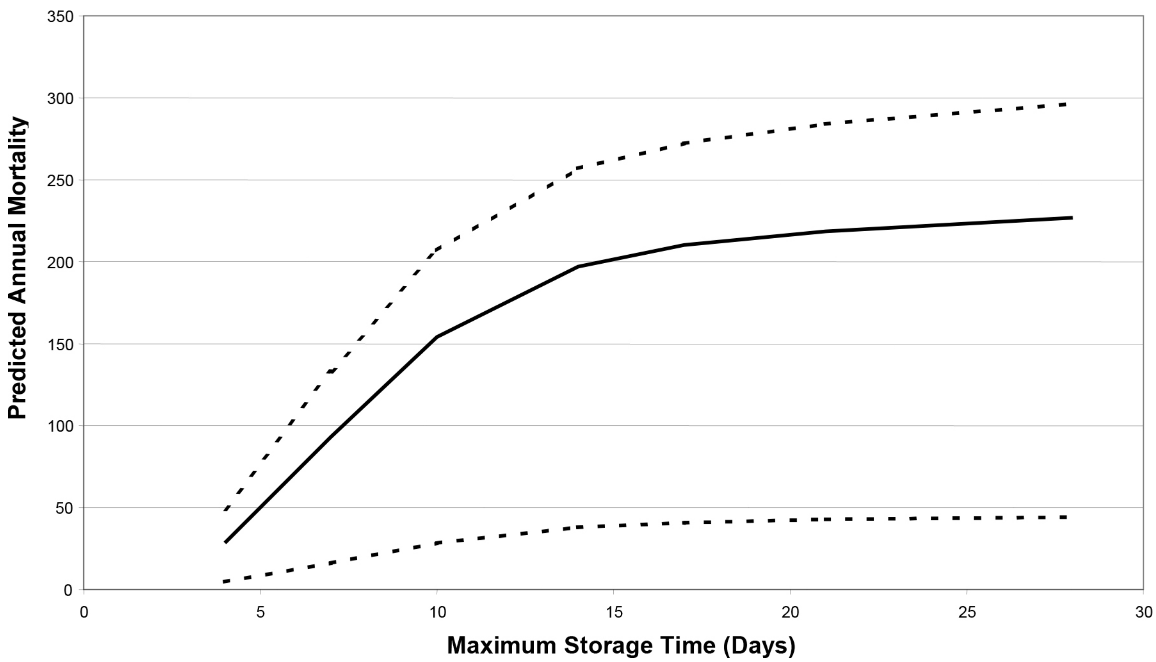


Figure VI-3. Predicted Annual Mortality in the Elderly Subpopulation Attributible to Deli Meats as a Function of Maximum Storage Time

[The solid line represents the median estimate. The dotted lines represent the 5th and 95th percentiles of the uncertainty distribution.]

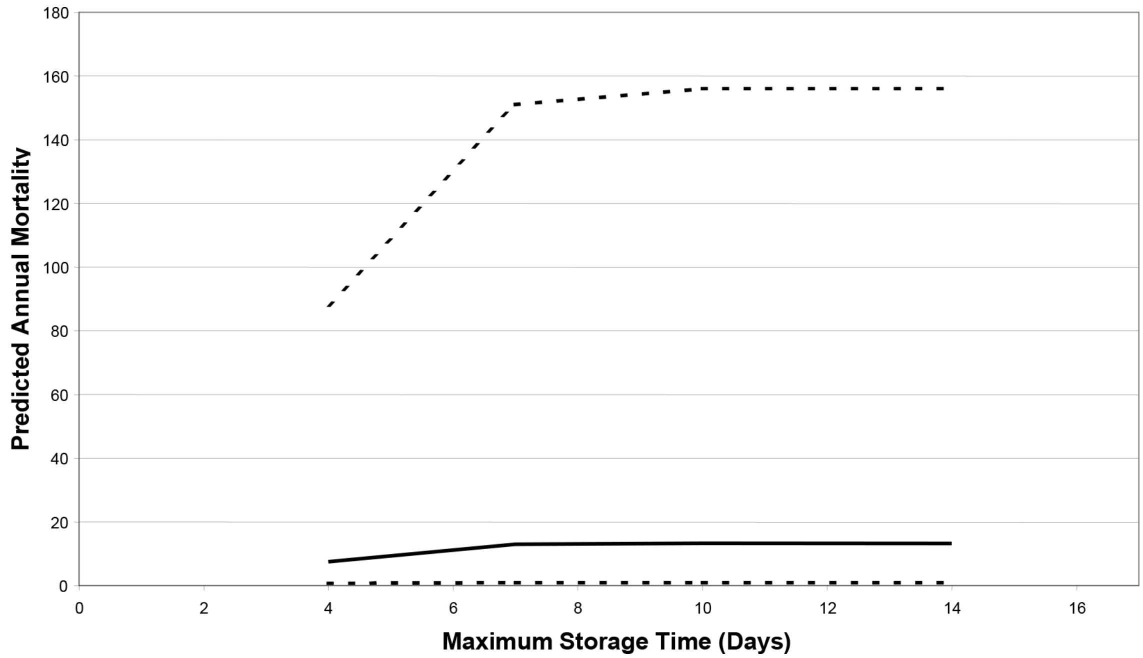


Figure VI-4. Predicted Annual Mortality in the Elderly Subpopulation Attributible to Pasteurized Milk as a Function of Maximum Storage Time

[The solid line represents the median estimate. The dotted lines represent the 5th and 95th percentiles of the uncertainty distribution.]

Extended Storage Times. A storage scenario was conducted using Smoked Seafood to estimate the impact of a lengthened storage time on the predicted– risks per serving and cases per annum for the elderly subpopulation. The estimates from the current 2003 risk assessment used the best estimates of the expert panel for the variation and uncertainty in the home storage times. A modified BetaPert distribution for the 2003 risk assessment had minimum, most likely and maximum values, with uniform uncertainty ranges, of 0.5 days, 3 to 5 days, and 15 to 30 days, respectively. For the extended storage time scenario, the modified BetaPert distribution was defined as 0.5 days (minimum), 6 to 10 days (most likely), and 15 to 45 days (maximum).

The distribution for the extended storage scenario is the same one used in the 2001 draft risk assessment for Smoked Seafoods. However, the calculated values are not the same as in the draft risk assessment because other data sets that are part of the calculation (such as contamination and growth data) have been revised and updated for the 2003 risk assessment.

The median and mean risks per serving and cases per annum are given on Table VI-2 with 5th and 95th values indicating the uncertainty distributions for the calculated risks. The median risk per serving for the elderly subpopulation increased from the baseline value of 1.9 x 10^{-8} to the extended storage time value 5.0x10^{-8} cases per serving, an increase of about 2.5 times. The median storage time increased from 5.3 to 9.3 days and the percentage of servings that exceeded 10 days of storage increased from 9 to 43%. The uncertainty range for the baseline scenario from the 5th to 95th percentile was approximately three logarithms. The mean risk per serving increased about 58% with the longer storage times. The estimates of the cases per annum follow the changes in risks per serving because the same dose-response relationship and number of servings are used in each scenario. The median number of cases per annum increases from 0.8 with the baseline scenario to 2.1 with the extended storage time scenario and the mean number of cases per annum increased from 10.6 to 17.

The difference between the median and mean reflect the skewed shape of the uncertainty distributions. The median indicates where the center of the distribution is and where the values tend to congregate. The mean will be larger because it is more affected by the few high values than the median, however, it does indicate the central tendency of repeated samplings of the distribution and can be viewed as the "average" value if the cases per annum were tracked over a number of years. The mean risk per serving and risk per annum for each food category is provided in Appendix 10.

The comparison for Smoked Seafood agrees with the truncated storage time scenarios used in the Deli Meats and Pasteurized Fluid Milk examples. Extending the storage times of a food that supports growth increase the probability that listeriosis will occur.

Table VI-2. Impact of Home Refrigerator Storage Times on the Number of Predicted Cases of Listeriosis Attributed to Smoked Seafood for the Elderly Subpopulation

Parameter	Number of Predicted Cases of Listeriosis	
	Current 2003[a]	'What if' Scenario[b]
Per Serving Basis		
Median	1.9×10^{-8}	5.0×10^{-8}
Lower bound (5th percentile)	9.7×10^{-10}	2.7×10^{-9}
Upper bound (95th percentile)	1.0×10^{-6}	1.8×10^{-6}
Mean	2.6×10^{-7}	4.1×10^{-7}
Per Annum Basis		
Median	0.8	2.1
Lower bound (5th percentile)	<0.1	0.1
Upper bound (95th percentile)	43	74
Mean	10.6	17

[a]For the current 2003 risk assessment, the assumed storage time was a distribution with minimum of 0.5 days, most likely of 3 to 5 days, and maximum of 15 to 30 days.
[b]For the 'What if' Scenario, the assumed storage time was a distribution with minimum of 0.5 days, most likely of 6 to 10 days, and maximum of 15 to 45 days. [Note this was the storage time used for the draft 2001 risk assessment.]

Storage Time and Temperature Interaction Scenario

As an example of the potential impact of dual interventions, the interaction modifying both storage time and temperature on the predicted annual mortality rate in the elderly subpopulation attributed to Deli Meats was simulated. The baseline models were adjusted in the same manner as the individual interventions. Results for the temperature and time interaction are shown in Figure VI-5.

The median estimates from the uncertainty distribution are plotted for each storage duration series. The baseline model estimated the upper right value, 228 cases as shown in Figure VI-5. Each line represents a range of maximum storage times at maximum refrigerator temperatures. Achieving a 50% reduction in cases of listeriosis from consumption of deli meats would require eliminating storage above approximately 8 °C or all storage times longer than 8 days. An example of a combination that would reduce cases of listeriosis by 50% is 10 °C and 11 days.

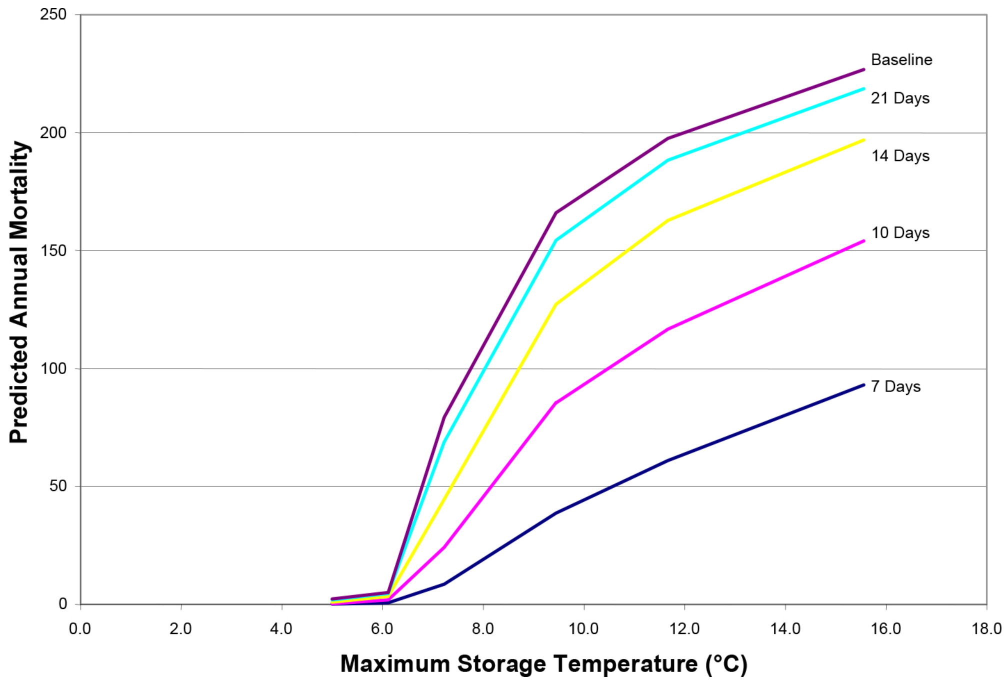


Figure VI-5. Predicted Annual Mortality in the Elderly Subpopulation Attributible to Deli Meats as a Function of Maximum Storage Time and Maximum Storage Temperature

Cooking Scenario

Cooking is a post-retail intervention. Because cooking is an effective method of killing *Listeria monocytogenes*, the risk from unreheated frankfurters is much greater than from adequately reheated frankfurters. A simulation was run in order to simulate the consequence of an intervention that reduces the number of frankfurters consumed without adequate reheating. The baseline assumption, a triangle distribution with an uncertainty range (minimum 4, most likely 7, and maximum 10), was replaced with values of 2, 4, and 6 (minimum, most likely, maximum, respectively). The impact of this change was to reduce the predicted median number of cases of listeriosis by approximately 58% (Table VI-3).

Table VI-3. Scenario testing: Reducing the Estimated Consumption of Unreheated Frankfurters

Scenario	Predicted Number of Cases of Listeriosis		
	Median	5th Percentile	95th Percentile
Baseline[a]	31	3.3	250
Reduced Consumption[b]	18	2.2	133

[a]Baseline model uses triangular distribution with minimum of 4%, most likely of 7%, and maximum of 10% frankfurters are consumed without reheating.
[b]Reduced consumption scenario assumes a triangular distribution of minimum of 2%, most likely of 4%, and maximum of 6% frankfurters are consumed without reheating.

Disease Rate as a Function of Concentration Levels at the Time of Consumption

This simulation utilizes the main elements of the dose-response simulation and the serving size component from the exposure simulation. Figure VI-6 illustrates the relationship between *Listeria monocytogenes* concentration at the time of consumption and mortality for Deli Meats, it is derived from Figure IV-8 and the serving size distribution for deli meats. Since the only food category specific component is serving size, a similar relationship would be expected for other food categories.

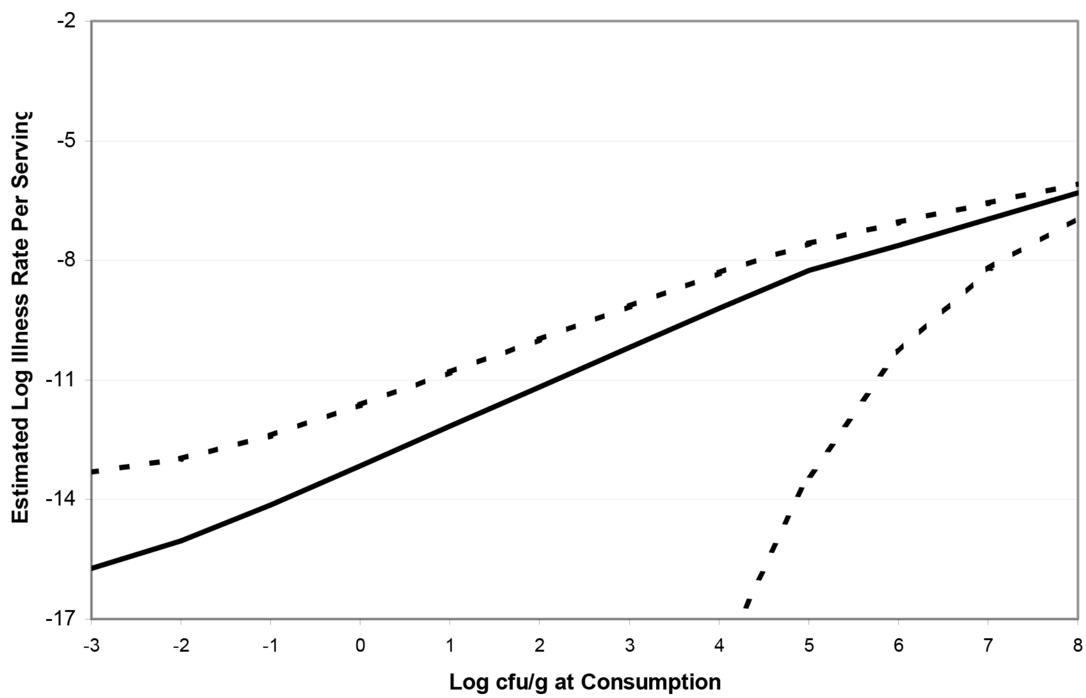


Figure VI-6. Cases of Listeriosis (per serving basis) for the Elderly Population as a Function of *Listeria monocytogenes* Concentration at Consumption in Deli Meats

Pre-Retail and At Retail Interventions

Reduction of the Number of Organisms Scenarios

Interventions might also be designed to reduce the number of *Listeria* in food before it is sold. There are a variety of ways in which this might be done. Effectively modeling a pre-retail intervention may require expanding the modeling effort to include the step at which the intervention takes place. However, a common method of representing or measuring an intervention that kills bacteria (e.g. pasteurization, cooking) is to calculate the number of surviving bacteria as a fraction of the initial number. Since the surviving fraction may be very small, the effectiveness of a kill step may be represented as a log reduction of cfu, where 10% survival represents a 1 log reduction, 1% survival a 2 log reduction, etc. To model an intervention that is measured this way, scenarios were run to calculate the predicted reduction in the number of cases in the elderly population attributable to deli meats as a function of the reduction in cfu prior to retail. This means that for a one log reduction, the distribution of servings containing a given number of *Listeria monocytogenes* at retail was shifted to values one log lower. For example, the 10^3 cfu/g level, which represented 0.5% of the servings, was shifted to 10^2 cfu/g. The contamination was not truncated at any specific cfu/g level, so high contamination levels could still occur but they would be observed less frequently compared to the baseline simulations. The growth after retail was modeled in the same manner as in the baseline model. The results are displayed in Figure VI-7.

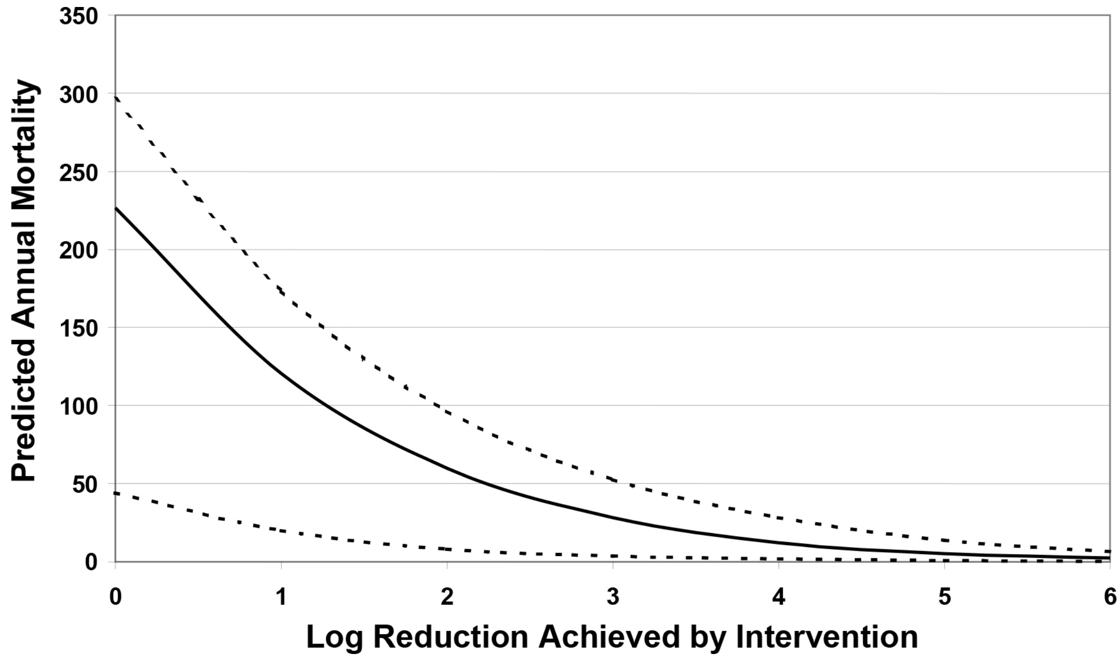


Figure VI-7. Reduction of Predicted Annual Mortality in the Elderly Subpopulation Attributible to Deli Meats as a Function of Log Kill Achieved by the Inclusion of a Lethal Intervention Prior to Retail
[The solid line represents the median estimate. The dotted lines represent the 5th and 95th percentiles of the uncertainty distribution.]

The scenarios shown in Figure VI-7 indicate that inclusion of treatment that produced a one log reduction in contamination at retail would reduce the number of predicted deaths in the elderly population attributed to Deli Meats nearly 50%, from 227 to 120. Reducing contamination two logs would result in a 74% reduction. This reduction could be achieved by a number of different means such as reduced contamination of raw materials, more effective sanitation, or a process step that results in some lethality.

Estimations of risk per serving from specific cfu/g at retail scenarios

The ability of *Listeria monocytogenes* to grow in a food is associated with the likelihood of that food causing illness. The following scenario provides insight on how the contamination level at retail in a food that supports growth affects the risk of listeriosis per serving. This example is based on Deli Meat and the elderly population where the contamination level is a single value, not a distribution with variation and uncertainty as in the other examples (Figure VI-8). Since the actual number of cases depends on the number of servings, only the case rate per serving is used as the endpoint.

There is a wide variation in growth resulting from the combination of exponential growth rate, temperature, time and maximum levels but some servings will grow to populations having high likelihood of causing illness. The level of *Listeria monocytogenes* is the determining factor in the resulting risk per serving. For example, if a 56-g serving that has one *Listeria monocytogenes* per gram at retail (i.e., 0 $\log_{10}$ cfu/g or approximately 56 total *Listeria monocytogenes* per serving) grows as described by the baseline model, it will result in a risk per serving of 1.1 x 10^{-6} (–5.96 $\log_{10}$ or approximately 1 death per million servings). For a 56-g serving with 100 cfu/g at retail, the model predicts a modest increase in the likelihood of death (1.3 x 10^{-6} deaths per serving). Conversely, if a 10-g serving has one *Listeria monocytogenes* per g, the model predicts a risk of 1.0 x 10^{-6} (–6.0 $\log_{10}$) and for a 100-g serving, the model predicts a reduction of the risk to 0.71 x 10^{-6} (–6.15 $\log_{10}$). These relatively small changes in risk despite a ten-fold change in contamination level are a consequence of the expected post-retail growth of *Listeria monocytogenes* in food before consumption.

Given the refrigerator temperature and storage time distributions, the relatively low numbers at retail have the potential to grow to levels at the time of consumption in a sufficient fraction of servings that the overall risk is in the range of 10^{-6} per serving. Reducing the levels from 10^3 to 10^2 and to even 10^0 cfu/g reduces the risk, but not very much. Only when the contamination level decreases to less than one *Listeria monocytogenes* per package does the risk fall in proportion to the frequency of contamination (10^{-3} cfu/g decreases the risk to 0.02 x 10^{-6} per serving). What this implies is that in foods that support growth, reducing contamination to some specified level (but not zero) is not adequate by itself in controlling the risk of listeriosis.

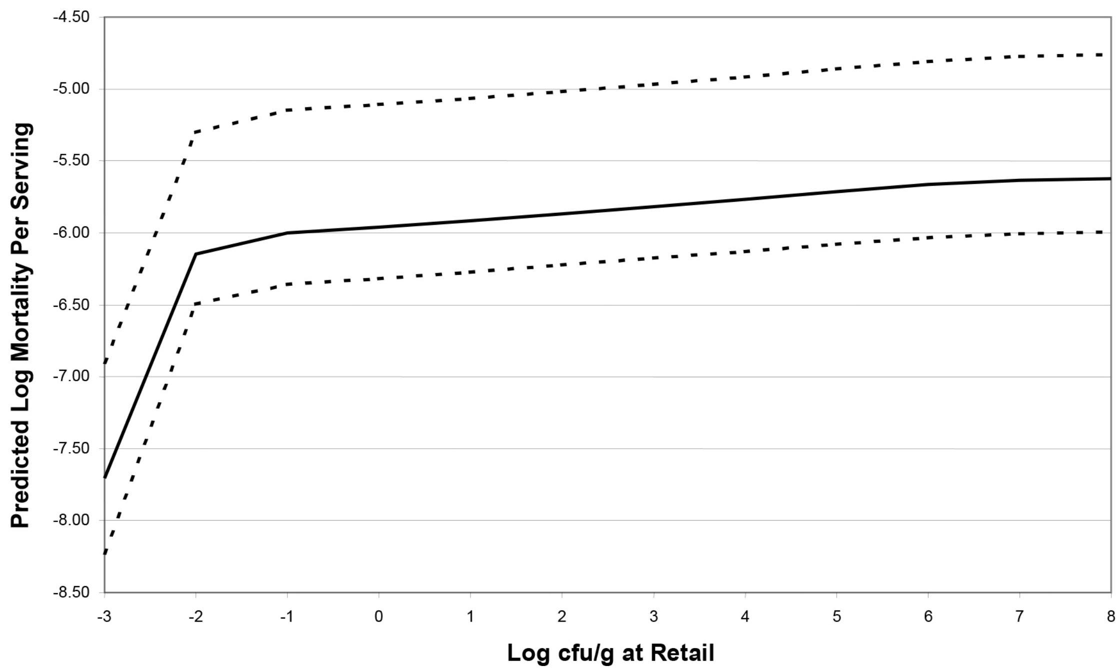


Figure VI-8. Predicted Mortality per Serving for the Elderly Subpopulation When Specific Concentrations of *Listeria monocytogenes* in Deli Meats at Retail are Allowed to Grow Before Consumption

Fresh Soft Cheese Made from Unpasteurized Milk Scenario

Unlike the 2001 draft risk assessment, the revised risk assessment indicates that the risk from Fresh Soft Cheese is low. This change is largely attributable to the inclusion of additional new data indicating a very low prevalence rate in this food category. However, there is a strong epidemiological correlation between Hispanic-style fresh soft cheese (Queso Fresco) and listeriosis. A likely explanation for this discrepancy is that the data collected for this category is not representative of the cheese linked to the disease (i.e., fresh soft cheese made from raw, unpasteurized milk). In particular, although most commercial sources of fresh soft cheese are manufactured from pasteurized milk, some sources of queso fresco are made from raw milk.

To characterize the risk from queso fresco made from raw milk, the exposure model was constructed using the same analog as in the 2001 draft risk assessment – soft unripened cheese made from raw milk (Loncarevik, *et al.*, 1995), where 50% of the samples tested were positive. A data set for the contamination distribution was developed using the methodology described in the Exposure Assessment chapter using the default range of 2 to 5 geometric standard deviations and applying a correction factor for overestimation from older data. The same growth and storage parameters were used as in the baseline estimation.

The estimated risk per serving for two sensitive populations is presented in Table VI-4. The risk per serving was 43 times greater for the perinatal population and 36 times greater for the elderly population when cheeses were assumed to be made from unpasteurized milk compared to manufacture with pasteurized milk. The tested 'high prevalence' scenario increased the predicted risk on a per serving basis from low to a high risk.

Table VI-4. Comparison of Baseline and a High Prevalence Scenerio Risk per Serving for Fresh Soft Cheese for Two Subpopulations

Population	Median Predicted Risk per Serving (5^{th} and 95^{th} percentiles)	
	Baseline[a]	High Prevalence[b]
Perinatal	4.7×10^{-9} (3.0×10^{-11}, $9.8\ 10^{-8}$)	2.0×10^{-7} (5.1×10^{-9}, $5.3\ 10^{-6}$)
Elderly	2.8×10^{-10} (1.3×10^{-12}, $4.5\ 10^{-9}$)	1.0×10^{-8} (3.2×10^{-10}, $2.3\ 10^{-7}$)

[a]Baseline uses a prevalence distribution based on available survey data.
[b]High Prevalence scenarios assumes that 50% of the samples tested are positive.

<u>Disease Rate as Function of Concentration Levels Measured at Retail</u>

To simulate the relationship between *Listeria monocytogenes* concentration at retail and public health, the growth component of the exposure assessment is also included. Since the growth model differs significantly across food categories, examples for both high (Deli Meats) and low (Hard Cheese) growth are shown in Figures VI-9, VI-10, and VI-11. Comparison of Figures VI-9 (elderly) and VI-10 (neonatal) suggests that similar dose-response relationships may be expected for different subpopulations. However, the comparison of Figure VI-9 (Deli Meat) and VI-11 (Hard Cheese) indicates that the growth component of the model for a particular food category can have a large influence on the relationship between concentration at retail and the rate of listeriosis. Foods with high growth rates (such as Deli Meats) exhibit a relatively flat curve that suggests that the number of cases is only slightly dependent on initial concentration. On the other hand, low growth foods (such as Hard Cheese) indicate a substantial increase in the disease rate as the concentration increases. This suggests that for foods that support growth, above some minimum concentration the risk is largely determined by the growth that occurs subsequent to purchase.

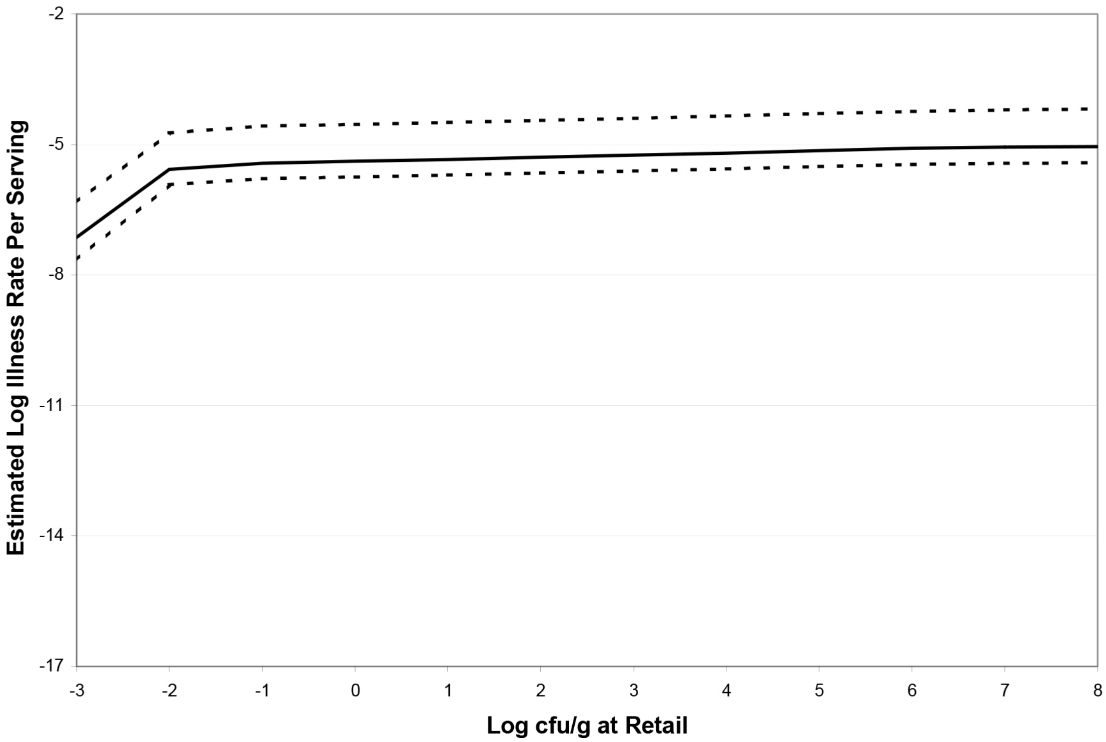


Figure VI-9. Cases of Listeriosis (per serving basis) for the Elderly Subpopulation as a Function of *Listeria monocytogenes* Concentration at Consumption for Deli Meat

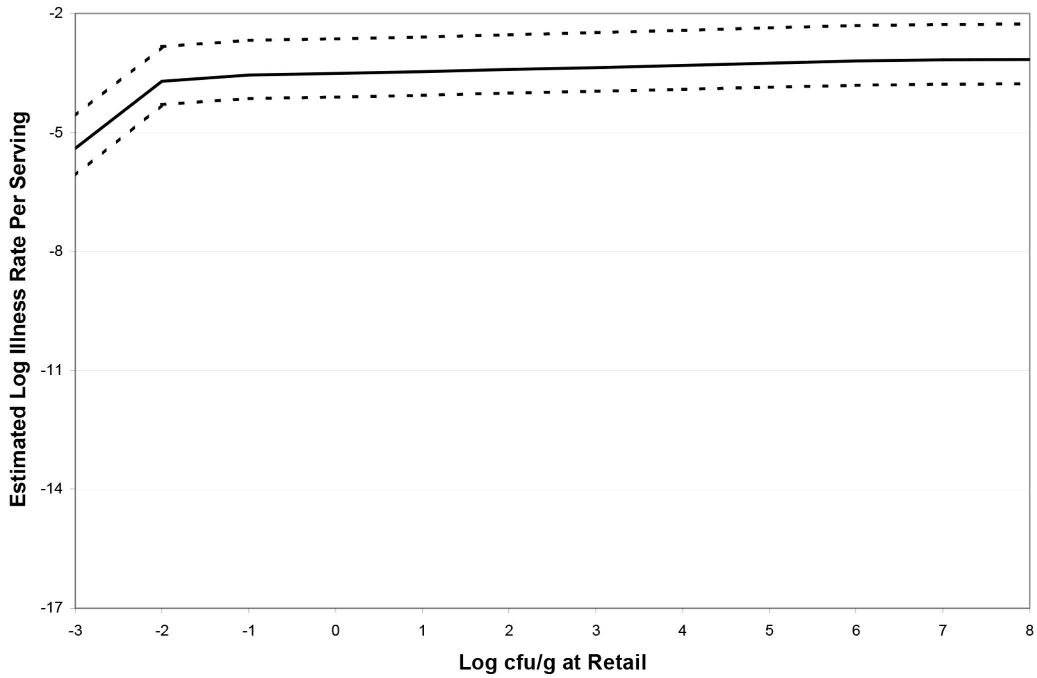


Figure VI-10. Cases of Listeriosis (per serving basis) for the Neonatal Subpopulation as a Function of *Listeria monocytogenes* Concentration at Retail for Deli Meat.

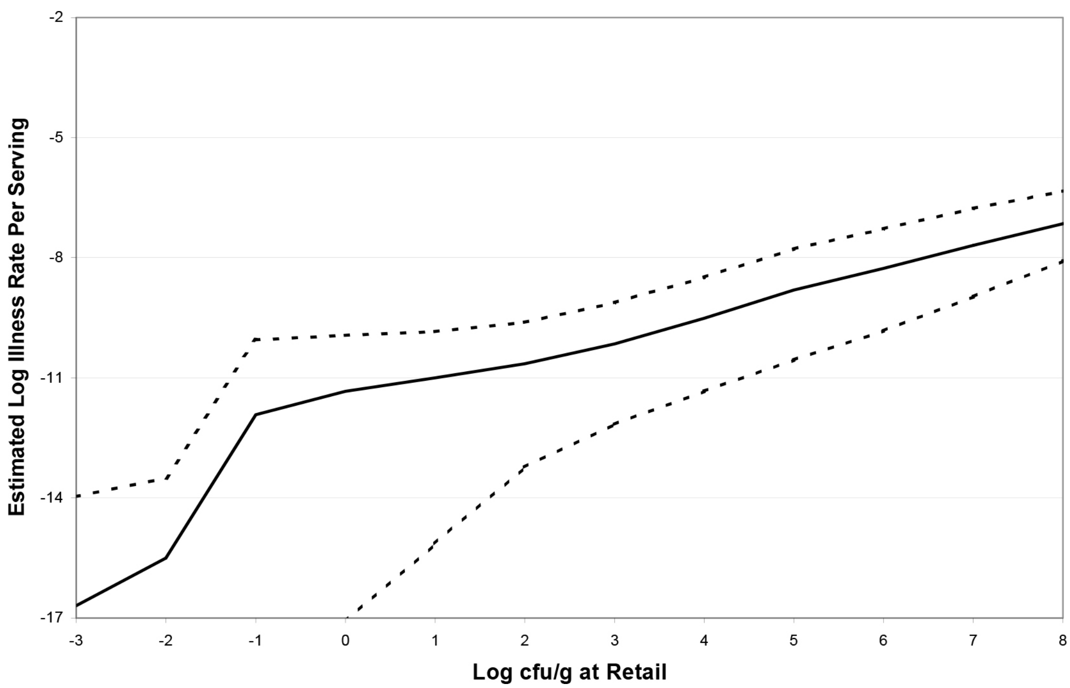


Figure VI-11. Cases of Listeriosis (per serving basis) for Elderly Subpopulation as a Function of *Listeria monocytogenes* Concentration at Retail for Hard Cheese

Pasteurized Fluid Milk Scenarios

The primary intervention for milk is pasteurization. Differences in pasteurization requirements and handling practices among different countries could result in different levels of frequency and amounts of *Listeria monocytogenes* in milk at consumption. The Pasteurized Fluid Milk food category contains 30 studies including 3 studies conducted in the United States. There are a total of 12,407 fluid milk samples including whole milk, low fat, skim milk, and chocolate milk. All of the milk samples are from cows, except for a single sample of goat milk. The average percent of positive samples across the 30 studies is 0.4%. As with all of the food categories, the data were weighted for location, study age, and study size.

A "what-if" analysis was conducted to evaluate the impact of including non-U.S. studies and chocolate milk in this food category. The results for the three subpopulations and the total U.S. population are presented below in Tables VI-5 And VI-6. Excluding non-U.S. milk and chocolate milk has little impact on the predicted number of cases of listeriosis attributed to Pasteurized Fluid Milk on both per serving and per annum basis.

Table VI-5. Impact of Excluding Non-U.S. and Chocolate Milk from the Pasteurized Fluid Milk Food Category on the Number of Cases of Listeriosis per Serving Basis

Scenario	Median Cases of Listeriosis per Serving (5^{th}, 95^{th} percentile)			
	Intermediate-Age	Perinatal	Elderly	Total
Baseline	$4.4x10^{-10}$ ($2.8x10^{-11}$, $5.7x10^{-9}$)	$1.6x10^{-8}$ ($1.3x10^{-9}$, $1.9x10^{-7}$)	$3.4x10^{-9}$ ($2.5x10^{-10}$, $3.9x10^{-8}$)	$1.0x10^{-9}$ ($7.5x10^{-11}$, $1.3x10^{-8}$)
Domestic Milk Only	$3.7x10^{-10}$ ($2.8x10^{-11}$, $3.5x10^{-9}$)	$8.0x10^{-7}$ ($7.1x10^{-8}$, $6.5x10^{-6}$)	$2.9x10^{-9}$ ($2.6x10^{-10}$, $2.5x10^{-8}$)	$8.8x10^{-10}$ ($7.5x10^{-11}$, $7.7x10^{-9}$)
Domestic Milk (excluding chocolate milk)	$3.8x10^{-10}$ ($3.0x10^{-11}$, $3.4x10^{-9}$)	$8.4x10^{-7}$ ($7.6x10^{-8}$, $6.0x10^{-6}$)	$3.0x10^{-9}$ ($2.7x10^{-10}$, $2.3x10^{-8}$)	$9.3x10^{-10}$ ($8.2x10^{-11}$. $7.5x10^{-9}$)
Domestic Chocolate Milk Only	$4.2x10^{-10}$ ($2.9x10^{-11}$, $7.9x10^{-9}$)	$9.4x10^{-7}$ ($7.6x10^{-8}$, $1.5x10^{-5}$)	$3.4x10^{-9}$ ($2.6x10^{-10}$, $6.1x10^{-8}$)	$5.8x10^{-10}$ ($4.3x10^{-11}$, $1.1x10^{-8}$)

Table VI-6. Impact of Excluding Non-U.S. and Chocolate Milk from the Pasteurized Fluid Milk Food Category on the Number of Cases of Listeriosis per Annum Basis

Scenario	Median Cases of Listeriosis per Annum (5^{th}, 95^{th} percentile)			
	Intermediate-Age	Perinatal	Elderly	Total
Baseline	31.4 (2.0, 410.1)	8.0 (0.7, 95.8)	49.8 (3.7, 584.4)	90.8 (6.5, 1084.6)
Domestic Milk Only	27 (2.0, 250)	6.7 (0.65, 55)	43 (3.8, 360)	77 (6.5, 670)
Domestic Milk (excluding chocolate milk)	26 (2.1, 240)	6.9 (0.7, 52)	45 (4.0, 340)	78 (6.9, 630)
Domestic Chocolate Milk Only	1.2 (0.8, 23)	0.3 (0.2, 4.7)	0.2 (0.2, 4.1)	1.7 (0.1, 32)

Summary

In these scenarios, selected food categories (Deli Meats, Frankfurters, Fresh Soft Cheese, Pasteurized Fluid Milk, Smoked Seafood, and Hard Cheese) were used as examples. Other foods which permit different rates of growth and are stored for different lengths of time may have different results, but the general interrelationships are representative of other food categories. These scenarios compared with the baseline estimations of risk illustrate the impact of storage time, storage temperature, and contamination level on the risks per serving.

- Reducing the ranges of refrigerator temperatures by eliminating storage at the high temperatures reduced the predicted cases of listeriosis by reducing growth of *Listeria monocytogenes* in the foods that permit growth.

- Eliminating the longest storage times reduced the number of cases of listeriosis, even with the full range of storage temperatures and contamination levels. However, reducing a percentage of the longest storage times appeared to be less effective than reducing the corresponding percentage of highest storage temperatures, unless the storage time is reduced to very short duration between retail and consumption.

- Reducing the overall frequency of high levels of contamination will reduce the number of cases, particularly when frequencies of the highest contamination levels are reduced. However, growth can occur from relatively low contamination levels at retail to levels at consumption that are likely to cause illness. Thus, in foods that permit growth, reducing the *Listeria monocytogenes* at or before retail to less than some specified level other than zero will not result in the elimination of the risk.

VII. INTERPRETATION AND CONCLUSIONS

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 *Listeria monocytogenes* from 23 food categories. The assessment focuses on predicting the comparative risk among ready-to-eat foods that have a history of either *Listeria monocytogenes* contamination or were implicated epidemiologically. The risk assessment demonstrates 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). Thus, continued vigilance of current food safety control systems and the targeted initiation of new controls will likely be needed to achieve further reductions 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 *Listeria monocytogenes*. This systematic assessment provides a foundation to assist 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, overall interpretation of the risk assessment requires more than just a simple consideration of only the relative risk rankings associated with the various food categories. As discussed above, the results must also be evaluated in relation to the degree of variability and uncertainty inherent in the predicted relative risk, and interpreted in relation to available scientific knowledge of the production, marketing, and consumption of the various food categories. Likewise, the results must be evaluated in relation to the available epidemiological record. A detailed consideration of the quantitative and qualitative findings for each food category is provided in the risk assessment and its appendices.

As part of the evaluation and interpretation of the predicted risk estimates and the accompanying relative risk rankings, the risk assessment considered various qualitative and quantitative methods of grouping the results that may be useful for risk management or risk communication purposes. For example, Table V-6 includes an arbitrary grouping of the per serving and per annum results into very high, high, medium, and low risk categories based on the criteria provided in the table's footnotes. In this instance, six food categories were considered to be high risk on a per serving basis: Deli Meats, Frankfurters (not reheated), Pâté and Meat Spreads, Unpasteurized Fluid Milk, Smoked Seafood, and Cooked Ready-to-Eat Crustaceans. Three food categories are considered to be moderate risk and the remaining 14 food categories are considered to be low risk on a per serving basis. On a per annum basis, the majority of the cases are predicted to be attributable to Deli Meats. The high-risk food categories included Pasteurized Fluid Milk, High Fat and Other Dairy Products, and Frankfurters (not reheated). Five food categories are considered to be moderate risks and the remaining 14 food categories are considered to be low risk on a per annum basis.

A number of methods for objectively grouping the results were evaluated, and are discussed in detail within the risk assessment. One approach that appears to be very useful for risk management/communication purposes is the evaluation of the relative risk ranking results using cluster analysis (see Appendix 12). When performed at the 90% confidence level, this analysis groups the per serving rankings into four clusters and the per annum rankings into five clusters (Table VII-1). These clusters are used, in turn, to develop a two-dimensional matrix of per serving vs. per annum rankings (see Figure VII-1) of the food categories. In this approach, the four per serving clusters were arrayed against the per annum clusters (A and B, C and D, and E). The matrix was then used to depict five overall risk designations: Very High, High, Moderate, Low, and Very Low. For example, as shown in Table VII-1, Deli Meats is included in the 'per serving' Cluster 1 and in the 'per annum' Cluster A, so it is placed in the two-dimensional matrix cell, Very High Risk, Cluster 1-A (See Summary Figure VII-1). Frankfurters (not reheated) is in the 'per serving' Cluster 1 and in the 'per annum' Cluster B, so it is also placed in the Very High Risk cell, representing Cluster 1-B. No food categories are in the Moderate Risk cell for Clusters 3-A and 3-B because there are no foods in the 'per serving' Cluster 3 that match with the 'per annum' Cluster A or Cluster B.

Table VII-1. Results of Cluster Analysis at the 0.1 Level

Risk per Serving	Risk per Annum
CLUSTER 1 Deli Meats Frankfurters, not reheated Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	**CLUSTER A** Deli Meats
CLUSTER 2 Cooked RTE Crustaceans High Fat and Other Dairy Products Pasteurized Fluid Milk Soft Unripened Cheese	**CLUSTER B** High Fat and Other Dairy Products Frankfurters, not reheated Pasteurized Fluid Milk Soft Unripened Cheese
CLUSTER 3 Deli-type Salads Dry/Semi-dry Fermented Sausages Fresh Soft Cheese Frankfurters, reheated Fruits Preserved Fish Raw Seafood Semi-soft Cheese Soft Ripened Cheese Vegetables	**CLUSTER C** Cooked RTE Crustaceans Fruits Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood
CLUSTER 4 Cultured Milk Products Ice Cream and Frozen Dairy Products Processed Cheese Hard Cheese	**CLUSTER D** Deli-type Salads Dry/Semi-dry Fermented Sausages Frankfurters, reheated Fresh Soft Cheese Soft Ripened Cheese Semi-Soft Cheese Vegetables **CLUSTER E** Cultured Milk Products Hard Cheese Ice Cream and Frozen Dairy Products Preserved Fish Processed Cheese Raw Seafood

Decreased Risk per Annum →

Decreased Risk per Serving ↓

	Clusters A and B	Clusters C and D	Cluster E
Cluster 1	**Very High Risk (Clusters 1-A, 1-B)** Deli Meats Frankfurters (not reheated)	**High Risk (Clusters 1-C, 1-D)** Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	**Moderate Risk (Cluster 1-E)** No food categories
Cluster 2	**High Risk (Clusters 2-A, 2-B)** High Fat and Other Dairy Products Pasteurized Fluid Milk Soft Unripened Cheese	**Moderate Risk (Clusters 2-C, 2-D)** Cooked RTE Crustaceans	**Moderate Risk (Cluster 2-E)** No food categories
Cluster 3	**Moderate Risk (Clusters 3-A, 3-B)** No food categories	**Moderate Risk (Clusters 3-C, 3-D)** Deli-type Salads Dry/Semi-dry Fermented Sausages Frankfurters (reheated) Fresh Soft Cheese Fruits Semi-soft Cheese Soft Ripened Cheese Vegetables	**Low Risk (Cluster 3-E)** Preserved Fish Raw Seafood
Cluster 4	**Moderate Risk (Clusters 4-A, 4-B)** No food categories	**Low Risk (Clusters 4-C, 4-D)** No food categories	**Very Low Risk (Cluster 4-E)** Cultured Milk Products Hard Cheese Ice Cream and Other Frozen Dairy Products Processed Cheese

Figure VII-1. Two-Dimensional Matrix of Food Categories Based on Cluster Analysis of Predicted per Serving and per Annum Relative Rankings

[The matrix was formed by the interception of the four per serving clusters vs. the per annum clusters A and B, C and D, and E. For example, Cluster 3-E (Low Risk) refers to the food categories that are in both Cluster level 3 for the risk per serving and Cluster level E for the risk per annum. See Table VII-1.]

The risk characterization combines the exposure and dose-response models to predict the relative risk of illness attributable to each food category. While the risk characterization must be interpreted in light of both the inherent variability and uncertainty associated with the extent of contamination of ready-to-eat foods with *Listeria monocytogenes* and the ability of the microorganism to cause disease, the results provide a means of comparing the relative risks among the different food categories and population groups considered in the assessment and should prove to be a useful tool in focusing control strategies and ultimately improving public health through effective risk management. As described above, cluster analysis techniques are employed as a means of discussing the food categories within a risk analysis framework. The food categories are divided into five overall risk designations (see Figure VII-1), which are likely to require different approaches to controlling foodborne listeriosis.

Risk Designation Very High. This designation includes two food categories, Deli Meats and Frankfurters, Not Reheated. These are food categories that have high predicted relative risk rankings on both a per serving and per annum basis, reflecting the fact that they have relatively high rates of contamination, support the relative rapid growth of *Listeria monocytogenes* under refrigerated storage, are stored for extended periods, and are consumed extensively. These products have also been directly linked to outbreaks of listeriosis. This risk designation is one that is consistent with the need for immediate attention in relation to the national goal for reducing the incidence of foodborne listeriosis. Likely activities include the development of new control strategies and/or consumer education programs suitable for these products.

Risk Designation High. This designation includes six food categories: High Fat and Other Dairy Products, Pasteurized Fluid Milk, Pâté and Meat Spreads, Soft Unripened Cheeses, Smoked Seafood, and Unpasteurized Fluid Milk. These food categories all have in common the ability to support the growth of *Listeria monocytogenes* during extended refrigerated storage. However, the foods within this risk designation appear to fall into two distinct groups based on their rates of contamination and frequencies of consumption.

- Pâté and Meat Spreads, Smoked Seafood, and Unpasteurized Fluid Milk have relatively high rates of contamination and thus high predicted per serving relative risks. However, these products are generally consumed only occasionally in small quantities and/or are eaten by a relatively small portion of the population, which lowers the per annum risk. All three products have been associated with outbreaks or sporadic cases, at least internationally.

These foods appear to be priority candidates for new control measures (i.e., Smoked Seafood, Pâté and Meat Spreads) or continued avoidance (i.e., Unpasteurized Fluid Milk).

- High Fat and Other Dairy Products, Pasteurized Fluid Milk, and Soft Unripened Cheeses have low rates of contamination and corresponding relatively low predicted per serving relative risks. However, these products are consumed often by a large percentage of the population, resulting in elevated predicted per annum relative risks. In general, the predicted per annum risk is not matched with an equivalent United States epidemiologic record. However, the low frequency of recontamination of individual servings of these products in combination with their broad consumption makes it likely that these products are primarily associated with sporadic cases and normal case control studies would be unlikely to lead to the identification of an association between these products and cases of listeriosis.

  These products (High Fat and Other Dairy Products, Pasteurized Fluid Milk, and Soft Unripened Cheeses) appear to be priority candidates for advanced epidemiologic and scientific investigations to either confirm the predictions of the risk assessment or identify the factors not captured by the current models that would reduce the predicted relative risk.

<u>Risk Designation Moderate.</u> This risk designation includes nine food categories (Cooked Ready-to-Eat Crustaceans, Deli Salads, Dry/Semi-Dry Fermented Sausages, Frankfurters-Reheated, Fresh Soft Cheese, Fruits, Semi-soft Cheese, Soft Ripened Cheese, and Vegetables) that encompass a range of contamination rates and consumption profiles. A number of these foods include effective bactericidal treatments in their manufacture or preparation (e.g., Cooked Ready-to-Eat Crustaceans, Frankfurters-Reheated, Semi-soft Cheese) or commonly employ

conditions or compounds that inhibit the growth of *Listeria monocytogenes* (e.g., Deli Salads, Dry/Semi-dry Fermented Sausages). The risks associated with these products appear to be primarily associated with product recontamination, which in turn, is dependent on continued, vigilant application of proven control measures.

It is worth noting that two food categories, Fresh Soft Cheese and Soft Ripened Cheese, were previously classified as higher risk products in the draft 2001 version of the risk assessment. This change reflects the acquisition of extensive new exposure data that indicate a significant reduction in contamination rates. The changes in contamination rates, in turn, appear to be the result of increased use of pasteurized or otherwise heat-treated milk, and reflect how relative risk can change as a result of effective food safety control programs.

<u>Risk Designation Low</u>. This risk designation includes two food categories, Preserved Fish and Raw Seafood. Both products have moderate contamination rates but include conditions (e.g., acidification) or consumption characteristics (e.g., short shelf-life) that limit *Listeria monocytogenes* growth and thus limit predicted per serving risks. The products are generally consumed in small quantities by a small portion of the population on an infrequent basis, which results in low predicted per annum relative risks. Exposure data for these products are limited so there is substantial uncertainty in the findings. However, the current results predict that these products, when manufactured consistent with current good manufacturing practices, are not likely to be a major source of foodborne listeriosis.

<u>Risk Designation Very Low</u>. This risk designation includes four food categories: Cultured Milk Products, Hard Cheese, Ice Cream and Other Frozen Dairy Products, and Processed Cheese. These products all have in common the characteristics of being subjected to a bactericidal treatment, having very low contamination rates, and possessing an inherent characteristic that either inactivates *Listeria monocytogenes* (e.g., Cultured Milk Products, Hard Cheese) or prevents its growth (e.g., Ice Cream and Other Frozen Dairy Products, Processed Cheese). This results in a very low predicted per serving relative risks. The predicted per annum relative risks are also low despite the fact that these products are among the more commonly consumed ready-

to-eat products considered by the risk assessment. The results of the risk assessment predict that unless there was a gross error in their manufacture, these products are highly unlikely to be a significant source of foodborne listeriosis.

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. United States consumers are exposed to low to moderate levels of *Listeria monocytogenes* on a regular basis.
- The risk assessment supports the findings of epidemiological investigations of both sporadic illness and outbreaks of listeriosis that certain foods are more likely to be vehicles for *Listeria monocytogenes*.
- Three dose-response models were developed that relate the exposure to different levels of *Listeria monocytogenes* in three age-based subpopulations [i.e., perinatal (fetuses and newborns), elderly, and intermediate-age] with the predicted number of fatalities. These models were used to describe the relationship between levels of *Listeria monocytogenes* ingested and the incidence of listeriosis. The dose of *Listeria monocytogenes* necessary to cause listeriosis depends greatly upon the immune status of the individual.
    1. Susceptible subpopulations (such as the elderly and perinatal) are more likely to contract listeriosis than the general population.
    2. Within the intermediate-age subpopulation group, almost all cases of listeriosis are associated with specific subpopulation groups with increased susceptibility (e.g., individuals with chronic illnesses, individuals taking immunosuppressive medication).

3. The strong association of foodborne listeriosis with specific population groups suggests that strategies targeted to these susceptible population groups, i.e., perinatal (pregnant women), elderly, and susceptible individuals within the intermediate-age group, would result in the greatest reduction in the public health impact of this pathogen.

- The dose-response models developed for this risk assessment considered, for the first time, the range of virulence observed among different isolates of *Listeria monocytogenes*. The dose-response curves suggest that the relative risk of contracting listeriosis from low dose exposures could be less than previously estimated.

- The exposure models and the accompanying 'what-if' scenarios identify five broad factors that affect consumer exposure to *Listeria monocytogenes* at the time of food consumption.

1. Amounts and frequency of consumption of a ready-to-eat food
2. Frequency and levels of *Listeria monocytogenes* in a ready-to-eat food
3. Potential of the food to support growth of *Listeria monocytogenes* during refrigerated storage
4. Refrigerated storage temperature
5. Duration of refrigerated storage before consumption

Any of these factors can affect potential exposure to *Listeria monocytogenes* from a food category. These factors are 'additive' in the sense that factors where multiple factors favor high levels of *Listeria monocytogenes* at the time of consumption are typically more likely to be riskier than foods where a single factor is high. These factors also suggest several broad control strategies that could reduce the risk of foodborne listeriosis such as reformulation of products to reduce their ability to support the growth of *Listeria monocytogenes* or encouraging consumers to keep refrigerator temperatures at or below 40 ºF and reduce refrigerated storage times. For example, the 'what-if' scenarios using Deli Meats predicts that consumer education and other strategies aimed at maintaining home refrigerator temperatures at 40 ºF could substantially reduce the risks associated with this food category. Combining this with pre-retail treatments that decrease the contamination levels in Deli Meats would be expected to reduce the risk even further.

The models generated as the basis for this risk assessment can be used to further evaluate the impact of listeriosis on the public health. For example, the FAO/WHO risk assessment on *Listeria monocytogenes*, which is largely based on the approaches used in the current risk assessment, is being developed to consider several risk management questions posed by Codex Alimentarius. 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 also be used to evaluate the expected public health impact of preventative 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. For example, the FSIS *Listeria* Risk Assessment in Deli Meats, used portions of the exposure and dose-response models from the current risk assessment to develop information about the effects of combining testing, sanitation, and post-lethality processing interventions to reduce cases of listeriosis.

The models may also be used to evaluate the impact of hypothetical changes in a process such as limits on storage time or temperature to provide insight in how the different components of the model interact. The ‘what if’ scenarios modeled in this risk assessment provide insight to the impact on public health of limiting storage times, avoiding high temperature refrigeration storage, and reducing contamination levels. Scenario testing emphasizes that the results of any 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 revised *Listeria monocytogenes* risk assessment, particularly the predicted relative risk ranking values, could change as a result of the availability of new information, changes in scientific approaches, or data.

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 public health enhancement.

NEW REFERENCES

[The references below are additional, new references that were not cited in the 2001 Draft *Listeria monocytogenes* Risk Assessment. Copies of these references are available in the public docket. FDA Docket No 99N-1168: Food and Drug Administration, Dockets Management Branch (HFA-305), 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and in the FSIS Docket No 00-048N: FSIS Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250-3700.]

Abou-Eleinin, A.-A. M., E.T. Ryser, and C.W. Donnelly. 2000. Incidence and seasonal variation of *Listeria* species in bulk tank goat's milk. *Journal of Food Protection* 63:1208-1213.

Adesiyun, A.A. 1993. Prevalence of *Listeria* spp., *Campylobacter* spp., *Salmonella* spp., *Yersinia* spp. and toxigenic *Escherichia coli* on meat and seafoods in Trinidad. *Food Microbiology* 10:395-403.

Aguado, V., A.I. Vitas, and I. García-Jalón. 2001. Random amplified polymorphic DNA typing applied to the study of cross-contamination by *Listeria monocytogenes* in processed food products. *Journal of Food Protection* 64:716-720.

American Meat Institute. 2001. Consumer handling of RTE meats. (unpublished data submitted to Docket No. 99N-1168).

Baek, S.-Y., S.-Y. Lim, D.-H. Lee, K.-H. Min, and C.-M. Kim. 2000. Incidence and characterization of *Listeria monocytogenes* from domestic and imported foods in Korea. *Journal of Food Protection* 63:186-189.

Bedie, G.K., J. Samelis, J.N. Sofos, K.E. Belk, J.A. Scanga, and G.C. Smith. 2001. Antimicrobials in the formulation to control *Listeria monocytogenes* postprocessing contamination on frankfurters stored at 4 degrees Celsius in vacuum packages. *Journal of Food Protection* 64:1949-1955.

Benezet, A, J.M. de la Osa, E. Pedregal, M. Botas, N. Olmo, and F. Pérez Flórez. 2001. Presencia de *Listeria monocytogenes* en especias (Presence of *Listeria monocytogenes* in spices). *Alimentaria* 321:41-43.

Berry, T.M., D.L. Park, and D.V. Lightner. 1994. Comparison of the microbial quality of raw shrimp from China, Ecuador, or Mexico at both wholesale and retail levels. *Journal of Food Protection* 57:150-153.

Bersot, L.S., M. Landgraf, B.D.G.M. Franco, and M.T. Destro. 2001. Production of mortadella: Behavior of *Listeria monocytogenes* during processing and storage conditions. *Meat Science* 57:13-17.

Boyartchuk, V., K., W. Broman, R. E. Mosher, S. E. F. D'Orazio, M.N. Starnbach, and W.F. Dietrich. 2001. Multigenic control of *Listeria monocytogenes* susceptibility in mice. *Nature Genetics* 27:259-260.

Bredholt, S., T. Nesbakken, and A. Holck. 1999. Protective cultures inhibit growth of *Listeria monocytogenes* and *Escherichia coli O157:H7* in cooked, sliced, vacuum- and gas-packaged meat. *International Journal of Food Microbiology* 53:43-52.

Cabanes, D., P. Dehoux, O. Dussurget, L. Frangeul, and P. Cossart. 2002. Surface proteins and the pathogenic potential of *Listeria monocytogenes*. *TRENDS in Microbiology* 10:238-245.

Carrington, C. and S. Dennis. 2001. LM Expert Panel's conclusions (unpublished data from CFSAN, FDA)

Cassin, M.H., A.M. Lammerding, E.C.D. Todd, W. Ross, and R.S. McColl. 1998. Quantitative risk assessment for *Escherichia coli O157:H7* in ground beef hamburgers. *International Journal of Food Microbiology* 41:21-44.

Centers for Disease Control and Prevention. 2000a. *FoodNet Surveillance Report for 1999 . Final report*.

Centers for Disease Control and Prevention. 2000b. Multistate outbreak of listeriosis- United States, 2000. *Morbidity and Mortality Weekly Report* 49:1129-1130.

Centers for Disease Control and Prevention. 2001. Outbreak of listeriosis associated with homemade Mexican-style cheese- North Carolina, October 2000- January 2001. *Morbidity and Mortality Weekly Report* 50:560-562.

Centers for Disease Control and Prevention. 2002a. Preliminary Foodnet data on the incidence of foodborne illness- Selected sites, United States, 2001. *Morbidity and Mortality Weekly Report* 51:325-329.

Centers for Disease Control and Prevention. 2002b. Outbreak of listeriosis-Northeastern United States, 2002. *Morbidity and Mortality Weekly Report* 51:950-951.

Choi, Y-C., S.-Y. Cho, B.-K. Park, D.-H. Chung, and D.-H. Oh. 2001. Incidence and characterization of *Listeria* spp. from foods available in Korea. *Journal of Food Protection* 64:554-558.

Conway, W.S., B. Leverentz, R.A. Saftner, W.J. Janisiewicz, C.E. Sams, and E. Leblanc. 2000. Survival and growth of *Listeria monocytogenes* on fresh-cut apple slices and its interaction with *Glomerella cingulata* and *Penicillium expansum*. *Plant Disease* 84:177-181.

Copes, J., K. Pellicer, H.G. Echeverría, N.O. Stanchi, C. Martínez, and N. Leardini. 2000. Investigación de *Listeria monocytogenes* en quesos de pasta blanda. (Investigation of *Listeria monocytogenes* in soft cheeses.) Revista *Argentina de Microbiologia* 32:49-52.

Daley, E.F., D. Bootsveld, D.W. Warburton, and J.M. Farber. 1999. A comparison of the health protection branch and the enzyme linked fluorescent assay methods for the isolation and identification of *Listeria* spp. and *Listeria monocytogenes* from foods. *Journal of Rapid Methods and Automation in Microbiology* 7:183-192.

Dauphin, G., C. Ragimbeau, and P. Malle. 2001. Use of PFGE typing for tracing contamination with *Listeria monocytogenes* in three cold-smoked salmon processing plants. *International Journal of Food Microbiology* 64:51-61.

Davies, A.R., C. Capell, D. Jehanno, G.J.E. Nychas, and R.M. Kirby. 2001. Incidence of foodborne pathogens on European fish. *Food Control* 12:67-71.

Dominguez, C., I. Gomez, and J. Zumalacarregui. 2001. Prevalence and contamination levels of *Listeria monocytogenes* in smoked fish and pâté sold in Spain. *Journal of Food Protection* 64:2075-2077.

Duffes, F., F. Leroi, P. Boyaval, and X. Dousset. 1999. Inhibition of *Listeria monocytogenes* by *Carnobacterium* spp. strains in a simulated cold smoked fish system stored at 4 degrees Celsius. *International Journal of Food Microbiology* 47:33-42.

Eblen, B. S. 2002a. JIFSAN-NFPA survey of *Listeria monocytogenes* in soft cheeses, (unpublished data from CFSAN, FDA).

Eblen, B. S. 2002b. *Listeria monocytogenes* growth values in deli salad, (unpublished data from CFSAN, FDA).

Farber, J.M., E.F. Daley, R. Holley, and W.R. Usborne. 1993. Survival of *Listeria monocytogenes* during the production of uncooked German, American and Italian-style fermented sausage. *Food Microbiology* 10:123-132.

Food Marketing Institute and Cornell University Institute of Food Science. 2002. *The food keeper: A consumer guide to food quality & safe handling*. Washington, D.C., Food Marketing Institute.

Food Safety and Inspection Service. 2003. *Listeria Risk Assessment in Deli Meats*. Washington, D.C., U.S. Department of Agriculture, Food Safety and Inspection Service. Retrieved on July 8, 2003 from http://www.fisis.usda.gov/OPPDE/rdad/FRPubs/97-013F/ListeriaReport.pdf.

Francis, G.A. and D. O'Beirne. 2001. Effects of acid adaptation on the survival of *Listeria monocytogenes* on modified atmosphere packaged vegetables. *International Journal of Food Science and Technology* 36:477-487.

Frye, C. P. 2000. *Milk product pathogen sampling (unpublished data)*. Washington, D.C., International Dairy Foods Association, Milk Industry Foundation, National Cheese Institute, International Ice Cream Association.

Geginat, G., S. Schenk, M. Skoberne, W. Goebel, and H. Hof. 2001. A novel approach of direct ex vivo epitope mapping identifies dominant and subdominant CD4 and CD8 T cell epitopes from *Listeria monocytogenes*. *The Journal of Immunology* 166:1877-1884.

Gill, C.O., J.C. McGinnis, K. Rahn, and A. Houde. 1996. The hygienic condition of manufacturing of beef destined for the manufacture of hamburger patties. *Food Microbiology* 13:391-396.

Glaser, P., L. Frangeul, C. Buchrieser, C. Rusniok, A. Amend, F. Baquero, P. Berche, H. Bloecker, P. Brandt, et al. 2001. Comparative genomics of *Listeria* species. *Science* 294:849-852.

Gombas, D.E., Y. Chen, R. S. Clavero, and V.N. Scott. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. *Journal of Food Protection* 66:559-569.

Gómez-Campillo, J.I., M.C. Domínguez-Fernández, and J.M. Zumalacárregui-Rodríguez. 1999. Incidencia de *Listeria monocytogenes* y *Eschericia coli O157:H7* en carnes y productos carnicos comercializados en Castilla y Leon (Incidence of *Listeria monocytogenes* and *Escherichia coli O157:H7* in meat and meat products retailed in Castilla and Leon, Spain). *Alimentaria* 303:71-75.

Hartung, M. 1999. Bericht über die epidemiologische situation der zoonosen in Deutschland für 1998. *Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedzin.*:158-161.. *Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. 2002. Risk Asssessment: Listeria monocytogenes in Ready-to-Eat Foods. Preliminary Report. Rome, Italy*

Hartung, M. 2000b. Bericht über die epidemiologische situation der zoonosen in Deutschland für 1999. *Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedzin.*:137-148.

Hartung, M. 2001. Ergebnisse der zoonosenerhegung 2000 bei lebensmitteln. (unpublished data from Germany)

Hatakka, M., T. Johansson, L. Rantala, P.Pakkala and T. Honkanen-Buzalski ,. 2001. Reduced *Listeria monocytogenes* occurrence in Finnish vacuum-packed fish products. In *ISOPOL XIV: International Symposium on Problems of Listeriosis*. Mannheim.

Hof, H. 2001. *Listeria monocytogenes*: A causative agent of gastroenteritis. *European Journal of Clinical Microbiological Infectious Disease* 20:369-373.

Hudson, J.A. and S.J. Mott. 1993. Growth of *Listeria monocytogenes*, *Aeromonas hydrophila*, and *Yersinia enterocolitica* on cooked beef under refrigeration and mild temperature abuse. *Food Microbiology* 10:429-437.

Hugas, M., M. Garriga, M.T. Aymerich, and J.M. Monfort. 1995. Inhibition of *Listeria* in dry fermented sausages by the bacteriocinogenic *Lactobacillus sake CTC494*. *Journal of Applied Bacteriology* 79:322-330.

Inoue, S., A. Nakama, Y. Arai, Y. Kokubo, T. Maruyama, A. Saito, T. Yoshida, M. Terao, S. Yamamoto, and S. Kumagai. 2000. Prevalence and contamination levels of *Listeria monocytogenes* in retail foods in Japan. *International Journal of Food Microbiology* 59:73-77.

Jain, A.K., M.N. Murty, and P.J. Flynn. 1999. Data Clustering: A Review. ACM Computing Surveys 31(3): 264-323.

Johnson, E. 1993. *Control of Listeria monocytogenes in fresh salad products*. Atlanta, Georgia, Refrigerated Foods Association.

Kamat, A.S. and P.M. Nair. 1994. Incidence of *Listeria* species in Indian seafoods and meat. *Journal of Food Safety* 14:117-130.

Karpíšková, R., M. Pejchalová, J. Mokrošová, J. Vytřasová, P. Šmuhařová, and J. Ruprich. 2000. Application of a chromogenic medium and the PCR method for the rapid confirmation of *Listeria monocytogenes* in foodstuffs. *Journal of Microbiological Methods* 41:267-271.

Kilsby, D.C. and M.E. Pugh. 1981. The relevance of the distribution of micro-organisms within batches of food to the control of microbiological hazards from foods. *Journal of Applied Bacteriology* 51:345-354.

Kramnik, I. and V. Boyartchuk. 2002. Immunity to intracellular pathogens as a complex genetic trait. *Current Opinion in Microbiology* 5:111-117.

Lanciotti, R., F. Gardini, F. Bandini, L. Vannini, and M.E. Guerzoni. 1999. Survey of the incidence of *Listeria* spp. in food of animal origin in northern Italy. *Advanced Food Science* 21:197-202.

Lando, A. M. 2003. *2001 FDA/FSIS food safety survey results. Ready to Eat Foods* (unpublished data from CFSAN, FDA).

Lay, J. 2001. *Listeria monocytogenes cases, hospitalizations, and deaths reported to Foodnet from 1997 to 2000* (unpublished data from Centers for Disease Control and Prevention).

Lecuit, M., S. Vandormael-Pournin, J. Lefort, M. Huerre, P. Gounon, C. Dupuy, C. Babinet, and P. Cossart. 2001. A transgenic model for listeriosis: Role of internalin in crossing the intestinal barrier. *Science* 292:1722-1725.

Levine, P. 2001. 1999-2000 *Listeria moncytogenes* data (unpublished data from FSIS, USDA)

McLauchlin, J. 1996. The role of the public health laboratory service in England and Wales in the investigation of human listeriosis during the 1980's and 1990's. *Food Control* 7:235-239.

Mendoza-Yepes, M.J., O. Abellan-Lopez, J. Carrion-Ortega, and F. Marin-Iniesta. 1999. Inhibition of *Listeria monocytogenes* and other bacteria in Spanish soft cheese made with *Lactococcus lactis* subsp. *Diacetylactis*. *Journal of Food Safety* 19:161-170.

Miettinen, H., K. Aarnisalo, S. Salo, and A.-M. Sjöberg. 2001. Evaluation of surface contamination and the presence of *Listeria monocytogenes* in fish processing factories. *Journal of Food Protection* 64:635-639.

Miettinen, M.K., L. Palmu, K.J. Björkroth, and H. Korkeala. 2001. Prevalence of *Listeria monocytogenes* in broilers at the abattoir, processing plant, and retail level. *Journal of Food Protection* 64:994-999.

Mitchell, M. 2001. Consumption of salad that support the growth of *Listeria monocytogenes* (unpublished data from Certified Laboratories, Plainview, NY).

National Food Processors Association. 2002. *Updated data for selected ready-to-eat retail foods*. (unpublished data.)

Ng, D.L.K. and H.L. Seah. 1995. Isolation and identification of *Listeria monocytogenes* from a range of foods in Singapore. *Food Control* 6:171-173.

Norton, D.M., M. McCamey, K.J. Boor, and M. Wiedmann. 2000. Application of the BAX for screening/genus *Listeria* polymerase chain reaction system for monitoring *Listeria* species in cold-smoked fish and in the smoked fish processing environment. *Journal of Food Protection* 63:343-346.

Norton, D.M., M.A. McCamey, K.L. Gall, J.M. Scarlett, K.J. Boor, and M. Wiedmann. 2001. Molecular studies on the ecology of *Listeria monocytogenes* in the smoked fish processing industry. *Applied and Environmental Microbiology* 67:198-205.

Nyati, H. 2000. Survival characteristics and the applicability of predictive mathematical modelling to *Listeria monocytogenes* growth in sous vide products. *International Journal of Food Microbiology* 56:123-132.

Ojeniyi, B., Christensen, and M. Bisgaard. 2000. Comparative investigations of *Listeria monocytogenes* isolated from a turkey processing plant, turkey products, and from human cases of listeriosis in Denmark. *Epidemiological Infection* 125:303-308.

Oregon Department of Agriculture. 2001. *Oregon department of agriculture laboratory services. Listeria results 1990 to current* (unpublished data).

Palumbo, S.A. and A.C. Williams. 1991. Resistance of *Listeria monocytogenes* to freezing in foods. *Food Microbiology* 8:63-68.

Pingulkar, K., A. Kamat, and D. Bongirwar. 2001. Microbiological quality of fresh leafy vegetables, salad components and ready-to-eat salads: An evidence of inhibition of *Listeria monocytogenes* in tomatoes. *International Journal of Food Science and Nutrition* 52:15-23.

Porto, E. and M.N.U. Eiroa. 2001. Occurrence of *Listeria monocytogenes* in vegetables. *Dairy, Food and Environmental Sanitation* 21:282-286.

Rosso, L., S. Bajard, J.P. Flandrois, C. Lahellec, J. Fournaud, and P. Veit. 1996. Differential growth of *Listeria monocytogenes* at 4 and 8 degrees Celsius: Consequences for the shelf life of chilled products. *Journal of Food Protection* 59:944-949.

Rudolf, M. and S. Scherer. 2001. High incidence of *Listeria monocytogenes* in European red smear cheese. *International Journal of Food Microbiology* 63:91-98.

Samelis, J. and J. Metaxopoulos. 1999. Incidence and principal sources of *Listeria* spp. and *Listeria monocytogenes* contamination in processed meats and a meat processing plant. *Food Microbiology* 16:465-477.

Scoglio, M.E., A.D. Pietro, A. Mauro, I. Picerno, P. Lagana, and S.A. Delia. 2000. Isolamento in prodotti ittici di *Listeria spp*., *Aeromonas* spp. E *Vibrio* spp. *Annali d' Igiene* 12:297-305.

Smith, M. A., K. Takeuchi, R. E. Brackett, H. M. McClure, R. B. Raybourne, K. Williams, M, U. S. Babu, G. O. Ware, J. R. Broderson, and M. P. Doyle. 2003. Nonhuman primate model for *Listeria monocytogenes*-induced stillbirths. *Infection and Immunity* 71:1574-1579.

Soriano, J.M., H. Rico, J.C. Moltó, and J. Mañes. 2001. *Listeria* species in raw and ready-to-eat foods from restaurants. *Journal of Food Protection* 64:551-553.

Szabo, E.A., K.J. Scurrah, and J.M. Burrows. 2000. Survey for psychrotrophic bacterial pathogens in minimally processed lettuce. *Letters in Applied Microbiology* 30:456-460.

Unilever. 2000. Industry data on contamination of final product and manufacturing environment by *Listeria monocytogenes*.

U.S. Department of Health and Human Services and United States Department of Agriculture (US DHHS/USDA). 2001. *Draft Assessment of Relative risk to pubic health from foodborne Listeria monocytogenes among selected categories of ready-to-eat foods*. Washington, D.C., FDA/USDA.

Varma, Jay. 2003. FoodNet *Listeria* case-control study (unpublished data from Centers for Disease Control and Prevention).

Vogel, B.F., H.H. Huss, B. Ojeniyi, P. Ahrens, and L. Gram. 2001. Elucidation of *Listeria monoctogenes* contamination routes in cold-smoked salmon processing plants detected by DNA-based typing methods. *Applied and Environmental Microbiology* 67:2586-2595.

Vogel, B.F., L.V. Jørgensen, B. Ojeniyi, H.H. Huss, and L. Gram. 2001. Diversity of *Listeria monocytogenes* isolates from cold-smoked salmon produced in different smokehouses as assessed by random amplified polymorphic DNA analyses. *International Journal of Food Microbiology* 65:83-92.

Warke, R., A. Kamat, M. Kamat, and P. Thomas. 2000. Incidence of pathogenic psychrotrophs in ice creams sold in some retail outlets in Mumbai, India. *Food Control* 11:77-83.

Whitley, E., D. Muir, and W.M. Waites. 2000. The growth of *Listeria monocytogenes* in cheese packed under a modified atmosphere. *Journal of Applied Microbiology* 88:52-57.

World Health Organization and Food Agriculture Organization of the United Nations. 2002. *Risk assessment of Listeria monocytogenes in ready-to-eat foods*. *Interpretative Summary*.

Yamazaki, K., T. Tateyama, Y. Kawai, and N. Inoue. 2000. Occurrence of *Listeria monocytogenes* in retail fish and processed seafood products in Japan. *Fisheries Science* 66:1191-1193.

REFERENCES

[These references were cited in the 2001 Draft *Listeria monocytogenes* risk assessment document and copies are available in the public docket. FDA Docket No 99N-1168: Food and Drug Administration, Dockets Management Branch (HFA-305), 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and in the FSIS Docket No 00-048N: FSIS Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250-3700.]

Anonymous, 1989. Le controle des residus dans les produits laitiers. *Bulletin d'Information du Ministere de l'Agriculture* 1273:22-24.

Anonymous, 1994. Meat inspection. Inspection requirements; adulteration and misbranding, *21 U.S. Code, Section 601*. Washington, D. C., U.S. Government Printing Office.

Anonymous, 1995. United States of America v Union Cheese Company, Pages 778-792, *902 Federal Supplement*, United States District Court, N. D. Ohio, Eastern Division.

Anonymous, 2000. Outbreak of *Listeria monocytogenes* serovar 4b infection in France. *Communicable Disease Report Weekly* 10:81, 84.

Ahrabi, S. S., S. Ergüven, and A. Günlap. 1997. Detection of *Listeria* in raw and pasteurized milk. *Central European Journal of Public Health* 6:254-255.

Alavi, S. H., V. M. Puri, S. J. Knabel, R. H. Mohtar, and R. C. Whiting. 1999. Development and validation of a dynamic growth model for *Listeria monocytogenes* in fluid whole milk. *Journal of Food Protection* 62:170-176.

Allerberger, F. and J. P. Guggenbichler. 1989. Listeriosis in Austria: Report of an outbreak in 1986. *Acta Microbiologica Hungarica* 36:149-152.

Anderson, G., Contra Costa County Health Department, San Francisco Department of Public Health, L. Mascola, G. W. Rutherford, M. S. Rados, R. Hutchenson, P. Archer, P. Zenker, C. Harvey, J. D. Smith, and Centers for Disease Control and Prevention. 1992. Update: Foodborne listeriosis -- United States, 1988-90, Pages 251, 257-258, *Morbidity and Mortality Weekly Report*.

Anderson, J. K. and B. Nørrung. 1995. Occurrence of *Listeria monocytogenes* in Danish retail foods. Annex II: Danish Government Comments, Pages 241-244 *Codex Alimentarius CL 1995/32-FH. Control of Listeria monocytogenes in foods. Proceedings of the XII International Symposium on Problems of Listeriosis*. Perth, Australia, Promaco Conventions Pty Ltd.

Andre, P., H. Roose, R. van Noyen, L. Dejaegher, I. Uyttendaele, and K. de Schrijver. 1990. Neuro-meningeal listeriosis associated with consumption of an ice cream. *Médecine et Maladies Infectieuses* 20:570-572.

Arias, M. L., R. Monge, F. Antillón, and E. Glenn. 1994. Occurance of the bacteria *Listeria* species in raw milk in Costa Rica. *Revista De Biologia Tropical* 42:711-713.

Arnold, G. J. and J. Coble. 1995. Incidence of *Listeria* species in foods in NSW. *Food Australia* 47:71-75.

Art, D. and P. André. 1991. Clinical and epidemiological aspects of listeriosis in Belgium, 1985-1990. *Zentralblatt fur Bakteriologie* 275:549-556.

Arumugaswamy, R. K., G. R. R. Ali, and S. N. B. A. Hamid. 1994. Prevalence of *Listeria monocytogenes* in food in Malaysia. *International Journal of Food Microbiology* 23:117-121.

Audits International 1999. *U.S. cold temperature evaluation (unpublished data)*.

Audurier, A., P. Pardon, J. Marly, and F. Lantier. 1980. Experimental infection of mice with *Listeria monocytogenes* and *L. innocua*. *Annales de Microbiologie (Institut Pasteur)* 131:47-57.

Aureli, P., G. C. Fiorucci, D. Caroli, G. Marchiaro, O. Novara, L. Leone, and S. Salmaso. 2000. An outbreak of febrile gastroenteritis associated with corn contaminated by *Listeria monocytogenes*. *New England Journal of Medicine* 342:1236-1241.

Azadian, B. S., G. T. Finnerty, and A. D. Pearson. 1989. Cheese-borne *Listeria* meningitis in immunocompetent patient. *Lancet* 333:322-323.

Bachmann, H. P. and U. Spahr. 1995. The fate of potentially pathogenic bacteria in Swiss hard and semihard cheeses made from raw milk. *Journal of Dairy Science* 78:476-483.

Back, J. P., S. A. Langford, and R. G. Kroll. 1993. Growth of *Listeria monocytogenes* in Camembert and other soft cheeses at refrigeration temperatures. *Journal of Dairy Research* 60:421-429.

Barnes, R., P. Archer, J. Strack, G. R. Istre, and Centers for Disease Control and Prevention. 1989. Epidemiologic notes and reports listeriosis associated with consumption of turkey franks. *Morbidity and Mortality Weekly Report* 38:267-268.

Beckers, H. J. 1988, The occurrence of *Listeria* in food. Foodborne Listeriosis:93-107.

Beckers, H. J., P. S. S. Soentoro, and E. H. M. Delfgou-van Asch. 1987. The occurrence of *Listeria monocytogenes* in soft cheeses and raw milk and its resistance to heat. *International Journal of Food Microbiology* 4:249-256.

Bemrah, N., M. Sanaa, M. H. Cassin, M. W. Griffiths, and O. Cerf. 1998. Quantitative risk assessment of human listeriosis from consumption of soft cheese made from raw milk. *Preventive Veterinary Medicine* 37:129-145.

Ben Embarek, P. K. 1994. Presence, detection, and growth of *Listeria monocytogenes* in seafoods: A review. *International Journal of Food Microbiology* 23:17-34.

Berrang, M. E., R. E. Brackett, and L. R. Beuchat. 1989. Growth of *Listeria monocytogenes* on fresh vegetables stored under controlled atmosphere. *Journal of Food Protection* 52:702-705.

Berrang, M. E., J. F. Frank, and R. E. Brackett. 1988. Behavior of *Listeria monocytogenes* in chocolate milk and ice cream mix made from post-expiration date skim milk. *Journal of Food Protection* 51:823.

Beuchat, L. R. and R. E. Brackett. 1990a. Inhibitory effects of raw carrots on *Listeria monocytogenes*. *Applied and Environmental Microbiology* 56:1734-1742.

Beuchat, L. R. and R. E. Brackett. 1990b. Survival and growth of *Listeria monocytogenes* on lettuce as influenced by shredding, chlorine treatment, modified atmosphere packaging and temperature. *Journal of Food Science* 55:755-758, 870.

Beuchat, L. R. and R. E. Brackett. 1991. Behavior of *Listeria monocytogenes* inoculated into raw tomatoes and processed tomato products. *Applied and Environmental Microbiology* 57:1367-1371.

Beuchat, L. R., R. E. Brackett, D. Y.-Y. Hao, and D. E. Connor. 1986. Growth and thermal inactivation of *Listeria monocytogenes* in cabbage and cabbage juice. *Canadian Journal of Microbiology* 32:791-795.

Beuchat, L. R. and J.-H. Ryu. 1997. Produce handling and processing practices. *Emerging Infectious Disease* 3:459-465.

Beumer, R. R., M. C. te Giffel, E. de Boer, and F. M. Rombouts. 1996. Growth of *Listeria monocytogenes* on sliced cooked meat products. *Food Microbiology* 13:333-340.

Bille, J. 1990. Epidemiology of human listeriosis in Europe, with special reference to the Swiss outbreak, Pages 71-74 *in* A. J. Miller, J. L. Smith, and G. A. Somkuti, eds. *Topics in Industrial Microbiology: Foodborne Listeriosis*, Society for Industrial Microbiology.

Boerlin, P., F. Boerlin-Petzold, E. Bannerman, J. Bille, and T. Jemmi. 1997. Typing *Listeria monocytogenes* isolates from fish products and human listeriosis cases. *Applied and Environmental Microbiology* 63:1338-1343.

Boerlin, P. and J.-C. Piffaretti. 1993. Typing of human, animal, food, and environmental isolates of *Listeria monocytogenes* by multilocus enzyme electrophoresis. *Applied and Environmental Microbiology* 57:1624-1629.

Bradshaw, J. G., J. T. Peeler, J. J. Corwin, J. M. Hunt, J. T. Tierney, E. P. Larkin, and R. M. Twedt. 1985. Thermal resistance of *Listeria monocytogenes* in milk. *Journal of Food Protection* 48:743-745.

Breer, C. 1986. The occurrence of *Listeria* species in cheese, Pages 230-233 *Proceedings of 2nd World Congress on Foodborne Infections and Intoxications*, Institute of Veterinary Medicine, Robert von Ostertag Institute Berlin.

Breer, C. 1988, Occurrence of Listeria species in different foods. WHO Working Group on Foodborne Listeriosis, Geneva, Feb. 15-19.

Breer, C. and K. Schopfer. 1989. *Listerien* in Nahrungsmitteln. *Schweizerische Medizinische Wochenschrift* 119:306-311.

Brett, M. S. Y., P. Short, and J. McLauchlin. 1998. A small outbreak of listeriosis associated with smoked mussels. *International Journal of Food Microbiology* 43:223-229.

Breuer, V. J. and O. Prändl. 1988. Nachweis von *Listerien* und deren vorkommen in hackfleisch und mettwürsten Österreich. *Archiv für Lebensmittelhygiene* 39:28-30.

Buazzi, M. M., M. E. Johnson, and E. H. Marth. 1992. Survival of *Listeria monocytogenes* during the manufacture and ripening of Swiss cheese. *Journal of Dairy Science* 75:380-386.

Buchanan, R. L. 2000. Changes made to the *Listeria monocytogenes* Risk Assessment (unpublished data). Washington, D.C.

Buchanan, R. L., W. G. Damert, R. C. Whiting, and M. van Schothorst. 1997. Use of epidemiologic and food survey data to estimate a purposefully conservative dose-response relationship for *Listeria monocytogenes* levels and incidence of listeriosis. *Journal of Food Protection* 60:918-922.

Buchanan, R. L. and L. A. Klawitter. 1992. Effectiveness of *Carnobacterium priscicola* LK5 for controlling the growth of *Listeria monocytogenes scott A* in refrigerated foods. *Journal of Food Safety* 12:219-236.

Buchanan, R. L., H. G. Stahl, M. M. Bencivengo, and F. del Corral. 1989. Comparison of lithium chloride-phenylethanol-moxalactam and modified Vogel Johnson agars for detection of *Listeria* species in retail-level meats, poultry, and seafood. *Applied and Environmental Microbiology* 55:599-603.

Buchholz, U. 2000. Los Angeles birth and population data from 1985-1999. Los Angeles Department of Health Services. Data includes perinatal listeriosis deaths per year and listeriosis deaths per year (unpublished data).

Büla, C. J., J. Bille, and M. P. Glauser. 1995. An epidemic of food-borne listeriosis in western Switzerland: Description of 57 cases involving adults. *Clinical Infectious Diseases* 20:66-72.

Buncic, S. 1991. The incidence of *Listeria monocytogenes* in slaughtered animals, in meat, and in meat products in Yugoslavia. *International Journal of Food Microbiology* 12:173-180.

Cantoni, C., C. Balzaretti, and M. Valenti. 1989. Episodio di *listeriosi* da consumo di insaccato (A case of *Listeria monocytogenes* human infection associated with consumption of "testa in cascetta" (cooked meat pork product)). *Archivio Veterinario Italiano* 40:141-142.

Cantoni, C., M. Valenti, and G. Comi. 1988. *Listeria* in formaggi e in salumi. *Industrie Alimentari* 27:859-861.

Carlin, F. and C. Nguyen-The. 1994. Fate of *Listeria monocytogenes* on four types of minimally processed green salads. *Letters in Applied Microbiology* 18:222-226.

Carlin, F., C. Nguyen-The, and C. E. Morris. 1996. Influence of background microflora on *Listeria monocytogenes* on minimally processed fresh broad-leaved endive (*Chichorium endivia var. latifolia*). *Journal of Food Protection* 59:698-703.

Carrington, C. D. 1996. Logical probability and risk assessment. *Human and Ecological Risk Assessment* 2:62-77.

Carter, M. 2000. Final report: Investigation of outbreak 99-372 (unpublished data). Baltimore, MD.

Casarotti, V. T., C. R. Gallo, and R. Camargo. 1994. Ocorrência de *Listeria monocytogenes* em leite cru, leite pasteurizado tipo C e queijo minas frescal commercializados em Piracicaba - S. P. *Archivos Latinoamericanos De Nutricion* 44:158-163.

Centers for Disease Control and Prevention 1998a. *1997 Annual Report. CDC/USDA/FDA Foodborne Diseases Active Surveillance Network. CDC's Emerging Infections Program (revised March 14, 2000).*

Centers for Disease Control and Prevention. 1998b. Multistate outbreak of listeriosis - United States, 1998. *Morbidity and Mortality Weekly Report* 47:1085-1086.

Centers for Disease Control and Prevention 1999a. *1998 Annual Report. CDC/USDA/FDA Foodborne Diseases. Active Surveillance Network. CDC's Emerging Infections Program*.

Centers for Disease Control and Prevention. 1999b. Update: Multistate outbreak of listeriosis - United States, 1998-1999. *Morbidity and Mortality Weekly Report* 47:1117-1118.

Centers for Disease Control and Prevention 2000. *FoodNet. Foodborne Diseases Active Surveillance Network. CDC's Emerging Infections Program. 1999 Surveillance Results. Preliminary Report*.

Cheers, C., and I. F. C. McKenzie. 1978. Resistance and susceptibility of mice to bacterial infection: Genetics of listeriosis. *Infection and Immunity* 19:755-762.

Chen, J. H. and J. H. Hotchkiss. 1993. Growth of *Listeria monocytogenes* and *Clostridium sporogenes* in cottage cheese in modified atmosphere packaging. *Journal of Dairy Science* 76:972-977.

Choi, H. K., M. M. Schaack, and E. H. Marth. 1988. Survival of *Listeria monocytogenes* in cultured buttermilk and yogurt. *Milchwissenschaft* 43:790-792.

Çíftçíoglu, G., M. T. Ûlgen, and K. Bostan. 1992. *Listeria monocytogenes*'in dondurmalardaki varligi üzerine bir arastirma (An investigation on the presence of *Listeria monocytogenes* in ice cream). *Veteriner-Fakultesi-Dergisi-Instanbul* 18:1-8.

Colburn, K. G., C. A. Kaysner, C. Abeyta, and M. M. Wekell. 1990. *Listeria* species in a California coast estuarine environment. *Applied and Environmental Microbiology* 56:2007-2011.

Coleman, M. and H. Marks. 1998. Topics and dose-response modeling. *Journal of Food Protection* 61:1550-1559.

Comi, G., C. Cantoni, and S. d'Aubert. 1987. Indagine sulla presenza di *Listeria monocytogenes* nei formaggi. *Industrie Alimentari* 26:216-218.

Comi, G., R. Frigerio, and C. Cantoni. 1992. *Listeria monocytogenes* serotypes in Italian meat products. *Letters in Applied Microbiology* 15:168-171.

Conlan, J. W. and R. J. North. 1992. Roles of *Listeria monocytogenes* virulence factors in survival: Virulence factors distinct from listeriolysin are needed for the organism to survive an early neutrophil-mediated host defense mechanism. *Infection and Immununity* 60:951-957.

Cook, L. V. 1998. Chapter 8. Isolation and identification of *Listeria monocytogenes* from red meat, poultry, egg and environmental samples, Pages 35 *Microbiology Laboratory Guidebook. 3rd ed.* Washington,D.C., U.S. Department of Agriculture, Food Safety and Inspection Service.

Cortesi, M. L., T. Sarli, A. Santoro, N. Murru, and T. Pepe. 1997. Distribution and behavior of *Listeria monocytogenes* in three lots of naturally-contaminated vacuum-packed smoked salmon stored at 2 and 10°C. *International Journal of Food Microbiology* 37:209-214.

Cottin, J., F. Picard-Bonnaud, and B. Carbonnelle. 1990. Study of *Listeria monocytogenes* survival during the preparation and the conservation of two kinds of dairy product. *Acta Microbiologica Hungarica* 37:119-122.

Cox, N. A., J. S. Bailey, and E. T. Ryser. 1999. Incidence and behavior of *Listeria monocytogenes* in poultry and egg products, Pages 565-600 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety*. New York, Marcel Dekker.

Curtin, S. C., J. C. Martin, and Centers for Disease Control and Prevention (CDC). 2000. Births: Preliminary data for 1999. *National Vital Statistics Reports* 48:1-21.

Czuprynski, C. J. and J. F. Brown. 1986. The relative difference in anti-*Listeria* resistance of C57BL/6 and A/J mice is not eliminated by active immunization or by transfer of *Listeria*-immune T cells. *Immunology* 58:437-443.

Czuprynski, C. J., C. Theisen, and J. F. Brown. 1996. Treatment with the antigranulocyte monoclonal antibody RB6-8C5 impairs resistance of mice to gastrointestinal infection with *Listeria monocytogenes*. *Infection and Immunity* 64:3946-3949.

Dalton, C. B., C. C. Austin, J. Sobel, P. S. Hayes, W. F. Bibb, L. M. Graves, B. Swaminathan, M. E. Proctor, and P. M. Griffin. 1997. An outbreak of gastroenteritis and fever due to *Listeria monocytogenes* in milk. *New England Journal of Medicine* 336:100-105.

Datta, A. R., B. A. Wentz, and W. E. Hill. 1988. Identification and enumeration of beta-hemolytic *Listeria monocytogenes* in naturally contaminated dairy products. *Journal of the Association of Official Analytical Chemists* 71:673-675.

Davidson, R. J., D. W. Sprung, C. E. Park, and M. K. Rayman. 1989. Occurence of *Listeria monocytogenes*, *Camplobacter* species and *Yersinia enterocolitica* in Manitoba raw milk. *Canadian Institute of Science and Technology Journal* 22:70-74.

de Boer, E. and D. Kuik. 1987. A survey of the microbiological quality of blue-veined cheeses. *Netherlands Milk and Dairy Journal* 41:227-237.

de Boer, E. and P. van Netten. 1990. The presence and growth of *Listeria monocytogenes* in paté. *Voedings Middelen Technol* 28:15-17.

de Simón, M. and M. D. Ferrer. 1998. Initial numbers, serovars, and phagevars of *Listeria monocytogenes* isolated in prepared foods in the city of Barcelona (Spain). *International Journal of Food Microbiology* 44:141-144.

de Simón, M., C. Tarragó, and M. D. Ferrer. 1992. Incidence of *Listeria monocytogenes* in fresh foods in Barcelona (Spain). *International Journal of Food Microbiology* 16:153-156.

Dean, J. P. and E. A. Zottola. 1996. Use of nisin in ice cream and effect on the survival of *Listeria monocytogenes*. *Journal of Food Protection* 59:476-480.

Decastelli, L., C. Ercolini, S. Fisichella, and C. Bianchi. 1993. Incidenza di *Listeria* species in mitili (Mytilus Galloprovincialis) di allevamento (Incidence of *Listeria* species in mussels from breeding). *Microbiologie Aliments Nutrition* 11:51-56.

Degnan, A. J., C. W. Kaspar, W. S. Otwell, M. L. Tamplin, and J. B. Luchansky. 1994. Evaluation of lactic acid bacterium fermentation products and food-grade chemicals to control *Listeria monocytogenes* in blue crab (Callinectes sapidus) meat. *Applied and Environmental Microbiology* 60:3198-3203.

del Corral, F., R. L. Buchanan, M. M. Bencivengo, and P. H. Cooke. 1990. Quantitative comparison of selected virulence associated characteristics in food and clinical isolates of *Listeria*. *Journal of Food Protection* 53:1003-1009.

Delgado da Silva, M. C., E. Hofer, and A. Tibana. 1998. Incidence of *Listeria monocytogenes* in cheese produced in Rio de Janeiro, Brazil. *Journal of Food Protection* 61:354-356.

Desmasures, N., F. Bazin, and M. Guéguen. 1997. Microbiological composition of raw milk from selected farms in the Camembert region of Normady. *Journal of Applied Microbiology* 83:53-58.

Di Lorenzo, G., C. R. Balistreri, G. Candore, D. Cigna, A. Colombo, G. C. Romano, A. T. Colucci, F. Gervasi, F. Listi, M. Potestio, and C. Caruso. 1999. Granulocyte and natural killer activity in the elderly. *Mechanisms of Aging and Development* 108:25-38.

Dillon, R. and T. Patel. 1993. Effect of cold smoking and storage temperatures on *Listeria monocytogenes* in inoculated cod fillets (Gadus morhus). *Food Research International* 26:97-101.

Dillon, R., T. Patel, and S. Ratnam. 1992. Prevalence of *Listeria* in smoked fish. *Journal of Food Protection* 55:866-870.

Dillon, R., T. Patel, and S. Ratnam. 1994. Occurrence of *Listeria* in hot and cold smoked seafood products. *International Journal of Food Microbiology* 22:73-77.

Dillon, R. M. and T. Patel. 1992. *Listeria* in seafoods: A review. *Journal of Food Protection* 55:1009-1015.

Dominguez Rodiguez, L., J. F. Fernandez Garayzbal, J. A. Vazquez Boland, E. Rodriguez Ferri, and G. Suarez Fernandez. 1985. Isolation de micro-organisms du genre *Listeria* á partir de lait cru destiné á la consommation humaine. *Canadian Journal of Microbiolgy* 31:938-941.

Donnelly, C. W., G. J. Baigent, and E. H. Briggs. 1988. Flow cytometry for automated analysis of milk containing *Listeria monocytogenes*. *Journal of Association Official Analytical Chemists* 71:655-658.

Dorozynski, A. 2000. Seven die in French listeria outbreak. *British Medical Journal* 320:601.

Doyle, M. P. and J. L. Schoeni. 1986. Selective-enrichment procedure for isolation of *Listeria monocytogenes* from fecal and biologic specimens. *Applied and Environmental Microbiology* 51:1127-1129.

Draughon, F. A., B. A. Anthony, and M. E. Denton. 1999. *Listeria* species in fresh rainbow trout purchased from retail markets. *Dairy, Food and Environmental Sanitation* 19:90-94.

Duffes, F., C. Corre, F. Leroi, X. Dousset, and P. Boyaval. 1999. Inhibition of *Listeria monocytogenes* by in situ produced and semipurified bacteriocins of *Carnobacterium* spp. on vacuum-packed, refrigerated cold-smoked salmon. *Journal of Food Protection* 62:1394-1403.

Duh, Y.-H. and D. W. Schaffner. 1993. Modeling the effect of temperature on the growth rate and lag time of *Listeria innocua* and *Listeria monocytogenes*. *Journal of Food Protection* 56:205-210.

Eklund, M. W., F. T. Poysky, R. N. Paranjpye, L. C. Lashbrook, M. E. Peterson, and G. A. Pelroy. 1995. Incidence and sources of *Listeria monocytogenes* in cold-smoked fishery products and processing plants. *Journal of Food Protection* 58:502-508.

El Marrakchi, A., A. Hamama, and F. el Othmani. 1993. Occurence of *Listeria monocytogenes* in milk and dairy products produced or imported into Morocco. *Journal of Food Protection* 56:256-259.

El-Leboudy, A. A., and M. A. Fayed. 1992. Incidence of *Listeria* in raw milk. *Assuit Veterinary Medical Journal* 27:134-146.

El-Shenawy, M. A. and M. A. El-Shenawy. 1995. Incidence of *Listeria monocytogenes* in seafood enhanced by prolonged cold enrichment. *Journal of the Medical Research Institute* 16:32-40.

El-Shenawy, M. A. and E. H. Marth. 1990. Behavior of *Listeria monocytogenes* in presence of gluconic acid and during preparation of cottage cheese curd using gluconic acid. *Journal of Dairy Science* 73:1429-1438.

Ericsson, H., A. Eklöw, M.-L. Danielson-Tham, S. Loncarevic, L.-O. Mentzing, I. Persson, H. Unnerstad, and W. Tham. 1997. An outbreak of listeriosis suspected to have been caused by rainbow trout. *Journal of Clinical Microbiolgy* 35:2904-2907.

Evans, J. S., J. D. Graham, G. M. Gray, and R. L. Sielken, Jr. 1994. A distributional approach to characterizing low-dose cancer risk. *Risk Analysis* 14:25-34.

Farber, J. M. 1991a. *Listeria monocytogenes*. *Journal of the Association of Official Analytical Chemists* 74:701-704.

Farber, J. M. 1991b. *Listeria monocytogenes* in fish products. *Journal of Food Protection* 54:922-924, 934.

Farber, J. M. 1997. A small outbreak of listeriosis linked to consumption of imitation crab meat. *Journal of Food Protection* 60, Supplement B:38.

Farber, J. M., E. Daley, F. Coates, N. Beausoleil, and J. Fournier. 1991. Feeding trials of *Listeria monocytogenes* with a nonhuman primate model. *Journal of Clinical Microbiology* 29:2606-2608.

Farber, J. M., E. M. Daley, M. T. Mackie, and B. Limerick. 2000. A small outbreak of listeriosis potentially linked to the consumption of imitation crab meat. *Letters in Applied Microbiology* 31:100-104.

Farber, J. M., J.-Y. D'Aoust, M. Diotte, A. Sewell, and E. Daley. 1998a. Survival of *Listeria* species on raw whole chickens cooked in microwave ovens. *Journal of Food Protection* 61:1465-1469.

Farber, J. M., M. A. Johnston, U. Purvis, and A. Loit. 1987. Surveillance of soft and semi-soft cheeses for the presence of *Listeria* species. *International Journal of Food Microbiology* 5:157-163.

Farber, J. M. and J. Z. Losos. 1988. *Listeria monocytogenes*: A foodborne pathogen. *Canadian Medical Association Journal* 138:413-418.

Farber, J. M., R. C. McKellar, and W. H. Ross. 1995. Modelling the effects of various parameters on the growth of *Listeria monocytogenes* on liver pâté. *Food Microbiology* 12:447-453.

Farber, J. M. and P. I. Peterkin. 1991. *Listeria monocytogenes*: A food-borne pathogen. *Microbiological Reviews* 55:476-511.

Farber, J. M. and P. I. Peterkin. 1999. Incidence and behavior of *Listeria monocytogenes* in meat products, Pages 505-5642 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety*. New York, Marcel Dekker, Inc.

Farber, J. M., W. H. Ross, and J. Harwig. 1996. Health risk assessment of *Listeria monocytogenes* in Canada. *International Journal of Food Microbiology* 30:145-156.

Farber, J. M., G. W. Sanders, and M. A. Johnston. 1989. A survey of various foods for the presence of *Listeria* species. *Journal of Food Protection* 52:456-458.

Farber, J. M., G. W. Sanders, and S. A. Malcolm. 1988. The presence of *Listeria* species in raw milk in Ontario. *Canadian Journal of Microbiolgy* 34:95-100.

Farber, J. M., G. W. Sanders, and J. I. Speirs. 1990. Growth of *Listeria monocytogenes* in naturally contaminated raw milk. *Lebensmittel Wissenschaft und Technologie* 23:252-254.

Farber, J. M., S. L. Wang, Y. Cai, and S. Zhang. 1998b. Changes in populations of *Listeria monocytogenes* inoculated on packaged fresh-cut vegetables. *Journal of Food Protection* 61:192-195.

Farkas, G., S. Szakály, and B. Ralovich. 1988, Occurence of *Listeria* strains in a Hungarian dairy plant. Round Table Discussion on Methods of Isolation and Characterization of *Listeria*. Program Abstracts:107.

Farrag, S. A., F. E. El-Gazzar, and E. H. Marth. 1990. Fate of *Listeria monocytogenes* in sweetened condensed and evaporated milk during storage at 7 or 21°C. *Journal of Food Protection* 53:747-750.

Fedio, W. M. and H. Jackson. 1990. Incidence of *Listeria monocytogenes* in raw bulk milk in Alberta. *Canadian Institute of Food Science and Technology Journal* 23:236-238.

Fedio, W. M., A. Macleod, and L. Ozimek. 1994. The effect of modified atmosphere packaging on the growth of microorganisms in cottage cheese. *Milchwissenschaft* 49:622-628.

Feldman, M., B. Cryer, D. Sammer, E. Lee, and S. J. Spechler. 1999. Influence of *H. pylori* infection on meal-stimulated gastric acid secretion and gastroesophageal acid reflux. *AJP- Gastrointestional and Liver Physiology* 277:G1159-G1164.

Fenlon, D. R., T. Stewart, and W. Donachie. 1995. The incidence, numbers and types of *Listeria monocytogenes* isolated from farm bulk tank milks. *Letters in Applied Microbiology* 20:57-60.

Fenlon, D. R. and J. Wilson. 1989. The incidence of *Listeria monocytogenes* in raw milk from farm bulk tanks in North-East Scotland. *Journal of Applied Bacteriology* 66:191-196.

Fenlon, D. R., J. Wilson, and W. Donachie. 1996. The incidence and level of *Listeria monocytogenes* contamination of food sources at primary production and initial processing. *Journal of Applied Bacteriology* 81:641-650.

Fernandes, C. F., G. J. Flick, and T. B. Thomas. 1998. Growth of inoculated psychrotrophic pathogens on refrigerated fillets of aquacultured rainbow trout and channel catfish. *Journal of Food Protection* 61:313-317.

Fernández Garayzábal, J. F., L. Domínguez Rodríguez, J. A. Vázquez Boland, L. Blanco Cancelo, and G. Suárez Fernández. 1986. *Listeria monocytogenes* dans le lait pasteurise. *Canadian Journal of Microbiolgy* 32:149-150.

Fernandez Garayzbal, J. F., L. Dominguez, J. A. Vazquez, E. Gomez-Lucia, E. R. Rodriguez Ferri, and G. Suarez. 1987. Occurence of *Listeria monocytogenes* in raw milk. *The Veterinary Record* 120:258-259.

Ferrer, M. D. and M. de Simón. 1993. Aislamiento de *Salmonella* species, *Vibrio parahaemolyticus*, *Yersinia enterocolitia* y *Listeria monocytogenes* en moluscos bivalvos. *Alimentaria* 30:33-35.

Fleming, D. W., S. L. Cochi, K. L. MacDonald, J. Brondum, P. S. Hayes, B. D. Plikaytis, M. B. Holmes, A. Audurier, C. V. Broome, and A. L. Reingold. 1985. Pasteurized milk as a vehicle of infection in an outbreak of listeriosis. *New England Journal of Medicine* 312:404-407.

Frye, C. and International Dairy Foods Association. 2000a. Diary,eggs,honey, etc. - U.S. general imports from world. January - December 1999.

Frye, C. and International Dairy Foods Association. 2000b. Final results for June 26 - July 8, 2000 - *Listeria monocytogenes* in pasteurized milk (unpublished data).

Fuchs, R. S. and P. J. A. Reilly. 1992. The incidence and significance of *Listeria monocytogenes* in seafoods, Pages 217-229 *in* H. H. Huss, M. Jakobsen, and J. Liston, eds. *Quality Assurance in the Fish Industry*. Amsterdam, Elsevier Science Publishers.

Fuchs, R. S. and S. Sirvas. 1991. Incidence of *Listeria monocytogenes* in an acidified fish product, cerviche. *Letters in Applied Microbiology* 12:88-90.

Fuchs, R. S. and P. K. Surendran. 1989. Incidence of *Listeria* in tropical fish and fishery products. *Letters in Applied Microbiology* 9:49-51.

García-Gimeno, R. M., G. Zurera-Cosano, and M. Amaro-López. 1996. Incidence, survival and growth of *Listeria monocytogenes* in ready-to-use mixed vegetable salads in Spain. *Journal of Food Safety* 16:75-86.

Garland, C. D. 1995. Microbiological quality of aquaculture products with special reference to *Listeria monocytogenes* in Atlantic salmon. *Food Australia* 47:559-563.

Gellin, B. G. and C. V. Broome. 1989. Listeriosis. *Journal of the American Medical Association* 261:1313-1320.

Gelosa, L. 1990. La *Listeria monocytogenes* quale contaminante di prodotti lattiero-caseari. *Industrie Alimentari XXIX* 29:137-139.

Genigeorgis, C., M. Carniciu, D. Dutulescu, and T. B. Farver. 1991. Growth and survival of *Listeria monocytogenes* in market cheeses stored at 4 to 30° C. *Journal of Food Protection* 54:662-668.

Genovese, F., G. Mancuso, M. Cuzzola, C. Biondo, C. Beninati, D. Delfino, and G. Teti. 1999. Role of IL-10 in a neonatal mouse listeriosis model. *Journal of Immunology* 163:2777-2782.

George, A. E. and P. N. Levett. 1990. Effect of temperature and pH on survival of *Listeria monocytogenes* in coleslaw. *International Journal of Food Microbiology* 11:345-349.

Gilbert, R. J., S. M. Hall, and A. G. Taylor. 1989. Listeriosis update. *Public Health Laboratory Service Microbiology Digest* 6:33-37.

Gilbert, R. J., J. McLauchlin, and S. K. Velani. 1993. The contamination of paté by *Listeria monocytogenes* in England and Wales in 1989 and 1990. *Epidemiology and Infection* 110:543-551.

Gillespie, I., C. Little, and R. Mitchell. 2000. Microbilogical examination of cold ready-to-eat sliced meats from catering establishments in the United Kingdom. *Journal of Applied Bacteriology* 88:467-474.

Gilot, P., C. Hermans, M. Yde, J. Gigi, M. Janssens, A. Genicot, P. André, and G. Wauters. 1997. Sporadic case of listeriosis associated with the consumption of a *Listeria monocytogenes*-contaminated 'Camembert' cheese. *Journal of Infection* 35:195-197.

Glass, K. A., B. Bhanu Prasad, J. H. Schyter, H. E. Uljas, N. Y. Farkye, and J. B. Luchansky. 1995. Effects of acid type and alta^{tm}2341 on *Listeria monocytogenes* in a queso blanco type of cheese. *Journal of Food Protection* 58:737-741.

Glass, K. A. and M. P. Doyle. 1989. Fate of *Listeria monocytogenes* in processed meat products during refrigerated storage. *Applied and Environmental Microbiology* 55:1565-1569.

Glass, K. A., K. M. Kaufman, and E. A. Johnson. 1998. Survival of bacterial pathogens in pasteurized process cheese slices stored at 30°C. *Journal of Food Protection* 61:290-294.

Gledel, J. 1986. Epidemiology and significance of Listeriosis in France, Pages 9-20 *in* A. Schonbelg, ed. *Listeriosis- Joint WHO/ROI Consultation on Prevention and Control*. West Berlin, Institut fur Veterinamedzin des Bundegesundheitamtes.

Gledel, J. 1988, *Listeria* and the dairy industry in France. Foodborne Listeriosis. Proceedings of a Symposium on September 7, 1988:81-92.

Gohil, V. S., M. A. Ahmed, R. Davies, and R. K. Robinson. 1995. Incidence of *Listeria species* in retail foods in the United Arab Emirates. *Journal of Food Protection* 58:102-104.

Golnazarian, C. A., C. W. Donnelly, S. J. Pintauro, and D. B. Howard. 1989. Comparison of infectious dose of *Listeria monocytogenes* F5817 as determined for normal versus compromised C57B1/6J mice. *Journal of Food Protection* 52:696-701.

Gouet, P., J. Labadie, and C. Serratore. 1978. Development of *Listeria monocytogenes* in monoxenic and polyxenic beef minces. *Zentralblatt fur Bakteriologie Hygiene* 166:87-94.

Goulet, V., C. Jacquet, V. Vaillant, I. Rebiere, E. Mouret, C. Lorente, E. Maillot, F. Stainer, and J. Rocourt. 1995. Listeriosis from consumption of raw-milk cheese. *Lancet* 345:1581-1582.

Goulet, V., J. Rocourt, I. Rebiere, C. Jacquet, C. Moyse, P. Dehaumont, G. Salvat, and P. Veit. 1998. Listeriosis outbreak associated with the consumption of rillettes in France in 1993. *Journal of Infectious Disease* 177:155-160.

Grant, L. R., C. R. Nixon, and M. F. Patterson. 1993. Comparison of the growth of *Listeria monocytogenes* in unirradiated and irradiated cook-chill roast beef and gravy at refrigeration temperatures. *Letters in Applied Microbiology* 17:55-57.

Grau, F. H. and P. B. Vanderlinde. 1992. Occurrence, numbers, and growth of *Listeria monocytogenes* on some vacuum-packaged processed meats. *Journal of Food Protection* 55:4-7.

Gravani, R. 1999. Incidence and control of *Listeria* in food-processing facilities, Pages 657-709 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety*. New York, Marcel Dekker, Inc.

Graves, L. M., B. Swaminathan, and S. B. Hunter. 1999. Subtyping *Listeria monocytogenes*, Pages 279-297 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety. Food Science and Technology*. New York, Marcel Dekker, Inc.

Greenaway, C. and P. G. Drew. 1990. Survey of dairy products in Victoria, Australia for *Listeria* species, Pages 129 *in* Organizing Committee of the XXIII International Dairy Congress, ed. *Posters and Brief. Communications of the XXIII International Dairy Congress. Dairying in a Changing World.* Montréal.

Greenwood, M. H., D. Roberts, and P. Burden. 1991. The occurrence of *Listeria* species in milk and dairy products: A national survey in England and Wales. *International Journal of Food Microbiology* 12:197-206.

Guyer, S. and T. Jemmi. 1990. Betriebsuntersuchungen zum vorkommen von *Listeria monocytogenes* in geräuchertem lachs. *Archiv für Lebensmittethygiene* 41:144-146.

Guyer, S. and T. Jemmi. 1991. Behavior of *Listeria monocytogenes* during fabrication and storage of experimentally contaminated smoked salmon. *Applied and Environmental Microbiology* 57:1523-1527.

Haas, C. N., A. Thayyar-Madabusi, J. B. Rose, and C. P. Gerba. 1999. Development and validation of dose-response relationship for *Listeria monocytogenes*. *Quantitative Microbiology* 1:89-102.

Harrison, M. A., Y.-W. Huang, C.-H. Chao, and T. Shineman. 1991. Fate of *Listeria monocytogenes* on packaged, refrigerated and frozen seafood. *Journal of Food Protection* 54:524-527.

Hartemink, R. and F. Georgsson. 1991. Incidence of *Listeria* species in seafood and seafood salads. *International Journal of Food Microbiology* 12:189-195.

Harvey, J. and A. Gilmour. 1992. Occurrence of *Listeria* species in raw milk and dairy products produced in Northern Ireland. *Journal of Applied Bacteriology* 72:119-125.

Harvey, J. and A. Gilmour. 1993. Occurrence and characteristics of *Listeria* in foods produced in Northern Ireland. *International Journal of Food Microbiology* 19:193-205.

Havell, E. A., L. L. Moldawer, D. Helfgott, P. L. Kilian, and P. B. Sehgal. 1992. Type I IL-1 receptor blockade exacerbates murine listeriosis. *Journal of Immunology* 148:1486-1492.

Hayes, P. S., J. C. Feeley, L. M. Graves, G. W. Ajello, and D. W. Fleming. 1986. Isolation of *Listeria monocytogenes* from raw milk. *Applied and Environmental Microbiology* 51:438-450.

Hayes, P. S., L. M. Graves, G. W. Ajello, B. Swaminathan, R. E. Weaver, J. D. Wenger, A. Schuchat, C. V. Broome, and Listeria Study Group. 1991. Comparison of cold enrichment and U.S. Department of Agriculture methods for isolating *Listeria monocytogenes* from naturally contaminated foods. *Applied and Environmental Microbiology* 57:2109-2113.

Hayes, P. S., L. M. Graves, B. Swaminathan, G. W. Ajello, G. B. Malcolm, R. E. Weaver, R. Ransom, K. Deaver, B. D. Plikaytis, A. Schuchat, J. D. Wenger, R. W. Pinner, C. V. Broome, and t. L. S. Group. 1992. Comparison of three selective enrichment methods for the isolation of *Listeria monocytogenes* from naturally contaminated foods. *Journal of Food Protection* 55:952-959.

Headrick, M. L., S. Korangy, N. H. Bean, F. J. Angulo, S. F. Altekruse, M. E. Potter, and K. C. Klontz. 1998. The epidemiology of raw milk-associated foodborne disease outbreaks reported in the United States, 1973 through 1992. *American Journal of Public Health* 88:1219-1221.

Health Canada. 1994. Field Compliance Guide: Ready-to-eat (RTE) Foods Contaminated with *Listeria monocytogenes* (Canada), Pages 1-20.

Heinitz, M. 1999. *Incidence of Listeria monocytogenes in food samples collected by FDA from 1990-1998 (unpublished data from Microbial Information System)*. U.S. Food and Drug Administration.

Heinitz, M. L. and J. M. Johnson. 1998. The incidence of *Listeria* species, *Salmonella* species and *Clostridium botulinum* in smoked fish and shellfish. *Journal of Food Protection* 61:318-323.

Heisick, J. E., D. E. Wagner, M. L. Nierman, and J. T. Peeler. 1989. *Listeria* species found on fresh market produce. *Applied and Environmental Microbiology* 55:1925-1927.

Heitmann, M., P. Gerner-Smidt, and O. Heltberg. 1997. Gastroenteritis caused by *Listeria monocytogenes* in a private day-care facility. *The Pediatric Infectious Disease Journal* 16: 827-828.

Hitchins, A. D. 1996. Assessment of alimentary exposure to *Listeria monocytogenes*. *International Journal of Food Microbiology* 30:71-85.

Hitchins, T. 1995, The epidemiological significance of the mean alimentary exposure to *Listeria monocytogenes* inferred from its foodborne occurrence and from food consumption data. Proceedings of the XII International Symposium on Problems of Listeriosis:357-363.

Ho, J. L., K. N. Shands, G. Friedland, P. Eckind, and D. W. Fraser. 1986. An outbreak of type 4b *Listeria monocytogenes* infection involving patients from eight Boston hospitals. *Archives of Internal Medicine* 146:520-524.

Hofer, E. and R. Ribeiro. 1990. Ocorrência de espécies de *Listeria* em camarão industrializado. *Revista de Microbiologia* 21:207-208.

Houang, E. and R. Hurley. 1991. Isolation of *Listeria* species from precooked chilled foods. *Journal of Hospital Infection* 19:231-238.

Huang, S., W. Hendriks, A. Althage, S. Hemmi, H. Bluethmann, R. Kamijo, J. Vicek, R. M. Zinkernagel, and M. Aguet. 1993. Immune response in mice that lack the interferon-γ receptor. *Science* 259:1742-1745.

Hudson, J. A. and S. J. Mott. 1993a. Growth of *Listeria monocytogenes*, *Aeromonas hydrophila* and *Yersinia enterocolitica* in pâté and a comparison with predictive models. *International Journal of Food Microbiology* 20:1-11.

Hudson, J. A. and S. J. Mott. 1993b. Growth of *Listeria monocytogenes*, *Aeromonas hydrophila* and *Yersinia enterocolitica* on cold-smoked salmon under refrigeration and mild temperature abuse. *Food Microbiology* 10:61-68.

Hudson, J. A., S. J. Mott, K. M. Delacy, and A. L. Edridge. 1992. Incidence and coincidence of *Listeria* species, motile aeromonads and *Yersinia enterocolitica* on ready-to-eat fleshfoods. *International Journal of Food Microbiology* 16:99-108.

Ibrahim, G. A. M., H. Domján-Kovács, A. Fábián, and B. Ralovich. 1992, *Listeria* in milk and dairy products in Hungary. *Listeria* 1992. The Eleventh International Symposium on Problems of Listeriosis. 11:297-298.

Iida, T., M. Kanzaki, A. Nakama, Y. Kokubo, T. Maruyama, and C. Kaneuchi. 1998. Detection of *Listeria monocytogenes* in humans, animals and foods. *Journal of Veterinary Medical Science* 60:1341-1343.

Ingham, S. C. and C. L. Tautorus. 1991. Survival of *Salmonella* Typhimurium, *Listeria monocytogenes* and indicator bacteria on cooked uncured turkey loaf stored under vacuum at 3°C. *Journal of Food Safety* 11:285-292.

International Commission on Microbiological Specifications for Foods (ICMSF). 1994. Choice of sampling plan and criteria for *Listeria monocytogenes*. *International Journal of Food Microbiology* 22:89-96.

International Dairy Foods Association. 1999. Prevalence of *Listeria monocytogenes*. International Ice Cream Association summarized historical data 1993-1998. Washington, D.C.

Jackson, T. C., M. D. Hardin, and G. R. Acuff. 1996. Heat resistance of *Escherichia coli* O157:H7 in a nutrient medium and in ground beef patties as influenced by storage and holding temperatures. *Journal of Food Protection* 59:230-237.

Jacquet, C., B. Catimel, R. Brosch, C. Buchrieser, P. Dehaumont, V. Goulet, A. Lepoutre, P. Veit, and J. Rocourt. 1995. Investigations related to the epidemic strain involved in the French listeriosis outbreak in 1992. *Applied and Environmental Microbiology* 61:2242-2246.

Jemmi, T., S. Guyer, and A. Keusch. 1992, Frequency, behavior and epidemiology of *Listeria monocytogenes* in smoked fishes. Listeria 1992. The Eleventh International Symposium on Problems of Listeriosis XI:301-302.

Jemmi, T. and A. Keusch. 1992. Behavior of *Listeria monocytogenes* during processing and storage of experimentally contaminated hot-smoked trout. *International Journal of Food Microbiology* 15:339-346.

Jemmi, V. T. 1990. Zum vorkommen von *Listeria monocytogenes* in importierten geräucherten and fermentierten fischen (Occurrence of *Listeria monocytogenes* in imported smoked and fermented fish). *Archiv für Lebensmittelhgiene* 41:107-109.

Jensen, A., W. Frederiksen, and P. Gerner-Smidt. 1994. Risk factors for listeriosis in Denmark, 1989-1990. *Scandinavian Journal of Infectious Diseases* 26:171-178.

Jeyasekaran, G., I. Karunasagar, and I. Karunasagar. 1996. Incidence of *Listeria* species in tropical fish. *International Journal of Food Microbiology* 31:333-340.

Jinneman, K. C., M. M. Wekell, and M. W. Eklund. 1999. Incidence and behavior of *Listeria monocytogenes* in fish and seafood, Pages 601-629 *in* E. T. Ryser and E. H. Marth, eds. *Food Science and Technology: Listeria, Listeriosis and Food Safety*. New York, Marcel Dekker, Inc.

Johnson, E. A., J. H. Nelson, and M. Johnson. 1990a. Microbiological safety of cheese made from heat-treated milk: Part I. Executive summary, introduction and history. *Journal of Food Protection* 53:441-452.

Johnson, E. A., J. H. Nelson, and M. Johnson. 1990b. Microbiological safety of cheese made from heat-treated milk, Part ll. Microbiology. *Journal of Food Protection* 53:519-540.

Johnson, E. A., J. H. Nelson, and M. Johnson. 1990c. Microbiological safety of cheese made from heat-treated milk: Part lll. Technology, discussion, recommendations, bibliography. *Journal of Food Protection* 53:610-623.

Johnson, J. L., M. P. Doyle, and R. G. Cassens. 1988. Survival of *Listeria monocytogenes* in ground beef. *International Journal of Food Microbiology* 6:243-247.

Joint Food and Agriculture Organization/World Health Organization Expert Consultation (Joint FAO/WHO) 1995. *Application of Risk Analysis to Food Standards Issues. Report of the Joint FAO/WHO Expert Consultation*. World Health Organization and Food and Agriculture Organization.

Jørgensen, L. V. and H. H. Huss. 1998. Prevalence and growth of *Listeria monocytogenes* in naturally contaminated seafood. *International Journal of Food Microbiology* 42:127-131.

Juneja, V. K., O. P. Snyder, Jr., A. C. Williams, and B. S. Marmer. 1997. Thermal destruction of *Escherichia coli* O157:H7 in hamburger. *Journal of Food Protection* 60:1163-1166.

Juntilla, J. and M. Brander. 1989. *Listeria monocytogenes* septicemia associated with consumption of salted mushrooms. *Scandinavian Journal of Infectious Disease* 21:339-342.

Karches, H. and P. Teufel. 1988. *Listeria monocytogenes* vorkommen in hackfleisch und vehalten in frischer zwiebelmettwurst. *Fleischwirtschaft* 68:1388-1392.

Karunasagar, I., K. Segar, K. I., and W. Goebel. 1992, Incidence of *Listeria* species in tropical seafoods. *Listeria* 1992. The Eleventh International Symposium on Problems of Listeriosis:306.

Kaufmann, U. 1990. Comportement de *Listeria monocytogenes* pendant la fabrication de fromages á pâte dure. *Revue suisse agriculture* 22:5-9.

Kaya, M. and U. Schmidt. 1989. Verhalten von *Listeria monocytogenes* in hackfleisch bei kühl- und gefrierlagersung. *Fleischwirtschaft* 69:617-620.

Kaysner, C., K. G. Colburn, C. Abeyta, and M. M. Wekell. 1990. Survival of *Listeria monocytogenes* in shellstock and shucked oysters, *Crassostrea gigas*, stored at 4ºC. *Annual Meeting. American Society Microbiology, Anaheim, CA May 13-17, Abstr*:P-52.

Kleinlein, N., F. Untermann, and H. Beissner. 1989. Zum vorkommen von *Salmonella* und *Yersinia*-spezies sowie *Listeria monocytogenes* in hackfleisch. *Fleischwirtschaft* 69:1274-1476.

Kocks, C., E. Gouin, M. Tabouret, P. Berche, H. Ohayon, and P. Cossart. 1992. *Listeria monocytogenes*-induced actin assembly requires the actA gene product, a surface protein. *Cell* 68:521-531.

Kovincic, I., I. F. Vujicic, M. Svabic-Vlahovic, M. Vulic, M. Gagic, and I. V. Wesley. 1991. Survival of *Listeria monocytogenes* during manufacture and ripening of Trappist cheese. *Journal of Food Protection* 54:418-420.

Kozak, J., T. Balmer, R. Byrne, and K. Fisher. 1996. Prevalence of *Listeria monocytogenes* in foods: Incidence in dairy products. *Food Control* 7:215-221.

Kuhn, M. and W. Goebel. 1999. Pathogenesis of *Listeria monocytogenes*, Pages 97-130 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis, and Food Safety. Food Science and Technology*. New York, Marcel Dekker, Inc.

Laciar, A. L., L. Vaca, and O. N. P. de Centorbi. 1999. *Listeria* species en alimentos de origen animal. *Revista Argentina de Microbiologia* 31:25-30.

Lahellec, C., G. Salvat, and A. Brisabois. 1996. Incidence des *Listeria* dans les denrées alimentaires. *Pathologie Biologie* 44:808-815.

Le Guillox, M., C. Dollinger, and G. Freyburger. 1980. *Listeria monocytogenes*. *Bulletin Mensuel de la Societe Veterinaire Pratique de France* 64:45-46, 48, 50, 52-53.

Le Souëf, P. N. and B. N. EWalters. 1981. Neonatal listeriosis. A summer outbreak. *Medical Journal of Australia* 2:188-191.

Lebrun, M., J. Mengaud, H. Ohayon, F. Nato, and P. Cossart. 1996. Internalin must be on the bacterial surface to mediate entry of *Listeria monocytogenes* into epithelial cells. *Molecular Microbiology* 21:579-592.

Lennon, D., B. Lewis, C. Mantell, D. Becroft, B. Dove, K. Farmer, S. Tonkin, N. Yates, R. Stamp, and K. Mickleson. 1984. Epidemic perinatal listeriosis. *Pediatric Infectious Disease* 3:30-34.

Leung, C.-K., Y.-W. Huang, and M. A. Harrison. 1992. Fate of *Listeria monocytogenes* and *Aeromonas hydrophila* on packaged channel catfish fillets stored at 4ºC. *Journal of Food Protection* 55:728-730.

Levine, P. 2000. USDA -FSIS microbiological monitoring RTE results 1994-1998 (unpublished data).

Lewis, D. B., A. Larsen, and C. B. Wilson. 1986. Reduced interferon-gamma mRNA levels in human neonates. *Journal of Experimental Medicine* 163:1018-1023.

Liewen, M. B. and M. W. Plautz. 1988. Occurence of *Listeria monocytogenes* in raw milk in Nebraska. *Journal of Food Protection* 51:840-841.

Lin, C.-M., S. Y. Fernando, and C. Wei. 1996. Occurrence of *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* and *E. coli* O157:H7 in vegetable salads. *Food Control* 7:135-140.

Lindqvest, R. and A. Westöö. 2000. Quantative risk assessment for *Listeria monocytogenes* in smoked or gavad salmon and rainbow troout in Sweden. *International Journal of Food Microbiology* 58:181-196.

Linnan, M. J., L. Mascola, X. D. Lou, V. Goulet, S. May, C. Salminen, D. W. Hird, M. L. Yonekura, P. Hayes, R. Weaver, and e. al. 1988. Epidemic listeriosis associated with Mexican-style cheese. *New England Journal of Medicine* 319:823-828.

Loncarevic, S., M. L. Danielsson-Tham, P. Gerner-Smidt, L. Sahlström, and W. Tham. 1998. Potential sources of human listeriosis in Sweden. *Food Microbiology* 15:65-69.

Loncarevic, S., M. L. Danielsson-Tham, and W. Tham. 1995. Occurrence of *Listeria monocytogenes* in soft and semi-soft cheeses in retail outlets in Sweden. *International Journal of Food Microbiology* 26:245-250.

Loncarevic, S., W. Tham, and M. L. Danielsson-Tham. 1996. Prevalence of *Listeria monocytogenes* and *Listeria* species in smoked and gravad fish. *Acta Veterinaria Scandinavica* 37:13-18.

Lou, Y. and A. E. Yousef. 1999. Characteristics of *Listeria monocytogenes* important to food processors, Pages 131-224 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety. Food Science and Technology*. New York, Marcel Dekker, Inc.

Lovett, J., D. W. Francis, and J. G. Bradshaw. 1990. Outgrowth of *Listeria monocytogenes* in foods, Pages 183-187 *in* A. J. Miller, J. L. Smith, and G. A. Somkuti, eds. *Topics in Industrial Microbiology: Foodborne Listeriosis*. Amsterdam, Elsevier.

Lovett, J., D. W. Francis, and J. M. Hunt. 1987. *Listeria monocytogenes* in raw milk: Detection, incidence, and pathogenicity. *Journal of Food Protection* 50:188-191.

Lowry, P. D. and I. Tiong. 1988, The incidence of *Listeria monocytogenes* in meat and meat products factors affecting distribution. Proceeding of the 34th Annual International Congress of Meat Science Technology.:125-127.

Luisjuan-Morales, A., R. Alaniz-De La O., M. Vázquez-Sandoval, and B. T. Rosas-Barbosa. 1995. Prevalence of *Listeria monocytogenes* in raw milk in Guadalajara, Mexico. *Journal of Food Protection* 58:1139-1141.

Lund, A. M., E. A. Zottola, and D. J. Pusch. 1991. Comparison of methods for isolation of *Listeria* from raw milk. *Journal of Food Protection* 54:602-606.

Lyytikäinen, O., T. Autio, R. Maijala, P. Ruutu, T. Honkanen-Buzalski, M. Miettinen, M. Hatakka, J. Mikkola, V.-J. Anttila, T. Johansson, and L. Rantala. 2000. An outbreak of *Listeria monocytogenes* serotype 3a infections from butter in Finland. *Journal of Infectious Diseases (in-press)* 181:1838-1841.

Maifreni, M., M. Civilini, C. Domenis, M. Manzano, R. di Prima, and G. Comi. 1993. Microbiological quality of artisanal ice cream. *Zeitblatt Hygiene* 194:553-570.

Manoj, Y. B., G. M. Rosalind, I. Karunasagar, and I. Karunasagar. 1991. *Listeria* species in fish and fish-handling areas, Mangalore, India. *Asian Fisheries Science* 4:119-122.

Maple, P. C. 1995, *Listeria monocytogenes* in fish and fish product exports. Proceedings of the XII International Symposium on Problems of Listeriosis:279-283.

Margolles, A., A. Rodriguez, and C. de los Reyes-Gavilan. 1996. Some chemical and bacteriological characteristics of regional cheeses from Asturias, Spain. *Journal of Food Protection* 59:509-515.

Marranzano, M., S. Pitrolo, O. Vicari, and R. Fallico. 1996. Presenza di *Listeria* species in ortaggi. *Annali di Igiene* 8:531-535.

Marshal, D. L., P. L. Weise-Lehigh, J. H. Wells, and A. J. Farr. 1991. Comparative growth of *Listeria monocytogenes* and *Pseudomonas fluorescens* on precooked chicken nuggets stored under modified atmospheres. *Journal of Food Protection* 54:841-843, 851.

Mascola, L., L. Lieb, J. Chiu, S. L. Fannin, and M. J. Linnan. 1988. Listeriosis: An uncommon opportunistic infection in patients with acquired immunodeficiency syndrome; A report of five cases and a review of the literature. *American Journal of Medicine* 84:162-164.

Mascola, L., F. Sorvillo, V. Goulet, B. Hall, R. Weaver, and M. Linnan. 1992. Fecal carriage of *Listeria monocytogenes*: Observations during a community-wide, common-source outbreak. *Clinical Infectious Diseases* 15:557-558.

Mascola, L., F. Sorvillo, J. Neal, K. Iwakoshi, and R. Weaver. 1989. Surveillance of listeriosis in Los Angeles County, 1985-1986: A first year's report. *Archives of Internal Medicine* 149:1569-1572.

Massa, S., D. Cesaroni, G. Poda, and L. D. Trovatelli. 1990. The incidence of *Listeria* secies in soft cheeses, butter and raw milk in the province of Bologna. *Journal of Applied Bacteriology* 68:153-156.

Masuda, T., M. Iwaya, H. Miura, Y. Kokubo, and T. Maruyama. 1992. Occurrence of *Lysteria* species in fresh seafood. *Japanese Journal of Microbiology* 33:599-601.

Mbawuike, I. N., C. L. Acuna, K. C. Walz, R. L. Atmr, S. B. Greenberg, and R. B. Couch. 1997. Cytokines and impaired $CD8^+$ CTL activity amoung elderly persons and the enhancing effect of IL-12. *Mechanisms of Aging and Development* 94:25-39.

McKellar, R. C., R. Moir, and M. Kalab. 1994. Factors influencing the survival and growth of *Listeria monocytogenes* on the surface of Canadian retail wieners. *Journal of Food Protection* 57:387-392.

McLauchlin, J. 1990. Human listeriosis in Britian, 1967-85: A summary of 722 cases. 1. Listeriosis during pregnancy and in the newborn. *Epidemiology Infection* 104: 181-189.

McLauchlin, J. 1996. The relationship between *Listeria* and listeriosis. *Food Control* 7:187-193.

McLauchlin, J., N. Crofts, and D. M. Campbell. 1989. A possible outbreak of listeriosis caused by an unusual strain of *Listria monocytogenes*. *Journal of Infection* 18:179-187.

McLauchlin, J. and R. J. Gilbert. 1990. *Listeria* in food: Report from the Public Health Laboratory Service Committee on Listeria and listeriosis. *Public Health Laboratory Service Microbiology Digest* 7:54-55.

McLauchlin, J., M. H. Greenwood, and P. N. Pini. 1990. The occurrence of *Listeria monocytogenes* in cheese from a manufacturer associated with a case of listeriosis. *International Journal of Food Microbiology* 10:255-262.

McLauchlin, J., S. M. Hall, S. K. Velani, and R. J. Gilbert. 1991. Human listeriosis and pâté: A possible association. *British Medical Journal* 303:773-775.

Mead, P. S. 1999. Multistate outbreak of listeriosis traced to processed meats, August 1998-March 1999. *(Record; Foodborne and Diarrheal Disease Branch, DBMD, NCID, CDC)* May 27:23.

Mead, P. S., L. Slutsker, V. Dietz, L. F. McCraig, S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food-related illness and death in the United States. *Emerging Infectious Diseases* 5:607-625.

Mícková, V. 1991. *Listeria monocytogenes* v. potavinách. *Veterinarni Medicina* 36:745-750.

Miettinen, M. K., A. Siitonen, P. Heiskanen, H. Haajanen, K. J. Björkroth, and H. J. Korkeala. 1999. Molecular epidemiology of an outbreak of febrile gastroenteritis caused by *Listeria monocytogenes* in cold-smoked rainbow trout. *Journal of Clinical Microbiolgy* 37:2358-2360.

Misrachi, A., A. J. Watson, and D. Coleman. 1991. *Listeria* in smoked mussels in Tasmania. *Communicable Diseases Intelligence* 15:427.

Mitchell, D. L. 1991. A case cluster of listeriosis in Tasmania. *Communicable Disease Intelligence* 15:427.

Monfort, P., J. Minet, J. Rocourt, G. Piclet, and M. Cormior. 1998. Incidence of *Listeria* species in Breton live shellfish. *Letters in Applied Microbiology* 20:205-208.

Monge, R., and M. L. Arias. 1996. Presencia de microorganismos patógenos en hortalizas de consumo crudo en Costa Rica. *Archivos Latinoamericanos de Nutricion* 46:292-294.

Monge, R., D. Utzinger, and M. L. Arias. 1994. Incidence of *Listeria monocytogenes* in pasteurized ice cream and soft cheese in Costa Rica, 1992. *Revista De Biologia Tropical* 42:327-328.

Morris, I. J. and C. D. Ribeiro. 1989. *Listeria monocytogenes* and pate. *Lancet* 334:1285-1286.

Morris, I. J. and C. D. Ribeiro. 1991. The occurrence of *Listeria* species in pâté: The Cardiff experience, 1989. *Epidemiology and Infection* 107:111-117.

Morris, J. G. and M. Potter. 1997. Emergence of new pathogens as a function of changes in host susceptibility. *Emerging Infectious Diseases* 3:435-441.

Motes, M. L., Jr. 1991. Incidence of *Listeria* secies in shrimp, oysters, and estuarine waters. *Journal of Food Protection* 54:170-173.

Moura, S. M., M. T. Destro, and B. D. G. M. Franco. 1993. Incidence of *Listeria* species in raw and pasteurized milk produced in São Paulo, Brazil. *International Journal of Food Microbiology* 19:229-237.

Munk, M. E. and S. H. E. Kaufmann. 1988. *Listeria monocytogenes* reactive T lymphocytes in healthy individuals. *Microbial Pathogenesis* 5:49-54.

Nakane, A., S. Nishikawa, S. Sasaki, T. Miura, M. Asano, M. Kohanawa, K. Ishiwata, and T. Minagawa. 1996. Endogenous interleukin-4, but not interleukin-10, is involved in suppression of host resistance against *Listeria monocytogenes* infection in gamma interferon-depleted mice. *Infection and Immununity* 64:1252-1258.

National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1991. *Listeria monocytogenes*: Recommendations by the National Advisory Committee on Microbiological Criteria for Foods. *International Journal of Food Microbiology* 14:185-246.

National Cheese Institute. 1998. *Cheese Facts*. Washington, DC: International Dairy Foods Association.

Newton, L., S. M. Hall, M. Pelerin, and J. McLauchlin. 1992. Listeriosis surveillance: 1991. *Communicable Disease Report. CDR Review* 2:R142-R144.

Ng, D. L. K. and H. L. Seah. 1995. Isolation and identification of *Listeria monocytogenes* from a range of foods in Singapore. *Food Control* 6:171-173.

Nguyen-the, C. and F. Carlin. 1994. The microbiology of minimally processed fresh fruits and vegetables. *Critical Review of Food Science and Nutrition* 34:371-401.

Nichols, G., J. McLauchlin, and J. de Louvois. 1998. The contamination of pâté with *Listeria monocytogenes*: Results from the 1994 European community-coordinated food control program for England and Wales. *Journal of Food Protection* 61:1299-1304.

Nicolas, J. A. and N. Vidaud. 1987. Contribution a l'étude des *Listeria* présentes dans les denrées d'origine animale destinées á la consommation humaine. *Recueil de Medicine Veterinaire* 163:283-285.

Nieman, R. E. and B. Lorber. 1980. Listeriosis in adults: A changing pattern. Report of eight cases and review of the literature, 1968-1978. *Reviews of Infectious Diseases* 2:207-227.

Nilsson, L., H. H. Huss, and L. Gram. 1997. Inhibition of *Listeria monocytogenes* on cold-smoked salmon by nisin and carbon dioxide atmosphere. *International Journal of Food Microbiology* 38:217-227.

Nørrung, B., J. K. Andersen, and J. Schlundt. 1999. Incidence and control of *Listeria monocytogenes* in foods in Denmark. *International Journal of Food Microbiology* 53:195-203.

Northolt, M. D., H. J. Beckers, U. Vecht, L. Toepoel, P. S. S. Soentoro, and H. J. Wisselink. 1988. *Listeria monocytogenes*: heat resistance and behaviour during storage of milk and whey and making of Dutch types of cheese. *Netherland Milk & Dairy Journal* 42:207-219.

O'Driscoll, B., C. G. M. Gahan, and C. Hill. 1996. Adaptive acid tolerance response in *Listeria monocytogenes:* Isolation of an acid-tolerant mutant which demonstrates increased virulence. *Applied and Environmental Microbiology* 62:1693-1698.

Odumeru, J. A., S. J. Mitchell, D. M. Alves, J. A. Lynch, A. J. Yee, S. L. Wang, S. Styliadis, and J. M. Farber. 1997. Assessment of the microbiological quality of ready-to-use vegetables for health-care food services. *Journal of Food Protection* 60:954-960.

Olsen, J. A., A. E. Yousef, and E. H. Marth. 1988. Growth and survival of *Listeria monocytogenes* during making and storage of butter. *Milchwissenschaft* 43:487-489.

Oni, O. O., A. A. Adesiyun, J. O. Adekeye, and S. N. A. Saidu. 1989. Prevalence and some characteristics of *Listeria monocytogenes* isolated from cattle and milk in Kaduna State, Nigeria. *Israel Journal of Veterinary Medicine* 45:12-17.

Oregon Department of Agriculture 2000. *Oregon Department of Agriculture Laboratory Services. Listeria results 1990 to current (unpublished data).*

Papageorgiou, D. K., M. Bori, and A. Mantis. 1996. Growth of *Listeria monocytogenes* in the whey cheeses Myzithra, Anthotyros, and Manouri during storage at 5, 12, and 22ºC. *Journal of Food Protection* 59:1193-1199.

Papageorgiou, D. K. and E. H. Marth. 1989a. Fate of *Listeria monocytogenes* during the manufacture and ripening of blue cheese. *Journal of Food Protection* 52:459-465.

Papageorgiou, D. K. and E. H. Marth. 1989b. Fate of *Listeria monocytogenes* during the manufacture and ripening of feta cheese. *Journal of Food Protection* 52:82-87.

Parish, M. E. and D. P. Higgins. 1989. Survival of *Listeria monocytogenes* in low pH model broth systems. *Journal of Food Protection* 52:144-147.

Patterson, R. L., D. J. Pusch, and E. A. Zottola. 1989. The isolation and identification of *Listeria* species from raw milk. *Journal of Food Protection* 52:745.

Pearson, L. J. and E. H. Marth. 1990. *Listeria monocytogenes*-threat to a safe food supply: A review. *Journal of Dairy Science* 73:912-928.

Pelroy, G., M. Peterson, R. Paranjpye, J. Almond, and M. W. Eklund. 1994a. Inhibition of *Listeria monocytogenes* in cold-process (smoked) salmon by sodium nitrite and packaging method. *Journal of Food Protection* 57:114-119.

Pelroy, G. A., M. E. Peterson, P. J. Holland, and M. Eklund. 1994b. Inhibition of *Listeria monocytogenes* in cold-process (smoked) salmon by sodium lactate. *Journal of Food Protection* 57:108-113.

Peterson, M. E., G. A. Pelroy, R. N. Paranjpye, F. T. Poysky, J. S. Almond, and M. W. Eklund. 1993. Parameters for control of *Listeria monocytogenes* in smoked fishery products: Sodium chloride and packaging method. *Journal of Food Protection* 56:938-943.

Petran, R. L., E. A. Zottola, and R. B. Gravani. 1988. Incidence of *Listeria monocytogenes* in market samples of fresh and frozen vegetables. *Journal of Food Science* 53:1238-1240.

Pine, L., S. Kathariou, F. Quinn, V. George, J. D. Wenger, and R. E. Weaver. 1991. Cytopathogenic effects in enterocytekile caco-2 cells differentiate virulent from avirulent *Listeria* strains. *Journal of Clinical Microbiolgy* 29:990-996.

Pine, L., G. B. Malcolm, and B. D. Plikaytis. 1990. *Listeria monocytogenes* intragastric and intraperitoneal approximate 50% lethal doses for mice are comparable, but death occurs earlier by intragastric feeding. *Infection and Immunity* 58:2940-2945.

Pini, P. N. and R. J. Gilbert. 1988. The occurence in the U. K. of *Listeria* species in raw chickens and soft cheeses. *International Journal of Food Microbiology* 6:317-326.

Pinner, R. W., A. Schuchat, B. Swaminathan, P. S. Hayes, K. A. Deaver, R. E. Weaver, B. D. Plikaytis, M. Reeves, C. V. Broome, J. D. Wenger, and Listeria Study

Group. 1992. Role of foods in sporadic listeriosis: II. Microbiologic and epidemiologic investigation. *Journal of the American Medical Association* 267:2046-2050.

Pinto, B. and D. Reali. 1996. Prevalence of *Listeria monocytogenes* and other Listerias in Italian-made soft cheeses. *Zentralblatt für Hygiene und Umweltzedizin* 199:60-68.

Piyasena, P., S. Liou, and R. C. McKellar. 1998. Predictive modelling of inactivation of *Listeria* species in bovine milk during high-temperature short-time pasteurization. *International Journal of Food Microbiology* 39:167-173.

Professional Food Microbiology Group of the Institute of Food Science and Technology. 1995. Microbiological criteria for retail foods. *Letters in Applied Microbiology* 20:331-332.

Pullela, S., C. F. Fernandes, G. J. Flick, G. S. Libey, S. A. Smith, and C. W. Coale. 1998. Indicative and pathogenic microbiological quality of aquacultured finfish grown in different production systems. *Journal of Food Protection* 61:205-210.

Qvist, S. and D. Liberski. 1991. *Listeria monocytogenes* i hot dog pølser og slicede pålaegsvarer. *Dansk Veterinaetidsskrift* 74:773-778.

Rajkowski, K. T., S. M. Calderone, and E. Jones. 1994. Effect of polyphosphate and sodium chloride on the growth of *Listeria monocytogenes* and *Staphylococcus aureus* in ultra-high temperature milk. *Journal of Dairy Science* 77:1503-1508.

Ratkowsky, D. A., J. Olley, T. A. McMeekin, and A. Ball. 1982. Relationship between temperature and growth rate of bacterial cultures. *Journal of Bacteriology* 149:1-5.

Ravomanana, D., N. Richard, and J. P. Rosec. 1993. *Listeria* species dans des produits alimentaires - Etude comparative de differents protocoles de recherche et d'une methode rapide par hybridation nucleique (*Listeria* species in food products: A comparative study of some analytical methods including a rapid procedures by nucleic hybridization). *Microbiologie Aliments Nutrition* 11:57-70.

Rawles, D., G. Flick, M. Pierson, A. Diallo, R. Wittman, and R. Croonenberghs. 1995. *Listeria monocytogenes* occurrence and growth at refrigeration temperatures in fresh blue crab (*Callinectes sapidus*) meat. *Journal of Food Protection* 58:1219-1221.

Razavi-Rohani, M. and Y. Hedaiatinia. 1990. A study of the contamination of milk to *Listeria monocytogen* in Urmia, Iran, Pages 195 *in* Organizing Committee of the XXIII International Dairy Congress, ed. *Posters and Brief. Communications of the XXIII International Dairy Congress. Dairying in a Changing World.* Montréal.

Rea, M. C., T. M. Cogan, and S. Tobin. 1992. Incidence of pathogenic bacteria in raw milk in Ireland. *Journal of Applied Bacteriology* 73:331-336.

Richmond, M. 1990. *The Microbiological Safety of Food. Part I. Appendix 3: Listeriosis*. United Kingdom. Committee on the Microbiological Safety of Food.

Riedo, F. X., R. W. Pinner, M. De Lourdes Tosca, M. L. Cartter, L. M. Graves, M. W. Reeves, R. E. Weaver, B. D. Plikaytis, and C. V. Broome. 1994. A point-source foodborne outbreak: Documented incubation period and possible mild illness. *Journal of Infectious Diseases* 170:693-696.

Rink, L., I. Cakman, and H. Kirchner. 1998. Altered cytokine production in the elderly. *Mechanisms of Aging and Development* 102:199-209.

Rocourt, J. 1999. The genus *Listeria* and *Listeria monocytogenes*: Phylogenetic position, taxonomy, and identifiication, Pages 1-20 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety. Food Science and Technology*. New York, Marcel Dekker, Inc.

Rodler, M. and W. Körbler. 1989. Examination of *Listeria monocytogenes* in milk products. *Acta Microbiologica Hungarica* 36:259-261.

Rohrbach, B. W., F. A. Draughon, P. M. Davidson, and S. P. Oliver. 1992. Prevalence of *Listeria monocytogenes, Campylobacter jejuni, Yersinia enterocolitica* and *Salmonella* in bulk tank milk: Risk factors and risk of human exposure. *Journal of Food Protection* 55:93-97.

Rola, J. 1994. Wystepowanie *Listeria monocytogenes* w mleku surowym i produktach mlecznch. *Medycyna Weterynaryina* 50:323-325.

Roll, J. T. and C. J. Czuprynski. 1990. Hemolysin is required for extraintestinal dissemination of *Listeria monocytogenes* in intragastrically inoculated mice. *Infection and Immunity* 58:3147-3150.

Rørvik, L. M., D. A. Caugant, and M. Yndestad. 1995. Contamination pattern of *Listeria monocytogenes* and other *Listeria* spp. in a salmon slaughterhouse and smoked salmon processing plant. *International Journal of Food Microbiology* 25:19-27.

Rørvik, L. M., E. Skjerve, B. R. Knudsen, and M. Yndestad. 1997. Risk factors for contamination of smoked salmon with *Listeria monocytogenes* during processing. *International Journal of Food Microbiology* 37:215-219.

Rørvik, L. M. and M. Yndestad. 1991. *Listeria monocytogenes* in foods in Norway. *International Journal of Food Microbiology* 13:97-104.

Rosenow, E. M. and E. H. Marth. 1987. Growth of *Listeria monocytogenes* in skim, whole and chocolate milk, and in whipping cream during incubation at 4, 8,13, 21 and 35ºC. *Journal of Food Protection* 50:452-459.

Roy, R. N. 1992, *Listeria monocytogenes* in dairy products & water. *Listeria* 1992. The Eleventh International Symposium on Problems of Listeriosis:327-328.

Ryser, E. T. 1999a. Foodborne listeriosis, Pages 299-358 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis, and Food Safety*. Food Science and Technology. New York, Marcell Dekker, Inc.

Ryser, E. T. 1999b. Incidence and behavior of *Listeria monocytogenes* in cheese and other fermented dairy products, Pages 411-503 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety. Food Science and Technology*. New York, Marcel Dekker, Inc.

Ryser, E. T. 1999c. Incidence and behavior of *Listeria monocytogenes* in unfermented dairy products, Pages 359-409 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety. Food Science and Technology*. New York, Marcel Dekker, Inc.

Ryser, E. T., S. M. Arimi, M. M.-C. Bunduki, and C. W. Donnelly. 1996. Recovery of different *Listeria* ribotypes from naturally contaminated, raw refrigerated meat and poultry products with two primary enrichment media. *Applied and Environmental Microbiology* 62:1781-1787.

Ryser, E. T. and E. H. Marth. 1987a. Behavior of *Listeria monocytogenes* during manufacture and ripening of Cheddar cheese. *Journal of Food Protection* 50:7-13.

Ryser, E. T. and E. H. Marth. 1987b. Fate of *Listeria monocytogenes* during manufacture and ripening of Camembert cheese. *Journal of Food Protection* 50:372-378.

Ryser, E. T. and E. H. Marth. 1989a. Behavior of *Listeria monocytogenes* during manufacture and ripening of brick cheese. *Journal of Dairy Science* 72:838-853.

Ryser, E. T. and E. H. Marth. 1989b. "New" food-borne pathogens of public health significance. *Journal of the American Dietetic Association* 89:948-954.

Ryser, E. T., E. H. Marth, and M. P. Doyle. 1985. Survival of *Listeria monocytogenes* during manufacture and storage of cottage cheese. *Journal of Food Protection* 48:746-750.

Ryu, C.-H., S. Igimi, S. Inoue, and S. Kumagai. 1992. The incidence of *Listeria* species in retail foods in Japan. *International Journal of Food Microbiology* 16:157-160.

Sado, P. N., K. C. Jinneman, G. J. Husby, S. M. Sorg, and C. J. Omiecinski. 1998. Identification of *Listeria monocytogenes* from unpasteurized apple juice using rapid test kits. *Journal of Food Protection* 61:1199-1202.

Salamah, A. A. 1993. Isolation of *Yersinia enterocolitica* and *Listeria monocytogenes* from fresh vegetables in Saudi Arabia and their growth in some vegetable juices. *Journal University of Kuwait (Science)* 20:283-290.

Salamina, G., E. Dalle Donne, A. Niccolini, G. Poda, D. Cesaroni, M. Bucci, R. Fini, M. Maldini, A. Schuchat, B. Swaminathan, W. Bibb, J. Rocourt, N. Binkin, and S. Salmaso. 1996. A foodborne outbreak of gastroenteritis involving *Listeria monocytogenes*. *Epidemiology and Infection* 117:429-436.

Saltijeral, J., A. Cordova, G. Rulz, and L. Saltijeral. 1998, Detection of *Listeria monocytogenes* in soft cheese in Mexico City. 4th World Congress Foodborne Infections and Intoxications Proceedings. II:920-923.

Saltijeral, J. A., V. B. Alvarez, and B. Garcia. 1999. Presence of *Listeria* in Mexican cheeses. *Journal of Food Safety* 19:241-247.

Salvat, G., M. T. Toquin, Y. Michel, and P. Colin. 1995. Control of *Listeria monocytogenes* in the delicatessen industries: The lessons of a listeriosis outbreak in France. *International Journal of Food Microbiology* 25:75-81.

Sanchez-Rey, R., B. Poullet, P. Caceres, and G. Larriba. 1993. Microbiological quality and incidence of some pathogenic microorganisms in La Serena cheese throughout ripening. *Journal of Food Protection* 56:879-881.

Santema, J. G., J. G. Broekman, H. P. Endtz, and H. C. Wallenburg. 1994. Perinatal listeriosis in a Dutch woman returning from holiday in France. *European Journal of Obstetics & Gynecology and Reproductive Biology* 53:69-71.

Sarimehmetoglu, B. and S. Kaymaz. 1994. Türk salamura beyaz peynirinde yapim ve olgunlasma asamalarinin *Listeria monocytogenes* üzerine etkisi. *Ankara Üniversitesi Veteriner Fakültesi Dergisi* 41:234-242.

Schaack, M. M. and E. H. Marth. 1988. Survival of *Listeria monocytogenes* in refrigerated cultured milks and yogurt. *Journal of Food Protection* 51:848-852.

Schlech, W. F. 1996. Overview of listeriosis. *Food Control* 7:183-186.

Schlech, W. F., III, D. P. Chase, and A. Badley. 1993. A model of food-borne *Listeria monocytogenes* infection in the Sprague-Dawley rat using gastric inoculation: development and effect of gastric acidity on infective dose. *International Journal of Food Microbiology* 18:15-24.

Schlech, W. F., III,, P. M. Lavigne, R. A. Bortolussi, A. C. Allen, E. V. Haldane, A. J. Wort, A. W. Hightower, S. E. Johnson, S. H. King, E. S. Nicholls, and C. V. Broome. 1983. Epidemic listeriosis: Evidence for transmission by food. *Medical Intelligence* 308:203-206.

Schmidt, U., H. P. R. Seeliger, E. Glenn, B. Langer, and L. Leistner. 1988. Listerienfunde in rohen fleischerzeugnissen. *Fleischwirtach* 68:1313-1316.

Schuchat, A., K. Deaver, P. S. Hayes, L. M. Graves, L. Mascola, and J. D. Wenger. 1993. Gastrointestional carriage of *Listeria monocytogenes* in household contacts of patients with listeriosis. *Journal of Infectious Diseases* 167:1261-1262.

Schuchat, A., K. A. Deaver, J. D. Wenger, B. D. Plikaytis, L. Mascola, R. W. Pinner, A. L. Reingold, C. V. Broome, and Listeria Study Group. 1992. Role of foods in sporadic listeriopsis. 1. Case-control study of dietary risk factors. *Journal of the American Medical Association* 267:2041-2045.

Schuchat, A., B. Swaminathan, and C. V. Broome. 1991. Epidemiology of human listeriosis. *Clinical Microbiological Review* 4:169-183.

Schwartz, B., C. A. Ciesielski, C. V. Broome, S. Gaventa, G. R. Brown, B. G. Gellin, A. W. Hightower, L. Mascola, and Listeriosis Study Group. 1988. Association of sporadic listeriosis with consumption of uncooked hot dogs and undercooked chicken. *Lancet* 332:779-782.

Schwartz, B., D. Hexter, C. V. Broome, A. W. Hightower, R. B. Hirschhorn, J. D. Porter, P. S. Hayes, W. F. Bibb, B. Lorber, and D. G. Faris. 1989. Investigation of an outbreak of listeriosis: New hypotheses for the etiology of epidemic *Listeria monocytogenes* infections. *Journal of Infectious Diseases* 159:680-685.

Schwartz, R. H. 1999. Immunological tolerance, Pages 701-739 *in* W. E. Paul, ed. *Fundemental Immunology, 4th edition*. Philadelphia, Lippincott-Raven Publishers.

Seaman, J. T., G. I. Carter, M. J. Carrigan, and F. A. Cockram. 1989. An outbreak of listerial myelitis in sheep. *Australian Veterinary Journal* 67:1215-1216.

Seeliger, H. P. R. and K. Höhne. 1979. Serotyping of *Listeria monocytogenes* and related species. *Methods in Microbiology* 13:31-49.

Sergelidis, D., A. Abrahim, A. Sarimvei, C. Panoulis, P. Karaioannoglou, and C. Genigeorgis. 1997. Temperature distribution and prevalence of *Listeria* spp. in domestic, retail and industrial refrigerators in Greece. *International Journal of Food Microbiology* 34:171-177.

Shank, F. R., E. L. Elliot, I. K. Wachsmuth, and M. E. Losikoff. 1996. US position on *Listeria monocytogenes* in foods. *Food Control* 7:229-234.

Sharif, A. and N. Tunail. 1991. Cesitli yörelere ait cig sütler ile Ankara piyasasinda satilan pastörize sütlerde *Listeria monocytogenes* knotaminasyonunun arastirilmasi (Investigation on *Listeria monocytogenes* contamination of raw milk obtained from different regions of Antolia and pasteurized milk sold in Ankara. *Mikrobiyoloji Bülteni* 25:15-20.

Shelef, L. A. 1989a. Listeriosis and its transmission by food. *Progress in Food and Nutrition Science* 13:363-382.

Shelef, L. A. 1989b. Survival of *Listeria monocytogenes* in ground beef or liver during storage at 4 and 25ºC. *Journal of Food Protection* 52:379-383.

Shineman, T. L. and M. A. Harrison. 1994. Growth of *Listeria monocytogenes* on different muscle tissues. *Journal of Food Protection* 57:1057-1062.

Simon, M. C., D. I. Gray, and N. Cook. 1996. DNA extraction and PCR methods for the detection of *Listeria monocytogenes* in cold-smoked salmon. *Applied Environmental Microbiology* 62:822-824.

Simpson, D. M. 1996. Microbiology and epidemiology in foodborne disease outbreaks: The whys and when nots. *Journal of Food Protection* 59:93-95.

Siragusa, G. R. and M. G. Johnson. 1988a. Detection by conventional culture methods and a commercial ELISA test of *Listeria monocytogenes* added to cooked chicken. *Poultry Science* 67:157.

Siragusa, G. R. and M. G. Johnson. 1988b. Persistence of *Listeria monocytogenes* in yogurt as determined by direct plating and cold enrichment methods. *International Journal of Food Microbiology* 7:147-160.

Siragusa, G. R., K. J. Moore, and M. G. Johnson. 1988. Persistence on and recovery of *Listeria* from refrigerated processed poultry. *Journal of Food Protection* 51:831-832.

Sizmur, K. and C. W. Walker. 1988. *Listeria* in prepacked salads. *The Lancet* 331:1167.

Skidmore, A. G. 1981. Listeriosis at Vancouver General Hospital, 1965-79. *Canadian Medical Association* 125:1217-1221.

Skovgaard, N. and C.-A. Morgan. 1988. Detection of *Listeria* species in feces from animals, in feeds, and in raw food of animal origin. *International Journal of Food Microbiology* 6:229-242.

Slade, P. J. and D. L. Collins-Thompson. 1988. Enumeration of *Listeria monocytogenes* in raw milk. *Letters in Applied Microbiology* 6:121-123.

Slade, P. J., D. L. Collins-Thompson, and F. Fletcher. 1988. Incidence of Listeria species in Ontario raw milk. *Canadian Institute Food Science and Technology Journal* 21:425-429.

Slutsker, L. and A. Schuchat. 1999. Listeriosis in humans, Pages 75-95 *in* E. T. Ryser and E. H. Marth, eds. *Listeria, Listeriosis and Food Safety*. Food Science and Technology. New York, Marcel Dekker, Inc.

Sprong, R. C., M. F. Hulstein, and R. Van der Meer. 1999. High intake of milk fat inhibits intestinal colonization of *Listeria* but not of *Salmonella* in rats. *Journal of Nutrition* 129:1382-1389.

Stecchini, M. L., V. Aquili, and I. Sarais. 1995. Behavior of *Listeria monocytogenes* in mozzarella cheese in the presence of *Lactococcus lactis*. *International Journal of Food Microbiology* 25:301-310.

Stecha, P. F., C. A. Heynen, J. T. Roll, J. F. Brown, and C. J. Czuprynski. 1989. Effects of growth temperature on the ingestion and killing of clinical isolates of *Listeria monocytogenes* by human neutrophils. *Journal of Clinical Microbiology* 27:1572-1576.

Steele, M. L., W. B. McNab, C. Poppe, M. W. Griffiths, S. Chen, S. A. Degrandis, L. C. Fruhner, C. A. Larkin, J. A. Lynch, and J. A. Odumeru. 1997. Survey of Ontario bulk tank raw milk for food-borne pathogens. *Journal of Food Protection* 60:1341-1346.

Steinbruegge, E. G., R. B. Maxcy, and M. B. Liewen. 1988. Fate of *Listeria monocytogenes* on ready to serve lettuce. *Journal of Food Protection* 51:596-599.

Stelma, G. N., A. L. Reyes, J. T. Peeler, D. W. Francis, J. M. Hunt, P. L. Spaulding, C. H. Johnson, and J. Lovett. 1987. Pathogenicity test for *Listeria monocytogenes* using immunocompromised mice. *Journal of Clinical Microbiology* 25:2085-2089.

Stone, D. L. 1987. A survey of raw whole milk for *Campylobacter jejuni, Listeria monocytogenes* and *Yersinia enterocolitica*. *New Zealand Journal of Dairy Science and Technology* 22:257-264.

Sulzer, G. and M. Busse. 1993. Behaviour of *Listeria* species during the production of Camembert cheese under various conditions of inoculation and ripening. *Milchwissenschaft* 48:196-199.

Swardson, A. 1999. In a ferment over cheese: Bacteria scare making French review production methods, Pages A18-A19, *The Washington Post, April 22*. Washington, DC.

Szabo, E. A. and M. E. Cahill. 1999. Nisin and ALTA^{tm} 2341 inhibit the growth of *Listeria monocytogenes* on smoked salmon packaged under vacuum or 100% CO_2. *Letters in Applied Microbiology* 28:373-377.

Takai, S., F. Orii, Yasuda, K., S. Inoue, and S. Tsubaki. 1990. Isolation of *Listeria monocytogenes* from raw milk and its environment at dairy farms in Japan. *Microbiology and Immunology* 34:631-634.

Tang, M. Y., Y. M. Cheong, and T. Zainuldin. 1994. Incidence of *Listeria* species in vegetables in Kuala Lumpur. *Medical Journal of Malaysia* 49:217-222.

Tappero, J. W., A. Schuchat, K. A. Deaver, L. Mascola, J. D. Wenger, and for the Listeriosis Study Group. 1995. Reduction in the incidence of human listeriosis in the United States. Effectiveness of prevention efforts? *Journal of the American Medical Association* 273:1118-1122.

Terplan, G. 1988. Facteurs De Contamination Alimentaire Par *Listeria*, Pages 11-12 *in* World Health Organization, ed. *Listérioses D'orgine Alimentaire*. Genéve, World Health Organization.

Terplan, G., R. Schoen, W. Springmeyer, I. Degle, and H. Becker. 1986. *Listeria monocytogenes* in Milch und Milchprodukten. *Deutsche Molkerei Zeitung* 41:1358-1368.

Teufel, P. and C. Bendzulla. 1993. *Bundesweite erhebung zum vorkommen von Listeria monocytogenes in lebensmitteln*. Berlin, Germany: Bundesinstitut für gesundheitlichen Verbraucherschultz und Veterinärmedzin.

Tham, W. 1988. Survival of *Listeria monocytogenes* in cheese made of unpasteurized goat milk. *Acta Veterinaria Scandinavica* 29:165-172.

Tiscione, E., A. Lo Nostro, R. Donato, L. Galassi, R. Pancini, and B. Ademollo. 1994. Problemi microbiologici relativi ai latticini in riferimento alla loro possible funzione di veicoli. Ricerca di *Listeria* spp. *E Pseudomonas* spp. nel ciclo di produzione delle mozzarelle. *Igiene e Sanitab Pubblica* 50:27-36.

Tripp, C. S., M. K. Gately, J. Hakimi, P. Ling, and E. R. Unanue. 1994. Neutralization of IL-12 decreases resistance to *Listeria* in SCID and C.B-17 mice: Reversal by IFN-γ. *Journal of Immunology* 152:1883-1887.

Truscott, R. B., and W. B. McNab. 1988. Comparison of media and procedures for the isolation of *Listeria monocytogenes* from ground beef. *Journal of Food Protection* 51:626-628.

Trüssel, M. 1989. The incidence of *Listeria* in the production of cured and air-dried beef, salami and mettwurst. *Schweizer Archiv fur Tierheilkunde* 131:409-421.

Tulzer, G., R. Bauer, W. D. Daubek-Puza, F. Eitelberger, C. Grabner, E. Heinrich, L. Hohenauer, M. Stojakovic, and F. Wilk. 1987. Local epidemic of neonatal listeriosis in Upper Austria -- report of 20 cases. *Klinische Pädiatrie* 199:325-328.

U.S. Department of Agriculture. 1997.*Pathogen Modeling Program*.USDA Agricultural Research Service, Wyndmoor, PA.

U.S. Department of Agriculture, Agricultural Research Service. 1998a. *Design and Operation: The Continuing Survey of Food Intakes by Individuals and the Diet and Health Knowledge Survey, 1994-1996*: U.S. Department of Agriculture, Agriculture Research Service, Nationwide Food Surveys Report. Springfield, VA: National Technical Information Service.

U.S. Department of Agriculture, Agricultural Research Service (ARS). 1998b. *1994-96 Continuing Survey of Food Intakes by Individuals and 1994-96 Diet and Health Knowledge Survey and technical support databases.*National Technical Information Service, Springfield, VA.

U.S. Department of Agriculture, Food Safety and Inspection Service 1990. *FSIS Directive 10,240.1: Microbiological Monitoring Program: Sampling, Testing Procedures and Actions for Listeria monocytogenes and Salmonella*. U.S. Department of Agriculture.

U.S. Department of Agriculture, Food Safety and Inspection Service 1996a. *Nationwide Federal Plant Raw Ground Beef Microbiological Survey August 1993-March 1994*.

U.S. Department of Agriculture, Food Safety and Inspection Service 1996b. *Nationwide Raw Ground Chicken Microbiological Survey*.

U.S. Department of Agriculture, Food Safety and Inspection Service 1996c. *Nationwide Raw Ground Turkey Microbiological Survey*.

U.S. Department of Agriculture, Food Safety and Inspection Service 1998. *FSIS Directive 10,240.2: Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System*. U.S. Department of Agriculture.

U.S. Department of Agriculture, Food Safety and Inspection Service. 2000. Focus on: Food product dating, Pages 1-5. http://www.fsis.usda.gov/oa/pubs/dating.htm.

U.S. Department of Health and Human Services. 1999a. Public health impact of foodborne *Listeria monocytogenes*. *Federal Register* 64:44225.

U.S. Department of Health and Human Services. 1999b. Public health impact of foodborne *Listeria monocytogenes*. *Federal Register* 64:24663.

U.S. Department of Health and Human Services. 1999c. Risk assessment of the public health impact of foodborne *Listeria monocytogenes*; request for comments and for scientific data and information. *Federal Register* 64:24661-24663.

U.S. Department of Health and Human Services (US DHHS). 1998. *Federal Food,Drug and Cosmetic Act*. Washington, D.C.

U.S. Department of Health and Human Services (US DHHS). 2000. *Healthy People 2010*, v. 1. Washington, D.C.

U.S. Department of Health and Human Services (US DHHS), National Center for Health Statistics. 1997 .*National Health and Nutrition Examination Survey, III 1988-94*, version CD-ROM Series 11, No. 1A.Centers for Disease Control and Prevention, Hyattsville, MD.

U.S. Department of Health Human Services (US DHHS), National Center for Health Statistics. 1998. *Third National Health and Nutrition Examination Survey, 1988-94: NHANES III Individual Foods Data File from the Dietary Recall*.Centers for Disease Control and Prevention, Hyattsville, MD.

U.S. Food and Drug Administration (US FDA) 1987. *Imported Analytical Cheese Summary as of June 1987*. Department of health and Human Services.

U.S. Food and Drug Administration (US FDA), Centers for Disease Control and Prevention (CDC). 1988. Epidemiologic notes and reports update: Listeriosis and pasteurized milk. *Morbidity and Mortality Weekly Report* 37:764-766.

Ubach, M., A. Miguel, and P. Puig. 1991. Aislamiento de *Listeria monocytogenes* y *Listeria* species en queso fresco pasteurizado y requeson. *Alimentaria* 28:45-46.

Unanue, E. R. 1997a. Studies in listeriosis show the strong symbiosis between the innate cellular system and the T-cell response. *Immunological Reviews* 158:11-25.

Unanue, E. R. 1997b. Why listeriosis? A perspective on cellular immunity to infection. *Immunological Reviews* 158:5-9.

Uyttendaele, M., P. De Troy, and J. Debevere. 1999. Incidence of *Listeria monocytogenes* in different types of meat products on the Belgian retail market. *International Journal of Food Microbiology* 53:75-80.

Valdimarsson, G., H. Einarsson, B. Gudbjörnsdottir, and H. Magnusson. 1998. Microbiological quality of Icelandic cooked-peeled shrimp (Pandalus borealis). *International Journal of Food Microbiology* 45:157-161.

Van Wagner, L. R. 1989. FDA takes action to combat seafood contamination. *Food Processing* 50:8-12.

Velani, S. and D. Roberts. 1991. *Listeria monocytogenes* and other *Listeria* spp. in prepacked mixed salads and individual salad ingredients. *Public Health Laboratory Service Microbiological Digest* 8:21-22.

Venables, L. J. 1989. *Listeria monocytogenes* in dairy products - The Victorian experience. *Food Australia* 41:942-943.

Vose, D. J. 1998. The application of quantitative risk assessment to microbial food safety. *Journal of Food Protection* 61:640-648.

Wachsmuth, I. K. 2000. FSIS recommendations and rationale for *Listeria monocytogenes* risk ranking changes (unpublished data). Washington, D.C.

Wang, C. and P. M. Muriana. 1994. Incidence of *Listeria monocytogenes* in packages of retail franks. *Journal of Food Protection* 57:382-386.

Warburton, D. W., J. M. Farber, A. Armstrong, R. Caldeira, N. P. Tiwari, T. Babiuk, P. LaCasse, and S. Read. 1991. A Canadian comparative study of modified versions of the FDA and USDA methods for detection of *Listeria monocytogenes*. *Journal of Food Protection* 54:669-676.

Watson, C., M. Jackson, H. Kelly, Health Department of Western Australia, K. Ott, S. Knowles, and J. Wells. 1990. *Listeria* outbreak in Western Australia. *Communicable Disease Intelligence* 24:9-12.

Weagant, S. D., P. N. Sado, K. G. Colburn, J. D. Torkelson, F. A. Stanley, M. H. Krane, S. C. Shields, and C. F. Thayer. 1988. The Incidence of *Listeria* species in frozen seafood products. *Journal of Food Protection* 51:655-657.

Weber, V. A., C. Baumann, J. Potel, and H. Friess. 1988. Nachweis van *Listeria monocytogenes* und *Listeria innocua* in käse. *Berlin München Tierärztliche Wochenschrift* 101:373-375.

Wederquist, H. J., J. N. Sofos, and G. R. Schmidt. 1994. *Listeria monocytogenes* inhibition in refrigerated vacuum packed turkey bologna by chemical additives. *Journal of Food Science* 59:498-500, 516.

Wenger, J. D., B. Swaminathan, P. S. Hayes, S. S. Green, M. Pratt, R. W. Pinner, A. Schuchat, and C. V. Broome. 1990. *Listeria monocytogenes* contamination of turkey franks: Evaluation of a production facility. *Journal of Food Protection* 53:1015-1019.

West and North Yorkshire Joint Working Group. 1991. *Listeria* in food: Report of the West and North Yorkshire Joint Working Group on a two year survey of the presence of *Listeria* in food. *Environmental Health* 99:132-137.

Wiedman, M., J. L. Bruce, C. Keating, A. E. Johnson, P. L. McDonough, and C. A. Batt. 1997. Ribotypes and virulence gene polymorphisms suggest three distinct *Listeria monocytogenes* lineages with differences in pathogenic potential. *Infection and Immunity* 65:2707-2716.

Wijtzes, T., P. J. McClure, M. H. Zwietering, and T. A. Roberts. 1993. Modelling bacterial growth of *Listeria monocytogenes* as a function of water activity, pH and temperature. *International Journal of Food Microbiology* 18:139-149.

Wilson, I. G. 1995. Occurrence of *Listeria* species in ready to eat foods. *Epidemiology and Infection* 115:519-526.

Wilson, I. G. 1996. Occurrence of *Listeria* species in prepacked retail sandwiches. *Epidemiology and Infectection* 117:89-93.

Wong, S. 2000. FoodNet *listria* data (unpublished data). Washington, D.C.

Wong, H.-C., W.-L. Chao, and S.-J. Lee. 1990. Incidence and characterization of *Listeria monocytogenes* in foods available in Taiwan. *Applied and Environmental Microbiology* 56:3101-3104.

World Health Organization Working Group. 1988. Foodborne listeriosis. *Bulletin of the World Health Organization* 66:421-428.

Yousef, A. E. and E. H. Marth. 1988. Behavior of *Listeria monocytogenes* during the manufacture and storage of Colby cheese. *Journal of Food Protection* 51:12-15.

Yousef, A. E. and E. H. Marth. 1990. Fate of *Listeria monocytogenes* during the manufacture and ripening of Parmesan cheese. *Journal of Dairy Science* 73:3351-3356.

Yu, L. S. L., R. K. Prasai, and D. Y. C. Fung. 1995. Most probable numbers of *Listeria* species in raw meats detected by selective motility enrichment. *Journal of Food Protection* 58:943-945.

APPENDICES

Appendix 1:

Chronology of Technical and Scientific Reviews of the *Listeria monocytogenes* Risk Assessment

Appendix 1: Chronology of Technical and Scientific Reviews of the *Listeria monocytogenes* Risk Assessment

FDA solicited the advice and opinions of scientific experts and the public throughout the conduct of this *Listeria monocytogenes* risk assessment. A summary of the dates, type of review activity, and participants is provided below.

Chronology of Technical and Scientific Reviews of the *Listeria monocytogenes* Risk Assessment

Date	Activity	Participants
January 1999	Risk Assessment Team assembled	FDA and FSIS
May 1999	Federal Register Notice; request for comments and for scientific data and information	Public
May 1999	Federal Register Notice of public meeting; request for comments	Public
May 1999	Public meeting (Chicago, IL)	NACMCF; public
August 1999	Federal Register Notice of public meeting	Public; Federal Register Notice
September 1999	Public meeting; request for comments on the risk assessment approach and assumptions (Washington, DC)	NACMCF; Public
December 1999	Request for scientific review of draft risk assessment document	RAC members
December 1999	Technical discussion of the draft risk assessment document	RAC annual meeting (closed)
December 1999	Intensive review of model	FDA
March 2000	Internal scientific review of draft document	Selected FDA risk managers
May 2000	Technical review of document	Selected government experts and SGE's
May 2000	Review of model and mathematics	Selected government experts and SGE's
May 2000	Data verification	FDA quality assurance team
September/ October 2000	Interagency review of draft document	FDA, FSIS, CDC
January 2001	Federal Register Notice of Availability of draft risk assessment document for public review and comment (66FR 5515)	Public
March 2001	Public meeting; presentation of assumptions, approach, and results of the risk assessment and request for comment (66FR 13544)	Public

Chronology of Technical and Scientific Reviews of the
***Listeria monocytogenes* Risk Assessment**
(continued)

Date	Activity	Participants
March 2001	1st extension of public comment period (66 FR13545)	Public
May 2001	2nd extension of public comment period (66 FR 28181)	Public
July 2001	Close of public comment period	
July 2001 to December 2002	Review of public comments including newly available data	FDA and FSIS
April 2003	Technical review of revised report and model	FDA and FSIS
2003	Federal Notice of Availability of revised risk assessment	Public
2003	Public meeting; presentation of revised risk assessment	Public

FDA= Food and Drug Administration
FSIS= Food Safety and Inspection Service
NACMCF = the National Advisory Committee on Microbiological Criteria for Foods.
RAC = the U.S. government Interagency Risk Assessment Consortium
CDC = Center for Disease Control and Prevention
SGE = Special Government Employees

Appendix 2:

Public Comments and FDA/FSIS Responses

Appendix 2: Public Comments and FDA/FSIS's Responses

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~a~~Assumptions	Five factors (i.e., amount and frequency of consumption of the food; frequency and levels of *Listeria monocytogenes* in ready-to-eat food; potential to support growth of *Listeria monocytogenes* in food during refrigerated storage; refrigerated storage temperature; and duration of refrigerated storage before consumption) affecting consumer exposure to *Listeria monocytogenes* at consumption are not necessarily additive or equally relevant.	The statement about five factors that influence exposure is an interpretation of the results of the risk assessment. Further work provided in the 2003 risk assessment ('what if' scenarios) gives examples of how factors such as storage time and temperature interact to influence risk. (See Chapter VI. `What If` Scenarios.) Any of these factors can affect potential exposure to *Listeria monocytogenes* from a food category. These factors are 'additive' in the sense that when more than one of these factors favor a higher level of *Listeria monocytogenes*, the foods are more likely to have an increased consumers' risk of listeriosis than when only one factor is high.
~~a~~Assumptions	This risk assessment doesn't consider contamination in homes, daycare centers, schools and other non-retail places. One cannot assume that they don't need to be incorporated into this risk assessment. Further, it is unacceptable to assume that such data do not need to be included just because no such data are available.	A consideration of sources of contamination from homes, daycare centers, schools, and other non-retail establishments is beyond the scope of this risk assessment. If data become available, these sources could be included in future risk assessment projects. The likely impact of these sources of contamination on the predicted risks is not known, however, the epidemiology of outbreaks and sporadic cases suggests that a majority of cases are associated with initial contamination prior to the home.
~~a~~Assumptions~~e~~	Inherent characteristics and processing methods of foods that result in *Listeria monocytogenes* inhibition are not taken into account.	A consideration of processing methods was outside the scope of this risk ranking approach.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Assumptions	Assumptions should be more protective of public health.	~~No further action, since this is a risk management decision.~~The risk assessment was purposely designed to minimize bias, focusing on the most accurate assessment of risk and its associated uncertainty that can be derived from the available scientific information. This "bias neutral" approach is critical for transparency and appropriately places the decision about the degree of precaution required to deal with scientific uncertainty with risk managers.
Assumptions	Multiple speculative assumptions regarding storage conditions and dose response models do not constitute a valid scientific basis for conclusion that *Listeria monocytogenes* is a risk in retail establishments.	Newly available data on consumer handling of frankfurters and deli meats were incorporated into this risk assessment. The epidemiological records, outbreak and recall data indicate that many of these foods do pose a risk. The dose response models are anchored to the CDC surveillance data. ~~We invite t~~The ~~submission of additional data to improve our approach.~~models developed and conclusions reached were based on the best available scientific data and expert judgment.
Assumptions	Some aspects of the exposure assessment contribute to the mis-characterization or over-estimation of risk associated with specific food categories.	The specific food categories were reviewed and discussed with subject matter experts and advisory committees to ensure that assumptions and modeling approach used were consistent with the unique characteristics of foods.
Assumptions	Deli salads are not known to have directly caused listeriosis, but the risk ranking places them above products that have (i.e., frankfurters, pasteurized milk, soft mold-ripened and blue-veined cheese, etc). This relates to an assumption in growth rate (use of deli meats as surrogate).	~~There is new data, and that category has been re-done.~~New data became available and the assumed values for growth rates were replaced with data specific for this food category. (See Chapter III. Exposure Assessment.)

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Assumptions	This risk assessment reports no listeriosis cases resulting from deli salads or frankfurters. Why were they included? Also, their risk is over-estimated as a result of assumptions in exposure assessment.	Deli-type Salads food category was revised with newly available data. Foods were included because of associations with outbreaks, recalls, and availability of contamination data. The epidemiology of cases associated with frankfurters is discussed within the technical document. (See Chapter II. Hazard Identification.)
~~a~~Assumptions, ~~d~~Distribution	Justify changing the weight of the Beta-Pert from 4 to 7.	The distribution is based on ~~subjective~~expert judgment, after examining proposed shape of the curve. The standard BetaPert had too many servings stored for long periods of time.
Assumptions, Growth	The potential to support growth should be a primary risk factor; refrigeration temperature and storage time should be sub-points, since many foods don't support growth. If the micro-organism cannot grow, temperature and time are not relevant to illness.	The 2003 risk assessment includes scenario testing to evaluate the impact of refrigerator temperature and storage time on the predicted risk. (See Chapter VI. `What If` Scenarios.) These 'what if' scenarios indicate that storage time and temperature interact to affect the amount of growth that would occur in foods that support growth.
~~a~~Assumptions, ~~v~~Variability, ~~d~~Distributions	Non-U.S. pasteurized milk may not have same variability in contamination since pasteurization methods are different. FDA/FSIS used U.S.-only data to calculate the detection rate and average contamination level for pasteurized and non-pasteurized milk, but variability in the distributions came from U.S. and non-U.S. data. The assumption of similar variability may not be supportable.	Geographic weighting that reduces the impact of non-U.S. data ~~is~~was implemented in the 2003 risk assessment.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Assumptions, ~~w~~Weight~~,~~, ~~d~~Distributions	Weights assigned to upper tails were up to 2.5 x 10^7 times larger than lower end. FDA/FSIS assigned weighting to data in proportion to reported concentration. This is incorrect because samples with high numbers or with bins with large endpoints are over-emphasized. Recalculate without weighting yields different distributions, e.g., 19 times lower 99 percentile in one example. It is more appropriate to state that weighting can yield much higher risk estimates than those derived from non-weighted data.	The weight referred to was a function of dose of $10^{0.25}$. The ~~weight was a function of dose to the 1/4 power. In any case, the~~revisedion ~~of the~~ procedure for incorporating quantitative information into the 2003 risk assessment has made high dose weighting unnecessary.
Categories	Current categories do not highlight food or processing characteristics. Regroup foods according to their characteristics and processing/handling.	This has been done, to the greatest extent feasible, based on available data. We have created food ~~categories which~~categories, which ~~include~~consider processing and food composition characteristics. Pertinent characteristics of the food that may have contributed to the contamination of a food category at retail are discussed in the technical document.
Categories	Focus on foods associated with *Listeria monocytogenes*, not food categories. Such groupings are inappropriate, introducing variability and uncertainty--lack of data is no excuse.	The goal of the risk assessment was to evaluate which foods that contribute to listeriosis cases. Individual foods were grouped into 23 food categories to accomplish this goal; in part, because insufficient data was available for individual foods and risk assessments for each of the over 640 ready-to-eat foods would be extremely complex.
Categories	It is recommended that the categories be split out, and to categorize foods separately for effective risk assessment and risk management.	The food categories used in this risk assessment were broad and the modeling techniques included consideration (as much as possible) of the variations within the food categories, including use of antimicrobials.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Categories	Low risk food items should not be included in the assessment. Remove frozen or acidified foods.	An objective of the risk assessment was to determine which foods are not contributing to listeriosis. This provides a quantitative estimation that they are not a problem that reinforces the qualitative judgment.
Categories	Regroup cheese according to ability to support *Listeria monocytogenes* growth.	Cheeses were regrouped according to ability to support *Listeria monocytogenes* in the 2003 risk assessment.
Categories	Divide Heat-Treated Natural Cheese and Process Cheese food category to "heat treated natural" and "pasteurized processed" cheese. Use of pasteurized milk data for distribution of processed cheese results in increased uncertainty.	The cheese categories were reorganized in the 2003 risk assessment, and the heat-treated natural cheeses are now grouped in either Soft Unripened Cheese or Soft Ripened Cheese food category. This risk assessment included some contamination data for processed cheese so surrogate data were not used. Processed cheese had very low risks because they do not support growth; further separation would not provide significant additional information.
Categories	Remove queso asadero and queso chihuahua from fresh soft cheese since they are firmer, drier cheeses.	Queso asadero and queso Chihuahua were removed from the Fresh Soft Cheese food category in the 2003 risk assessment and placed in the Hard Cheese food category as appropriate.
Categories	Rename category "fresh soft cheese" from "unpasteurized milk" to account for high contamination level. Also, only consider products made in "legally registered and approved establishments."	The specific recommendation was not feasible. However, a "what if" scenario analysis was conducted to evaluate the impact of higher contamination levels on the predicted risk attributed to fresh soft cheese. (See Chapter VI. `What If' Scenarios.)
~~c~~Categories	Deli meats contain products that differ substantially with respect to matrices, characteristics, production and handling.	Yes, variation in ~~the category~~these categories include~~s~~s ~~this~~food products that were different in regards to matrices, characteristics, production and handling. ~~Further consideration would be a risk management decision~~The assessment has captured that variability to the extent possible.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Categories	Many deli meats are either frozen, have a kill step after packaging, or inhibit *Listeria monocytogenes* growth. They should be separated since they are low-risk products---relates to placement of foods within categories (splitting Deli Meats food category before analysis).	Since data was at retail this was inherently captured in the data set and would thus be captured in the variability and uncertainty. Contamination at retail is an important factor that may over-ride processing factors.
Categories	Deli salads contain products that differ substantially with respect to matrices, characteristics, production and handling.	Yes, variation in these categories includes food products that were different in regards to matrices, characteristics, production and handling. The assessment has captured that variability to the extent possible.
Categories	Potato salad should be moved to Deli-type Salads food category.	Potato salad was moved to the Deli-type Salads food category in the 2003 risk assessment.
Categories	There is great variety in each of the seafood categories (i.e., different characteristics, handling, consumption, etc.,). Many examples are given, but it is unfair to assume similar patterns of contamination for all foods in category. Some ready-to-eat seafood is cooked, frozen, hand harvested, and etc., which impacts contamination; they should not be pooled together.	We have created food ~~categories which~~categories, which ~~include~~consider processing and food composition characteristics. Pertinent characteristics of the food that may have contributed to the contamination of a food category at retail are discussed in the technical document.
~~c~~Categories	Hot and cold smoked seafood have differences in storage time, distribution practices, shelf life, and consumption patterns.	~~Evaluation of these differences is beyond the scope of this risk assessment. These differences could be addressed~~Available data including consumption patterns would not allow the differentiation. Furthermore, the data suggest pre-contamination after processing tends to limit the reduction in risk achieved by hot smoking.
~~c~~Categories	Vegetables are ranked as low risk even though there is a high level of contamination of sprouts. Therefore, this should probably be subdivided.	In using a food category approach, there will be some foods that will not ideally fit that category perfectly. ~~We note that~~There were insufficient data ~~are available~~on the extent of *Listeria monocytogenes* in

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		sprouts to ~~conduct a risk assessment for this food.~~warrant its inclusion as a separate food category.
Categories	Divide vegetables into raw, pickled, and dry. Exclude soy products (eaten hot).	The Vegetables food category was revised to exclude pickled and dried vegetables, and soy products.
Categories, Assumptions	Consider if grouping foods in categories affects risk estimates (i.e., see if taking foods out of current groupings affects risk).	A risk parameter is always for a defined population, and this must be considered in interpreting the risk assessment.
~~c~~Categories, ~~a~~Assumptions	Combining data across broad categories will not compensate for lack of d~~deli meat~~eli salad data.	Newly available data on deli salad contamination and *Listeria monocytogenes* growth were incorporated into the 2003 risk assessment. The existence of growth and non-growth salads was recognized. (See Chapter III. Exposure Assessment, Modeling: Growth Between Retail and Consumption; and Chapter V. Risk Characterization, Food Category: Deli-Type Salads section.)
~~c~~Categories, ~~c~~Contamination	Cabbage should not be in the Vegetables food category; listed only because linked to cabbage in slaw. Also, studies indicate *Listeria monocytogenes* grows well in refrigerated cabbage.	Cole slaw was moved to the Deli-type ~~s~~Salads food category.
~~c~~Categories, ~~d~~Data	Re-categorize the ready-to-eat foods based on characteristics associated with contamination or growth of *Listeria monocytogenes* such as pH. Current categories are too broad, e.g., deli salads with and without meat and/or seafood/vegetables, vinegar vs. mayonnaise.	Consideration was given to the balance between categories, the availability of data, and the number of categories that can be dealt with. Every new category would need specific data for every step of the risk assessment from consumption to contamination to growth rates. For example, o~~It could be argued~~ne could say that normal and low salt hams would have different growth rates and should be separated. ~~This~~Ultimately, it was decided that this risk assessment ~~had to~~should be "broad" in its approach to facilitate interpretation ~~and readers need to interpret it~~

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		~~with that in mind~~. ~~Future risk assessments can be more focused.~~Focusing on how specific products are produced can be done in future risk assessments.
Categories, Data	Fruits category should include dry, fresh, frozen.	The Fruits food category includes raw and dried in the 2003 risk assessment. Consideration was given to the balance between categories, the availability of data, and the number of categories that can be dealt with. Every new category would need specific data for every step of the risk assessment from consumption to contamination to growth rates.
~~c~~Categories, ~~d~~Data, ~~a~~Assumptions	National Food Processors Association (NFPA) has data on deli salads. The growth rate for deli meat should not be used for deli salads, which over-estimates risk in this matrix.	Newly available data on deli salad contamination and *Listeria monocytogenes* growth were incorporated into the 2003 risk assessment. (See Chapter III. Exposure Assessment, Modeling: Growth Between Retail and Consumption; and Chapter V. Risk Characterization, Food Category: Deli-Type Salads section.)
~~c~~Categories, ~~g~~Growth	Divide ~~f~~Fruits category by pH, since low pH fruits do not support growth. Exponential growth rate from vegetables should not be used for fruits with low pH.	More data on fruits would be needed to ~~do so.~~further divide the Fruits category. The ~~V~~vegetable data was not used in the 2003 risk assessment.
~~c~~Categories, ~~g~~Growth	Separate deli meats components, since not all deli meats support growth.	~~More data on deli meats would be needed to do so.~~Dry fermented sausages were separated from other

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		deli meats. The variability of the products in the Deli Meats food category is captured in the measures of variability and uncertainty. Further separation of deli meats would be better examined in subsequent risk assessments, specifically focused on the manufacture of these products.
~~c~~Categories, ~~m~~Matrix	Group foods according to matrix, i.e., freezing, heating, or preparation.	~~This was done, as much as was possible.~~The categories were based on matrix and growth characteristics of *Listeria monocytogenes*. Frankfurters had special consideration for consumer freezing and cooking. Generally, the level of detail was appropriate to make the desired inferences.
~~c~~Categories, ~~p~~Proxy ~~d~~Data, ~~u~~Uncertainty	Some food categories are not uniform, especially vegetables. Grouping diverse foods obscures factors associated with *Listeria monocytogenes* risk reduction. Applying proxy data increases the uncertainty. This may be unavoidable because of data limits, but may not highlight unique characteristics relevant to risk management. Food categories contain foods that differ by characteristics, by processing, handling, diet consider.	Use of proxy data have been largely eliminated in the 2003 risk assessment (and completely eliminated for contamination). Each category would still have to be interpreted with the understanding ~~what went into it.~~of the specific foods that comprise the respective category. A more detailed examination of a specific food category would require a product-specific risk assessment, which was not the purpose of the current work.
~~c~~Consumption	Most cases are not related to foodservice since they do not occur as outbreaks. Therefore, it is incorrect to state in this risk assessment that increased consumption of food from outside of the home or ready-to-eat foods is causing slowdown in *Listeria monocytogenes* reduction.	We agree that the consequences of the shift to consumption outside of the home are not known. In the 2003 risk assessment, r~~This can not be determined at this time. (check reference)~~isks in a food service were assumed to be comparable to those in home preparation. Surveys have shown that similar food handling problems are found in both places. A contaminated food in a restaurant would still be most likely to result in a single sporadic case rather than an outbreak.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~c~~Consumption~~-~~, ~~c~~Categories, ~~d~~Distribution	Bi-modality may result from differences in consumption of aged cheese within the group, not because there were a high percentage of samples without *Listeria monocytogenes*. The concern with aged cheeses is that grouping with medium serving size of 27g obscures vastly disparate consumption patterns (e.g., many portions are Parmesan, but much larger amount is cheddar). Non-uniformity of category can affect distribution.	~~We agree.~~This is correct, and as a result a distribution of serving sizes was employed, rather than a single value for the entire group. Non-uniformity within a category for any factor will widen the distribution. With the improved data used in the 2003 risk assessment, the uncertainty in the risk assessment was greatly reduced.
Consumption, Cooking	Steamed or boiled cooked ready-to-eat crustaceans that are eaten hot were excluded. Much of this food is eaten hot, thus not risk.	This is a valid point. Unfortunately, the consumption databases did not ask whether shrimp were eaten hot. As a result, there may be some inaccuracies for cases per annum but the risk per serving would still reflect the risks for the unheated shrimp, which is of most concern.
~~c~~Consumption, ~~c~~Cooking, ~~d~~Data	Use AMI data for frankfurter storage time and consumer behavior. (AMI data show that 7% of frankfurters are consumed without reheating.) Modify distribution to 1-6% uniform from 1-14% uniform.	The new American Meat Institute (AMI) survey was used as the basis for consumer handling of frankfurters (i.e., frankfurters eaten without reheating). The percentage of non-frozen frankfurters that were not reheated was represented by a triangle distribution of 4, 7, and 10.
Cooking	Model used to cook frankfurters is appropriate for risk management. Supports use of 1-6% versus 1-14%.	We concur.
~~c~~Consumption, ~~d~~Data	Indicate serving sizes used to calculate data in Tables III-5 and III-11.	The serving sizes are distributions that are described on Table III-3. A graph is in Appendix 5.
Contamination	This risk assessment does not consider how food became contaminated, unlike other risk assessments. The focus on retail data misguided because the majority of outbreaks are associated with processing and management. Outbreaks	The design of the risk assessment was specifically developed to compare the risks associated with different classes of ready-to-eat foods and was extensively reviewed as providing the appropriate approach for addressing the stated purpose of the

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
	associated with retail and restaurants most often occurred with already contaminated foods.	work.
~~c~~Contamination	Data from outside the U.S. may have different contamination frequencies since processing varies. Do not assume that contamination distributions are the same. Examine extent to which variation in a food type (particularly if level of contamination in U.S. is lower) reflects true variation in part food or reflects different processing practices and country customs.	Weighting was employed to give greater impact to the current U.S. food supply in the 2003 risk assessment. Imported foods are a significant portion of the foods consumed within the U.S. ~~Weighting is done.~~ However, countries such as Western Europe, Japan, Australia, and Canada are assumed to be similar to the U.S.
Contamination	Data more than 10 years old do not show the recent reduction in *Listeria monocytogenes* illness. Therefore, do not use older data.	A study date weighting system was implemented that gives greater importance to more recent studies.
~~c~~Contamination	The importance of foreign contamination data should be proportionate to the consumption rate.	~~This goes beyond the level of this risk assessment and quality of data sets.~~The U.S. food supply includes many imported foods. Geographical weighting was used to reduce the impact of contamination data from other countries. To ascertain the fraction of servings from individual countries is beyond the capabilities of the current risk assessment, both in terms of data availability and methodology.
Contamination	Foreign contamination data are a poor proxy for U.S. cheese; gives misleading estimate of risk of U.S. cheese.	For the 2003 risk assessment, studies were weighted in consideration of the geographic location. Less weight was given to countries that do not export foods to the U.S.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Contamination	Foreign manufacturers have different processing conditions that may result in higher contamination, skewing data. Do not use foreign data as proxy for contaminated levels in pasteurized milk in the U.S. Foreign manufacturers may have higher contamination levels.	Countries such as Western Europe, Japan, Australia, and Canada are assumed to be similar to the U.S. Using only U.S. data would be preferred, but in the 2001 draft there was insufficient data from the U.S. As a consequence of these data gaps, surveys were initiated to address this problem. The IDFA has provided new U.S. data that comprises the majority of samples.
Contamination	Distribution is based on contamination of fresh soft cheese made with unpasteurized milk. Fresh soft cheese must be made from pasteurized milk in the U.S. Omit this category until data are available.	The 2002 NFPA study provided recent contamination data for fresh soft cheese. The data reflected the fact that the majority of fresh soft cheeses are made from pasteurized milk. Some fresh soft cheeses are made from unpasteurized milk, and 'what if' scenario calculations were conducted to assess the impact of those cheeses. (See Chapter VI. 'What If' Scenarios.)
Contamination	Recent NCI study of soft-ripened cheese from pasteurized milk has a contamination rate of 0.06%.	The recent NFPA study had approximately 1% contamination. All recent studies are included in the 2003 risk assessment.
~~c~~Contamination	The presence/absence data for *Listeria monocytogenes* in ice cream w~~as~~ere provided by the Industry Council for Development of the Food and Allied Industries (ICD) for FAO/WHO Exposure Assessment of *Listeria monocytogenes* in ready-to-eat foods. Can you provide more recent contaminant level (enumeration) data? Also, new industry ice cream (and frozen dairy products) contamination data (from the International Ice Cream Association) ~~is~~are lower (0.18%) than data used in this risk assessment (0.7%).	~~Ice cream was still low after revision of this risk assessment~~Ice cream contamination data is now study date weighted in favor of data currency. The 2003 risk assessment includes more recent contamination data. (See Appendix 7.)
Contamination	Use more recent FSIS data for ready-to-eat meat and poultry.	The recent FSIS data were incorporated into the 2003 risk assessment.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~c~~Contamination	The risk of pasteurized milk is over-estimated since pasteurization kills pathogens.	~~New data has been included, i.e., high consumption data. Re-contamination does occur.~~Pasteurization may not kill all pathogens. However, more important is the frequency of post-pasteurization recontamination. In the 2003 risk assessment, the predicted per annum risk is not matched with an equivalent U.S. epidemiological record. Advanced epidemiologic and scientific investigations are needed to either confirm the predictions of the risk assessment or identify the factors not captured by the current models that would reduce the predicted relative risk.
~~c~~Contamination	The contamination in unpasteurized milk is probably under-estimated; should not assume that competition from other micro-organisms will result in a decrease in *Listeria monocytogenes* over time. Rather than base contamination level of unpasteurized fluid milk at retail on assumptions about competition and limited data, instead base on data for pasteurized milk at retail, correlated with limited unpasteurized fluid milk data.	In the 2003 risk assessment, the contamination level for unpasteurized milk is 4.1% compared to 0.35% for pasteurized milk. In the 2003 risk assessment, the same exponential growth rates, maximum growth levels and storage times were used for both pasteurized and unpasteurized milk, based on published scientific investigations.
Contamination	Level of imported milk is 0.03%. Stating it is less than 1% is misleading	This percentage was deleted from text.
Contamination	Legume and vegetable sprout data should have been given more emphasis---treat sprouts separately.	Diversity within a food category is accounted for, however, the fact that certain foods may be at the extremes of the diversity needs to be considered when interpreting the risk assessment. Certain foods such as spouts may merit a specific product pathway risk assessment in the future, but this would require data on contamination at retail and frequency of consuming raw sprouts.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Contamination, Assumptions, Data, Categories	If climate in non-U.S. country is different then the implications should be considered and discussed. In some food categories, all data are non-U.S. or include data from countries with different climates. The relevance to the U.S. food supply should be considered.	The initial data set was contamination at retail; therefore, the U.S. would receive the effect of the local climate if a food were imported. Countries were weighted for each food category, depending on the importance of the food and the country of source. The growth was modeled using only U.S. refrigeration temperature data.
Contamination, Assumptions, Data	Excluding non-U.S. data for goat and feta (cheese) results in upper percentiles that are orders of magnitude lower than this risk assessment.	Goat and feta cheeses are no longer a separate category, and their contamination data are included with the Soft Ripened Cheese category. Cheeses from countries that do not contribute to the U.S. food supply are given low weightings, and the data set now includes the large recent U.S. survey (NFPA) of these cheeses.
~~c~~Contamination, Data	The data in this risk assessment compared studies published pre- and post-1993. (Why is 1993 a dividing year for data?) The increase in the frequency of detection and problem awareness may be related to improvements in the detection methods and targeted sampling. As such, increased *Listeria monocytogenes* frequency post-1993 does not necessarily indicate a higher incidence of *Listeria monocytogenes* in the food supply. For some food categories (e.g., cooked ready-to-eat crustaceans), contamination levels are actually lower in post-1993 studies. Using pre-1993 data may over-estimate risk. Use post-1993 data for more accurate assessment.	A search of the published literature revealed that many of the studies were conducted in the late 1980s and early 1990s. From the published literature, it was difficult to ascertain the extent that improved sanitation and other control measures implemented by the food industry have reduced the frequency and level of contamination since 1993. Since some food categories had little data, which would result in a biased estimate, the overall trend in contamination for all of the food categories from before 1993 to after was obtained and applied to these data sets. (See Chapter III. Exposure Assessment, Food Contamination Data section.) The purpose of the pre- and post-1993 comparison was to assess any bias that may have been introduced unintentionally due to "study date." This has been dealt with in a different manner in the 2003 risk assessment through the

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		inclusion of "study date" weighting system, which was employed to give recent data more influence on the contamination distribution. Post-1993 data is not available for all food categories. In addition, a correction factor was applied to anticipate reductions in prevalence estimates if new data were available for categories without new data.
Contamination, Data	Using only post-1993 data shows the 99th percentile is 5.6x lower for frankfurters than when all data are used. There is a concern in this risk assessment of similarity between pre- and post-1993, because some post-1993 publications contain pre-1993 data. Modeling change with only post-1993 data also changes the relative risks for frankfurters.	A weighting system was employed to give recent data more influence on the contamination distribution. Post-1993 data is not available for all food categories. In addition, a correction factor was applied to anticipate reductions in prevalence estimates if new data were available for categories without new data. Most of the frankfurter contamination data is from FSIS (2000 and 2001). Knowledge of when the samples were collected vs. the date of the publication would be the same for all food categories.
Contamination, Data	Use of pre-1993 data over-estimates predicted fresh soft cheese relative risk.	A weighting system was employed to give recent data more influence on the contamination distribution. With the inclusion of the newly available NFPA data, the majority of the contamination data set is comprised of recent data and has the most impact on determining the distribution.
Contamination, Data	Kozak (1996) pasteurized milk data is from the late 1980's and is outdated. The risk assessment should reflect when data was collected, not when published (regarding pre-1993/post-1993 split).	A weighting system was employed to give recent data more influence on the contamination distribution. For most studies, it is not known when data were actually collected. Even with the delay in publishing these data, Kozak data were not given full weight since

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		these were not the most recent data.
Contamination, Data	Include the cheese data provided by National Cheese Institute (NCI) in the revised risk assessment. It includes both industry wide data on many cheeses and one manufacturer data on soft ripened cheese.	The data from NCI were included in the 2003 risk assessment.
~~c~~Contamination, ~~d~~Data	Use new NFPA data on deli meats, deli salads, fresh soft cheese, soft mold-ripened and blue-veined cheese, vegetables, seafood salads, and smoked seafood.	The newly available 2002 NFPA retail study data were incorporated into the 2003 risk assessment.
~~c~~Contamination, ~~d~~Data	New industry contamination pasteurized milk data is lower (0.018%) than data used in this risk assessment; data set includes one positive with enumeration.	~~Any newly available data were incorporated.~~The data set from the International Dairy Foods Association (IDFA) was used in the 2001 draft risk assessment and also in the 2003 risk assessment.
~~c~~Contamination, ~~d~~Data	Older Dry/semi-dry fermented sausages data should be weighted; the recent data show a 5-log reduction for *E. coli* 0157:H7 for product produced in the U.S.	A weighting system was employed to give recent data more influence on the contamination distribution. The dry/semi-dry fermented sausages data included large surveys by FSIS in 2000 and 2001. Excluding certain data for one food category but not another would not be justified.
~~c~~Contamination, ~~r~~Risk, ~~r~~Rank, ~~d~~Data	The risk per serving in deli meats is 400 times higher in risk assessment than when NFPA data ~~is~~were used. The relative rank changed sharply from 4 to 16 on a per serving basis, and from 1 to 13 on a per annum basis.	For the 2003 risk assessment, a different approach~~w~~ was used to estimate the distribution contamination curves; this approach yields a more continuous uncertainty distribution~~ is more stable~~. The NFPA data were not available for the draft 2001 risk assessment. New data for many food categories were used in this risk assessment.

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Contamination, Uncertainty, Foreign Data	Wide variation between studies in high *Listeria monocytogenes* occurrence levels, which contributes to the uncertainty. This may reflect different handling practices outside of the U.S. As such this may over-estimate the risk to U.S. consumers.	The uncertainty is acknowledged in the assessment and represented in the results through the uncertainty analysis component. For the 2003 risk assessment, the contamination data were weighted to try to more appropriately represent current U.S. conditions. However, Western Europe, Japan, Canada, and Australia are probably comparable to the U.S. It is difficult to use the available data to prove that the U.S. industry is more stringent.
Contamination Data	Quantitative data is hard to come by because of zero tolerance policy.	FDA/FSIS supports the need for systematic, regular collection of levels of *L. monocytogenes* in foods.
Contamination Data	Data in risk assessment should reflect experience of mainstream commercial food processors and purveyors, not small producers with problems.	The contamination data were collected from diverse sources, generally at retail. Most likely, the prevalence of retail samples reflects the respective prevalence of different classes of manufacturers.
Contamination Data	The contamination data come from diverse sources, may be out of date (with respect to food processing and handling practices), are largely nonquantitative, and do not specify the variables in handling (e.g., duration of time held at retail or distribution before sampling).	Each of the statements are correct, however, by considering a broad range of data with appropriate weighting, this risk assessment does provide a "national profile" of what exists at the retail level.
~~c~~Cooking	Undercooking food can cause illness. One shouldn't assume that cooked foods have low likelihood of containing *Listeria monocytogenes*.	~~We wil~~The cooking model employed in the 2003 risk assessment took into account the potential impact of different cooking times and temperatures.
~~c~~Cooking	How were numbers for the triangular distribution assigned? Were they taken from Juneja (*et al*., 1997)? This is a different product; frequency distribution should not be applied to frankfurters.	~~The answer to the first question is Yes.~~Yes, the numbers assigned for the triangular distribution were taken from Juneja (*et al*., 1997), because inadequate data were found with which to directly model thermal inactivation in the frankfurters that were cooked. ~~The response to the second statement is that~~Although this

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		is a different product, a hamburger study was used because it was the closest available analog for which data ~~is~~are available. (See Chapter III. Exposure Assessment, section Modeling: Thermal Inactivation.)
~~c~~Cooking, ~~a~~Assumptions	One cannot assume that *Listeria monocytogenes* has similar thermal resistance to *E. coli* O157:H7. Why not use *Listeria monocytogenes* inactivation data? This needs justification.	We acknowledge that data on the D value of *Listeria monocytogenes* is available. However, the amount of thermal inactivation is not just the D value of *Listeria monocytogenes* vs. *E. coli* O157:H7. Heat penetration and the thermal profile within the product ~~is~~ are also very important. We are not aware of data on thermal properties, heating rates, temperatures, and time that would be needed to make such a model. There are several different ways to cook frankfurters, each requiring the aforementioned data plus frequency of cooking method. This approach gave an estimate from a meat product and vegetative bacteria.
~~c~~Cross ~~c~~Contamination	Collect data on handling practices to determine effect of cross contamination	Data on cross contamination were not adequate to put this factor into the model. There is considerable research activity in this area and it may be possible to consider cross contamination in the future.
~~c~~Cross ~~c~~Contamination	Twenty percent of household patient-contacts are asymptomatic *Listeria monocytogenes* carriers; therefore refrigerator items that are positive for *Listeria monocytogenes* does not mean contamination resulted from processing or production failure. Table II-3 implies sporadic cases were caused by foods with *Listeria monocytogenes* found in them, ~~-~~but these data may reflect person to food transmission or cases may reflect person-to-person transmission.	This risk assessment is very strong on the point that proper post-production storage is an important component in preventing listeriosis. The outbreak data ~~o~~are used only to illustrate the widespread occurrence of ~~*Lm*~~*Listeria monocytogenes*; the data are not used in the risk assessment calculations. However, the epidemiological data strongly indicate that listeriosis is predominantly foodborne and not transmitted person-to-person (e.g., physical contact, sneezing, bodily fluids, etc.,).

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~c~~Cross ~~c~~Contamination	One must consider cross-contamination, otherwise uncertainty is high; challenge assumption in exposure assessment that food categories contribute through direct consumption, while epidemiological data suggests cross-contamination plays major role.	It is recognized that the CDC study linking cooked chicken is likely a result of cross contamination. However, only recently has any data that quantitates cross-contamination become available. No data on frequency of cross-contamination or subsequent growth is available that would permit modeling.
Cross-contamination	Illnesses attributed to retail contamination may have resulted from cross-contamination. This possibility invalidates or argues against adjustment of data to retail levels.	The number of cases that result from cross-contamination is unknown. The use of retail data inherently takes into account contamination prior to and within the retail environment. For those food categories where data from production samples were used and adjusted to levels expected at retail, the data would not inherently include the impact of cross-contamination.
~~d~~Data	Use data from the FAO/WHO Exposure Assessment and Hazard Characterization for *Listeria monocytogenes* in ready-to-eat foods. Compare assumptions, approaches and outcomes.	This risk assessment was conducted prior to the FAO/WHO project, even though the latter has become public first. The FAO/WHO assessment was developed for different purposes than the FDA/FSIS assessment; however, the international assessment is largely based on the U.S. evaluation. This includes a high degree of overlap in the exposure data employed.
~~d~~Data, ~~a~~Assumptions	How did agencies treat data from sample sizes smaller than 25 g, particularly for quantitative enumeration studies? How does this affect contamination levels within and between food categories? Risks associated with those foods with the largest number of data points resulting from smaller sample sizes could be under-estimated.	~~Whether a sample was positive or negative in a 25 g vs 10 g sample is not a major factor in the risk assessment.~~The contamination distributions include samples with 10^3 to over 10^6 cfu/g. The difference between 1 cfu/25g and 1 cfu/10g is not a major source of uncertainty.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~d~~Data, ~~c~~Contamination~~,~~ ~~SS~~	Contamination studies used here may be biased and not represent random sampling, e.g., Eklund study (*et al*., 1995) was from smoked seafood plants that were known to have *Listeria monocytogenes* problems. This skews contamination frequency data.	Many studies were available for smoked seafoods. Eklund (*et al*., 1995) is a small part of presence/absence data and represents only a fraction (less than 1%) of the data points comprising the entire data set.
~~d~~Data, ~~r~~Rank	Substantial data uncertainties, data quality issues, and assumptions have significant impact on rankings. Changing data will alter rankings.	The new contamination data and other changes did reduce the uncertainties in this risk assessment compared to the 2001 draft. A risk assessment, just like a subjective judgment, depends on the quality of the data that is available and interpretations may change with additional information. However, this is also transparent by articulating the uncertainty of the measures. This risk assessment does provide additionally evaluations of the differences among the rankings.
Distribution	How does the choice of frequency distribution affect the final outcome?	The choice of the frequency distribution has a big impact on the final outcome. For example, the triphasic uncertainty distributions employed in the 2001 draft risk assessment resulted from the three different frequency distributions used to describe the *Listeria monocytogenes* concentrations. In the 2003 risk assessment, the degree of uncertainty was reduced by the use of lognormal distribution exclusively to describe *Listeria monocytogenes* concentration frequency; however, the range of parameter values employed still expresses considerable uncertainty.
Distribution, Cooking	Uniform instead of triangular distribution should be used for frankfurters consumption data.	A uniform distribution has an emphasis on the extremes. A triangular distribution was used for frankfurters eaten unheated (since there was evidence that there is a central tendency).

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~d~~Distribution, ~~d~~Data	Why was a +/-20% uniform distribution used for the most frequent value and a +/-50% uniform distribution used for maximum value for post-retail storage data?	Like the frequency distributions themselves, ~~T~~the magnitude of the uncertainty~~, as well as~~and the central value~~s~~ are products of consensual judgment. The uncertainty at the maximum value~~e~~ is greater since these values are (by definition) very rare.
Distribution, Model, Uncertainty	This risk assessment did not provide goodness-of-fit for distributions; it is important to provide goodness of fit measure for individual distributions (not just ranking them or giving percentages of use) so that reader can judge uncertainty of individual fits.	Goodness-of-fit statistics are now reported in the Appendix 5.
Distribution, Model, Uncertainty	Parametric distributions used to describe sparse data sets introduce uncertainty; it is important to provide goodness-of-fit measure for individual distributions (not just ranking them or giving percentages of use) so that reader can judge uncertainty of individual fits.	The results in the 2003 risk assessment emphasize the medians along with the 5th and 95th percentiles more than the 2001 draft. As such, this should offer the reader a better perspective on the final uncertainty ranges. Goodness-of-fit statistics are reported in the Appendix 5.
~~d~~Distribution, Storage	This risk assessment used cumulative instead of BetaPert to estimate concentration of *Listeria monocytogenes* in frankfurters after storage time.~~.~~	The distributions currently used for frankfurters are based on USDA and AMI data (the mean comes from the latter, the bounds from the former).
Dose-Response	Table IV-2, there are more data on virulence. Docket copy has references; may require incorporating new data in model, not just revising text.	The mouse data's function was to provide the initial shape and spread for virulence. Studies from three independent laboratories were used to establish the mouse dose response. This distribution is five logs in width and additional data will not change that. The most critical step in the dose-response modeling was to adjust the position of the curve so the calculated contamination matched the CDC's estimates for illness and death.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~d~~Dose~~-~~-~~r~~Response	New data is being generated with transgenic mice that will reduce uncertainty.	Transgenic mouse model has great potential to increase the relevance of mouse oral dosing model to human illness, however this data is not yet available. To date, no testing of a large number of *Listeria monocytogenes* strains from food, outbreak or other sources in this model has been undertaken. Practical consideration for developing the model for large-scale studies would be availability and cost of transgenic mice. Alternatively, use of the guinea pig as a model (e.g., guinea pig shares critical e-cadherin residues for internalin A binding with humans) for oral infection may be more readily available.
~~d~~Dose~~-~~-~~r~~Response	Stillbirth and neonatal infection in human cannot be predicted in mouse model. Use data from the University of Georgia on pregnant rhesus monkeys to adjust mouse data.	The University of Georgia primate study (Smith, *et al*., 2003) funded by FDA has not yet been completed~~.~~, and will include only a relatively small number of monkeys. It is important to note that the mouse model provides only the shape of the dose-response curve and the measure of strain variability.
~~d~~Dose~~-~~-~~r~~Response	Study human cases (epidemiology) of *Listeria monocytogenes* to get dose response data instead of extrapolating animal data; need to get data on humans before doing risk assessment.	There are only two ~~,outbreaks which~~outbreaks where food contamination, consumption, and attack rates are known. (See Appendix 9.) The incomplete data from these outbreaks does suggest that the numbers of *Listeria monocytogenes* consumed were large.
Dose-Response	The lack of data on *Listeria monocytogenes* serotypes results in over-estimation of potential illnesses. Assumption that all serotypes *Listeria monocytogenes* lead to listeriosis over-estimates potential rate illness and contradicts evidence that 3 out of 13 serotypes lead to 90% of food-borne listeriosis.	This risk assessment uses CDC's estimates of illnesses. If only a portion of the *Listeria monocytogenes* strains are causing the illnesses, then this risk assessment underestimates the virulence of those strains. Better knowledge on the virulence of individual strains is clearly needed. More information on the relative frequencies of contamination would also be needed to consider this. The estimates of virulence have uncertainties of two orders of

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		magnitude to allow for strain differences. The rankings of the food categories would probably be unaffected by assuming only some strains cause the illnesses. (See Chapter IV. Hazard Characterization.)
Dose-Response, Assumptions	We agree with this risk assessment that there are not enough data to say whether specific strains cause disease or to change dose-response function.	The comment is appreciated. However, it must be noted that the 2003 risk assessment does explicitly recognize that there is a wide range in virulence among strains.
Dose-Response, Data	Update risk assessment to include new FoodNet data on illnesses.	For the 2003 risk assessment, four years (1998-2001) of FoodNet data were used.
~~d~~Dose~~-~~-~~r~~Response, ~~t~~Transparency	How is the dose-response adjustment factor derived?	The dose-response ~~adjustment~~scaling factor (new name for adjustment factor) is used to adapt the other portions of the model to the annual estimates of listeriosis derived from CDC FoodNet data. ~~intended to compensate for differences between the mouse model, from which the shape of the relative risk distribution is derived, and human illness. It incorporate both the apparent higher susceptibility of normal mice vs normal humans and the multitude of uncertainties associated w/extrapolating from mouse to man. The size of the factor is based on having it produce a predicated number of cases that is equivalent to the FoodNet data. One can observe that the factor decreases dramatically in more susceptible populations.~~

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Dose-Response, Transparency, Model	Information on the algorithms and assumptions used by program to fit dose response with mouse data was limited. Information is needed from FDA and FSIS--that is, more information needs to be provided for readers to use model.	The text of the 2003 risk assessment has been revised extensively and should be more transparent. The CD-ROM version of the risk assessment contains all of the files, which should therefore offer a greater understanding of the model.
Dose-Response, Uncertainty	The adjustment factor for mouse model is so high that it is a great source of uncertainty: mouse model and its relevance to listeriosis is one of greatest sources of uncertainty in this risk assessment.	The dose-response scaling factor (new name for the adjustment factor) is adjusted so that the amount of *Listeria monocytogenes* consumed leads to the number of cases determined by the epidemiological data. While it is acknowledged that there is much uncertainty, the mouse data comprises but a minor part. Additionally, the mouse model is not the only source of uncertainty contributing to the magnitude of the scaling factor.
~~f~~Future	Follow up on high-risk categories and generate product/pathway-specific risk assessments for more effective risk management.	A product/pathway-specific risk assessment was not an objective of this risk assessment. However, c~~This is being considered by the risk managers.~~ontinued attention to high-risk categories as well as the development of product/pathway-specific risk assessments is being considered.~~ The current risk assessment is recognized as a "broad" approach; virtually every part of the risk assessment could be analyzed in greater detail~~
Future	Conduct "process risk assessments" to determine effect of interventions.	The risk assessment design was appropriate for the task given the risk assessors. (See Chapter I. Introduction.) If asked in the future to examine risk reduction strategies for specific foods, then a product pathway analysis would be appropriate.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~f~~Future	The model should be able to perform sensitivity analysis to develop effective risk management strategies.	The complexity and method of calculating the risk assessment do not provide for simple tornado graphs and make traditional sensitivity analyses more difficult. The uncertainty distributions are described. The "what if" scenarios now provide one type of sensitivity analysis. This risk assessment does provide better information needed for broad risk management strategies among food categories whereas risk management choices within individual foods may require additional product pathway analyses. (See Chapter VI. `What If` Scenarios.)
~~f~~Future	Periodically update risk assessment with new data.	A risk assessment uses data available at the time to answer specific questions from the risk manage~~rs.~~ment team. ~~If new data show that previous knowledge was incomplete/incorrect or the risk managers have new/additional questions, the risk managers can request additional risk assessments.~~New and/or additional questions may be posed by FDA or FSIS in the future that would lead to an updating of the risk assessment. New data naturally would be included in such updates.
Growth	Use the American National Standards Institute/National Sanitation Foundation (ANSI/NSF) Standard 75- 2000: Non-potentially Hazardous Foods test to determine if a product can support growth of *Listeria monocytogenes* to dangerous levels (e.g., limit the acceptable level of growth to less than two logs within the product's shelf, or to levels no greater than 100 cfu/g at time of consumption).	A protocol to implement a growth/no growth policy would have to specify the amount of allowable growth and the methods to determine that growth. Whether or not to differentiate between growth and non-growth foods or to allow a specified amount of growth is a risk management policy question and, as such, is not within the scope of this risk assessment.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Growth	How did FDA/FSIS adjust for differences in inoculum levels (from inoculum studies) within and between food categories in order to accurately model post-retail growth?	The assumption is that at the exponential growth rates are independent of the initial inoculum levels. This is generally assumed for modeling and the interpretation of any inoculated pack study. (See Chapter III. Exposure Assessment.)
~~g~~Growth	We agree with FDA/FSIS that modeling refrigeration and storage time distributions independently would be inappropriate. High temperature and long storage time would cause products to spoil and would competitively inhibit *Listeria monocytogenes* growth.	An inverse correlation is included in the modeling to avoid extreme combinations of high temperature and long storage times.
~~g~~Growth	Justify use of square root model to emulate decline, since the model has only been tested for growth.	Many inoculated pack studies in several of the food categories found slow rates of decline in the numbers of *Listeria monocytogenes*. To improve the accuracy of the modeling beyond that of considering "no growth," a simple model for decline was needed that would evaluate the effect of refrigeration temperature and smoothly integrate the samples that had growth with those that had declines. Because the square root mode was used for growth, and a negative parameter value decreased the populations and the model had temperature in the model, it was a logical choice for making an estimate. Previous research has found that rates of decline are faster as the temperature increases (Pathogen Modeling Program), which is what this approach does. (See Chapter III. Exposure Assessment, Modeling: Growth Between Retail and Consumption section.)
~~g~~Growth	Modify Table A5.1.9 to limit maximum growth to 4 log cfu/g at <5°C.	There is literature data cited in Appendix 8 where growth exceeded 4 log at 5°C. For example, Pelroy (*et al*. 1994a) found growth to five logs at 5°C in smoked salmon.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Growth	The growth factor for cooked ready-to-eat crustaceans was inappropriate, and should be lower or none. Cooked ready-to-eat crustaceans are frequently stored on ice, which is also a critical point under HACCP inspection.	This was based on three studies-- all indicating relative rapid growth rates for this food category. The growth that was modeled was for home refrigerator storage, not retail storage, therefore, the impact of storage in ice would not be included in this risk assessment.
~~g~~Growth	Growth rate in fruit is based only upon orange juice serum study. Higher pH foods, different sugar content, and etc., would yield very different growth rates.	Additional ~~D~~data were found, specifically on apple slices. A broad range for variance ~~will be~~was used to encompass the diverse characteristics of fruits.
Growth	The use of deli meats growth for deli salads was not scientifically sound. (Deli meats and deli salads have different pH levels, water activity, and preservatives profiles.) No justification is given beyond absence of deli salad data.	Newly available data on deli salads were incorporated into the 2003 risk assessment, and surrogate data were not used. (See Chapter III. Exposure Assessment, Modeling: Growth Between Retail and Consumption; and Chapter V. Risk Characterization, Food Category: Deli-Type Salads section.) The previous model used deli meats because they are frequently ingredients in deli salads and would provide a microenvironment favorable for growth.
~~g~~Growth	Only used some data from Dillon and Patel (1992); Docket copy references other studies with lower smoked seafood growth rates. Also, some data shows naturally contaminated smoked seafood grows more slowly than where smoked seafood is inoculated.	The data in Dillon and Patel (1992) had only single replicates, and was a very limited data set. We chose the portion of this data set that was considered the most relevant~~We used the~~.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~g~~Growth, ~~a~~Assumption	Data on lag phase and cell viability are essential to valid calculations. Consider these factors in determining growth under various processing, handling, and storage conditions.	The risk assessment does not model the manufacturing ~~process,~~process. The rationale for disregarding the lag phase is discussed in depth in Chapter III. Exposure Assessment.
~~g~~Growth, ~~a~~Assumption	Using only U.S. data for pasteurized milk allows results in dramatic shift of predicted rank. Use of estimated exponential growth rate to determine levels at retail is wrong, leading to per serving risk 4000 times higher than without growth adjustment. Omitting growth rate adjustment changes risk from 10 to 18 per serving and from 3 to 17 per annum.	In the 2003 risk assessment, contamination data sets were weighted for survey size, study date, and country. There is also an extensive new contamination data set for milk. A new approach to modeling the distribution was used that reduced the uncertainties for the extremely high contamination~~s~~ was~~was~~ also employed. Omitting growth rate adjustment changes risk from 10 to 18 per serving and from 3 to 17 per annum is based on an erroneous calculation. The adjusted concentration in milk after 0.25 logs of growth is only 0.07 cfu/g, not 0.7 cfu/g.
~~g~~Growth, ~~a~~Assumptions	The importance of assumptions about growth and the need to estimate *Listeria monocytogenes* levels accurately should be noted in this risk assessment. For example, the way the data was used in this risk assessment may have artificially inflated estimates of concentration levels at retail, for samples collected pre-retail, resulting in artificially inflated risk estimates for certain food categories.	The majority of data used in this risk assessment were from retail samples. When pre-retail data were used, expert opinions were sought on the likely conditions that these products would encounter. The contamination table (Table III-4) indicates what samples were taken pre-retail. Ignoring the potential conditions between manufacture and retail would have inappropriately deflated the values for the limited number of food categories where pre-retail data were considered an important source of information.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~g~~Growth, ~~c~~Categories	This risk assessment fails to consider different growth rates of *Listeria monocytogenes* in foods combined in specific categories. That is, for many categories, disparate foods are combined inappropriately (e.g., roast beef with poultry meats, sprouts and cabbage with vegetables, high pH and low pH fruits, and etc.,).	The food categories do consider product characteristics, for example deli meats vs. dry fermented sausages. There is a limit to the number of categories that can be created considering the complexity of the risk assessment and the need for data for each factor for each food category. Some distributions for growth rates are relatively wide but are determined by the diversity of the growth rates within a category.
~~g~~Growth, ~~c~~Contamination	The Institute of Food Technologist (IFT) report (2000) indicates that cold smoking decreases *Listeria monocytogenes*, contrary to this risk assessment.	This risk assessment is not concerned with changes during processing. Retail surveys show the contamination at retail, and ~~It is not clear what is being referred to in this comment. Changes during manufacture?~~ many studies show ~~*Lm*~~*Listeria monocytogenes* growth during storage of finished product.
Growth, Data	Reference articles observing inflated growth in inoculated pack studies compared to natural contamination of seafood. Advise not to use inoculated data as basis for post-retail growth estimates.	Growth rates are generally independent of contamination levels. There is very little natural contamination data to use. The scientific data employed is provided in Appendix 8.
~~g~~Growth, ~~t~~Transparency	For time and temperature data, how were values interpolated from empirical distributions of the table of percentages in Table III-8?	The home refrigerator data (of Audits International) ~~was~~were used as a histogram, the frequencies in the table were assigned to the average -temperature of that group. For example, 3% of the refrigerators were at 49° F.
~~m~~Management	Knowledge gaps must be filled in before a response plan can be developed.	Unavoidably, knowledge will always have gaps. A risk assessment is intended to get the maximum value from existing data. The uncertainty allows the agencies to determine whether the data is sufficient to support their decisions. HHS and USDA have proposed short and long term initiatives to reduce

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		listeriosis~~.~~, which will be modified as new data becomes available.
~~m~~Management	Labeling should be a new *Listeria monocytogenes* strategy to alert high-risk consumers of potential risk.	This approach is addressed in the~~a draft 2001~~ HHS/USDA report, "Reducing the Risk of *Listeria monocytogenes*: Joint Report to the President." This report is available at: http://www.foodsafety.gov/~dms/lmriplan.html.
Management	The degree of variability and uncertainty should be considered before proposing new regulations based on risk assessment results.	FDA/FSIS agrees that variability and uncertainty should be considered in interpreting and using risk assessments.
Management	Eliminate "zero tolerance" for foods that do not present a risk of listeriosis.	The HHS/USDA report, "Reducing the Risk of *Listeria monocytogenes*: Joint Response to the President," explains the proposed action plans to reduce listeriosis. This report is available at: http://www.foodsafety.gov/~dms/lmriplan.html.
Management	Cite High Pressure Processing as an intervention method to reduce *Listeria monocytogenes* in food.	This risk assessment begins with foods at retail, and an evaluation of the impact of specific intervention methods is outside its scope. Additional risk assessments to evaluate specific interventions such as High Pressure Processing would require product specific pathway analyses.
~~m~~Management	Omit feta cheese from FDA consumer food safety message.	~~We will re-evaluate the~~The consumer messages will be re-evaluated in consideration of the re-organization of cheeses based on moisture content.
Management	Direct efforts to products that support *Listeria monocytogenes* growth. Ice cream and frozen dairy products do not.	The HHS/USDA report, "Reducing the Risk of *Listeria monocytogenes*: Joint Response to the President," explains the proposed action plans to reduce listeriosis. This report is available at: http://www.foodsafety.gov/~dms/lmriplan.html.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Management	Relative rankings have fundamental uncertainties that impede risk management, and they will change with new data and assumptions.	The 2003 risk assessment gives the measurement values and their uncertainties for risks per serving and cases per annum. The rankings are a tool to help communicate these results and it is recognized any ranking procedure looses information. The agencies (FDA and FSIS) have both types of information for their evaluation and use.
~~m~~Management, ~~r~~Risk, ~~r~~Rank	Relative risk ranking does not give details to develop effective control strategies. More data are needed.	Evaluating specific control strategies was not an objective of this risk assessment.
~~m~~Model	Overall, commend the risk assessment.	The comment is appreciated.
~~m~~Model, ~~t~~Transparency	Where there is lack of data, this risk assessment is reasonable, transparent and conservative. It used distributions for key variables, rather than point estimates. It also identified explicitly and quantitatively data variability and uncertainty and areas where critical research was needed. Overall, this risk assessment is transparent and amenable to review and evaluation.	~~No action necessary.~~The comment is appreciated.
~~m~~Modeling	Storage times and temperatures were not estimated for production or retail.	The model does not attempt to model the production process. However, because some samples collected during production were used to estimate *Listeria monocytogenes* concentration at retail -- an adjustment was made to the concentration associated with the prevalence value that was based on estimated growth. The storage times and temperatures used for this adjustment are listed on Tables III-6 and III-7. Foods were assumed to be sampled from retail cases without consideration to their retail storage times or shelf life. The data reflect a random sampling of what is purchased and there is no need to consider growth during retail storage.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~m~~Modeling	Compare current presence/absence approach with a different approach, i.e., estimate prevalence based on the number of positive/negative samples and the concentration based on quantitative levels in positive samples. This would alleviate the need for extra weighting step for data at higher concentration levels. Refer to FAO/WHO Exposure Assessment of *Listeria monocytogenes* in RTE foods.	Different approaches for evaluating the data were considered in this risk assessment. The present approach takes the size of the sample into account in evaluating the implication of prevalence assays on ~~*LM*~~*Listeria monocytogenes* concentration values. The FAO/WHO Exposure Assessment used much of the same data as this risk assessment. (See Chapter III. Exposure Assessment, Food Contamination Data section and Modeling: *L. monocytogenes* Levels in at Retail section.)
~~m~~Modeling	For presence/absence data, how was <0.04 cfu/g treated in the distribution? Which value or distribution was used? (For qualitative studies, if "absence" = 0.04 cfu/g, what value is given to "presence?")	When fitting the distributions, the data are converted to cumulative values (i.e., the fraction of values above or below a particular value is calculated). "Presence is ≥0.04 cfu/g, and "absence" is <0.04. The 0.04 cfu/g value (for 25 g samples) is used to place a prevalence value on a cumulative distribution; it is not a concentration estimate.
~~m~~Modeling	Adjusting data for foods sampled at pre-retail does not consider factors that would impact the level at retail. Also, using post-retail data assumes *Listeria monocytogenes* was present on food at retail, which may not be the case or may be cross-contamination. Reconsider use of adjusted data for retail.	~~We did consider s~~Some data sets were of contamination levels at manufacture. To include them with the majority of the data from retail samples, an adjustment for growth between manufacture and retail was necessary. Representative times and temperatures were chosen based on expert opinion, and a single point adjustment value was determined for each food category. (See Table III-12, and supporting text in Chapter III. Exposure Assessment, Modeling: *L. monocytogenes* Levels in Food at Retail section.)

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Modeling	Do risk assessment for pooled data and compare to non-pooling. Also break some foods out of categories and compare to check grouping effect on risk estimates.	The approach to deriving *Listeria monocytogenes* concentrations has been revised. It would be possible to pool the results of the various studies instead of employing them separately to characterize an uncertainty distribution. Whether or not this is appropriate depends on the willingness to claim that each study reports a sample that is: a) perhaps analogous to the U.S. food supply, or b) partly analogous to the U.S. food supply. This need not be an all or none choice -- some further pooling could be considered without necessarily pooling all the data. This is potentially an analytically intensive project. The initial evaluations of this suggestion indicated that the gains achieved would not justify the degree of analysis required, and would substantially delay the publication of the risk assessment.
Modeling, Contamination	Bin size may give greater influence to points at upper end of distribution.	Since the dose range is much greater than the bin interval, the bin size should not have a greater influence on the upper end of the distribution.
~~o~~Outbreak, ~~d~~Data	CDC data suggests outbreaks are common. Identifying each *Listeria monocytogenes* positive as a separate occurrence implicitly over-estimates the number of events that led to positives (i.e., number of episodes of contamination) and thus overstates risks per annum for some foods.	A small percentage of the total number of cases ~~are~~is associated with outbreaks. Since the assessment targets an annual case rate that represents a four-~~-~~year average, it is only necessary to assume that the distribution represents average (i.e., a 4-~~-~~year average) contamination rates. (See Chapter IV. Hazard Characterization, Dose-Response Adjustment Factor section; and the introduction of Chapter V. Risk Characterization.)
~~o~~Outbreak, ~~d~~Data, ~~a~~Assumption, ~~c~~Contamination	The assumption that contamination distribution is relatively constant is not supportable, considering the outbreak data (e.g., pasteurized milk).	~~Since the~~The assessment targets an annual case rate that represents a four-year average; therefore it is ~~only necessary to~~ assumed that the distribution represents average (i.e., a 4 year average) contamination rates.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		(See Chapter III. Exposure Assessment, Food Contamination Data section.) Also, the predicted per annum risk is not matched with an equivalent U.S. epidemiological record in the 2003 risk assessment. Advanced epidemiologic and scientific investigations are needed to either confirm the predictions of the risk assessment or identify the factors not captured by the current models that would reduce the predicted relative risk.
~~o~~Outbreak, ~~d~~Data, ~~m~~Model, ~~r~~Ranking	Use outbreak data to identify sources of pathogen in the food supply, to validate models and rankings, and to identify attack rate.	~~Because t~~Outbreak investigations are not sufficiently complete to identify all of the source foods, particularly foods more likely to cause sporadic cases.
Risk	Non-reheated frankfurters are not included in the four interpretation/conclusion groups. They, as well as heated frankfurters should be in the "those that warrant identification of new approaches" because of potential, regardless of cooking, and through cross-contamination of other foods in kitchen.	Non-reheated frankfurters are now a separate food category and are given a complete discussion in the text of the risk assessment. (See Chapter III. Exposure Assessment, Modeling: Thermal Inactivation section.) Cross contamination could not be evaluated in this risk assessment because of a lack of information. However, the potential is recognized and is discussed more fully in this risk assessment. Even frankfurters that are reheated could be a source of cross contamination to another food prior to heating.
~~r~~Risk	The risk assessment estimate of smoked seafood in Figure V-1 is inconsistent with CDC findings.	The risk assessment was specifically designed to start with contamination data and product characteristics, and predict risk of listeriosis. The results were then compared against the epidemiological record. Foods such as smoked ~~fish which are manufactured in relatively small lots and infrequently consumed~~fish, which are manufactured in relatively small lots and infrequently consumed, would not cause outbreaks that would be detected. These types of products would lead to sporadic ~~cases which~~cases, which are

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		rarely traceable in epidemiological studies. The limitations in trace back are one of the reasons this risk assessment was conducted.
~~r~~Risk, ~~d~~Data	The risk assessment may over-estimate the risk associated with seafood (e.g., smoked seafood may cause 16 cases per 100 million servings, and 32 annual illnesses), yet no culture confirmed cases in CDC database.	There have been no laboratory confirmed outbreaks involving smoked seafood in the U.S., however, there have been episodes reported internationally. (See Chapter II. Hazard Identification, Outbreak-Associated Listeriosis section, and Table II-5.) Foods such as smoked ~~fish which are manufactured in relatively small lots and infrequently consumed~~fish, which are manufactured in relatively small lots and infrequently consumed, would not cause outbreaks that would be detected. These types of products cause sporadic ~~cases which~~cases, which are rarely traceable in epidemiological studies. The limitations in trace-back are but one of the reasons this risk assessment was conducted.
~~s~~Sensitivity ~~a~~Analysis	Hypothesis testing of grouping foods will elucidate uncertainties and data gaps.	Since the~~re are millions~~ number of potential food groupings is innumerable, ~~this sounds like an endless task.~~consideration of all of them would have made the risk assessment overly complex. The foods were therefore grouped into 23 manageable food categories. However, 'what if' scenarios were tested in the 2003 risk assessment that provided further insight into the relationships between contamination, growth rate, storage temperature, and storage time. (See Chapter VI. `What If` Scenarios.)

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~s~~Sensitivity ~~a~~Analysis	Test the influence of food matrix, packaging, and processing conditions to determine which foods do not support *Listeria monocytogenes* growth.	The~~current model does~~ risk assessment was not intended to model food production. It does indicate, however, the difference between foods that support or do not support growth.
Storage	Either adjust with expert judgment or don't use FSIS and Georgetown data. Preliminary data from survey of callers to FSIS Meat and Poultry Hot Line is unrepresentative because Georgetown survey provided only preliminary data, and the information from the hot line does not reflect the practices of the average consumer. The survey data should be adjusted based on expert judgments and average/mean expiration dates on prepackaged deli meats.	The newly available AMI survey data have been incorporated into this risk assessment. These data are not significantly different from the data provided by FSIS.
Storage	Use the new AMI data to generate new distributions of storage times to model these data.	The new AMI survey data are incorporated into this risk assessment. However, the AMI survey recorded 'average' storage times across households. It therefore dose not represent the distribution of storage times for individual servings.
Storage	The 10-20 day maximum storage time is too long for cooked ready-to-eat crustaceans, especially for cooked lobster and shrimp.	With the shape of the distribution used, only a very few samples would reach these times. Expert opinion indicated that a small percentage of consumers would store these foods for an extended period.
Storage	Consider the likelihood and duration of refrigeration and frozen storage of frankfurters.	New data on the refrigerated storage of frankfurters were included in the risk assessment. Consideration of

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		the percentage of frozen frankfurters was also considered. (See Chapter III. Exposure Assessment, Modeling: Thermal Inactivation section.)
Storage	There is new data on consumer deli meats storage times.	The new AMI data were incorporated into the 2003 risk assessment.
Storage	The 180-day frankfurter storage time is believed to be an outlier.	The AMI data was used as the basis for a revised storage time distribution. This study asked consumers about their "average" storage times, it did not determine the times for individual frankfurters. Outliers do occur at a predictable frequency. This was the extreme example but there was no justification for dismissing the validity of the single data point. However, its impact on the overall distribution is minimal.
Storage	Frankfurter and deli meat storage times are probably under-estimated. The "moderate" time frame is inconsistent with use-by dates, which many customers exceed. The timeframe should be "long."	The moderate vs. long designations on Table V-5a are intended as qualitative aids to understanding the many factors in the risk assessment, and~~,~~ are ~~subjective and~~ arbitrary and based on expert opinion. (See Table III-5 for actual values used.) The designations had no influence on the calculations. Hopefully, ~~a reader would look at~~ the respective tables clearly indicate ~~to see~~ the actual values for any food category ~~they are~~one would be interested in. (The data sets employed are presented in Appendix 8.)
Storage	Before risk assessment can be valid, accurate data describing holding times and temperatures is needed. Use real data on storage times for food in home~~,~~; do not include estimates.	Th~~e~~is risk assessment strived to use~~s~~ the best information or expert opinions available ~~and must be interpreted with that in mind.~~. Considerable effort was expended to get additional information on consumer practices for different food categories prior to developing this risk assessment. An uncertainty value was incorporated into the storage time distributions. (See Chapter III. Exposure Assessment, Growth Data

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		section.)
Storage	New data: queso blanco normally eaten 2-3 days after buying. Queso blanco storage distribution should be minimum: 0.5, mode: 1-5, maximum: 30 days.	In the 2003 risk assessment, the times were adjusted to fit this new data.
~~s~~Storage, ~~a~~Assumptions, ~~s~~Sensitivity ~~a~~Analysis, ~~r~~Rank	Change fresh soft cheese values to mode: 1-5, maximum: less than 30 days. Using indicated values in the storage distribution lowers the estimated per serving risk for the elderly population by a factor of 9. This result shows the impact of a small change in assumptions used by FDA and FSIS, and illustrates the need for an assessment of impact of the uncertainty in each input parameter (on the uncertainty of the derived risk estimates).	Showing that a change in an input will affect the output is no sufficient grounds for either changing or doubting the model. It is still necessary to argue that the input values should be changed -- i.e. the estimates should be shifted or the uncertainty bounds made wider or narrower. This is why an uncertainty analysis is more important than a sensitivity analysis.
Storage, Consumption	Much ready-to-eat seafood is frozen before consumption, which should be taken into account. Some storage time after retail may be frozen (e.g., finfish for sushi, cooked ready-to-eat shrimp), and should be reflected in post retail growth assumptions.	This was factored into frankfurters, but in seafood this could not be carried further for lack of data on amounts stored frozen for each food.
~~sto~~Storage, ~~d~~Data	The per-serving risk in frankfurters in this risk assessment is 27 times higher than when AMI data used. The relative rank changed from 8 to 15 on a per serving basis, and from 4 to 11 on a per annum basis.	The AMI data was used as the basis for a revised storage time distribution. However, this study asked consumers about their "average" storage times, it did not determine the times for individual frankfurters.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~s~~Storage, ~~d~~Data	The most likely storage duration time duration for frankfurters was modeled to be between 5 and 7 days, yet 88% modeled storage durations were longer than 7 days. The mean and median storage durations were 35 and 28 days, respectively.	This illustrates some of the characteristics of skewed distributions. The mean is much affected by a few high ~~values,~~values; this is why the median is usually reported in the risk assessment to describe a distribution. The shape of the distribution is highly uncertain, particularly with the frequencies of longer storage times. The AMI data improved the distribution for frankfurters but there is still considerable uncertainty associated with our knowledge about consumer handling of all ready-to-eat foods.
Storage, Distribution, Temperature	For storage temperature, are the minimum and maximum temperatures the absolute values?	The storage temperature distributions are empirical -- the maximum and minimum values are taken directly from the Audits International data set.
~~s~~Storage, ~~t~~Temperature, ~~m~~Model	Negative correlation between storage time and temperature was intuitively correct, but mathematically arbitrary.	~~Since we are unsure~~There was uncertainty about the nature of the correlation; ~~we~~ therefore ~~employed~~ a simple model with a large uncertainty range was employed.
~~t~~Temperature	Why is T_0 a point estimate and not a distribution? Or is it a distribution? If it is a point estimate, it is inconsistent with other choices.	There could have been a small uncertainty distribution added for T_0 but the different sigmoidal models for the growth rates were a significant source of uncertainty in the estimate of the exponential growth rate.
Transparency	This risk assessment is reasonably transparent to the technical professional.	The comment is appreciated.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Transparency	Establish a mechanism for comments through JIFSAN Risk Analysis Clearinghouse.	Comments should be submitted to the public dockets.
Transparency	There are several inconsistencies in data described in the draft risk assessment. Examples include: inconsistencies in the summary concentration data vs. the published contamination data and the cumulative distributions used; Cortesi *et al*. 1997, gives same frequency at two different concentrations; and text has different numbers for Weibull-Gamma and Beta distributions than the table.	A detailed, critical review of this risk assessment was conducted to eliminate data inconsistency as much as possible.
Transparency	Can model determine which inputs affect the risk estimate the most, and what effect a change would have on predicted illness?	The scenarios that were added to this risk assessment should provide much the requested information. The structure and complexity of this risk assessment did not lend itself to simple sensitivity analyses and tornado plots.
Transparency	There seems to be more certainty in numbers at the high and low ends of the food categories than for the middle rankings. Instead of a numeric rating system, group according to High Risk, Low Risk, and Uncertain.	The 2003 risk assessment focuses more on the actual values and distributions. Hopefully, the uncertainties of the rankings are adequately demonstrated in the latitude graphs. In addition, examples of cluster analyses are provided to provide a potential qualitative grouping of food categories. Rankings, cluster analysis, and use of high/medium/low categories are communication tools.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Transparency	Do not revise the risk rankings; instead focus on risk per-serving and per-annum. As new data comes in and risk assessment is revised over time, revise risks rather than ranks.	Ranking is a communication tool, and, inherently some information is lost when one ranks. In addition to the rankings, the 2003 risk assessment offers the actual values (and uncertainties) for both risks per-serving and cases per-annum more prominently than the 2001 draft.
Transparency	How do you run the programs in the various spreadsheets? How can the outputs from the spreadsheets be linked? How can assumptions be modified? Which default settings can be changed in the spreadsheets? When must changes be made in the software code?	The descriptions in the 2003 risk assessment hopefully are more explicit about how the spreadsheets relate to each other. The modeling software on the JIFSAN clearinghouse website (http://www.foodriskclearinghouse.umd.edu) should be helpful to many people who wish to test different scenarios. Although portions of the previous model were written in Excel worksheet language, the 2003 risk assessment is almost entirely written in Excel Visual Basic for Applications. The worksheets are only used to store parameters inputs and to record the model output. As a result, the model's "user-friendly" software is much easier to follow, but modification requires knowledge of Visual Basic and the Visual Basic Editor.
Transparency	Provide additional explanatory text and instructions for use of this risk assessment (i.e., update and simplify Appendix 6, Software), and create modules that allow the user to look at data for specific foods. Also, create a mechanism for users to offer input on the model by submitting comments and/or data.	The 2003 risk assessment is almost entirely written in Excel Visual Basic for Applications. The worksheets are only used to store parameters inputs and to record the model output. As a result, the model's "user-friendly" software is much easier to follow, but modification requires knowledge of Visual Basic and the Visual Basic Editor. An abbreviated version of the model was placed on the JIFSAN Risk Analysis Clearinghouse website to allow interested parties to test changes of interest to them.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Transparency	Add more sub-results so others can recalculate. Also, clarify quantitative assumptions.	The CD-ROM (new version) contains all data tables. New, "friendlier" software should make process more transparent.
Transparency	Use of unpublished data is unacceptable.	All of the data (published and unpublished) sources are made available in the public dockets and are available for review. Although laboratory data from government laboratories oftentimes are not published, such data were considered appropriate and valid.
Transparency	It is unclear how to run "what if" scenarios.	The 2003 risk assessment includes some 'what-if' scenarios that will help illustrate the interactions of contamination, temperature, time, and growth rate on the rates of illness. A software model that allows scenarios for individual foods has been developed and is available on the JIFSAN clearinghouse website: http://www.foodriskclearinghouse.umd.edu.
~~t~~Transparency	Appendix 5 is in black and white---can't identify which lines correspond to which model.	Some are not clear although the qualitative point being made by the graph is still evident. The electronic version of the risk assessment is in color, and available at www.cfsan.dfa.gov, www.fsis.usda.gov, www.foodsafety.gov, and www.foodriskclearinghouse.umd.edu.
~~t~~Transparency	Charts with ranges of predicted risk per-serving and per annum should be moved to follow Tables V-2 and V-3 since the rankings are not hard numbers.	~~The charts are based upon the data in the tables, therefore the tables should come first.~~ In the 2003 risk assessment, the figures with the predicted risk rankings per serving and per annum follow the corresponding tables containing the median, 5th, and 95th percentiles. (See Tables V-1 and V-3, and Figures V-1 and V-3). The tables for the predicted relative risk ranking per serving and per annum are Tables V-2 and V-4, respectively.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~t~~Transparency	Table A5.1.8 shows N=25, but in Figure A5.1.3 there are 28 data points.	The mean and standard deviation in Table A5.1.8 describes the data in a simple manner; it is not exactly what was used in the modeling. However, the N value and number of points should correspond. Additional data has been added for some food categories and this modeling method has been replaced.
Transparency	Why are there 15 references in Table A5.1.3 but 16 data points in Figure A5.1.2?	Each study can have several points on the graph if that study has more than one quantitative value.
~~t~~Transparency	Figure A5.1.3, p. 47 (also see App. 5, p. 234) shows growth at 5°C. How are other temperatures included in the calculation?	~~While the method is stated, it will be further clarified.~~Individual studies used different storage temperatures. To create the model, the growth rates were calculated for 5°C for all growth curves, which is on Figure A5.1.3. When the modeling requests another storage temperature, the same calculation is used to determine the rate of that temperature.
Transparency	For the data point at cumulative frequency of 0.93 in Figure A 5.1.2, where is the other 7%?	That point on the figure means in one study, 93% of the samples were negative at the specified detection level and 7% were positive.
~~t~~Transparency	Table III-7 and A5.1.8 present the same smoked seafood data, however page 45 states that this mean and standard deviation weren't used, cumulative table of actual data points used instead. Delete Table A5.1.8.	The means and standard deviations ~~are~~were provided for comparison even though the modeling may differ slightly.
Transparency	For smoked seafood, two different sample numbers are given (71 & 309), and two different relative frequencies cited for *Listeria monocytogenes* concentration level of 0.04 cfu/g for Teufel and Bendzulla, 1993 study.	Some studies have more than one data set. Each would have a different fraction of samples positive at the same detection level (0.04 cfu/g)

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Transparency, Data	Clearer explanation of how FDA/FSIS used the data is needed.	The modeling sections have been rewritten and, hopefully, are clearer. Examples have also been added to explain the distribution fitting for contamination. (Refer to Chapter III. Exposure Assessment.)
~~t~~Transparency, ~~d~~Data	The underlying data should be available for review and evaluation.	The 2003 risk assessment includes the contamination tables. (~~s~~See Appendix 7.) All data are available on CD-ROM with the model.~~.~~
Transparency, Distribution	In general, provide more explanation for why certain distributions were chosen (e.g., uniform distribution for storage temperatures). Why use a uniform distribution instead of normal distribution to describe storage temperature?	In the 2003 risk assessment, more extensive explanations are given on why a particular distribution was selected. A histogram of the actual data was used for storage temperature. The data were roughly normally distributed with a mean of 39°F. Generally, uniform distributions were used to describe the degree of uncertainty about a parameter value (most like storage time) that described variation. The adjustment for growth pre-retail was a uniform distribution with a narrow range whose purpose was to estimate a point adjustment value.
Transparency, Model, Distribution	It is not clear how ParamFit derives the parameters of some of the distributions.	The documentation for ParamFit is included in Appendix 6. It is similar to other algorithms that fit equations to data sets that used a series of approximations that get closer to the best values for the parameters with each iteration.
~~t~~Transparency, ~~t~~Temperature, ~~s~~Storage	What are the parameters of uniform distribution (Table III-6)? What were the minimum and maximum storage times?	A uniform distribution is defined by its low and high values, which are given. Every value between the high and low ~~have~~has an equal chance of being selected.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~t~~Transparency, ~~u~~Uncertainty	The uncertainly around numbers and how it affects risk ranking is not clear. How do tables of data relate to numbers actually used in risk assessment, especially with respect to uncertainty about numbers, and how this uncertainty affects the risk ranking?	The uncertainty of the estimated number of cases leads to uncertainty of the rank. The principal ranking reported is based on the median number of cases estimated for each food category.
~~u~~Uncertainty, ~~d~~Distribution	How were the most frequent and maximum values selected?	These values were reached by consensus of the risk assessment team and reviewed by the risk manager team, scientific experts, and advisory committees who are knowledgeable of the products.
~~u~~Uncertainty, ~~d~~Distribution	Why were 20% and 50% chosen in the distributions? Why was a uniform distribution used?	~~The distributions are based on judgment.~~The variation in storage times is largely unknown. The uniform uncertainty ranges are based on expert judgment. Uniform uncertainty reflects a state of minimal knowledge.
~~u~~Uncertainty, ~~d~~Distributions	Please explain potential uncertainty introduced by using fitted distributions.	~~The procedure was changed in the 2003 revised risk assessment;~~Uncertainty, by definition, attempts to quantify what is not known. It is based on expert judgment (of the risk assessors) of the quality of the available data. Text added to the 2003 risk assessment ~~hopefully~~ better describes the process used.
~~u~~Uncertainty, ~~m~~Management	Use uncertainties identified to prioritize new data collection.	The 2001 draft risk assessment was used to determine priorities for the collection of additional data ~~that are described in the research, needs section~~. These new data have been incorporated into the 2003 risk assessment.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
~~u~~Uncertainty, ~~m~~Model	The greatest sources of uncertainty are dose response model and virulence of contaminant strains--can be addressed under dose-response and virulence specific sections.	These uncertainties are described in Chapter IV. Hazard Characterization. Sensitivity analyses were not run to determine which uncertainties made the greatest contribution to the final uncertainties in the risks, because the primary objective of the risk assessment was to compare the food categories. Any uncertainty with the dose-response modeling would be equally applicable to all categories. The level of uncertainty was sufficiently low to allow distinguishing pregnancy related and elderly from the total population.
Uncertainty, Rank	Large differences in uncertainty resulting from scarce and/or incomplete data over-estimates risk of *Listeria monocytogenes* and skews the risk ranking	There are large uncertainties associated with the *L. monocytogenes* concentration characterizations. To some extent, these are represented in the uncertainty analysis. Furthermore, any consistent overestimate in the *L. monocytogenes* concentrations will be counteracted by the dose-response scaling factor. If the uncertainty is large, then there is a possibility that an extreme is "correct."
~~v~~Variance	Compare the outcomes of a probabilistic risk assessment to the outcomes of risk assessments using interval and/or fuzzy arithmetic to decrease variance due to multiplication.	~~Parts of the risk assessment are performed by matrix addition.~~A comparison of the outcomes of a probabilistic risk assessment to the outcomes of risk assessments utilizing interval and/or fuzzy mathematics to minimize variance is an interesting concept. However, FDA/FSIS utilized the most accepted approach to modeling. Multiplying two databases result in a "real" increase in the width of the distribution.
~~v~~Variance	The variance for product of distributions is larger than the variances of the original distributions. What is the practical consequence?	Distributions increase in width when added or multiplied with other distributions. ~~They~~Since combined distributions do not ~~never~~ get smaller~~.~~, this ~~This~~ is a ~~argument~~justification for keeping risk

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
		assessments as simple as possible.
~~v~~Variation, ~~d~~Distribution	Why a one log uniform variation for maximum growth? Why not a normal distribution?	~~The distributions are based on judgment.~~ There were few studies where the maximum growth was clearly determined. Therefore, the minimum knowledge distribution was used.
Virulence	Not all strains of *Listeria monocytogenes* are equally virulent. (Some evidence suggests a frequent finding of low levels of *Listeria monocytogenes* with strains not connected with human outbreaks. Strains may not be as much a risk factor as found infrequently in large amounts or with more pathogenic strains.) In the absence or virulence markers, it is agreed that one must assume all strains have the same potential for causing illness. *Listeria monocytogenes* subtypes differ in ability to cause disease. More research is needed on population-based studies, combined with comparative virulence characterization of different *Listeria monocytogenes* subtypes to ascertain differences in human pathogenicity of subtypes. Studies should include tissue culture models using human and animal cell lines and animal models. Short term changes in risk assessment are not sufficient.	~~The prevalence ratios of illness-causing strains to those in foods suggests that the virulence is not uniform for different strains. The mouse data also show this. However, the contamination date does not indicate which strains are present nor does almost all of the other data. Without methodology to determine the virulence and data collected with this information, it is not possible to incorporate virulence into this risk assessment other than assign an uncertainty range in the dose-response modeling to allow for it.~~Consideration of strain differences based on best available scientific information was an integral part of the dose-response model. (See Chapter IV. Hazard Characterization, Variability in Virulence section.)
~~w~~Weight	Weighting of studies should not only be based on sample size. Quality of data, method, study design, and representativeness should also be considered	Sample size is a well-established and accepted criterion for weighting. In the 2003 risk assessment, ~~we weighted~~ the contamination studies were weighted by sample size, country of origin, and study date.

Topic Areas	Public Comment: 2001 Draft Risk Assessment	FDA/FSIS's Response
Weight	Why use 54% times 1% instead of 50% times 1% for unpasteurized milk.	28 out of 52 jurisdictions permit unpasteurized milk, thus, 54%. However, the assessment does round to a figure of 0.5% to calculate raw milk consumption from the total.
~~w~~Weight, ~~d~~Data, ~~c~~Contamination	Giving greater weight to higher percentiles gives more weight to less precise studies or gives undue importance to some data points.	The consequence of not weighting high doses is to generally flatten the curves (i.e., predict higher *L*~~.~~*isteria monocytogenes* levels in samples) because the algorithm is dominated by the greater preponderance of studies at the 0.04 cfu/g level. However, the dose-weighting algorithm is not necessary or used in the procedures employed in this risk assessment to characterized *Listeria monocytogenes* concentration at retail. Knowledge about the frequency of high levels of *Listeria monocytogenes* is more uncertain than about the percent positive samples, but these are where the cases of listeriosis come from. This is a tail-driven risk assessment. Further, the approach to modifying contamination was changed to provide more stability, however 100,000 variation iterations and 300 uncertainty iterations were used. The NFPA data did show that high levels of contamination do occur at very low frequency. (See Chapter V. Risk Characterization, Simulation Modeling section.)

Appendix 3:

An overview of the FDA/FSIS Risk Assessment

Overview of the Risk Assessment

The FDA/FSIS *Listeria monocytogenes* risk assessment organizes currently available information on listeriosis. It was designed to examine broad groups of foods most likely to cause listeriosis; it does not determine whether a food category is 'safe.' We did not model the source or process of contamination of the food, but did include expected growth between retail and consumption. For frankfurters that are usually heated before consumption, the reheating step was modeled, to allow for those occasions where the food is not adequately heated to kill all microorganisms. The model provided a baseline or description of our best prediction of the role the selected foods play in the threat from listeriosis in the United States. The model did not attempt to evaluate any mitigations that might be imposed during the manufacturing of any specific foods to reduce the risk from listeriosis; this could be the objective of a subsequent risk assessment. However, this risk assessment model was used to estimate the likely impact of intervention strategies by changing one or more input parameters and measuring the change in the model outputs. These changes to the model, which are commonly referred to as 'what if' scenarios, can be used to test the likely impact of new or different processing parameters or regulatory actions. These 'what if' scenarios can also be hypothetical, not necessarily reflecting achievable changes but designed instead to show how different components of the complex model interact.

Another objective of this risk assessment was to collect information on the dose-response relationship and develop a model to estimate the likelihood of listeriosis from consuming specific numbers of *L. monocytogenes*.

This risk assessment provides an estimate of the degree of certainty associated with the data. To accomplish this, we used distributions of the data so that real differences that exist for an individual parameter would be represented instead of using point estimates or means. Contamination levels in different samples, amount consumed per servings, *L. monocytogenes* growth rates for foods within a group and lengths of storage time by the consumer are data that were considered in the model as distributions.

The risk assessment presents the scientific information, both what is known and the degree of certainty. Although the risk assessment uses the best data available, one of the important roles of the risk assessment is to determine critical absences of adequate data that drive the uncertainty in the overall risk assessment. Thus, risk assessment can be used as a link between risk management and research. Risk managers should consider uncertainty when evaluating the significance of a parameter. In some instances, uncertainty may be too large to allow making inferences from the risk assessment. The risk assessment does not impose a judgement or make value decisions based upon the information, that is the role for risk management.

Model Design: The Inferential Structure of the *Listeria monocytogenes* Risk Assessment

The overall structure of the exposure assessment and dose-response models are depicted in figures A3-1 and A3-2, respectively.

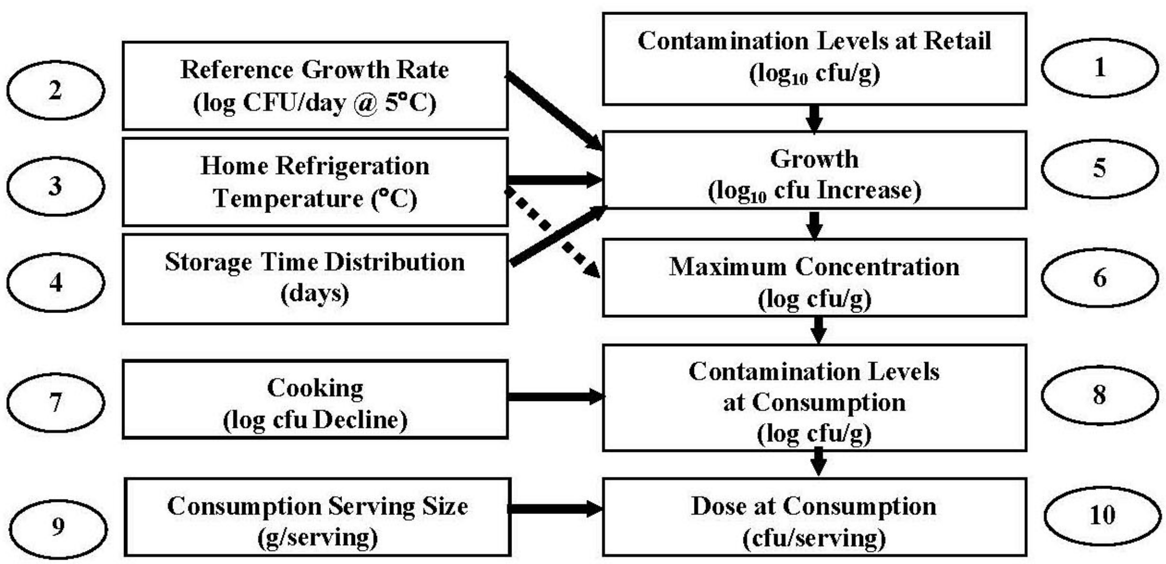

Figure A3-1. Flow chart of *Listeria monocytogenes* risk assessment model for individual exposure components. This part of the model was integrated with a two-dimensional simulation where one dimension characterized the variability among meals, while the second dimension characterized the uncertainty in the prediction. A different simulation was performed for each of the 23 food categories.

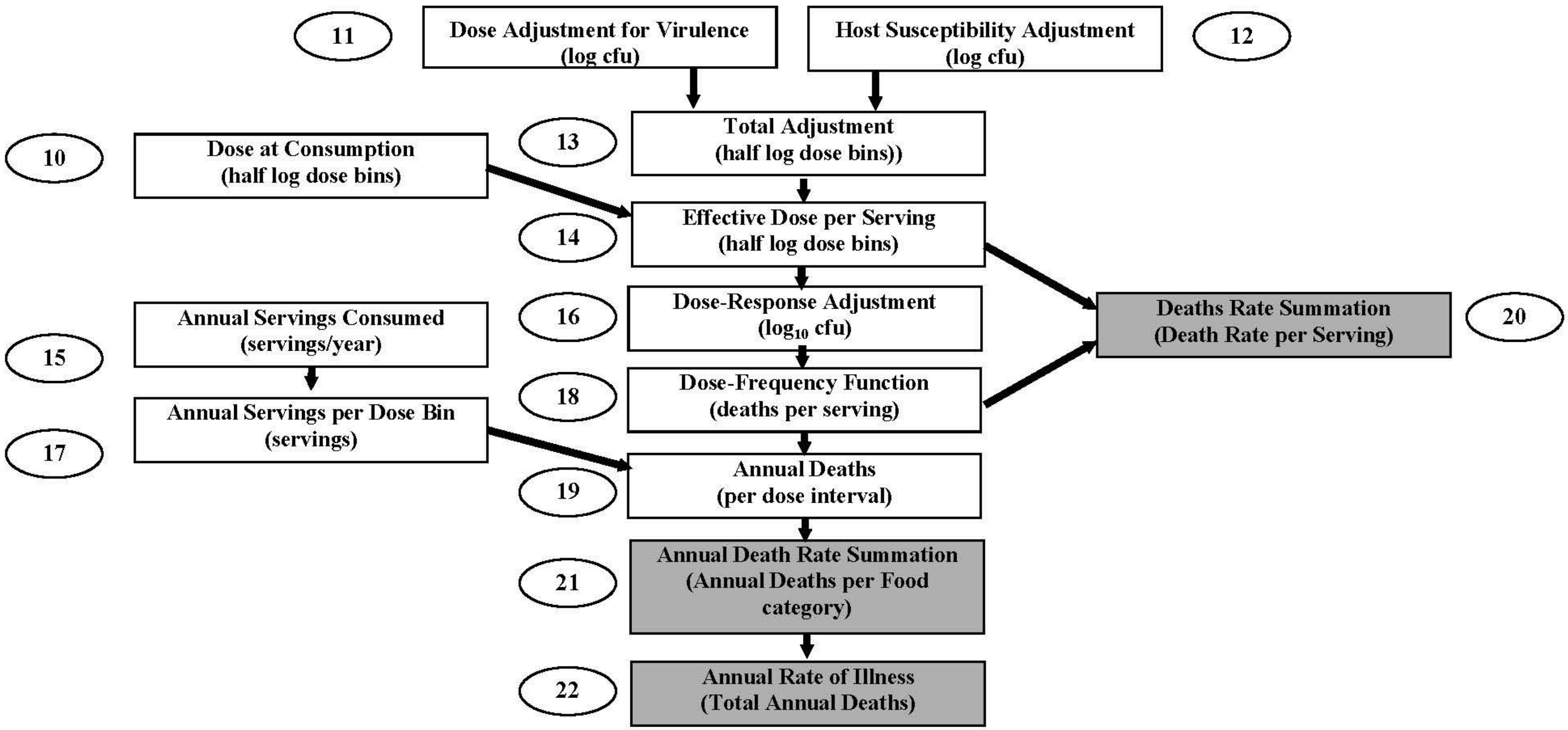

Figure A3-2. Flowchart of *Listeria monocytogenes* risk assessment calculation of population estimates. This part of the model was integrated with a one-dimensional Monte-Carlo, where the single dimension represents uncertainty. The subpopulations were modeled separately. The outputs of the model that appear in the hazard characterization steps are in dark gray boxes.

Description of Calculations for Each Step in the Model

Figures A3-1 and A3-2 show the flow of the calculations used in the risk assessment.

Step 1. Distributions for contamination at retail for each food category.

Step 2. Distributions for the reference growth rate at 5°C for each food category.

Step 3. A distribution of home refrigerator temperatures in the United States- the same distribution was used for all food categories.

Step 4. Distributions for post-retail storage time for each food category.

Step 5. A growth model used for all food categories but was triggered only for servings with one or more bacterium. In this module, the exponential growth rate for the refrigeration temperature was calculated and multiplied by the storage time. The parameters included in the growth model were specific to the characteristics of the foods in each food category.

Step 6. The maximum concentration for each food category. Post growth *L. monocytogenes* concentrations were truncated at this level. The maximum growth was temperature dependent with more growth allowed at higher refrigeration temperatures.

Step 7. A model representing the effect of reheating frankfurters on *L. monocytogenes* concentration, used for frankfurters only.

Step 8. Net contamination at time of consumption. Calculated with inputs from steps 1, 6, and 7.

Step 9. Distributions of serving size for each food category.

Step 10. Distributions of dose at consumption for each food category. This is the final output of the 2D simulation. After collapsing the variability dimension to half-log dose bins, the output for each food category was conveyed to the 1D dose-response simulation for each population group.

Step 11. A distribution for variability of *L. monocytogenes* strain virulences in mice, with the implicit assumption that a similar range will be observed in humans.

Step 12. A distribution adjusting for variability in host susceptibility among humans, with three (High, Medium, Low) separate adjustments applied to represent different possible ranges. The adjustment increased the range of effective doses.

Step 13. The sum of the strain variability (step 11) and host susceptibility distributions (step 12) obtained by 2D Monte-Carlo, with 100,000 variability iterations and 300 uncertainty iterations. The variability dimension was then collapsed to half log dose bins.

Step 14. Summation of the exposure assessment (step 10) and adjustment factor (step 13) for each food category

Step 15. The annual number of meals consumed for each food category.

Step 16. Addition of the dose-response adjustment factor that is applied to make the predictions consistent with CDC estimates of the annual death rate attributable to the population group. For baseline calculations this value was recalculated for every uncertainty iteration. For subsequent evaluations (i.e. intervention analysis) the values established for each iteration for the baseline were retained.

Step 17. An intermediate calculation of the number of annual servings falling in each dose bin for each food category. This was obtained by multiplying the number of servings (step 15) by the fraction falling in each effective dose bin (step 14).

Step 18. Calculation of the death rate per serving for each dose bin (from step 14), using the dose-response function derived from mouse data.

Step 19. An intermediate calculation of the number of annual deaths for each dose bin and food category. This was obtained by multiplying the death rate per serving (step 18) by the number of servings for the dose bin (step 17).

Step 20. Calculation of the death rate per serving for each food category by summing across dose bins. This was obtained by summing the product of the death rate (step 18) and serving fraction (step 14) across all bins.

Step 21. Calculation of the annual number of deaths for each food category by summing across dose bins (step 19).

Step 22. Calculation of the total number of deaths by summing across food categories.

A Risk Assessment Framework

A risk assessment framework separates the assessment activities into four components; hazard identification, exposure assessment, dose-response assessment (hazard characterization), and risk characterization. This framework allows organization of a highly complex array of varied data, characterization of the predicted consequences, definition of uncertainties, and identification of data gaps.

Hazard Identification

Hazard Identification is one interface between risk assessment and risk management where the problems that the assessment is intended to address are identified and specific questions about model design are resolved. Endpoints in this assessment include death and serious illness for the intermediate-age subpopulation and two readily identifiable vulnerable subpopulations: perinates (fetuses and newborns) and the elderly (60 years of age and older).

Exposure Assessment

Exposure related to foodborne *L. monocytogenes* consumption can be separated into two main subcategories: pathways of contamination and frequency of consumption of contaminated foods. This risk assessment did not consider the pathway of contamination or any events occurring prior to retail. The exposure assessment emphasized modeling foods that have a potential for *L. monocytogenes* contamination at retail. The development of the exposure assessment included:

- Identification of ready-to-eat foods that are known to have been associated with *L. monocytogenes* from outbreaks, sporadic cases, and national and international recalls and other sources. Foods with a history of *L. monocytogenes* concentration were also evaluated.
- Food categories, grouped according to primary origin, epidemiological and surveillance experience, processing operations and food characteristics, and the availability of consumption and contamination data or useable proxy data.

- Development of distributions of the amount consumed per serving for each food category and estimates of the annual number of servings in U.S. using national food consumption surveys and other food consumption and census information.
- Calculation of distributions of contamination levels at retail for each food category, based on published studies of naturally-occurring *L. monocytogenes* contamination. For contamination data of foods after manufacture, growth to the retail store was estimated.
- Modeling of data to describe the opportunity for growth, decline, or inactivation of *L. monocytogenes* between the time that a food was purchased and the time it was consumed.
- Development of a mathematical model to represent reheating of frankfurters in the home. Normally a cooking or reheating step will kill vegetative microorganisms.
- Derivation of distributions of contamination levels at consumption for each food category, based on initial *L. monocytogenes* contamination, growth potential, storage duration, refrigeration temperatures and reheating.
- Derivation of estimates of the frequencies and levels of contamination of a serving, by combining distributions of food consumption frequency and amount with distributions of food contamination frequency and levels.
- Because of a lack of data, foods prepared outside the home were not modeled separately. The food consumption survey data included all eating occasions within and outside the home. It was therefore assumed that contamination at retail, refrigeration temperature, and storage times included the meals served or prepared outside of the home (restaurant and food service meals).

Hazard Characterization

For *L. monocytogenes*, the overall incidence of severe illness, and predicted relative risk to age-related susceptible subpopulations are well characterized. The relation between the amount of *L. monocytogenes* consumed (dose) and the likelihood or severity of resultant illness from that dose (response) is not well understood. The dose-response effect is a complex function of the number of pathogens consumed, their level of expressed virulence, the food matrix that the pathogen is in, and the susceptibility and immunity of the human host.

For this *L. monocytogenes* risk assessment the following information was considered:

- Accumulating epidemiological information indicates that different strains of *L. monocytogenes* vary in their ability to cause illness. Data were utilized from animal studies that compare the virulence of *L. monocytogenes* strains isolated from humans and from foods in order to describe the distribution of virulence among strains encountered in foods.
- Immunological and physiological factors in humans determine the distribution of susceptibility that may be found throughout a population.
- Food matrix effects have been theorized to affect the ability of a pathogen to survive inside the body (*e.g.*, the fat content of foods appears to affect the infectious dose of *Salmonella* sp.). Quantitative data specifically related to *L. monocytogenes* in humans were not available.
- Epidemiological data with the number of deaths in each population per year and the ratio of serious illness/deaths.

The probability of illness in three different subpopulations of consumers is described; perinatal (with exposure occurring *in utero* from foodborne infection of the mother during pregnancy); elderly (60 years of age and older); and intermediate-age subpopulation, which includes both healthy and immunocompromised individuals (but excludes the other two subpopulations). A host susceptibility adjustment was applied to each of the three subpopulation curves. The adjustments used animal data to establish a susceptibility range and human epidemiological surveillance data to adjust for increased susceptibility of these subpopulations.

Risk Characterization

Risk characterization integrates the distributions generated in the exposure assessment and the hazard characterization. The published literature provides an estimate of the number of illnesses and deaths attributed to *L. monocytogenes*. Therefore, the primary component of this risk characterization is a probabilistic estimate of the likelihood of illness from consumption of contaminated food from each of the 23 food categories.

The risk characterization section of this risk assessment provides the results of the assessment, and the associated uncertainty around those results. Additionally, data gaps, which, if filled, would contribute to reducing the uncertainty in the assessment, are identified to highlight critical needs for additional research.

Characteristics of Monte-Carlo Simulations Used in Risk Assessment

Monte-Carlo simulations are an integral part of most quantitative risk assessments. They include repetitive calculations with minor variations and are made possible by the development of the computer.

The exposure assessment portion (see Figure A3-1) of this risk assessment model employs a two-dimensional Monte-Carlo simulation. One dimension represents variations associated with the capacity of individual servings of food to cause listeriosis. Sources of variation modeled include *L. monocytogenes* concentration at the retail level, amount consumed per serving, microbial growth rates, product storage times and temperatures, strain virulence, and host susceptibility. The second dimension represents the uncertainty in the predictions made. This is described more fully below.

The dose-response portion (see Figure A3-2) of the risk assessment employ a one-dimensional Monte-Carlo simulation, where the range of predicted values represent uncertainty only. In this part of the assessment, the U.S. population is modeled as a whole, beginning with the estimate of the fraction of servings falling in particular dose ranges from the first part of the risk assessment.

The results of the FDA/FSIS *L. monocytogenes* risk assessment are based on statistical calculations. Thus the parameters modeled by this risk assessment are represented by distributions of values. These distributions represent either the known variation or uncertainty about a quantitative value. As a result, instead of using deterministic calculations (adding or multiplying single values, usually means), this risk assessment uses simulation modeling techniques, i.e., Monte Carlo modeling, to make its calculations. In this technique, the model is repeatedly calculated and in each iteration the process picks a new value from each of the distributions. This means that there is not a single answer to the calculation; instead, a distribution of calculated values is generated.

Mathematical calculations with distributions do not always form simple symmetrical normal distributions. Many distributions are asymmetrically skewed with long tails on one side. When any two independent distributions are added the resulting distribution has a larger variance than either original distribution, and may not be of the same shape as either of the original distributions. When distributions are multiplied, skewed distributions often result with a tail extending toward larger values. The magnitude of the variance for the product of two distributions is typically larger than the variances of the original distributions. The practical effect of this is that multi-step calculations have increasingly wider output distributions. This occurs whether the distribution describes variation or uncertainty.

A skewed distribution does not have the same value for the mean and the median (half of the values above and half are below that value) as does the normal distribution. In extremely skewed distributions, the median is frequently considered a better parameter than the mean to represent the distribution, because it is not as affected by extreme values as the mean. However, summing the median values for two or more distributions does not equal the median of the summed distributions.

Variability

Variability is real variation in the individual members of a population or system with which a decision-maker is concerned. It cannot be eliminated by improved measurement technique. It is information the decision-maker needs. A distribution describing variability describes the frequency of occurrence.

When statistical distributions are used, the distinction between variability and uncertainty is in some circumstances contextual, and depends on the question which is being answered. Variability which is present in the experiment that is not also present in the real world circumstances with which the decision-maker is concerned is a source of uncertainty. Uncertainty reflects imperfections in our knowledge about what is real. It can be reduced through additional research. Although, the decision-maker should want to know the extent of the uncertainty associated with a calculation, he/she would prefer not to have it. A distribution describing uncertainty describes the likelihood or expectation of occurrence. There is often very little basis for segregating true variability from experimental error, where the former is expected to be reproduced in the problem at hand, while the latter is not. The extent of the variability is quite often itself a source of uncertainty.

Adaptation of a Monte-Carlo simulation process to provide for separate accounting of both variability and uncertainty requires modification of both the front and back ends of the procedure. The descriptive statistics used to describe the variance for each of the data sets must have separate distributions for each source. The output from the iteration collection procedure must have two dimensions: one for variability, and one for uncertainty.

The technique known as two-dimensional Monte-Carlo is simply a simulation of simulations, in which one simulation is nested inside the other. The two-dimensional collection routine proceeds by collecting the results of a specified number of uncertainty iterations, each of which consists of a specified number of population iterations. Each of the two-dimensional functions has one or more random elements which are identified as either uncertainty or variability terms. The random terms identified as arising as a result of variability are varied after each iteration, while those identified as uncertainty terms are reset only at the start of each uncertainty iteration (i. e., at the conclusion of an entire population simulation). This procedure is very calculation intensive.

Running a Monte-Carlo simulation where variability and uncertainty are distinguished allows model selection to be included as a source of uncertainty. In order to simulate model uncertainty, a probability tree may be used which distributes the use of two or more models as a source of uncertainty. Which model is used for a given uncertainty iteration (an entire population simulation) can vary randomly. The frequency of use may be varied by how well the model fits. This will ensure that the uncertainty contributed by model selection is reflected in the final analysis. Monte-Carlo is not a cure for not having data, nor does it require any more data than would otherwise be needed. It is simply a better way of a) retaining information regarding variability in an analysis, and b) retaining quantitative descriptions of the degree of uncertainty. If this is not done, the end result will appear less variable and more certain than it should.

Appendix 4:

The Foodborne Diseases Active Surveillance Network

Appendix 4: The Foodborne Diseases Active Surveillance Network

The Foodborne Diseases Active Surveillance Network (FoodNet) is a collaborative project of the CDC, nine Emerging Infections Program sites (California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon and Tennessee), the Food Safety and inspection Service (FSIS), and the Food and Drug Administration (FDA). The project consists of active surveillance for foodborne diseases and related epidemiological studies designed to help public health officials better understand the epidemiology of foodborne diseases in the United States.

Foodborne diseases include infections caused by bacteria such as *Salmonella, Shigella, Campylobacter, Escherichia coli* O157, *Listeria monocytogenes, Yersinia enterocolitica,* and *Vibrio*, and parasites such as *Cryptosporidium* and *Cyclospora*. In 1995, FoodNet surveillance began in five locations: California, Connecticut, Georgia, Minnesota and Oregon. Each year the surveillance area, or catchment, has expanded, with the inclusion of additional counties or additional sites (New York and Maryland in 1998, Tennessee in 2000 and Colorado in 2001). The total population of the current catchment is 30.5 million persons, or 10% of the United States population.

FoodNet provides a network for responding to new and emerging foodborne diseases of national importance, monitoring the burden of foodborne diseases, and identifying the sources of specific foodborne diseases.

The mission of FoodNet is to contribute to the prevention of illness, disability, and death due to foodborne and diarrheal diseases by providing high-quality surveillance data. These data help determine the burden of foodborne diseases, monitor changes in the incidence of specific foodborne diseases in the United States, determine the proportion of specific foodborne diseases attributable to specific foods, and contribute to a network designed to respond rapidly to emerging foodborne diseases. FoodNet accomplishes its mission through active surveillance of laboratory-confirmed cases, laboratory studies, epidemiologic studies focused on specific infections, other epidemiologic studies, and investigations of outbreaks of foodborne diseases.

Appendix 5:
Food Categories Modeled Distributions and Related Information

Appendix 5:
Food Categories Modeled Distributions and Related Information

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Appendix 5: Food Categories Modeled Distributions and Related Information

1. Smoked Seafood Food Category

Consumption

Table A5.1.1. Foods Included in Consumption Data Set

Food Code	Food
26100190	Fish, smoked
26119190	Herring, smoked, kippered
26137190	Salmon, smoked
26151190	Trout, smoked
26315190	Oysters, smoked

Source Survey: CSFII

Figure A5.1.1. Cumulative Distribution for the Serving Size

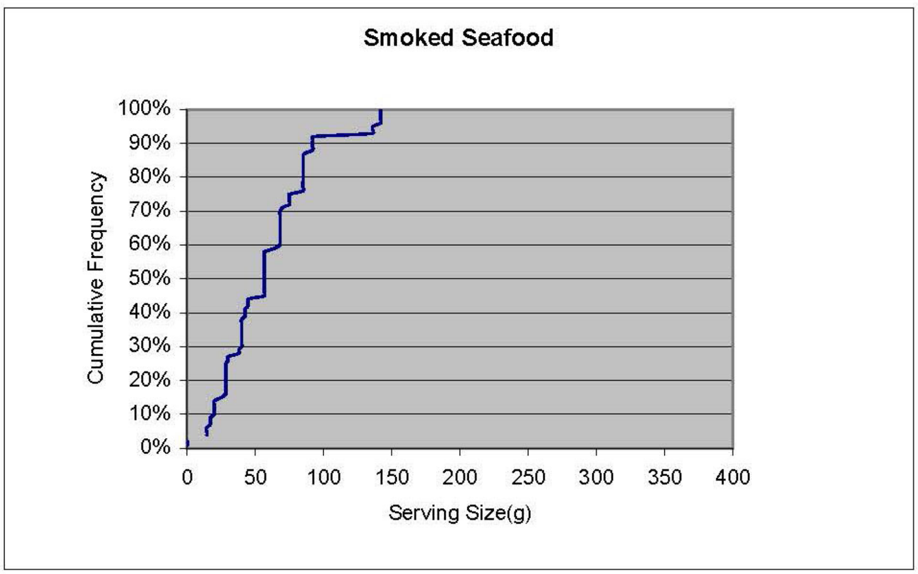

Table A5.1.2. Frequency Distribution for Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	
57	75	136	142

Contamination at Retail

Table A5.1.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Coalfish, smoked
Cod, smoked
Cold vacuum-packed, smoked
Fin fish, cold smoked
Fin fish, hot smoked
Finfish, hot/cold smoked
Fish, cold smoked
Fish, hot smoked
Halibut, cold, smoked
Halibut, smoked
Herring, smoked
Mussels, smoked
Mussels-frozen, smoked
Oysters, smoked
Salmon fresh, smoked
Salmon, cold smoked
Salmon, smoked
Seafood, smoked
Shad, smoked
Snapper, smoked
Sockeye, smoked
Sturgeon, smoked
Trout, smoked
Tuna, smoked

Post Retail Growth

Table A5.1.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Cod, cold smoked
Salmon, cold smoked
Salmon, smoked
Trout, hot smoked

Table A5.1.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	3 to 5	15 to 30

Figure A5.1.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C

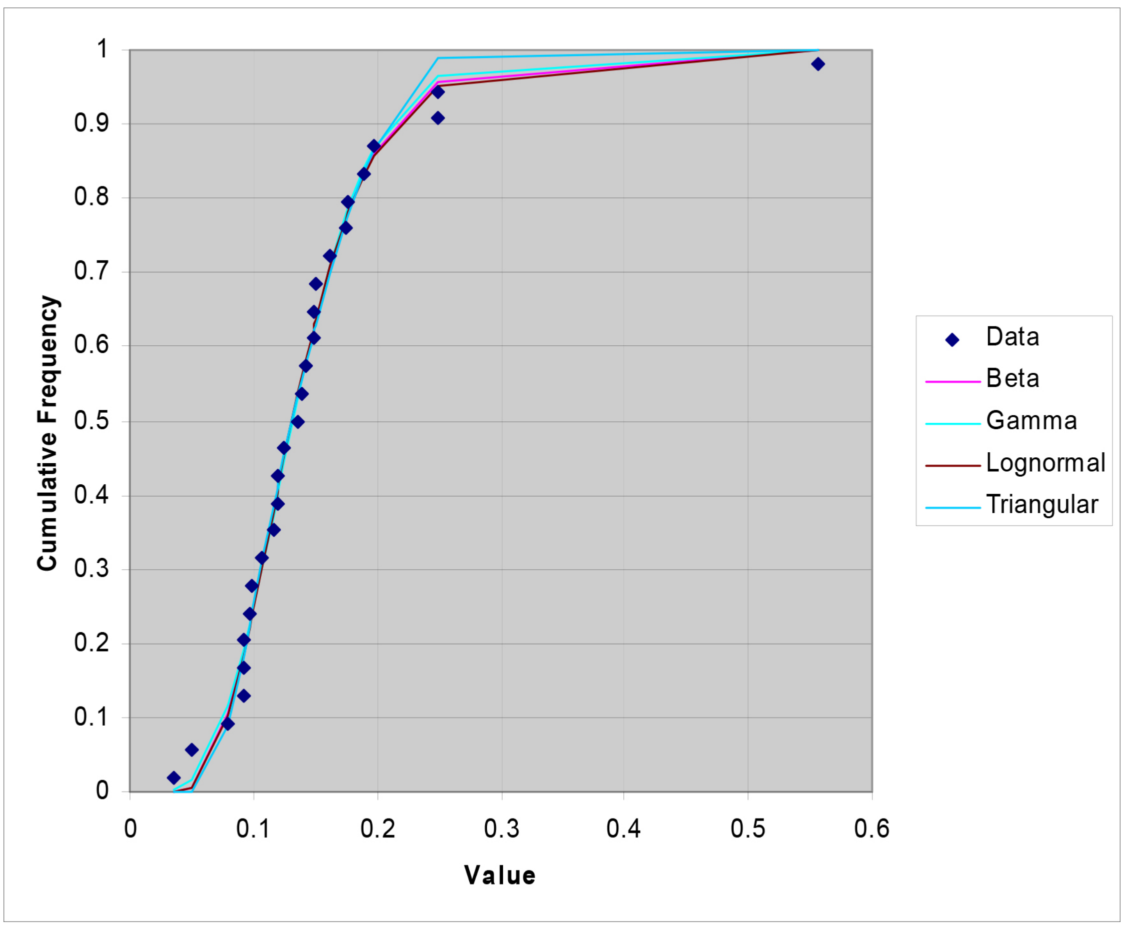

Table A5.1.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Lognormal	-2.03325	0.389008			0.018	0.40
Gamma	6.91	0.020056			0.020	0.31
Beta	3.742776	10550.12	0.03465	298.2289	0.019	0.16
Triangular	0.0519	0.0930	0.269635		0.026	0.13

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.1.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
0.150	0.96	27

Table A5.1.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth ($\log_{10}$ cfu/g)	5	6.5	8

2. Raw Seafood Food Category

Consumption

Table A5.2.1. Foods Included in Consumption Data Set

Food Code	Food
26115000	Flounder, raw
26131100	Pompano, raw
26153100	Tuna, fresh, raw
26211100	Roe, sturgeon
26213100	Squid, raw
26315100	Oysters, raw
58151130	Sushi, with vegetables and fish
Source Survey:	**NHANES III**

Figure A5.2.1. Cumulative Distribution for the Serving Size

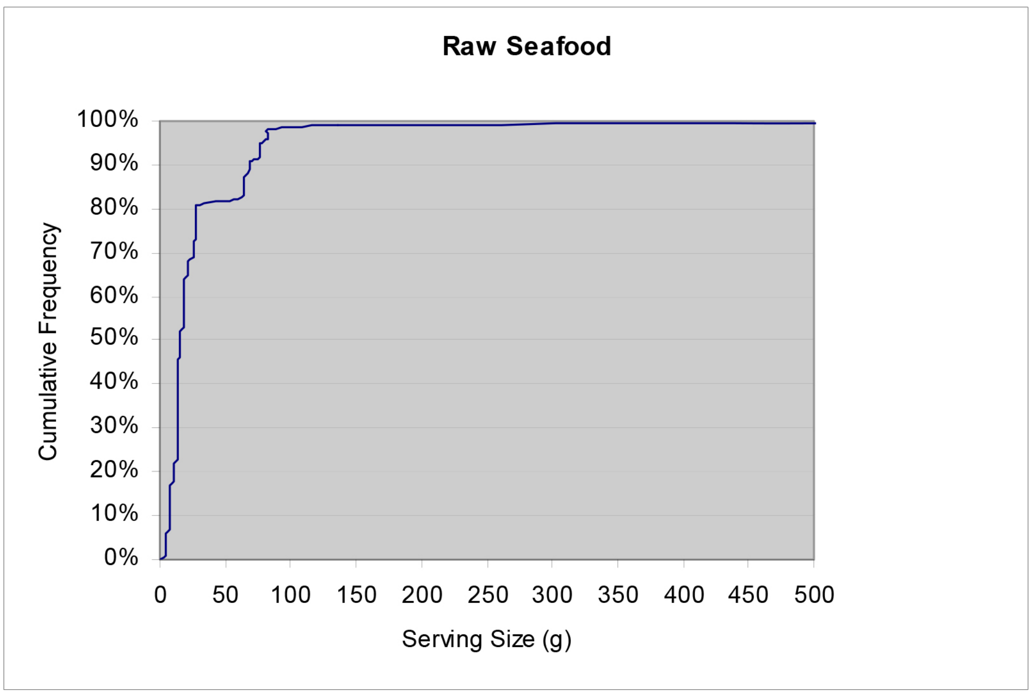

Table A5.2.2. Frequency Distribution for Amount Consumed per Serving

Percentiles (grams per serving)			
50th	**75th**	**95th**	**99th**
16	28	77	136

Contamination at Retail

Table A5.2.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Anchovy
Blue crab meat
Bombay Duck-fish
Butterfish
Catfish, fresh[a]
Clam, fresh
Clam, raw
Coalfish fillet
Cod
Cod Fillet
Coquina, fresh
Crab[a]
Crabmeat/scallops[a]
Crustacean/shellfish
Cut raw salmon
Doma-local fish
Fin fish & non-fin fish
Fin fish, fresh
Fin fish, frozen
Fin fish, minced
Fin fish/shellfish
Finfish, aquaculture
Finfish, raw
Finfish, tropical
Fish
Fish & fish parts
Fish & fish products
Fish & non-fish, local frozen and refrigerated
Fish cakes, fingers[a]
Fish, fresh
Fish, frozen
Fish, other
Fish, raw
Fish, salt, sushi
Fish, sushi
Frozen herring
Golden anchovy
Hake, raw
Halibut
Indian salmon
Lobster tail, frozen[a]
Mackerel
Mollusks, bivalve, mussels
Mussels, depurated
Mussels, fresh

Mussels, predepuration
Non-oyster shellfish
Ocean cats fillets
Other
Oysters, fresh
Oysters, frozen
Oysters, live
Oysters, raw
Oysters, uncooked
Perch
Plaice/raw food
Pom fret
Prawn, raw, 'sushi'
Rainbow trout
Raw fish & shrimp
Raw halibut
Raw octopus, squid, trepang
Raw salmon (fillets) surfaces
Raw salmon (whole) surfaces
Raw salmon surfaces
Raw seafood
Raw surimi
Ready-to-eat seafood
Rock fish
Roe
Sable
Salmon
Salmon, raw
Salmon/raw seafood
Sardine/raw seafood
Scallops, raw[a]
Scallops, frozen[a]
Shellfish/raw
Shell fish
Shellfish, raw
Shellfish, tropical
Shrimp[a]
Shrimp raw[a]
Shrimp, frozen[a]
Shrimp, live
Shrimp, raw
Shrimp, raw, fresh
Shrimp, raw, frozen[a]
Shrimp, retail
Shrimp, raw/process[a]
Shrimp-imported frozen
Snapper
Sole
Sole, raw
Squid, langostinos, frozen
Surimi and minced seafood

Squirmy, crab[a]
Surimi, etc
Surimi, frozen[a]
Sushi-with and without rice
Thread fin
Trout, fresh
Trout/raw seafood
Tuna
Tuna, minced, sushi
Turbot fillets

[a] These foods are not generally eaten raw, but contamination data for these foods are likely to reflect contamination levels in seafoods that are consumed raw.

Post Retail Growth

Table A5.2.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Catfish, raw
Crab, raw
Fin fish, raw
Oysters, raw
Shrimp, raw
Surimi
Trout, raw
Whitefish, raw

Table A5.2.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	1 to 2	10 to 20

Figure A5.2.2. Cumulative Distribution for the Reference Exponential Growth Rates (EGR) at 5 °C

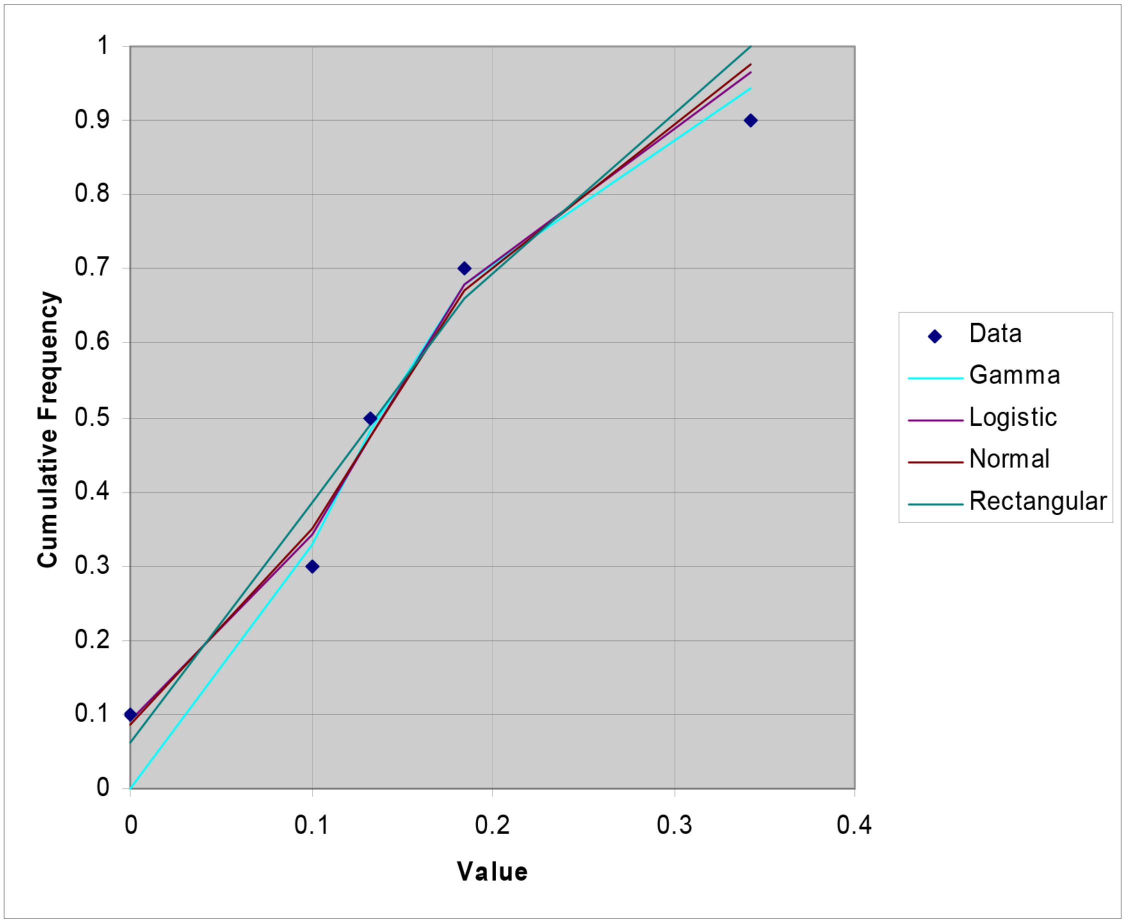

Table A5.2.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	RSQ	Probability
Logistic	.139	.0606	0.007	0.37
Normal	0.139624	0.102976	0.010	0.26
Rectangular	-0.01953	0.290551	0.020	0.22
Gamma	2.44	0.064856	0.013	0.16

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.2.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5°C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
0.152	0.126	5

Table A5.2.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth (log $_{10}$ cfu/g)	5	6.5	8

3. Preserved Fish Food Category

Consumption

Table A5.3.1. Foods Included in Consumption Data Set

Food Code	Food
26100170	Fish, not specified as to type, dried
26109180	Cod, dried, salted, salt removed in water
26119180	Herring, pickled
27151030	Marinated fish (Ceviche)
Source Survey:	**NHANES III**

Figure A5.3.1. Cumulative Distribution for the the Serving Size

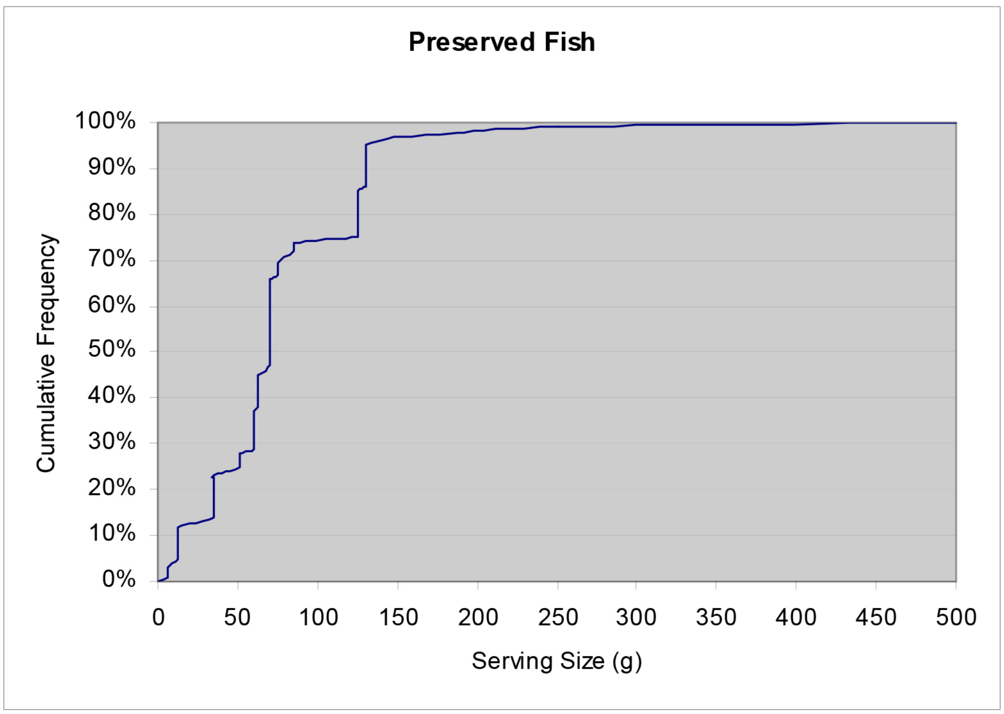

Table A5.3.2 Frequency Distribution of Amount Consumed per Serving

Percentile (grams per serving)			
50th	**75th**	**95th**	**99th**
70	125	130	250

Contamination at Retail

Table A5.3.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Anchovy, dried
Brined shrimp
Ceviche
Cooked fish & fish products
Dried fish ‘Bombay Duck’
Dried shrimp, squid & mussels
Dried squid & mussels
Dried squid, salmon, shishamo smelt
Fermented seafood
Fermented sushi flatfish
Fermented sushi sandfish
Fin fish, pickled
Fish, dried, salted
Fish, gravad
Fish, preserved
Fish, processed
Gravad
Haddock, dried
Mackerel, dried
Salted clams
Salted salmon
Seasoned anchovies
Shrimp, dried
Trout, gravad

Post Retail Growth

Table A5.3.4. Foods Included in Post Retail Growth Data Set

Not applicable; no growth.

Table A5.3.5. Consumer Storage Times Used in this Risk Assessment (days)

Not applicable; no growth

Figure A5.3.2. Cumulative Distribution for the Reference Exponential Growth Rates (EGR) at 5 °C

Not applicable; no growth

Table A5.3.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Not applicable; no growth

Table A5.3.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Not applicable; no growth

Table A5.3.8. Maximum Growth at Various Temperatures

Maximum growth = 10^8 cfu/g

4. Cooked Ready-to-Eat Crustaceans Food Category

Consumption

Table A5.4.1. Foods Included in Consumption Data Set

Food Code	Food
26305160	Crab, hard shell, steamed
26319130	Shrimp, steamed or boiled
27150110	Shrimp cocktail (shrimp with cocktail sauce)

Source Survey: CSFII

Figure A5.4.1. Cumulative Distribution for the Serving Size

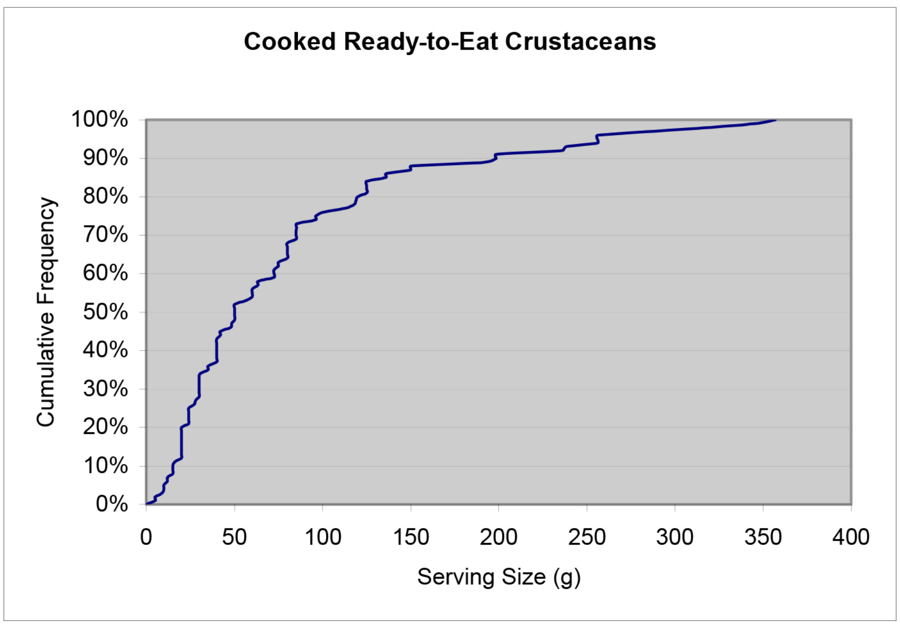

Table A5.4.2. Frequency Distribution of Amount Consumed per Serving

Percentile (grams per serving)			
50th	75th	95th	99th
50	96	256	345

Contamination at Retail

Table A5.4.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Crab
Crab, cooked
Imitation crab
Mussels, shelled cooked
Seafood, boiled
Shellfish, cooked
Shrimp, cooked
Shrimp, cooked, frozen
Shrimp, cooked/processed
Shrimp, wholesale

Post Retail Growth

Table A5.4.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Food
Crab, cooked
Crabmeat, pasteurized
Fish, smoked
Lobster, cooked
Shrimp, cooked

Table A5.4.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	1 to 2	10 to 20

Figure A5.4.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C

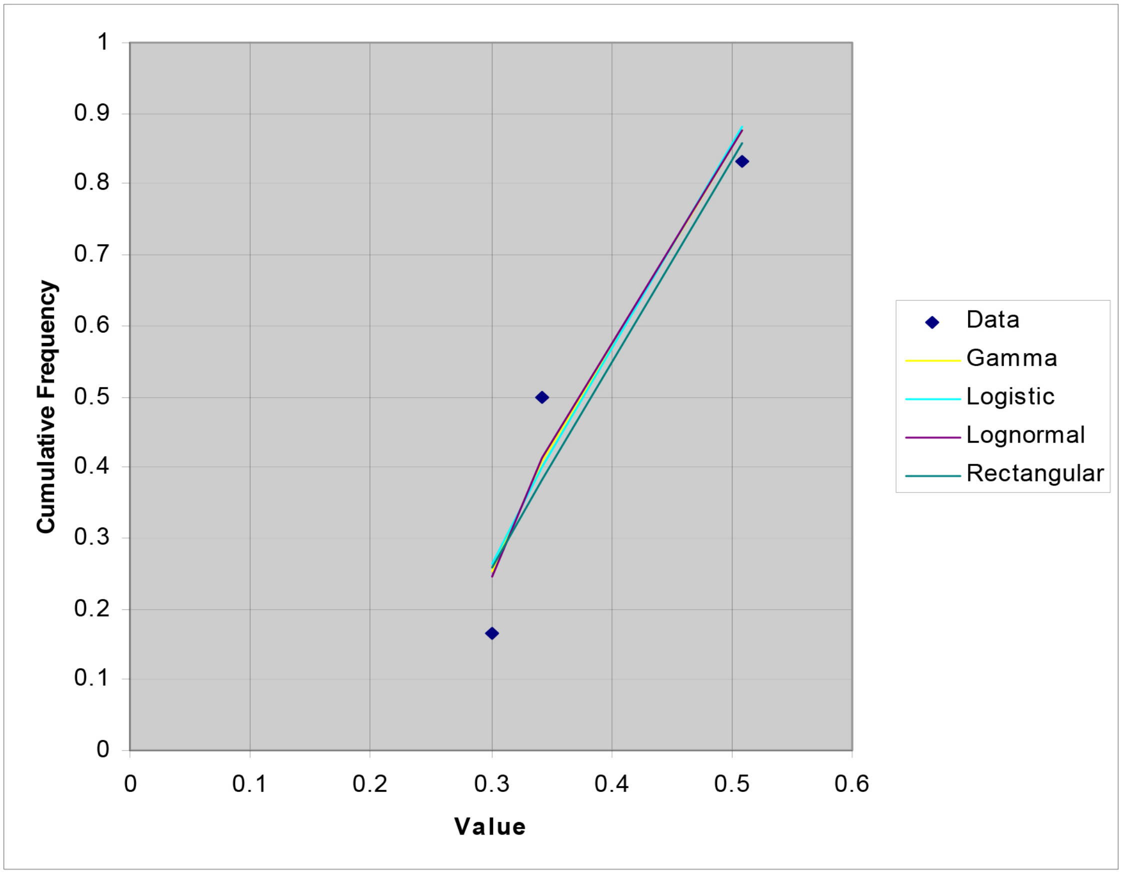

Table A5.4.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	RSQ	Probability
Rectangular	0.209777	0.557556	0.023	0.38
Lognormal	-1.00726	0.286849	0.016	0.29
Gamma	11.7	0.032484	0.018	0.21
Logistic	.371	.0689	0.021	0.12

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.4.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
0.384	0.110	3

Table A5.4.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth (log_{10} cfu/g)	5	6.5	8

5. Vegetables Food Category

Consumption

Table A5.5.1. Foods Included in Consumption Data Set

Food Code	Food
71905000	Ripe plantain, raw
72101100	Beet greens, raw
72113100	Dandelion greens, raw
72116000	Endive, chicory, escarole, or romaine lettuce, raw
72116140	Caesar salad (with romaine)
72124100	Radicchio, raw
72125100	Spinach, raw
72130100	Watercress, raw
72201100	Broccoli, raw
73101010	Carrots, raw
74101000	Tomatoes, raw
74102000	Tomatoes, green, raw
74402110	Salsa, red, uncooked
75100250	Raw vegetable, not further specified
75100300	Sprouts, not further specified
75100500	Alfalfa sprouts, raw
75100750	Artichoke, Jerusalem, raw
75100800	Asparagus, raw
75101000	Bean sprouts, raw (soybean or mung)
75101800	Beans, string, green, raw
75102500	Beets, raw
75102750	Brussels sprouts, raw
75103000	Cabbage, green, raw
75104000	Cabbage, Chinese, raw
75105000	Cabbage, red, raw
75105500	Cactus, raw
75107000	Cauliflower, raw
75109000	Celery, raw
75109500	Chives, raw
75109550	Cilantro, raw
75109600	Corn, raw
75111000	Cucumber, raw
75111200	Eggplant, raw
75111500	Garlic, raw
75111800	Jicama, raw
75112500	Leek, raw
75113000	Lettuce, raw
75113060	Lettuce, Boston, raw
75113080	Lettuce, arugula, raw

75114000	Mixed salad greens, raw
75115000	Mushrooms, raw
75117010	Onions, young green, raw
75117020	Onions, mature, raw
75119000	Parsley, raw
75120000	Peas, green, raw
75121000	Pepper, hot chili, raw
75121400	Pepper, poblano, raw
75121500	Pepper, Serrano, raw
75122000	Pepper, raw, not further specified
75122100	Pepper, sweet, green, raw
75122200	Pepper, sweet, red, raw
75124000	Pepper, banana, raw
75125000	Radish, raw
75127500	Seaweed, raw
75127750	Snowpeas (pea pod), raw
75128000	Squash, summer, yellow, raw
75128010	Squash, summer, green, raw
75129000	Turnip, raw
75143000	Lettuce, salad with assorted vegetables including tomatoes and/or carrots, no dressing
75143050	Lettuce, salad with assorted vegetables excluding tomatoes and carrots, no dressing
75143100	Lettuce, salad with avocado, tomato, and/or carrots, with or without other vegetables, no dressing
75143200	Lettuce, salad with cheese, tomato and/or carrots, with or without other vegetables, no dressing
75143300	Lettuce, salad with egg, tomato, and/or carrots, with or without other vegetables, no dressing
75143350	Lettuce salad with egg, cheese, tomato, and/or carrots, with or without other vegetables, no dressing
75147000	Spinach salad, no dressing

Source Survey: CSFII

Figure A5.5.1. Cumulative Distribution for the Serving Size

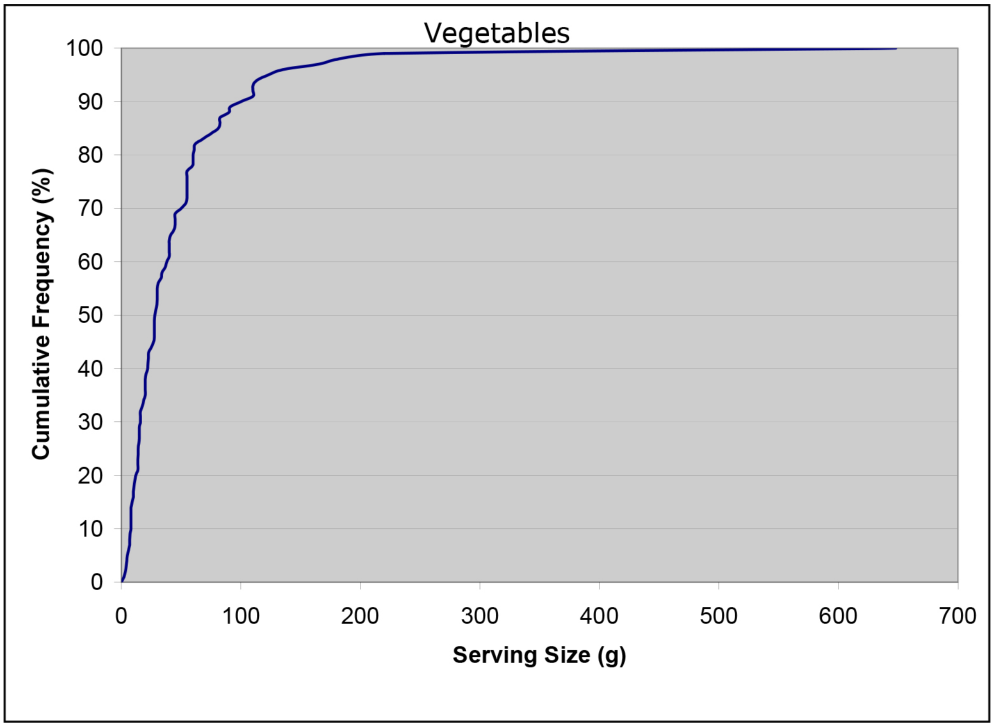

Table A5.5.2. Frequency Distribution of Amount Consumed per Serving

Percentile (grams per serving)			
50th	**75th**	**95th**	**99th**
28	55	123	220

Contamination at Retail

Table A5.5.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Bagged precut leafy salad
Beet root
Broccoli
Cabbage
Cabbage salad
Carrot
Celery
Cilantro
Coleslaw mix
Coriander
Cucumber
Fennel
Fresh cut vegetables
Green beans
Green peppers

Individual salad ingredients (bean sprouts, cabbage, carrot, celery, cress, cucumber, lettuce, mushroom, peppers, radish, spring onions, tomato, vegetables, watercress)
Jalapeno
Kelp
Kidney, Mung Bean
Kim chee
Laurel
Legumes
Lettuce
Math leaves-veg
Math roots
Mixed vegetable salad
Mushroom
Olive
Onion
Parsley
Pea
Potato
Prepacked mixed salads
Processed vegetables and salads
Radish
Radishes
Raw vegetables
Ready-to-eat salads
Salads, vegetable
Spinach
Spinach washed w/ sodium hypochlorite
Sprouts
Thyme
Tomato
Unprocessed vegetables
Vegetables, fresh
Watercress
Winter sweet
Yam

Post Retail Growth

Table A5.5.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Asparagus
Asparagus
Bean sprout
Broccoli
Cabbage, raw, shreds
Carrots, whole and shredded
Cauliflower
Endive, broad leaved
Endive, broad leaved
Endive, curly-leaved
Lettuce, butterhead
Lettuce, lamb's
Lettuce, shredded
Lettuce, whole
Lettuce, whole, ready to serve
Lettuce, whole, ready to serve, open
Lettuce, whole, ready to serve, sealed
Rutabaga
Salads, mixed
Tomatoes

Table A5.5.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	3 to 4	8 to 12

Figure A5.5.2. Cumulative Distribution for the Exponential Growth Rate (EGR) at 5 °C

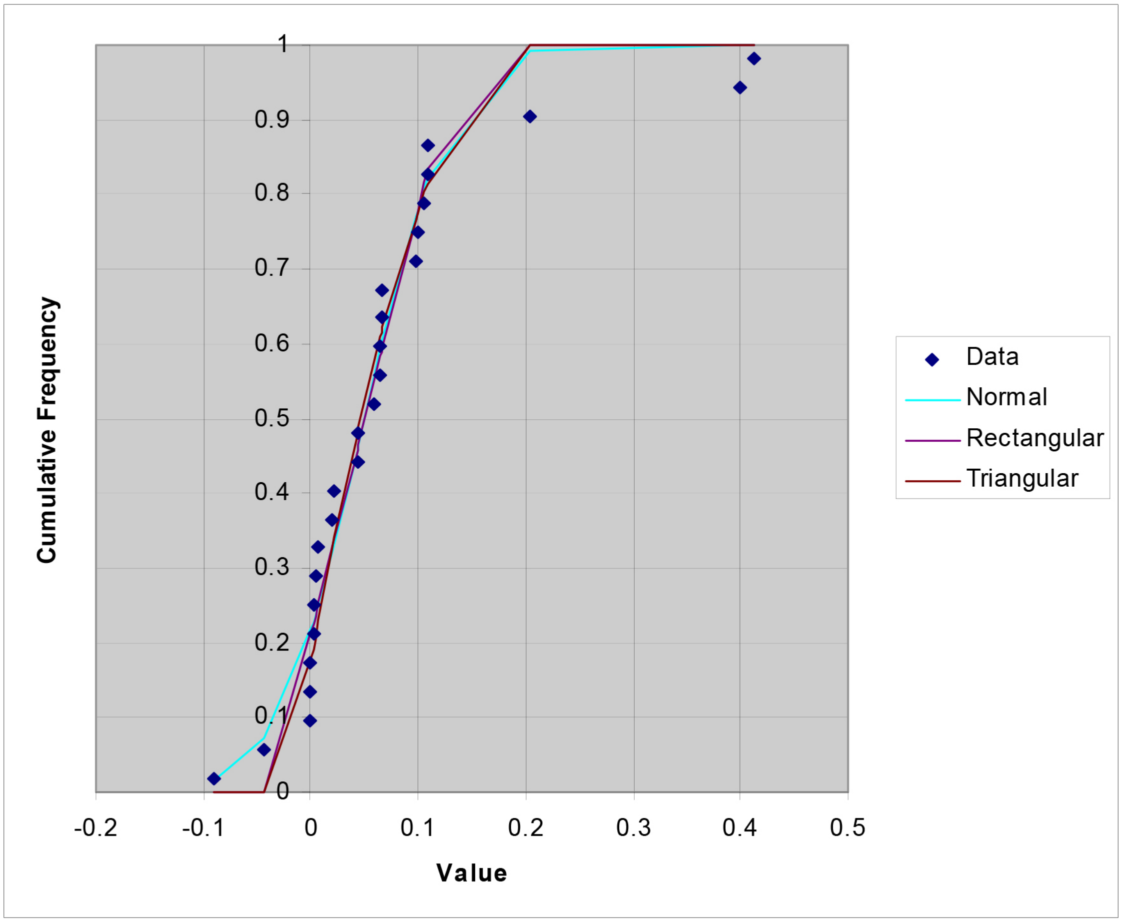

Table A5.5.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	RSQ	Probability
Rectangular	-0.03737	0.138017		0.069	0.60
Normal	0.049855	0.064067		0.067	0.20
Triangular	1.00E-04	-4.40E-02	0.207461	0.068	0.19

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.5.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
0.072	0.114	26

Table A5.5.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth ($\log_{10}$ cfu/g)	5	6.5	8

6. Fruits Food Category

Consumption

Table A5.6.1. Foods Included in Consumption Data Set

Food Code	Food
61101010	Grapefruit, raw
61119010	Orange, raw
61125000	Tangelo, raw
61125010	Tangerine, raw
62101000	Fruit, dried, not further specified (assume uncooked)
62101050	Fruit mixture, dried (mixture includes three or more of the following: apples, apricots, dates, papaya, peaches, pears)
62101100	Apple, dried, uncooked
62101300	Apple chips
62104100	Apricot, dried, uncooked
62107200	Banana chips
62110100	Date
62113100	Fig, dried, uncooked
62114050	Mango, dried
62114110	Papaya, dried
62120100	Pineapple, dried
62121100	Plum, rock salt, dried
62122100	Prune, dried, uncooked
62125100	Raisins
63100100	Fruit, not specified as to type
63101000	Apple, raw
63101150	Applesauce with other fruits
63101420	Apple, pickled
63103010	Apricot, raw
63105010	Avocado, raw
63107010	Banana, raw
63107080	Banana, red, ripe (guineo morado)
63109010	Cantaloup (muskmelon), raw
63109700	Carambola (starfruit), raw
63110010	Cassaba melon, raw
63113010	Cherries, sour, red, raw
63115010	Cherries, sweet, raw (Queen Anne, Bing)
63115200	Cherries, frozen
63119010	Fig, raw
63123010	Grapes, European type, adherent skin, raw
63123020	Grapes, American type, slip skin, raw
63125010	Guava, raw
63126500	Kiwi fruit, raw

63127010	Honeydew melon, raw
63127610	Honeydew, frozen (balls)
63129010	Mango, raw
63129020	Mango, pickled
63131010	Nectarine, raw
63133010	Papaya, raw
63134010	Passion fruit, raw
63135010	Peach, raw
63135620	Peach, frozen, unsweetened
63135630	Peach, frozen, with sugar
63137010	Pear, raw
63137050	Pear, Japanese, raw
63139010	Persimmon, raw
63141010	Pineapple, raw
63143010	Plum, raw
63145010	Pomegranate, raw
63149010	Watermelon, raw
63201010	Blackberries, raw
63201600	Blackberries, frozen
63203010	Blueberries, raw
63203600	Blueberries, frozen, unsweetened
63205010	Boysenberries, raw
63219020	Raspberries, red, raw
63219610	Raspberries, frozen, unsweetened
63219620	Raspberries, frozen, with sugar
63223020	Strawberries, raw
63223030	Strawberries, raw, with sugar
63223610	Strawberries, frozen, unsweetened
63223620	Strawberries, frozen, with sugar
63311000	Fruit cocktail or mix (excluding citrus fruits), raw
63311050	Fruit cocktail or mix (including citrus fruits), raw
63311080	Fruit cocktail or mix, frozen
63320100	Fruit salad, Puerto Rican style (Mixture includes bananas, papayas, oranges, grapefruit, etc.) (Ensalada de frutas tropicale)

Source Survey: CSFII

Figure A5.6.1. Cumulative Distribution for the Serving Size

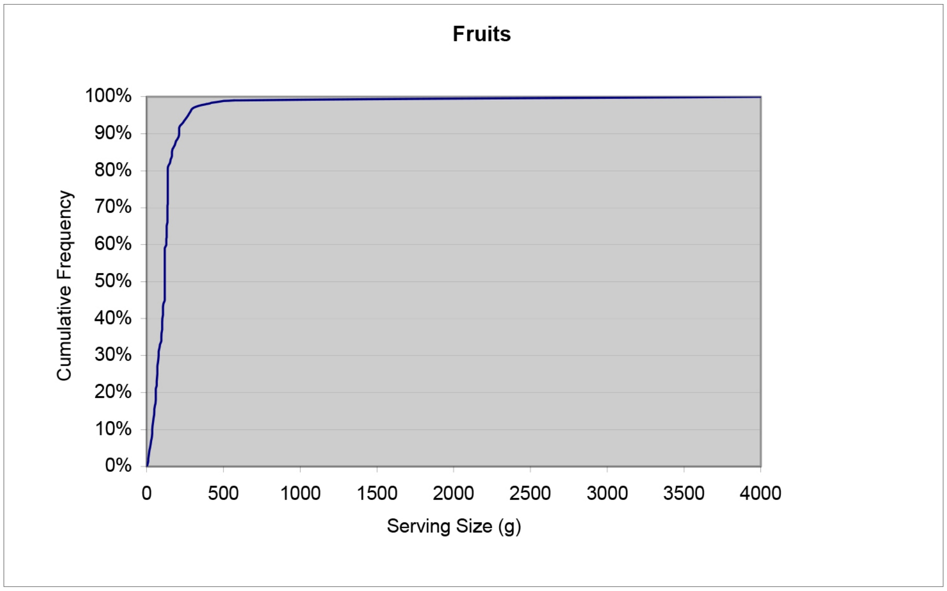

Table A5.6.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
118	138	272	570

Contamination at Retail

Table A5.6.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Apples
Blueberries
Cantaloupe
Fruit products
Fruit salad
Fruit, fresh
Fruit, product
Fruit-dried
Fruit-various
Melons
Pears
Pineapples
Watermelons

Post Retail Growth

Table A5.6.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Apple slices (fresh cut)
Orange, serum (juice)

Table A5.6.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	3 to 4	8 to 12

Figure A5.6.2. Cumulative Distribution for the Exponential Growth Rate (EGR) at 5 °C

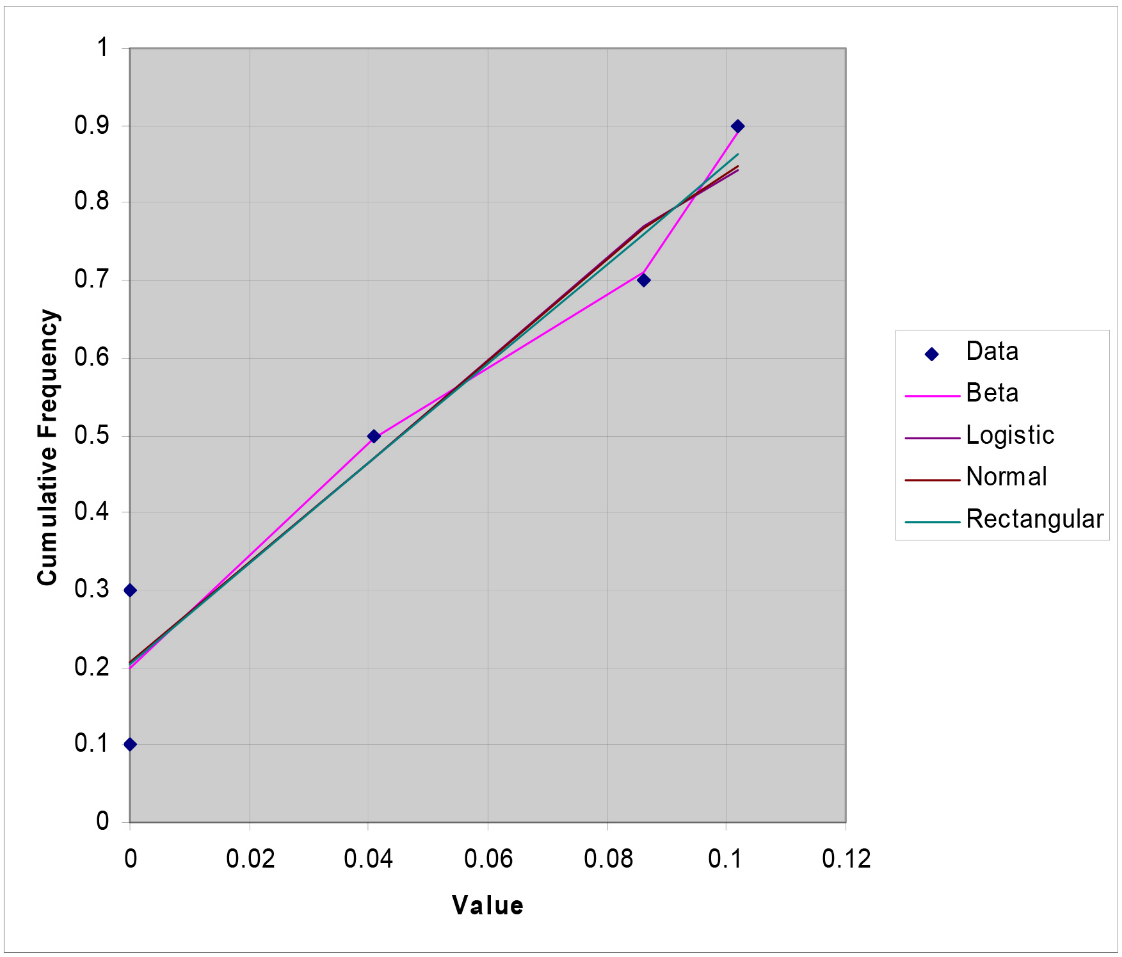

Table A5.6.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Rectangular	-0.03172	0.123324			0.026	0.61
Beta	0.297799	0.339917	-0.00264	0.10302	0.020	0.17
Normal	0.045299	0.055485			0.029	0.11
Logistic	4.51×10^{-2}	3.37×10^{-02}			0.029	0.10

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.6.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
0.046	0.47	5

Table A5.6.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth ($\log_{10}$ cfu/g)	5	6.5	8

7. Fresh Soft Cheese Food Category

Consumption

Table A5.7.1. Foods Included in Consumption Data Set

Food Code	Food
14133000	Queso Fresco
Source Survey:	**CSFII**

Figure A5.7.1. Cumulative Distribution for the Serving Size

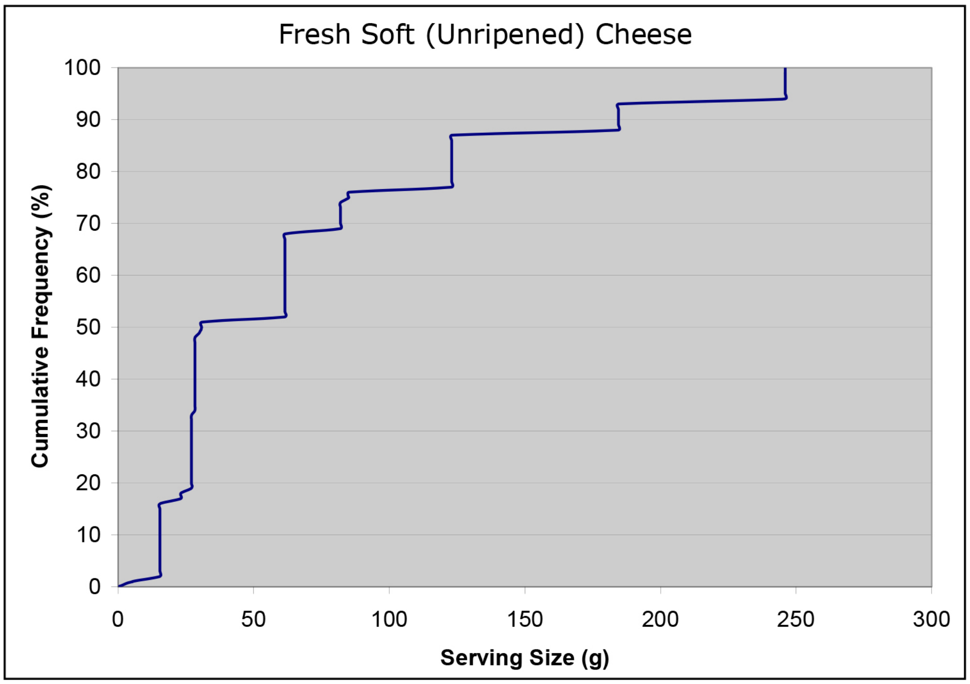

Table A5.7.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50^{th}	**75^{th}**	**95^{th}**	**99^{th}**
31	85	246	246

Contamination at Retail

Table A5.7.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Fresh cheese (fornaggio fresco)
Fresh cheese, cow and goat milk
Hispanic style cheese
Brazilian soft cheese eaten fresh
Panela
Panellá
Queso Fresco
Queso Fresco, Requesoy

Post Retail Growth

Table A5.7.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Queso Panella
Queso Blanco
Queso Fresco
Queso Ranchero

Table A5.7.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	1 to 5	15 to 30

Figure A5.7.2. Cumulative Distribution for the Exponential Growth Rate (EGR) at 5 °C

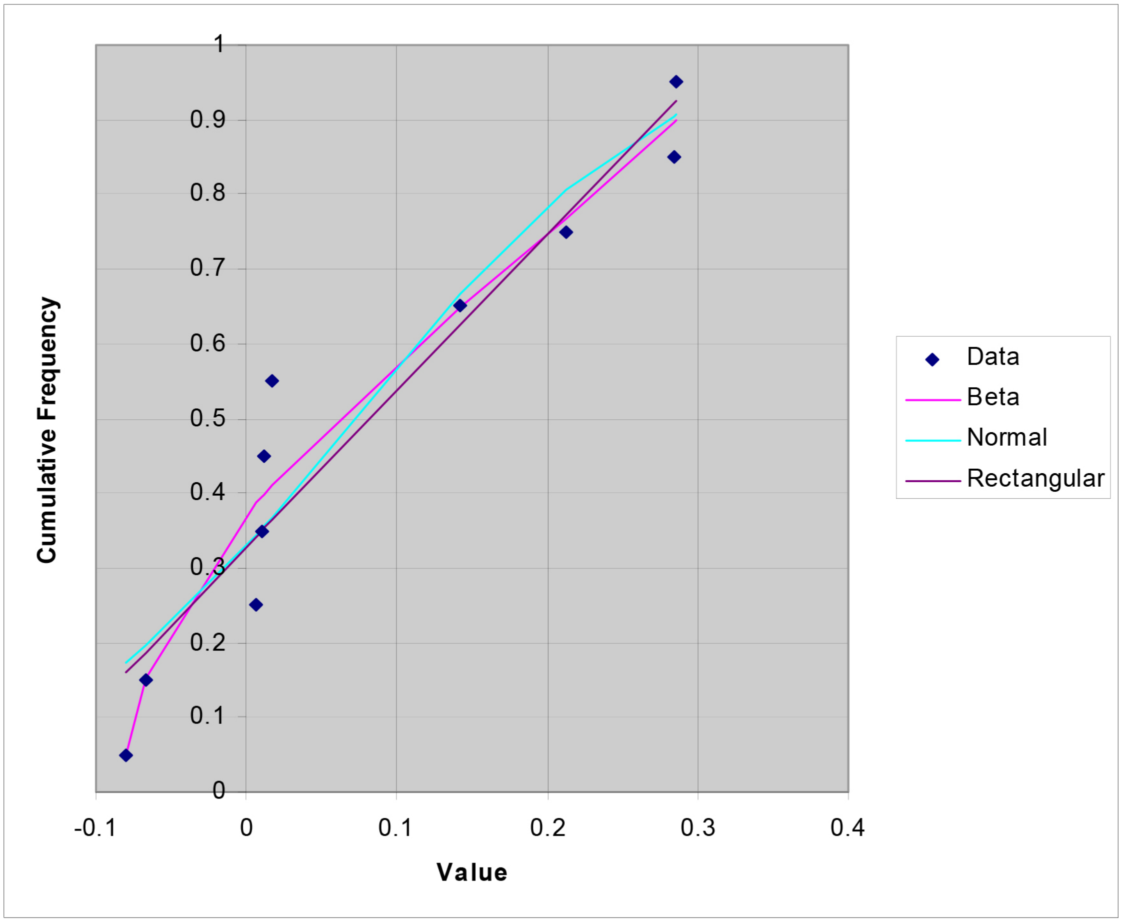

Table A5.7.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Beta	0.511485	0.741846	-0.0816	0.323527	0.048	0.83
Rectangular	-0.15621	0.320609			0.073	0.15
Normal	0.071799	0.161944			0.077	0.02

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.7.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5°C

Mean (log_{10} cfu/g/day)	Std. Dev.	
0.082	0.138	10

Table A5.7.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth (log_{10} cfu/g)	5	6.5	8

8. Soft Unripened Cheese Food Category

Consumption

Table A5.8.1. Foods Included in Consumption Data Set

Food Code	Food
14200100	Cheese, cottage, not further specified
14201010	Cheese, cottage, creamed, large or small curd
14201200	Cottage cheese, farmer's
14201500	Cheese, ricotta
14202010	Cheese, cottage, with fruit
14203010	Cheese, cottage, dry curd
14203020	Cheese, cottage, salted, dry curd
14204010	Cheese, cottage, lowfat (1-2% fat)
14204020	Cheese, cottage, lowfat, with fruit
14204030	Cheese, cottage, lowfat, with vegetables
14205010	Cheese, cottage, low sodium
14206010	Cheese, cottage, lowfat, low sodium
14301010	Cheese, cream
14303010	Cheese, cream, lowfat

Source Survey: CSFII

Figure A5.8.1. Cumulative Distribution for the Serving Size

Table A5.8.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
29	105	226	420

Contamination at Retail

Table A5.8.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Anari
Cheese, cottage
Cheese, unripened
Cottage cheese
Cream cheese
Crème Mexicana
Farmer cheese
Gournay
Halloumi
Port fresh cheese
Soft paste cheeses

Post Retail Growth

Table A5.8.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Cottage cheese
Cottage cheese (multiple brands)
Cream cheese
Ricotta (3 company brands)
Ricotta (whey cheese)
Teleme cheese

Table A5.8.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	15 to 45

Figure A5.8.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5^{0}C

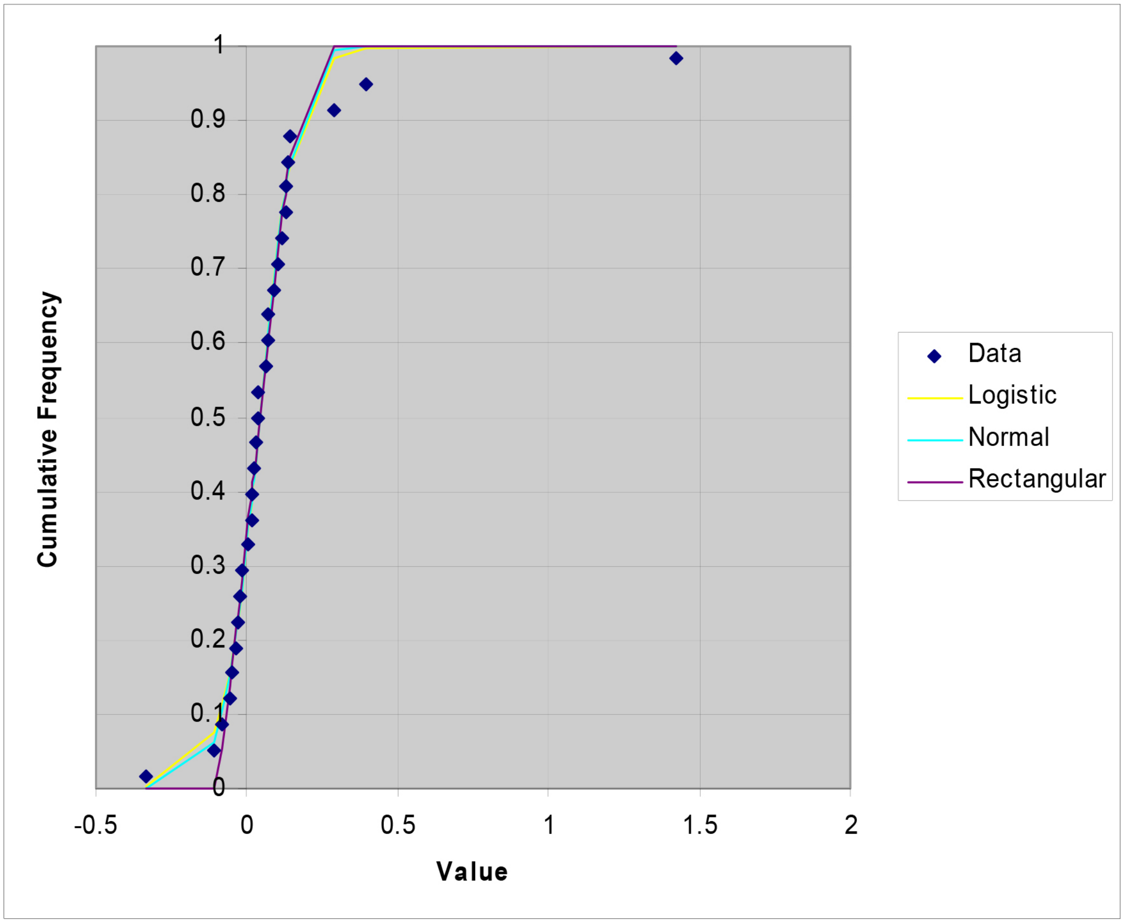

Table A5.8.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	RSQ	Probability
Rectangular	-0.09419	0.181873	0.028	0.60
Normal	0.043709	0.09762	0.026	0.20
Logistic	0.0436	0.0595	0.026	0.20

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.8.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
0.090	0.286	29

Table A5.8.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth (log_{10} cfu/g)	5	6.5	8

9. Soft Ripened Cheese Food Category

Consumption

Table A5.9.1. Foods Included in Consumption Data Set

Food Code	Food
14103010	Cheese, Camembert
14103020	Cheese, Brie
14104400	Cheese, Feta
14107010	Cheese, Mozzarella, not further specified
14107030	Cheese, Mozzarella, part skim
14107040	Cheese, Mozzarella, low sodium
14107060	Cheese, Mozzarella, nonfat or fat free

Source Survey: CSFII

Figure A5.9.1. Cumulative Distribution for the Serving Size

Table A5.9.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
28	48	85	168

Contamination at Retail

Table A5.9.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Brie
Brie/camembert
Brie/cheese, soft, short-ripened
Camambert
Cheese, white mold
Crescenza/cheese, soft, short-ripened
Feta cheese
Hartz mountain cheese Harzerkase
La Serena cheese, from raw ewes milk
Brazilian soft cheese eaten fresh
Mozzarella
Pyramid goat cheese
Soft, mold-ripened cheese
Soft mold ripened cheese
Taleggio

Post Retail Growth

Table A5.9.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Blue
Brie
Camembert
Feta
Mozzarella

Table A5.9.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	15 to 45

Figure A5.9.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C

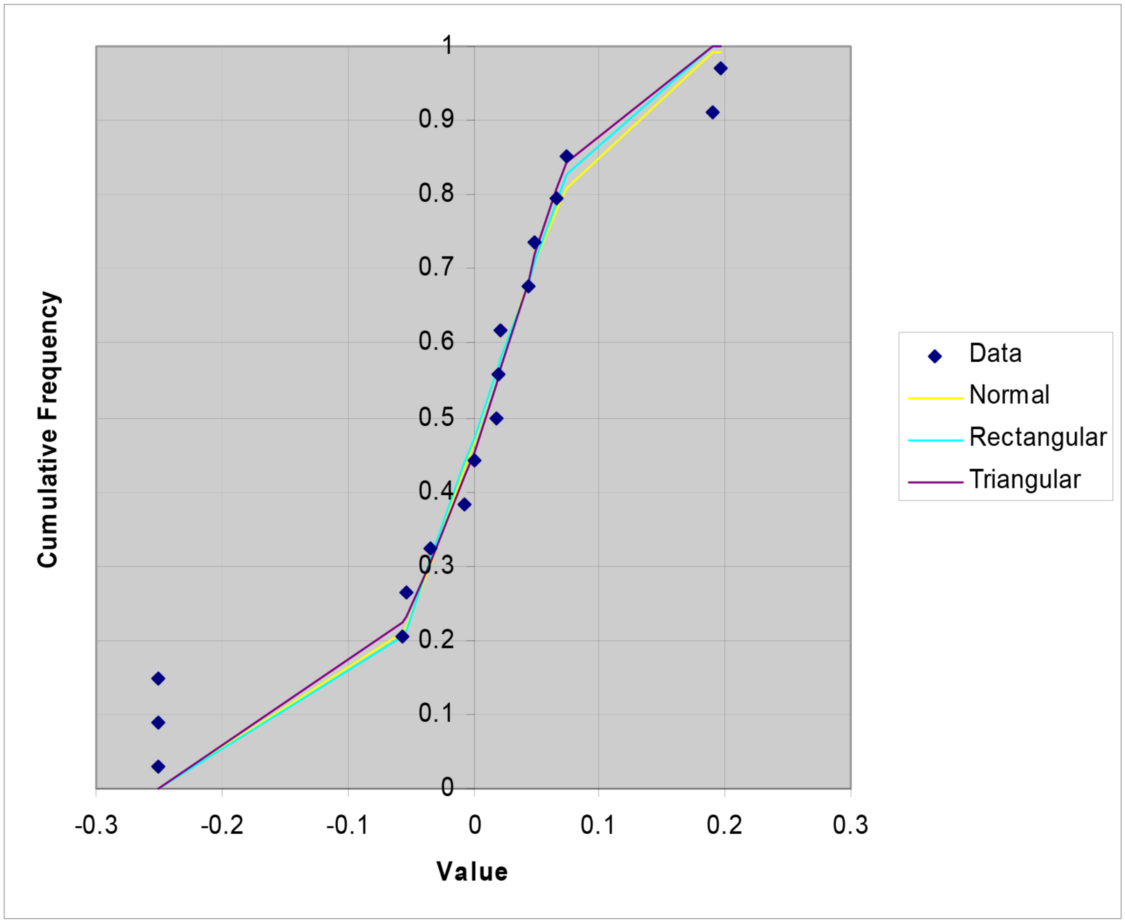

Table A5.9.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	RSQ	Probability
Rectangular	-0.09855	0.109798		0.053	0.52
Triangular	-0.189	.0459	0.146452	0.048	0.29
Normal	0.006416	0.077436		0.051	0.19

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.9.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5°C

Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
-0.013	0.133	17

Table A5.9.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth ($\log_{10}$ cfu/g)	5	6.5	8

10. Semi-soft Cheese Food Category

Consumption

Table A5.10.1. Foods Included in Consumption Data Set

Food Code	Food
14101010	Cheese, blue or Roquefort
14102010	Cheese, brick
14104600	Cheese, fontina
14105010	Cheese, gouda or edam
14106010	Cheese, Limburger
14106200	Cheese, Monterey
14106500	Cheese, Monterey, lowfat
14107200	Cheese, Muenster
14108400	Cheese, provolone
14108410	Cheese, provolone, reduced fat, reduced sodium

Source Survey: CSFII

Figure A5.10.1. Cumulative Distribution for the Serving Size

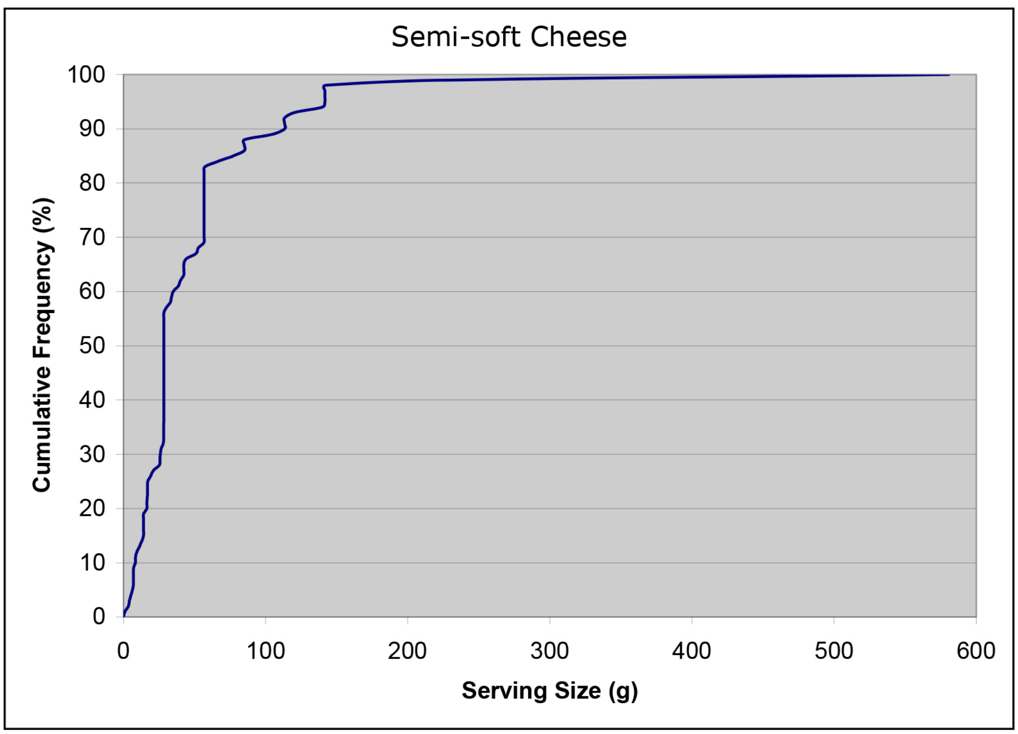

Table A5.10.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
28	57	142	227

Contamination at Retail

Table A5.10.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Blue veined soft cheese
Butter cheese
Edam
Gorgonzola
Gouda cheese
Havarti
Jack cheese
Limburger
Manchego
Monterey Jack cheese
Muenster
Pinna ricotta
Roquefort
Semi soft cheese
String
Swiss cheese

Post Retail Growth

Table A5.10.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Brick (surface ripened)
Emmenthaler, tilster
Gouda
Havarti
Limburger
Monterey Jack
Muenster
Provolone
String cheese
Trappist

Table A5.10.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	15 to 45

Figure A5.10.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C

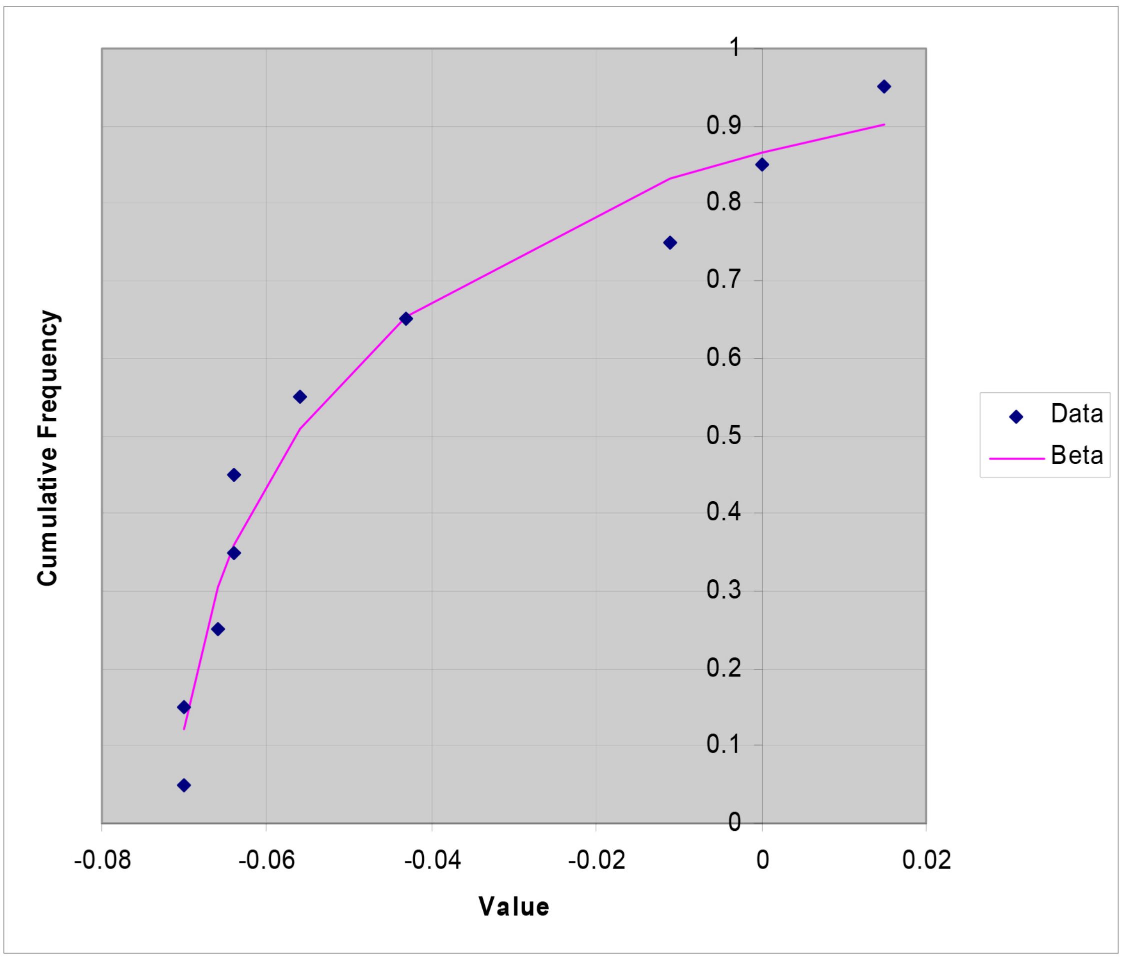

Table A5.10.6. Model Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Beta	0.489794	360.3561	-0.0707	23.05749	0.028	1.0

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.10.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
-0.043	0.032	10

Table A5.10.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth (log_{10} cfu/g)	5	6.5	8

11. Hard Cheese Food Category

Consumption

Table A5.11.1. Foods Included in Consumption Data Set

Food Code	Food
14104010	Cheese, natural, Cheddar or American type
14104020	Cheese, Cheddar or American type, dry, grated
14104200	Cheese, Colby
14104250	Cheese, Colby Jack
14105200	Cheese, Gruyere
14108010	Cheese, Parmesan, dry grated
14108020	Cheese, Parmesan, hard
14108050	Cheese, Parmesan, low sodium
14108060	Parmesan cheese topping, fat free
14109010	Cheese, Swiss
14109020	Cheese, Swiss, low sodium
14109030	Cheese, Swiss, lowfat
14110010	Cheese, Cheddar or Colby, low sodium
14110020	Cheese, Cheddar or Colby, low sodium, lowfat
14110030	Cheese, Cheddar or Colby, lowfat
14131000	Queso Anejo (aged Mexican cheese)
14131500	Queso Asadero
14132000	Queso Chihuahua

Source Survey: CSFII

Figure A5.11.1. Cumulative Distribution for the Serving Size

Table A5.11.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
28	38	85	122

Contamination at Retail

Table A5.11.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Cacique Asadero
Cheddar
Cheese, hard
Chihuahua
Colby Jack cheese
Gjestost
Parmesan
Provolone
Quesco Cotija
Queso Anejo

Post Retail Growth

Table A5.11.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Cheddar
Cheddar, cracker barrel
Cheddar, mild
Cheddar, sharp
Colby
Emmenthaler, gruyere
Parmesan
Stilton cheese
Swiss

Table A5.11.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	90 to 180

Figure A5.11.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C

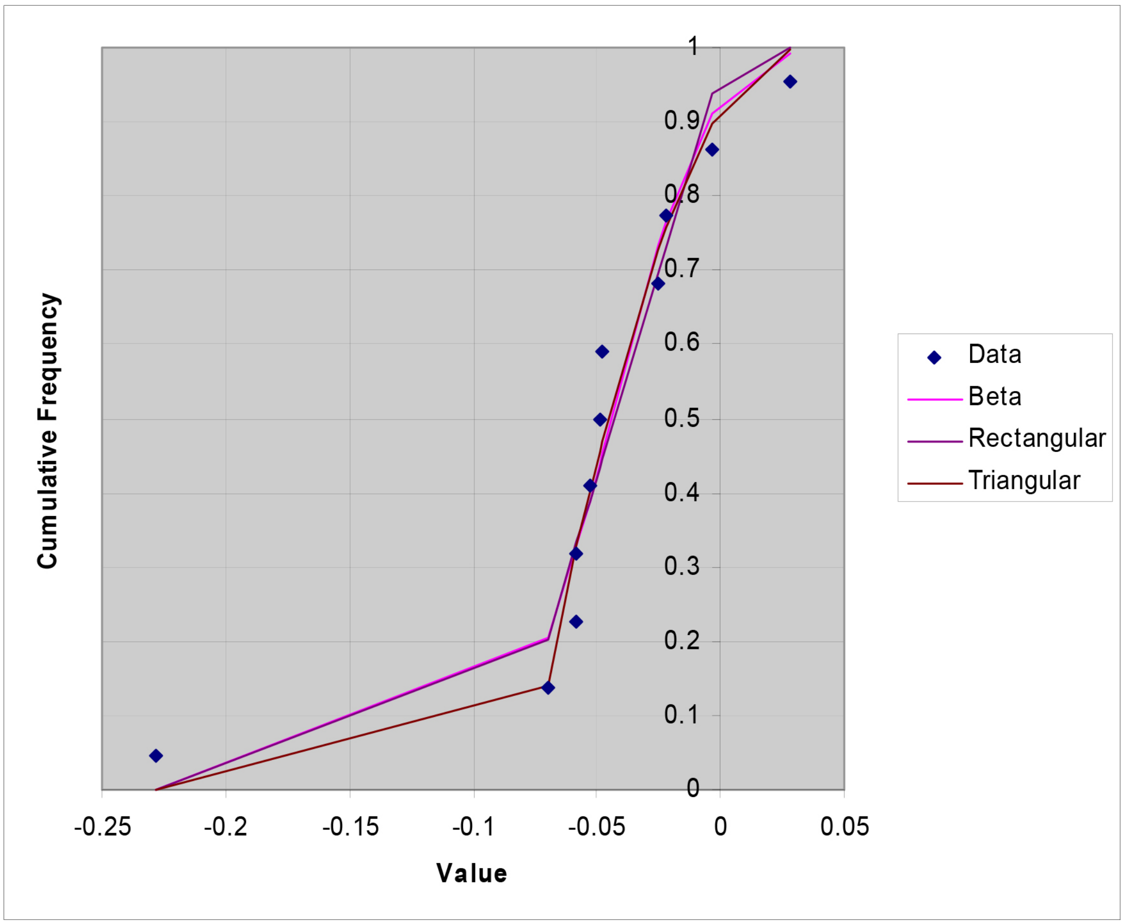

Table A5.11.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Triangular	-0.0788	-0.0773	0.032607		0.035	0.77
Rectangular	-0.08847	0.002697			0.054	0.17
Beta	5455.206	2166.964	-4.33172	1.658675	0.047	0.06

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.11.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
-0.053	0.065	11

Table A5.11.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth (log_{10} cfu/g)	5	6.5	8

12. Processed Cheese Food Category

Consumption

Table A5.12.1. Foods Included in Consumption Data Set

Food Code	Food
14410100	Cheese, processed, American and Swiss blends
14410200	Cheese, processed, American or Cheddar type
14410210	Cheese, processed, American or Cheddar type, low sodium
14410300	Cheese, processed, American or Cheddar type, lowfat
14410310	Cheese, processed, American, Cheddar, or Colby, lowfat, low sodium
14410330	Cheese, processed cheese product, American or Cheddar type, reduced fat
14410340	Cheese, processed cheese product, American or Cheddar type, reduced fat, reduced sodium
14410350	Cheese, processed, American or Cheddar type, nonfat or fat free
14410380	Cheese, processed cream cheese product, nonfat or fat free
14410400	Cheese, processed, Swiss
14410410	Cheese, processed, Swiss, low sodium
14410420	Cheese, processed, Swiss, lowfat
14410440	Cheese, processed, Swiss, lowfat, low sodium
14410450	Cheese, processed cheese product, Swiss, reduced fat
14410500	Cheese, processed cheese food
14410600	Cheese, processed, with vegetables
14410710	Cheese, processed, Mozzarella, low sodium
14420000	Cheese spread, not further specified
14420100	Cheese spread, American or Cheddar cheese base
14420140	Cheese spread, American or Cheddar cheese base, lowfat, low sodium
14420160	Cheese spread, Swiss cheese base
14420200	Cheese spread, cream cheese or Neufchatel base
14650100	Cheese sauce
Source Survey: CSFII	

Figure A5.12.1. Cumulative Distribution for the Serving Size

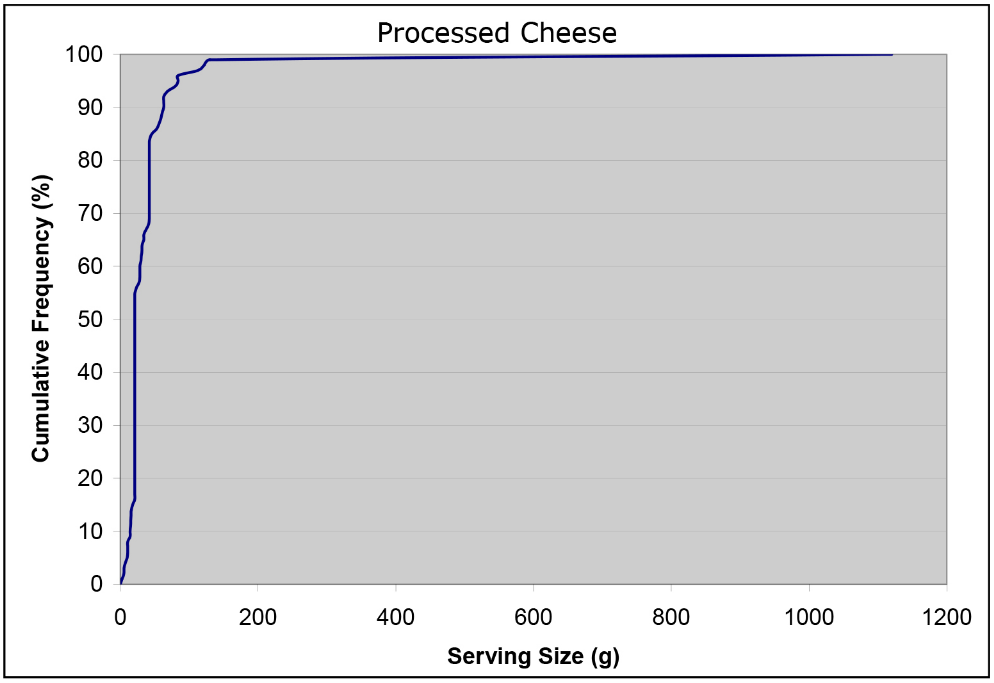

Table A5.12.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	**75th**	**95th**	**99th**
21	42	84	130

Contamination at Retail

Table A5.12.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Cheese, pasteurized and processed
Cheese and spreads
Cheese, processed
Cheese, Schnittkase-sliced

Post Retail Growth

Table A5.12.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
American process cheese
American process cheese with sorbate and citrate
Piedmont process cheese
Cold pack cheese
Non-acid
Pasteurized process cheese

Table A5.12.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	45 to 90

Figure A5.12.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C

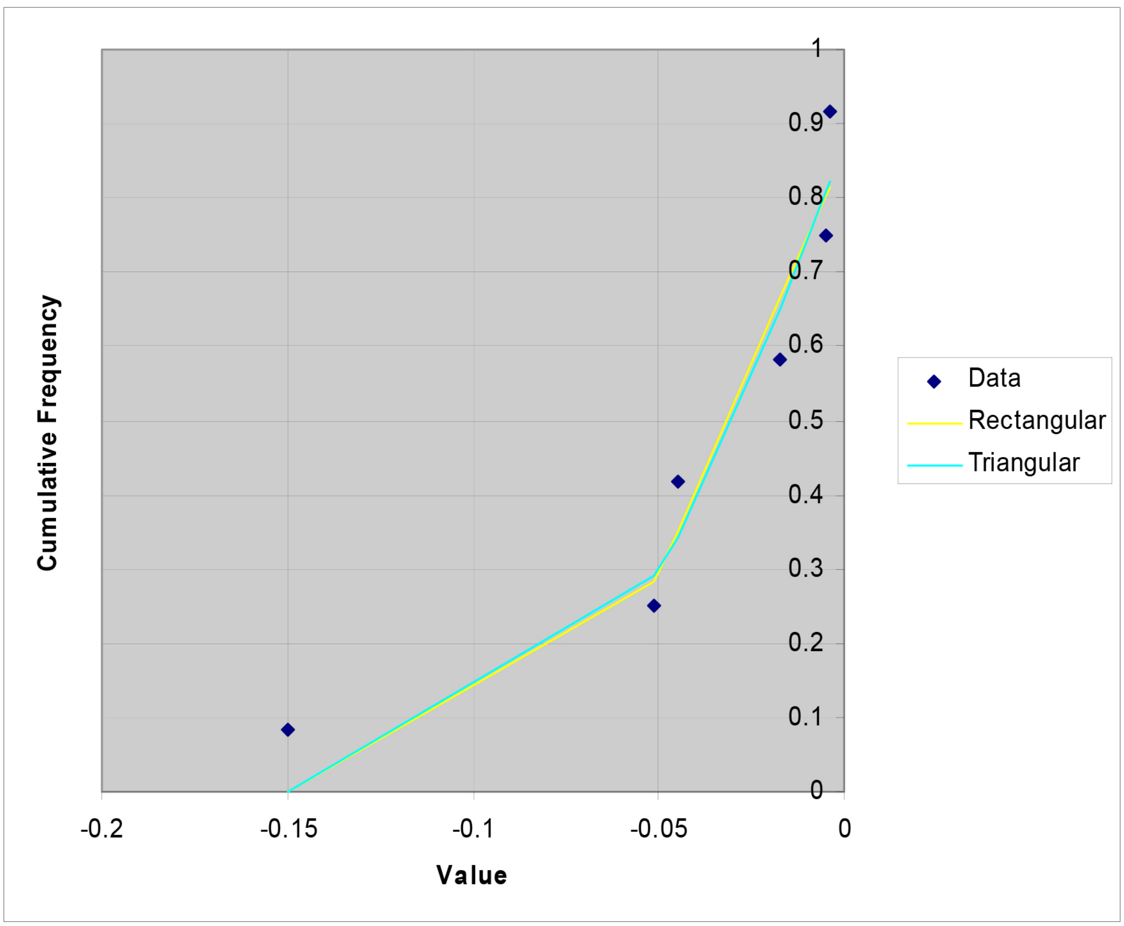

Table A5.12.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	RSQ	Probability
Rectangular	-0.0761	0.012525		0.033	0.73
Triangular	-0.120	0.0187	-0.00219	0.030	0.27

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.12.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
-0.045	0.055	6

Table A5.12.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth (log_{10} cfu/g)	5	6.5	8

13. Pasteurized Fluid Milk Food Category

Consumption

Table A5.13.1. Foods Included in Consumption Data Set

Food Code	Food
11100000	Milk, not further specified
11111000	Milk, cow's, fluid, whole
11111160	Milk, calcium fortified, cow's, fluid, 1% fat
11111170	Milk, calcium fortified, cow's, fluid, skim or nonfat
11112000	Milk, cow's, fluid, lowfat, not specified as to percent fat
11112110	Milk, cow's, fluid, 2% fat
11112120	Milk, cow's, fluid, acidophilus, 1% fat
11112130	Milk, cow's, fluid, acidophilus, 2% fat
11112210	Milk, cow's, fluid, 1% fat
11113000	Milk, cow's, fluid, skim or nonfat, 0.5% or less butterfat
11114300	Milk, cow's, fluid, lactose reduced, 1% fat
11114310	Milk, cow's, fluid, lactose reduced, 1% fat, fortified with calcium
11114320	Milk, cow's, fluid, lactose reduced, nonfat
11114321	Milk, cow's, fluid, lactose reduced, nonfat, fortified with calcium
11114330	Milk, cow's, fluid, lactose reduced, 2% fat
11116000	Milk, goat's, fluid, whole
11511000	Milk, chocolate, not further specified
11511100	Milk, chocolate, whole milk based
11511200	Milk, chocolate, low fat milk based
11511300	Milk, chocolate, skim milk based
11519050	Milk, flavors other than chocolate, whole milk based

Source Survey: CSFII

(Pasteurized Fluid Milk consumption was estimated to be 99.5% of total milk)

Figure A5.13.1. Cumulative Distribution for the Serving Size

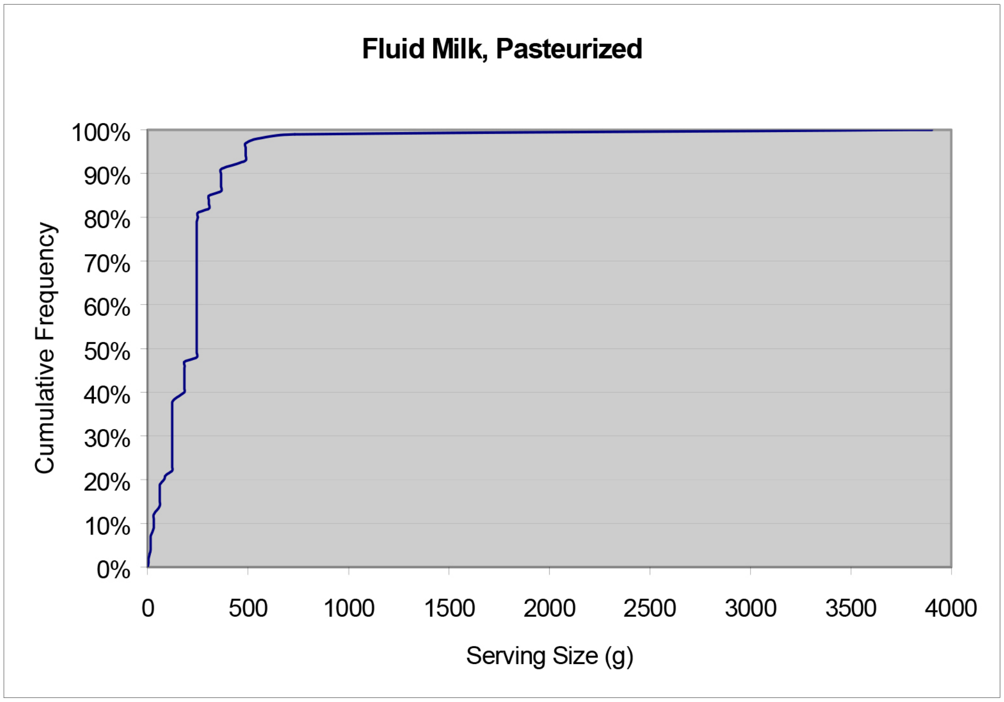

Table A5.13.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	**75th**	**95th**	**99th**
244	245	488	732

Contamination at Retail

Table A5.13.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Pasteurized fluid milk
Milk, cow's
Milk, sterilized
Milk, chocolate
Milk, lowfat
Milk, skim
Milk, whole
Milk, treated

Post Retail Growth

Table A5.13.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Food
Fluid milk, pasteurized Fluid milk, un-pasteurized
Fluid milk, skim/whole/chocolate Fluid milk, UHT

Table A5.13.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	3 to 5	10 to 15

Figure A5.13.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 ^{0}C

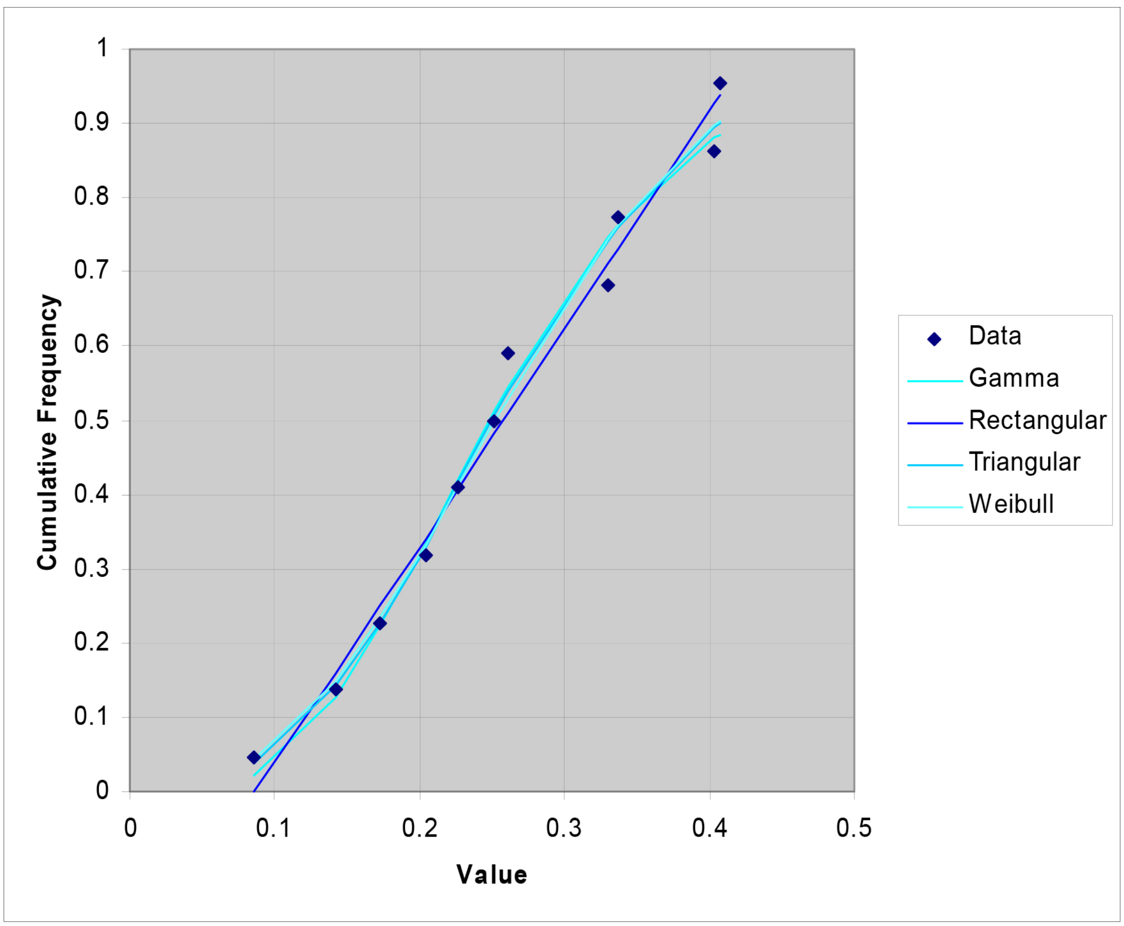

Table A5.13.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	RSQ	Probability
Rectangular	0.088151	0.428324		0.018	0.35
Triangular	0.0237	0.217	0.534217	0.011	0.25
Weibull	2.53	0.291744		0.012	0.21
Gamma	5.26	0.050411		0.013	0.19

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.13.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
0.257	0.105	11

NOTE: EGR derived using random sampling of growth data.

Table A5.13.8 Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth ($\log_{10}$ cfu/g)	7	7.5	8

14. Unpasteurized Fluid Milk Food Category

Consumption

Table A5.14.1. Foods Included in Consumption Data Set

Food Code	Food
Unpasteurized Fluid Milk consumption was estimated to be 0.5% of total milk (see Table A5.13.1. Fluid milk, pasteurized food category)	

Figure A5.14.1. Cumulative Distribution for the Serving Size

The cumulative distribution for Pasteurized Fluid Milk was used, see Fig. A5.13.1.

Table A5.14.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50^{th}	75^{th}	95^{th}	99^{th}
244	245	488	732

Contamination at Retail

Table A5.14.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods[a]
Unpasteurized fluid milk, cow
Raw milk for sale (raw milk off farm)
Milk, untreated (bulk raw milk)
Unpasteurized fluid milk, goat
Unpasteurized fluid milk, non-bovine

Post Retail Growth

Table A5.14.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

The foods included in the post retail growth data set for pasteurized fluid milk were used, see Table A5.13.4

Table A5.14.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	2 to 3	7 to 10

Figure A5.14.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 ^{0}C

The cumulative distribution for the exponential reference growth rate (EGR) at 5 ^{0}C for pasteurized milk was used, see Figure A5.13.2

Table A5.14.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

The models used to characterize the cumulative distribution for the exponential reference growth rate (EGR) at 5 ^{0}C for pasteurized milk were used, see Table A5.13.6

Table A5.14.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

The mean, standard deviation and number of samples (N) for exponential growth rate (EGR) at 5 °C for pasteurized milk were used, see Table A5.13.7

Table A5.14.8. Maximum Growth at Various Temperatures

Temperature (°C)	**<5**	**5-7**	**>7**
Maximum Growth (log $_{10}$ cfu/g)	7	7.5	8

15. Ice cream and Frozen Dairy Products Food Category

Consumption

Table A5.15.1. Foods Included in Consumption Data Set

Food Code	Food
11459990	Yogurt, frozen, not specified as to flavor, not specified as to type of milk
11460000	Yogurt, frozen, flavors other than chocolate, not specified as to type of milk
11460100	Yogurt, frozen, chocolate, not specified as to type of milk
11460150	Yogurt, frozen, not specified as to flavor, lowfat milk
11460160	Yogurt, frozen, chocolate, lowfat milk
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk
11460190	Yogurt, frozen, not specified as to flavor, nonfat milk
11460200	Yogurt, frozen, chocolate, nonfat milk
11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet coated
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk
11460400	Yogurt, frozen, chocolate, nonfat milk, with low calorie sweetener
11460410	Yogurt, frozen, flavors other than chocolate, nonfat milk, with low calorie sweetener
11460420	Yogurt, frozen, not specified as to flavor, whole milk
11460430	Yogurt, frozen, chocolate, whole milk
11460440	Yogurt, frozen, flavors other than chocolate, whole milk
11461200	Yogurt, frozen, sandwich
11461250	Yogurt, frozen, cone, chocolate
11461260	Yogurt, frozen, cone, flavors other than chocolate
11461270	Yogurt, frozen, cone, flavors other than chocolate, lowfat milk
13110000	Ice cream, not further specified
13110100	Ice cream, regular, flavors other than chocolate
13110110	Ice cream, regular, chocolate
13110120	Ice cream, rich, flavors other than chocolate
13110130	Ice cream, rich, chocolate
13110200	Ice cream, soft serve, flavors other than chocolate
13110210	Ice cream, soft serve, chocolate
13110220	Ice cream, soft serve, not specified as to flavor
13110400	Milk dessert, frozen, flavors other than chocolate (no butterfat)
13110450	Milk dessert, frozen, chocolate (no butterfat)
13120050	Ice cream bar or stick, not chocolate covered or cake covered
13120100	Ice cream bar or stick, chocolate covered
13120110	Ice cream bar or stick, chocolate or caramel covered, with nuts
13120120	Ice cream bar or stick, rich chocolate ice cream, thick chocolate covering
13120121	Ice cream bar or stick, rich ice cream, thick chocolate covering
13120130	Ice cream bar or stick, rich ice cream, chocolate covered, with nuts

13120140	Ice cream bar or stick, chocolate ice cream, chocolate covered
13120300	Ice cream bar, cake covered
13120400	Ice cream bar or stick with fruit
13120500	Ice cream sandwich
13120550	Ice cream cookie sandwich
13120700	Ice cream cone with nuts, flavors other than chocolate
13120710	Ice cream cone, chocolate covered, with nuts, flavors other than chocolate
13120720	Ice cream cone, chocolate covered or dipped, flavors other than chocolate
13120730	Ice cream cone, no topping, flavors other than chocolate
13120740	Ice cream cone, no topping, not specified as to flavor
13120750	Ice cream cone with nuts, chocolate ice cream
13120770	Ice cream cone, no topping, chocolate ice cream
13120790	Ice cream sundae cone
13120800	Ice cream soda, flavors other than chocolate
13120810	Ice cream soda, chocolate
13121100	Ice cream sundae, fruit topping, with whipped cream
13121200	Ice cream sundae, prepackaged type, flavors other than chocolate
13121300	Ice cream sundae, chocolate or fudge topping, with whipped cream
13122100	Ice cream pie, no crust
13122500	Ice cream pie, with cookie crust, fudge topping, and whipped cream
13124100	Sorbet and ice cream
13125100	Ice cream with sherbet
13126000	Ice cream, fried
13130100	Ice milk, not further specified
13130300	Ice milk, flavors other than chocolate
13130310	Ice milk, chocolate
13130350	Ice milk, premium, flavors other than chocolate
13130360	Ice milk, premium, chocolate
13130590	Ice milk, soft serve, not specified as to flavor
13130600	Ice milk, soft serve, flavors other than chocolate
13130610	Ice milk, soft serve, chocolate
13130620	Ice milk, soft serve cone, flavors other than chocolate
13130630	Ice milk, soft serve cone, chocolate
13130640	Ice milk, soft serve cone, not specified as to flavor
13135000	Ice milk sandwich
13140100	Ice milk bar or stick, chocolate coated
13140110	Ice milk bar or stick, chocolate covered, with nuts
13140550	Ice milk cone, chocolate
13140600	Ice milk sundae, soft serve, chocolate or fudge topping, with whipped cream
13140630	Ice milk sundae, soft serve, fruit topping, with whipped cream
13140660	Ice milk sundae, soft serve, chocolate or fudge topping (without whipped cream)
13140670	Ice milk sundae, soft serve, fruit topping (without whipped cream)

13140680	Ice milk sundae, soft serve, not fruit or chocolate topping (without whipped cream)
13140700	Ice milk creamsicle or dreamsicle
13140900	Ice milk, fudgesicle
13141100	Ice milk, with sherbet or ice cream
13142000	Milk dessert bar or stick, frozen, with coconut
13150000	Sherbet, all flavors
13160100	Milk dessert, frozen, lowfat, made with low calorie sweetener, flavors other than chocolate
13160150	Milk dessert, frozen, nonfat, made with low calorie sweetener, chocolate
13160160	Milk dessert, frozen, nonfat, made with low calorie sweetener, flavors other than chocolate
13160200	Milk dessert, frozen, lowfat, flavors other than chocolate
13160210	Milk dessert, frozen, lowfat, chocolate
13160400	Milk dessert, frozen, milkfat free, flavors other than chocolate
13160410	Milk dessert, frozen, milkfat free, chocolate
13160600	Milk dessert, frozen, made with low calorie sweetener, flavors other than chocolate
13160650	Milk dessert, frozen, made with low calorie sweetener, chocolate
13161000	Milk dessert bar, frozen, made from lowfat milk
13161600	Milk dessert bar, frozen, made from lowfat milk and low calorie sweetener
13161630	Ice milk bar or stick, with low calorie sweetener, chocolate coated

Source Survey: CSFII

Figure A5.15.1. Cumulative Distribution for the Serving Size

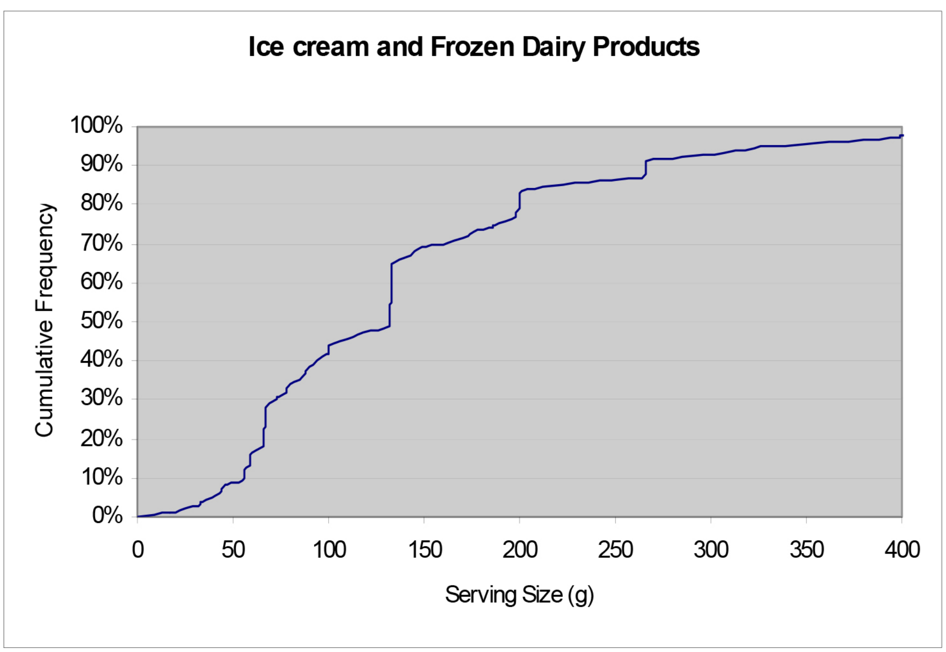

Table A5.15.2. Frequency Distribution of Amount Consumed per Serving

Percentile (grams per serving)			
50th	75th	95th	99th
132	186	330	454

Contamination at Retail

Table A5.15.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Ice cream
Frozen, dairy products
Ice cream/frozen yogurt
Frozen yogurt
Ice cream samples from finished products
Ice cream, iced products
Ice cream, mix
Ice cream novelty
Ice milk

Post Retail Growth

Table A5.15.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
No growth was modeled for this category.

Table A5.15.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	8 to 10	90 to 180

Figure A5.15.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 ^{0}C

Not applicable – No growth model for this category.

Table A5.15.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Not applicable – No growth model for this category.

Table A5.15.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Not applicable – No growth model for this category.

Table A5.15.8. Maximum Growth at Various Temperatures

Temperature (^{0}C)	**<5**	**5-7**	**>7**
Maximum Growth	5	6.5	8

16. Cultured Milk Products Food Categories

Consumption

Table A5.16.1. Foods Included in Consumption Data Set

Food Code	Food
11115000	Buttermilk, fluid, nonfat
11115200	Buttermilk, fluid, 2% fat
11410000	Yogurt, not specified as to type of milk or flavor
11411010	Yogurt, plain, not specified as to type of milk
11411100	Yogurt, plain, whole milk
11411200	Yogurt, plain, lowfat milk
11411300	Yogurt, plain, nonfat milk
11420000	Yogurt, vanilla, lemon, or coffee flavor, not specified as to type of milk
11421000	Yogurt, vanilla, lemon, or coffee flavor, whole milk
11422000	Yogurt, vanilla, lemon, maple, or coffee flavor, lowfat milk
11423000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk
11424000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk, sweetened with low calories
11425000	Yogurt, chocolate, not specified as to type of milk
11427000	Yogurt, chocolate, nonfat milk
11430000	Yogurt, fruit variety, not specified as to type of milk
11431000	Yogurt, fruit variety, whole milk
11432000	Yogurt, fruit variety, lowfat milk
11433000	Yogurt, fruit variety, nonfat milk
11433500	Yogurt, fruit variety, nonfat milk, sweetened with low calorie sweetener
12310100	Sour cream
12310200	Sour cream, half and half
12310300	Sour cream, reduced fat
12310350	Sour cream, light
12310370	Sour cream, fat free
12320200	Sour cream, filled, sour dressing, non-butterfat
12350000	Dip, sour cream base
12350020	Dip, sour cream base, reduced calorie
12350100	Spinach dip, sour cream base

Source Survey: **CSFII**

Figure A5.16.1. Cumulative Distribution for the Serving Size

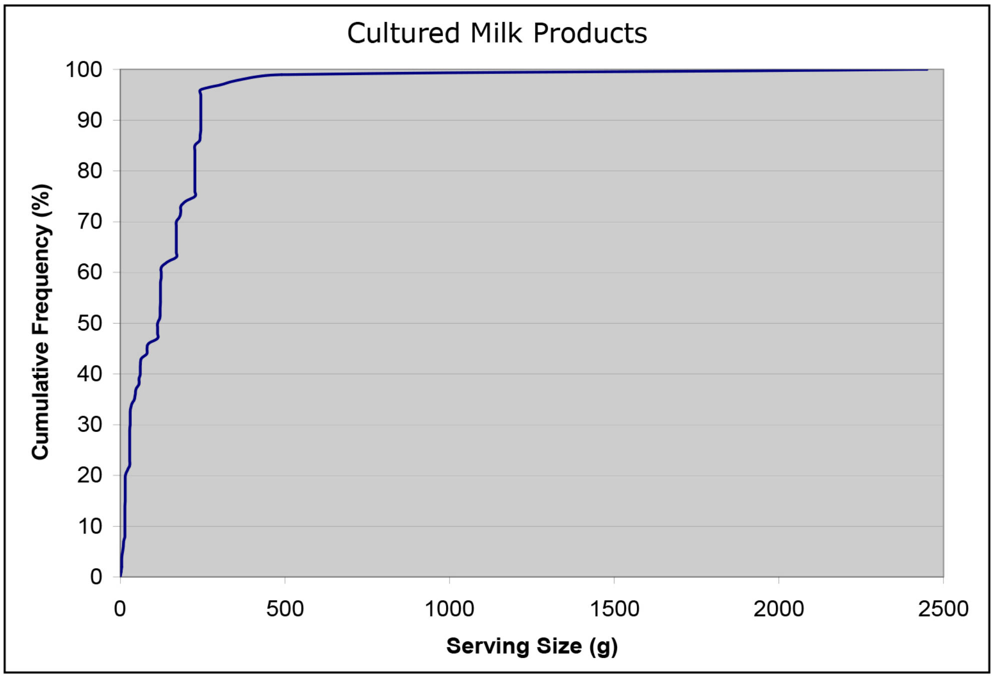

Table A5.16.2. Frequency Distribution of Amount Consumed per Serving

Percentile (grams per serving)			
50th	75th	95th	99th
114	227	245	490

Contamination at Retail

Table A5.16.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Yogurt
Buttermilk
Sour cream

Post Retail Growth

Table A5.16.4. Growth Rate (See appendix 8 for corresponding references)

Foods
Buttermilk
Yogurt

Table A5.16.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	15 to 45

Figure A5.16.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 ^{0}C

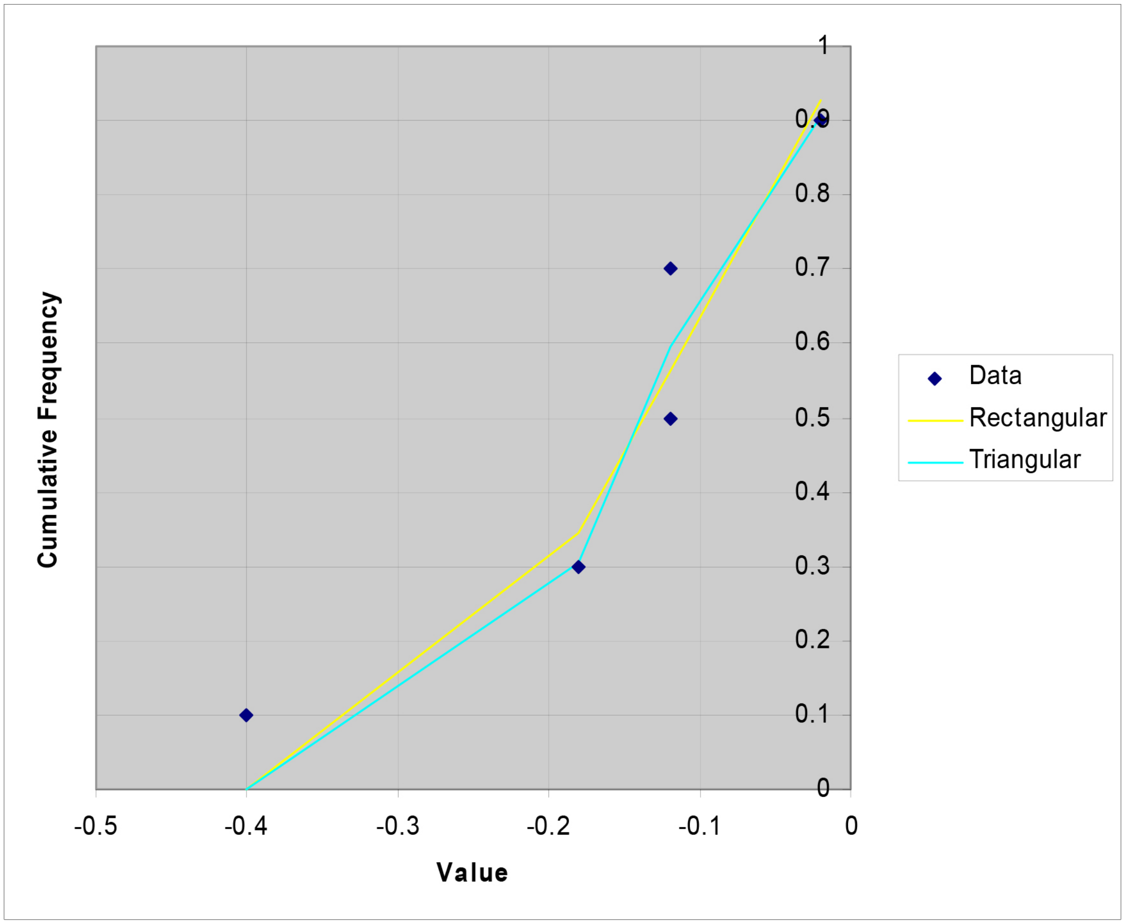

Table A5.16.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	RSQ	Probability
Rectangular	-0.275	-2×10^{-9}		0.035	0.63
Triangular	-0.290	-0.180	0.072379	0.030	0.37

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.16.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
-0.168	0.1432	5

Table A5.16.8. Maximum Growth at Various Temperatures

Temperature (°C)	**<5**	**5-7**	**>7**
Maximum Growth (log $_{10}$ cfu/g)	5	6.5	8

17. High Fat and Other Dairy Products Food Category

Consumption

Table A5.17.1. Foods Included in Consumption Data Set

Food Code	Food
11512000	Cocoa, hot chocolate, not from dry mix, made with whole milk
11512500	Spanish-style hot chocolate drink, Puerto Rican style, made with evaporated milk
11513000	Cocoa and sugar mixture, milk added, not specified as to type of milk
11513100	Cocoa and sugar mixture, whole milk added
11513200	Cocoa and sugar mixture, lowfat milk added
11513300	Cocoa and sugar mixture, skim milk added
11513400	Chocolate syrup, milk added, not specified as to type of milk
11513500	Chocolate syrup, whole milk added
11513600	Chocolate syrup, lowfat milk added
11513700	Chocolate syrup, skim milk added
11516000	Cocoa, whey, and low-calorie sweetener mixture, lowfat milk added
11519000	Milk beverage, made with whole milk, flavors other than chocolate
11520000	Milk, malted, unfortified, not specified as to flavor, made with milk
11525000	Milk, malted, fortified, natural flavor, made with milk
11526000	Milk, malted, fortified, chocolate, made with milk
11527000	Milk, malted, fortified, not specified as to flavor, made with milk
11531000	Eggnog, made with whole milk
11541000	Milk shake, not specified as to flavor or type
11541110	Milk shake, homemade or fountain-type, chocolate
11541120	Milk shake, homemade or fountain-type, flavors other than chocolate
11541400	Milk shake with malt
11541500	Milk shake, made with skim milk, chocolate
11541510	Milk shake, made with skim milk, flavors other than chocolate
11542100	Carry-out milk shake, chocolate
11542200	Carry-out milk shake, flavors other than chocolate
11551050	Milk fruit drink
11552200	Milk-based fruit drink
11560000	Chocolate-flavored drink, whey and milk-based
11560020	Flavored milk drink, whey and milk-based, flavors other than chocolate
12100100	Cream, not specified as to light, heavy, or half and half
12110100	Cream, light, fluid
12110300	Cream, light, whipped, unsweetened
12120100	Cream, half and half
12130100	Cream, heavy, fluid
12140000	Cream, heavy, whipped, sweetened
14620100	Dip, cream cheese base
14620120	Shrimp dip, cream cheese base
14620150	Dip, cheese with chili pepper (chili con queso)

14620200	Dip, cheese base other than cream cheese
81100500	Butter, not further specified
81101000	Butter, stick, salted
81101010	Butter, whipped, tub, salted
81101020	Butter, whipped, stick, salted
81101100	Butter, stick, unsalted
81101110	Butter, whipped, tub, unsalted
81101500	Light butter, stick, salted
81101510	Light butter, stick, unsalted
81101520	Light butter, whipped, tub, salted
81104500	Vegetable oil-butter spread, stick, salted
81104510	Vegetable oil-butter spread, tub, salted
81104550	Vegetable oil-butter spread, reduced calorie, stick, salted
81104560	Vegetable oil-butter spread, reduced calorie, tub, salted
81105010	Butter-margarine blend, stick, salted
81105020	Butter-margarine blend, tub, salted
81105030	Butter-margarine blend, stick, unsalted
81105500	Butter-vegetable oil blend

Source Survey: CSFII

Figure A5.17.1. Cumulative Distribut ion for the Serving Size

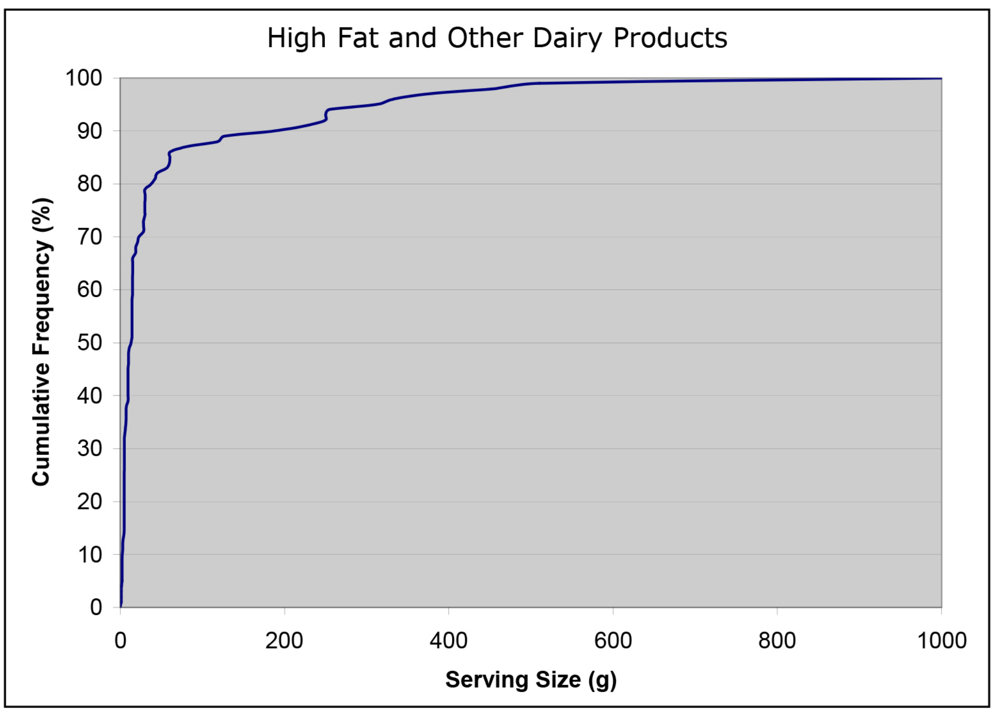

Table A5.17.2 Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
13	30	312	510

Contamination at Retail

Table A5.17.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Butter
Chocolate pudding
Cream
Cream half&half
Cream, pasteurized
Dairy products
Egg nog
Half and half
Milk shake
Whipping cream

Post Retail Growth

Table A5.17.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Cream
Butter
Sweetened condensed milk
Evaporated milk

Table A5.17.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	15 to 45

Figure A5.17.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 ^{0}C

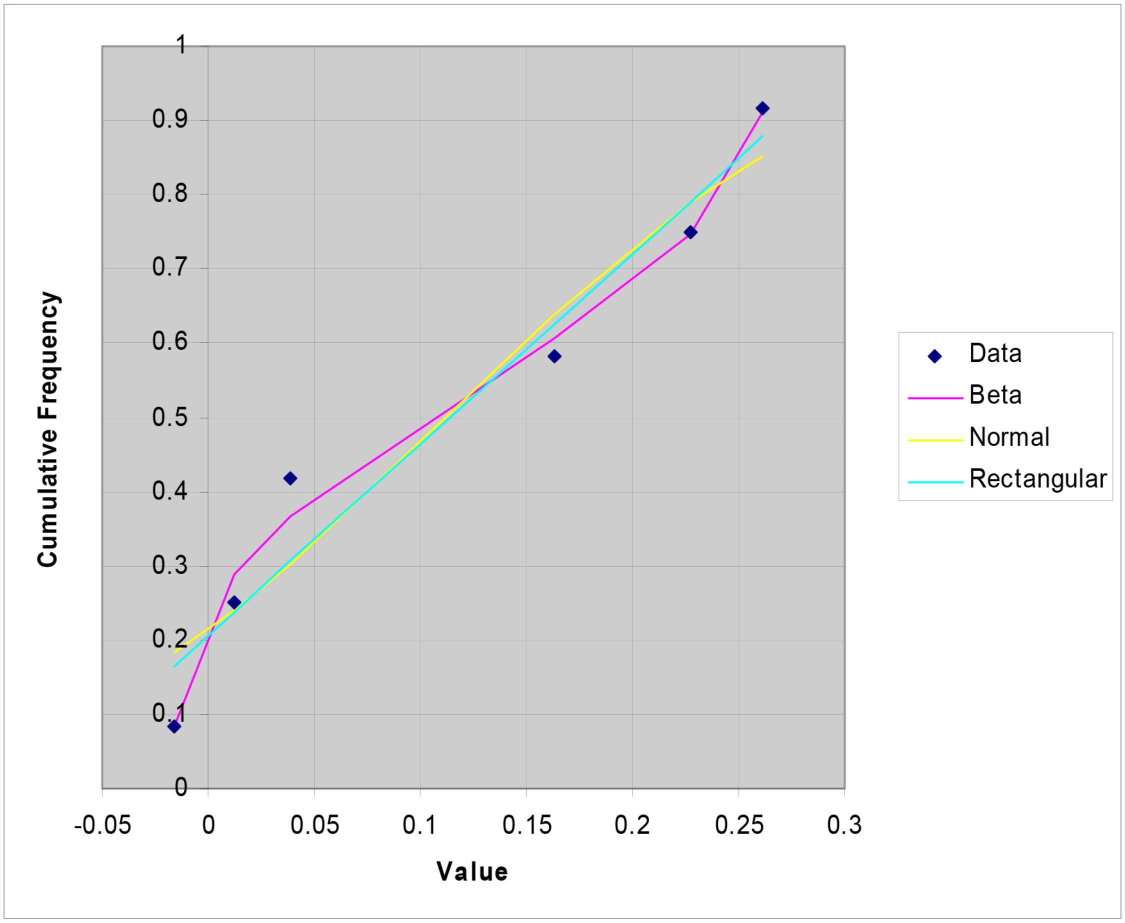

Table A5.17.6. Models Used to Characterize the Cumulative Distribution for the Exponential Growth Rate

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Beta	0.339278	0.3841	-0.01676	0.26361	0.005	0.65
Rectangular	-0.07984	0.308504			0.024	0.33
Normal	0.112672	0.142126			0.032	0.03

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.17.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
0.114	0.118	6

Table A5.17.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth ($\log_{10}$ cfu/g)	5	6.5	8

18. Frankfurters – Reheated Food Category

Consumption

Table A5.18.1. Foods Included in Consumption Data Set

Food Code	Food
25210110	Frankfurter, wiener, or hot dog, not further specified
25210150	Frankfurter or hot dog, cheese-filled
25210210	Frankfurter or hot dog, beef
25210220	Frankfurter or hot dog, beef and pork
25210230	Frankfurter or hot dog, beef and pork, lowfat
25210250	Frankfurter or hot dog, meat and poultry, fat free
25210280	Frankfurter or hot dog, meat and poultry
25210310	Frankfurter or hot dog, chicken
25210410	Frankfurter or hot dog, turkey
25210510	Frankfurter or hot dog, low salt
25210610	Frankfurter or hot dog, beef, lowfat
25210700	Frankfurter or hot dog, meat and poultry, lowfat
27120210	Frankfurter or hot dog, with chili, no bun
27120250	Frankfurter or hot dog with tomato-based sauce (mixture)
27560300	Corn dog (frankfurter or hot dog with cornbread coating)
27560320	Frankfurter or hot dog, plain, on bun
27560330	Frankfurter or hot dog, with cheese, plain, on bun
27560340	Frankfurter or hot dog, with catsup and/or mustard, on bun
27560350	Pig in a blanket (frankfurter or hot dog wrapped in dough)
27560360	Frankfurter or hot dog, with chili, on bun
27560370	Frankfurter or hot dog with chili and cheese, on bun

Source Survey: CSFII

Figure A5.18.1. Cumulative Distribution for the Serving Size

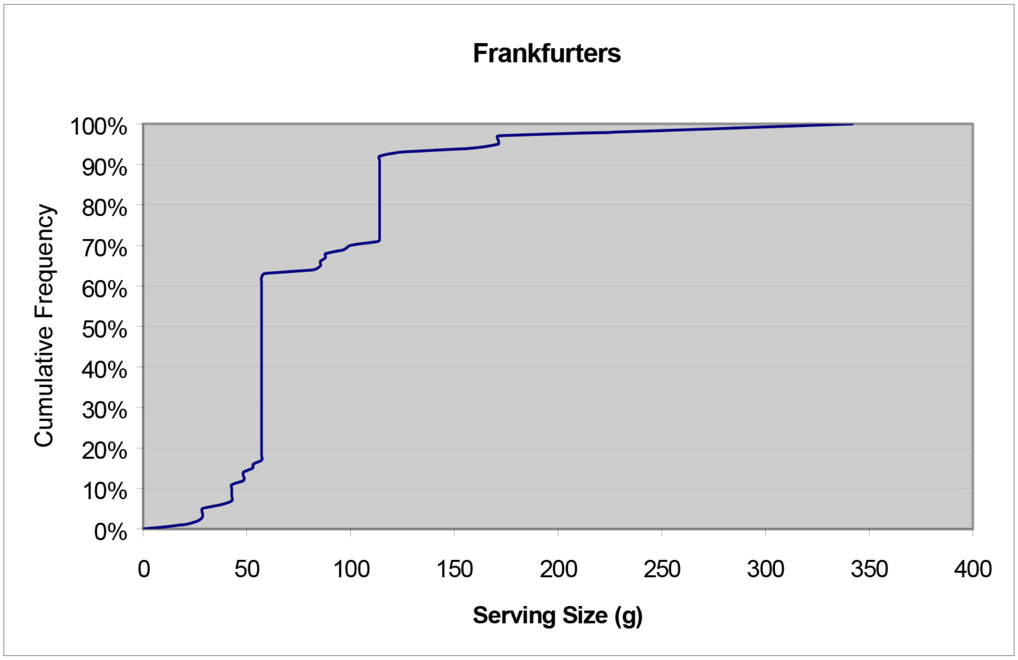

Table A5.18.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
57	114	171	285

Contamination at Retail

Table A5.18.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Hot dogs
Hot dogs, beef
Frankfurter, sausage type
Hot dogs, chicken/pork
Hot dogs, turkey

Post Retail Growth

Table A5.18.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Frankfurters
Hot dog, poultry
Hot dog, turkey
Hot dog, pork

Table A5. 18.5. Consumer Storage Times Used in this Risk Assessment (days)

Storage times were modeled using AMI survey data – see Chapter III. Exposure Assessment, section "Modeling: Growth Between Retail and Consumption" for details. See Figure III-7.

Figure A5.18.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5°C

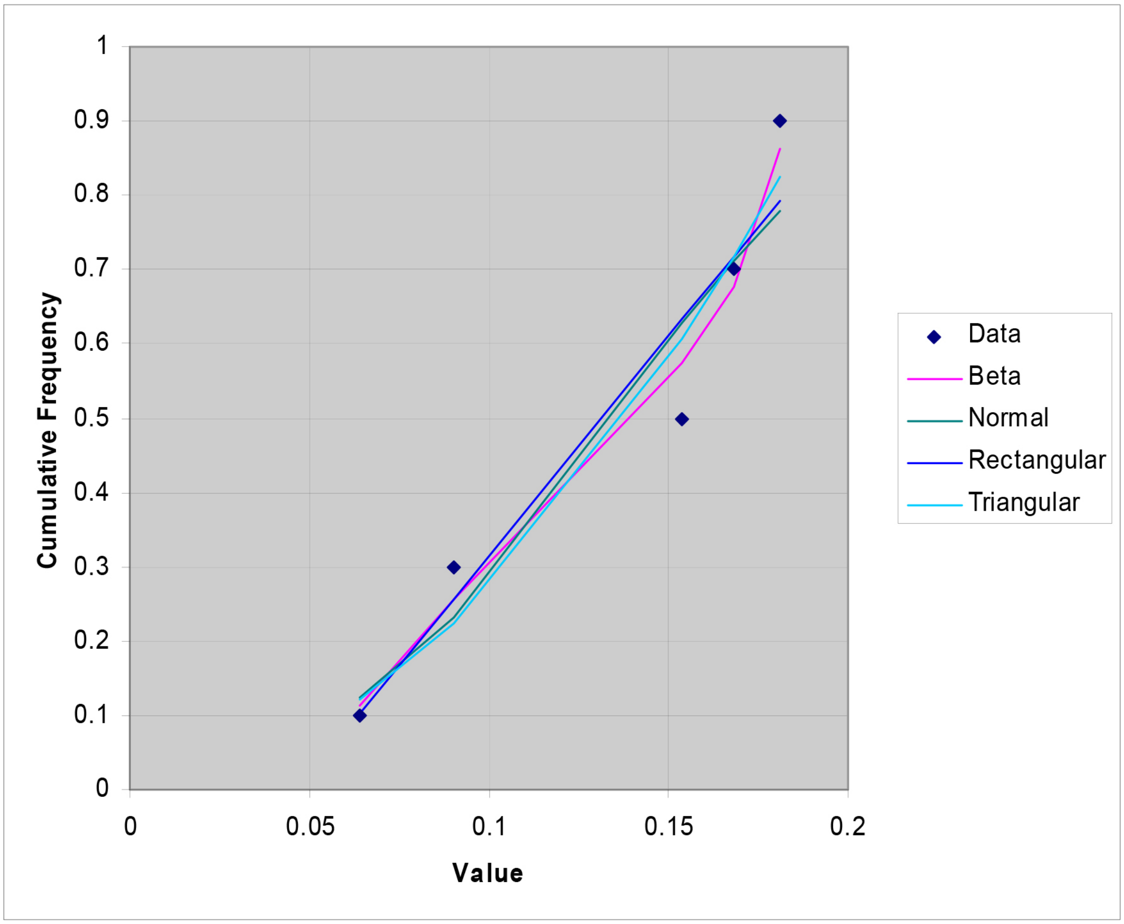

Table A5.18.6. Models Used to Characterize the Cumulative Exponential Growth Rate

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Beta	0.590786	0.39764	0.054009	0.18281	0.010	0.59
Rectangular	0.046727	0.216073			0.032	0.20
Triangular	-8.75×10^{-3}	0.181	0.22089		0.024	0.17
Normal	0.134343	0.060556			0.036	0.03

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.18.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
0.131	0.051	5

Table A5.18.8. Maximum Growth at Various Temperatures

Temperature (^{0}C)	<5	5-7	>7
Maximum Growth (log $_{10}$ cfu/g)	5	6.5	8

19. Frankfurters – Not Reheated Food Category

Consumption

Table A5.19.1. Foods Included in Consumption Data Set

The foods included in the consumption data set for Frankfurters – Reheated were used, see Table A5.18.1

Figure A5.19.1. Cumulative Distribution for Serving Size

The cumulative distribution for Frankfurters – Reheated was used, see Figure A5.18.1

Table A5.19.2. Frequency Distribution of Amount Consumed per Serving

The frequency distribution of amount consumed per serving for Frankfurters – Reheated was used, see Table A5.18.2

Contamination at Retail

Table A5.19.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

The foods included in the contamination level data set for Frankfurters – Reheated were used, see Table A5.18.3

Post Retail Growth

Table A5.19.4. Foods Included in Post Retail Growth Data Set

The foods included in the post retail growth data set for Frankfurters – Reheated were used, see Table A5.18.4

Table A5.19.5. Consumer Storage Times Used in this Risk Assessment (days)

Storage times were modeled using AMI survey data – see section Chapter III. Exposure Assessment, section "Modeling: Growth Between Retail and Consumption" for details. (Figure III-7)

Figure A5.19.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5°C

The cumulative distribution for the exponential reference growth rate (EGR) at 5°C for Frankfurters – Reheated was used, see Figure A5.18.2

Table A5.19.6. Models Used to Characterize the Cumulative Exponential Growth Rate

The models used to characterize the cumulative exponential growth rate for Frankfurters – Reheated were used, see Table A5.18.6

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.19.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

The mean, standard deviation and number of samples (N) for exponential growth rate (EGR) at 5 °C for Frankfurters – Reheated were used, see Table A5.18.7

Table A5.19.8. Maximum Growth at Various Temperatures

The maximum growth at various temperatures for Frankfurters – Reheated were used, see Table A5.18.8

20. Dry/Semi-Dry Fermented Sausages Food Category

Consumption

Table A5.20.1. Foods Included in Consumption Data Set

Food Code	Food
25220120	Beef sausage, smoked, stick
25220420	Bologna, Lebanon
25221250	Pepperoni
25221500	Salami, not further specified
25221520	Salami, dry or hard
25221530	Salami, beef
25221810	Thuringer
Source Survey:	**CSFII**

Figure A5.20.1. Cumulative Distribution For the Serving Size

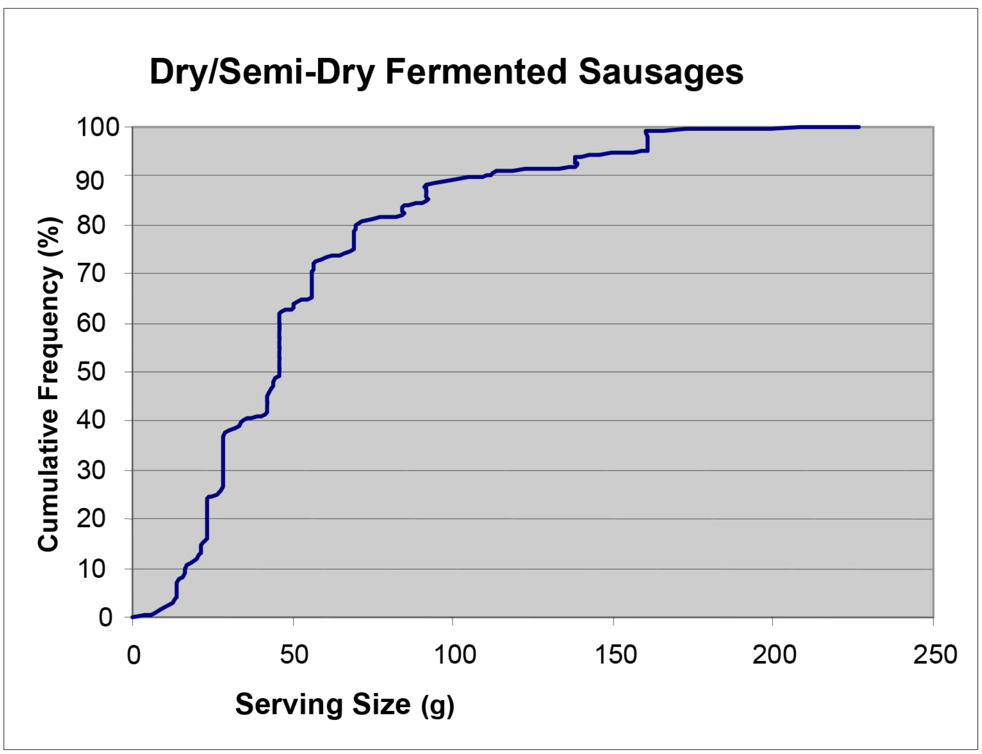

Table A5.20.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
46	69	161	161

Contamination at Retail

Table A5.20.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Beef, salami, and mettwurst
Salami
Salami and pork
Sausage
Sausage, smoked
Sausage, cooked, cured
Sausage, fermented
Cured chorizo
Beef stick
Pepperoni/sausage, fermented
Sausage, dried

Post Retail Growth

Table A5.20.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Summer sausage
Fermented sausage
German-style American Italian sausage
Norwegian fermented dry sausage

Table A5.20.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	45 to 90

Figure A5.20.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5°C

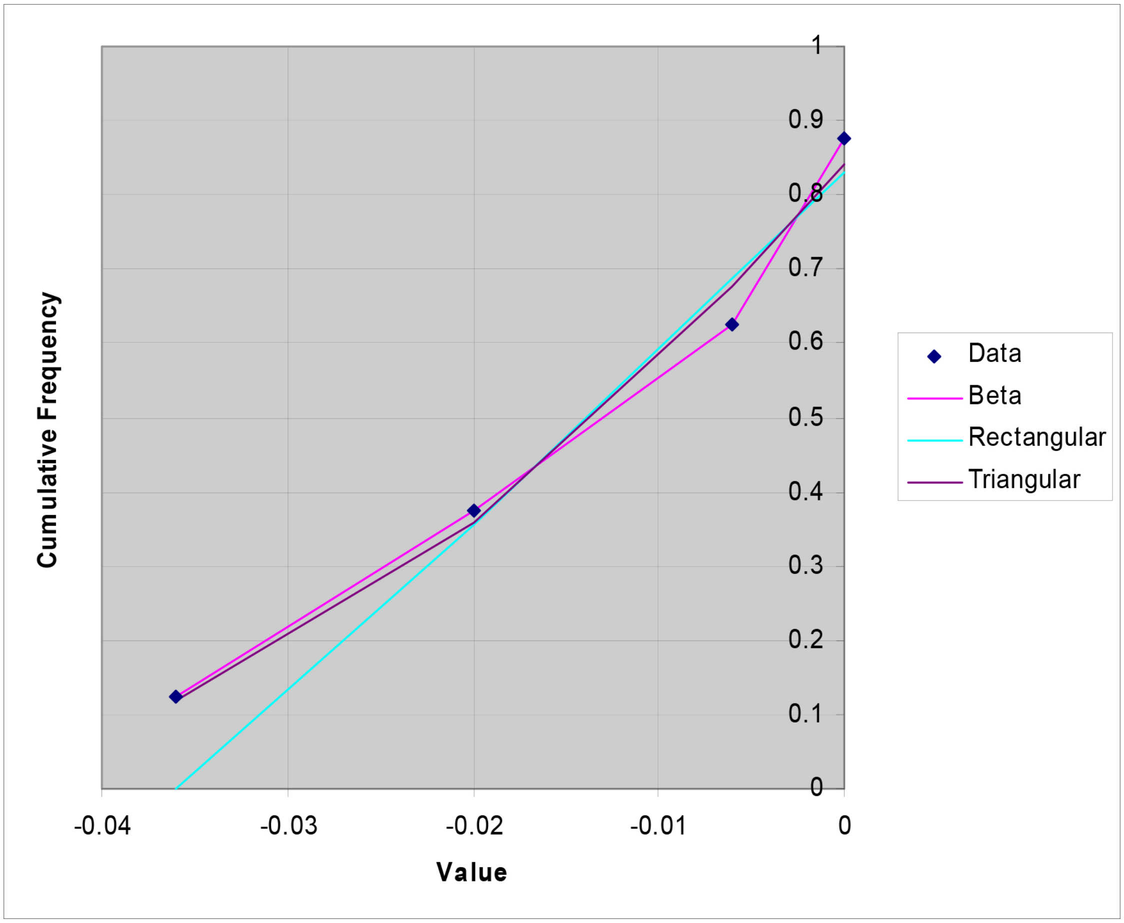

Table A5.20.6. Models Used to Characterize the Cumulative Exponential Growth Rate

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Triangular	-5.78×10^{-2}	1.23×10^{-4}	0.010738		0.004	0.48
Beta	0.608426	0.397069	-0.04	0.000422	< 0.001	0.38
Rectangular	-0.035	0.007133			0.022	0.19

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.20.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
-0.016	0.016	4

Table A5.20.8. Maximum Growth at Various Temperatures

Temperature (^{0}C)	<5	5-7	>7
Maximum Growth (log_{10} cfu/g)	5	6.5	8

21. Deli Meats Food Category

Consumption

Table A5.21.1. Foods Included in Consumption Data Set

Food Code	Food
21002000	Beef, pickled
22311210	Ham, smoked or cured, low sodium, cooked, lean and fat eaten
22311450	Ham, prosciutto
23322100	Deer bologna
25220010	Cold cut, not further specified
25220390	Bologna, beef, lowfat
25220400	Bologna, pork and beef
25220410	Bologna, not further specified
25220430	Bologna, beef
25220440	Bologna, turkey
25220450	Bologna ring, smoked
25220460	Bologna, pork
25220470	Bologna, beef, lower sodium
25220480	Bologna, chicken, beef, and pork
25220500	Bologna, beef and pork, lowfat
25220910	Head cheese
25221210	Mortadella
25221480	Mettwurst
25221710	Souse
25230210	Ham, sliced, prepackaged or deli, luncheon meat
25230220	Ham, sliced, low salt, prepackaged or deli, luncheon meat
25230230	Ham, sliced, extra lean, prepackaged or deli, luncheon meat
25230310	Chicken or turkey loaf, prepackaged or deli, luncheon meat
25230410	Ham loaf, luncheon meat
25230430	Ham and cheese loaf
25230510	Ham, luncheon meat, chopped, minced, pressed, spiced, not canned
25230520	Ham, luncheon meat, chopped, minced, pressed, spiced, lowfat, not canned
25230550	Ham, pork, and chicken, luncheon meat, chopped, minced, pressed, spiced, canned, reduced sodium
25230560	Liverwurst
25230610	Luncheon loaf (olive, pickle, or pimiento)
25230710	Sandwich loaf, luncheon meat
25230790	Turkey ham, sliced, extra lean, prepackaged or deli, luncheon meat
25230800	Turkey ham
25230810	Veal loaf
25230820	Turkey pastrami
25230840	Turkey salami
25230900	Turkey or chicken breast, prepackaged or deli, luncheon meat
25231110	Beef, sliced, prepackaged or deli, luncheon meat
25231150	Corned beef, pressed
27500100	Meat sandwich, not further specified
27510700	Meatball and spaghetti sauce submarine sandwich, on roll
27510950	Reuben sandwich (corned beef sandwich with sauerkraut and cheese), with spread

27513010	Roast beef sandwich
27513040	Roast beef submarine sandwich, on roll, with lettuce, tomato and spread
27513050	Roast beef sandwich with cheese
27513060	Roast beef sandwich with bacon and cheese sauce
27513070	Roast beef submarine sandwich, on roll, au jus
27515000	Steak submarine sandwich, on roll, with lettuce and tomato
27515010	Steak sandwich, plain, on roll
27515020	Steak and cheese submarine sandwich, on roll, with lettuce and tomato
27515030	Steak and cheese sandwich, plain, on roll
27515040	Steak and cheese submarine sandwich, plain, on roll
27515070	Steak and cheese submarine sandwich, with fried peppers and onions, on roll
27515080	Steak sandwich, plain, on biscuit
27515150	Steak patty (breaded, fried) sandwich, with mayonnaise or salad dressing, lettuce, and tomato, on bun
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread
27520130	Bacon, chicken, and tomato club sandwich, with lettuce and spread
27520160	Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and spread
27520250	Ham on biscuit
27520300	Ham sandwich, with spread
27520320	Ham and cheese sandwich, with lettuce and spread
27520360	Ham and cheese sandwich, on bun, with lettuce and spread
27520370	Hot ham and cheese sandwich, on bun
27520380	Ham and cheese on English muffin
27520390	Ham and cheese submarine sandwich, on multigrain roll, with lettuce, tomato and spread
27520500	Pork, barbecue sauce, onions and dill pickles on white roll
27520540	Ham and tomato club sandwich, with lettuce and spread
27540110	Chicken sandwich, with spread
27540130	Chicken barbecue sandwich
27540140	Chicken fillet (breaded, fried) sandwich
27540150	Chicken fillet (breaded, fried) sandwich with lettuce, tomato and spread
27540180	Chicken patty sandwich or biscuit
27540190	Chicken patty sandwich, with lettuce and spread
27540200	Fajita-style chicken sandwich with cheese, on pita bread, with lettuce and tomato
27540230	Chicken patty sandwich with cheese, on wheat bun, with lettuce, tomato and spread
27540240	Chicken fillet, (broiled), sandwich, on whole wheat roll, with lettuce, tomato and spread
27540260	Chicken fillet, broiled, sandwich, on oat bran bun, with lettuce, tomato and spread
27540270	Chicken fillet, broiled, sandwich, with lettuce, tomato and non-mayonnaise type spread
27540280	Chicken fillet, broiled, sandwich with cheese, on bun, with lettuce, tomato and spread
27540310	Turkey sandwich, with spread
27540350	Turkey submarine sandwich, on roll, with cheese, lettuce, tomato and spread
27560110	Bologna sandwich, with spread
27560120	Bologna and cheese sandwich, with spread
27560910	Submarine, cold cut sandwich, on bun, with lettuce

Source Survey: CSFII

Figure A5.21.1. Cumulative Distribution for the Serving Size

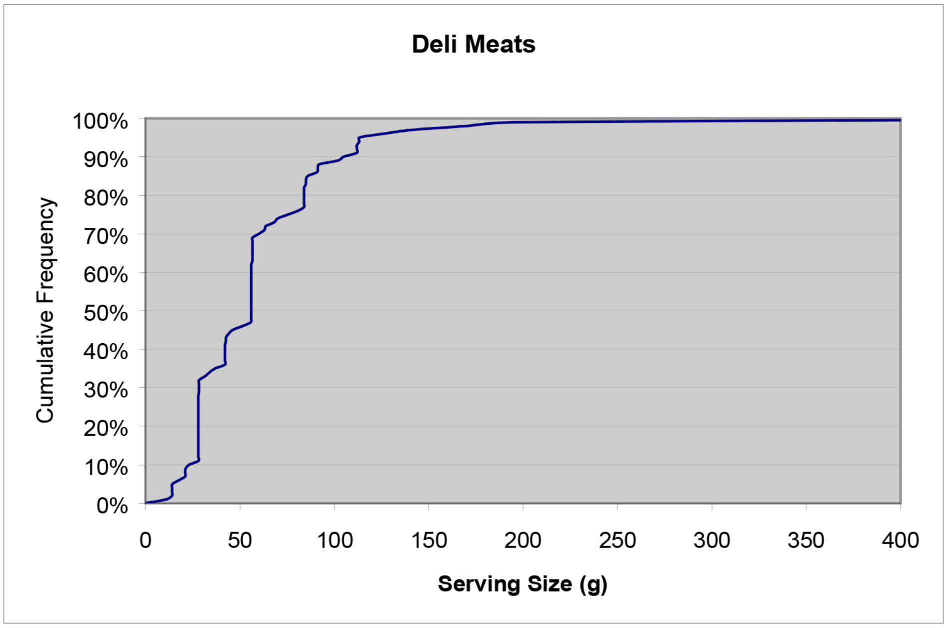

Table A5.21.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	75th	95th	99th
56	75	113	196

Contamination at Retail

Table A5.21.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Bacon
BBQ beef
BBQ chicken
BBQ meat
BBQ pork
Beef, ready-to-eat
Bologna
Chicken breaded
Chicken, ready-to-eat
Cold cuts
Corned beef
Corned beef, roast and cooked
Corned beef, roast cooked
Deli meats
Ham and luncheon meats, sliced
Ham like products
Ham, cooked
Ham, sliced vacuum packed
Ham, cooked, sliced
Ham/salami/bacon/luncheon meat
Ham, sliced/sliced luncheon
Mortadella
Olive loaf
Pariza
Pastrami
Pork
Pork loin
Pork shoulder, sliced vacuum packed
Pork, ready-to-eat
Poultry, cooked
Roast beef
Ready-to-eat broiler products
Ready-to-eat meats
Sausages
Turkey breast sliced
Turkey breast, cooked smoked
Turkey breast, smoked
Turkey cuvette, smoked
Turkey fillet, smoked ready-to-eat
Turkey ham
Turkey parts

Turkey pastrami
Turkey ready-to-eat
Turkey wings
Turkey, cooked smoked diced

Post Retail Growth

Table A5.21.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Beef sirloin
Bologna
Chicken, cooked
Chicken, fillets/breaded
Chicken, homogenate
Chicken, sliced/vacuum packed
Corned beef
Ham, cooked
Ham, cooked and vacuum packed
Ham, vacuum packed
Roast beef
Turkey loaf, cooked, uncured, vacuum packed
Turkey, sliced
Turkey, sliced, vacuum packed

Table A5.21.5. Consumer Storage Times Used in this Risk Assessment (days)

Storage times were modeled using AMI survey data – see section Chapter III. Exposure Assessment, section “Modeling: Growth Between Retail and Consumption” for details. (See Figure III-1)

Figure A5.21.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C

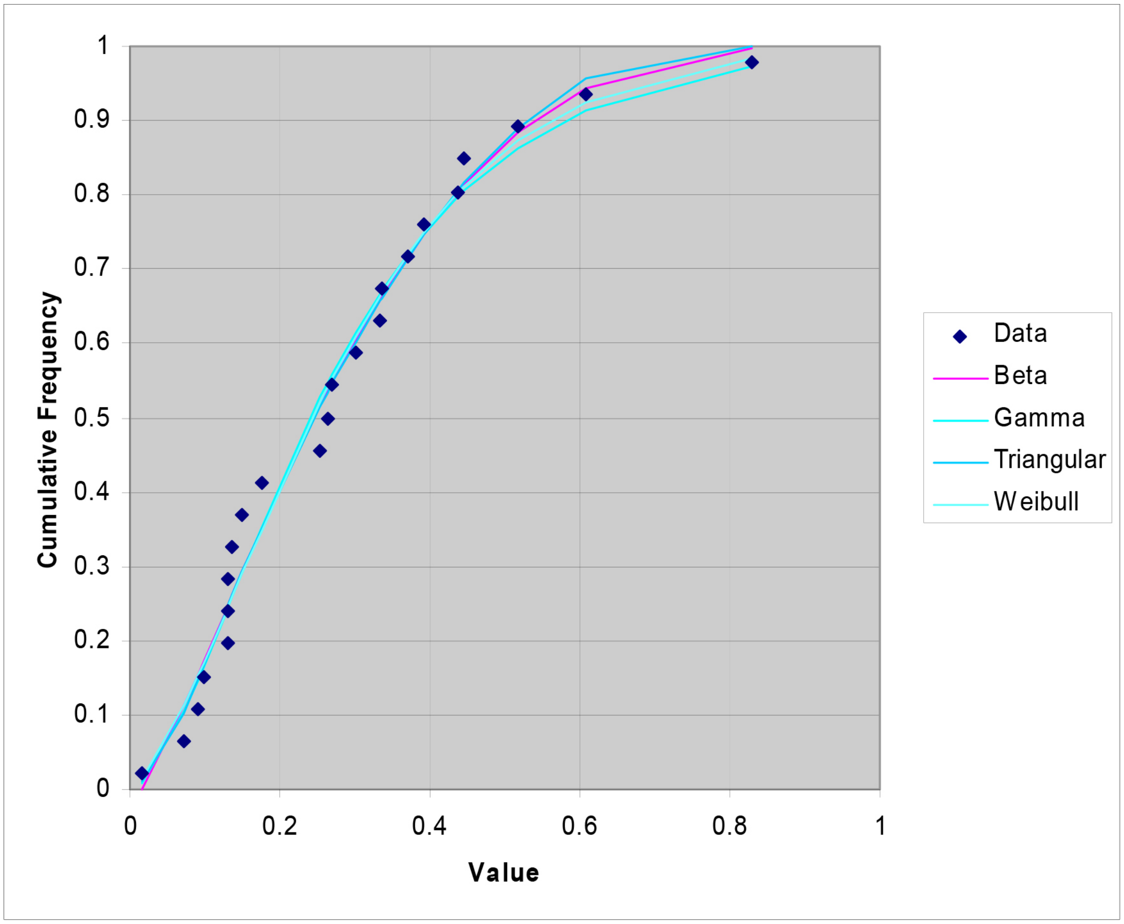

Table A5.21.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Triangular	-0.0113	0.0785	0.755007		0.029	0.42
Weibull	1.45	0.314009			0.033	0.24
Gamma	1.82	0.160235			0.034	0.20
Beta	1.232895	3.038674	0.01584	0.921607	0.031	0.14

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.21.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
0.282	0.196	23

NOTE: EGR derived using random sampling of growth data.

Table A5.21.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth ($\log_{10}$ cfu/g)	5	6.5	8

22. Pâté and Meat Spreads Food Category

Consumption

Table A5.22.1. Foods Included in Consumption Data Set

Food Code	Food
25112200	Liver paste or pâté, chicken
25240000	Meat spread or potted meat
25240110	Chicken salad spread
25240210	Ham, deviled or potted
25240220	Ham salad spread
25240310	Roast beef spread
27563010	Meatspread or potted meat sandwich

Source Survey: CSFII

Figure A5.22.1. Cumulative Distribution for the Serving Size

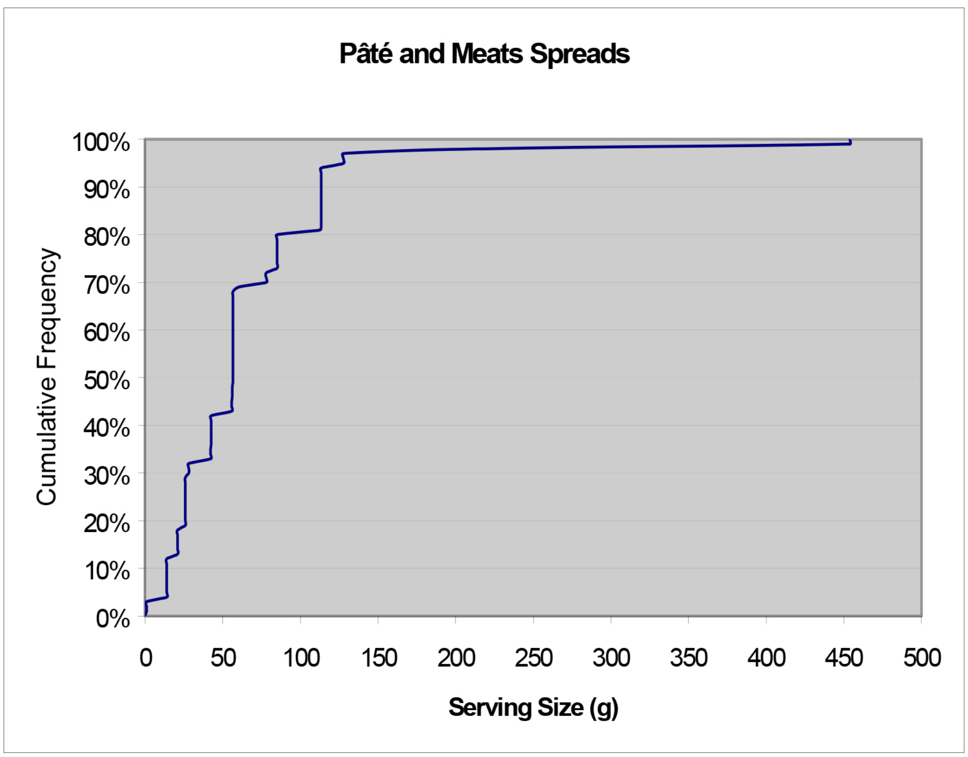

Table A5.22.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50th	**75th**	**95th**	**99th**
57	85	128	454

Contamination at Retail

Table A5.22.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Aspic mince, prepackaged, cooked
Aspic mince, un-prepackaged, cooked
Ham spread
Meat spreads
Pâté
Pâté mince, prepackaged, cooked
Pâté mince, un-prepackaged, cooked
Pâté, fish & seafood
Pâté, meat-based
Pâté, poultry-based
Pâté, undefined
Salmon pâté
Shrimp pâté
Tuna pâté

Post Retail Growth

Table A5.22.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Pâté

Table A5.22.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	6 to 10	15 to 45

Figure A5.22.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C

Since only two data points were available for this group, EGR distributions were not derived by curve-fitting. Instead, a probability tree with two alternate distributions (rectangular and normal) was employed where each distribution was given equal weight.

Table A5.22.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates

Model	Parameter 1	Parameter 2	Probability
Normal	0.25	0.15	0.5
Rectangular	0.143	0.361	0.5

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Table A5.22.7. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

Mean (log_{10} cfu/g/day)	Std. Dev.	N
0.250	0.156	2

Table A5.22.8. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth (log_{10} cfu/g)	5	6.5	8

23. Deli-type Salads Food Category

Consumption

Table A5.23.1. Foods Included in Consumption Data Set

Food Code	Food
14610200	Cheese, cottage cheese, with gelatin dessert
14610210	Cheese, cottage cheese, with gelatin dessert and fruit
27416250	Beef salad
27420020	Ham or pork salad
27446200	Chicken or turkey salad
27446220	Chicken or turkey salad with egg
27446300	Chicken or turkey garden salad (chicken and/or turkey, tomato and/or carrots, other vegetables), no dressing
27446310	Chicken or turkey garden salad (chicken and/or turkey, other vegetables excluding tomato and carrots), no dressing
27446350	Oriental chicken or turkey garden salad (chicken and/or turkey, lettuce, fruit, nuts), no dressing
27450010	Crab salad
27450020	Lobster salad
27450030	Salmon salad
27450060	Tuna salad
27450070	Shrimp salad
27450080	Seafood salad
27450090	Tuna salad with cheese
27450100	Tuna salad with egg
27450110	Shrimp garden salad (shrimp, eggs, tomato and/or carrots, other vegetables), no dressing
27450120	Shrimp garden salad (shrimp, eggs, vegetables excluding tomato and carrots), no dressing
27450130	Crab salad made with imitation crab
27450180	Seafood garden salad with seafood, vegetables excluding tomato and carrots, no dressing
27450190	Seafood garden salad with seafood, tomato and/or carrots, other vegetables, no dressing
27460490	Julienne salad (meat, cheese, eggs, vegetables), no dressing
27460510	Antipasto with ham, fish, cheese, vegetables
27520340	Ham salad sandwich
27540120	Chicken salad or chicken spread sandwich
27540320	Turkey salad or turkey spread sandwich
27550710	Tuna salad sandwich, with lettuce
27550720	Tuna salad sandwich
27550750	Tuna salad submarine sandwich, on roll, with lettuce
32103000	Egg salad
32203010	Egg salad sandwich

41203020	Kidney bean salad
41205070	Hummus
58101930	Taco or tostada salad with beef and cheese, fried flour tortilla
58101940	Taco or tostada salad, meatless, with cheese, fried flour tortilla
58148110	Macaroni salad
58148120	Macaroni salad with egg
58148130	Macaroni salad with tuna
58148140	Macaroni salad with crab meat
58148150	Macaroni salad with shrimp
58148160	Macaroni salad with tuna and egg
58148170	Macaroni salad with chicken
58148180	Macaroni salad with cheese
58148500	Pasta salad (macaroni or noodles, vegetables, dressing)
58148550	Pasta salad with meat (macaroni or noodles, vegetables, meat, dressing)
63301010	Ambrosia
63307010	Cranberry-orange relish, uncooked
63401010	Apple salad with dressing
63401020	Apple and cabbage salad with dressing
63402950	Fruit salad (excluding citrus fruits) with salad dressing or mayonnaise
63402960	Fruit salad (excluding citrus fruits) with cream
63402970	Fruit salad (excluding citrus fruits) with cream substitute
63402980	Fruit salad (excluding citrus fruits) with marshmallows
63403000	Fruit salad (excluding citrus fruits) with pudding
63403010	Fruit salad (including citrus fruits) with salad dressing or mayonnaise
63403020	Fruit salad (including citrus fruit) with cream
63403030	Fruit salad (including citrus fruits) with cream substitute
63403040	Fruit salad (including citrus fruits) with marshmallows
63403100	Fruit dessert with cream and/or pudding and nuts
63408010	Guacamole with tomatoes
63408200	Guacamole with tomatoes and chili peppers
63409010	Guacamole, not further specified
63411010	Cranberry salad, congealed
63412010	Pear salad with dressing
63413020	Pineapple salad with cream cheese
71601010	Potato salad with egg
71602010	Potato salad, German style
71603010	Potato salad
72116140	Caesar salad (with romaine)
73101110	Carrots, raw, salad
73101210	Carrots, raw, salad with apples
74506000	Tomato and cucumber salad made with tomato, cucumber, oil, and vinegar
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing
75141000	Cabbage salad or coleslaw, with dressing
75141100	Cabbage salad or coleslaw with apples and/or raisins, with dressing
75141200	Cabbage salad or coleslaw with pineapple, with dressing
75142500	Cucumber salad with creamy dressing

75142550	Cucumber salad made with cucumber, oil, and vinegar
75142600	Cucumber salad made with cucumber and vinegar
75144100	Lettuce, wilted, with bacon dressing
75145000	Seven layer salad (lettuce salad made with a combination of onion, celery, green pepper, peas, mayonnaise, cheese, eggs)
75146000	Greek Salad
75201030	Artichoke salad in oil
75302080	Bean salad, yellow and/or green string beans
75416500	Pea salad
75416600	Pea salad with cheese
91501020	Gelatin dessert with fruit
91501040	Gelatin dessert with fruit and whipped cream
91501080	Gelatin dessert with fruit and cream cheese
91501090	Gelatin dessert with fruit, vegetable, and nuts
91501100	Gelatin salad with vegetables
91511020	Gelatin dessert, dietetic, with fruit, sweetened with low calorie sweetener
91511090	Gelatin dessert, dietetic, with fruit and vegetable(s), sweetened with low calorie sweetener
91511100	Gelatin salad, dietetic, with vegetables, sweetened with low calorie sweetener
91511110	Gelatin dessert, dietetic, with fruit and whipped topping, sweetened with low calorie sweetener

Source Survey: CSFII

Figure A5.23.1. Cumulative Distribution for the Serving Size

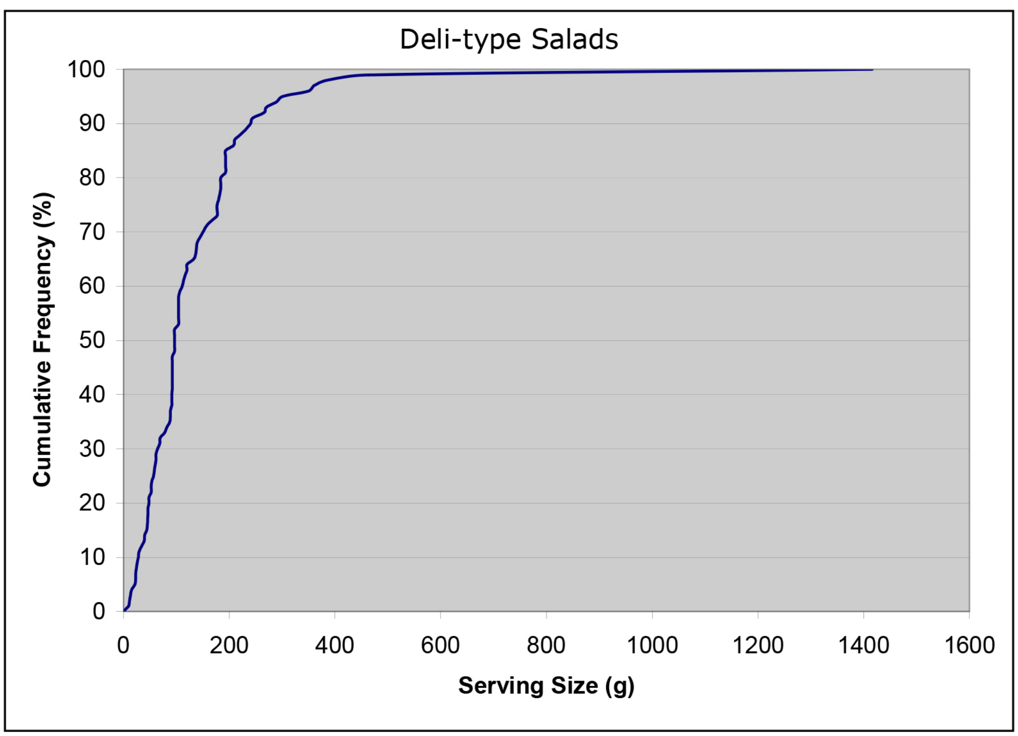

Table A5.23.2. Frequency Distribution of Amount Consumed per Serving

Percentiles (grams per serving)			
50^{th}	75^{th}	95^{th}	99th
97	177	301	464

Contamination at Retail

Table A5.23.3. Foods Included in Contamination Level Data Set (See appendix 7 for corresponding references)

Foods
Antipasto
Broccoli and cheese salad
Caesar
Chef
Chicken salad
Cole slaw
Crab salad
Creamy fruit
Deli Salads
Deli, mayonnaise
Egg salad
Egg/egg mayonnaise salad
Delicatessen salads, unspecified
Fish & shrimp salad
Fish marinate and seafood salad
Fish salad
Fruit/nut salad
Greek salad
Ham salad
Macaroni salad with cheese
Meat & egg salad
Meat salad
Other salad (veg) with mayonnaise
Pasta salad
Pea salad
Salad, potato
Salads (2 egg, 2 cheese,1 dressing)
Salads, seafood
Salmon salad
Shrimp salad
Tortellini salad
Tuna salad
Turkey salad
Various meat and poultry salads

Post Retail Growth

Table A5.23.4. Foods Included in Post Retail Growth Data Set (See appendix 8 for corresponding references)

Foods
Crab salad, store prepared
Shrimp salad, store prepared
Shrimp salad, plant prepared
Chicken salad, store prepared
Chicken salad, plant prepared
Potato salad, store prepared
Potato salad, plant prepared
Cole slaw, store prepared
Cole slaw, plant prepared
Egg salad, store prepared
Tuna salad, store prepared
Ham salad, store prepared
Imitation crab salad, store prepared
Chicken salad, high pH
Chicken salad, low pH
Potato salad, high pH
Potato salad, low pH
Pasta salad, high pH
Pasta salad, low pH
Seafood salad, high pH
Seafood salad, low pH

Table A5.23.5. Consumer Storage Times Used in this Risk Assessment (days)

Minimum	Mode	Maximum
0.5	3 to 4	8 to 12

Figure A5.23.2. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C – Low Growth Salads

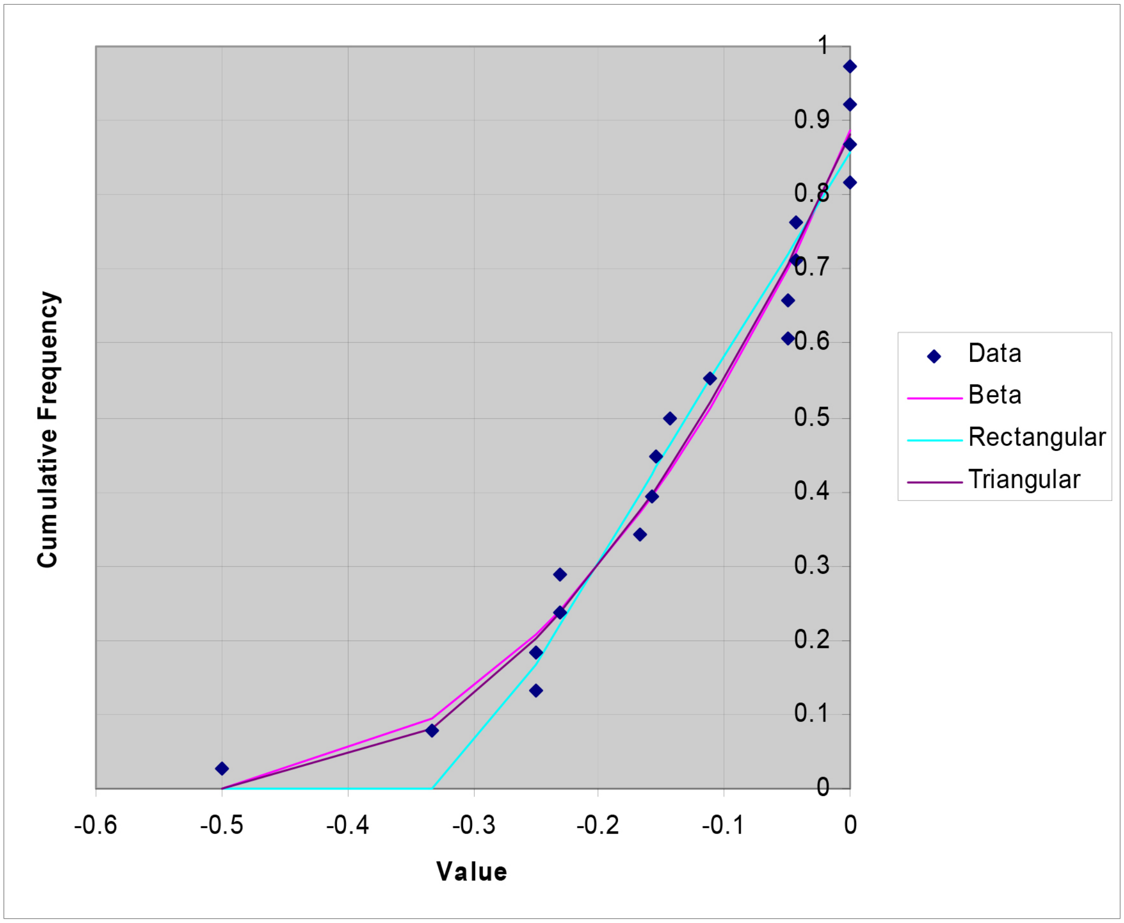

Table A5.23.6. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates–Low Growth Deli Salads

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	RSQ	Probability
Triangular	-0.479	2.60×10^{-3}	0.061947		0.046	0.45
Rectangular	-0.31072	0.051316			0.057	0.34
Beta	1.990244	0.897964	-0.505	0.023533	0.046	0.21

See Appendix 6: Software for a description of the common names used for the parameters for these statistical distributions (models).

Figure A5.23.3. Cumulative Distribution for the Exponential Reference Growth Rate (EGR) at 5 °C – High Growth Salads

Since only two data points were available for this group, EGR distributions were not derived by curve-fitting. Instead, a probability tree with two alternate distributions (rectangular and normal) was employed where each distribution was given equal weight.

Table A5.23.7. Models Used to Characterize the Cumulative Distribution for Exponential Growth Rates – High Growth Deli Salads

Model	Parameter 1	Parameter 2	Parameter 3	Parameter 4	Probability
Rectangular	0.100	0.143			0.5
Normal	0.122	0.030406			0.5

Table A5.23.8. Mean, Standard Deviation and Number of Samples (N) for Exponential Growth Rate (EGR) at 5 °C

	Mean ($\log_{10}$ cfu/g/day)	Std. Dev.	N
High Growth	0.122	0.30	2
Low Growth	-0.143	0.134	19

Table A5.23.9. Maximum Growth at Various Temperatures

Temperature (°C)	<5	5-7	>7
Maximum Growth ($\log_{10}$ cfu/g)	5	6.5	8

Appendix 6:

Software

Appendix 6: Software

This section contains a description of some of the software routines used in preparing the *Listeria monocytogenes* risk assessment.

The Dose Frequency Curve-Fitting Program

This routine takes a data set that contains historical records of an association between a continuous measure and the frequency of occurrence of a discrete event in a population. It is similar in operation to ParamFit, except that it is designed to be used with data sets that correlate a dose with an outcome, rather than a simple distribution. After fitting one of more models to the data, the parameters are written to a file that may be used with the DoseFrequency object. The parameter file may also be examined with the DoseFrequency plotting routine, or the parameter estimates may examined in Excel and used without the object.

Data

In order to proceed, the routine must be supplied with data in the proper format. There are two ways to do that.

The first is to supply a data file that is in the correct format. The "File Open" button may be used to browse for the file name. The file is not actually opened unless the "Data Edit" or "Run" buttons are selected. Alternatively, the file name, including the path, may be entered into the text box to the right of the "File Open" button.

Alternatively, data may be entered using the "Data Editor," which is started with the "Data Edit" button. If a file name has already been entered the Data Editor will open this data file. If it has not, then the "Editor" begins with no entries.

Choosing Models

The models used by the DoseFrequency curve-fitting routine have 1 to 3 components. The total number of models fit will be equal to the number of possible permutations of each of the three components selected.

The mandatory component is the primary dose-response function listed in the "Models-to-be-Fit" box. At least one model must be selected for the program to proceed. However, any combination may be selected. The curve-fitting routine will attempt to fit all models selected. A description of the models currently supported is given below.

Models currently supported by the DF curve-fitting program and object:

Model Name	Parameters	Equation for Frequency Given Dose
Beta Poisson	alpha, beta	1 - ((1 + (dose / beta) alpha)
Logistic	alpha, beta	$e^{alpha + beta * \ln(dose)} / (1 + e^{alpha + beta * \ln(dose)})$
Exponential	slope	$1 - e^{-dose * slope}$
Gompertz – Log	alpha, beta	$1 - e^{-e \wedge (alpha + (beta * \ln(dose)))}$
Gompertz – Power	alpha, beta, power	$1 - e^{-e \wedge (alpha + (beta * (dose \wedge power)))}$
Probit	alpha, beta	normal_cdf(alpha + beta*ln(dose))
Multihit	gamma, k	gamma_cdf(gamma*dose, k)
GammaWeibull	alpha, beta, gamma	$1 - (1 + (dose^{gamma/beta}) - alpha)$

Ln = natural log. cdf = cumulative distribution function. ^ = raised to the power of

Background Parameter

A parameter may be added to the model to accommodate other influences on the outcome of the causal event. There are three options:

- No background parameter.
- Background Dose. A background dose specified by an extra model parameter is added to the nominal dose when predicting frequency.
- Background Frequency. A background frequency specified by an extra model parameter is added to the predicted frequency. The dose-frequency function is applied to the fraction of the population who would otherwise not respond.

The program will attempt to fit all options that are checked. For example, if all three boxes are checked, then the program will examine all three different options. At least one box must be checked.

If there are fewer than five data points, then a Background Parameter cannot be employed.

Threshold Parameter

If a threshold dose parameter is included in the model, and if the nominal dose is less than the threshold dose value, then the effective dose used to predict frequency is zero. If the nominal dose is greater than the threshold dose value, then the effective dose used to predict frequency is the nominal dose minus the threshold dose. The program attempts to fit all options that are checked. If both boxes are checked, then the program examines both options. At least one box must be checked. If there are fewer than five data points, then a “Threshold Parameter” cannot be employed.

Options

Selecting the “Options” button opens another dialog, which gives the user some additional choices regarding how the routine operates. These include choosing the goodness-of-fit measure, how the program weights models when creating a probability tree, and the initial estimates for each of the model parameters.

Bootstraps

In order to represent uncertainty arising from sampling error, dose measurement error, or the size of the exposed population in which illnesses are observed, multiple bootstraps may be performed. Sampling error, where the small sample of observed values is presumed to come from a much larger sample that is of interest, is represented by presuming a binomial distribution where the total set of values is infinitely large. The likelihood of a series of possible values for the actual frequency are computed by comparing the relative likelihood of generating the observed value. Dose and population size measurement error are sampled from distributions supplied with the data set. The total number of models fit equals the number of models selected times the number of bootstraps. While very large numbers are possible, the program has not been tested with more than 10,000 models.

Initial Parameter Estimates

The default initial parameter estimates that are used by the IMSL nonlinear regression program to produce an optimum fit may not work well for all data sets. The initial estimate for the primary functions can be changed in this dialog. Initial estimates for the threshold and background parameters cannot be changed at this time. Selecting “OK” results in retention of the new parameter estimate. Selecting “Cancel” will not.

Model Weighting

Even if bootstrapping is selected, the first bootstrap (the first set of models in the parameter file) always uses the original data.

Run

The routine begins by fitting curves when the “Run” button is selected. The “Parameter File” dialog appears when the routine is finished. A progress bar displays the percentage of the task that has been completed. However, unless bootstrapping is selected, the results are nearly instantaneous. Selecting the “Cancel” button causes the program to exit.

As the program fits the alternative models to the data set, it calculates a weight for each of the models that is used by the object to assign probabilities to each of the models. The weighting algorithm used by the program rewards models for goodness of fit, and penalizes for parameters. Moving the slider bar to the left increases the importance of producing a good fit, while moving it to the right emphasizes the use of fewer parameters.

When bootstraps are run, the weights are recalculated on a relative basis for each bootstrap, so that the total weight for each bootstrap is identical. This means if the routine is used solely to represent the uncertainty in the parameters for a given model (*i.*

e., parameter uncertainty with no model uncertainty), then the model weighting algorithm has no effect.

ParamFit

ParamFit is a procedure for fitting a statistical distribution to a set of individual values for use in a subsequent Monte-Carlo simulation. It is similar in function to the routine included with Crystal Ball (Decisioneering) or BestFit, the add-on sold by Palisade as a companion to @Risk. The principle difference is that ParamFit is specifically intended for use in a population modeling exercise (*e. g*., public health). In this circumstance, the primary purpose of a distribution is to represent variability in the measured quantity among individuals in a population, rather than the uncertainty associated with the prediction of a single event. Under such circumstances, the uncertainty is associated with the distribution used to generalize the data and draw inferences about the population as a whole. The end product of ParamFit is an Excel function containing a list of plausible alternative models which may be used to draw an inference in a two-dimensional Monte-Carlo model. It was written in Excel Visual Basic for Applications and requires Excel 5.0 or later versions and the Toxfunct add-in.

Models and Common Names of Their Parameters

There are ten distributional models that may be employed for the purpose of describing the data and drawing inferences. Any models that are checked will be fit to the data. You may select only one model, all the models, or any subset. The following distributions (and the common names of their parameters) are supported by ParamFit.

Statistical Distributions – Common Names of the Parameters:

Beta: Parameter 1 = alpha, Parameter 2 = beta, Parameter 3 = minimum,
Parameter 4= maximum.
Cauchy: Parameter 1 = median, Parameter 2 = beta.
Exponential: Parameter 1 = lambda.
Gamma: Parameter 1 = alpha, Parameter 2 = beta.
Logistic: Parameter 1 = mean, Parameter 2 = beta.
Lognormal: Parameter 1 = geometric mean, Parameter 2 = geometric standard deviation.
Normal: Parameter 1 = mean, Parameter 2 = standard deviation.
Rectangular function: Parameter 1 = minimum, Parameter 2 = maximum.
Triangular Function: Parameter 1= minimum, Parameter 2 = most frequent,
Parameter 3 = maximum.
Weibull: Parameter 1 = alpha, Parameter 2 = beta.

Model Weighting Criteria

The frequency of use of each model is allocated according to it relative model weight which is calculated as follows:

Model Weight = (((1 + n / Pn) ^ O) * ((1 - gof) ^ H)
Where:

n = number of observations. This value reflects the number of data points to which the curve is fit. Values below the limit of detection (i.e. text values) are not counted for this purpose.

* = Multiplication symbol.

Pn = Number of Model Parameters. In general, this refers to the number of parameters which are adjusted to fit the curve. However, the minimum values for the beta, linear, and triangular models would fit equally well if they are not truncated at a minimum value; that is, two points describe a line which could be represented as a single parameter (a slope).

gof = Goodness-of-Fit. ParamFit uses a least residual squares for the predicted percentiles as an optimization criteria. The ratio of the sum of residual squares to the sum of total squares for the predicted percentile is used as a goodness-of-fit statistic. This criteria emphasizes fit in the middle of the distribution, so that outliers have less impact on the shape of the distribution, other methods such as the “likelihood ratio” rate residual deviations in predicted distribution values.

O = The Parameter penalty, an arbitrary constant named after William of Ockam. Increasing this number increases the penalty for using an extra parameter, which influences the extent to which models are penalized for using an extra parameter The maximum value is 10. Setting this value to 0 nulifies the parameter penalty.

H = The Association factor, an arbitrary constant named after David Hume. This value can be modified to increase or decrease the reward for providing a better fit. The minimum value is 0, in which case the models are weighted without regard to how well they fit the data. Increasing this value places greater emphasis on model fit.

The specific optimization criteria for the *L. monocytogenes* concentration were:

$\text{Gof} = \Sigma\,(\text{predicted} - \text{Observed})^2 * n * \text{concentration}^{0.25}$

Where the parameters for the goodness of fit were Predicted and Observed are the cumulative percentiles for a given concentration of *L. monocytogenes*, n is the number of samples in the report, concentration is in cfu/g. The model weight for the *L. monocytogenes* concentration = 1 / (pN * Gof ^{2}). Where pN is the number of adjustable parameters in the distribution being fitted.

Appendix 7:

Contamination Data sets

Smoked Seafood Food Category: Contamination Data

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Aguado *et al*., 2001	Salmon, smoked	1	Spain	3	R	52	36	16																								
Baek *et al*., 2000	Mussels, frozen & smoked	1	Korea	3	R	68	65	3																								
Cortesi *et al*., 1997	Salmon, smoked	1	Italy	2	P	100	80	8					11														1					
Cortesi *et al*., 1997	Salmon, smoked	1	Italy	2	P	65	53	6					2		2					1							1					
Dauphin *et al*., 2001	Coalfish, smoked	1	France	3	P	1	0	1																								
Dauphin *et al*., 2001	Salmon, fresh & smoked	1	France	3	P	11	0	11																								
Dauphin *et al*., 2001	Salmon Skin, smoked	1	France	3	P	2	1	E[4]							1																	
Dauphin *et al*., 2001	Salmon, smoked	1	France	3	P	21	19	2																								
Dauphin *et al*., 2001	Tuna, smoked	1	France	3	P	1	0	1																								
Dillon *et al*., 1994	Fin-fish, hot/cold-smoked	1	Canada	2	?	258	246	12																								
Dominguez *et al*., 2001	Salmon, cold-smoked	1	Spain	3	R	170	132	E										18		18							2					
Eklund *et al*., 1995	Salmon, cold-smoked	1	USA	2		61	13	E										48														
Ericsson *et al*., 1997	Trout, smoked	1	Sweden	2	P&R	9	6	E										3														
Farber, 1991b	Salmon, cold-smoked	1	Canada/ etc	1	P	32	22	10																								
Garland, 1995	Salmon, cold-smoked	1	Australia	2	P	285	284	1																								
Guyer and Jemmi, 1990	Salmon, cold-smoked	1	Switzer-land	1	P	64	60	4																								
Hartemink and Georgsson, 1991	Fish, smoked	1	Iceland	1	P/R	31	30	1																								
Heinitz and Johnson, 1998	Fish, smoked	1	USA	1	P	1080	929	151																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Hudson *et al*., 1992	Mussels, smoked	1	New Zealand	1	R	14	9	5																								
Hudson *et al*., 1992	Salmon, smoked	1	New Zealand	1	R	12	4	8																								
Inoue *et al*., 2000	Salmon, smoked	1	Japan	3	R	92	87	E			4		1																			
Jemmi, 1990	Fin-fish, cold-smoked	1	Switzer-land	1	R	324	280	44																								
Jemmi, 1990	Fin-fish, hot-smoked	1	Switzer-land	1	R	496	452	44																								
Jørgensen and Huss, 1998	Halibut, cold-smoked	1	Denmark	2	P	20	11	E					9																			
Jørgensen and Huss, 1998	Halibut, cold-smoked	1	Denmark	2	P	20	8	E					6		2					3						1						
Jørgensen and Huss, 1998	Salmon, cold-smoked	1	Denmark	2	P	190	126	E					53		9					2												
Jørgensen and Huss, 1998	Salmon, cold-smoked	1	Denmark	2	P	115	69	E					11		23					10						2						
Jørgensen and Huss, 1998	Salmon, cold-smoked	1	Denmark	2	P	75	43	E					17		11					2						2						
Hatakka *et al*., 2001	Smoked, cold & vacuum-packed	1	Finland	3	R	232	222	E										10														
	Fish, cold-smoked	1	Finland	3	P	12	10	2																								
Miettinen, H., *et al*., 2001	Fish, hot-smoked	1	Finland	3	P	13	12	1																								
	Seafood, smoked	1	USA-CA	3	R	1363	1292	E	44	5			11		5					4							1				1	
NFPA, 2002	Seafood, smoked	1	USA-MD	3	R	1324	1281	E	23	6			8		3					2											1	
Ng and Seah, 1995	Mussels, smoked	1	Singapore	2	R	2	1	1																								
Norton *et al*., 2000	Fish, cold-smoked	1	USA	3	P	38	32	6																								
Norton *et al*., 2001	Fish, cold-smoked	1	USA	3	P	96	85	11																								
Oregon State Dept of Agriculture, 2001	Cod, smoked	1	USA	3	R	5	5	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Oregon State Dept of Agriculture, 2001	Halibut,smoked	1	USA	3	R	3	3	0																								
Oregon State Dept of Agriculture, 2001	Oysters, smoked	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Salmon, smoked	1	USA	3	R	130	129	1																								
Oregon State Dept of Agriculture, 2001	Seafood, smoked	1	USA	3	R	4	4	0																								
Oregon State Dept of Agriculture, 2001	Shad, smoked	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Snapper, smoked	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Sockeye, smoked	1	USA	3	R	3	3	0																								
Oregon State Dept of Agriculture, 2001	Sturgeon, smoked	1	USA	3	R	10	10	0																								
Oregon State Dept of Agriculture, 2001	Trout, smoked	1	USA	3	R	7	7	0																								
Scoglio *et al*., 2000	Salmon, smoked	1	Italy	3	R	21	18	3																								
Teufel and Bendzulla, 1993	Fish, smoked	1	Germany	1	R?	71	66	5																								
Teufel and Bendzulla, 1993	Fish, smoked	1	Germany	1	R?	309	287	E										14			4							4				
Vogel *et al*., 2001a	Salmon, cold-smoked	1	Denmark	3	P	324	231	93																								
Vogel *et al*., 2001b	Salmon, cold-smoked	1	Denmark	3	P	200	65	135																								
Yamazaki *et al*., 2000	Herring, smoked	1	Japan	3	R	1	0	1																								

Reference	*Food*	*Geographic Region[1]*	*Country*	*Pub. Date[2]*	*Sample Collection[3]*	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Yamazaki *et al.*, 2000	Salmon, smoked	1	Japan	3	R	12	10	2																								
					Total=	7855	6844	589	67	11	4		129		56			93		42	4					5	5	4			2	

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.
[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Raw Seafood Food Category: Contamination Data

Number of Samples (values in cfu/g units)

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Adesiyun, 1993	Fish & shrimp, raw	2	Trinidad	1	R	102	100	2																								
Anderson and Nørrung, 1995	Fish, raw	1	Denmark	2	R	232	199	E[4]					26		6				1													
Baek *et al*., 2000	Halibut, raw	1	Korea	3	R	45	45	0																								
Baek *et al*., 2000	Shellfish	1	Korea	3	R	250	247	3																								
Berry *et al*., 1994	Shrimp, imported & frozen	1	USA	2	R	30	28	2																								
Buchanan *et al*., 1989	Catfish, fresh	1	USA	1	R	1	1	0																								
Buchanan *et al*., 1989	Clam, raw	1	USA	1	R	1	1	0																								
Buchanan *et al*., 1989	Fin-fish, fresh	1	USA	1	R	4	2	2																								
Buchanan *et al*., 1989	Oysters, uncooked	1	USA	1	R	2	2	0																								
Buchanan *et al*., 1989	Scallops, raw	1	USA	1	R	1	1	0																								
Buchanan *et al*., 1989	Shrimp, raw & frozen	1	USA	1	R	4	4	0																								
Buchanan *et al*., 1989	Surimi, crab	1	USA	1	R	1	1	0																								
Colburn *et al*., 1990	Oysters, live	1	USA	1	P	35	35	0																								
Dauphin *et al*., 2001	Fillet, coalfish	1	France	3	P	2	0	2																								
Dauphin *et al*., 2001	Fillet, cod	1	France	3	P	4	0	4																								
Dauphin *et al*., 2001	Salmon, cut & raw	1	France	3	P	1	0	1																								
Dauphin *et al*., 2001	Herring, frozen	1	France	3	P	5	0	5																								
Dauphin *et al*., 2001	Surfaces, raw salmon (filets)	1	France	3	P	8	1	7																								

Reference	***Food***	***Geographic Region***[1]	***Country***	***Pub. Date***[2]	***Sample Collection***[3]	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Dauphin *et al*., 2001	Surfaces, raw salmon (whole)	1	France	3	P	7	1	6																								
Dauphin *et al*., 2001	Surfaces, raw salmon	1	France	3	P	18	16	2																								
Davies *et al*. 2001	Plaice/raw food	1	Great Britain	3	R	5	5	0																								
Davies *et al*. 2001	Salmon/raw seafood	1	Great Britain	3	R	5	5	0																								
Davies *et al*. 2001	Sardine/raw seafood	1	Portugal	3	R	10	10	0																								
Davies *et al*. 2001	Trout/raw seafood	1	Great Britain	3	R	20	18	2																								
Davies *et al*. 2001	Trout/raw seafood	1	Portugal	3	R	10	10	0																								
Davies *et al*. 2001	Whiting/raw seafood	1	France	3	R	26	26	0																								
de Simon *et al*., 1992	Molluscs, bivalve, mussels	1	Spain	1	R	40	37	3																								
Decastelli *et al*., 1993	Mussels, depurated	1	Italy	1	P	110	110	0																								
Decastelli *et al*., 1993		1	Italy	1	P	175	175	0																								
Degnan *et al*., 1994	Meat, blue crab	1	Australia	2	R	4	3	1																								
Draughon *et al*., 1999	Trout, rainbow	1	USA	3	R	74	36	E								30	8															
El-Shenawy and El-Shenawy, 1995	Clam, fresh	2	Egypt	2	R	4	3	1																								
El-Shenawy and El-Shenawy, 1995	Coquina, fresh	2	Egypt	2	R	6	5	1																								
El-Shenawy and El-Shenawy, 1995	Crab	2	Egypt	2	R	5	5	0																								
El-Shenawy and El-Shenawy, 1995	Fin-fish, fresh	2	Egypt	2	R	39	34	5																								
El-Shenawy and El-Shenawy, 1995	Fin-fish, frozen	2	Egypt	2	R	17	16	1																								

Reference	*Food*	*Geographic Region[1]*	*Country*	*Pub. Date[2]*	*Sample Collection[3]*	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
El-Shenawy and El-Shenawy, 1995	Oysters, raw	2	Egypt	2	R	2	2	0																								
El-Shenawy and El-Shenawy, 1995	Shrimp	2	Egypt	2	R	5	4	1																								
Farber, 1991b	Shrimp, retail	1	Canada	1	R	20	16	4																								
Farber, 1991b	Surimi, etc	1	Canada	1	R	46	45	1																								
Ferrer and de Simón, 1993	Mussels, fresh	1	Spain	1	R	35	32	3																								
Ferrer and de Simón, 1993	Oysters, fresh	1	Spain	1	R	40	39	1																								
Fuchs and Surendran, 1989	Clam, raw	1	India	1	R	1	1	0																								
Fuchs and Surendran, 1989	Fish, fresh	2	India	1	R	9	9	0																								
Fuchs and Surendran, 1989	Fish, frozen	2	India	1	R	14	14	0																								
Hartemink and Georgsson, 1991	Fish, other	1	Iceland	1	P or R	5	4	1																								
Hartemink and Georgsson, 1991	Trout, fresh	1	Iceland	1	P or R	2	2	0																								
Heinitz, 1999	Fin-fish/shellfish	1	USA	3	P	9495	8791	704																								
Hofer and Ribeiro, 1990	Shrimp, frozen	1	Brazil	1	P	45	41	4																								
Hudson *et al*, 1992	Ready-to-eat seafood	1	New Zealand	1	R	50	37	13																								
Iida *et al*., 1998	Fin-fish & non-fin-fish	1	Japan	2	R	781	771	10																								
Inoue *et al*., 2000	Seafood, raw	1	Japan	3	R	213	206	E			1	1	2		2				1													
Jeyasekaran *et al*., 1996	Fin-fish, tropical	2	India	2	P or R	29	24	5																								
Jeyasekaran *et al*., 1996	Shellfish, tropical	1	India	2	P or R	36	32	4																								
Kamat and Nair, 1994	Anchovy	2	India	2	R	2	2	0																								
Kamat and Nair, 1994	Duck-fish, Bombay	2	India	2	R	2	2	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Kamat and Nair, 1994	Crab	1	India	2	R	2	2	0																								
Kamat and Nair, 1994	Fish, Doma-local	2	India	2	R	3	3	0																								
Kamat and Nair, 1994	Anchovy, Golden	2	India	2	R	2	2	0																								
Kamat and Nair, 1994	Salmon, Indian	2	India	2	R	1	1	0																								
Kamat and Nair, 1994	Mackeral	2	India	2	R	3	3	0																								
Kamat and Nair, 1994	Pom fret	2	India	2	R	2	2	0																								
Kamat and Nair, 1994	Shrimp, raw	1	India	2	R	5	5	0																								
Kamat and Nair, 1994	Fin, thread	2	India	2	R	3	3	0																								
Karpiskova *et al*., 2000	Fish, raw	1	Czech Republic	3	R	120	118	2																								
Karunasagar *et al*., 1992	Fish	2	India	1	P	200	200	0																								
Manoj *et al*., 1991	Fin-fish, fresh	2	India	1	P or R	51	51	0																								
Manoj *et al*., 1991	Shrimp, raw/process	1	India	1	P or R	19	19	0																								
Masuda *et al*., 1992	Fin-fish, fresh	1	Japan	1	R	382	373	9																								
Masuda *et al*., 1992	Shellfish, non-oyster	1	Japan	1	R	147	145	2																								
Masuda *et al*., 1992	Oysters, raw	1	Japan	1	R	84	84	0																								
McLauchlin and Gilbert, 1990	Fish & fish products	1	UK	1	?	46	29	17																								
Miettinen *et al*., 2001	Fish, raw	1	Finland	3	P	18	16	2																								
Miettinen *et al*., 2001	Roe	1	Finland	3	P	5	5	0																								
Monfort *et al*., 1998	Shellfish	1	France	1	P	120	109	11																								
Motes, 1991	Oysters, live	1	USA	1	P	75	75	0																								
Motes, 1991	Shrimp, live	1	USA	1	P	74	66	8																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Ng and Seah, 1995	Crabmeat/scallops	1	Singapore	2	P or R	16	16	0																								
Ng and Seah, 1995	Fish cakes, fingers	2	Singapore	2	P or R	16	13	3																								
Ng and Seah, 1995	Tuna	2	Singapore	2	P or R	5	5	0																								
Norton *et al*., 2000	Fish, raw	1	USA	3	P	43	40	3																								
Norton *et al*., 2001	Fish, raw	1	USA	3	P	102	93	9																								
Oregon State Dept of Agriculture, 2001	Butterfish	1	USA	3	R	6	6	0																								
Oregon State Dept of Agriculture, 2001	Cod	1	USA	3	R	40	22	18																								
Oregon State Dept of Agriculture, 2001	Crab	1	USA	3	R	393	375	18																								
Oregon State Dept of Agriculture, 2001	Halibut	1	USA	3	R	6	0	6																								
Oregon State Dept of Agriculture, 2001	Fillets, ocean cats	1	USA	3	R	6	6	0																								
Oregon State Dept of Agriculture, 2001	Perch	1	USA	3	R	17	17	0																								
Oregon State Dept of Agriculture, 2001	Seafood, raw	1	USA	3	R	40	28	12																								
Oregon State Dept of Agriculture, 2001	Surimi, raw	1	USA	3	R	3	2	1																								
Oregon State Dept of Agriculture, 2001	Fish, rock	1	USA	3	R	29	22	7																								
Oregon State Dept of Agriculture, 2001	Roe	1	USA	3	R	8	8	0																								
Oregon State Dept of Agriculture, 2001	Sable	1	USA	3	R	6	6	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Oregon State Dept of Agriculture, 2001	Salmon	1	USA	3	R	8	8	0																								
Oregon State Dept of Agriculture, 2001	Shrimp	1	USA	3	R	106	99	7																								
Oregon State Dept of Agriculture, 2001	Snapper	1	USA	3	R	12	12	0																								
Oregon State Dept of Agriculture, 2001	Sole	1	USA	3	R	54	35	19																								
Oregon State Dept of Agriculture, 2001	Sushi-with & without rice	1	USA	3	R	42	41	1																								
Oregon State Dept of Agriculture, 2001	Fillets, turbot	1	USA	3	R	6	6	0																								
Pullela *et al*., 1998	Fin-fish, aquaculture	1	USA	1	P	140	140	0																								
Ravomanana *et al*., 1993	Shrimp, raw & fresh	1	France	1	R?	17	15	2																								
Rorvik and Yndestad, 1991	Fin-fish, minced	1	Norway	1	P	8	7	1																								
Ryu *et al*., 1992	Fish, other	1	Japan	1	R	6	6	0																								
Ryu *et al*., 1992	Fish, salt sushi	1	Japan	1	R	10	10	0																								
Ryu *et al*., 1992	Fish, sushi	1	Japan	1	R	18	15	3																								
Ryu *et al*., 1992	Prawn, raw, 'sushi'	1	Japan	1	R	38	37	1																								
Ryu *et al*., 1992	Tuna, minced sushi	1	Japan	1	R	37	34	3																								
Scoglio *et al*., 2000	Shellfish, raw	1	Italy	3	R	23	23	0																								
Scoglio *et al*., 2000	Shrimp, raw	1	Italy	3	R	17	17	0																								
Soriano *et al*.,2001	Hake, raw	1	Spain	3	R	4	4	0																								
Soriano *et al*.,2001	Salmon, raw	1	Spain	3	R	4	4	0																								
Soriano *et al*.,2001	Sole, raw	1	Spain	3	R	6	6	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Teufel and Bendzulla, 1993	Crustacean/shellfish	1	Germany	1	R?	32	32	E																								
Teufel and Bendzulla, 1993	Crustacean/shellfish	1	Germany	1	R?	80	80	0																								
Teufel and Bendzulla, 1993	Fish & fish parts	1	Germany	1	R?	35	33	E										1			1											
Teufel and Bendzulla, 1993	Fish & fish parts	1	Germany	1	R?	238	232	6																								
Vogel *et al*., 2001a	Salmon, raw	1	Denmark	3	P	92	90	2																								
Weagant *et al*., 1988	Fin-fish, frozen	1	USA	1	R or P	40	39	1																								
Weagant *et al*., 1988	Lobster tail, frozen	1	USA	1	R or P	20	19	1																								
Weagant *et al*., 1988	Oysters, frozen	1	USA	1	R or P	10	10	0																								
Weagant *et al*., 1988	Scallops, frozen	1	USA	1	R or P	18	18	0																								
Weagant *et al*., 1988	Shrimp, raw & frozen	1	USA	1	R or P	70	60	10																								
Weagant *et al*., 1988	Squid, langostinos, frozen	1	USA	1	R or P	20	20	0																								
Weagant *et al*., 1988	Surimi, frozen	1	USA	1	R or P	66	46	20																								
Wong *et al*., 1990	Fish & non-fish, local frozen and refrigerated	2	Taiwan	1	R	57	51	6																								
Yamazaki *et al*., 2000	Finfish, raw	1	Japan	3	R	10	10	0																								
Yamazaki *et al*., 2000	Octopus, raw, squid, trepang	1	Japan	3	R	7	7	0																								
Yamazaki *et al*., 2000	Salmon, raw	1	Japan	3	R	12	11	1																								
Yamazaki *et al*., 2000	Shellfish, raw	1	Japan	3	R	10	10	0																								
Yamazaki *et al*., 2000	Shrimp, raw	1	Japan	3	R	10	10	0																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Yamazaki *et al*., 2000	Seafood, surimi and minced	1	Japan	3	R	10	10	0																								
Yamazaki *et al*., 2000	Seafood,	1	Japan	3	R	8	8	0																								
					Total=	15634	14541	1013			1	1	28		8	30	8	1	2		1											

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.
[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Preserved Fish Food Category: Contamination Data						Number of Samples (values in cfu/g units)																										
Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Anderson and Nørrung, 1995	Fish, preserved	1	Denmark	2	R	335	300	E[4]					18		11				6													
Baek *et al*., 2000	Dried shrimp, squid & mussels	1	Korea	3	R	12	12	0																								
Choi *et al*.,2001	Dried squid & mussels	1	Korea	3	R	20	20	0																								
El-Shenawy and El-Shenawy, 1995	Fin-fish, smoke & salted	2	Egypt	2	R	11	10	1																								
Ericsson et al, 1997	Trout, gravad	1	Sweden	2	P/R	8	3	E										3		1												1
Fuchs and Sirvas, 1991	Ceviche	1	Peru	1	R	32	29	3																								
Fuchs and Surendran, 1989	Fish, dried & salted	2	India	1	R	11	11	0																								
Hartemink and Georgsson, 1991	Gravad	1	Iceland	1	P or R	23	17	6																								
Hartemink and Georgsson, 1991	Haddock, dried	1	Iceland	1	P or R	5	5	0																								
Jemmi, 1990	Fin-fish, pickled	1	Switzer-land	1	R	89	66	23																								
Jorgensen and Huss, 1998	Fish, gravad	1	Denmark	2	P	91	68	E					5		10					5						3						
Kamat and Nair, 1994	Anchovy, dried	2	India	2	R	3	3	0																								
Kamat and Nair, 1994	Anchovy, Golden dried	2	India	2	R	2	2	0																								
Kamat and Nair, 1994	Dried fish "Bombay Duck"	2	India	2	R	3	3	0																								
Kamat and Nair, 1994	Mackeral, dried	2	India	2	R	2	2	0																								
Kamat and Nair, 1994	Shrimp, dried	1	India	2	R	3	3	0																								
Loncarevic *et al*, 1996	Fish, gravad	1	Sweden	2	R	58	46	12																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Hatakka *et al*, 2001	Fish, cold-salted & vacuum-packed	1	Finland	3	R	82	77	E										5														
McLauchlin & Gilbert, 1990	Cooked fish & fish products	1	UK	1	?	346	334	12																								
Miettinen *et al*, 2001	Fish, cold & salted	1	Finland	3	P	10	8	2																								
Oregon State Dept of Agriculture, 2001	Clams, salted		USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Salmon, salted	1	USA	3	R	4	4	0																								
Oregon State Dept of Agriculture, 2001	Anchovies, seasoned	1	USA	3	R	1	1	0																								
Rorvik and Yndestad, 1991	Shrimp, brined	1	Norway	1	P	16	13	3																								
Teufel and Bendzulla, 1993	Fish, processed	1	Germany	1	R?	186	185	E										1														
Teufel and Bendzulla, 1993	Fish, processed	1	Germany	1	R?	119	106	13																								
Yamazaki *et al*, 2000	Dried squid, salmon, shishamo smelt	1	Japan	3	R	4	4	0																								
Yamazaki *et al*, 2000	Seafood, fermented	1	Japan	3	R	7	7	0																								
Yamazaki *et al*, 2000	Sushi flatfish, fermented	1	Japan	3	R	1	0	1																								
Yamazaki *et al*, 2000	Salad, marinated seafood	1	Japan	3	R	8	8	0																								
Yamazaki *et al*, 2000	Sushi sandfish, fermented	1	Japan	3	R	1	0	1																								
					Total=	1495	1349	77					23		21			9	6	6						3						1

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[4] E = samples ≥ 0.04 cfu/g that were enumerated

Ready-to-eat Crustacean Food Category: Contamination Data

Number of Samples (values in cfu/g units)

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Dauphin *et al*, 2001	Mussels, shelled cooked	1	France	3	P	2	0	2																								
Degnan *et al*, 1994	Crab	1	USA	2	R	4	1	2							1																	
Farber, 1991b	Shrimp, wholesale	1	Canada	1	R	49	45	1			1		2																			
Hartemink and Georgsson, 1991	Shellfish, cooked	1	Iceland	1	P or R	11	11	0																								
Hartemink and Georgsson, 1991	Shrimp, cooked & processed	1	Iceland	1	P or R	11	10	1																								
Oregon State Dept of Agriculture, 2001	Crab, cooked	1	USA	3	R	95	90	5																								
Oregon State Dept of Agriculture, 2001	Shrimp, cooked	1	USA	3	R	236	234	2																								
Oregon State Dept of Agriculture, 2001	Crab, imitation	1	USA	3	R	24	24	0																								
Ravomanana *et al*, 1993	Shrimp, cooked	1	France	1	R?	35	31	4																								
Rawles *et al*, 1995	Crab	1	USA	2	P	126	116	E[4]					1		8												1					
Richmond, 1990	Miscellany, cooked	1	UK	1	R	40	40	0																								
Valdimarsson, *et al*, 1998	Shrimp, cooked & frozen	1	Iceland	2	P	3331	3259	72																								
Weagant *et al*, 1988	Crab, cooked	1	USA	1	R or P	24	17	7																								
Weagant *et al*, 1988	Shrimp, cooked	1	USA	1	R or P	8	6	2																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Yamazaki *et al*, 2000	Seafood, boiled	1	Japan	3	R	8	8	0																								
					Total=	4004	3892	98			1		3		9												1					

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Vegetables Food Category: Contamination Data							Number of Samples (values in cfu/g units)																									
Reference	***Food***	***Geographic Region***[1]	***Country***	***Pub. Date***[2]	***Sample Collection***[3]	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Beckers *et al*, 1987	Vegetables, fresh & cut	1	Nether-lands	1	?	25	14	E[4]										11														
Benezet *et al*., 2001	Celery,	1	Spain	3	P	3	3	0																								
Benezet *et al*., 2001	Cilantro	1	Spain	3	P	1	1	0																								
Benezet *et al*., 2001	Onion,	1	Spain	3	P	3	3	0																								
Benezet *et al*., 2001	Laurel	1	Spain	3	P	1	1	0																								
Benezet *et al*., 2001	Parsley	1	Spain	3	P	1	1	0																								
Benezet *et al*., 2001	Thyme	1	Spain	3	P	1	1	0																								
Benezet *et al*., 2001	Winter sweet	1	Spain	3	P	2	2	0																								
Breer, 1988	Salads	1	Switzer-land	1	R	64	61	3																								
Breer, 1988	Vegetables	1	Switzer-land	1	R	27	27	0																								
Choi *et al*.,2001	Vegetables, raw	2	Korea	3	R	205	205	0																								
Daley *et al*., 1999	Vegetables	1	Canada	3	R	25	25	0																								
de Simon *et al.,* 1992	Vegetables, fresh	1	Spain	1	R	103	95	8																								
Farber *et al*., 1989	Celery	1	Canada	1	R	30	30	0																								
Farber *et al*., 1989	Lettuce	1	Canada	1	R	50	50	0																								
Farber *et al*., 1989	Radishes	1	Canada	1	R	10	10	0																								
Farber *et al*., 1989	Tomatoes	1	Canada	1	R	20	20	0																								
Garcia-Gimeno *et al*., 1996	Salads	1	Spain	2	P	70	49	21																								
Hartung, 2000b	Salads, minimally processed fresh vegetables	1	Germany	3	R	59	58	1																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Hartung, 2001	Vegetable foods, other	1	Germany	3	R?	676	671	5																								
Hartung, 2001	Vegetable foods, other	1	Germany	3	R?	672	667	E										5														
Hartung, 1999	Salad	1	Germany	3	R	23	20	3																								
Heinitz, 1999	Salads, vegetable	1	USA	3	P	361	341	20																								
Heisick *et al*., 1989	Cabbage	1	USA	1	R	92	91	1																								
Heisick *et al*., 1989	Cucumbers	1	USA	1	R	92	90	2																								
Heisick *et al*., 1989	Lettuce	1	USA	1	R	92	92	0																								
Heisick *et al*., 1989	Mushrooms	1	USA	1	R	92	92	0																								
Heisick *et al*., 1989	Radishes	1	USA	1	R	132	113	19																								
Inoue *et al*., 2000	Vegetables	1	Japan	3	R	285	285	0																								
Karpiskova *et al*., 2000	Vegetables	1	Czech Republic	3	R	156	152	4																								
Lin *et al*., 1996	Salads, vegetable	1	USA	2	R	58	57	1																								
Marranzano *et al*., 1996	Celery	1	Italy	2	R	20	18	2																								
Marranzano *et al*., 1996	Fennel	1	Italy	2	R	31	30	1																								
Marranzano *et al*., 1996	Lettuce	1	Italy	2	R	32	31	1																								
McLauchlin and Gilbert, 1990	Vegetables & salads,	1	UK	1	?	567	495	69																			3					
McLauchlin and Gilbert, 1990	Vegetables & salads,	1	UK	1	?	279	255	24																								
Monge and Arias, 1996	Cabbage salad	1	Costa Rica	2	R	50	40	10																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
NFPA, 2002	Salad, leafy bagged & precut	1	USA-CA	3	R	1515	1501	E	12	1					1																	
NFPA, 2002	Salad, leafy bagged & precut	1	USA-MD	3	R	1448	1440	E	5				1		1					1												
Odumeru *et al*., 1997	Broccoli florets	1	Canada	2	P	15	13	E											2													
Odumeru *et al*., 1997	Broccoli florets	1	Canada	2	P	20	20	E																								
Odumeru *et al*., 1997	Coleslaw mix	1	Canada	2	P	15	14	E											1													
Odumeru *et al*., 1997	Coleslaw mix	1	Canada	2	P	20	20	E																								
Odumeru *et al*., 1997	Green peppers	1	Canada	2	P	20	20	E																								
Odumeru *et al*., 1997	Green peppers	1	Canada	2	P	15	14	E										1														
Odumeru *et al*., 1997	Lettuce, chopped	1	Canada	2	P	24	22	E										2														
Odumeru *et al*., 1997	Lettuce, chopped	1	Canada	2	P	15	12	E										2	1													
Odumeru *et al*., 1997	Salad mix	1	Canada	2	P	15	9	E										2	4													
Odumeru *et al*., 1997	Salad mix	1	Canada	2	P	24	21	E										2	1													
Oregon State Dept of Agriculture, 2001	Broccoli	1	USA	3	R	3	3	0																								
Oregon State Dept of Agriculture, 2001	Cabbage	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Celery	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Cilentro	1	USA	3	R	1	1	0																								
Oregon State Dept of Agriculture, 2001	Green Beans	1	USA	3	R	1	1	0																								
Oregon State Dept of Agriculture, 2001	Jalapeno	1	USA	3	R	1	1	0																								
Oregon State Dept of Agriculture, 2001	Kelp	1	USA	3	R	11	10	1																								
Oregon State Dept of Agriculture, 2001	Kidney, Mung. Bean	1	USA	3	R	33	33	0																								

Reference	***Food***	***Geographic Region***[1]	***Country***	***Pub. Date***[2]	***Sample Collection***[3]	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Oregon State Dept of Agriculture, 2001	Lettuce	1	USA	3	R	15	15	0																								
Oregon State Dept of Agriculture, 2001	Salad, mixed vegetable	1	USA	3	R	49	47	2																								
Oregon State Dept of Agriculture, 2001	Mushroom	1	USA	3	R	6	6	0																								
Oregon State Dept of Agriculture, 2001	Onion	1	USA	3	R	6	6	0																								
Oregon State Dept of Agriculture, 2001	Pea	1	USA	3	R	6	6	0																								
Oregon State Dept of Agriculture, 2001	Potato	1	USA	3	R	14	14	0																								
Oregon State Dept of Agriculture, 2001	Radish	1	USA	3	R	5	5	0																								
Oregon State Dept of Agriculture, 2001	Spinach	1	USA	3	R	3	2	1																								
Oregon State Dept of Agriculture, 2001	Sprouts	1	USA	3	R	109	109	0																								
Oregon State Dept of Agriculture, 2001	Tomato	1	USA	3	R	5	5	0																								
Oregon State Dept of Agriculture, 2001	Vegetable	1	USA	3	R	12	12	0																								
Oregon State Dept of Agriculture, 2001	Yam	1	USA	3	R	2	2	0																								
Pingulkar *et al.*, 2001	Root, beet	2	India	3	R	4	4	0																								
Pingulkar *et al.*, 2001	Cabbage	2	India	3	R	4	3	1																								
Pingulkar *et al.*, 2001	Carrot	2	India	3	R	4	4	0																								
Pingulkar *et al.*, 2001	Coriander	1	India	3	R	10	9	1																								
Pingulkar *et al.*, 2001	Cucumber	2	India	3	R	4	4	0																								
Pingulkar *et al.*, 2001	Lettuce	2	India	3	R	4	4	0																								
Pingulkar *et al.*, 2001	Leaves, math vegetable	2	India	3	R	4	4	0																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Pingulkar *et al.*, 2001	Roots, math	2	India	3	R	4	4	0																								
Pingulkar *et al.*, 2001	Leaves, radish	2	India	3	R	4	4	0																								
Pingulkar *et al.*, 2001	Roots, radish	2	India	3	R	4	4	0																								
Pingulkar *et al.*, 2001	Salads, ready-to-eat	2	India	3	R	12	12	0																								
Pingulkar et al., 2001	Capsicum	2	India	3	R	4	3	1																								
Porto *et al*., 2001	Cabbage	2	Brazil	3	R	50	50	0																								
Porto *et al*., 2001	Lettuce	2	Brazil	3	R	100	96	2				2																				
Porto *et al*., 2001	Parsley	1	Brazil	3	R	50	48	2																								
Porto *et al*., 2001	Watercress	1	Brazil	3	R	50	48	2																								
Salamah, 1993	Cabbage	2	Saudi Arabia	1	R	70	68	2																								
Salamah, 1993	Carrot	2	Saudi Arabia	1	R	120	104	16																								
Salamah, 1993	Cucumber	2	Saudi Arabia	1	R	110	106	4																								
Salamah, 1993	Lettuce	2	Saudi Arabia	1	R	80	79	1																								
Sizmur and Walker, 1988	Vegetables, mixed	1	UK	1	R	60	56	4																								
Soriano *et al*.,2001	Lettuce	1	Spain	3	R	10	9	1																								
Soriano *et al*.,2001	Lettuce,	1	Spain	3	R	10	9	1																								
Soriano *et al*.,2001	Spinach	1	Spain	3	R	10	10	0																								
Soriano *et al*.,2001	Spinach	1	Spain	3	R	10	10	0																								
Szabo *et al*.,2000	Lettuce	1	Australia	3	R	60	59	1																								
Szabo *et al*.,2000	Lettuce	1	Australia	3	P	60	58	2																								
Teufel and Bendzulla, 1993	Legumes	1	Germany	1	R?	13	12	1																								
Teufel and Bendzulla, 1993	Mushrooms	1	Germany	1	R?	8	8	0																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Teufel and Bendzulla, 1993	Vegetables, fresh	1	Germany	1	R?	6	6	0																								
Velani and Roberts, 1991	Individual salad ingredients (bean sprouts, cabbage, carrot, celery, cress, cucumber, lettuce, mushroom, peppers, radish, spring onions, tomato, vegetables, watercress)	1	UK	1	R	108	106	E														2										
Velani and Roberts, 1991	Salads, mixed & prepacked	1	UK	1	R	42	34	E														8										
West and North Yorkshire Joint Working Group, 1991	Salad, raw vegetables	1	UK	1	R	237	224	2								5	3			2						1						
Wong *et al*., 1990	Vegetables	2	Taiwan	1	R	49	43	6																								
					Total=	9223	8892	249	17	1		2	1		2	5	3	25	9	3		10				1	3					

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.
[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Fruit Food Category: Contamination Data						Number of Samples (values in cfu/g units)																										
Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Heinitz, 1999	Fruit products	1	USA	3	P	117	89	28																								
Karpiskova *et al*., 2000	Fruit, dried	1	Czech Republic	3	R	12	12	0																								
Oregon State Dept of Agriculture, 2001	Apples	1	USA	3	R	12	12	0																								
Oregon State Dept of Agriculture, 2001	Blueberries	1	USA	3	R	6	4	2																								
Oregon State Dept of Agriculture, 2001	Cantalope	1	USA	3	R	8	8	0																								
Oregon State Dept of Agriculture, 2001	Salad, fruit	1	USA	3	R	23	23	0																								
Oregon State Dept of Agriculture, 2001	Fruit, various	1	USA	3	R	17	17	0																								
Oregon State Dept of Agriculture, 2001	Gelatin dessert with fruit	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Melons	1	USA	3	R	8	8	0																								
Oregon State Dept of Agriculture, 2001	Pears	1	USA	3	R	35	35	0																								
Oregon State Dept of Agriculture, 2001	Pineapples	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Watermelons	1	USA	3	R	4	4	0																								
Teufel and Bendzulla, 1993	Fruit, fresh	1	Germany	1	R?	7	7	0																								
Teufel and Bendzulla, 1993	Fruit, product	1	Germany	1	R?	1	1	0																								
					Total=	254	224	30																								

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.

Fresh Soft Cheese Food Category: Contamination Data

Number of Samples (values in cfu/g units)

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Frye, 2000	Queso Fresco	1	USA	3	R	1724	1678	46																								
Frye, 2000	Queso Fresco	1	USA	3	R	22	20	2																								
Gelosa, 1990	Cheese, fresh (fornaggio fresco)	1	Italy	1	R	17	17	0																								
NFPA, 2002	Cheese, Hispanic style	1	USA-CA	3	R	1482	1481	E[4]							1																	
NFPA, 2002	Cheese, Hispanic style	1	USA-MD	3	R	1454	1450	E	2						2																	
Oregon State Dept of Agriculture, 2001	Queso Fresco	1	USA	3	R	13	11	2																								
Oregon State Dept of Agriculture, 2001	Panela	1	USA	3	R	1	1	0																								
Saltijeral *et al.*, 1999	Panellá	1	Mexico	3	R	40	34	6																								
Ubach *et al.*, 1991	Quesofresco, requesoy	1	Spain	1	R?	91	84	7																								
Weber *et al.*, 1988	Cheese, fresh cow & goat milk	1	Germany	1	?	22	20	2																								
					Total=	4866	4796	65	2						3																	

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Soft Unripened Cheese Food Category: Contamination Data							Number of Samples (values in cfu/g units)																									
Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Copes *et al.*, 2000	Cheeses, soft paste	2	Argentina	3	R	35	31	4																								
Frye, 2000	Cheese, farmer	1	USA	3	R	18	18	0																								
Frye, 2000	Gournay	1	USA	3	R	1	1	0																								
Frye, 2000	Cheese, fresh port	1	USA	3	R	84	83	1																								
Frye, 2000	Quark	1	USA	3	R	1	1	0																								
Frye, 2000	Cheese, sheep milk	1	USA	3	R	1	1	0																								
Greenwood *et al.*, 1991	Cheese, unripened	1	UK	1	R	366	362	E[4]																	4							
McLauchlin and Gilbert, 1990	Cheese, cottage	1	UK	1	?	137	137	0																								
McLauchlin *et al.*, 1990	Anari	1	UK	1	R/P	23	9	E					10																			4
McLauchlin *et al.*, 1990	Halloumi	1	UK	1	R/P	11	3	E					8																			
Oregon State Dept of Agriculture, 2001	Cheese, cottage	1	USA	3	R	12	12	0																								
Oregon State Dept of Agriculture, 2001	Cheese, cream	1	USA	3	R	5	5	0																								
Oregon State Dept of Agriculture, 2001	Creme Mexicana	1	USA	3	R	4	4	0																								
Teufel and Bendzulla, 1993	Spieisequark	1	Germany	1	R	22	21	E										1														
Teufel and Bendzulla, 1993	Spieisequark-quargel	1	Germany	1	R	20	20	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
West and North Yorkshire Joint Working Group, 1991	Cheese, cottage	1	UK	1	R	74	74	0																								
					Total=	814	782	5					18					1							4							4

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Soft Ripened Cheese Food Category: Contamination Data						Number of Samples (values in cfu/g units)																											
Reference	***Food***	***Geographic Region***[1]	***Country***	***Pub. Date***[2]	***Sample Collection***[3]	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Beckers *et al*, 1987	Brie/ Camembert (from pasteurized milk)	1	Nether-lands	1	?	51	51	0																								
Beckers *et al*, 1987	Brie/ Camembert (from raw milk)	1	Nether-lands	1	?	18	8	0																		10						
Botarelli *et al*., 1999	Feta/cheese, soft & short-ripened	1	Italy	3	R	15	15	0																								
Botarelli *et al*., 1999	Brie/cheese, soft & short-ripened	1	Italy	3	R	15	15	0																								
Botarelli *et al*., 1999	Crescenza/ cheese, soft & short-ripened	1	Italy	3	R	15	15	0																								
Botarelli *et al*., 1999	Taleggio/ cheese, soft, short-ripened	1	Italy	3	R	15	15	0																								
Breer and Schopfer, 1989	Cheese, white mold	1	Switzer-land	1	?	261	254	7																								
Delgado da Silva *et al*., 1998	Minas frescal chomemadel, Brazilian soft cheese eaten fresh	2	Brazil	2	R	17	10	7																								
Frye, 2000	Cheese, feta	1	USA	3	R	34	34	0																								
Frye, 2000	Brie	1	USA	3	R	20	20	0																								
Frye, 2000	Camambert	1	USA	3	R	12	12	0																								
Frye, 2000	Mozzarella	1	USA	3	R	17	17	0																								
Hartung, 2000a.	soft, mold-ripened cheese	1	Germany	3	R	234	230	4																								
Hartung, 2001	soft, mold-ripened cheese	1	Germany	3	?	62	59	3																								
Hartung, 2001	soft, mold-ripened cheese	1	Germany	3	?	41	39	E[4]										1										1				

Reference	***Food***	***Geographic Region*** [1]	***Country***	***Pub. Date*** [2]	***Sample Collection*** [3]	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Hartung, 1999	soft, mold-ripened cheese	1	Germany	3	R	82	74	8																								
Loncarevic *et al*., 1995	soft, mold-ripened cheese	1	Europe Sweden	2	R	31	18	E										9		1							2				1	
McLauchlin *et al*., 1990	Feta	1	UK	1	R	3	3	0																								
NFPA, 2002	Cheese, soft mold ripened	1	USA	3	R	1347	1333	E	12				2																			
Oregon State Dept of Agriculture, 2001	Cheese, Camembert	1	USA	3	R	1	1	0																								
Oregon State Dept of Agriculture, 2001	Cheese, pyramid goat	1	USA	3	R	10	10	0																								
Oregon State Dept of Agriculture, 2001	Cheese, feta goat	1	USA	3	R	9	9	0																								
Oregon State Dept of Agriculture, 2001	Mozzarella	1	USA	3	R	2	2	0																								
Pinto and Reali, 1996	Taleggio	1	Italy	2	R	45	45	0																								
Pinto and Reali, 1996	Mozzarella	1	UK	2	R	29	25	4																								
Rudolf *et al*., 2001	Cheese, soft	1	Europe	3	P or R	192	180	12																								
Sanchez-Rey *et al*., 1993	La Serena cheese, from raw ewes milk	1	Spain	1	P	15	10	5																								
Teufel and Bendzulla, 1993	Hartz mountain cheese Harzerkase	1	Germany	1	R	19	19	E																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Teufel and Bendzulla, 1993	Hartz mountain cheese Harzerkase	1	Germany	1	R?	19	14	5																								
Teufel and Bendzulla, 1993	Cheese, Sauermulchkase-sour milk hand	1	Germany	1	R	53	48	5																								
Teufel and Bendzulla, 1993	Cheese, Sauermulchkase-sour milk hand	1	Germany	1	R	69	64	E										2			3											
Teufel and Bendzulla, 1993	Romadur	1	Germany	1	R	23	18	E										5														
Weber *et al.*, 1988	Cheese, soft	1	Germany	1	?	22	22	0																								
Weber *et al.*, 1988	Cheese, soft cow	1	Germany	1	?	307	299	8																								
Weber *et al.*, 1988	Cheese, soft goat & sheep	1	Germany	1	?	4	4	0																								
					Total=	3109	2992	68	12				2					17		1	3					10	2	1			1	

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Semi-Soft Cheese Food Category: Contamination Data							Number of Samples (values in cfu/g units)																									
Reference	***Food***	***Geographic Region***[1]	***Country***	***Pub. Date***[2]	***Sample Collection***[3]	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Botarelli *et al.*, 1999	Gorgonzola/ cheese	1	Italy	3	R	40	38	E[4]															2									
Breer and Schopfer, 1989	Cheese, semi-soft	1	Switzer-land	1	?	205	201	4																								
de Boer and Kuik, 1987	Cheese, blue-veined	1	Nether-lands	1	R	20	18	2																								
Frye, 2000	Cheese, blue	1	USA	3	R	22	22	0																								
Frye, 2000	Butter cheese	1	USA	3	R	1	1	0																								
Frye, 2000	Gorgonzola	1	USA	3	R	2	2	0																								
Frye, 2000	Cheese, Gouda	1	USA	3	R	39	39	0																								
Frye, 2000	Cheese, Gouda	1	USA	3	R	1	1	0																								
Frye, 2000	Havarti	1	USA	3	R	4	4	0																								
Frye, 2000	Cheese, Jack	1	USA	3	R	2	2	0																								
Frye, 2000	Limburger	1	USA	3	R	7	7	0																								
Frye, 2000	Pinna Ricotta	1	USA	3	R	5	2	3																								
Frye, 2000	Roquefort	1	USA	3	R	2	2	0																								
Frye, 2000	Cheese, semi-soft	1	USA	3	R	135	135	0																								
Frye, 2000	Cheese, semi-soft	1	USA	3	R	6	6	0																								
Frye, 2000	Cheese, string	1	USA	3	R	4	4	0																								
NFPA, 2001	Cheese, blue-veined soft	1	USA	3	R	1623	1600	E	18	3			1		1																	
Oregon State Dept of Agriculture, 2001	Cheese, blue	1	USA	3	R	21	21	0																								
Oregon State Dept of Agriculture, 2001	Cheese, Monterey Jack	1	USA	3	R	54	54	0																								
Oregon State Dept of Agriculture, 2001	Muenster	1	USA	3	R	1	1	0																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Oregon State Dept of Agriculture, 2001	Cheese, semi-soft goat	1	USA	3	R	6	6	0																								
Oregon State Dept of Agriculture, 2001	Cheese, string	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Cheese, Swiss	1	USA	3	R	12	12	0																								
Pinto and Reali, 1996	Gorgonzola	1	UK	2	R	58	55	3																								
Rudolf and Scherer, 2001	Cheese, semi-soft	1	Europe	3	P or R	92	85	7																								
Saltijeral *et al.*, 1999	Manchego	1	Mexico	3	R	40	40	0																								
Teufel and Bendzulla, 1993	Edam	1	Germany	1	R	3	1	E										2														
Teufel and Bendzulla, 1993	Edam	1	Germany	1	R	9	9	0																								
Teufel and Bendzulla, 1993	Limburger	1	Germany	1	R	21	19	E										1			1											
Teufel and Bendzulla, 1993	Limburger	1	Germany	1	R	1	1	0																								
Teufel and Bendzulla, 1993	Muenster	1	Germany	1	R	5	0	5																								
Teufel and Bendzulla, 1993	Muenster	1	Germany	1	R	8	0	E										1			6							1				
Teufel and Bendzulla, 1993	Stangenkase, Limburger type	1	Germany	1	R	3	3	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Teufel and Bendzulla, 1993	Stangenkase, Limburger type	1	Germany	1	R	11	10	E													1											
Weber *et al*., 1988	Cheese, semi-soft	1	Germany	1	?	144	125	19																								
Weber *et al*., 1988	Cheese, sheep semi-soft	1	Germany	1	?	6	6	0																								
					Total=	2615	2534	43	18	3			1		1			4			8		2					1				

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.
[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Hard Cheese Food Category: Contamination Data						Number of Samples (values in cfu/g units)																										
Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Breer and Schopfer, 1989	Cheese, hard Hartkase	1	Switzerland	1	?	88	88	0																								
Delgado da Silva *et al.*, 1998	Cheese, Cheddar	2	Brazil	2	R	2	2	0																								
Frye, 2000	Cacique Asadero	1	USA	3	R	1	1	0																								
Frye, 2000	Cheese, Colby Jack semi-soft	1	USA	3	R	1	1	0																								
Frye, 2000	Cheese, Parmesan	1	USA	3	R	2	2	0																								
Frye, 2000	Cheese, Provolone	1	USA	3	R	1	1	0																								
Frye, 2000	Queso Anejo	1	USA	3	R	1	1	0																								
Greenwood *et al.*, 1991	Cheese, hard	1	UK	1	R	66	65	E[4]																	1							
Lanciotti *et al.*, 1999	Cheese, hard ripened	1	Italy	3	P	45	45	0																								
McLauchlin and Gilbert, 1990	Cheese, hard	1	UK	1	?	448	442	6																								
McLauchlin *et al.*, 1990	Cheese, Cheddar goat	1	UK	1	R/P	8	4	E					2																		1	1
McLauchlin *et al.*, 1990	Gjestost	1	UK	1	R	1	0	E					1																			
Oregon State Dept of Agriculture, 2001	Cheese, Cheddar	1	USA	3	R	65	65	0																								
Oregon State Dept of Agriculture, 2001	Cheese, Cheddar	1	USA	3	R	19	19	0																								
Oregon State Dept of Agriculture, 2001	Cheese, Colby Jack	1	USA	3	R	9	9	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Oregon State Dept of Agriculture, 2001	Cheese, hard	1	USA	3	R	48	48	0																								
Oregon State Dept of Agriculture, 2001	Quesco Cotija	1	USA	3	R	5	5	0																								
Rudolf and Scherer, 2001	Cheese, hard	1	Europe	3	P or R	45	43	2																								
Saltijeral *et al.*, 1999	Chihuahua	1	Mexico	3	R	40	40	0																								
Weber *et al.*, 1988	Cheese, hard	1	Germany	1	?	4	4	0																								
West and North Yorkshire Joint Working Group, 1991	Cheese, hard	1	UK	1	R	74	74	0																								
					Total=	973	959	8					3												1						1	1

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.

[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.

[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.

[4] E = samples ≥ 0.04 cfu/g that were enumerated

Processed Cheese Food Category: Contamination Data

Number of Samples (values in cfu/g units)

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Baek *et al*., 2000	Cheese, pasturized & processed	2	Korea	3	R	45	45	0																								
Ng and Seah, 1995	Cheese & spreads	2	Singapore	2	P/R	103	103	0																								
Oregon State Dept of Agriculture, 2001	Cheese, processed	1	USA	3	R	4	4	0																								
Teufel and Bendzulla, 1993	Cheese, Schnittkase-sliced	1	Germany	1	R	96	95	1																								
Teufel and Bendzulla, 1993	Cheese, Schnittkase-sliced	1	Germany	1	R	77	75	E[4]										2														
					Total=	325	322	1										2														

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.
[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Pasteurized Milk Food Category: Contamination Data

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
						Number of Samples (values in cfu/g units)																										
Ahrabi *et al*., 1997	Milk, cow's	2	Turkey	2	R	20	19	1																								
Arnold and Coble, 1995	Milk, cow's	1	Australia	2	R	33	33	0																								
Baek *et al*., 2000	Milk, pasteurized	2	Korea	3	R	26	26	0																								
Beckers *et al*, 1987	Milk, cow's	1	Nether-lands	1	?	41	41	0																								
Casarotti *et al.*, 1994	Milk, cow's	2	Brazil	2	R	20	20	0																								
Farber *et al*., 1989	Milk, cow's	1	Canada	1	R	14	14	0																								
Fernandez Garayzabal *et al*., 1986	Milk, cow's	1	Spain	1	P	28	22	6																								
Gelosa, 1990	Milk, cow's	1	Italy	1	R	7	7	0																								
Gohil *et al*., 1995	Milk, cow's	2	UA Emirates	2	R	182	182	0																								
Greenaway and Drew, 1990	Milk, cow's	1	Australia	1	P	77	77	0																								
Greenwood *et al*., 1991	Milk, cow's	1	UK	1	R	1039	1028	11																								
Hartung, M. 2000b	Milk, pasteurized	1	Germany	3	R	651	651	0																								
Hartung, 2001	Milk, pasteurized	1	Germany	3	R	1452	1451	E[4]										1														
Hartung, M., 1999	Milk, UHT	1	Germany	3	R	28	28	0																								
Hartung, M., 1999	Pasteurized milk	1	Germany	3	R	690	690	0																								
Harvey and Gilmour, 1992	Milk, cow's	1	Northern Ireland	1		95	94	1																								
Ibrahim *et al*., 1992	Milk, cow's	1	Hungary	1	R	100	100	0																								
Ibrahim *et al*., 1992	Milk, cow's	1	Hungary	1	R	60	53	7																								
Frye/IDFA, 2000b	Milk, cow's whole	1	USA	3	R	1897	1897	0																								
Frye/IDFA,2000b	Milk, cow's skim	1	USA	3	R	1846	1845	1																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Frye/IDFA, 2000b	Milk, cow's Chocolate	1	USA	3	R	1669	1669	0																								
Frey/IDFA, 2000b	Milk, cow's reduced fat	1	USA	3	R	107	107	0																								
Frye/IDFA, 2000b	Milk, cow's	1	USA	3	R	285	285	0																								
Kozak *et al*., 1996	Milk, chocolate	1	USA	1	P	415	410	5																								
Kozak *et al*., 1996	Milk, lowfat	1	USA	1	P	282	282	0																								
Kozak *et al*., 1996	Milk, skim	1	USA	1	P	98	98	0																								
Kozak *et al*., 1996	Milk, whole	1	USA	1	P	350	348	2																								
Laciar *et al*., 1999	Milk, cow's	2	Argentina	3	P	80	80	0																								
McLaughlin and Gilbert, 1990	Milk, cow's	1	UK	1	?	469	469	0																								
Mickova, 1991	Milk, cow's	1	Czecho-slovakia	1	P	30	30	0																								
Moura *et al*., 1993	Milk, cow's	2	Brazil	1	P	220	220	0																								
Oregon State Dept of Agriculture, 2001	Milk, chocolate	1	USA	3	R	7	7	0																								
Oregon State Dept of Agriculture, 2001	Milk, cow's	1	USA	3	R	39	39	0																								
Oregon State Dept of Agriculture, 2001	Milk, goat's	1	USA	3	R	1	1	0																								
Rola, 1994	Milk, cow's	1	Poland	1	?	73	73	0																								
Roy, 1992	Milk, cow's	1	Scotland	1	?	115	111	4																								
Sharif and Tunail, 1991	Milk, cow's	2	Turkey	1	R	22	22	0																								
Teufel and Bendzulla, 1993	Milk, cow's	1	Germany	1	R?	443	442	1																								
Teufel and Bendzulla, 1993	Milk, treated	1	Germany	1	R?	41	39	E										2														
Tiscione *et al*., 1994	Milk, cow's	1	Italy	2	P	50	50	0																								
Venables, 1989	Milk, cow's	1	Australia	1	P	206	205	1																								
West and North Yorkshire Joint Working Group, 1991	Milk, cow's	1	UK	1	R	66	65	E								1																
					Total=	12407	12363	40								1		3														

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1. [2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown. [4] E = samples ≥ 0.04 cfu/g that were enumerated

Non-pasteurized Milk Food Category: Contamination Data

Number of Samples (values in cfu/g units)

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Abou-Eleinin *et al.*, 2000	Milk, raw goat	1	USA	3	P	450	433	17																								
Anonymous, 1989	Cows' milk	1	France	1	?	1409	1324	85																								
Arias *et al.*, 1994	Cows' milk	2	Costa Rica	2	P	220	220	0																								
Baek *et al.*, 2000	Milk, raw	2	Korea	3	R	45	43	2																								
Beckers *et al.*, 1987	Cows' milk	1	Nether-lands	1	?	137	131	E[4]										6														
Casarotti *et al.*, 1994	Cows' milk	2	Brazil	2	R	20	20	0																								
Davidson *et al.*, 1989	Cows' milk	1	Canada	1	P	256	252	4																								
Desmasures *et al.*, 1997	Cows' milk	1	France	2	P	69	65	4																								
Dominguez Rodrigues *et al.*, 1985	Cows' milk	1	Spain	1	P	95	52	43																								
Donnelly *et al.*, 1988	Cows' milk	1	USA	1	P	939	924	15																								
Doyle and Schoeni, 1986	Cows' milk	1	USA	1	P	50	50	0																								
El Marrakchi *et al.*, 1993	Cows' milk	2	Morocco	1	R	30	27	3																								
El-Leboudy and Fayad, 1992	Cows' milk	2	Egypt	1	P	236	229	7																								
Farber *et al.*, 1988	Cows' milk	1	Canada	1	P	445	439	6																								
Fedio and Jackson, 1990	Cows' milk	1	Canada	1	P	36	35	1																								
Fedio and Jackson, 1990	Cows' milk	1	Canada	1	P	36	32	4																								
Fedio and Jackson, 1990	Cows' milk	1	Canada	1	P	426	418	8																								
Fenlon and Wilson, 1989	Cows' milk	1	Scotland	1	P	540	526	14																								
Fenlon *et al.*, 1995	Cows' milk	1	Scotland	2	P	727	638	44					32		13																	

Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Fernandez Garayzabul *et al.*, 1987	Cows' milk	1	Spain	1	P	67	37	30																								
Frye/IDFA, 2000	Milk, raw goat	1	USA	3	R	65	64	1																								
Frye/IDFA, 2000	Milk, raw	1	USA	3	R	194	193	1																								
Gledel, 1986	Milk, cow's	1	France	1	?	51	41	10																								
Gledel, 1986	Milk, cow's	1	France	1	?	337	323	14																								
Greenwood *et al.*, 1991	Milk, cow's	1	UK	1	P	361	348	13																								
Hartung, 2000a.	Raw milk for sale (raw milk off farm)	1	Germany	3	R	187	184	3																								
Hartung, 2000a.	Milk, untreated (bulk raw milk)	1	Germany	3	R	964	955	9																								
Hartung, 2000a.	Milk, certified raw	1	Germany	3	R	415	415	0																								
Hartung, 1999	Raw milk for sale (raw milk off farm)	1	Germany	3	R	166	165	1																								
Hartung, 1999	Milk, untreated (bulk raw milk)	1	Germany	3	R	1273	1263	10																								
Hartung, 1999	Milk, certified & raw	1	Germany	3	R	439	439	0																								
Harvey and Gilmour, 1992	Milk, cow's	1	N. Ireland	1	P	176	149	27																								
Laciar *et al.*, 1999	Milk, cow's	2	Argentina	3	P?	208	207	1																								
Liewen and Plautz, 1988	Milk, cow's	1	USA	1	P	200	192	8																								
Lovett *et al.*, 1987	Milk, cow's	1	USA	1	P	650	623	27																								
Luisjuan-Morales *et al.*, 1995	Milk, cow's	1	Mexico	2	R	100	100	0																								
Lund *et al.*, 1991	Milk, cow's	1	USA	1	P	300	291	9																								
McLauchlin and Gilbert, 1990	Milk, cow's	1	UK	1	?	331	323	8																								
McLauchlin and Gilbert, 1990	Non-bovine	1	UK	1	?	412	412	0																								
McLauchlin *et al.*, 1990	Milk, goat's	1	UK	1	P	7	7	0																								
Moura *et al.*, 1993	Milk, cow's	2	Brazil	1	P	220	199	21																								
Oni *et al.*, 1989	Milk, cow's	2	Nigeria	1	P	150	149	1																								

Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Oregon State Dept of Agriculture, 2001	Milk, cow's	1	USA	3	R	385	384	1																								
Oregon State Dept of Agriculture, 2001	Milk, goat's	1	USA	3	R	171	171	0																								
Patterson *et al*., 1989	Milk, cow's	1	USA	1	P	12	12	0																								
Razavi-Rohani and Hedaiatinia, 1990	Milk, cow's	2	Iran	1	P/R	190	186	4																								
Rea *et al*., 1992	Milk, cow's	1	Ireland	1	P	589	560	29																								
Rodler and Köerbler, 1989	Milk, cow's	1	Hungary	1	P	80	77	3																								
Rohrbach *et al*., 1992	Milk, cow's	1	USA	1	P	292	280	12																								
Slade and Collins-Thompson, 1988	Milk, cow's	1	Canada	1	P	315	298	17																								
Steele *et al*., 1997	Milk, cow's (farm bulk tank)	1	Canada	2	P	1720	1673	47																								
Stone, 1987	Milk, cow's	1	New Zealand	1	P	71	71	0																								
Takai *et al*., 1990	Milk, cow's	1	Japan	1	P	120	120	0																								
Teufel and Bendzulla, 1993	Milk, cow's	1	Germany	1	R?	97	93	E										4														
Teufel and Bendzulla, 1993	Milk, cow's	1	Germany	1	R?	256	256	0																								
Teufel and Bendzulla, 1993	Non-bovine	1	Germany	1	R?	39	39	0																								
Teufel and Bendzulla, 1993	Non-bovine	1	Germany	1	R?	4	4	0																								
Vázquez-Salinas *et al*. 2001	Milk, raw	1	Mexico	3	P	1300	1138	162																								
					Total=	19080	18299	726					32		13			10														

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1. [2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present. [3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown. [4] E = samples ≥ 0.04 cfu/g that were enumerated

Frozen Dairy Products Food Category: Contamination Data						**Number of Samples (values in cfu/g units)**																										
Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Arnold and Coble, 1995	Ice cream	1	Australia	2	R	166	143	23																								
Baek *et al*., 2000	Ice cream	2	Korea	3	R	132	124	8																								
Choi et al.,2001	Ice cream	2	Korea	3	R	25	25	0																								
Ciftcioglu *et al*., 1992	Ice cream	2	Turkey	1	?	50	45	5																								
Farber *et al*., 1989	Ice cream, novelty	1	Canada	1	P	51	50	1																								
Farber *et al*., 1989	Ice cream	1	Canada	1	P	394	393	1																								
Farber *et al*., 1989	Ice cream mix	1	Canada	1	P	85	85	0																								
Frye, 2000	Frozen dairy products	1	USA	3	R	69	65	4																								
Greenwood *et al*., 1991	Ice cream	1	UK	1	R	150	147	3																								
Hartung, 2000a.	Ice cream =speiseeis	1	Germany	3	R	2490	2489	1																								
Hartung, 2001	Speiseeis = icecream	1	Germany	3	R	1694	1692	2																								
Hartung, 2001	Speiseeis = icecream	1	Germany	3	R	1696	1694	E[4]										2														
Hartung, 1999	Ice cream =speiseeis	1	Germany	3	R	2628	2625	3																								
Heinitz, 1999	Ice cream	1	USA	3	P	294	270	24																								
IDFA, 1999	Ice cream, novelties	1	USA	3	R	1227	1196	31																								
IDFA, 1999	Ice cream, novelties (0.01 detection limit)	1	USA	3	R	19320	19311	9																								
IDFA, 1999	Ice cream/ frozen yogurt	1	USA	3	R	517	517	0																								
Kozak *et al*., 1996	Ice cream, novelty	1	USA	2	P	351	321	30																								
Kozak *et al*., 1996	Ice cream	1	USA	2	P	716	688	28																								
Kozak *et al*., 1996	Ice milk	1	USA	2	P	42	42	0																								

Reference	*Food*	*Geographic Region[1]*	*Country*	*Pub. Date[2]*	*Sample Collection[3]*	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Maifreni *et al*., 1993	Ice cream	1	Germany	1	R	396	396	0																								
McLauchlin and Gilbert, 1990	Ice cream	1	UK	1	?	274	257	17																								
Monge *et al.*, 1994	Ice cream	1	Costa Rica	2	R	50	49	1																								
Monge *et al*., 1994	Ice cream	1	Costa Rica	2	R	50	49	1																								
Ng and Seah, 1995	Ice cream	2	Singapore	2	P/R	61	61	0																								
Oregon State Dept of Agriculture, 2001	Frozen yogurt	1	USA	3	R	31	31	0																								
Oregon State Dept of Agriculture, 2001	Ice cream	1	USA	3	R	106	106	0																								
Oregon State Dept of Agriculture, 2001	Ice cream mix	1	USA	3	R	57	57	0																								
Oregon State Dept of Agriculture, 2001	Ice cream, novelty	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Ice milk	1	USA	3	R	82	82	0																								
Teufel and Bendzulla, 1993	Ice cream, iced products	1	Germany	1	R?	63	63	0																								
Teufel and Bendzulla, 1993	Ice cream, iced products	1	Germany	1	R?	5	5	0																								
Unilever, 2000	Ice cream	2	Oceania/ Asia/ Africa	3	P	21416	21413	3																								
Unilever, 2000	Ice cream	1	America	3	P	16387	16382	5																								
Unilever, 2000	Ice cream	1	Europe	3	P	99216	99160	56																								
Warke *et al*., 2000	Ice creams	2	India	3	R	30	29	1																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
West and North Yorkshire Joint Working Group, 1991	Ice cream	1	UK	1	R	68	65	2								1																
					Total=	170391	170129	259								1		2														

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Cultured Milk Products Category: Contamination Data						Number of Samples (values in cfu/g units)																										
Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Greenwood *et al*., 1991	Yogurt	1	UK	1	R?	180	176	3																			1					
McLauchlin and Gilbert, 1990	Yogurt	1	UK	1	?	209	209	0																								
McLauchlin *et al*., 1990	Yogurt	1	UK	1	R	2	2	0																								
Ng and Seah, 1995	Yogurt	2	Singapore	2	P/R	40	40	0																								
Oregon State Dept of Agriculture, 2001	Buttermilk	1	USA	3	R	5	5	0																								
Oregon State Dept of Agriculture, 2001	Sour cream	1	USA	3	R	5	5	0																								
Oregon State Dept of Agriculture, 2001	Yogurt	1	USA	3	R	4	4	0																								
West and North Yorkshire Joint Working Group, 1991	Yogurt	1	UK	1	R	45	45	0																								
					Total=	490	486	3																			1					

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.

High Fat and Other Dairy Products: Contamination Data						**Number of Samples (values in cfu/g units)**																										
Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Frye, 2000	Butter	1	USA	3	R	23	23	0																								
Greenwood *et al*., 1991	Cream, pasteurized	1	UK	1	R	40	40	0																								
Hartung, 2000a.	milk products	1	Germany	3	R	958	956	2																								
Hartung, 2000a.	milk products,	1	Germany	3	R	6567	6538	29																								
Hartung, 2001	milk products,	1	Germany	3	R	266	264	2																								
Hartung, 2001	milk products,	1	Germany	3	R	537	533	E[4]										4														
Hartung, 1999	milk products	1	Germany	3	R	45	45	0																								
Hartung, 1999	milk products,	1	Germany	3	R	8732	8552	180																								
Heinitz, 1999	milk product	1	USA	3	P	32	32	0																								
Heinitz, 1999	Milk products (not cheese or ice cream)	1	USA	3	P	271	267	4																								
Karpiskova *et al*., 2000	Dairy products	1	Czech Republic	3	R	209	207	2																								
Kozak *et al*., 1996	Butter	1	USA	2	P	30	30	0																								
Kozak *et al*., 1996	Cream	1	USA	2	P	52	52	0																								
Kozak *et al*., 1996	Cream half & half	1	USA	2	P	42	42	0																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
McLauchlin and Gilbert, 1990	Cream	1	UK	1	?	116	116	0																								
Ng and Seah, 1995	cream	2	Singapore	2	P/R	17	17	0																								
Oregon State Dept of Agriculture, 2001	Pudding, chocolate	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Egg nog	1	USA	3	R	4	4	0																								
Oregon State Dept of Agriculture, 2001	Half & half	1	USA	3	R	7	7	0																								
Oregon State Dept of Agriculture, 2001	Milkshake	1	USA	3	R	55	55	0																								
Oregon State Dept of Agriculture, 2001	Dip	1	USA	3	R	42	40	2																								
Oregon State Dept of Agriculture, 2001	Whipping cream	1	USA	3	R	6	6	0																								
Teufel and Bendzulla, 1993	Butter	1	Germany	1	R?	19	14	E										5														
Teufel and Bendzulla, 1993	Butter	1	Germany	1	R?	97	97	0																								
					Total=	18169	17939	221										9														

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Frankfurter Food Category: Contamination Data						Number of Samples (values in cfu/g units)																									
Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100 <20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Hayes *et al.*, 1992	Hotdogs	1	USA	1	R	40	28	E[4]			9		1		2																
Levine, 2000	Hotdogs	1	USA	3	P	1593	1516	77																							
Levine, 2001	Hotdogs	1	USA	3	P	1800	1766	34																							
Ng and Seah, 1995	Franks, chicken & pork	2	Singapore	2	P/R	78	73	5																							
Oregon State Dept of Agriculture, 2001	Hotdog	1	USA	3	R	11	11	0																							
Oregon State Dept of Agriculture, 2001	Hotdogs, beef	1	USA	3	R	3	3	0																							
Oregon State Dept of Agriculture, 2001	Hotdogs, turkey	1	USA	3	R	3	3	0																							
Qvist and Liberski, 1991	Frankfurter	1	Sweden?	1	R	64	56	8																							
Samelis and Metaxopoulos, 1999	Frankfurter, sausage type	1	Greece	3	P	8	8	0																							
Wang and Muriana, 1994	Hotdogs	1	USA	2	R	117	93	16					8																		
Wenger *et al.*, 1990	Wieners, turkey	1	USA	1	P	46	25	21																							
					Total=	3763	3582	161			9		9		2																

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Dry/Semi-dry Sausage Food Category: Contamination Data							Number of Samples (values in cfu/g units)																											
Reference	***Food***	***Geographic Region***[1]	***Country***	***Pub. Date***[2]	***Sample Collection***[3]	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Breer and Schopfer, 1989	Salami	1	Australia	1	?	63	59	4																										
Buncic, 1991	Sausage, fermented	1	Yugo-slavia	1	R	21	17	4																										
Cantoni *et al*., 1988	Salami & pork, seasoned meat products	1	Italy?	1	R?	225	219	6																										
Choi *et al.*,2001	Sausage, fermented	2	Korea	3	R	15	13	2																										
Farber *et al*., 1989	Sausages, fermented	1	Canada	1	R	30	24	6																										
Gomez-Campillo *et al*., 1999	Cured chorizo	1	Spain	3	R	20	19	1																										
Lahellec *et al*., 1996	Sausage, dry	1	France	2	?	116	83	33																										
Lahellec *et al*., 1996	Sausage, smoked	1	France	2	?	45	39	6																										
Levine, 2000	Sausages, fermented	1	USA	3	P	352	335	17																										
Levine, 2001	Sausage, dry & semi-dry fermented	1	USA	3	P	856	841	15																										
Oregon State Dept of Agriculture, 2001	Beef Stick	1	USA	3	R	3	3	0																										
Oregon State Dept of Ag, 2001	Pepperoni	1	USA	3	R	7	6	1																										
Oregon State Dept of Agriculture, 2001	Salami	1	USA	3	R	5	5	0																										
Samelis and Metaxopoulos, 1999	Sausage, dry & fermented	1	Greece	3	P	4	4	0																										
Teufel and Bendzulla, 1993	Sausage	1	Germany	1	R?	850	806	44																										

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Teufel and Bendzulla, 1993	Sausage, cooked & cured	1	Germany	1	R?	338	314	E[4]										21			3											
Trüssel, 1989	Beef, salami & mettwurst	1	Germany	1	P	99	95	E								4																
Uyttendaele *et al.*, 1999	Sausage, raw & fermented	1	Belgium	3	R	308	259	36						13																		
					Total=	3357	3141	175						13		4		21			3											

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[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.

[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.

[4] E = samples ≥ 0.04 cfu/g that were enumerated

Deli Meats Food Category: Contamination Data							Number of Samples (values in cfu/g units)																									
Reference	*Food*	*Geographic Region[1]*	*Country*	*Pub. Date[2]*	*Sample Collection[3]*	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Aguado *et al*., 2001	Deli meats	1	Spain	3	R	369	335	34																								
Baek *et al*., 2000	Ham	2	Korea	3	R	50	50	0																								
Bersot *et al*, 2001	Mortadella	2	Brazil	3	R	30	22	8																								
Daley *et al*., 1999	Meats, ready-to-eat	1	Canada	3	R	19	18	1																								
Gillespie *et al*., 2000	Deli meats	1	UK	3	R	3455	3442	E[4]										8		5												
Gomez-Campillo *et al*., 1999	Cold cuts	1	Spain	3	R	20	20	0																								
Kamat and Nair, 1994	Ham, cooked	2	India	2	R	2	2	0																								
Lahellec *et al*., 1996	Ham	1	France	2	?	45	44	1																								
Levine, 2000	Corned beef, roast and cooked	1	USA	3	P	2587	2523	64																								
Levine, 2000	Ham and luncheon meats, sliced	1	USA	3	P	978	930	48																								
Levine, 2000	Poultry, cooked	1	USA	3	P	4125	4036	89																								
Levine, 2000	Sausage, large diameter cooked	1	USA	3	P	2174	2148	26																								
Levine, 2001	Corned beef, roast cooked	1	USA	3	P	1939	1892	47																								
Levine, 2001	Ham-sliced/sliced luncheon	1	USA	3	P	2048	1971	77																								
Levine, 2001	Poultry, cooked	1	USA	3	P	2325	2294	31																								
Levine, 2001	Sausage, large diameter cooked	1	USA	3	P	2725	2712	13																								
Miettinen, *et al*., 2001	Broiler products, ready-to-eat	1	Finland	3	P	25	25	0																								
NFPA, 2002	Deli meats	1	USA-CA	3	R	4600	4572	E	10	8			6		1					2							1					
NFPA, 2002	Deli meats	1	USA-MD	3	R	4599	4545	E	32	12			4		1					5												

Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Ng and Seah, 1995	Ham/salami/bacon/ luncheon meat	2	Singapore	2	R	17	14	3																								
Ojeniyi *et al*., 2000	Turkey breast, smoked	1	Denmark	3	P	2	2	0																								
Ojeniyi *et al*., 2000	Turkey breast, cooked smoked	1	Denmark	3	P	18	18	0																								
Ojeniyi *et al*., 2000	Turkey cuvette, smoked	1	Denmark	3	P	17	17	0																								
Ojeniyi *et al*., 2000	Turkey fillet, smoked & ready-to-eat	1	Denmark	3	P	14	11	3																								
Ojeniyi *et al*., 2000	Turkey parts	1	Denmark	3	P	1	1	0																								
Ojeniyi *et al*., 2000	Turkey wings	1	Denmark	3	P	1	0	1																								
Ojeniyi *et al*., 2000	Turkey, cooked & smoked & diced	1	Denmark	3	P	2	2	0																								
Oregon State Dept of Agriculture, 2001	Beef, barbecue	1	USA	3	R	11	11	0																								
Oregon State Dept of Agriculture, 2001	Chicken, barbecue	1	USA	3	R	4	4	0																								
Oregon State Dept of Agriculture, 2001	Meat, barbecue	1	USA	3	R	1	1	0																								
Oregon State Dept of Agriculture, 2001	Pork, barbecue	1	USA	3	R	5	5	0																								
Oregon State Dept of Agriculture, 2001	Beef	1	USA	3	R	1	1	0																								
Oregon State Dept of Agriculture, 2001	Bologna	1	USA	3	R	4	4	0																								
Oregon State Dept of Agriculture, 2001	Chicken, breaded	1	USA	3	R	22	22	0																								
Oregon State Dept of Agriculture, 2001	Chicken, ready-to-eat	1	USA	3	R	74	72	2																								
Oregon State Dept of Agriculture, 2001	Corned beef	1	USA	3	R	6	6	0																								
Oregon State Dept of Agriculture, 2001	Ham	1	USA	3	R	56	56	0																								
Oregon State Dept of Agriculture, 2001	Olive loaf	1	USA	3	R	4	4	0																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Oregon State Dept of Agriculture, 2001	Pastrami	1	USA	3	R	14	14	0																								
Oregon State Dept of Agriculture, 2001	Pork	1	USA	3	R	3	1	2																								
Oregon State Dept of Agriculture, 2001	Beef, roast	1	USA	3	R	108	108	0																								
Oregon State Dept of Agriculture, 2001	Turkey breast, sliced	1	USA	3	R	118	118	0																								
Oregon State Dept of Agriculture, 2001	Turkey ham	1	USA	3	R	8	8	0																								
Oregon State Dept of Agriculture, 2001	Turkey pastrami	1	USA	3	R	8	7	1																								
Oregon State Dept of Agriculture, 2001	Turkey, ready-to-eat	1	USA	3	R	4	4	0																								
Qvist and Liberski, 1991	Ham	1	Sweden?	1	R	80	72	8																								
Qvist and Liberski, 1991	Pork loin	1	Sweden?	1	R	80	62	18																								
Qvist and Liberski, 1991	Sausages	1	Sweden?	1	R	80	72	8																								
Samelis and Metaxopoulos, 1999	Bacon	1	Greece	3	P	4	4	0																								
Samelis and Metaxopoulos, 1999	Ham like products	1	Greece	3	P	4	3	1																								
Samelis and Metaxopoulos, 1999	Ham, sliced & vacuum-packed	1	Greece	3	P	6	5	1																								
Samelis and Metaxopoulos, 1999	Mortadella	1	Greece	3	P	4	4	0																								
Samelis and Metaxopoulos, 1999	Pariza	1	Greece	3	P	2	2	0																								
Samelis and Metaxopoulos, 1999	Pork shoulder, sliced & vacuum-packed	1	Greece	3	P	6	6	0																								
Samelis and Metaxopoulos, 1999	Sausage, country type	1	Greece	3	P	10	9	1																								
Samelis and Metaxopoulos, 1999	Sausage, Emulsion type	1	Greece	3	P	12	12	0																								
Samelis and Metaxopoulos, 1999	Turkey breast, smoked	1	Greece	3	P	4	4	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Soriano *et al*., 2001	Beef, ready-to-eat	1	Spain	3	R	5	5	0																								
Soriano *et al*., 2001	Chicken, ready-to-eat	1	Spain	3	R	5	5	0																								
Soriano *et al*., 2001	Pork, ready-to-eat	1	Spain	3	R	5	5	0																								
Uyttendaele *et al*., 1999	Ham, cooked sliced	1	Belgium	3	R	879	817	54						8																		
					Total=	33824	33179	542	42	20			10	8	2			8		12							1					

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.
[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Pâté and Meat Spreads Food Category: Contamination Data

Number of Samples (values in cfu/g units)

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Anderson and Nørrung, 1995	Pâté	1	Denmark	2	R	341	333	6							1					1												
Dominguez *et al.*, 2001	Pâté	1	Spain	3	R	182	172	E[4]										9		1												
Gomez-Campillo *et al.*, 1999	Pâté	1	Spain	3	R	20	20	0																								
Lahellec *et al.*, 1996	Pâté	1	France	2	?	110	96	14																								
Levine, 2000	Meat spreads	1	USA	3	P	264	254	10																								
Levine, 2000	Pâté	1	USA	3	P	249	244	5																								
Levine, 2001	Meat spreads	1	USA	3	P	105	103	2																								
Levine, 2001	Pâté	1	USA	3	P	103	103	0																								
McLauchlin and Gilbert, 1990	Pâté	1	UK	1	?	696	580	99																		17						
Morris and Ribeiro, 1989	Pâté	1	UK	1	R	73	36	E								18	5			4							3		4	3		
Morris and Ribeiro, 1991	Pâté	1	UK	1	R	216	141	6								42	6			7							4	10				
Nichols *et al.*, 1998	Pâté, fish & seafood	1	UK	2	R	122	113	1														6		2								
Nichols *et al.*, 1998	Pâté, meat-based	1	UK	2	R	1804	1767	1														29		1			2		2			2
Nichols *et al.*, 1998	Pâté, poultry-based	1	UK	2	R	528	511	E														11		2			1		2		1	
Nichols *et al.*, 1998	Pâté, undefined	1	UK	2	R	380	369	E														9							1			1
Oregon State Dept of Agriculture, 2001	Ham spread	1	USA	3	R	1	1	0																								
Oregon State Dept of Agriculture, 2001	Pâté, salmon	1	USA	3	R	7	7	0																								
Oregon State Dept of Agriculture, 2001	Pâté, shrimp	1	USA	3	R	1	1	0																								
Oregon State Dept of Agriculture, 2001	Pâté, tuna	1	USA	3	R	1	1	0																								

Reference	*Food*	*Geographic Region*[1]	*Country*	*Pub. Date*[2]	*Sample Collection*[3]	*Total # of Samples from the reference*	*<0.04*	*≥0.04*	*>0.01-0.1*	*>0.1-1*	*<0.3*	*0.3-<10*	*<10*	*≥10*	*10-100*	*<20*	*20-100*	*<100*	*>100*	*100-1000*	*1E2- 1E4*	*<200*	*200-500*	*200-1000*	*<500*	*>1000*	*1E3-1E4*	*>1E4*	*1E4-1E5*	*>1E5*	*1E5-1E6*	*>1E6*
Uyttendaele *et al*., 1999	Aspic mince, prepacked, cooked	1	Belgium	3	R	48	43	4						1																		
Uyttendaele *et al*., 1999	Aspic mince, unprepackaged & cooked	1	Belgium	3	R	67	66	1																								
Uyttendaele *et al*., 1999	Pâté mince, prepacked & cooked	1	Belgium	3	R	217	211	6																								
Uyttendaele *et al*., 1999	Pâté mince, unprepackaged & cooked	1	Belgium	3	R	130	123	6						1																		
					Total=	5665	5295	161						2	1	60	11	9		13		55		5		17	10	10	9	3	1	3

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.
[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Deli-type Salad Food Category: Contamination Data							Number of Samples (values in cfu/g units)																									
Reference	***Food***	***Geographic Region[1]***	***Country***	***Pub. Date[2]***	***Sample Collection[3]***	***Total # of Samples from the reference***	***<0.04***	***≥0.04***	***>0.01-0.1***	***>0.1-1***	***<0.3***	***0.3-<10***	***<10***	***≥10***	***10-100***	***<20***	***20-100***	***<100***	***>100***	***100-1000***	***1E2- 1E4***	***<200***	***200-500***	***200-1000***	***<500***	***>1000***	***1E3-1E4***	***>1E4***	***1E4-1E5***	***>1E5***	***1E5-1E6***	***>1E6***
Buchanan *et al.*, 1989	Salad, seafood	1	USA		R	2	2	0																								
Hartemink and Georgsson 1991	Salads, seafood	1	Iceland	1	P/R	37	31	6																								
Hartung, 2000a.	Delicatessen salads, other	1	Germany	3	R	485	479	6																								
Hartung, 2001	Delicatessen salads, other	1	Germany	3	R	26	25	1																								
Hartung, 2001	Delicatessen salads, other	1	Germany	3	R	389	374	E[4]										15														
Hartung, 1999	Delicatessen salads, unspecified	1	Germany	3	R	354	351	3																								
Levine, 2000	Various meat & poultry salads	1	USA	3	P	1645	1594	51																								
Levine, 2001	Salads, deli	1	USA	3	P	630	623	7																								
Lin et al., 1996	Salads(2 egg, 2 cheese, 1dressing)	1	USA	2	R	5	5																									
NFPA, 2002	Salads, deli	1	USA-CA	3	R	4256	4157	E	78	14			4		2												1					
NFPA, 2002	Salad, seafood	1	USA-CA	3	R	1248	1221	E	26	1																						
NFPA, 2002	Salads, deli	1	USA-MD	3	R	4293	4190	E	84	14			5																			
NFPA, 2002	Salad, seafood	1	USA-MD	3	R	1313	1225	E	56	18			10		2					2												
Ng and Seah, 1995	Cole slaw/vegetable salad	2	Singapore	2	R	50	48	2																								

Reference	Food	Geographic Region[1]	Country	Pub. Date [2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Ng and Seah, 1995	Fish, tuna salad	2	Singapore	2	R	5	5	0																								
Oregon State Dept of Agriculture, 2001	Antipasto	1	USA	3	R	3	3	0																								
Oregon State Dept of Agriculture, 2001	Salad, broccoli & cheese	1	USA	3	R	50	50	0																								
Oregon State Dept of Agriculture, 2001	Caesar salad	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Chef salad	1	USA	3	R	31	31	0																								
Oregon State Dept of Agriculture, 2001	Salad, chicken	1	USA	3	R	222	218	4																								
Oregon State Dept of Agriculture, 2001	Cole slaw	1	USA	3	R	161	159	2																								
Oregon State Dept of Agriculture, 2001	Salad, crab	1	USA	3	R	9	9	0																								
Oregon State Dept of Agriculture, 2001	Creamy Fruit	1	USA	3	R	5	5	0																								
Oregon State Dept of Agriculture, 2001	Salad, egg	1	USA	3	R	7	7	0																								
Oregon State Dept of Agriculture, 2001	Salad, Greek	1	USA	3	R	8	8	0																								
Oregon State Dept of Agriculture, 2001	Salad, ham	1	USA	3	R	7	7	0																								
Oregon State Dept of Agriculture, 2001	Salad, macaroni with cheese	1	USA	3	R	194	193	1																								

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Oregon State Dept of Agriculture, 2001	Salad, meat	1	USA	3	R	17	17	0																								
Oregon State Dept of Agriculture, 2001	Salad, pasta	1	USA	3	R	115	115	0																								
Oregon State Dept of Agriculture, 2001	Salad, pea	1	USA	3	R	45	42	3																								
Oregon State Dept of Agriculture, 2001	Salad, potato	1	USA	3	R	302	302	0																								
Oregon State Dept of Agriculture, 2001	Salad, salmon	1	USA	3	R	2	2	0																								
Oregon State Dept of Agriculture, 2001	Salad, seafood	1	USA	3	R	211	211	0																								
Oregon State Dept of Agriculture, 2001	Salad, shrimp	1	USA	3	R	48	48	0																								
Oregon State Dept of Agriculture, 2001	Salad, tortellini	1	USA	3	R	14	14	0																								
Oregon State Dept of Agriculture, 2001	Salad, tuna	1	USA	3	R	16	16	0																								
Oregon State Dept of Agriculture, 2001	Salad, turkey	1	USA	3	R	22	22	0																								
Ryu *et al.*, 1992	Salad, potato	1	Japan	1	R	3	3	0																								
Scoglio *et al.*, 2000	Fish marinate & seafood salad	1	Italy	3	R	5	5	0																								
Teufel and Bendzulla 1993	Salad, meat & egg	1	Germany	1	R?	252	241	11																								
Teufel and Bendzulla 1993	Deli, mayonnaise	1	Germany	1	R?	360	333	E										24			3											
Uyttendaele *et al.*, 1999	Salad, chicken	1	Belgium	3	R	152	110	41						1																		

Reference	Food	Geographic Region[1]	Country	Pub. Date[2]	Sample Collection[3]	Total # of Samples from the reference	<0.04	≥0.04	>0.01-0.1	>0.1-1	<0.3	0.3-<10	<10	≥10	10-100	<20	20-100	<100	>100	100-1000	1E2- 1E4	<200	200-500	200-1000	<500	>1000	1E3-1E4	>1E4	1E4-1E5	>1E5	1E5-1E6	>1E6
Uyttendaele *et al*., 1999	Salad, fish & shrimp	1	Belgium	3	R	362	249	99						14																		
Uyttendaele *et al*., 1999	Salad, ham	1	Belgium	3	R	159	121	33						5																		
Uyttendaele *et al*., 1999	Other salad (veg) with mayonnaise	1	Belgium	3	R	201	186	13						2																		
West and North Yorkshire Joint Working Group, 1991	Salad, egg/egg mayonnaise	1	UK	1	R	101	83	E								2	6									10						
West and North Yorkshire Joint Working Group, 1991	Salad, fish	1	UK	1	R	33	32	E								1																
West and North Yorkshire Joint Working Group, 1991	Salad, meat/egg	1	UK	1	R	15	13	E								1	1															
West and North Yorkshire Joint Working Group, 1991	Salad, fruit/nut	1	UK	1	R	43	42	E								1																
					Total=	17915	17229	283	244	47			19	22	4	5	7	39		2	3					10	1					

[1] Group 1 includes North America including the United States, Canada, Mexico, EU countries, Japan, Australia, New Zealand. Other countries were also included in group 1 on a case-by-case basis if they import the product to the United States. Group 2 includes any country not in group 1.
[2] 1 = time period pre-1993 to 1993; 2 = time period 1994 to 1998; 3 = time period 1999 to present.
[3] R = sample collected at retail; P = sample collected at plant/ manufacturer; ? = location of sample collection unknown.
[4] E = samples ≥ 0.04 cfu/g that were enumerated

Appendix 8:

Growth of *Listeria monocytogenes* in Foods

Appendix 8 Table 1: Growth Rate of *Listeria monocytogenes* in Food Categories Considered for this Risk Assessment Growth Product -

Food Category Reference	Food	Literature Values		EGR[c] at 5 °C (log_{10} cfu/day)
		Temperature	Growth Rate [a,b]	
SEAFOOD				
Smoked Seafood				
Duffes *et al*., 1999	cold-smoked salmon	4 °C 8 °C 4 °C 8 °C	2.1 logs in 28 days 5.4 logs in 21 days 2.0 logs in 21 days 4.6 logs in 14 days	0.107 0.116 0.136 0.149
Jemmi and Keusch, 1992	hot-smoked trout	4 °C 8 to 10 °C	0.5 logs in 20 days 6.5 logs in 20 days	0.035 0.120
Hudson and Mott, 1993b	cold-smoked salmon	5 °C 10 °C	4 logs in 650 hours 4 to 4.5 logs in 125 hours	0.148 0.249
Szabo and Cahill, 1999	smoked salmon	4 °C 10 °C	3.9 logs in 28 days 2.7 to 4.3 logs in 9 days	0.198 0.119
Dillon and Patel, 1993	cold-smoked cod	4 °C	2.8 logs in 21 days	0.190
Guyer and Jemmi, 1991	smoked salmon (26 to 30 °C)	4 °C 10 °C	1.0 to 1.5 logs in 10 days 3 to 3.5 logs in 10 days	0.177 0.099
Pelroy *et al*., 1994b	cold-smoked salmon	5 °C 5 °C 10 °C 10 °C	2.5 to 5 logs in 40 days 2 logs in 40 days 4.5 to 7 logs in 10 days 5 logs in 11 days	0.092 0.050 0.249 0.139
Pelroy *et al*., 1994a	cold-smoked salmon	5 °C 10 °C	4 logs in 50 days 4.5 logs in 15 days	0.080 0.092
Peterson *et al*., 1993	cold-smoked salmon	5 °C 5 °C 10 °C 10 °C 10 °C	3 logs in 20 days 2.5 logs in 20 days 4 logs in 7 days 3.7 logs in 7 days 6 logs in 20 days	0.150 0.125 0.175 0.162 0.092
Rosso *et al*., 1996	smoked salmon	4 °C 8 °C	1 log in 10 days 3 logs in 14 days	0.142 0.097
Nilsson *et al*., 1997	cold-smoked salmon	5 °C	5 logs in 9 days	0.556
Raw Seafood				
Fernandes *et al*., 1998	fresh trout catfish	4 °C 4 °C	1 logs in 15 days 2 logs in 15 days	0.100 0.185
Lovett *et al*., 1990	raw shrimp, crab, surimi and whitefish	7 °C	GT in 12 hours	0.342
Kaysner *et al*., 1990	raw oysters	4 °C	No growth in 21 days	0.000
Leung *et al*., 1992	catfish	4 °C	1-1.5 logs in 12 days	0.133
Shineman and Harrison, 1994	raw shrimp and fin fish	ice chest	No growth [1 log decrease in 21 days]	—

[a]logs = Log_{10} cfu/g
[b]GT = Generation Time
[c]EGR = Exponential Growth Rate

Food Category Reference	Food	Literature Values: Temperature	Literature Values: Growth Rate [a,b]	EGR[c] at 5 °C (log_{10} cfu/day)
Raw Seafood (Cont'd)				
Harrison *et al*., 1991	raw shrimp and fin fish	ice chest	No growth [0.5 log decrease in 14 days]	—
Preserved Fish				
No data available			No growth	0.000 used in risk assessment
Cooked Ready-to-Eat Crustaceans				
Rawles *et al*., 1995	pasteurized crab	5 °C	GT in 21.8 hours	0.343
Farber, 1991b	cooked lobster, shrimp, crab and smoked fish	4 °C	2-3 logs in 7 days	0.508
Buchanan and Klawitter, 1992	pasteurized crabmeat	5 °C	3 logs in 10 days	0.300
PRODUCE				
Vegetables				
Steinbrugge *et al*., 1988	lettuce, whole, ready to serve	5 °C 12 °C	0.00 to 0.3 logs in 7 days 0.00 to 2.03 logs in 7 days	0.043 0.004
	lettuce, whole, ready to serve, sealed	25 °C	0.00 to 0.31 logs in 7 days	0.002
	lettuce, whole, ready to serve, open	25 °C	0.00 to 0.35 logs in 7 days	0.002
Beuchat and Brackett, 1990b	lettuce, shredded lettuce, shredded lettuce, whole	5 °C 10 °C 10 °C	0.00 to 0.1 logs in 15 days 1.5-2.0 logs in 3 days 1.0 logs in 15 days	0.007 0.204 0.067
Nguyen and Carlin, 1994	lettuce, butterhead	10 °C	1.5 logs in 7 days	0.065
Nguyen and Carlin, 1994	lettuce, lamb's	10 °C	1.0 logs decrease in 7 days	-0.044
Francis and O'Beirne, 2001	lettuce	8 °C	1.5 logs in 7 days	0.097
Carlin *et al*., 1996	endive, broad leaved	10 °C	1.0 logs in 7 days	0.044
Nguyen and Carlin, 1994	endive, broad leaved	10 °C	1.5 logs in 7 days	0.065
Nguyen and Carlin, 1994	endive, curly-leaved	10 °C	0.5 logs in 7 days	0.022
Beuchat and Brackett, 1991	tomatoes	10 °C 21 °C	no growth (death in chopped tomatoes) Growth	0.00 —

[a]Logs = Log_{10} cfu/g
[b]GT = Generation Time
[c]EGR = Exponential Growth Rate

Food Category Reference	Food	Literature Values: Temperature	Literature Values: Growth Rate [a,b]	EGR[c] at 5 °C (log_{10} cfu/day)
Vegetables (Cont'd)				
Castillego Rodriguez *et al*., 2000	Asparagus	4 °C 8 °C	0.0087 log decrease per hour 0.038 logs per hour	-0.09 0.413
Beuchat and Brackett, 1990a	carrots, whole and shredded	5 °C 15 °C	no growth up to 7 days no growth up to 7 days	0.00 0.00
Beuchat *et al*., 1986	cabbage, raw, shreds	5 °C	4 logs in 10 days	0.400
Berrang *et al*., 1989	Broccoli	4 °C 15 °C	0.25 to 0.5 logs in 14 to 21 days 3.0 logs in 4 days	0.059 0.109
Berrang *et al*., 1989	Cauliflower	4 °C 15 °C	≤ 0.25 logs in 14 to 21 days 3.0 logs in 4 days	0.020 0.109
Francis and O'Beirne, 2001	Rutabaga	8 °C	1.75 logs in 12 days	0.066
Francis and O'Beirne, 2001	Bean sprout	8 °C	1.75 logs in 8 days	0.099
Sizmur and Walker, 1988	salads, mixed , prepacked including fruits/nuts	4 °C	0.30 logs in 4 days	0.106
Fruits				
Parish and Higgins, 1989	orange, serum (juice)	4 °C	1.0 logs in 35 days (pH 5.0)	0.041
Conway *et al*., 2000	Apple slices (fresh cut)	5 °C 10 °C	0 logs in 6 days 2 logs in 6 days	0 0.102 (air)
Conway *et al*., 2000	Apple slices (fresh cut)	5 °C 10 °C	0 logs in 4 days 2.8 logs in 10 days	0 0.086 (0.5% O, 15% CO_2)
<u>DAIRY PRODUCTS</u>				
Fresh Soft Cheese				
Glass *et al*., 1995	Queso blanco	4 °C	1.4 logs in 14 days	0.142
Mendoza-Yepes *et al*., 1999	Queso fresco	3 °C 7 °C	0.13 log in 1 day 0.5 log in 1 day	0.284 0.285
Genigeorgis *et al*., 1991	Queso fresco, Queso Ranchero Queso Panella	4 °C	-2.0 logs in 30 days -0.8 logs in 10 days 0.3 logs in 30 days 0.3 logs in 18 days 2.127 logs in 10 days 0.21 logs in 30 days 0.44 logs in 36 days	-0.067 -0.080 0.010 0.017 0.212 0.007 0.012

Food Category Reference	Food	Literature Values		EGR[c] at 5 °C (log_{10} cfu/day)
		Temperature	Growth Rate [a,b]	
Soft Unripened Cheese				
Genigeorgis *et al*., 1991	cottage cheese (multiple brands)	8 °C	0.59 logs in 18 days	0.015
			1.87 decrease in 36 days	-0.024
			0.42 logs in 24 days	0.007
			1.13 logs in 8 days	0.064
			1.87 decrease in 8 days	-0.106
		4 °C	0.39 logs in 24 days	0.023
			0.34 logs in 24 days	0.020
			0.41 logs in 16 days	0.036
			0.94 logs in 36 days	0.037
			1.87 logs decrease in 8 days	-0.333
	teleme cheese	8 °C	2.2 logs in 36 days	0.028
		4 °C	0.42 logs decrease in 36 days	-0.017
	ricotta (3 company brands)	8 °C	2.11 logs in 8 days	0.120
			1.75 logs in 6 days	0.132
			1.88 logs in 8 days	0.106
		4 °C	1.53 logs in 30 days	0.072
			3.58 logs in 36 days	0.141
			1.97 logs in 22 days	0.127
	cream cheese	8 °C	2.0 logs decrease in 30 days	-0.030
		4 °C	2.0 logs decrease in 36 days	-0.079
			>2.0 logs decrease in 36 days	-0.056
Cottin *et al*., 1990	cream cheese	4 °C	2 logs in 2 days	1.423
Papageorgiou *et al*., 1996	ricotta (whey cheese)	5 °C	16.2 – 20.2 hr in GT	0.397
		12 °C	5.1 – 5.8 hr in GT	0.292
Chen and Hotchkiss, 1993	cottage cheese	4 °C	2.0 logs in 40 days	0.071
		7 °C	2.4 logs in 10 days	0.137
Fedio *et al*., 1994	cottage cheese	5 °C	2 logs in 22 days	0.091
El-Shenawy and Marth, 1990	cottage cheese	refrigerated	0.5 to 1.5 logs decrease in 1 to 5 weeks	-0.048
		6 °C	assume 1 log in 21 days	-0.035

Food Category Reference	Food	Literature Values		EGR[c] at 5 °C (log_{10} cfu/day)
		Temperature	Growth Rate [a,b]	
Soft Ripened Cheese				
Papageorgiou and Marth, 1989b	Feta	4 °C	survival > 90 days [Scott A 1.28 logs decrease, 3.07 logs in 90 days]	0 -0.034
Stecchini *et al*., 1995	mozzarella	5 °C	4 logs in 21 days	0.190
Genigeorgis *et al*., 1991	Brie	4 °C	0.6 logs in 30 days 0.6 logs in 14 days	0.020 0.043
	Feta	4 °C	>2.0 logs decrease in 8 day >2.0 logs decrease in 8 days >2.0 logs decrease in 8 days	-0.250 -0.250 -0.250
Ryser and Marth, 1987b	Camembert	6 °C ripening	4 logs in 45 days	0.066
Farber *et al*., 1987	Camembert	4 °C	2 to 3 longs decrease in 365 days	-0.007
Back *et al*., 1993	Camembert	3°C 6°C 10C	0.9 logs in 10 days 1.5 logs in 15 days 2.4 logs in 15 days	0.197 0.074 0.049
Papageorgiou and Marth, 1989a	Blue cheese	5°C	Decreased during storage, 3 logs in 56 days	-0.054
Sulzer and Busse, 1993	Camembert Camembert (surface growth)	14 °C 7 °C 4 °C	4.5 logs in 34 days — —	0.022 — — [Not used in risk assessment]
Genigeorgis *et al*., 1991	Blue	4 °C	>2.0 logs decrease in 36 days	-0.056
Genigeorgis *et al*., 1991	Camembert	4 °C	0.64 logs in 36 days	0.018
Semi-Soft Cheese				
Ryser and Marth, 1989a	Brick (surface ripened)	10 °C	1 to 7-fold decrease in 20 weeks	-0.043
Ryser and Marth, 1989a	tilsiter, trappist, havarti, limburger	10 °C	< 1 logs in 20 wk	0.015
Kovincic *et al*., 1991	Trappist	10 °C	Initial 1 log during ripening, stable 30 days, 1 log decrease for 90 days	-0.011
Bachmann and Spahr, 1995	emmenthaler, tilster	—	no survival after 24 hours (initial level was 10^4 cfu/g)	— [not used in risk assessment]
Northolt *et al*., 1988	gouda	—	Survival 6 weeks	0.000

Food Category Reference	Food	Literature Values: Temperature	Literature Values: Growth Rate [a,b]	EGR[c] at 5 °C (log_{10} cfu/day)
Semi-Soft Cheese con't				
Genigeorgis *et al*., 1991	Monterey Jack	4 °C	>2.1 logs decrease in 30 days > 2.1 logs decrease in 30 days	-0.070 -0.070
Genigeorgis *et al*., 1991	Limburger	4 °C	2.26 logs decrease in 36 days	-0.064
Genigeorgis *et al*., 1991	Provolone	4 °C	2.36 logs decrease in 36 days	-0.066
Genigeorgis *et al*., 1991	String cheese	4 °C	2.29 logs decrease in 36 days	-0.064
Genigeorgis *et al*., 1991	Muenster	4 °C	2.0 logs decrease in 36 days	-0.056
Hard Cheese				
Whitley *et al*., 2000	Stilton cheese	4 °C (2 to 8.3°C reported)	0.7 log in 6 weeks	0.0285
Yousef and Marth, 1988	colby	4 °C	1.5 logs decrease in 100 days (after 40 days)	-0.053
Ryser and Marth, 1987a	cheddar	13 °C	2 logs decrease in 75 to 150 days	-0.003
Buazzi *et al*., 1992	swiss	7 °C	4 logs decrease in 10 days (complete inactivation 66-80 days ripening at 24 °C)	-0.228
Yousef and Marth, 1990	parmesan	—	2.0 logs decrease in 40 days 2.0 logs decrease in 80 days	-0.048 -0.025
Genigeorgis *et al*., 1991	swiss	4 °C	>2.1 logs decrease in 36 days	-0.058
Kaufmann, 1990	emmenthaler, gruyere	—	no survival after 24 hours (initial level was 10^4 cfu/g)	— [not used in risk assessment]
Genigeorgis *et al*., 1991	Cheddar, cracker barrel	4 °C	1.17 logs decrease in 34 days	-0.049
	Cheddar, mild	4 °C	>2.1 logs decrease in 30 days	-0.070
	Cheddar, sharp	4 °C	>2.1 logs decrease in 36 days	-0.058
	Colby	4 °C	0.81 logs decrease in 36 days	-0.022
Processed Cheese				
Genigeorgis *et al*., 1991	American process cheese	4 °C	0.18 logs decrease in 36 days	-0.005
	American process cheese with sorbate and citrate	4 °C	1.84 logs decrease in 36 days	-0.051
	Piedmont process cheese	4 °C	1.62 logs decrease in 36 days	-0.045
Glass et al., 1998	Pasteurized process cheese		0.6 logs decrease during 96 hours	-0.15
Ryser and Marth, 1989b	Cold pack cheese Non-acid	3°C	0.5 logs decrease in 110 days	-0.004
	Acidified or preservatives	3°C	1.0 logs decrease in 60 days	-0.017

Food Category Reference	Food	Literature Values: Temperature	Literature Values: Growth Rate [a,b]	EGR[c] at 5 °C ($\log_{10}$ cfu/day)
Fluid Milk, Pasteurized and Unpasteurized				
Northolt *et al*, 1988	unpasteurized milk	5 °C 7 °C	GT 3.5 in days GT 1.0 in days	0.085 0.173
Northolt *et al*, 1988	pasteurized milk	4 °C	2 logs in 7 days	0.407
Farber *et al*., 1990	unpasteurized fluid milk	4 °C 10 °C 15 °C	GT in 25.3 hours GT in 10.8 hours GT in 7.4 hours	0.404 0.204 0.142
Rajkowski *et al*., 1994	uht milk	12 °C	GT in 4.7 hours	0.337
Rosenow and Marth, 1987	skim, whole, chocolate milk	4 °C 8 °C	3.3 logs in 18 days 4 logs in 8 days	0.261 0.227
Rosso *et al*., 1996	Skim, whole, Chocolate milk	4 °C 8 °C	1.3 days (generation time) 0.54 days (generation time)	0.33 0.252
Ice Cream & Frozen Dairy Products				
Berrang *et al*., 1988	ice cream	-18 to -25 °C	0 logs in 2 months	0.000
Dean and Zottola, 1996	soft serve	-18 °C	0 logs in 3 months	0.000
Palumbo and Williams, 1991	Ice cream	-18 °C	0 logs in 14 weeks	0.000
Cultured Dairy Products				
Schaack and Marth, 1988	buttermilk	4 °C	decrease, survives 2.5-13 wk	-0.02
	yogurt	4 °C	decrease, survived 4-12 days (~1 log decline detectable)	-0.18
Choi *et al*., 1988	yogurt	4 °C	survives 21-24 days, most drop in first 8-12 days (~2 log decline detectable)	-0.12
	buttermilk	4 °C	survives 18-26 days	-0.12
Siragusa and Johnson, 1988b	yogurt		high level survived 9 days [2 logs drop in 3-6 days]	-0.40
Miscellaneous Milk Products				
Rosenow and Marth, 1987	cream	4 °C	3.3 logs in 18 days	0.261
		8 °C	4 logs in 8 days	0.227
Farrag *et al*., 1990	sweetened condensed milk	7 °C	decrease 1.2 logs in 42 days	-0.016
Olsen *et al*., 1988	evaporated milk butter	7 °C 4 to 6 °C 13 °C	4 logs in 14 days 1.9 logs in 49 days 2.7 logs in 42 days	0.163 0.039 0.012

Food Category Reference	Food	Literature Values		EGR[c] at 5 °C (log_{10} cfu/day)
		Temperature	Growth Rate [a,b]	
Frankfurters				
Glass and Doyle, 1989	frankfurters	4.4 °C	2.3 logs in 6 weeks	0.064
McKellar *et al*., 1994.	frankfurters	5 °C	3.5 logs in 21 days	0.168
McKellar *et al*., 1994.	poultry wieners	5 °C	3.5 logs in 21 days	0.090
Wederquist *et al*., 1994	turkey	4 °C	7.0 logs in 55 days	0.181
Bedie et al., 2001	Pork frankfurters	4 °C	3.8 logs in 35 days	0.154
Dry/Semi-Dry Fermented Sausages				
Glass and Doyle, 1989	Summer sausage	4.4 °C	No change in 12 weeks	0.000
Hugas, 1995	Fermented sausage	12 to 14 °C	1.25 logs decrease in 25 days	-0.02
Farber *et al*., 1993	German-style American Italian sausage	4 °C	Approximately 1 log in 4 weeks	-0.036
Nisson, 1998	Norwegian fermented dry sausage	4 °C	1 log in 5.5 months	-0.006
Deli Meats				
Glass and Doyle, 1989	bologna	4.4 °C	1 to 2 logs in 14 days	0.131
Grau and Vanderline, 1992	corned beef	4.8 °C	0.13	0.130
Grau and Vanderline, 1992	vacuum packed ham	5 °C	0.30	0.300
Glass and Doyle, 1989	cooked ham	4.4 °C	2 to 3 logs in 28 days	0.131
Beumer *et al*., 1996	cooked ham	7 °C	6 logs in 35 days	0.098
Bredholt *et al*., 1999	Vacuum packed Cooked ham	8 °C 8 °C	0.16 logs per day 0.2 logs per day	0.0725 0.091
Nyati, 2000	Cooked chicken Beef sirloin	4.5 4.5	19.5 days (generation time) 21.8 days (generation time)	0.438 0.392
Grant *et al*., 1993	roast beef	5 °C 10 °C	5 logs in 15 days 5 logs in 6 days	0.333 0.254

Food Category Reference	Food	Literature Values: Temperature	Literature Values: Growth Rate [a,b]	EGR[c] at 5 °C (log_{10} cfu/day)
Deli Meats con't				
Glass and Doyle, 1989	chicken, sliced vacuum packed	4.4 °C 4.4 °C	4.15 logs in 14 days 5.90 logs in 14 days	0.364 0.517
Siragusa and Johnson, 1988a	chicken, homogenate	4.0 °C	5.2 logs in 20 days	0.370
Siragusa and Johnson, 1988a	chicken fillets, breaded	5.0 °C	0.9 logs in 6 days	0.150
Glass and Doyle, 1989	turkey, sliced	4.4 °C 4.4 °C 4.4 °C	2.0 logs in 14 days 3.11 logs in 28 days 3.08 logs in 14 days	0.175 0.136 0.270
Glass and Doyle, 1989	turkey, sliced vacuum packed	4.4 °C 4.4 °C	3.83 logs in 14 days 5.09 logs in 14 days	0.336 0.446
Ingham and Tautorus, 1991	turkey loaf, cooked, uncured, vacuum	3 °C	0.09 logs in 12 days	0.016
Hudson and Mott, 1993a	cooked beef	5 °C 5 °C	11.9 hour GT 8.7 hour GT	0.607 (aerobic) 0.83 (vacuum- packed)
Pâté and Meat Spreads				
Farber *et al*., 1995	pâté	5 °C	0.361 log in 1 day	0.361
Hudson and Mott, 1993a	pâté	4 °C	4 logs in 680 hours	0.143
COMBINATION FOODS				
Deli-type Salads				
Eblen, 2002a [Growth permitting]	Crab salad, store prepared	5 °C	1 log in 10 days	0.100
	Shrimp salad, store prepared	5 °C	2 logs in 14 days	0.143
[No growth permitting]	Shrimp salad, plant prepared	5 °C	No change	0.000
	Chicken salad Store prepared Plant prepared		No change 3 log decrease in 18 days	0.000 -0.167
	Potato salad Store prepared Plant prepared	5 °C	2 log decrease in 13 days 3 log decrease in 10 days	-0.154 -0.333
	Cole slaw Store prepared Plant prepared	5 °C	3 log decrease in 13days 3 log decrease in 6 days	-0.231 -0.500
	Egg salad Store prepared	5 °C	No change	0.000

Food Category Reference	Food	Literature Values		EGR[c] at 5 °C (log_{10} cfu/day)
		Temperature	Growth Rate [a,b]	
Deli-type Salads con't				
Eblen, 2002a [No growth permitting]	Tuna salad Store prepared	5 °C	No change	0.000
	Ham salad Store prepared	5 °C	3 log decrease in 13 days	-0.231
	Imitation crab salad, store prepared	5 °C	3 log decrease in 19 days	-0.158
Johnson, 1993	Chicken salad	4 °C		
	High pH		1 log decrease in 20 days	-0.050
	Low pH		1 log decrease in 7 days	-0.143
	Potato salad			
	High pH		1 log decrease in 20 days	-0.050
	Low pH		1 log decrease in 4 days	-0.250
	Pasta salad			
	High pH		1 log decrease in 9 days	-0.111
	Low pH		1 log decrease in 6days	-0.250
	Seafood salad			
	High pH		1 log decrease in 23 days	-0.043
	Low pH		1 log decrease in 23 days	-0.043

Appendix 9:

Using Outbreak Investigations in Quantitative Risk Assessment

Appendix 9: Using Outbreak Investigations in Quantitative Risk Assessment

The dose-response model developed for the revised FDA/FSIS risk assessment can be used to make predictions about the public health impact of *L. monocytogenes* isolated from a food source. For example, in the best case, a clinical isolate may be traced to the source food. If the source of the food is known or suspected, the number of servings of the source food that are likely to be consumed can be estimated. If the isolate strain can or has been tested in a manner consistent with the LD_{50} mouse experiment, the virulence potential can be established. With these inputs, the dose-response model can predict, with acceptable uncertainty, the median number of deaths for different populations. If not all of this information is available, the dose-response model still can predict the probability of death for different populations and different consumption scenarios, and provides an estimate of the uncertainty for that prediction.

There have been many foodborne listeriosis outbreaks and reports of sporadic individual cases in the past 15 years, with a variety of foods implicated as vehicles of infection. Those outbreak and individual case reports that identify the food vehicle for infection have been very helpful to the hazard identification phase of the *L. monocytogenes* risk assessment. However, identification of the food source of *L. monocytogenes* contamination is infrequent and estimation of cfu/g at consumption even less frequent.

To be informative for quantitative risk assessment, outbreak reports must include quantitative exposure data linked to individuals. Many reports have provided information about the food source, serotype, and contamination in food, but the amount of food consumed by each person and the number of people exposed is usually not reported. For example, an outbreak of listeriosis occurred in Massachusetts in 1983 involving 49 cases (Fleming *et al*., 1985). Illness was strongly associated with the consumption of pasteurized milk. The investigation revealed attack rate, food source, and serotype data, but information was not provided about the level of contamination and amount of milk consumed. In addition, outbreak reports with information about the dose and attack rate are rare. The total number of people exposed (number of servings consumed) and immune status of those exposed is also rarely known.

Tables A9-1 and A9-2 list examples of outbreak and sporadic case reports where data on contamination level in the implicated food were reported. These tables also provide the location and year of occurrence, the implicated food source(s), *L. monocytogenes* serotype, level of contamination of implicated food(s), amount of food consumed, number of persons affected, and the attack rate. Of the outbreaks listed in Table A9-1, only the report of the outbreak in 1994 associated with chocolate milk contained the critical details necessary to estimate the dose-response relationship. However, the primary endpoint of this outbreak (gastrointestinal illness) makes it of minimal usefulness in characterizing outbreaks of severe listeriosis. None of the other reports contained information on the amount of either the food or *L. monocytogenes* consumed per serving by individuals or the attack rate. However in two cases, the Mexican-style soft cheese and the Finnish butter outbreaks, an attack rate and dose range could be estimated. The Mexican-style soft cheese would be similar to the Fresh Soft Cheese food category used in this risk assessment. Butter is one of the foods included in the High Fat and Other Dairy Products category.

Table A9-1. Location, Year of Occurrence, and Epidemiologic Data for Outbreaks of Listeriosis

Location, Year (Reference)	Food Source	Serotype	Contamination Level (cfu/g)	Amount Consumed	No. Ill	Attack Rate
LA County, 1985 (Linnan *et al.*, 1988)	Mexican-style soft cheese	82% 4b	$1.4x10^4$ to $5x10^4$	NA [a]	142	NA
Switzerland, 1983-87 (Bula *et al.*, 1995)	Soft smear-ripened cheese	75% 4b	$1x10^4$ to $1x10^6$	NA	122	NA
IL, MO, WI, 1994 (Dalton *et al.*, 1997)	Chocolate milk	1/2b	$1x10^9$ (cfu/mL)	240 mL	45	45/60 (median)
Italy, 1993 (Salamina *et al.*, 1996)	Cream cheese fruit tart Rice Salad [b]	1/2b 1/2b NA	460 0.93 NA	NA NA NA	18	18/39
Finland, 1998-99 (Lyytikäinen *et al.*, 2000)	Butter	3a	<100 [c]	NA	25	NA
Multistate, 1998-99 (CDC, 1998b)	Frankfurters	4b	<0.3	NA	101	NA

[a] NA = Not available
[b] Rice salad implicated by epidemiology; p<0.001
[c] One sample contained 11,400 cfu/g

Table A9-2. Location, Year of Occurrence, and Epidemiologic Data for Sporadic Cases of Listeriosis not Reported in Outbreaks

Location (Reference)	Year	Confirmed Food Source	Serotype	Contamination Level (cfu/g)	Amount Consumed	Number Ill	Attack Rate
England (Azadian *et al.*, 1989)	1988	Goat Cheese	4b	4×10^7	85 g	1	NA [a]
Oklahoma (Barnes *et al.*, 1989)	1988	Frankfurter Sausage	NA	>1100[b]	1 per day	1	NA
Italy (Cantoni, 1989)	1989	Homemade Sausage	NA	2.7×10^6	NA	1	NA
New Jersey (Ryser, 1999b)	NA	Ricotta Cheese	NA	100 to 10^6	NA	1	NA
Finland (Juntilla and Brander, 1989)	1989	Salted Mushrooms	4b	1×10^6	NA	1	NA
Belgium (Andre *et al.*, 1990)	1989-90	Commercial Ice Cream	4b	1×10^4	NA	1	NA
Tasmania (Brett *et al.*, 1998)	1991	Smoked Mussels	NA	1.6×10^7	90 g	2	NA
Canada (Farber, 1997)	1997	Imitation Crabmeat	NA	2.1×10^9	NA	2	NA

[a] NA= Not Available
[b] >1100 cfu/g, in opened package, patient refrigerators; <0.3 cfu/g in closed package, retail.

The 1985 Los Angeles Mexican-Style Soft Cheese Outbreak

Between January 1 and August 15, 1985, 142 cases of listeriosis were reported in Los Angeles County. There were 48 deaths (including 19 fetal and 10 neonatal). The overall case fatality rate was 33%. Of the 142 cases, 93 (65%) were perinatal. The mean age of mothers was 26 years and the mean gestational age of fetus or neonate was 32 weeks. Eighty-six percent of the cases were Hispanic individuals. Of the remaining non-perinatal cases, the mean age was 58 years and only 29% were Hispanic individuals. Mexican-style soft cheese was epidemiologically and bacteriologically associated with the occurrence of disease.

At the time the Los Angeles County Department of Public Health reported on the outbreak, their report did not contain information on either the amount of cheese consumed per serving by individuals or the attack rate. Fortunately, consumption data by individuals were collected and records from the outbreak were saved. Therefore, in 1998, an attack rate was estimated (Buchholz,

2000) based upon information in the outbreak records and Los Angeles County demographics. Table A9-3 shows the calculation of the attack rate for the listeriosis outbreak among pregnant Hispanic females in Los Angeles County in 1985 associated with consumption of Mexican-style soft cheese.

There were a total of 81 listeriosis cases among pregnant Hispanic females. Only cases infected with the outbreak phage type were used in the analysis (63 of 142). Two matched case-control studies (n=39) were conducted during the outbreak (Linnan *et al*., 1988). The total number of controls (31) and the number of controls that were exposed to the implicated food (11) were determined by re-construction of the odds ratio table. This allowed for an estimate of the proportion of the population that consumed the implicated food (11/31=35%).

To estimate the dose-response for pregnant females, it was assumed that the same percentage of pregnant Hispanic females as in the case-control studies ate the implicated cheese. The total number of pregnant Hispanic females within the marketing area during the time interval of interest (33,642) was multiplied by the calculated proportion of the population that consumed the implicated food (35%), providing an estimate of the number of pregnant Hispanic women who ate the implicated food (11,775).

Two studies were used to determine the Mexican-style soft cheese contamination rate. Laboratory data from one study were examined to determine the total number of food samples qualitatively tested (85) and the number of samples that were positive (22) outbreak (Linnan *et al*., 1988). The number of positive tests divided by the number of foods sampled yielded an estimate of the proportion of food contaminated (22/85 = 26%). That proportion multiplied by the estimate of the number of pregnant women who ate the implicated food (11,775), provides one estimate of the total number of pregnant women who were exposed to *L. monocytogenes* (3,061).

A second estimate of the proportion of food contaminated was determined based on the second contamination study (Ryser, 1999a). Samples (665) were tested, with 56 positive results, to give an estimated contamination frequency of 8.4%. It should be noted that these outbreak related cheese samples were recovered from a landfill after disposal, which had an unknown impact on the results. The low estimate of pregnant Hispanic women who ate contaminated cheese (989) was derived by multiplying this contamination rate (8.4%) by the total number of Hispanic females who ate the implicated cheese (11,775).

For the high estimate, the estimated attack rate (2.1%) is equal to the number of cases that developed listeriosis from the outbreak phage type (63) divided by the high estimate of the total number of pregnant Hispanic females who were exposed (3,061). The proportion of actual cases that were identified during the outbreak was then estimated based on 100% of cases identified (best case scenario) and 75% of cases identified (based on estimates from health care workers in Los Angeles at the time of the outbreak).

For the low estimate, the estimated attack rate (6.4%) is equal to the number of cases that were infected with the outbreak phage type (63) divided by the low estimate of the total number of exposed persons in the population (989). The proportion of actual cases that were identified during the outbreak was again estimated based on 75% and 100% of cases identified.

Using this strategy, the estimated attack rate during the Mexican-style soft cheese outbreak ranges between a low of 2.1-2.7% and a high of 6.4 to 8.5%.

From the outbreak records, it was possible to estimate the one-day consumption of the implicated cheese from 39 of 63 pregnant Hispanic females infected. The consumption ranged from 0.5 ounces/day to 21 ounces/day (median about 5.5 ounces/day). In addition to reporting consumption for one day, about 38% of the females reported their usual consumption of cheese for more than one day. The effect of cumulative doses on the attack rate and pathogenesis is not well understood and was not estimated.

Listeria monocytogenes contamination levels in this outbreak were reported twice, at 1,000 to 10,000 cfu/g (NACMCF, 1991) and 14,000 to 50,000 cfu/g (Ryser, 1999a). The dose of *L. monocytogenes* consumed in the contaminated cheese in one day was calculated to range between 15,000 cfu/day (0.5 oz/day X 30 g/oz X 1,000 cfu/g) and 31,500,000 cfu/day (21 oz/day X 30 g/oz X 50,000 cfu/g). It was therefore estimated that approximately 2.1%-8.5% of pregnant Hispanic females who consumed between 1.5×10^4 and 3.15×10^7 *L. monocytogenes* 4b organisms in a single day became ill.

Table A9-3. Calculation of Attack Rate for an Outbreak of *Listeria monocytogenes* 4b in Pregnant Hispanic Females Using Data from the 1985 Mexican-style Soft Cheese Outbreak

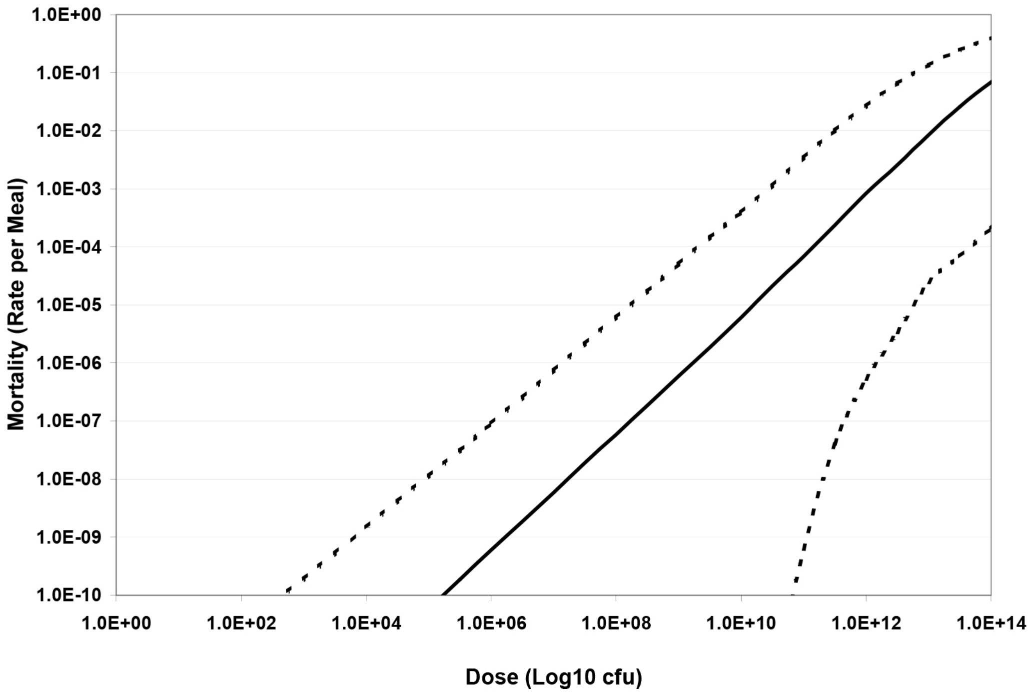
Hispanic births (January - June, 1985), LA County	33628
Hispanic fetal and neonatal deaths (January - June, 1985)	+ 350
Proportion of multigestational births (1%)	- 336
Population giving rise to cases (Total Hispanic pregnant females, January - June, 1985)	33642
Total Hispanic pregnant females who ate the implicated cheese (based on an estimate that 35% of controls ate implicated cheese)	11775
High estimate of Hispanic pregnant females who ate contaminated cheese (based on a estimate of 26% product contamination x 11775)	3061
Total Listeriosis cases among Hispanic pregnant females	81
Cases with outbreak phage type	63
Attack rate if all cases were identified (63 x 100 /3061)	2.1%
Attack rate if 75% of cases identified (63 x 100/3061)/0.75	2.7%
Low estimate of Hispanic pregnant females who ate contaminated cheese (based on an estimated rate of 8.4% product contamination x 11775)	989
Attack rate if all cases were identified (63 x 100 /989)	6.4%
Attack rate if 75% of cases identified (63 x 100/989)/0.75	8.5%

A dose-response model of this outbreak was developed using the same structure as the dose-response model for the national estimates (Figure A9-1). However, two of the components of the outbreak dose-response model were modified to reflect specific information from the outbreak.

First, a distribution ranging from 10^2 to 10^4 was used as an estimate of the *L. monocytogenes* concentration in the contaminated cheese. Because the cheese samples were obtained from consumer refrigerators, it is reasonable to assume that the measurements producing these estimates included growth during storage. Therefore, no additional growth was modeled.

Second, the strain virulence model was modified to include only mouse LD_{50} values for the single strain associated with the outbreak. Attribution of all the cases to a single strain implies that strain virulence is no longer a source of variability in the cause of illness. The frequency distribution in the national model is therefore replaced by a single uncertain value. Since mouse LD_{50} values are available, the uncertainty in the virulence is much less than it otherwise would be (e.g., as shown in

FigureA9-1). A normal distribution of the three LD_{50} values was used to represent the uncertainty; since the doses were measured in logs and the distribution is essentially Lognormal.



FigureA9-1. *Listeria monocytogenes* Dose-Response with Single Strain Virulence Derived from 1985 Los Angeles Mexican-style Soft Cheese Outbreak

Without a dose-response scaling factor, the Los Angeles model also overestimated the number of cases expected in the epidemic. However, a much smaller scaling factor (3.5 to 4.5 logs) was required to produce an estimate that roughly corresponded to the observed number of cases than was required for the national model for neonatal (6 to 10 logs). Since the main difference between the national and Los Angeles outbreak models are the estimates of *L. monocytogenes* concentrations and strain virulence, it appears that a major portion of the uncertainty described by the dose-response adjustment factor may be attributed to these two model components. More specifically, the national estimates for *L. monocytogenes* concentrations may be too high or the Los Angeles estimates are low, and/or the number of low-virulence *L. monocytogenes* strains may be underrepresented in the frequency distributions for strain virulence. The Los Angeles model, based on our limited data, primarily provides assurance that the population-based model can be useful as a predictive tool that is reasonably accurate (within a several log range) when *L. monocytogenes* concentrations and strain virulence information are known. The dose response model using the 1985 Mexican-style soft cheese outbreak represents an application of the model to a specific set of circumstances. Therefore, those data were not used in this *L. monocytogenes* risk assessment to develop the dose-response relationship.

The 1999 Finland Pasteurized Butter Outbreak

The Finland pasteurized butter outbreak attack rate and dose was calculated in a manner similar to the method used to calculate these parameters for the Mexican-style soft cheese outbreak. Between December 1998 and February 1999, an increase in cases of listeriosis due to *L. monocytogenes* serotype 3a in Finland was recognized (Lyytikäinen *et al.*, 2000). Review of national laboratory surveillance data from June 1, 1998 to March 31, 1999 identified 25 *L. monocytogenes* 3a cases, which included six deaths. Cultures of blood, cerebrospinal fluid, and samples from other sterile sites were used to identify cases of listeriosis. Most of the cases were hematological or organ transplant patients. The median age of cases was 53 years (range 12-85). Ten males and no pregnant females or newborns were identified as listeriosis cases. The average annual number of hematological and organ transplant patients admitted to the hospital is 410. Therefore, the number of persons at risk for the 9-month period of concern was approximately 308.

Butter was implicated as the vehicle of infection. Isolates of *L. monocytogenes* 3a from the butter and from the 25 cases were indistinguishable by PFGE. At the tertiary care hospital where a majority of the cases (15/25) occurred, only one brand of butter was consumed during the outbreak period. The hospital is the only site in Finland for organ transplants and is where most bone marrow transplants are performed.

Thirteen butter samples obtained from the hospital kitchen and 139 butter samples obtained from the dairy and a wholesale store were analyzed for the presence of *L. monocytogenes.* The outbreak strain was detected in all thirteen hospital-kitchen samples. The outbreak strain was also detected in several lots from the dairy and wholesale store. The level of *L. monocytogenes* contamination was <100 cfu/g (range 5 to 60 cfu/g) for all positive butter samples, except for one sample that contained 11,000 cfu/g. A complete description of the environmental investigation is described in Lyytikäinen *et al*. (2000).

It was possible to estimate butter consumption for five case patients based on interviews about dietary practices (number of times per week and per day). Researchers assumed that patients ate one package of butter per meal (7 g). The estimated consumption was divided by 31 days (median hospital stay) to estimate daily butter consumption. To determine the median dose range, the minimum butter consumption (1.1 g/day) was multiplied by the minimum contamination level for the hospital kitchen samples (5 cfu/g) and the maximum butter consumption (55 g/day) was multiplied by the maximum contamination level for the hospital samples (60 cfu/g). Using the hospital samples, the consumed dose would be 5.5 to 3,300 cfu/day. By using the maximum contamination level found in the wholesale samples (11,000 cfu/g), then the daily dose consumed would range between 1.21×10^{4} to 6.6×10^{5} cfu/day.

Table A9-4 shows the calculation for the attack rate of the 1999 Finland butter outbreak. Approximately 6.4% to 10.7% of the hematological/transplant patients at the hospital who consumed between 5.5 cfu/g and 6.6×10^{5} cfu/g developed listeriosis. We assumed that hospitalized patients ate the implicated butter on each of 31 days (median hospital stay) while hospitalized. The majority of the illnesses were associated with severe symptoms. The effect of cumulative doses on the attack rate and pathogenesis was not estimated.

Table A9-4. Calculation of Attack Rate for an Outbreak of *Listeria monocytogenes* Serotype 3a Infections from Butter in Finland for Hematological and Transplant Patients

Annual number of new diagnoses for acute leukemias/lymphomas plus annual number of kidney/liver transplants performed at the hospital.	410
Total persons at risk (time interval x annual new diagnoses, time interval: June 1998 to February 1999, 9/12 months)	308
Estimated number of hematological and transplant patients in the population that ate the butter (estimated proportion of controls that ate implicated butter, 76%)	234
Number of cases during the outbreak	25
Number of cases at tertiary care hospital	15
High estimate of product contamination (100%)	
Population at risk (100%)	234
Attack rate (15 x 100/234)[1]	6.4%
Mid-estimate of product contamination (80%)	
Population at risk 80%	187
Attack rate (15 x 100/187)	8.0%
Low estimate of product contamination (60%)	
Population at risk 60%	140
Attack rate (15 x 100/140)	10.7%

The Finland outbreak demonstrates the serious consequences of even low dose exposure when the severely immunocompromised are exposed. Because this outbreak currently lacks strain information and the relative susceptibility of transplant patients is unknown, it is not possible to calculate a new dose-response curve for this population. However, intensive outbreak investigations such as this one are applauded. They help to explain the sources of uncertainty in our dose-response model and they provide controlled environments in which accurate dose and attack rate data may be collected.

Appendix 10:

ADDITIONAL RISK CHARACTERIZATION INFORMATION

Table A10-1. Predicted Mean Number of Cases of Listeriosis per Serving for Each Food Category and Subpopulation

Food Category	Predicted Number of Cases of Listeriosis per Serving[a]											
	Intermediate-Age [b]			Elderly			Perinatal[c]			Total		
	Percentiles			Percentiles			Percentiles			Percentiles		
	Mean	5th	95th	Mean	5th	95th	Mean	5th	95th	Mean	5th	95th
SEAFOOD												
Smoked Seafood	$3.1x10^{-8}$	$8.8x10^{-11}$	$1.2x10^{-7}$	$2.6x10^{-7}$	$9.7x10^{-10}$	$1.0x10^{-6}$	$1.1x10^{-5}$	$4.3x10^{-8}$	$4.6x10^{-5}$	$8.4x10^{-8}$	$3.0x10^{-10}$	$3.3x10^{-7}$
Raw Seafood	$8.6x10^{-11}$	$1.1x10^{-17}$	$2.9x10^{-10}$	$8.9x10^{-10}$	$1.7x10^{-14}$	$2.9x10^{-9}$	$6.8x10^{-8}$	$7.4x10^{-12}$	$2.0x10^{-7}$	$1.4x10^{-10}$	$7.4x10^{-15}$	$4.6x10^{-10}$
Preserved Fish	$9.6x10^{-10}$	$5.5x10^{-20}$	$2.6x10^{-9}$	$8.2x10^{-9}$	$3.9x10^{-17}$	$2.2x10^{-8}$	$3.6x10^{-7}$	$2.1x10^{-14}$	$9.9x10^{-7}$	$2.7x10^{-9}$	$6.9x10^{-17}$	$7.5x10^{-9}$
Cooked RTE Crustaceans	$5.4x10^{-9}$	$2.5x10^{-10}$	$2.1x10^{-8}$	$4.2x10^{-8}$	$2.4x10^{-9}$	$1.6x10^{-7}$	$1.6x10^{-6}$	$9.7x10^{-8}$	$6.1x10^{-6}$	$1.2x10^{-8}$	$6.5x10^{-10}$	$4.6x10^{-8}$
PRODUCE												
Vegetables	$1.2x10^{-11}$	$1.5x10^{-19}$	$6.3x10^{-11}$	$1.1x10^{-10}$	$3.7x10^{-16}$	$5.7x10^{-10}$	$5.8x10^{-9}$	$1.4x10^{-13}$	$3.1x10^{-8}$	$3.6x10^{-11}$	$2.8x10^{-16}$	$1.9x10^{-10}$
Fruits	$1.3x10^{-9}$	$6.0x10^{-20}$	$9.6x10^{-9}$	$8.0x10^{-9}$	$5.3x10^{-17}$	$5.7x10^{-8}$	$4.3x10^{-7}$	$1.3x10^{-14}$	$3.0x10^{-6}$	$3.2x10^{-9}$	$4.5x10^{-17}$	$2.3x10^{-8}$
DAIRY												
Fresh Soft Cheese	$5.0x10^{-10}$	$4.6x10^{-13}$	$2.1x10^{-9}$	$4.1x10^{-9}$	$5.0x10^{-12}$	$1.7x10^{-8}$	$1.6x10^{-7}$	$2.6x10^{-10}$	$7.0x10^{-7}$	$6.9x10^{-10}$	$8.0x10^{-13}$	$2.9x10^{-9}$
Soft Unripened Cheese	$3.1x10^{-9}$	$8.4x10^{-14}$	$1.6x10^{-8}$	$2.5x10^{-8}$	$7.2x10^{-13}$	$1.2x10^{-7}$	$1.1x10^{-6}$	$4.8x10^{-11}$	$5.3x10^{-6}$	$8.9x10^{-9}$	$2.8x10^{-13}$	$4.4x10^{-8}$
Soft Ripened Cheese	$2.7x10^{-10}$	$1.8x10^{-21}$	$1.3x10^{-9}$	$2.4x10^{-9}$	$3.3x10^{-18}$	$1.1x10^{-8}$	$1.2x10^{-7}$	$3.5x10^{-15}$	$5.2x10^{-7}$	$5.6x10^{-10}$	$7.9x10^{-18}$	$2.6x10^{-9}$
Semi-soft Cheese	$1.3x10^{-10}$	$9.3x10^{-17}$	$2.9x10^{-10}$	$1.2x10^{-9}$	$5.5x10^{-15}$	$2.7x10^{-9}$	$6.3x10^{-8}$	$9.2x10^{-13}$	$1.4x10^{-7}$	$2.6x10^{-10}$	$2.5x10^{-15}$	$5.8x10^{-10}$
Hard Cheese	$1.2x10^{-12}$	$5.3x10^{-47}$	$1.9x10^{-12}$	$1.1x10^{-11}$	$5.8x10^{-39}$	$1.9x10^{-11}$	$8.9x10^{-10}$	$3.4x10^{-32}$	$1.3x10^{-9}$	$3.1x10^{-12}$	$2.5x10^{-35}$	$5.5x10^{-12}$
Processed Cheese	$5.2x10^{-13}$	$3.2x10^{-30}$	$2.3x10^{-12}$	$5.1x10^{-12}$	$8.8x10^{-25}$	$2.2x10^{-11}$	$4.8x10^{-10}$	$6.6x10^{-20}$	$1.4x10^{-9}$	$1.4x10^{-12}$	$5.4x10^{-23}$	$6.0x10^{-12}$
Pasteurized Fluid Milk	$1.2x10^{-9}$	$2.8x10^{-11}$	$5.7x10^{-9}$	$8.6x10^{-9}$	$2.5x10^{-10}$	$3.9x10^{-8}$	$3.8x10^{-7}$	$1.2x10^{-8}$	$1.7x10^{-6}$	$2.7x10^{-9}$	$7.5x10^{-11}$	$1.3x10^{-8}$
Unpasteurized Fluid Milk	$1.6x10^{-8}$	$3.5x10^{-11}$	$6.8x10^{-8}$	$1.2x10^{-7}$	$3.4x10^{-10}$	$5.1x10^{-7}$	$5.5x10^{-6}$	$1.7x10^{-8}$	$2.3x10^{-5}$	$3.8x10^{-8}$	$9.7x10^{-11}$	$1.6x10^{-7}$
Ice Cream/Frozen Dairy Products	$2.2x10^{-12}$	$2.7x10^{-35}$	$1.8x10^{-12}$	$1.7x10^{-11}$	$1.4x10^{-28}$	$1.9x10^{-11}$	$7.4x10^{-10}$	$2.7x10^{-23}$	$1.3x10^{-9}$	$5.7x10^{-12}$	$1.7x10^{-26}$	$6.3x10^{-12}$
Cultured Milk Products	$6.6x10^{-12}$	$2.4x10^{-40}$	$1.7x10^{-11}$	$6.4x10^{-11}$	$6.5x10^{-33}$	$1.7x10^{-10}$	$3.8x10^{-9}$	$5.1x10^{-26}$	$9.9x10^{-9}$	$1.8x10^{-11}$	$3.3x10^{-29}$	$4.9x10^{-11}$
High Fat and Other Dairy Products	$2.2x10^{-9}$	$1.0x10^{-10}$	$8.2x10^{-9}$	$1.6x10^{-8}$	$8.9x10^{-10}$	$5.7x10^{-8}$	$5.8x10^{-7}$	$3.7x10^{-8}$	$2.0x10^{-6}$	$5.3x10^{-9}$	$2.9x10^{-10}$	$1.9x10^{-8}$
MEATS												
Frankfurters (reheated)	$8.3x10^{-11}$	$4.2x10^{-15}$	$3.4x10^{-10}$	$8.5x10^{-10}$	$8.6x10^{-13}$	$3.4x10^{-9}$	$6.1x10^{-8}$	$2.1x10^{-10}$	$2.6x10^{-7}$	$2.0x10^{-10}$	$2.7x10^{-13}$	$8.0x10^{-10}$
Frankfurters (not reheated)	$7.1x10^{-8}$	$3.1x10^{-9}$	$2.8x10^{-7}$	$6.1x10^{-7}$	$3.2x10^{-8}$	$2.3x10^{-6}$	$2.2x10^{-5}$	$1.3x10^{-6}$	$8.3x10^{-5}$	$1.4x10^{-7}$	$7.1x10^{-9}$	$5.2x10^{-7}$
Dry/Semi-Dry Fermented Sausages	$5.7x10^{-10}$	$6.8x10^{-20}$	$2.7x10^{-9}$	$5.2x10^{-9}$	$2.0x10^{-16}$	$2.4x10^{-8}$	$2.5x10^{-7}$	$5.1x10^{-14}$	$1.1x10^{-6}$	$1.4x10^{-9}$	$1.5x10^{-16}$	$6.3x10^{-9}$
Deli Meats	$3.0x10^{-8}$	$6.8x10^{-9}$	$4.1x10^{-8}$	$2.7x10^{-7}$	$5.8x10^{-8}$	$3.9x10^{-7}$	$1.1x10^{-5}$	$3.2x10^{-6}$	$1.4x10^{-5}$	$7.0x10^{-8}$	$1.7x10^{-8}$	$9.9x10^{-8}$
Pâté and Meat Spreads	$3.9x10^{-8}$	$1.0x10^{-9}$	$1.4x10^{-7}$	$3.2x10^{-7}$	$1.1x10^{-8}$	$1.1x10^{-6}$	$1.3x10^{-5}$	$4.7x10^{-7}$	$4.5x10^{-5}$	$9.6x10^{-8}$	$3.1x10^{-9}$	$3.3x10^{-7}$
COMBINATION FOODS												
Deli-type Salads	$4.7x10^{-11}$	$1.8x10^{-31}$	$1.3x10^{-10}$	$3.5x10^{-10}$	$3.3x10^{-25}$	$1.2x10^{-9}$	$1.4x10^{-8}$	$9.3x10^{-20}$	$5.5x10^{-8}$	$1.3x10^{-10}$	$8.0x10^{-23}$	$4.1x10^{-10}$

[a]This table provides estimates of the mean rate of listeriosis per serving and the confidence intervals about that estimate. [b]The Intermediate-age group includes susceptible populations not captured in the other groups. [c]The Perinatal population is a susceptible population that includes fetuses and neonates. Exposure occurs *in utero* from contaminated food eaten by the pregnant woman. The predicted cases are predominately neonatal, therefore to estimate the perinatal cases presented in this table, an exposure period of 10 days was used. The value of 10 approximately corresponds to the mean of the triangle distribution (1, 7, 30) used in the simulation.

Table A10-2. Predicted Mean Number of Cases of Listeriosis per Annum for Each Food Category and Subpopulation

Food Category	Predicted Number of Cases of Listeriosis per Annum[a]											
	Intermediate-Age [b]			Elderly			Perinatal[c]			Total		
		Percentiles			Percentiles			Percentiles			Percentiles	
	Mean	5th	95th	Mean	5th	95th	Mean	5th	95th	Mean	5th	95th
SEAFOOD												
Smoked Seafood	5.1	<0.1	19.4	10.6	<0.1	43.2	1.4	<0.1	5.8	17.2	0.1	68.1
Raw Seafood	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Preserved Fish	0.1	<0.1	0.2	0.2	<0.1	0.5	<0.1	<0.1	0.1	0.3	<0.1	0.8
Cooked Ready-to-Eat Crustaceans	2.5	0.1	10.0	3.5	0.2	13.2	0.6	<0.1	2.2	6.6	0.4	25.7
PRODUCE												
Vegetables	0.8	<0.1	4.3	1.9	<0.1	9.7	0.3	<0.1	1.6	3.0	<0.1	15.7
Fruits	47.3	<0.1	351.4	95.8	<0.1	680.4	12.2	<0.1	85.4	155.2	<0.1	1127.7
DAIRY												
Fresh Soft Cheese	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	<0.1	0.2
Soft Unripened Cheese	10.5	<0.1	52.3	26.0	<0.1	128.8	2.8	<0.1	13.6	39.3	<0.1	193.5
Soft Ripened Cheese	0.5	<0.1	2.1	0.5	<0.1	2.1	0.2	<0.1	0.7	1.1	<0.1	4.9
Semi-soft Cheese	0.2	<0.1	0.5	0.2	<0.1	0.4	0.1	<0.1	0.2	0.5	<0.1	1.1
Hard Cheese	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Processed Cheese	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Pasteurized Fluid Milk	85.9	2.0	410.1	127.9	3.7	584.4	20.9	0.7	95.8	234.7	6.5	1084.6
Unpasteurized Fluid Milk	6.0	<0.1	24.7	9.1	<0.1	38.3	1.5	<0.1	6.5	16.6	<0.1	69.2
Ice Cream/Frozen Dairy Products	<0.1	<0.1	<0.1	0.1	<0.1	0.1	<0.1	<0.1	<0.1	0.1	<0.1	0.1
Cultured Milk Products	<0.1	<0.1	0.1	0.1	<0.1	0.2	<0.1	<0.1	<0.1	0.1	<0.1	0.4
High Fat and Other Dairy Products	35.3	1.7	135.0	66.2	3.8	241.3	7.3	0.5	25.3	108.8	6.0	398.9
MEATS												
Frankfurters (reheated)	0.5	<0.1	1.9	0.5	<0.1	2.0	0.3	<0.1	1.1	1.2	<0.1	4.9
Frankfurters (not reheated)	29.9	1.3	119.4	27.0	1.4	103.0	7.3	0.4	26.9	64.2	3.3	245.4
Dry/Semi-Dry Fermented Sausages	0.9	<0.1	4.1	1.3	<0.1	6.0	0.3	<0.1	1.3	2.5	<0.1	11.2
Deli Meats	528.1	120.6	736.4	767.1	164.6	1106.2	146.6	44.5	197.0	1441.7	341.2	2038.2
Pâté and Meat Spreads	3.8	0.1	13.2	6.6	0.2	23.5	1.0	<0.1	3.4	11.4	0.4	39.5
COMBINATION FOODS												
Deli-type Salads	0.5	<0.1	1.3	1.1	<0.1	3.7	0.1	<0.1	0.4	1.7	<0.1	5.4

[a]This table provides estimates of the mean rate of listeriosis per annum and the confidence intervals about that estimate. [b]The intermediate-age group includes susceptible populations not captured in other goups, such as cancer, AIDS, and transplant patients, for whom there are insufficient data to consider as a separate population. [c]The Perinatal population is a susceptible population that includes fetuses and neonates. Exposure occurs *in utero* from contaminated food eaten by the pregnant woman.

Table A10-3. Predicted Median Number of Deaths From Listeriosis per Serving Basis for Each Food Category and Subpopulation

Food Category	Predicted Number of Deaths of Listeriosis per Serving[a]											
	Intermediate-Age [b] Percentiles			Elderly Percentiles			Perinatal[c] Percentiles			Total Percentiles		
	Median	5th	95th	Median	5th	95th	Median	5th	95th	Median	5th	95th
SEAFOOD												
Smoked Seafood	1.9×10^{-10}	7.8×10^{-12}	1.1×10^{-08}	5.2×10^{-09}	2.6×10^{-10}	2.8×10^{-07}	1.8×10^{-08}	9.5×10^{-10}	1.0×10^{-06}	1.3×10^{-09}	6.5×10^{-11}	7.0×10^{-08}
Raw Seafood	1.1×10^{-12}	9.7×10^{-19}	2.6×10^{-11}	3.5×10^{-11}	4.5×10^{-15}	7.8×10^{-10}	1.5×10^{-10}	1.6×10^{-13}	4.4×10^{-09}	2.5×10^{-12}	1.4×10^{-15}	6.0×10^{-11}
Preserved Fish	5.6×10^{-13}	4.9×10^{-21}	2.3×10^{-10}	1.8×10^{-11}	1.0×10^{-17}	6.0×10^{-09}	9.0×10^{-11}	4.6×10^{-16}	2.2×10^{-08}	5.0×10^{-12}	1.4×10^{-17}	1.6×10^{-09}
Cooked RTE Crustaceans	1.9×10^{-10}	2.2×10^{-11}	1.9×10^{-09}	5.0×10^{-09}	6.4×10^{-10}	4.4×10^{-08}	1.6×10^{-08}	2.1×10^{-09}	1.3×10^{-07}	1.0×10^{-09}	1.3×10^{-10}	8.8×10^{-09}
PRODUCE												
Vegetables	7.4×10^{-14}	1.4×10^{-20}	5.6×10^{-12}	2.2×10^{-12}	1.0×10^{-16}	1.5×10^{-10}	1.1×10^{-11}	3.1×10^{-15}	6.7×10^{-10}	5.8×10^{-13}	5.9×10^{-17}	3.9×10^{-11}
Fruits	4.4×10^{-13}	5.3×10^{-21}	8.5×10^{-10}	1.4×10^{-11}	1.4×10^{-17}	1.5×10^{-08}	6.2×10^{-11}	2.9×10^{-16}	6.7×10^{-08}	4.2×10^{-12}	9.6×10^{-18}	4.8×10^{-09}
DAIRY												
Fresh Soft Cheese	1.1×10^{-11}	4.0×10^{-14}	1.8×10^{-10}	2.8×10^{-10}	1.3×10^{-12}	4.6×10^{-09}	9.1×10^{-10}	5.7×10^{-12}	1.5×10^{-08}	2.2×10^{-11}	1.2×10^{-13}	3.7×10^{-10}
Soft Unripened Cheese	5.2×10^{-11}	7.5×10^{-15}	1.4×10^{-09}	1.3×10^{-09}	1.9×10^{-13}	3.3×10^{-08}	4.4×10^{-09}	1.0×10^{-12}	1.2×10^{-07}	3.7×10^{-10}	6.1×10^{-14}	9.5×10^{-09}
Soft Ripened Cheese	1.8×10^{-13}	1.6×10^{-22}	1.1×10^{-10}	5.9×10^{-12}	8.8×10^{-19}	3.1×10^{-09}	2.9×10^{-11}	7.7×10^{-17}	1.1×10^{-08}	9.5×10^{-13}	1.4×10^{-18}	4.7×10^{-10}
Semi-soft Cheese	2.6×10^{-13}	8.2×10^{-18}	2.6×10^{-11}	8.0×10^{-12}	1.5×10^{-15}	7.3×10^{-10}	3.4×10^{-11}	2.0×10^{-14}	3.2×10^{-09}	1.2×10^{-12}	4.0×10^{-16}	1.0×10^{-10}
Hard Cheese	3.0×10^{-16}	4.7×10^{-48}	1.7×10^{-13}	2.5×10^{-15}	1.5×10^{-39}	5.1×10^{-12}	1.8×10^{-14}	7.5×10^{-34}	2.8×10^{-11}	6.8×10^{-16}	5.0×10^{-36}	1.1×10^{-12}
Processed Cheese	1.3×10^{-15}	2.8×10^{-31}	2.1×10^{-13}	2.5×10^{-14}	2.4×10^{-25}	5.9×10^{-12}	1.5×10^{-13}	1.4×10^{-21}	3.1×10^{-11}	7.9×10^{-15}	1.2×10^{-23}	1.2×10^{-12}
Pasteurized Fluid Milk	3.9×10^{-11}	2.5×10^{-12}	5.1×10^{-10}	9.0×10^{-10}	6.6×10^{-11}	1.1×10^{-08}	3.2×10^{-09}	2.6×10^{-10}	3.8×10^{-08}	2.1×10^{-10}	1.5×10^{-11}	2.4×10^{-09}
Unpasteurized Fluid Milk	2.6×10^{-10}	3.1×10^{-12}	6.1×10^{-09}	6.0×10^{-09}	9.2×10^{-11}	1.4×10^{-07}	2.2×10^{-08}	3.8×10^{-10}	5.1×10^{-07}	1.4×10^{-09}	2.0×10^{-11}	3.2×10^{-08}
Ice Cream/Frozen Dairy Products	1.1×10^{-15}	2.4×10^{-36}	1.6×10^{-13}	2.5×10^{-14}	3.9×10^{-29}	5.1×10^{-12}	1.4×10^{-13}	6.0×10^{-25}	2.8×10^{-11}	1.0×10^{-14}	3.8×10^{-27}	1.3×10^{-12}
Cultured Milk Products	8.4×10^{-16}	2.1×10^{-41}	1.5×10^{-12}	1.5×10^{-14}	1.7×10^{-33}	4.5×10^{-11}	1.0×10^{-13}	1.1×10^{-27}	2.2×10^{-10}	6.6×10^{-15}	6.5×10^{-30}	9.9×10^{-12}
High Fat and Other Dairy Products	9.2×10^{-11}	9.1×10^{-12}	7.3×10^{-10}	2.2×10^{-09}	2.4×10^{-10}	1.5×10^{-08}	6.9×10^{-09}	8.2×10^{-10}	4.4×10^{-08}	5.7×10^{-10}	6.2×10^{-11}	4.0×10^{-09}
MEATS												
Frankfurters (reheated)	2.4×10^{-12}	3.7×10^{-16}	3.0×10^{-11}	7.1×10^{-11}	2.3×10^{-13}	9.1×10^{-10}	3.4×10^{-10}	4.5×10^{-12}	5.6×10^{-09}	1.1×10^{-11}	5.7×10^{-14}	1.5×10^{-10}
Frankfurters (not reheated)	2.9×10^{-09}	2.7×10^{-10}	2.5×10^{-08}	7.9×10^{-08}	8.6×10^{-09}	6.3×10^{-07}	2.4×10^{-07}	2.9×10^{-08}	1.8×10^{-06}	1.2×10^{-08}	1.3×10^{-09}	9.2×10^{-08}
Dry/Semi-Dry Fermented Sausages	5.3×10^{-13}	6.0×10^{-21}	2.4×10^{-10}	1.7×10^{-11}	5.3×10^{-17}	6.5×10^{-09}	8.1×10^{-11}	1.1×10^{-15}	2.4×10^{-08}	3.4×10^{-12}	2.8×10^{-17}	1.2×10^{-09}
Deli Meats	2.9×10^{-09}	6.0×10^{-10}	3.7×10^{-09}	8.0×10^{-08}	1.6×10^{-08}	1.0×10^{-07}	2.6×10^{-07}	7.1×10^{-08}	3.1×10^{-07}	1.5×10^{-08}	3.2×10^{-09}	1.9×10^{-08}
Pâté and Meat Spreads	1.1×10^{-09}	9.2×10^{-11}	1.2×10^{-08}	2.9×10^{-08}	2.9×10^{-09}	3.0×10^{-07}	9.8×10^{-08}	1.0×10^{-08}	9.9×10^{-07}	6.5×10^{-09}	6.5×10^{-10}	6.9×10^{-08}
COMBINATION FOODS												
Deli-type Salads	1.5×10^{-14}	1.6×10^{-32}	1.1×10^{-11}	3.8×10^{-13}	8.8×10^{-26}	3.2×10^{-10}	1.9×10^{-12}	2.0×10^{-21}	1.2×10^{-09}	1.2×10^{-13}	1.6×10^{-23}	9.1×10^{-11}

[a]This table provides estimates of the median rate of listeriosis per serving and the confidence intervals about that estimate. [b]The Intermediate-age group includes susceptible populations not captured in other groups, such as cancer, AIDS, and transplant patients, for whom there are insufficient data to consider as a separate population. [c]The Perinatal population is a susceptible population that includes fetuses and neonates. Exposure occurs *in utero* from contaminated food eaten by the pregnant woman. (Estimates for the perinatal group can be made by multiplying the neonatal values by 2.5.) To estimate the number of servings in each food category for the perinatal group, the number of servings for the intermediate-aged population was multiplied by 0.0174 (fraction of pregnant women) and 3/12 (for exposure during the last three months of pregnancy).

Table A10-4. Predicted Median Number of Deaths From Listeriosis per Annum Basis for Each Food Category and Subpopulation

Food Category	Predicted Number of Deaths of Listeriosis per Annum[a]											
	Intermediate-Age [b] Percentiles			Elderly Percentiles			Perinatal[c] Percentiles			Total Percentiles		
	Median	5th	95th	Median	5th	95th	Median	5th	95th	Median	5th	95th
SEAFOOD												
Smoked Seafood	<0.1	<0.1	1.7	0.2	<0.1	11.6	<0.1	<0.1	1.1	0.3	<0.1	14.4
Raw Seafood	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Preserved Fish	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.2
Cooked RTE Crustaceans	0.1	<0.1	0.9	0.4	0.1	3.5	0.1	<0.1	0.4	0.6	0.1	4.9
PRODUCE												
Vegetables	<0.1	<0.1	0.4	<0.1	<0.1	2.6	<0.1	<0.1	0.3	<0.1	<0.1	3.3
Fruits	<0.1	<0.1	31.1	0.2	<0.1	182.4	<0.1	<0.1	16.9	0.2	<0.1	231.4
DAIRY												
Fresh Soft Cheese	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Soft Unripened Cheese	0.2	<0.1	4.6	1.4	<0.1	34.5	0.10	<0.1	2.7	1.7	<0.1	41.9
Soft Ripened Cheese	<0.1	<0.1	0.2	<0.1	<0.1	0.6	<0.1	<0.1	0.1	<0.1	<0.1	0.9
Semi-soft Cheese	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.2
Hard Cheese	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Processed Cheese	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Pasteurized Fluid Milk	2.8	0.2	36.3	13.4	1.0	156.7	1.6	0.1	18.9	18.1	1.3	208.7
Unpasteurized Fluid Milk	0.1	<0.1	2.2	0.5	<0.1	10.3	0.1	<0.1	1.3	0.6	<0.1	13.8
Ice Cream/Frozen Dairy Products	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Cultured Milk Products	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
High Fat and Other Dairy Products	1.5	0.2	12.0	9.4	1.0	64.7	0.8	0.1	5.0	11.8	1.3	82.0
MEATS												
Frankfurters (reheated)	<0.1	<0.1	0.2	<0.1	<0.1	0.5	<0.1	<0.1	0.2	0.1	<0.1	0.9
Frankfurters (not reheated)	1.2	0.1	10.6	3.5	0.4	27.6	0.7	0.1	5.3	5.4	0.6	42.9
Dry/Semi-Dry Fermented Sausages	<0.1	<0.1	0.4	<0.1	<0.1	1.6	<0.1	<0.1	0.3	<0.1	<0.1	2.2
Deli Meats	52.1	10.7	65.2	227.8	44.1	296.6	31.8	8.8	38.9	311.6	65.5	400.4
Pâté and Meat Spreads	0.1	<0.1	1.2	0.6	0.1	6.3	0.1	<0.1	0.7	0.8	0.1	8.1
COMBINATION FOODS												
Deli-type Salads	<0.1	<0.1	0.1	<0.1	<0.1	1.0	<0.1	<0.1	0.1	<0.1	<0.1	1.2

[a]This table provides estimates of the median rate of listeriosis per annum and the confidence intervals about that estimate.
[b]The Intermediate-age group includes susceptible populations not captured in other groups, such as cancer, AIDS, and transplant patients, for whom there are insufficient data to consider as a separate population. [c]The perinatal population is a susceptible population that includes fetuses and neonates. Exposure occurs i*n utero* from contaminated food eaten by the pregnant woman.

Appendix 11:

RESEARCH NEEDS

APPENDIX 11: 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 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.

Appendix 12:

CLUSTER ANALYSIS FOR GROUPING OF FOOD CATEGORIES

APPENDIX 12: CLUSTER ANALYSIS FOR GROUPING OF FOOD CATEGORIES

The results of the uncertainty analysis of the risk assessment were summarized by a cluster analysis of food categories. The similarity between categories was evaluated for the predicted number of cases of listeriosis expressed as the risk per serving and per annum. Cluster analysis is a descriptive statistical technique by which a set of objects are partitioned or classified into subsets according to some measure of similarity between objects[1]. Typically, this partitioning is defined to generate hierarchical subsets of the objects to be classified. A single level of disjoint partitioning, without any sub-partitioning of the objects within the primary clusters, is a special case of the more general objective of obtaining a hierarchical classification.

The use of a cluster analysis to summarize the results of the *L. monocytogenes* risk assessment provides a means to convey the implications of the uncertainty analysis of the rankings of food categories which is, in some sense, more informative than statistical point null hypothesis tests of differences in the location of the distribution of ranks across food categories (e.g., as provided by Kruskal-Wallis test or sign test). Testing for differences in location (e.g., the median) of the uncertainty distributions of risk rankings, according to either risk per serving or cases per annum, does not incorporate any consideration of whether or not the differences obtained are meaningful on a practical level.

Although the possibility exits that the elicitation and specification of the variability and uncertainty of the model could result in two or more pairings of food categories with identical distributions for either risk per serving or expected cases per annum, this is very unlikely and small differences in the location of rank distributions are expected. In this event, statistical analysis of the output of the simulation based on use of point null hypothesis tests to define differences between food categories is likely to result in categorizing all such (small) differences as significant (i.e., provided that the output of the simulation is sufficiently large). While composite rather than point null hypotheses could be used to define practical or meaningful differences between the risk rankings of different food categories (e.g., by equivalence testing methods), the application of these methods is not readily available. Consequently, a cluster analysis approach was adopted as an alternative.

Central to any cluster analysis is the specification of a definition of similarity, or conversely dissimilarity, between the objects to be classified[1]. With respect to a cluster analysis of risk ranking of the food categories, the "objects" to classified are the uncertainty distributions (of risk per serving and expected cases per annum) and thus a classification requires a definition of the "distance" or dissimilarity between any two such distributions. The measure of similarity adopted here for the cluster analysis was defined

[1] Jain A.K., Murty M.N. and Flynn P.J. (1999). Data Clustering: A review. ACM Computing Surveys 31(3), pg 264-323.

by the degree to which any two uncertainty distributions overlap. If, for two food categories, the uncertainty distribution of their risk rankings were identical then the distributions would overlap maximally and it would be reasonable to infer that they are two food categories that should be judged to be similar in risk ranking. Conversely, if the risk rank distributions of two food categories did not overlap at all then it would be reasonable to infer that they are very dissimilar foods in regard to risk ranking.

Based on this intuitive notion of distance between two distributions the following measure of dissimilarity was used:

$$\text{distance}(A, B) \quad = \quad \Pr(\text{rank}(A) > \text{rank}(B))$$

where A and B denote any two food categories, and rank() denotes their rank distributions (according to either risk per serving or expected number of cases per annum). Thus, if the rank of food category A is higher than that of food category B with a high probability of belief (i.e., according to their uncertainty distributions) then A and B would be considered sufficiently dissimilar to belong in different clusters. A level of 90% probability of belief that the rank of one food category was higher than another was chosen as a cut-off value for classifying any two distributions as dissimilar. That is to say, any two food categories A and B were considered to be of different risk category (or cluster) if:

$$\text{distance}(A, B) \quad > \quad 0.90$$

Obviously, both the definition of distance used and what constitutes a "significant" distance based on the definition are subjective. With respect to the latter, this is not intrinsically different from the specification of confidence levels in frequentist-based hypothesis testing. A level of 0.05 is common by convention but it is a subjective choice nonetheless and other significance levels can and often have been advocated. With respect to the former, we note that the chosen measure of distance is not the only one that could be made. Also, it is a pseudo-distance measure because it does not satisfy all properties of distance measure proper; specifically it is not a symmetric function of the argument. However, other more sophisticated information-theoretic measures of the distance between two distributions such as the Kullback-Leibler divergence are computationally difficult and also do not satisfy all of the properties of a distance measure per se (i.e., they are quasi- or pseudo-distances).

Given the chosen definition of distance between two distributions and the cut-off probability value for significant distance, all food categories were compared in a pairwise fashion. Based on these comparisons a partitioning of the food categories into disjoint subsets of similar risk (either by risk per serving or cases per annum) was obtained by defining clusters in the ordering of food categories from highest median rank to lowest median rank. Specifically, the food categories were ranked according their median rank and then partitions where formed by taking the first cluster as being the largest set of ordered food categories (starting from the first) for which all pairwise comparisons of food categories within the set were equivalent based on the definition of significant distance between their respective uncertainty distributions. This process was repeated with all of the remaining food categories until each food category was assigned to one (and only one) cluster. If, for any given food category, there was no other food category that was similar, based on the definition, then that single food category was taken to form a cluster of one.

The results of the calculations of dissimilarity (or distance) between the twenty-three food categories are shown in Tables A12-1 and A12-2 based on the simulation output of the uncertainty distributions of mean risk per serving and expected number of cases per annum, respectively (n = 4,000 uncertainty samples or iterations). Based on these calculations the results of clustering the food categories according to either per serving risk or cases per annum are shown in Table A13-3. The sensitivity of the results to different specification of cut-off values for belief that one food category ranks higher than another, and is therefore dissimilar, is shown in Table A12-4. A level of 90% probability was chosen here as a reasonable summarization in order to obtain a relatively small number of clusters. At the 90% cut-off value there is a high degree of belief that, based on the uncertainty distributions, the foods in one cluster are of appreciably higher risk than those foods in any lower ranked cluster. While there are differences in risk rankings of food categories within any given cluster we are not "confident at a 90% level" that the differences are practically significant given all the attendant uncertainties that have been incorporated into the assessment.

Table A12-1. Probabilities[1] (over uncertainty) that food categories rank higher (or lower) than other food categories based on the mean risk per serving.

	DM	FNR	P	UM	SS	CR	HFD	SUC	PM	FSC	FR	PF	RS	F	DFS	SSC	SRC	V	DS	IC	PC	CD	HC
DM	0.0%	50.6%	65.8%	84.9%	82.8%	94.7%	98.5%	95.1%	97.4%	100.0%	100.0%	99.1%	100.0%	95.8%	99.6%	99.9%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
FNR	49.5%	0.0%	71.8%	86.5%	84.7%	96.3%	98.3%	96.8%	97.8%	99.9%	100.0%	99.1%	100.0%	96.1%	99.8%	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
P	34.2%	28.2%	0.0%	77.4%	76.6%	90.1%	96.0%	91.0%	96.0%	99.9%	100.0%	98.7%	100.0%	93.1%	99.2%	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
UM	15.1%	13.6%	22.6%	0.0%	49.9%	56.0%	68.9%	69.2%	80.1%	92.0%	94.9%	91.0%	96.5%	84.4%	92.2%	97.0%	95.3%	98.4%	98.3%	100.0%	99.9%	99.5%	99.8%
SS	17.3%	15.3%	23.5%	50.2%	0.0%	52.8%	66.6%	69.1%	81.7%	95.1%	99.8%	92.0%	99.5%	84.8%	93.6%	98.8%	97.0%	100.0%	99.3%	100.0%	100.0%	100.0%	100.0%
CR	5.4%	3.7%	10.0%	44.0%	47.2%	0.0%	71.0%	68.0%	84.6%	97.6%	99.8%	93.3%	99.7%	83.5%	94.4%	99.4%	97.3%	100.0%	99.6%	100.0%	100.0%	100.0%	100.0%
HFD	1.5%	1.8%	4.0%	31.2%	33.5%	29.0%	0.0%	57.9%	74.9%	94.6%	98.8%	87.9%	99.3%	79.5%	91.1%	98.3%	95.6%	99.9%	99.1%	100.0%	100.0%	99.9%	100.0%
SUC	4.9%	3.2%	9.0%	30.8%	30.9%	32.0%	42.1%	0.0%	57.2%	78.1%	85.2%	78.5%	87.3%	73.4%	81.6%	87.9%	84.8%	90.7%	91.7%	97.2%	97.0%	96.7%	98.3%
PM	2.6%	2.2%	4.0%	19.9%	18.4%	15.5%	25.1%	42.8%	0.0%	80.0%	93.2%	78.3%	96.6%	75.0%	84.1%	95.8%	88.9%	99.2%	97.0%	99.8%	100.0%	99.4%	100.0%
FSC	0.0%	0.2%	0.1%	8.1%	5.0%	2.5%	5.4%	21.9%	20.0%	0.0%	66.6%	63.1%	78.2%	61.8%	68.4%	83.2%	75.1%	88.6%	89.2%	98.0%	98.4%	95.7%	98.5%
FR	0.0%	0.0%	0.0%	5.2%	0.2%	0.3%	1.2%	14.9%	6.8%	33.4%	0.0%	57.4%	77.1%	58.0%	62.8%	82.3%	70.2%	86.5%	86.6%	99.2%	99.5%	96.0%	99.0%
PF	1.0%	0.9%	1.4%	9.1%	8.0%	6.7%	12.1%	21.5%	21.7%	36.9%	42.6%	0.0%	50.6%	48.4%	50.7%	57.5%	57.6%	62.6%	69.8%	84.5%	83.7%	83.3%	91.1%
RS	0.0%	0.0%	0.0%	3.6%	0.5%	0.4%	0.7%	12.7%	3.4%	21.8%	23.0%	49.5%	0.0%	50.3%	51.8%	65.9%	60.2%	73.1%	78.0%	96.8%	97.8%	91.7%	96.7%
F	4.2%	3.9%	6.9%	15.6%	15.2%	16.6%	20.5%	26.6%	25.0%	38.2%	42.0%	51.6%	49.7%	0.0%	50.5%	57.2%	57.8%	60.9%	69.5%	84.5%	84.3%	83.2%	91.3%
DFS	0.4%	0.2%	0.8%	7.8%	6.4%	5.6%	8.9%	18.4%	15.9%	31.6%	37.2%	49.3%	48.2%	49.5%	0.0%	58.1%	58.3%	64.4%	71.8%	88.8%	89.1%	85.8%	92.7%
SSC	0.1%	0.0%	0.0%	3.0%	1.2%	0.6%	1.7%	12.1%	4.2%	16.9%	17.7%	42.5%	34.2%	42.9%	42.0%	0.0%	50.5%	58.5%	69.0%	89.7%	90.4%	84.7%	92.3%
SRC	0.1%	0.1%	0.1%	4.7%	3.0%	2.8%	4.5%	15.2%	11.2%	24.9%	29.8%	42.4%	39.8%	42.2%	41.7%	49.5%	0.0%	55.3%	63.1%	80.7%	80.9%	79.3%	88.5%
V	0.0%	0.0%	0.0%	1.6%	0.0%	0.0%	0.1%	9.3%	0.9%	11.4%	13.5%	37.4%	26.9%	39.1%	35.7%	41.5%	44.7%	0.0%	63.0%	86.1%	85.8%	81.1%	91.8%
DS	0.0%	0.0%	0.1%	1.8%	0.7%	0.5%	0.9%	8.3%	3.1%	10.9%	13.4%	30.2%	22.0%	30.6%	28.2%	31.0%	36.9%	37.0%	0.0%	72.7%	72.3%	71.2%	85.1%
IC	0.0%	0.0%	0.0%	0.1%	0.0%	0.0%	0.1%	2.9%	0.2%	2.0%	0.8%	15.5%	3.3%	15.5%	11.3%	10.4%	19.3%	14.0%	27.4%	0.0%	50.9%	53.0%	70.5%
PC	0.0%	0.0%	0.0%	0.2%	0.0%	0.0%	0.0%	3.1%	0.0%	1.6%	0.5%	16.3%	2.2%	15.7%	11.0%	9.6%	19.1%	14.2%	27.8%	49.1%	0.0%	51.9%	69.4%
CD	0.0%	0.0%	0.0%	0.6%	0.1%	0.1%	0.2%	3.3%	0.6%	4.3%	4.0%	16.7%	8.3%	16.8%	14.2%	15.3%	20.8%	18.9%	28.8%	47.1%	48.2%	0.0%	65.9%
HC	0.0%	0.0%	0.0%	0.2%	0.0%	0.0%	0.0%	1.7%	0.1%	1.5%	1.1%	8.9%	3.3%	8.7%	7.3%	7.7%	11.5%	8.2%	14.9%	29.5%	30.7%	34.1%	0.0%

1 Probabilities are defined as Prob(rank(A) > rank(B)) where A is the food category identified in the row labels and B is the food category identified in the column labels (based on 4,000 uncertainty iterations of the model).

LEGEND	
DM = Deli Meats	RS = Raw Seafood
FNR = Frankfurters (not reheated)	F = Fruits
P = Pâté and Meat Spreads	DFS = Dry/Semi-Dry Fermented Sausages
UM = Unpasteurized Fluid Milk	SSC = Semi-soft Cheese
SS = Smoked Seafood	SRC = Soft Ripened Cheese
CR = Cooked Ready-To-Eat Crustaceans	V = Vegetables
HFD High Fat and Other Dairy Products	DS = Deli-type Salads
SUC = Soft Unripened Cheese	IC = Ice Cream and Frozen Dairy Products
PM = Pasteurized Fluid Milk	PC = Processed Cheese
FSC = Fresh Soft Cheese	CD= Cultured Milk Products
FR = Frankfurters (reheated)	HC = Hard Cheese
PF = Preserved Fish	

Table A12-2. Probabilities [1] (over uncertainty) that food categories rank higher (or lower) than other food categories based on the number of cases per annum.

	DM	PM	HFD	FNR	SUC	P	CR	UM	SS	F	FR	V	DFS	FSC	SSC	SRC	DS	RS	PF	IC	PC	CD	HC
DM	0.0%	91.9%	98.5%	99.6%	99.8%	100.0%	100.0%	99.8%	99.6%	92.4%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PM	8.1%	0.0%	60.3%	75.1%	83.8%	96.0%	98.0%	93.8%	94.5%	77.9%	100.0%	99.2%	99.1%	100.0%	99.9%	99.6%	99.5%	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%
HFD	1.5%	39.7%	0.0%	69.7%	80.4%	95.3%	97.9%	93.1%	94.0%	75.4%	99.8%	99.1%	99.0%	100.0%	99.8%	99.8%	99.4%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
FNR	0.4%	24.9%	30.3%	0.0%	70.2%	92.0%	95.8%	87.2%	91.0%	72.5%	99.3%	98.5%	98.0%	100.0%	99.7%	99.6%	98.9%	100.0%	99.8%	100.0%	100.0%	100.0%	100.0%
SUC	0.2%	16.2%	19.7%	29.9%	0.0%	60.6%	64.9%	60.8%	69.8%	59.5%	83.8%	78.8%	85.8%	91.1%	90.3%	88.4%	88.2%	92.8%	92.9%	95.6%	95.7%	96.0%	97.7%
P	0.1%	4.0%	4.7%	8.0%	39.4%	0.0%	57.2%	54.0%	69.8%	59.6%	94.0%	82.2%	90.1%	100.0%	98.2%	93.6%	93.2%	100.0%	98.9%	99.7%	100.0%	99.6%	100.0%
CR	0.0%	2.0%	2.2%	4.2%	35.1%	42.8%	0.0%	48.7%	65.8%	57.0%	91.8%	79.3%	89.2%	99.9%	98.0%	92.2%	92.5%	100.0%	98.5%	99.6%	100.0%	99.2%	99.9%
UM	0.3%	6.2%	6.9%	12.8%	39.2%	46.0%	51.3%	0.0%	61.3%	56.5%	80.5%	76.2%	85.7%	96.6%	93.9%	89.3%	89.4%	97.7%	95.3%	98.4%	98.7%	97.4%	99.0%
SS	0.4%	5.5%	6.0%	9.0%	30.2%	30.2%	34.3%	38.7%	0.0%	54.0%	72.7%	71.0%	82.2%	98.7%	94.7%	87.0%	88.8%	99.5%	95.4%	99.5%	99.8%	97.6%	99.3%
F	7.6%	22.1%	24.7%	27.6%	40.5%	40.5%	43.0%	43.5%	46.0%	0.0%	54.7%	57.6%	69.7%	75.9%	74.6%	74.5%	76.8%	82.3%	79.9%	89.7%	89.4%	89.1%	94.2%
FR	0.0%	0.1%	0.2%	0.7%	16.2%	6.0%	8.2%	19.5%	27.3%	45.4%	0.0%	58.5%	75.2%	89.8%	88.9%	78.4%	82.4%	98.4%	88.4%	98.7%	99.3%	95.7%	98.5%
V	0.0%	0.9%	0.9%	1.6%	21.3%	17.8%	20.7%	23.8%	29.0%	42.5%	41.6%	0.0%	66.4%	78.6%	77.6%	72.9%	76.7%	89.5%	81.2%	92.8%	94.7%	91.0%	96.4%
DFS	0.0%	1.0%	1.0%	2.0%	14.2%	9.9%	10.8%	14.4%	17.9%	30.3%	24.9%	33.7%	0.0%	59.2%	58.0%	57.9%	58.9%	67.6%	66.2%	78.2%	79.6%	79.7%	88.3%
FSC	0.0%	0.0%	0.0%	0.0%	8.9%	0.0%	0.1%	3.4%	1.3%	24.1%	10.2%	21.5%	40.8%	0.0%	50.1%	50.1%	51.4%	67.1%	60.1%	76.2%	78.7%	77.1%	87.2%
SSC	0.0%	0.2%	0.2%	0.3%	9.7%	1.8%	2.0%	6.2%	5.3%	25.4%	11.1%	22.4%	42.0%	49.9%	0.0%	50.1%	53.1%	66.7%	60.4%	77.5%	78.5%	76.8%	86.8%
SRC	0.0%	0.4%	0.2%	0.4%	11.6%	6.4%	7.8%	10.7%	13.1%	25.6%	21.6%	27.1%	42.1%	49.9%	49.9%	0.0%	50.6%	58.6%	60.1%	69.0%	70.5%	72.6%	81.3%
DS	0.0%	0.5%	0.6%	1.1%	11.8%	6.8%	7.5%	10.6%	11.2%	23.2%	17.6%	23.3%	41.1%	48.6%	47.0%	49.4%	0.0%	53.3%	58.8%	71.9%	72.8%	74.5%	86.3%
RS	0.0%	0.0%	0.0%	0.0%	7.2%	0.0%	0.0%	2.3%	0.5%	17.7%	1.6%	10.5%	32.5%	33.0%	33.3%	41.5%	46.7%	0.0%	52.6%	69.8%	72.0%	72.8%	84.9%
PF	0.0%	0.1%	0.0%	0.2%	7.1%	1.1%	1.5%	4.7%	4.6%	20.1%	11.7%	18.8%	33.8%	39.9%	39.6%	39.9%	41.2%	47.5%	0.0%	59.0%	60.7%	62.0%	71.4%
IC	0.0%	0.0%	0.0%	0.1%	4.4%	0.3%	0.4%	1.7%	0.5%	10.3%	1.3%	7.2%	21.8%	23.8%	22.5%	31.0%	28.2%	30.2%	41.1%	0.0%	53.0%	59.8%	74.9%
PC	0.0%	0.0%	0.0%	0.0%	4.3%	0.0%	0.0%	1.3%	0.2%	10.6%	0.7%	5.3%	20.4%	21.3%	21.5%	29.5%	27.3%	28.0%	39.3%	47.0%	0.0%	57.0%	72.6%
CD	0.0%	0.0%	0.0%	0.0%	4.0%	0.4%	0.9%	2.7%	2.4%	10.9%	4.3%	9.0%	20.3%	22.9%	23.2%	27.4%	25.6%	27.2%	38.1%	40.2%	43.0%	0.0%	62.0%
HC	0.0%	0.0%	0.0%	0.0%	2.3%	0.0%	0.2%	1.1%	0.7%	5.8%	1.6%	3.6%	11.7%	12.9%	13.3%	18.7%	13.8%	15.1%	28.6%	25.1%	27.5%	38.0%	0.0%

[1] Probabilities are defined as Prob(rank(A) > rank(B)) where A is the food category identified in the row labels and B is the food category identified in the column labels (based on 4,000 uncertainty iterations of the model).

LEGEND

DM =	Deli Meats	DFS =	Dry/Semi-Dry Fermented Sausages
PM =	Pasteurized Fluid Milk	FSC =	Fresh Soft Cheese
HFD	High Fat and Other Dairy Products	SSC =	Semi-soft Cheese
FNR =	Frankfurters (not reheated)	SRC =	Soft Ripened Cheese
SUC =	Soft Unripened Cheese	DS =	Deli-type Salads
P =	Pâté and Meat Spreads	RS =	Raw Seafood
CR =	Cooked Ready-To-Eat Crustaceans	PF =	Preserved Fish
UM =	Unpasteurized Fluid Milk	IC =	Ice Cream and Frozen Dairy Products
SS =	Smoked Seafood	PC =	Processed Cheese
F =	Fruits	CD=	Cultured Milk Products
FR =	Frankfurters (reheated)	HC =	Hard Cheese
V =	Vegetables		

Table A12-3. Clustering of Similar Food Categories Based on the Uncertainty Distribution of Relative Risk Ranking on Per Serving and Per Annum Basis.

Cluster	Risk per Serving	Risk per Annum
Cluster 1	Deli Meats Frankfurters, not reheated Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	Deli Meats
Cluster 2	Cooked RTE Crustaceans High Fat and Other Dairy Products Pasteurized Fluid Milk Soft Unripened Cheese	High Fat and Other Dairy Products Frankfurters, not reheated Pasteurized Fluid Milk Soft Unripened Cheese
Cluster 3	Deli-type Salads Dry/Semi-dry Fermented Sausages Fresh Soft Cheese Frankfurters, reheated Fruits Preserved Fish Raw Seafood Semi-soft Cheese Soft Ripened Cheese Vegetables	Cooked RTE Crustaceans Fruits Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood
Cluster 4	Cultured Milk Products Ice Cream and Frozen Dairy Products Processed Cheese Hard Cheese	Deli-type Salads Dry/Semi-dry Fermented Sausages Frankfurters, reheated Fresh Soft Cheese Semi-Soft Cheese Soft Ripened Cheese Vegetables
Cluster 5	Not Applicable	Cultured Milk Products Hard Cheese Ice Cream and Frozen Dairy Products Preserved Fish Processed Cheese Raw Seafood

Table A12-4. Sensitivity of clustering procedure to the cut-off probability used to define similar versus dissimilar food categories.

Measure for ranking	Cut-off probability (distance) for defining any two categories as dissimilar	Total # of pairwise comparisons for which food categories are not judged dissimilar [1]	# of distinct disjoint clusters [2] of similarly ranked food categories
Risk per serving	0.95	139	4
Risk per serving	0.90	116	4
Risk per serving	0.75	61	7
Cases per annum	0.95	149	4
Cases per annum	0.90	124	5
Cases per annum	0.75	69	7

[1]There are a total of 276 pairwise comparisons of 23 food types; two food categories where considered dissimilar if Pr(rank(A) > rank(B)) > the cut-off probability value where A is the food with higher mean rank and B is the food with lower mean rank

[2]A cluster is defined here as a collection of food categories for which Pr(rank(A) > rank(B)) < cut-off probability value for any pair (A,B) in the cluster; each food is assigned to only one cluster and therefore clusters are disjoint.