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 *L. monocytogenes* from consumption of foods in the 20 food categories with the adverse health outcomes. This risk characterization focuses primarily on a prediction of the relative probability of contracting listeriosis from consumption of a single serving of food in one of the 20 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 sporadic and outbreak cases. Outbreaks frequently represent a breakdown in food production, manufacturing, or distribution systems instituted to prevent *L. 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.

Modeling

Because listeriosis is a rare event, straight Monte-Carlo modeling is unable to provide adequate characterization of the tails of the distributions in the model. Therefore, the model was divided into two major components — the exposure assessment and the dose-adjustment factors. Each of these portions of the model covered a 10 to 15 $\log_{10}$ range. This process was conducted as follows:

1. A two-dimensional Monte-Carlo simulation was used to integrate the components of the exposure models for each of the food groups, with 30,000 variability iterations and 300 uncertainty iterations.

2. A two-dimensional Monte-Carlo simulation was used to integrate the variability and uncertainty of the strain-virulence and host susceptibility functions, with 100,000 variability iterations and 300 uncertainty iterations.
3. The variability dimension for both was condensed to half-$\log_{10}$ bins, which ranged from -5 to +10 logs for each of the 300 uncertainty iterations.
4. During the one-dimensional (uncertainty only) dose-response simulation, one of the 300 dose bins (from the exposure assessment for each food group) and the dose-adjustment bins were combined algebraically by adding the arrays.

For a more detailed explanation of two-dimensional Monte-Carlo and the dose-binning process, see Appendix 6.

The exposure assessment modeled the effect of various factors (e. g., frequency and extent of contamination at retail, consumption patterns, the growth potential of *L. monocytogenes* in foods, length of refrigerated storage, and refrigeration temperatures) that might affect levels of *L. monocytogenes* contamination in a food at the time of consumption. These models were combined with the three dose-response models for the susceptible subpopulations (developed in the hazard characterization) to yield predictions of the relative role of each of the 20 food categories in listeriosis in the United States, on a per serving and a per annum basis. Since the risk characterization is anchored such that the overall predicted incidence of listeriosis is in line with the actual incidence of listeriosis, an implicit assumption is that the foods encompassed by the 20 food categories account for all cases of foodborne listeriosis.

The risk characterization was developed in two steps. The first step was a simulation that completed the exposure assessment calculations and produced the number of annual servings for each of three subpopulations at designated dose levels for each food category. The number of annual servings at each dose level was calculated to include both population variability and uncertainty due to lack of information. Three hundred simulations, each of 30,000 iterations, were conducted for each food category and each population group. The result of the calculations is the fraction of servings that occur at designated dose levels (broken out at half-$\log_{10}$ intervals) for each food category and population group. In order to be useable with the dose-response simulations, translation of this "two-dimensional" (variability and uncertainty) exposure assessment had to be converted to a "one dimensional"

(uncertainty only) simulation. This was accomplished by grouping the estimated doses from the exposure simulations into 42 bins (at half-$\log_{10}$ intervals) for each of the 20 food categories.

The second step calculated predictions of the relative risk of listeriosis to each subpopulation from each food category, by combining the three sets of the 4,000 dose-response simulation uncertainty iterations, one set for each subpopulation, with the condensed results of the annual serving per dose interval simulation. The 4,000 iterations produce distributions of predicted incidence rate per serving and per year for each food category and subpopulation.

The relative rank of the medians of the 4,000 iterations for each food category and each subpopulation for the per annum predictions were then reported. Because of the variability of consumption of the food categories, pathogen virulence, host susceptibility, and inherent uncertainty, the predicted relative ranking of food categories may change within 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 can then be ranked and compared. To this end, the ranking of each food group from first to twentieth was determined for each set of the 4,000 risk characterization iterations. The number of times each food group was observed to be ranked at each specific position was then determined. These data were then compiled and presented graphically (see the latitude graphs in the discussion of individual food categories).

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 current risk assessment and prior attempts to evaluate the risks associated with ready-to-eat foods is the complexity of factors considered in the hazard characterization. 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 *L. monocytogenes* isolates. Prior evaluations have typically considered only highly virulent strains in a single population group. As discussed in more detail earlier in the hazard characterization section, such simplifications provide a less accurate estimate of the risk associated with this pathogen. Including human susceptibility variability and pathogen virulence variability substantially reduces the estimates of risk in relation to a particular dose. It also emphasizes the fact that most exposures to *L. monocytogenes* seldom lead to listeriosis, even among highly susceptible segments of the population.

Medians (the value with 50 percent of the values above and 50 percent of the values below) are used to represent the "expected" predicted risk. 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 distribution by a single value (see Appendix 2).

Risk Per Serving

A key value used to assess the predicted relative risk among the 20 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. These 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. In addition, the median relative ranking developed by considering all three subpopulations was used to model the uncertainty associated with these rankings. This is described in the discussion of individual food categories that follows.

As expected, the risk assessment indicates that listeriosis could potentially be caused by foods in any of the food categories; that is, no food category is risk-free if the potential exists that a food can become contaminated with *L. monocytogenes.* It is apparent, however, that there are substantial differences in risk among the different food categories. For example, the

greatest risk differential for the total population is between Pâté and Meat Spreads versus Ice Cream and Frozen Dairy Products, where the median predicted relative risk differs by almost a million-fold. The differential in median predicted risk per serving is readily seen in Figure V-1. It illustrates the point that elimination of *L. monocytogenes* from any single food will not eliminate foodborne listeriosis; control of listeriosis will require consideration of a variety of foods. However, it is equally evident that some foods represent a substantially greater risk per serving and are likely to warrant additional attention from industry and regulators.

Table V-1. Estimates of Number of Cases of Listeriosis per Serving per Food Category and Population

Food Category	Number of Cases of Listeriosis per Serving[a]								
	Perinatal[b]			Elderly			Intermediate-Age[c]		
	Percentiles			Percentiles			Percentiles		
	Median	5th	95th	Median	5th	95th	Median	5th	95th
SEAFOOD									
Smoked Seafood	2.6×10^{-5}	3.2×10^{-6}	2.7×10^{-4}	4.4×10^{-7}	5.7×10^{-9}	2.6×10^{-5}	5.3×10^{-8}	4.0×10^{-11}	7.9×10^{-6}
Raw Seafood	3.5×10^{-7}	1.7×10^{-8}	7.2×10^{-6}	5.0×10^{-9}	2.3×10^{-11}	6.2×10^{-7}	5.6×10^{-10}	5.4×10^{-14}	1.7×10^{-7}
Preserved Fish	5.8×10^{-6}	1.6×10^{-9}	6.1×10^{-5}	7.9×10^{-8}	6.2×10^{-12}	6.1×10^{-6}	7.5×10^{-9}	7.7×10^{-14}	1.8×10^{-6}
Cooked Ready-to-Eat Crustaceans	5.9×10^{-6}	6.2×10^{-7}	5.7×10^{-5}	1.0×10^{-7}	1.4×10^{-9}	6.1×10^{-6}	1.2×10^{-8}	1.7×10^{-11}	1.8×10^{-6}
PRODUCE									
Vegetables	2.3×10^{-8}	7.5×10^{-11}	3.6×10^{-6}	3.4×10^{-10}	8.1×10^{-16}	1.7×10^{-7}	4.1×10^{-11}	1.4×10^{-20}	3.1×10^{-8}
Fruits	8.7×10^{-9}	4.1×10^{-13}	7.6×10^{-7}	1.0×10^{-10}	3.0×10^{-18}	3.8×10^{-8}	1.0×10^{-11}	2.0×10^{-23}	9.7×10^{-9}
DAIRY									
Soft Mold-Ripened and Blue-Veined Cheese	1.2×10^{-6}	1.2×10^{-7}	3.3×10^{-5}	2.1×10^{-8}	1.9×10^{-10}	2.4×10^{-6}	2.5×10^{-9}	1.3×10^{-12}	6.1×10^{-7}
Goat, Sheep, and Feta Cheese	3.7×10^{-8}	2.4×10^{-12}	3.8×10^{-6}	5.5×10^{-10}	3.9×10^{-17}	2.0×10^{-7}	5.6×10^{-11}	3.7×10^{-22}	3.9×10^{-8}
Fresh Soft Cheeses	4.4×10^{-5}	6.9×10^{-6}	3.2×10^{-4}	8.1×10^{-7}	1.6×10^{-8}	3.5×10^{-5}	5.8×10^{-8}	1.5×10^{-10}	7.4×10^{-6}
Heat-Treated Natural Cheese and Processed Cheese	1.7×10^{-7}	1.7×10^{-8}	1.4×10^{-6}	2.8×10^{-9}	3.6×10^{-11}	1.5×10^{-7}	3.3×10^{-10}	2.3×10^{-13}	4.9×10^{-8}
Aged Cheeses	2.9×10^{-10}	6.2×10^{-19}	4.2×10^{-6}	3.0×10^{-12}	9.6×10^{-29}	1.7×10^{-7}	3.2×10^{-13}	2.4×10^{-36}	2.8×10^{-8}
Pasteurized Fluid Milk	6.5×10^{-7}	1.2×10^{-7}	2.7×10^{-6}	1.5×10^{-8}	5.2×10^{-10}	2.7×10^{-7}	1.6×10^{-9}	1.3×10^{-11}	9.3×10^{-8}
Unpasteurized Fluid Milk	5.7×10^{-7}	1.3×10^{-8}	4.2×10^{-6}	1.0×10^{-8}	5.3×10^{-11}	3.7×10^{-7}	1.1×10^{-9}	8.1×10^{-13}	1.2×10^{-7}
Ice Cream/Frozen Dairy Products	8.5×10^{-11}	7.8×10^{-19}	1.1×10^{-5}	1.1×10^{-12}	5.0×10^{-29}	3.5×10^{-7}	1.2×10^{-13}	6.5×10^{-37}	5.7×10^{-8}
Miscellaneous Dairy Products	4.0×10^{-7}	5.7×10^{-8}	2.1×10^{-6}	7.5×10^{-9}	1.6×10^{-10}	2.1×10^{-7}	8.7×10^{-10}	2.1×10^{-12}	7.4×10^{-8}
MEATS									
Frankfurters	3.0×10^{-6}	3.1×10^{-7}	2.6×10^{-5}	5.0×10^{-8}	5.4×10^{-10}	2.4×10^{-6}	5.9×10^{-9}	2.4×10^{-12}	7.7×10^{-7}
Dry/Semi-Dry Fermented Sausages	5.6×10^{-7}	2.9×10^{-10}	1.4×10^{-5}	8.4×10^{-9}	1.1×10^{-12}	9.0×10^{-7}	8.1×10^{-10}	1.1×10^{-14}	2.4×10^{-7}
Deli Meats	1.3×10^{-5}	1.7×10^{-6}	1.0×10^{-4}	2.2×10^{-7}	3.0×10^{-9}	1.1×10^{-5}	2.6×10^{-8}	3.0×10^{-11}	3.5×10^{-6}
Pâté and Meat Spreads	3.1×10^{-5}	5.0×10^{-6}	1.9×10^{-4}	5.8×10^{-7}	1.2×10^{-8}	2.1×10^{-5}	6.6×10^{-8}	1.6×10^{-10}	7.0×10^{-6}
COMBINATION FOODS									
Deli Salads	2.1×10^{-6}	3.6×10^{-7}	1.8×10^{-5}	9.4×10^{-8}	2.2×10^{-9}	3.9×10^{-6}	1.4×10^{-8}	4.8×10^{-11}	1.5×10^{-6}

[a] This table provides estimates of the true risk per serving and the uncertainty about that estimate. For example, for the perinatal group, Smoked Seafood category, the risk assessment estimates that there is only a 5% probability that the true risk is less than 3.2×10^{-6} and a 95% probability that it is less than 2.7×10^{-4} (or a 5% probability that it is greater). The median risk estimate has a 50% probability of being greater or smaller than the true risk.

[b] 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.

[c] The Intermediate Age includes susceptible populations not captured as elderly or perinatal, such as cancer, AIDS, and transplant patients, for whom there are insufficient data to consider as a separate population.

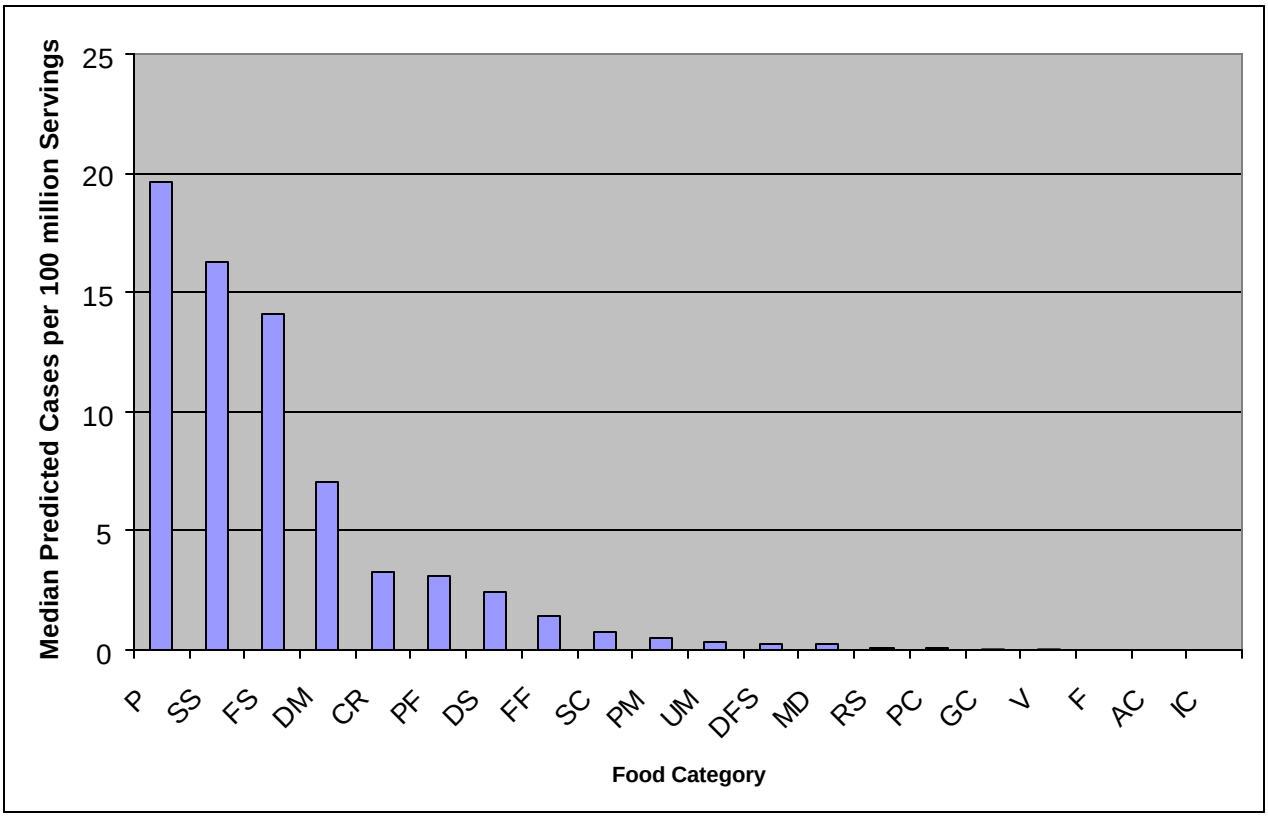

Figure V-1. Predicted Relative Risks Associated with Food Categories for the Total Population based on the Median Predicted Cases of Listeriosis per 100 million Servings

P= Pâté and Meat Spreads; SS= Smoked Seafood; FS= Fresh Soft Cheese; DM= Deli Meats; CR= Cooked Ready-To-Eat Crustaceans; PF= Preserved Fish; DS= Deli Salads; FF= Frankfurters; SC= Soft Mold-Ripened and Blue-Veined Cheese; PM= Pasteurized Fluid Milk; UM= Unpasteurized Fluid Milk; DFS= Dry/Semi-Dry Fermented Sausages; MD= Miscellaneous Dairy Products; RS= Raw Seafood; PC= Heat-Treated Natural Cheese and Processed Cheese; GC= Goat, Sheep, and Feta Cheese; V= Vegetables; F= Fruits; AC= Aged Cheese; IC= Ice Cream and Frozen Dairy Products.

In addition to the median values, the 5th and 95th percentile values were also calculated for each of the subpopulations (Table V-1). These values provide a means of estimating the variability and uncertainty associated with the predictions. 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 is discussed in greater depth for each of the individual food categories.

The predicted risk per serving values were used to develop a predicted relative risk ranking using the previously described ranking simulation. The median predicted relative risk ranking among the different food categories is summarized for the three subpopulations (Table V-2). More detailed analyses of the uncertainty and interpretation of the predicted relative risk ranking simulation models are provided in the discussion of the individual food categories. 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. It is important to note that there were often only minor differences separating the rankings of various food categories.

Table V-2. Predicted Relative Risk Rankings For Listeriosis among Food Categories for Three U.S. Age-Based Subpopulations 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]
SEAFOOD			
Smoked Seafood	3	3	3
Raw Seafood	14	14	14
Preserved Fish	7	7	6
Cooked Ready-to-Eat Crustaceans	6	5	5
PRODUCE			
Vegetables	17	17	17
Fruits	18	18	18
DAIRY			
Soft Mold-Ripened & Blue-Veined Cheese	9	9	9
Goat, Sheep, and Feta Cheese	16	16	16
Fresh Soft Cheese (e.g., queso fresco)[c]	2	1	1
Heat-Treated Natural/Process Cheese	15	15	15
Aged Cheese	19	19	19
Fluid Milk, Pasteurized[d]	10	10	10
Fluid Milk, Unpasteurized[d]	11	11	11
Ice Cream and Frozen Dairy Products	20	20	20
Miscellaneous Dairy Products	12	13	13
MEATS			
Frankfurters			
All frankfurters[e]	8	8	7
Only reheated frankfurters[f]	[15]	[15]	[15]
Only non-reheated frankfurters[f]	[1]	[2]	[2]
Dry/Semi-Dry Fermented Sausages	13	12	12
Deli Meats	4	4	4
Pâté and Meat Spreads	1	2	2
COMBINATION FOODS			
Deli Salads	5	6	8

[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 20 indicates the lowest predicted relative risk of causing listeriosis.

[c] Data from soft ripened cheese made from unpasteurized milk were used in the modeling to define the shape of the distribution of contamination data for fresh soft cheese.

[d] All available data for this food category were used in the modeling to define the shape of the distribution for this food category but only contamination data from North America were used to determine the frequency of contamination.

[e] This ranking is based on the assumption that 1% to 14 % of frankfurters are consumed without reheating and the remainder are assumed to be adequately heated before consumption.

[f] The bracketed values reflect the ranking of frankfurters, reheated and not reheated, when modeled independently. The rankings of the other food categories would be adjusted accordingly. For example, for the intermediate age, the predicted risk ranking is 1 for non-reheated frankfurter, and would be 2 for Pâté and Meat Spreads.

It is apparent that the predicted relative risk ranking of the food categories is similar, but not identical, for the three subpopulations. As discussed in the hazard characterization, there are substantial differences in the relative susceptibility in the subpopulations.

As anticipated, based on 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:

- Frequency and extent of *L. monocytogenes* in the food
- Amounts and frequency of food consumption
- Potential for growth of *L. 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 *L. 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 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, frankfurters are fully cooked to temperatures that are lethal for *L. monocytogenes.* However, subsequent recontamination prior to packaging may occur with continued growth of the pathogen. Although they are usually reheated prior to consumption, a portion of the population consumes frankfurters

without reheating. Due to lack of specific data, the risk assessment had to assume a "reasonable" level for the extent of consumption without reheating. A triangular distribution was used with a minimum of 1%, most likely of 3.3% and maximum of 14%. The impact of these types of assumptions on the predicted relative risk is considered in the discussion of the individual food categories. In addition, the public is invited to comment on these and all of the other assumptions that were made in the conduct of this risk assessment (See Request for Comment and Information at the front of this document).

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 relative risk 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. Table III-2 shows the wide range in number of annual servings among the food categories. Thus, the per annum relative risk determinations inherently have a greater degree of variability and uncertainty. 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 and then used to generate a predicted relative risk ranking for the uncertainty. The predicted relative risk ranking is presented in Table V-3. The uncertainty associated with the ranking is described using individual latitude ranking graphs based on the rankings for the combined population groups. 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.

Table V-3. Predicted Relative Risk Rankings for Listeriosis among Food Categories for Three U.S. Age-Based Subpopulations Using Median Estimates of Relative Predicted Risks for Listeriosis on a Per Annum Basis

Food Categories[a]	Subpopulation		
	Intermediate Age[b]	Elderly[b]	Perinatal[b]
SEAFOOD			
Smoked Seafood	6	6	7
Raw Seafood	17	20	17
Preserved Fish	13	13	13
Cooked Ready-to-Eat Crustaceans	9	8	9
PRODUCE			
Vegetables	11	9	11
Fruits	16	14	14
DAIRY			
Soft Mold-Ripened and Blue-Veined Cheese	14	15	15
Goat, Sheep, and Feta Cheese	18	17	18
Fresh Soft Cheese (e.g., queso fresco)[c]	7	11	6
Heat-Treated Natural Cheese and Processed Cheese	10	10	10
Aged Cheese	19	18	19
Fluid Milk, Pasteurized[d]	3	2	2
Fluid Milk, Unpasteurized[d]	15	16	16
Ice Cream and Frozen Dairy Products	20	19	20
Miscellaneous Dairy Products	5	4	5
MEATS			
Frankfurters[e]	4	5	4
Dry/Semi-Dry Fermented Sausages	12	12	12
Deli Meats	1	1	1
Pâté and Meat Spreads	8	7	8
COMBINATION FOODS			
Deli Salads	2	3	3

[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 20 indicates the lowest predicted relative risk of causing listeriosis.
[c] Data from soft ripened cheese made from unpasteurized milk were used in the modeling to define the shape of the distribution of contamination data for fresh soft cheese.
[d] All available data for this food category were used in the modeling to define the shape of the distribution for this food category but only contamination data from North America were used to determine the frequency of contamination. Also see text for discussion of the effects of uncertainty on the ranking for pasteurized milk and other foods that are consumed in high amounts.
[e] This ranking is based on the assumption that 1% to 14% of frankfurters are consumed without reheating and the remainder are adequately heated before consumption.

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 low 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 it did 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). 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 serving sizes are typically large and the numbers of servings consumed annually are several orders of magnitude higher than other foods. 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.

Overview and Discussion of Food Categories

Because *L. 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, twenty categories were formed. 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 (raw vs. cooked, pH, salt level), contamination with *L. 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 heavier in another, and growth most likely 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 2.1×10^9 servings consumed of the foods identified in the 20 categories. Extrapolated to an annual basis, there were 3.8×10^{11} servings consumed in a year. The vast majority (97.4% or 2.6×10^8 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, 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 greater than 10^6 cfu/g in the samples of food 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. Samples from studies where detection was limited to 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 15.3 % (Smoked Seafood). All food categories demonstrated some contamination, with a range of positive samples from 0.8 % to 15.3 % (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 fifteen years (1985-2000). Because there was a major effort worldwide to control foodborne listeriosis, the incidence of contamination was evaluated for differences pre- and post-1993.

Growth of *L. 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 *L. 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 Rates (EGR) from individual studies were used to develop a distribution of growth rate values. As previously mentioned, no data were available that adequately described the distribution of storage times. Therefore, a triangular distribution was created for each food category, with minimum, most likely and maximum times (days) to account for the likely variations in storage times. The minimum time for all food categories was 0.5 or 1 day, which represents food consumed within 24 hours of purchase. For each specific food category, the most likely and maximum values were assigned and given an uncertainty range. In each iteration of the growth simulation, the model program 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 *L. monocytogenes* to calculate the total *L. 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 high storage temperature and long storage times, a combination 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 keep track 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 as low/moderate/high or short/moderate/long for each parameter are presented in Table V-4a. Table V-4b provides a characterization of each of the parameters for each food category. See Appendix 5 for a list of the various data used for each food category.

An overview of each of the 20 food categories follows Tables V-4a and V-4b. It includes information for each food category on cases of listeriosis, consumption, contamination, and growth of *L. monocytogenes*, and a summary of the designated parameter levels based on the criteria listed in

Table V-4a. In addition, the latitude graphs used to describe the uncertainty associated with the predicted relative risk rankings are provided for each food category.

The relative predicted risk on a per serving basis was classified as high, moderate, or low using Figure V-1 based on the criteria: high = >1 predicted cases of listeriosis per 100 million servings; moderate = <1 but > 0.1 predicted cases per 100 million servings, and low = < 0.1 predicted cases per 100 million servings. Based on these criteria, 8 of the foods were considered to be a higher risk, 5 were in the moderate risk group, and the remaining foods fell into the low risk per serving category.

Table V-4a. 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	$\leq 5 \times 10^8$	$> 5 \times 10^8$ to $< 1 \times 10^{10}$	$\geq 1 \times 10^{10}$
Median Amount Consumed per Serving (g)	≤ 45 g	> 45 g to < 100 g	≥ 100 g
Contamination Frequency (%)	≤ 4%	> 4% to < 10%	≥ 10%
Contamination at Retail—Predicted Servings at 10^6 to 10^9 cfu (%)	< 0.1%	≥ 0.1% to < 1.0%	≥ 1.0%
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 days to < [range 6 to10 days]	≥ range 6 to 10 days

Table V-4b. Qualitative 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	Long
Raw Seafood	Low	Low	Moderate	Low	Moderate	Short
Preserved Fish	Low	Moderate	High	Moderate	—[a]	—[a]
Cooked Ready-to-Eat Crustaceans	Moderate	Moderate	Low	Low	High	Short
PRODUCE						
Vegetables	High	Low	Moderate	Low	Low	Moderate
Fruits	High	High	High	Low	Low	Moderate
DAIRY						
Soft Mold-Ripened and Blue-Veined Cheese	Low	Low	Moderate	Moderate	Moderate	Long
Goat, Sheep, and Feta Cheese	Low	Low	Moderate	Moderate	Low	Long
Fresh soft cheese (e.g., queso fresco)	Low	Low	High	High	Moderate	Long
Heat-Treated Natural Cheese and Processed Cheese	High	Low	Low	Low	Moderate	Long
Aged Cheese	High	Low	Low	Low	Low	Long
Fluid Milk, Pasteurized	High	High	Low	Low	High	Moderate
Fluid Milk, Unpasteurized	Low	High	Moderate	Low	High	Moderate
Ice Cream and Frozen Dairy Products	High	High	Low	Low	—[a]	—[a]
Miscellaneous Dairy Products	High	Low	Low	Low	Low	Long
MEATS						
Frankfurters	Moderate	Moderate	Moderate	Low	Moderate	Moderate
Dry/Semi-Dry Fermented Sausages	Moderate	Moderate	Moderate	Moderate	—[a]	—[a]
Deli Meats	High	Moderate	Moderate	Moderate	High	Moderate
Pâté and Meat Spreads	Low	Moderate	Moderate	Moderate	High	Long
COMBINATION FOODS						
Deli Salads	Moderate	High	Moderate	Moderate	High[b]	Moderate

[a] A no-growth food category; growth rates and storage times are not applicable. [b] No data for this food category; surrogate data used from deli meats.

Food Category: Smoked Seafood

The foods in the Smoked Seafood category had a high predicted relative risk of causing listeriosis to individual consumers on a per serving basis. This reflects the fact that smoked seafood has a moderate serving size and high frequency of contamination; promotes moderate growth; and is often stored for long periods of time. This is offset somewhat by the relatively smaller serving sizes (i.e., the lower side of the moderate serving size range*)* and the number of servings associated with this food category. 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 U.S. is only 2.1×10^8 (i.e., less than 1 serving per person per annum, on average).

The per serving predicted relative risk 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).

Data from twelve smoked seafood studies provided the contamination data used for this category. Only two of these studies were conducted in the U.S. Almost half of the studies were published after 1993. Comparing the percentage of contaminated samples from studies conducted before and after 1993 showed there was a relatively substantial increase over time (Appendix 7, Table 7-1). This, in part, could be related to improvements in the detection methods. Four studies provided quantitative contamination data, primarily for smoked finfish (salmon, haddock). No quantitative studies for smoked shellfish were available. 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 that inactivation resulting from hot smoking is often lost due to recontamination. Cold smoking has no significant effect on *L. monocytogenes*. The percentage of samples with contamination was high; about 15%. On relatively infrequent occasions, the observed levels of contamination were greater than 10^4 cfu/g. The predicted percentage of servings at the higher levels of contamination (10^6 to 10^9 cfu) at retail was high.

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. Salt levels were 3 and 5%, and some products were vacuum packed. The average exponential growth rate adjusted to 5°C was a moderate 0.16 logs/day. Storage times can be lengthy for this food category. The most likely and maximum storage times used were 6 to10 and 15 to 45 days, respectively.

The predicted median per serving relative risk rankings for the Smoked Seafood category were third for each of the three subpopulations. The range for the per serving ranking distribution for Smoked Seafood is narrow and concentrated in the higher ranks, with a normal distribution with a single mode (Figure V-2a). This indicates relatively little uncertainty in the ranking for the Smoked Seafood category. The predicted median per annum relative risk rankings were seventh for the perinatal subpopulation and sixth for the intermediate-age and elderly subpopulations. The relative ranking distribution for the per annum value (Figure V-2b) was shifted to the lower risk ranks, reflecting the moderate consumption of food in this category. While greater than the per serving value, the uncertainty associated with the per annum value still is indicative of relatively low variability and uncertainty.

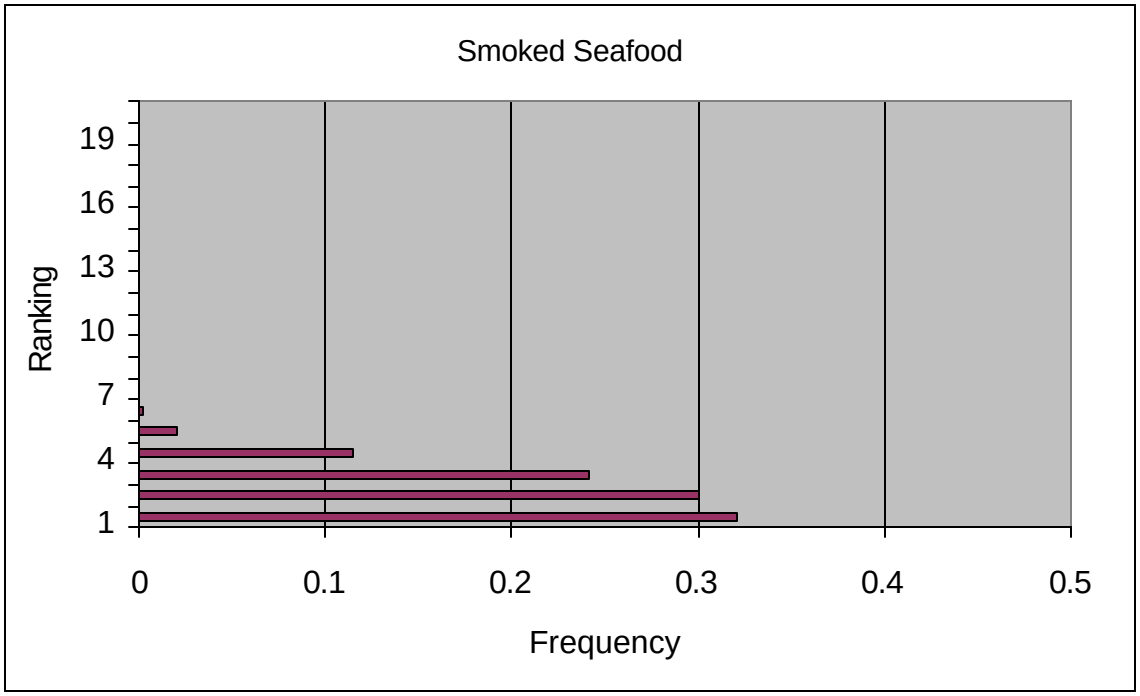

Figure V-2a. Rankings of total predicted listeriosis cases per serving for Smoked Seafood

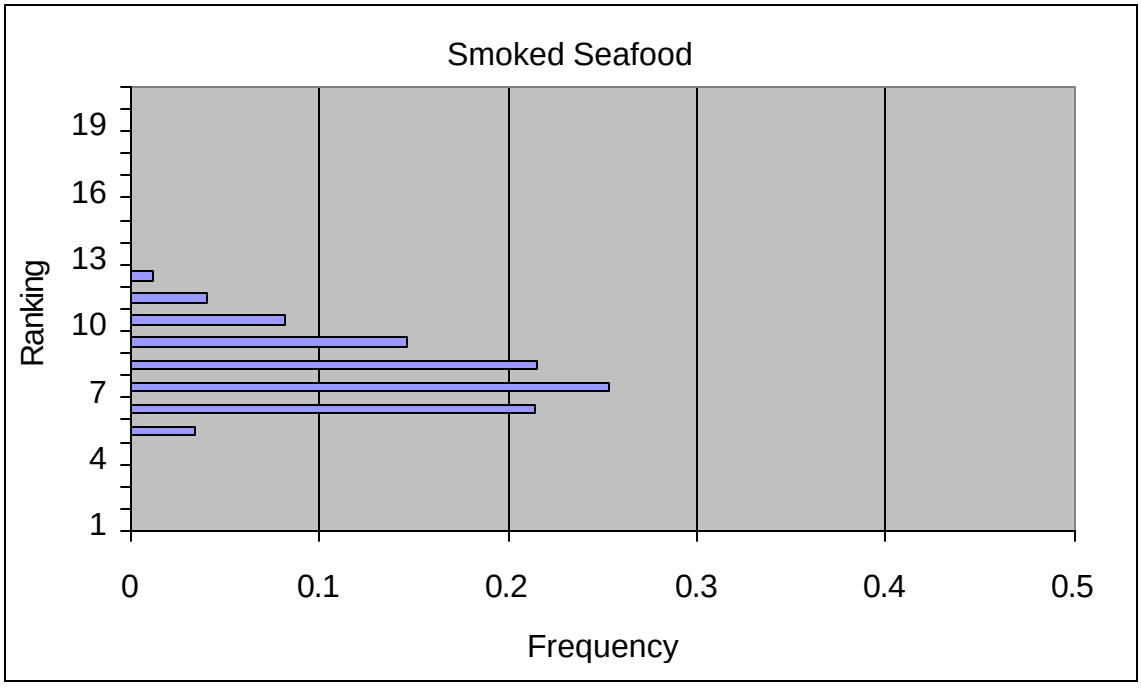

Figure V-2b. Rankings of total predicted listeriosis cases per annum for Smoked Seafood

Food Category: Raw Seafood

Raw Seafood has a low predicted relative risk per serving of causing listeriosis in the U. S. The foods in this category generally were characterized by a low annual number of servings, a low percent of the population consuming the food, a small serving size, and low contamination levels at retail. Exponential growth rates were moderate, but storage times were short. This combination of factors made the predicted estimates of exposure and illness typically low. Though the Raw Fish category has a low predicted relative risk of causing listeriosis in the U. S., 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 herring, ocean perch, pompano, porgy, tuna, sturgeon roe, clams, 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 1.8×10^8.

Thirty-one contamination studies (including seven from the U. S.) analyzed over 13,000 samples of uncooked seafood and seafood products, primarily to determine the presence or absence of *L. monocytogenes.* Only three studies had quantitative data. About one third of the studies were published after 1993. Comparing the percentage of contaminated samples from studies conducted before and after 1993 showed there was an increase over time (Appendix 7, Table 7-1). Thus, the use of pre-1993 data did not overestimate the overall contamination data used in the assessment.

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, red snapper, trout, and tuna, and both wild caught and aquacultured fish. 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 moderate (7.1%). Pathogen levels greater than 10^3 cfu/g were only rarely reported and the predicted percentage of servings with 10^6 to 10^9 cfu at retail was low.

Six papers provided *L. 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 per serving relative risk rankings for the Raw Seafood category were fourteenth for each of the three subpopulations. The range for the per serving ranking distribution (Figure V-3a) 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 rankings were seventeenth for the perinatal and intermediate-age subpopulations and twentieth for the elderly subpopulation. The range for the per annum ranking distribution (Figure V-3b) was narrow, indicating that there is also little uncertainty associated with the per annum predicted relative risk for Raw Seafood. This is consistent with the small number of servings consumed per year.

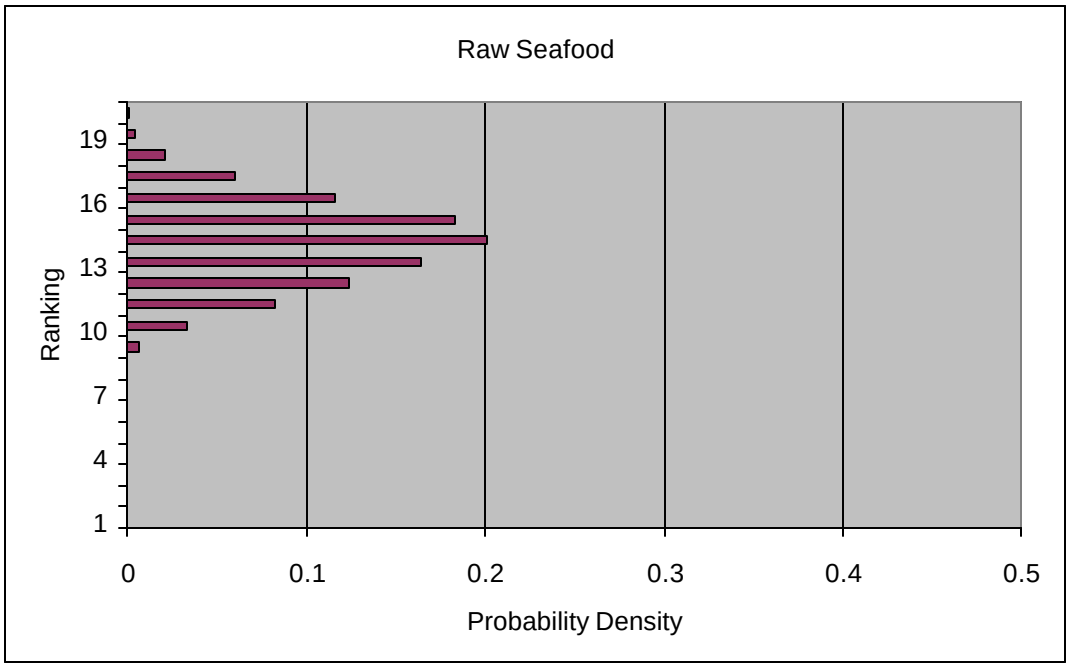

Figure V-3a. Rankings of total predicted listeriosis cases per serving for Raw Seafood

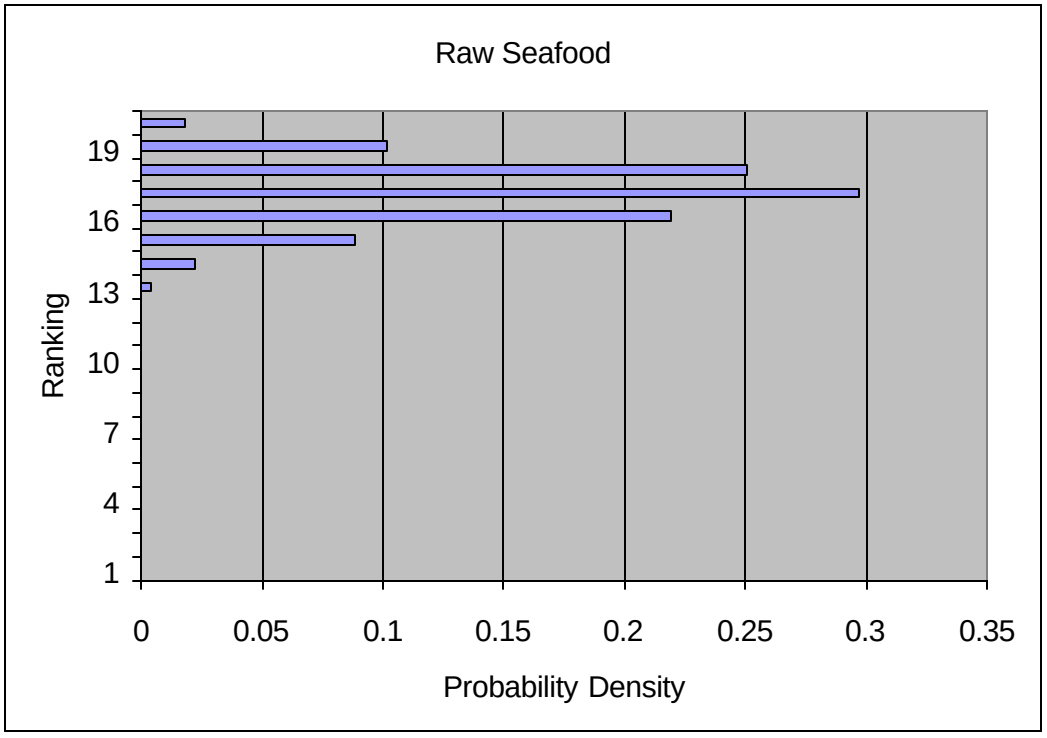

Figure V-3b. Rankings of total predicted listeriosis cases per annum for Raw Seafood

Food Category: Preserved Fish

Preserved Fish, including pickled, marinated, or dried products, had a high predicted relative risk of causing listeriosis in the U. S. on a per serving basis. The foods in this category had a relatively low annual number of servings and a low percent of the population consuming the food, but had moderate serving sizes and moderate contamination levels at retail. The frequency of contamination, especially higher levels of contamination, is high. 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 *L. 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. Higher 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 *L. monocytogenes* during different 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, and dried fish, such as sardines, 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 came from eleven non-U. S. studies with over 1,300 samples of fish and shrimp that were preserved by processes that did not involve smoking (heating, cooking, curing, pickling). Gravad trout and ceviche samples were included, though they are not indigenous to the U.S. Four of these studies contained quantitative data. The percentage of samples with detectable contamination was 10.2%, higher than for Raw Seafood, but less than Smoked Seafood. The predicted percentage of servings contaminated with 10^6 to 10^9 cfu at retail was moderate.

Over one third of the studies were conducted after 1993. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed a recent increase in

contamination rates (Appendix 7, Table 7-1). Thus, the use of pre-1993 data did not overestimate the overall contamination data used in the assessment.

Because these products do not allow growth of *L. monocytogenes,* storage times are not a factor in the levels of *L. monocytogenes* present at the time of consumption. Although not a factor, storage times were also believed to be relatively shorter than those for Smoked Seafood.

The number of servings and the percent of the population consuming Preserved Fish products were low, but the amount consumed per serving (predicted) was moderate and the contamination frequency was high. The high salt and acidity present in the final products prevent growth of *L. monocytogenes.* However, the microorganism is known to survive these conditions, particularly if held at refrigeration temperatures. The contamination rate at retail resulted in moderate levels of contamination at consumption.

The predicted median per serving relative risk rankings of the Preserved Fish category were sixth for the perinatal subpopulation and seventh for the intermediate-age and elderly subpopulations. The range for the per serving relative ranking distribution is relatively broad (Figure V-4a) with a bimodal distribution. This indicates that the per serving relative ranking for the Preserved Fish category has a moderate to high degree of uncertainty. The bimodal distribution may indicate that there are differences among different foods within this food category, and may require that the category be subdivided when 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 predicated median per annum relative risk rankings were thirteenth for each of the three subpopulations. The range for the per annum ranking distribution is less broad, but also has a bimodal distribution (Figure V-4b); again indicating a substantial degree of uncertainty or variability.

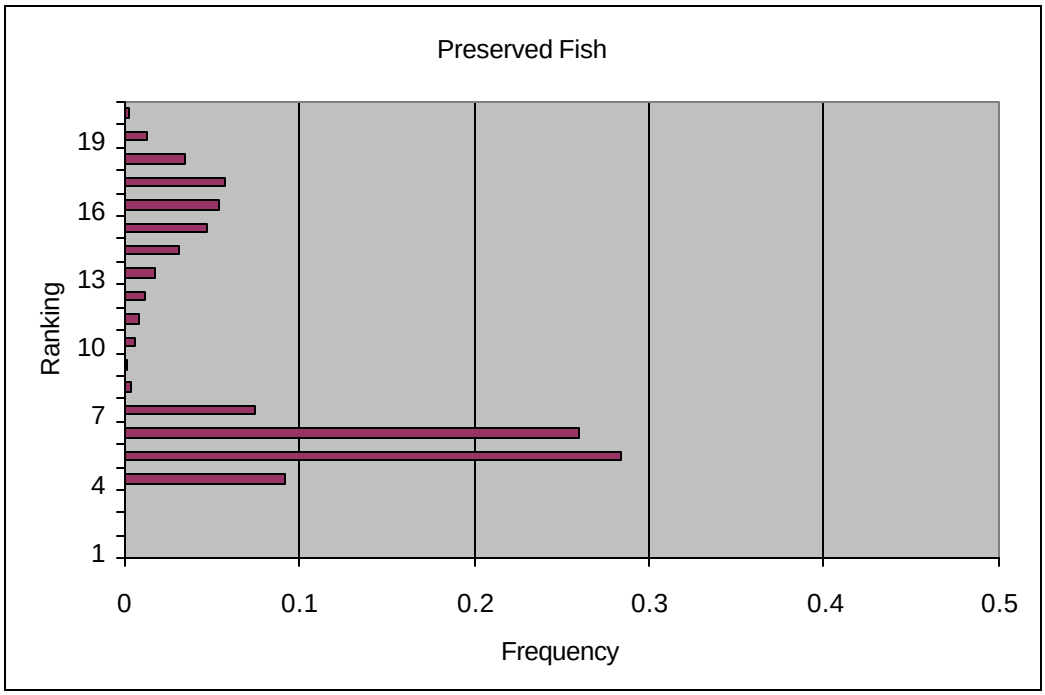

Figure V-4a. Rankings of total predicted listeriosis cases per serving for Preserved Fish

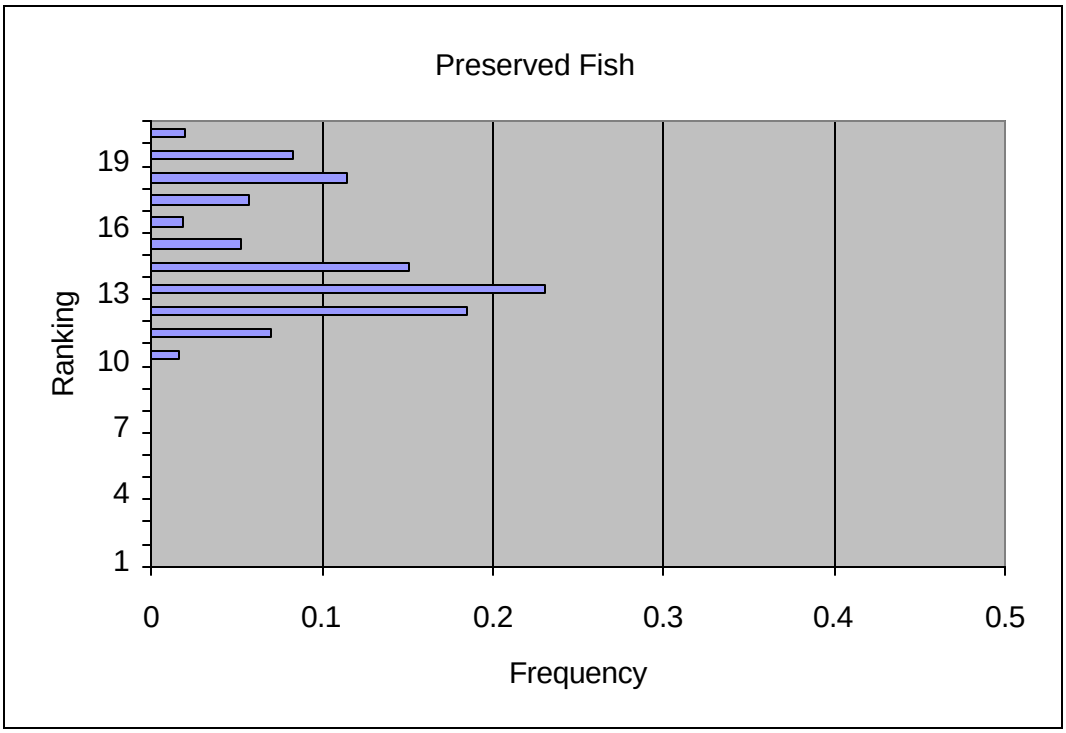

Figure V-4b. Rankings of total predicted listeriosis cases per annum for Preserved Fish

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 U. S. on a per serving basis. The foods in this category generally were consumed on a moderate basis with moderate serving sizes. The relatively high growth rate, which is one of the usual factors that drives listeriosis risk in foods, was offset by storage times that are short. It would be expected that the cooking step in the preparation of these foods would eliminate *L. monocytogenes.* However, foods in this category may often be stored refrigerated after cooking, allowing for recontamination and growth. It is assumed that contamination is a result of post-cooking recontamination. Contamination frequency and levels are low. Imitation crabmeat has been linked to an outbreak of listeriosis in Canada and shrimp was epidemiologically linked to an outbreak in the U. S. (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.

Eight contamination studies (including three studies from the U.S., two of which were quantitative) provided data mainly for cooked crab and shrimp. The data from these studies included more than 3,600 samples. Three of the studies were published after 1993. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed there was a substantial decrease (Appendix 7, Table 7-1). Thus, the relative risk may be lower than that calculated in the risk assessment. The percentage of samples with contamination was low 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 10^6 to 10^9 cfu at retail was low. Only three papers were found that reported growth for pasteurized crab and for cooked shrimp and lobster. However, this category had the fastest growth rate 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 per serving relative risk rankings of the Cooked RTE Crustaceans category were fifth for the perinatal and elderly subpopulations and sixth for the intermediate-age subpopulation. The range for the per serving ranking distribution for Cooked RTE Crustaceans (Figure V-5a) is moderately wide , generally normal, and concentrated in the higher risk ranks. 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 relative risk rankings were ninth for the intermediate-age and perinatal subpopulations and eighth for the elderly subpopulation. The range for the per annum ranking distribution is moderately broad and generally normally distributed (Figure V-5b), suggesting substantial variability or uncertainty in the extent to which this food category is consumed.

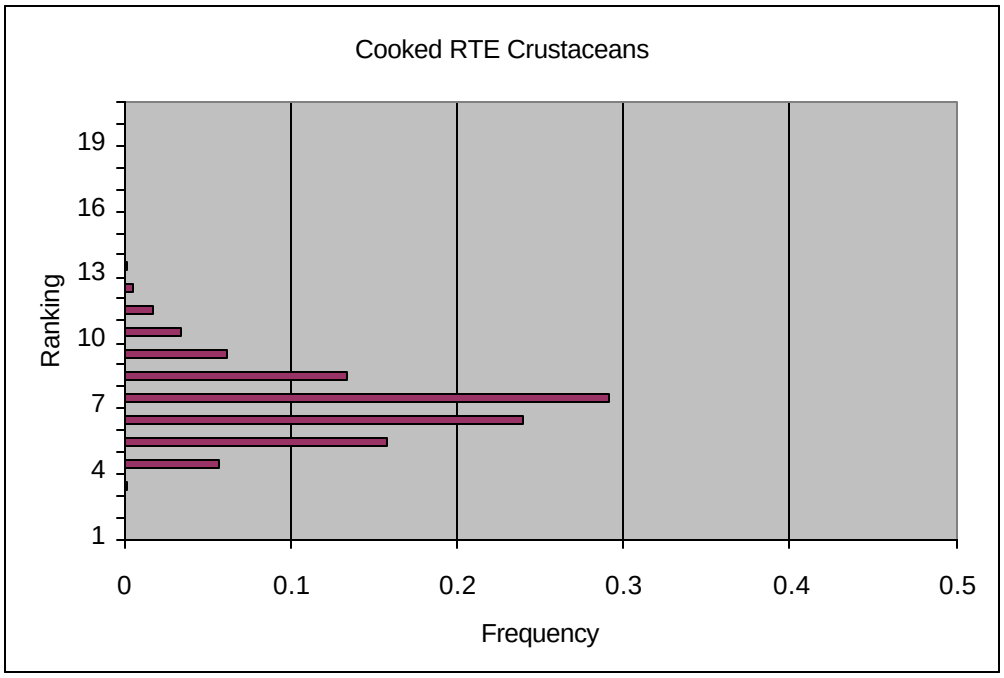

Figure V-5a. Rankings of total predicted listeriosis cases per serving for Cooked Ready-to-Eat Crustaceans

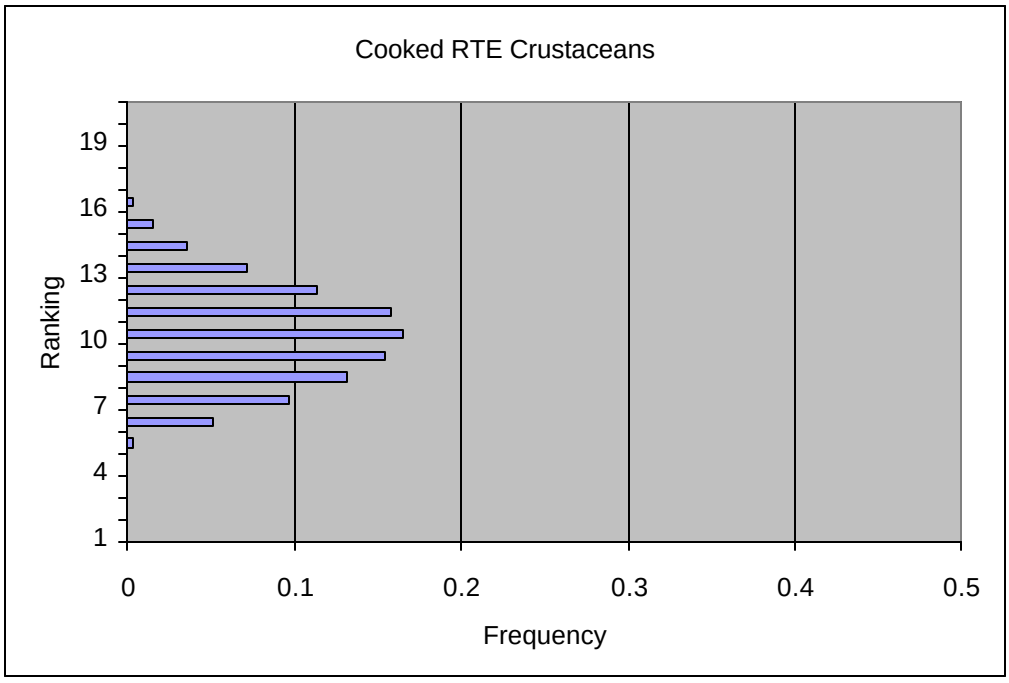

Figure V-5b. Rankings of total predicted listeriosis cases per annum for Cooked Ready-to-Eat Crustaceans

Food Category: Vegetables

Foods in the Vegetables category had a low predicted relative risk of causing listeriosis in the U.S. on a per serving basis. The Vegetables category is difficult to characterize because it encompasses such a diversity of products. The annual number of servings of Vegetables is high, while the median serving size, contamination level, and growth rate are relatively low, and the storage time and 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; coleslaw in Canada; frozen broccoli and cauliflower in the U.S.; potato salad in the U.S. and Australia; sweet corn and rice salad in Italy; and cauliflower, celery, tomatoes, and lettuce in the U.S. (epidemiological link) (Ryser, 1999a; Salamina *et al.*, 1996; 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 (coleslaw, other raw vegetables), the U.K. (English lettuce, vegetable rennet), Italy (pickled olives), and Finland (salted mushrooms) (Ryser, 1999a; Farber and Peterkin, 1991).

Foods included in the Vegetables category can be raw, pickled, or dried vegetables, as well as vegetable salads that contain raw vegetables and cooked vegetables (e. g., potatoes in potato salad), which may be allowed to cool and held before consumption. The median amount consumed per serving for this category is 28 g (i.e., ~ 1 ounce), and the annual total number of servings is 1.2×10^{11}. The relatively 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., potatoes).

Twenty-two contamination studies were found that examined non-meat containing salad mixtures or the individual raw vegetables. Of the 22, three studies were from the U.S. The vegetables analyzed were raw bean sprouts, broccoli, cabbage, carrot, celery, cilantro, coleslaw, cress, cucumber, fennel, legumes, lettuce, mushrooms, parsley, green peppers, onions, radish, scallion, tomato, and watercress. Over 3,300 samples were analyzed, and 1,363 provided quantitative contamination data. The percentage of samples with detectable contamination was a moderate 7.8%. The predicted percentage of servings with 10^6 to 10^9 cfu at retail was low. Over one third of the studies were published after 1993. Comparison of the percentage of contaminated samples from studies

conducted before and after 1993 showed there was a slight increase (Appendix 7, Table 7-1). Thus, the relative risk for this food category is not likely to be affected by inclusion of the earlier data.

Fourteen papers provided 22 estimates of growth rates for *L. 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; 0.5, 3 to 4, and 8 to 12 days for minimum, most likely, and maximum, respectively.

The predicted median per serving relative risk rankings for the Vegetables category were seventeenth for each of the three subpopulations. The range for per serving distribution for Vegetables (Figure V-6a) is narrow to moderately wide and concentrated in the lower risk ranks. This indicates that there is little uncertainty associated with the predicted per serving relative risk for the Vegetables category. The predicted median per annum relative risk rankings were eleventh for the perinatal and intermediate-age subpopulations and eighth for the elderly subpopulation. The per annum ranking distribution (Figure V-6b) had a relatively broad range, indicating uncertainty, and was shifted to the higher risk ranks compared with 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.

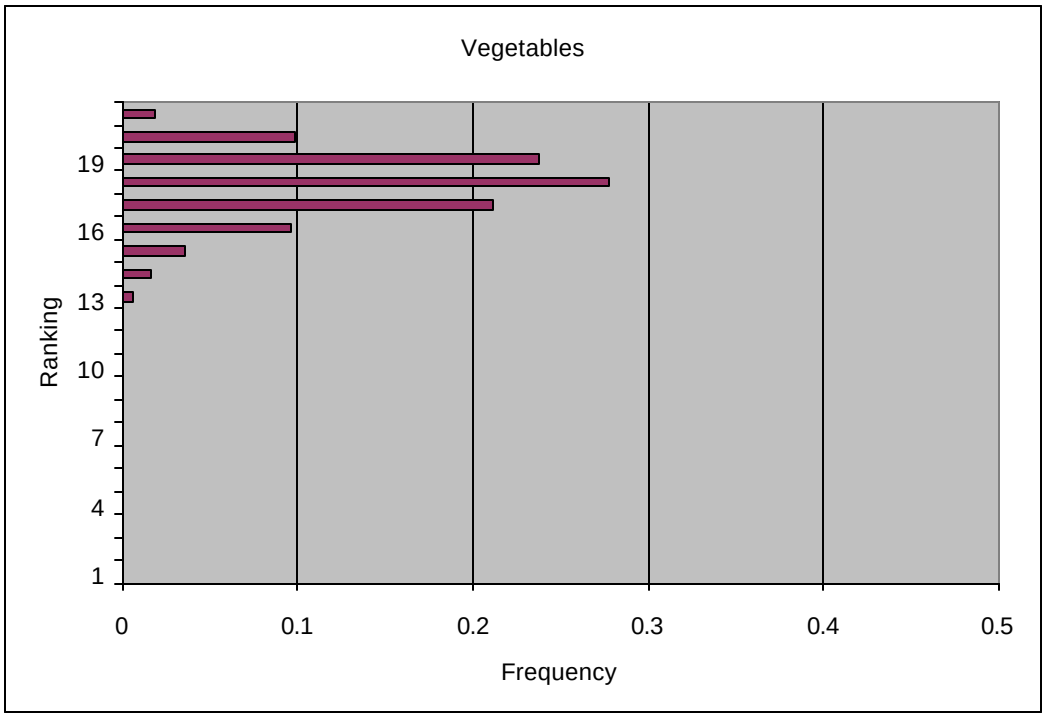

Figure V-6a. Rankings of total predicted listeriosis cases per serving for Vegetables

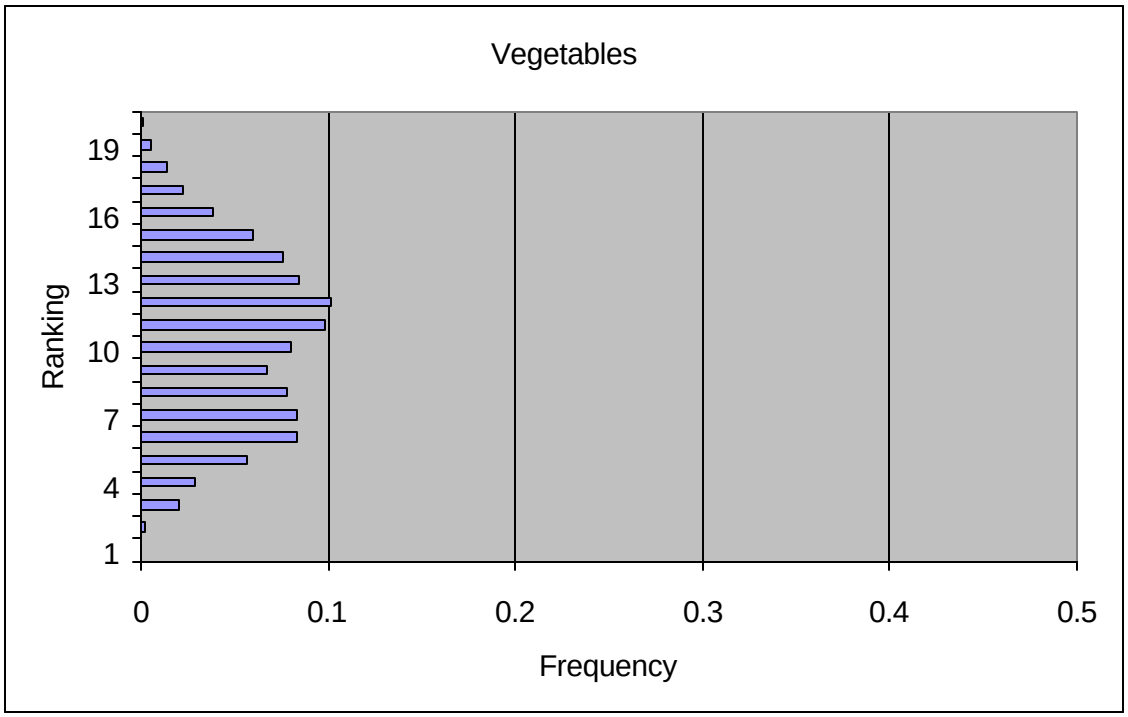

Figure V-6b. Rankings of total predicted listeriosis cases per annum for Vegetables

Food Category: Fruits

Foods in the Fruits category had a low predicted relative risk of causing listeriosis in the U. S. on a per serving basis. Fruits have not been linked to outbreaks or sporadic cases of listeriosis. The annual number of servings, median serving size and contamination frequency of Fruits are high, but the median contamination level and growth rate are low, and storage time is moderate.

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) and nuts with dried fruits and seeds. 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 5.0×10^{10}.

Only four studies (one quantitative) contained contamination data on Fruits, including dried fruits, fruit bars, nuts, edible seeds, fruit and nut salads, and unspecified fresh fruit and fruit products. One of the studies was from the U.S. All but one of the studies was published before 1993. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed there was a significant increase in contamination. The only fresh fruits with contamination data were chayote, peach, and plum, so this set of data may not be representative of other fresh fruits, such as apples, grapes, berries, pears, bananas, and melons. Available contamination studies also included data on chocolate-covered almonds, grated coconut, banana bars, and raisins.

The percentage of samples with detectable contamination was 10.7%, a high contamination frequency. The highest extent of contamination reported was 10 to 100 cfu/g for chayote, a tropical vine fruit. Slightly over 500 samples were analyzed, with about 40 being quantitatively analyzed. The predicted level of contamination per serving was low at retail.

One study was found that characterized the rate of *L. monocytogenes* growth in orange juice. When the pH was less than 4.8, *L. monocytogenes* did not grow. At pH 5.0, growth was slow, at 0.04 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 per serving relative risk rankings for the Fruits category were eighteenth for each of the three subpopulations. The range for the ranking distribution for Fruits (Figure V-7a) is concentrated in the lower risk ranks with a single mode. The predicted median per annum relative risk rankings for Fruits were fourteenth for the perinatal and elderly subpopulations and sixteenth for the intermediate age subpopulation (Figure V-7b). 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 and apparently bimodal, indicating moderate to substantial uncertainty in the predicted relative risk ranking. This likely reflects both the limited data available 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.

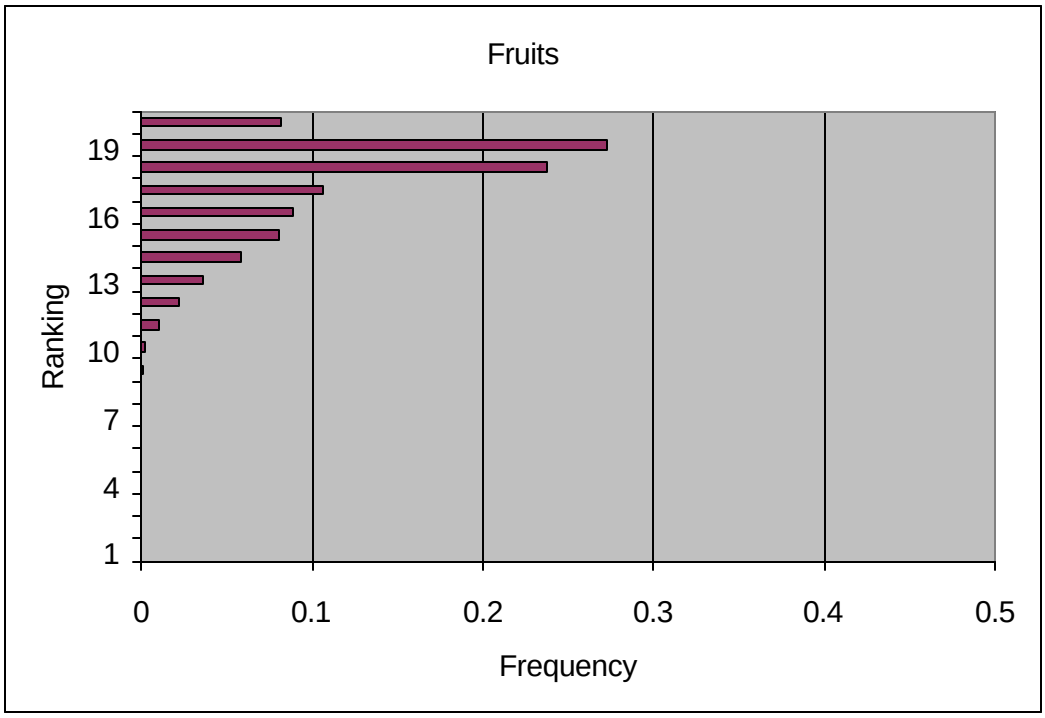

Figure V-7a. Rankings of total predicted listeriosis cases per serving for Fruits

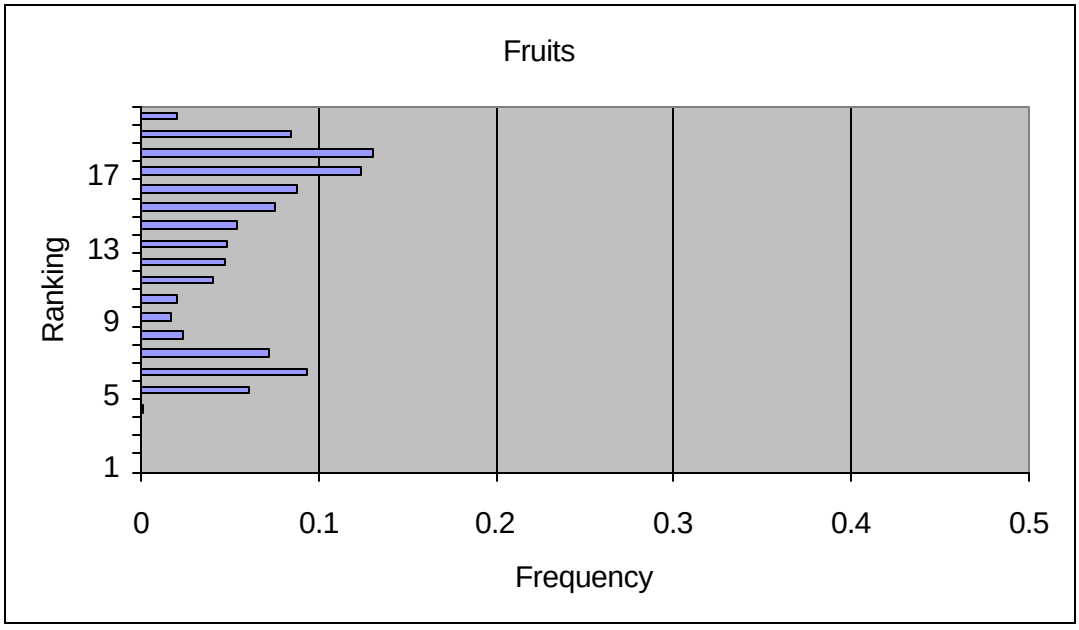

Figure V-7b. Rankings of total predicted listeriosis cases per annum for Fruits

Food Category: Soft Mold-Ripened and Blue-Veined Cheese

Soft Mold-Ripened and Blue-Veined Cheese, like Camembert, Brie, Roquefort, blue and Gorgonzola, had a moderate predicted relative risk of causing listeriosis in the U. S. on a per serving basis. There are a low number of annual servings and small serving sizes. Contamination frequencies and levels at retail and growth rates during storage were moderate. However, this was offset by long storage times. Soft Mold-Ripened and Blue-Veined Cheese have been linked to outbreaks of listeriosis in France, Switzerland, and Denmark; epidemiologically linked to an outbreak in the U.S.; and linked to sporadic cases in Belgium, Canada, and the U.K. (Ryser, 1999a; Jensen *et al.*, 1994; Riedo *et al.*, 1994; Art and Andre, 1991; Farber and Peterkin, 1991).

The median amount consumed per serving for this category is 17 g (just over 0.5 ounce), and the annual number of servings is 2.4×10^8. Data are not available to describe the small proportion of U.S. or imported cheese that is made from unpasteurized fluid milk. Market data indicate that the U.S. imports approximately 50% of the Camembert and Brie cheese and under 20% of the blue cheese (including Gorgonzola) sold in the U.S. (National Cheese Institute, 1998).

Seven non-U.S. studies (three post-1993) provided contamination data for this category, of which three studies provided quantitative data. A few of the studies indicated whether the cheese was made from pasteurized or unpasteurized milk, but the majority did not specify how the milk was treated. Data were also received from a U.S. state regulatory agency. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 (Appendix 7, Table 7-1) indicated that there was a decrease in the frequency of contamination after 1993. This, in turn, may have led to an overestimation of the predicted relative risk for this food category.

The cheeses that were analyzed in these studies were rarely described in detail, but included Gorgonzola, blue-veined, and mold-ripened cheese. The percentage of samples with detectable contamination was a moderate 5.7%. About 0.5% of the samples had counts greater than 1000 cfu/g. The predicted percentage of servings with 10^6 to 10^9 cfu at retail was moderate.

Seven growth rates from five studies were found and the average growth rate at 5°C was moderate (0.06 logs/day). There was wide variability among the growth rates in this category because of the

diverse nature of the cheeses, particularly in relation to pH and the potential for more rapid growth near the surface of the cheeses. Storage times for these types of cheeses were long; the most likely and maximum storage times assigned were 6 to10 days and 15 to 45 days, respectively.

The predicted median per serving relative risk rankings for the Soft Mold-Ripened and Blue-Veined Cheese category were ninth for each of the three subpopulations. The range of the per serving distribution for Soft Mold-Ripened and Blue-Veined Cheese is relatively narrow (Figure V-8a), with a normal distribution and a single mode. This indicates that there was a reasonable degree of certainty associated with the predicted per serving ranking for the Soft Mold-Ripened and Blue-Veined Cheese. The predicted median per annum relative risk rankings for the Soft Mold-Ripened and Blue-Veined Cheese category (Figure V-8a) were fourteenth for the intermediate-age and fifteenth for the perinatal and elderly subpopulations. The distribution for the per annum predicted relative risk (Figure V-8b) was similarly shaped, but centered on lower risk ranks. This shift reflects the low number of annual servings and small serving sizes for foods in this category.

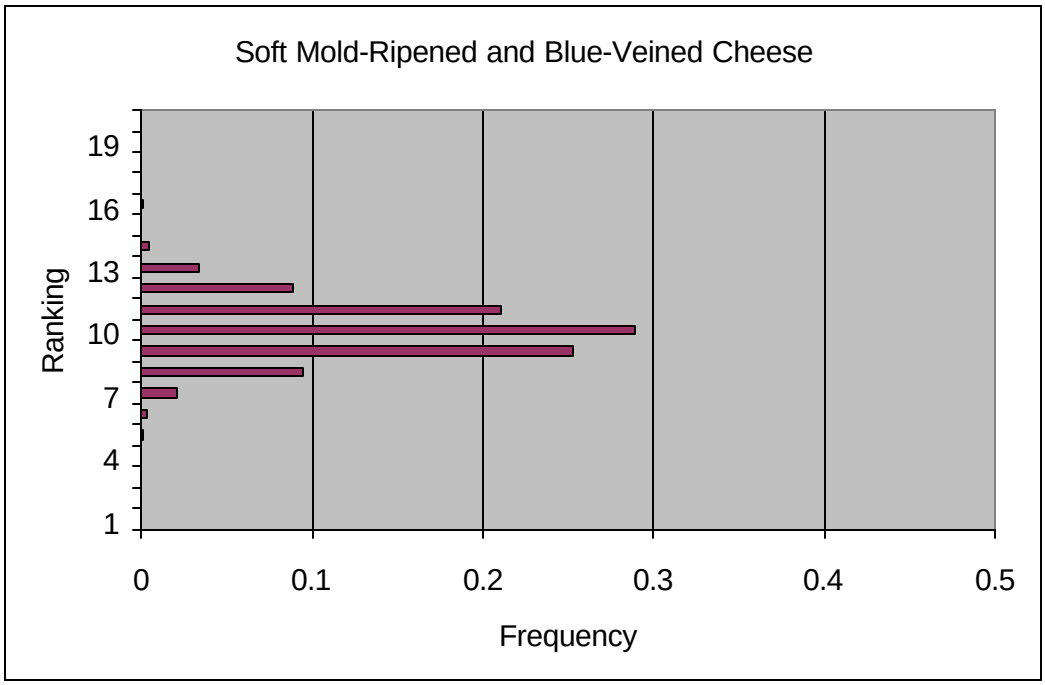

Figure V-8a. Rankings of total predicted listeriosis cases per serving for Soft Mold-Ripened and Blue-Veined Cheese

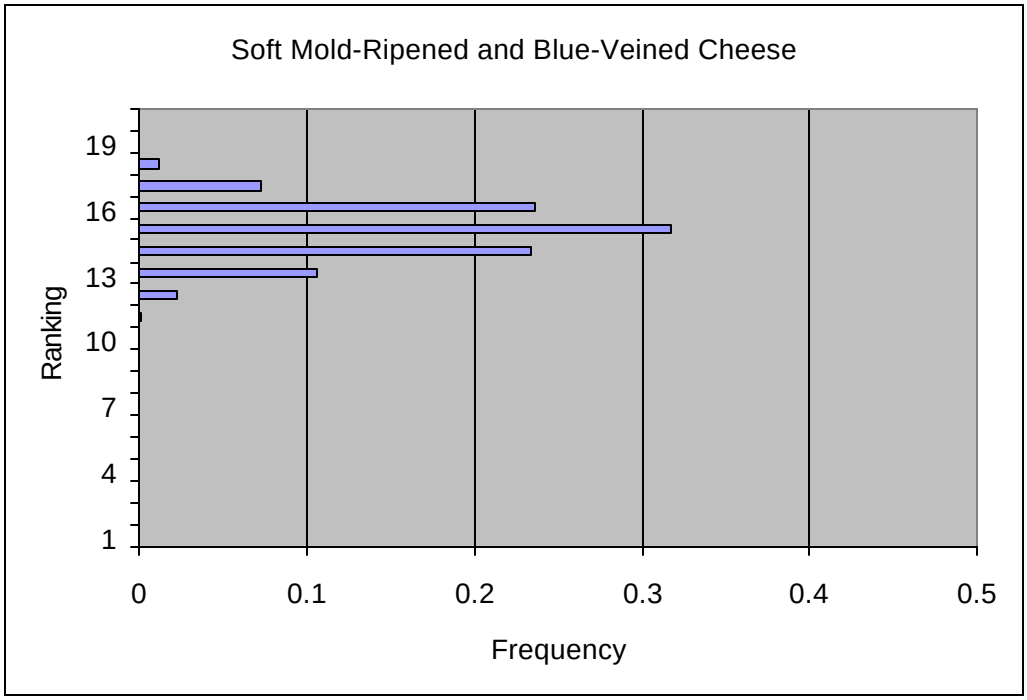

Figure V-8b. Rankings of total predicted listeriosis cases per annum for Soft Mold-Ripened and Blue-Veined Cheese

Food Category: Goat, Sheep, and Feta Cheese

Goat, Sheep, and Feta Cheese had a low predicted relative risk of causing listeriosis on a per serving basis. The low level of risk can be attributed to the low number of annual servings, small amounts consumed, and inactivation of the pathogen during storage. This category includes soft, semi-soft, and hard cheeses.

Goat cheese has been linked to sporadic cases of listeriosis in the U.K. (McLauchlin *et al.*, 1990). There have not been any confirmed reports of sporadic cases or outbreaks associated with Feta, Goat, and Sheep Cheeses in the U.S. There are no market data to describe the percentage of these cheeses that are made from pasteurized vs. unpasteurized milk, either in the U.S. or in other countries. In 1997, about 20% of the feta cheese sold in the U.S. was imported (National Cheese Institute, 1998).

The median amount consumed per serving for this category is 26 g (slightly less than 1 ounce), and the annual number of servings is 2.6×10^8. Five contamination studies (four non-U.S. and published prior to 1993) were available for this category. Only two of the studies identified whether the cheese was made from pasteurized or unpasteurized milk. Three of the studies provided quantitative data. The percentage of samples with detectable contamination was 7.0%, a moderate contamination frequency. The predicted percentage of servings with 10^6 to 10^9 cfu at retail was moderate.

There were three growth studies found for this food category. They indicated that there is little or no increase and, in many cases, a decrease in *L. monocytogenes* contamination over time. This appears to be due to the relatively high level of salt in these cheeses. An average inactivation rate of 0.008 logs/day at 5°C was used in the modeling. Storage times were long, with the assumed most likely storage time of 6 to10 days and the maximum time of 15 to 45 days.

The median per serving predicted relative risk rankings for the Goat, Sheep, and Feta Cheese category were sixteenth for all three subpopulations. The range for the ranking distribution for Goat, Sheep, and Feta Cheese (Figure V-9a) was moderately wide and concentrated in the lower risk numbers with a single mode. This indicates that there is a modeate degree of uncertainty associated with the predicted relative risk ranking for the Goat, Sheep, and Feta Cheese category. This reflects the limited amount of data available pertaining to this food category. The median per annum

predicted relative risk rankings were eighteenth for the perinatal and intermediate-age subpopulations and seventeenth for the elderly subpopulation. The range of the per annum ranking distribution (Figure V-9b) was narrower and shifted to the lower risk rankings compared with the per serving rankings. This shift likely reflects the small number of servings and the small serving sizes associated with this food category. The narrow range of the distribution indicates that there is little uncertainty associated with the predicted per annum relative risk ranking.

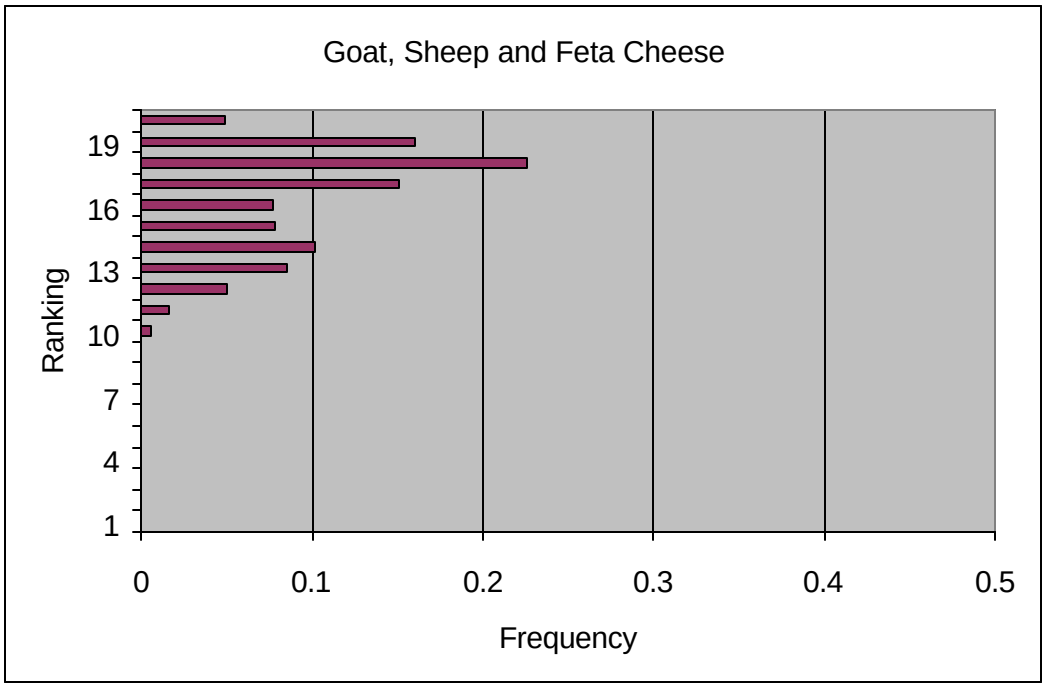

Figure V-9a. Rankings of total predicted listeriosis cases per serving for Goat, Sheep and Feta Cheese

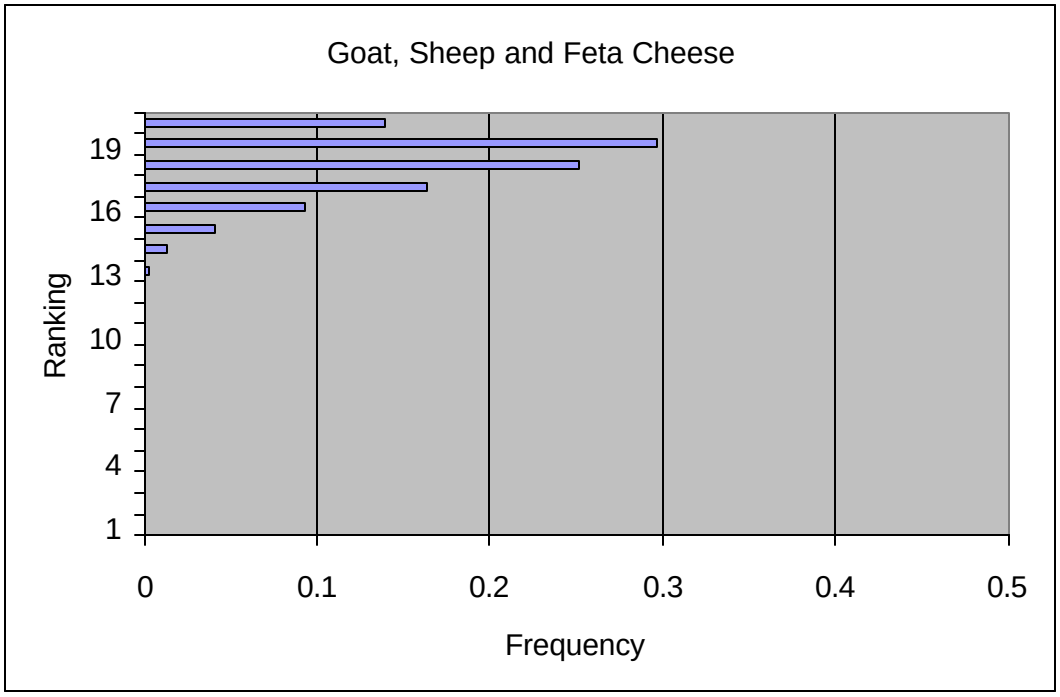

Figure V-9b. Rankings of total predicted listeriosis cases per annum for Goat, Sheep, and Feta Cheese

Food Category: Fresh Soft Cheese

Fresh Soft Cheese (e.g., queso fresco) had a high predicted relative risk of causing listeriosis on a per serving basis. The high predicted relative risk is associated with the high contamination frequency, high contamination levels at retail, moderate growth rate during storage, and long storage time. Fresh Soft Cheese (suspected to be made from unpasteurized milk) has been linked to both outbreaks and sporadic cases of listeriosis in the U.S. (Ryser, 1999a; Linnan *et al.*, 1988), including an outbreak in Los Angeles in 1985.

This category represents the following soft cheeses: queso asiadero, queso chihuahua, queso fresco, queso para freir, queso blanco fresco, queso de puna, requeson, and Puerto Rican white cheese. The consumption data included queso asadero, queso chihuahua, queso fresco, and Puerto Rican white cheese (queso del pais, blanco). The median amount consumed per serving for this category is 34 g (just over 1 ounce), and the annual number of servings is 1.3×10^8. Data are not available on the proportion of Fresh Soft Cheese made from unpasteurized milk that is consumed in the U.S.

Data from two contamination studies and a U.S. state regulatory agency were used to model the frequency of contamination for the Fresh Soft Cheese category. However, there were no quantitative data on the extent of contamination for this category. Therefore, a distribution for the extent of contamination had to be assumed. Data on contamination levels in soft ripened cheese made with unpasteurized milk were used as a surrogate. This is a purposefully conservative (worst-case) assumption that may have increased the relative risk attributed to this food category. Almost one half of the studies considered were published after 1993. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed there was a substantial increase over time, which could lead to the risk assessment underestimating the relative risk associated with Fresh Soft Cheese.

Only one growth rate study of these cheeses was available. That study reported a moderate growth rate of 0.14 logs/day when adjusted to 5° C. The assumed storage times for Fresh Soft Cheese were 6 to 10 days and 15 to 45 days for most likely and maximum times, respectively.

The median per serving predicted relative risk rankings for the Fresh Soft Cheese category were first for the perinatal and elderly subpopulations and second for the intermediate-age subpopulation. The range for the predicted per serving risk rankings for Fresh Soft Cheese (Figure V-10a) is quite narrow and concentrated in the lower rankings (i.e., greatest relative risk). This indicates that there is little uncertainty associated with the per serving predicted relative risk for the Fresh Soft Cheese category. The median per annum predicted relative risk rankings for the Fresh Soft Cheese category were sixth, seventh, and eleventh for the perinatal, intermediate-age, and elderly subpopulations, respectively. The range for the per annum ranking distribution is slightly broader (Figure V-10b), and centered in the middle of the risk rankings. The broader range indicates that there was a little 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.

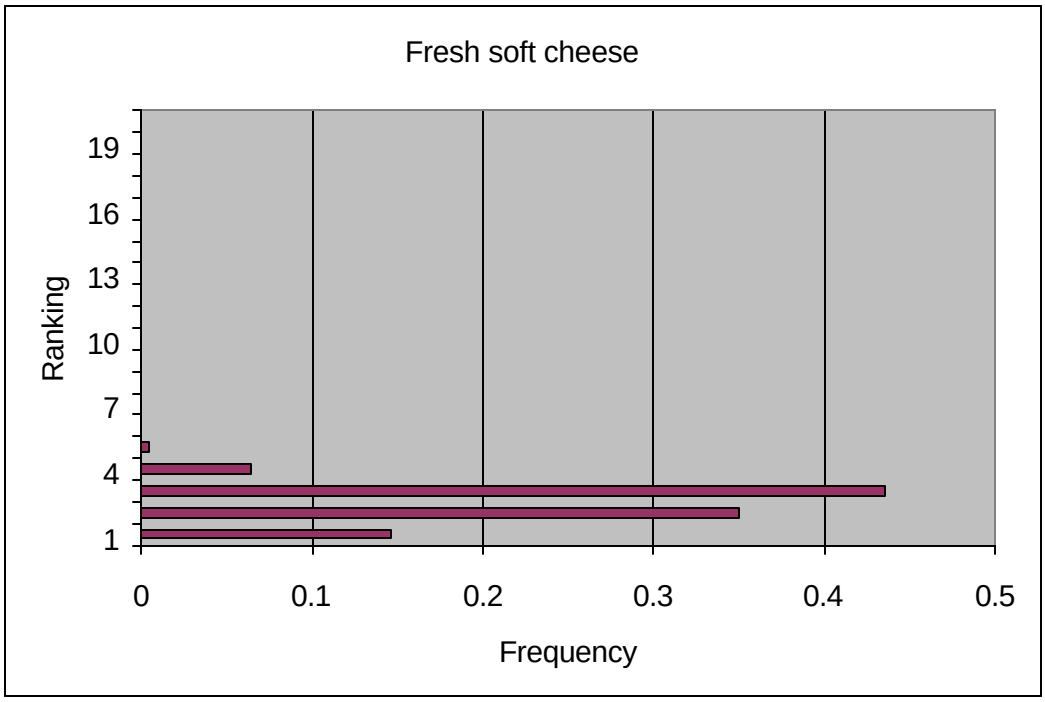

Figure V-10a. Rankings of total predicted listeriosis cases per serving for Fresh Soft Cheese

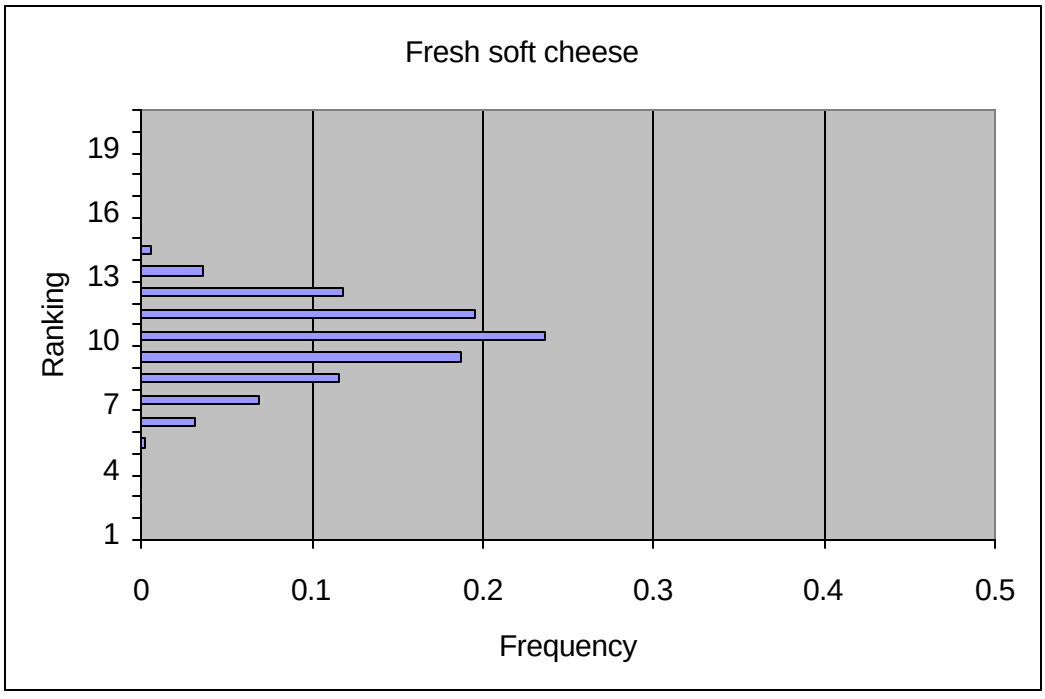

Figure V-10b. Rankings of total predicted listeriosis cases per annum for Fresh Soft Cheese

Food Category: Heat-Treated Natural Cheese and Processed Cheese

The Heat-Treated Natural Cheese and Processed Cheese category had a low predicted relative risk of causing listeriosis on a per serving basis This category have a moderate growth rate during storage , whereas the median amount consumed, contamination frequency, and contamination levels at retail are low. There was a sporadic listeriosis case in the U.S. 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.

This category represents natural cheeses required by regulations to be manufactured from pasteurized milk and pasteurized process cheese and cheese spreads. The natural cheeses include soft unripened cheese (such as cottage cheese, ricotta, impastata, cream cheese, and American-type neufchatel), mozzarella and string cheese, muenster, and monterey jack. The Heat-Treated Natural Cheese and Processed Cheese category includes consumption data for mozzarella, cottage cheese, ricotta, cream cheese, muenster, monterey jack, and process cheeses and cheese spreads. The median amount consumed per serving for this category is 21 g (about 0.75 ounce), and the annual total number of servings is 1.8×10^{10}.

There were five contamination studies available for this category, of which one was from the U.S. A total of 666 samples were analyzed with only 1.2% found to contain *L. monocytogenes*. Two of the five studies were published after 1993. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed an increase in contamination rates over time. Insufficient quantitative data were available to directly derive a distribution for the extent of contamination for this food category. Contamination data from pasteurized milk were used as a surrogate to model the extent of contamination for the Heat-Treated Natural Cheese and Processed Cheese category. The predicted percentage of servings with 10^6 to 10^9 cfu at retail was low.

The diversity of this category makes it difficult to make generalizations about growth rates. Seven experimental studies provided 25 growth rate estimates. Overall, a lower growth rate of 0.10 logs/day at 5°C was used, but the distribution included negative values indicating inactivation of *L. monocytogenes* during storage. The research literature showed both growth and decline of *L.*

monocytogenes in cottage cheese, depending upon the pH. Ricotta cheese permitted rapid growth, whereas *L. monocytogenes* levels declined in cream cheese and processed cheeses. Storage times were long for this category; the assumed most likely time was 6 to 10 days and the maximum time was 15 to 45 days.

The predicted median per serving relative risk rankings for the Heat-Treated Natural Cheese and Processed Cheese category were fifteenth for each of the three subpopulations. The predicted median per annum relative risk rankings were tenth for each of the three subpopulations. Both ranking distributions for Heat-Treated Natural Cheese and Processed Cheese (Figures V-11a and V-11b) are moderately wide and approximately normal. The degree of uncertainty was 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 Heat-Treated Natural Cheese and Processed Cheese category. This is reinforced by the facts that there was only limited data that were available for this food category and that there is substantial diversity among the foods in this food category. This is another food category that would likely benefit from being subdivided if additional exposure data were available.

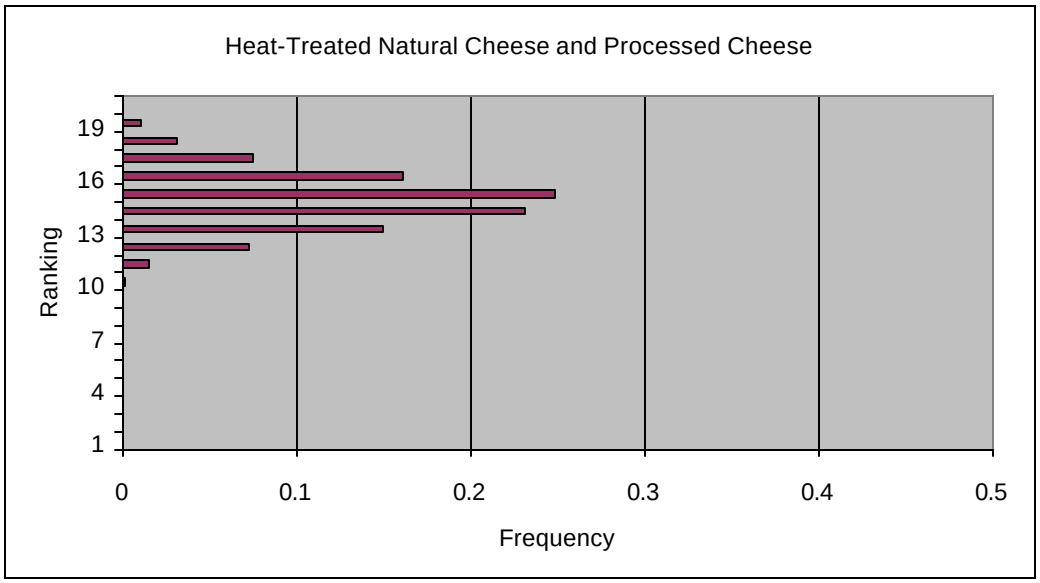

Figure V-11a. Rankings of total predicted listeriosis cases per serving for Heat-Treated Natural Cheese and Processed Cheese.

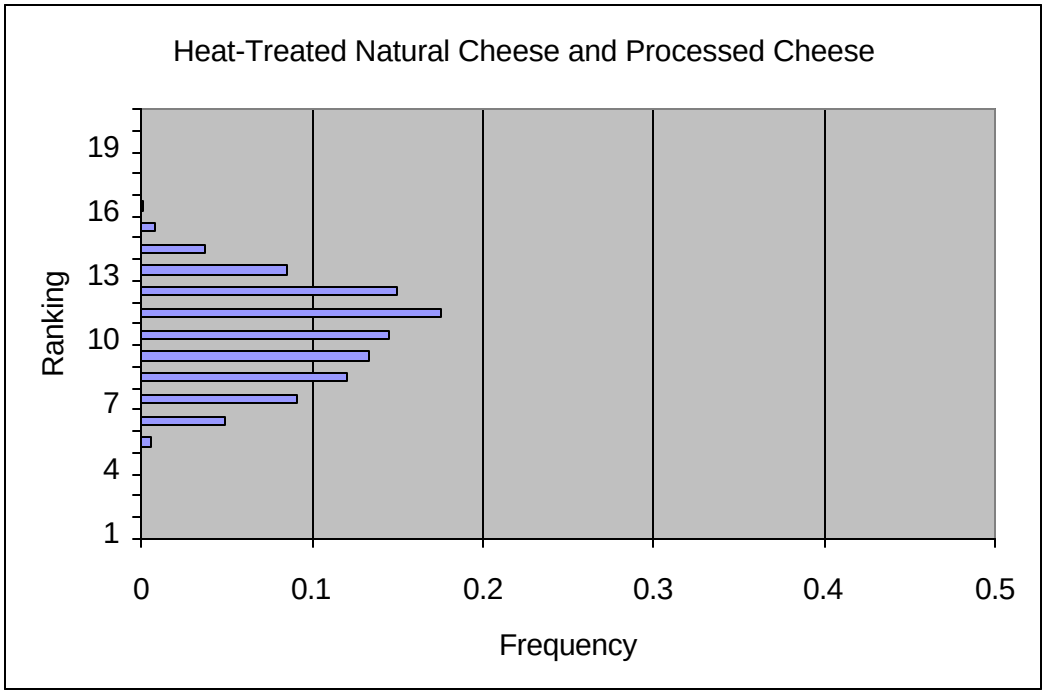

Figure V-11b. Rankings of total predicted listeriosis cases per annum for Heat-Treated Natural Cheese and Processed Cheese

Food Category: Aged Cheese

Aged Cheese had a low predicted relative risk of causing listeriosis on a per serving basis. The low relative risk can be attributed to the low contamination frequency, low contamination level at retail, and little, if any, growth during storage, despite the high amount of product consumed and long storage times. These types of cheeses typically have very low moisture content and a high salt content, both of which limit the growth of *L. monocytogenes*.

This cheese category includes consumption data for a variety of cheese types, including hard cheese, semi-hard cheese, and semi-soft cheeses. The median amount consumed per serving for this category is 27 g (slightly less than 1 ounce) and the annual number of servings is 1.4×10^{10}.

Eight studies (one study from the U.S.) provided contamination data for this category, two of which were quantitative studies. One quarter of the studies were published after 1993. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed there was a decrease over time (Appendix 7, Table 7-1). The inclusion of older contamination data may have increased the predicted relative risk attributed to this food category.

The contamination data primarily include semi-soft and hard cheeses. The percentage of samples with detectable contamination was 1.9%, which is in the lower contamination range. About 1,000 of over 3,300 samples were quantitatively analyzed.

A total of nine studies were found that estimated the growth rate of *L. monocytogenes* in aged cheeses. Six studies found no growth or a decline in the initial population during storage for these cheeses. Based upon three of these studies, a negative growth rate of 0.03 logs/day at 5°C was calculated for this category. 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 predicted relative risk rankings for the Aged Cheese category were nineteenth for all three subpopulations. The median per annum predicted relative risk rankings for the Aged Cheese category were nineteenth for the perinatal and intermediate-age subpopulations and eighteenth for the elderly subpopulation. The per serving ranking distribution (Figure V-12a) was

moderately narrow, and may have been bimodal. This may reflect the large number of samples in which *L. monocytogenes* were not detected. The per annum ranking distribution (Figure V-12b) was broader, with a more pronounced bimodality. The broader range for the per annum sample indicates that there was uncertainty in the ranking for the Aged Cheese category, possibly due to the high level of consumption amplifying the variability observed in the initial levels of contamination. This uncertainty could be potentially reduced through the acquisition of new quantitative data.

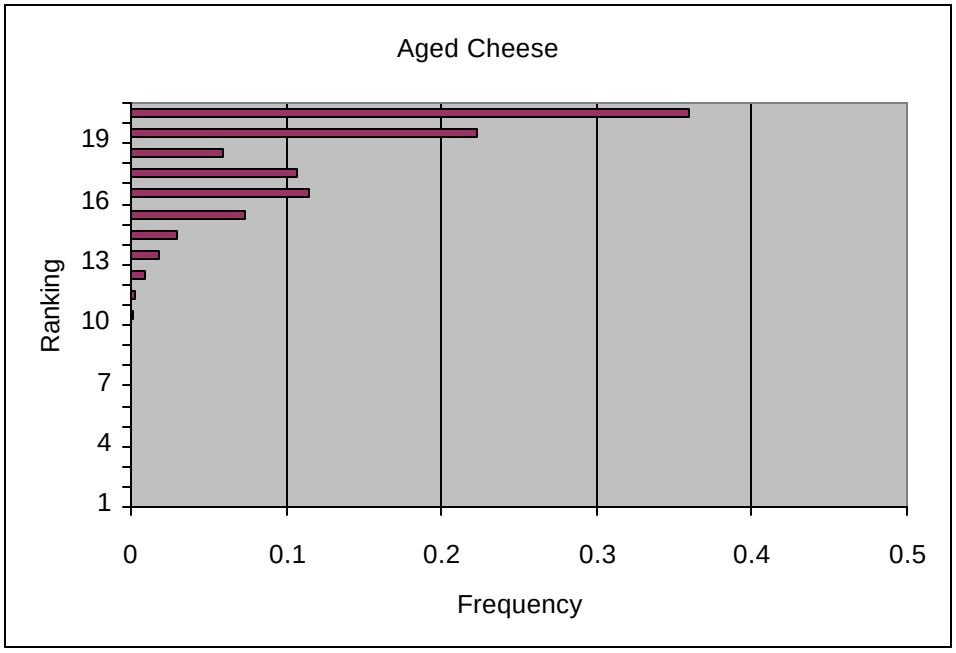

Figure V-12a. Rankings of total predicted listeriosis cases per serving for Aged Cheese

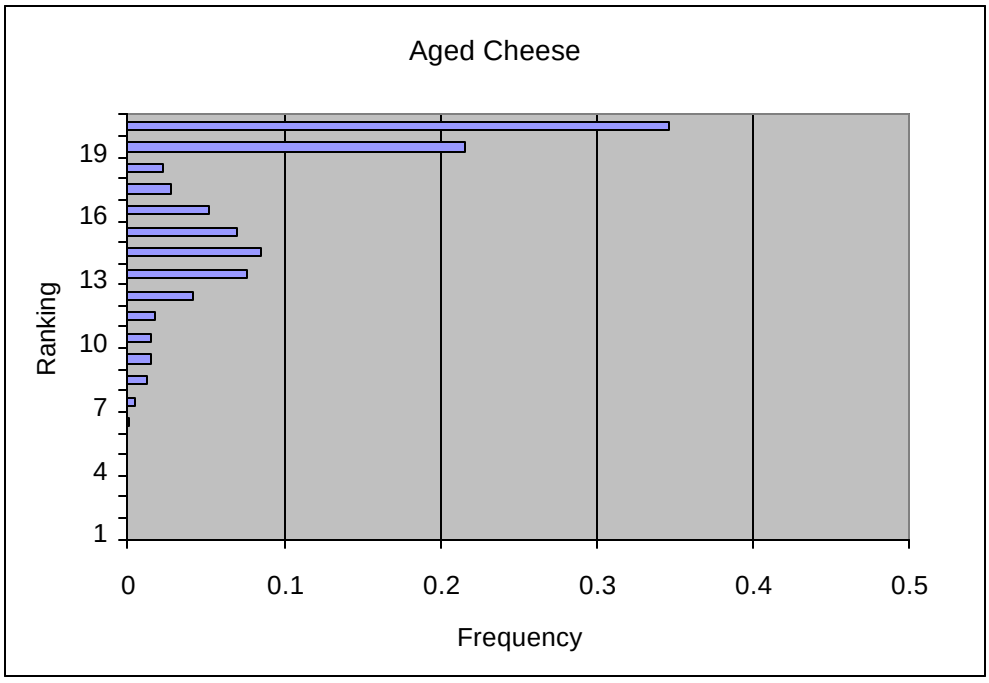

Figure V-12b. Rankings of total predicted listeriosis cases per annum for Aged Cheese

Food Category: Pasteurized Fluid Milk

Pasteurized fluid milk had a moderate predicted relative risk of causing listeriosis on a per serving basis. Contamination frequency at retail for this category is low (mean = 0.12% based on North American data) due to pathogen inactivation during pasteurization. However, this is offset somewhat by the large serving sizes associated with this product. 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. 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. Accordingly, control of recontamination is likely to be a key factor in further reduction in risk. Experimental studies have demonstrated that pasteurized milk will support growth of *L. monocytogenes* to high levels at refrigeration temperatures within the normal shelf-life of the food. The number of servings predicted to contain 10^6 to 10^9 CFU/g after refrigerated storage is low. However, because of the limited number of quantitative data available, the uncertainty associated with these values required use of a broad distribution for post storage contamination levels. This could have led to an overestimation of the relative risk associated with this product. 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).

The Pasteurized Fluid Milk category includes various types of cow's milk, goat's milk, chocolate milk, other flavored milk, and malted milk. The total annual number of servings consumed is 8.7 x 10^{10}. This is second only to vegetables as the most commonly consumed food category. Products in this category are eaten 4 to 100 times more often than foods in most other categories.

Over 10,400 samples from 25 studies were available to provide data on the frequency of detectable contamination and most of these studies were from samples collected outside of the US. However, less than 1% of the milk consumed in the US is imported (Frey, 2000a), but, only two reports (Kozak *et al.*, 1996; Frey and IDFA, 2000) of surveys conducted in the U.S. and one survey from Canada were available to estimate the frequency of contamination in North America. None of these reports contained sufficient quantitative data to allow elucidation of a predicted distribution of levels of *L.*

monocytogenes. Only two international studies were available that provided quantitative data (107 samples). These had to be used to develop the distribution for the levels of *L. monocytogenes* that would likely be encountered in contaminated samples. This increased substantially the degree of uncertainty associated with predicted relative risk, and could have led to an overestimation of the relative risk associated with this group of foods.

Eight studies were published after 1993. Comparison of the studies conducted before and after 1993 showed there was a substantial decrease in the percentage of contaminated samples. However, since the data used for calculating contamination frequency were limited to recent studies, the increased focus on *L. monocytogenes* since 1993 would not be a factor.

Five laboratory investigations of the growth rate of *L. monocytogenes* in unpasteurized, pasteurized, 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. The 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 tenth for each of the three subpopulations. The range for per serving ranking distribution for Pasteurized Fluid Milk was moderately broad (Figure V-13a), and normally distributed. Thus, a moderate degree of uncertainty was associated with the predicted per serving relative risk ranking. This reflects a general lack of quantitative data related to the levels of *L. monocytogenes* in contaminated samples. While the frequency of contamination was based solely on North American data, the extent of contamination had to be based on both North American and non-North American data, which does introduce a degree of uncertainty.

The median per annum predicted relative risk rankings for Pasteurized Fluid Milk were second, third, and second for the perinatal, intermediate-age, and elderly subpopulations, respectively.

The increase in the predicted per annum relative risk ranking compared to the per serving ranking appears to reflect the interaction of two factors. The first is the fact that pasteurized milk is one of the most extensively consumed food categories in terms of both the frequency of

consumption and the serving sizes. The second is the general lack of quantitative data related to the levels of *L. monocytogenes* in contaminated pasteurized milk. These result in the small percentage of contaminated servings being assigned a high degree of uncertainty in relation to the extent of contamination. While the per annum ranking distribution is relatively narrow (Figure V-13b), it is strongly influenced by the highly uncertain values in the "tails" of the broad distributions that had to be incorporated into the models. Thus, there is a high degree of uncertainty associated with the per annum ranking, and there is a strong potential that the low predicted per annum (high risk) ranking is an unintended consequence of the lack of sufficient quantitative data. Definitive interpretation of the per annum ranking will have to await the acquisition of additional quantitative data. In the interim, the predicted per serving ranking is considered a better estimate of the relative risk associated with this food category. Because recontamination is presumably a relatively rare event that involves low numbers of *L. monocytogenes*, proper storage temperatures and punctual consumption reduces even further, the low probability of listeriosis associated with this food category.

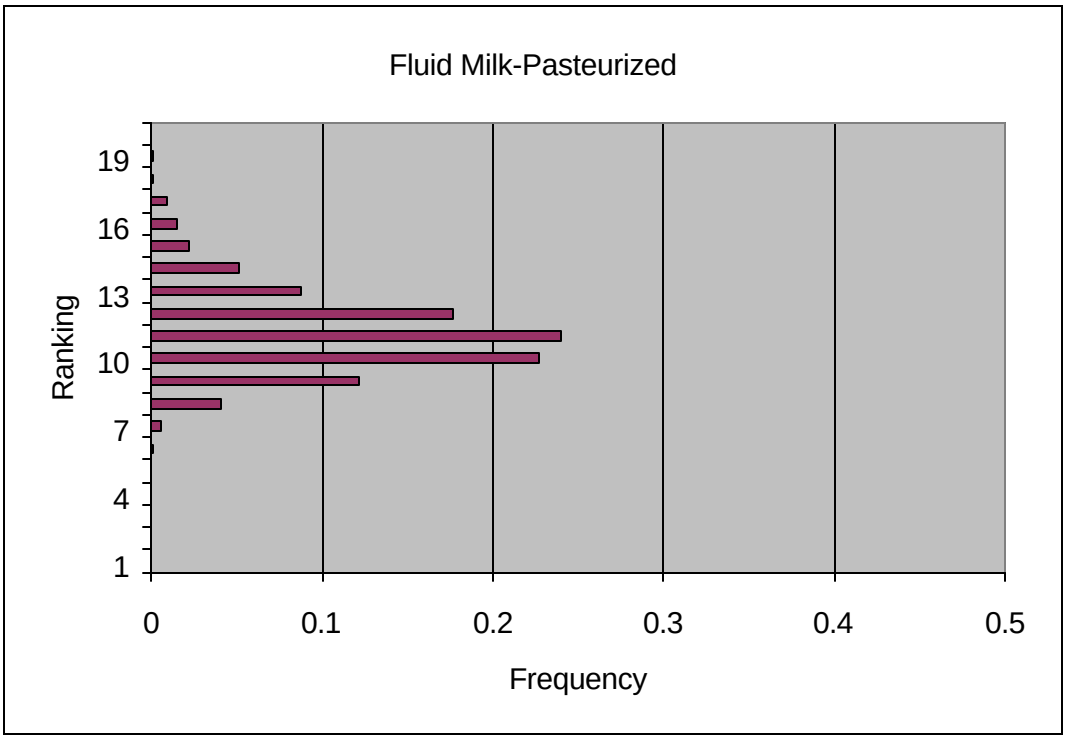

Figure V-13a. Rankings of total predicted listeriosis cases per serving for Pasteurized Fluid Milk

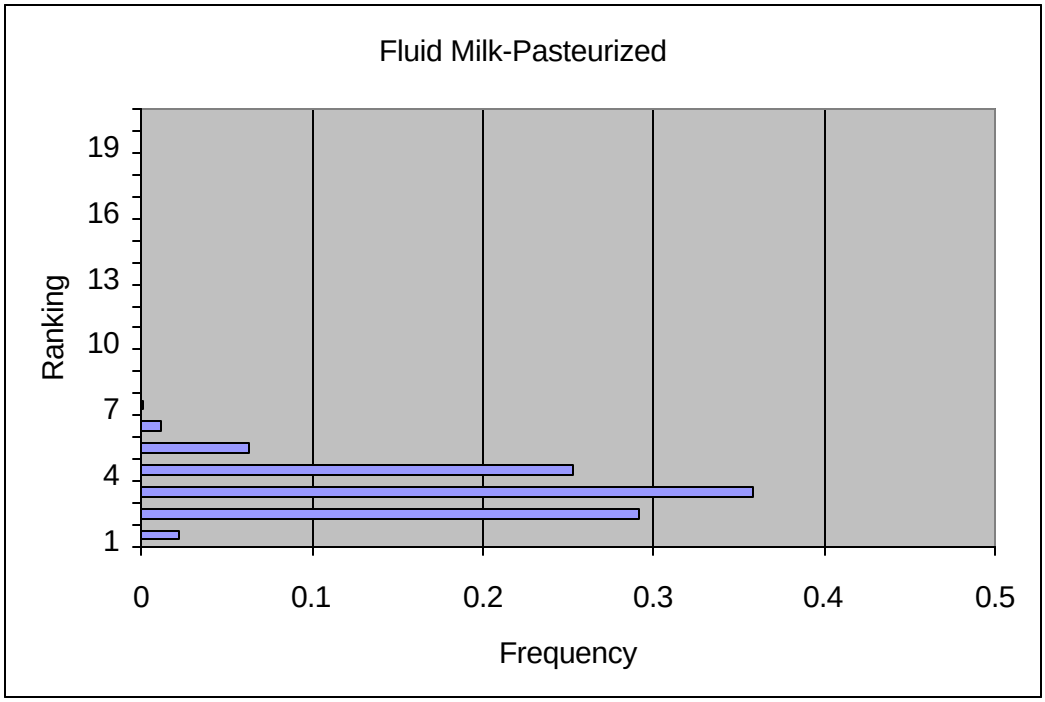

Figure V-13b. Rankings of total predicted listeriosis cases per annum for Pasteurized Fluid Milk

Food Category: Unpasteurized Fluid Milk

Unpasteurized fluid milk had a moderate 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 potential for growth during its refrigerated shelf-life affect the relative risk for this category. 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) for all states (Headrick *et al.*, 1998). Several studies have shown that *L. monocytogenes* is present in 1 to 6% of unpasteurized milk 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 annual number of servings consumed of Unpasteurized Fluid Milk was estimated to be low, 4.4 x 10^8 servings. Like Pasteurized Fluid Milk, the median serving size is large, and the same median sample size, 244 g, (approximately 8 ounces) was assumed. There were 38 contamination studies, including seven from the U.S. All seven U.S. studies were post-1993. Comparing the percentage of contaminated samples from studies conducted before and after 1993 (when attention to control of *L. monocytogenes* heightened) showed there was a small increase over time (Appendix 7, Table 7-1). Therefore, the inclusion of older data would be expected to have little effect on the risk assessment. Three studies (all non-U.S.) provided quantitative data. Thus, like Pasteurized Fluid Milk, the frequency of contamination was based on North American studies, while the extent of contamination had to be based on non-North American studies.

The average percentage of North American samples with detectable contamination was approximately 4%. North American Unpasteurized Fluid Milk had a rate of contamination that was similar or somewhat less when compared to international values. In general, the initial frequency of contamination is greater in unpasteurized milk than in pasteurized milk, 4% 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 3 to 4 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 led to a substantially narrow 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. In addition to being consumed directly, Unpasteurized Fluid Milk is also used as the starting ingredient for a number of dairy products (e.g., soft fresh cheeses) that support the growth of *L. monocytogenes*.

The predicted percentage of servings contaminated with 10^6 to 10^9 cfu/serving at retail was low. Because unpasteurized milk does not receive any treatment that would reduce *L. 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 *L. 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 *L. 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 (i.e., relatively high growth rate and moderate storage time). 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 were eleventh for each of the three subpopulations (Figure V-14a). The range of the ranking

distributions for Unpasteurized Fluid Milk was broad (Figures V-14a and V-14b) and tended to the higher relative risk rankings (i.e., lower risk). This indicates that there was moderate to substantial uncertainty associated with the relative ranking for the Unpasteurized Fluid Milk category, likely due to the variability in the frequencies and extents of contamination among the different studies. This variability would have been even greater if non-North American studies had been included in the analysis. The median per annum predicted relative risk rankings were sixteenth, fifteenth, and sixteenth for the perinatal, intermediate-age, and elderly subpopulations, respectively (Figure V-14b). 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 normally distributed, indicating a moderate degree of uncertainty associated with the predicted per annum risk ranking. The relative risk rankings were calculated on the basis of the direct consumption of Unpasteurized Fluid Milk produced and marketed under the conditions required for the sale of this product in individual states. Any breakdown in the on-farm and sanitary controls in North America could greatly increase the relative risk associated with this product. Furthermore, a complete interpretation of the risk of listeriosis associated with this product must also consider that Unpasteurized Fluid Milk is also a raw ingredient for a number of products epidemiologically linked to listeriosis worldwide.

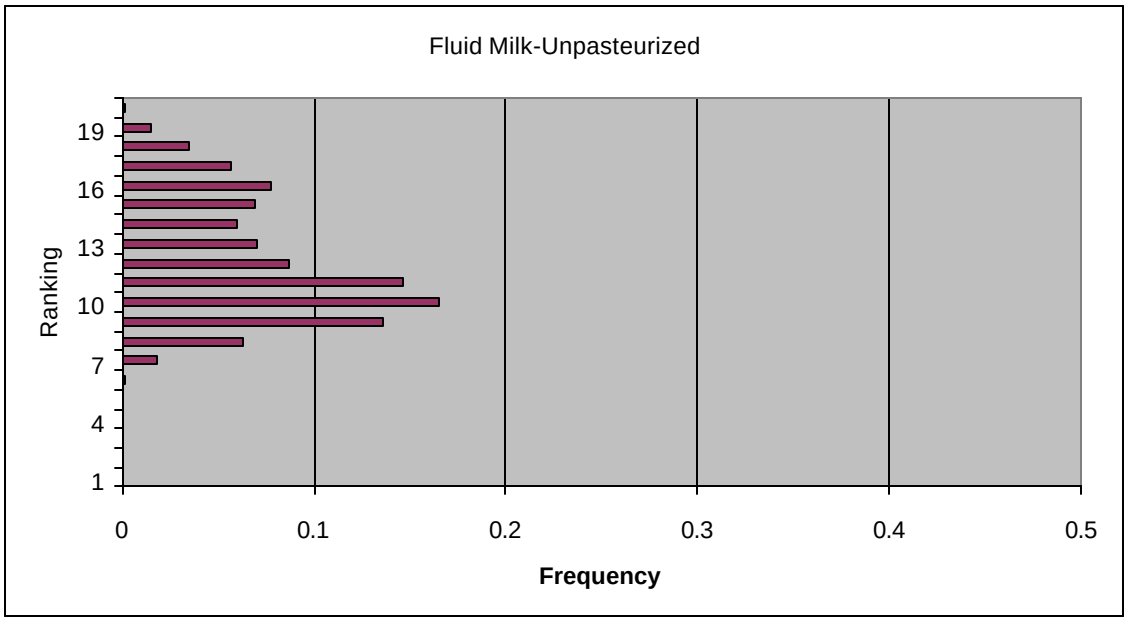

Figure V-14a. Rankings of total predicted listeriosis cases per serving for Unpasteurized Fluid Milk

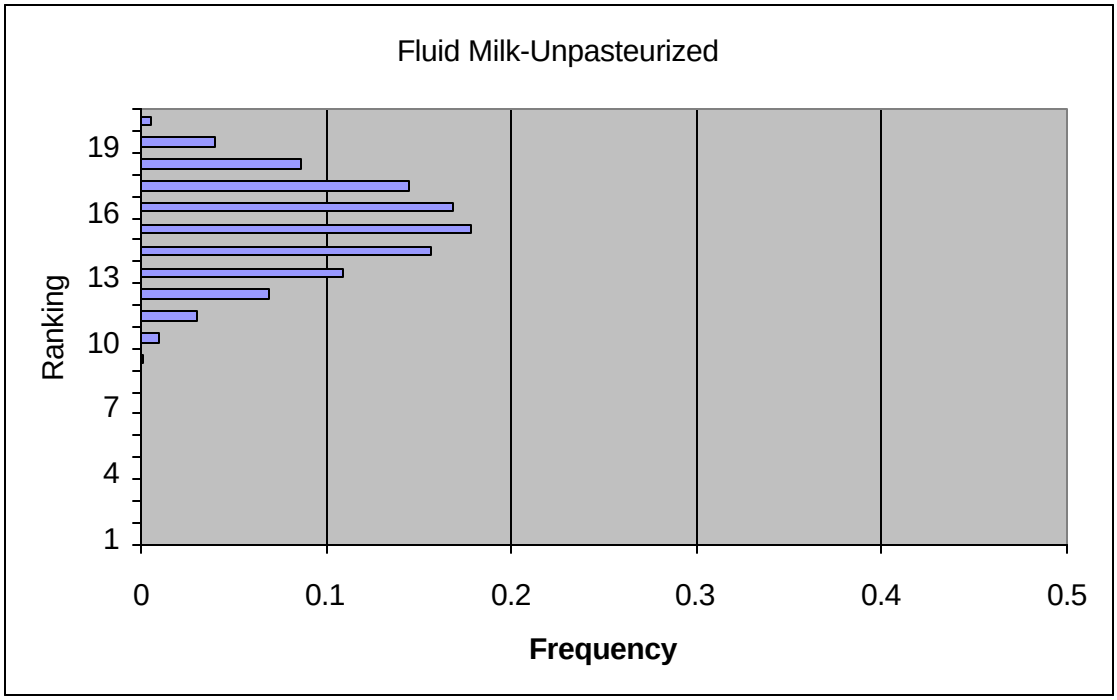

Figure V-14b. Rankings of total predicted listeriosis cases per annum for Unpasteurized Fluid Milk

Food Category: Ice Cream and Frozen Dairy Products

Ice Cream and Frozen Dairy Products had the lowest predicted relative risk of listeriosis of the 20 categories in this risk assessment on a per serving 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 temperature. 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).

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}.

Thirteen studies (three conducted in the U.S.) provided contamination data. Six studies were conducted after 1993. A comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed there was a decrease over time (Appendix 7, Table 7-1). However, most samples were recent, so this decline had little effect on the risk assessment. Over 24,000 samples were analyzed (68 of them quantitatively) and the contamination frequency was relatively low (0.7%). The predicted percentage of servings with 10^6 to 10^9 cfu at retail was also low.

L. monocytogenes cannot grow at freezer temperatures, although it is able to survive. Even 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 *L. monocytogenes* growth. More drastic temperature abuse, of the kind that would allow growth, results in an inedible product. The levels of *L. monocytogenes* found in the retail surveys of ice cream and frozen dairy products would not increase prior to consumption.

The predicted median per serving relative risk rankings for the Ice Cream and Frozen Dairy Products category were twentieth for each of the three subpopulations. The predicted median per annum relative risk rankings for the Ice Cream and Frozen Dairy Products Category were twentieth for the perinatal and intermediate-age subpopulations and nineteenth for the elderly subpopulation. The

ranges for both predicted ranking distributions for ice cream and frozen dairy products are broad (Figures V-15a and V-15b), but weighted to the highest rank (i.e., lowest risk). There is clear evidence of a bimodal distribution for both rankings. This reflects the small number of quantitative samples (68 out of 24,000) that were available to establish the levels of contamination. The resultant uncertainty required the inclusion of a distribution that likely overestimated the level of contamination that would occur in a small percentage of the sample. However, the extensive data base available and the characteristics of the food category provides significant confidence in the relative rankings for the Ice Cream and Frozen Dairy Products category.

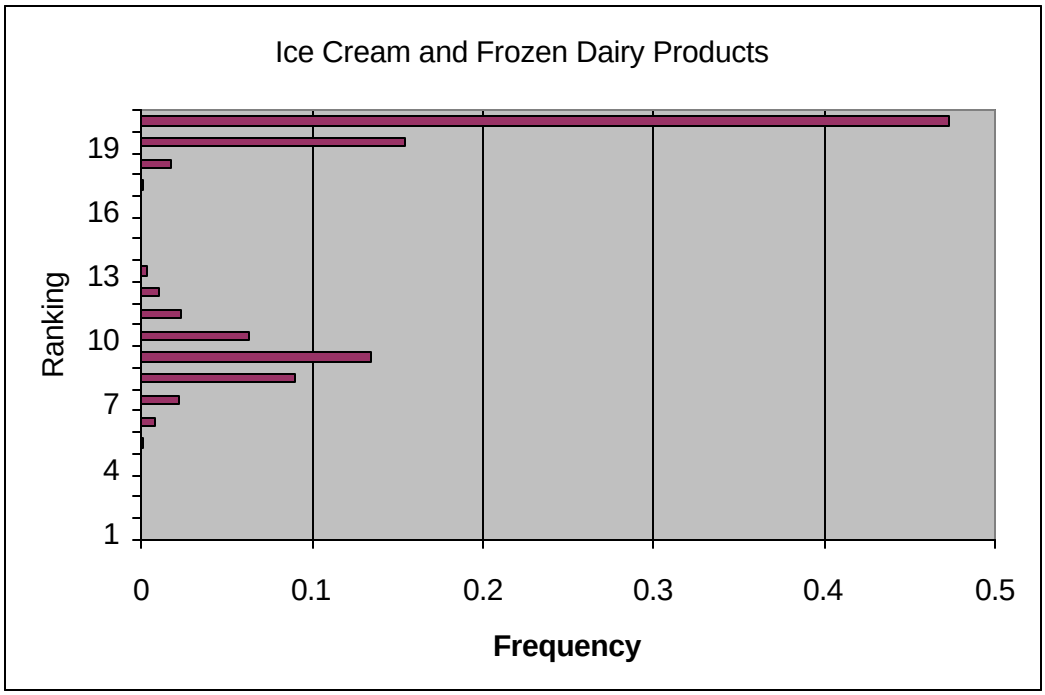

Figure V-15a. Rankings of total predicted listeriosis cases per serving for Ice Cream and Frozen Dairy Products

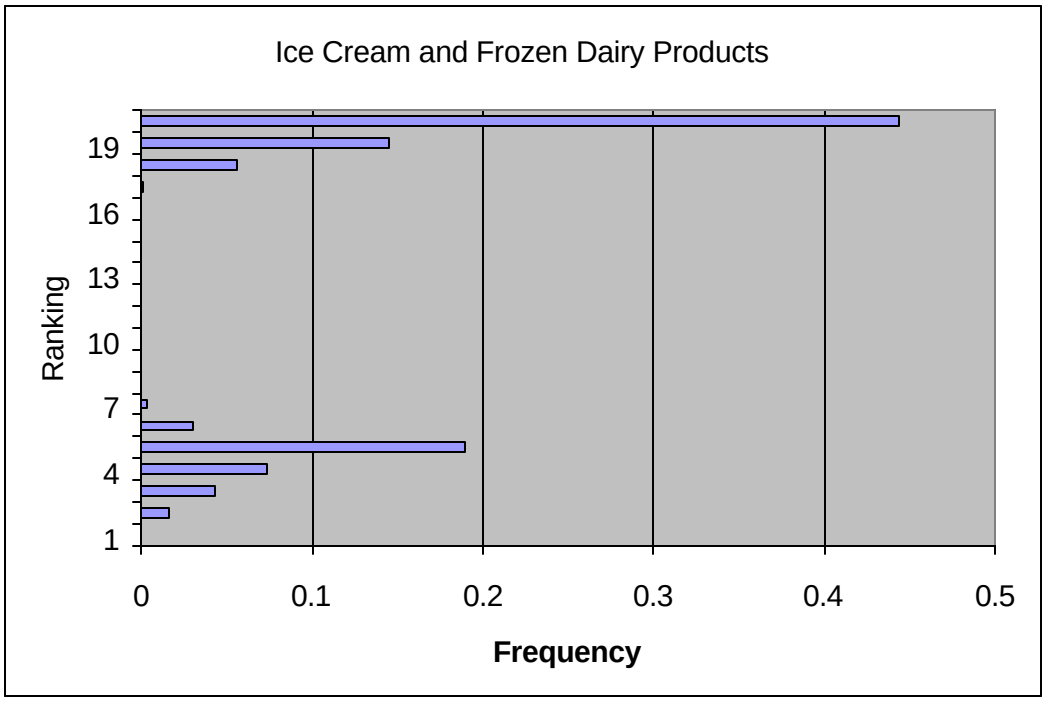

Figure V-15b. Rankings of total predicted listeriosis cases per annum for Ice Cream and Frozen Dairy Products

Food Category: Miscellaneous Dairy Products

Miscellaneous Dairy Products had a moderate predicted relative risk of listeriosis to individual consumers on a per serving basis. This category is difficult to characterize because it encompasses such a diversity of products. The Miscellaneous Dairy Products category had a relatively low contamination frequency and levels of contamination. 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, although the amount consumed was low. This affected the predicted relative risk on a per annum basis. This diverse food category contains some products that permit growth, such as cream, and some that do not. Two products, pasteurized cream (in the U.K.) and butter (in the U.S. and Finland), have been linked to outbreaks of listeriosis (Ryser, 1999a; Lyytikäinen *et al.*, 2000). Acquisition of additional data to address product-specific questions and subdivision of this category into smaller product groupings may be warranted in the future.

Miscellaneous Dairy Products consumption data include many types of dairy products (buttermilk, yogurt, milk shakes, cream, sour cream, dips, butter). The median amount consumed per serving for this category is 15 g (a little less than 0.5 ounces), and the annual number of eating occasions is 2.8×10^{10}.

Contamination data for this category were comprised of about 1,300 samples of all types of dairy products other than cheeses, frozen dairy products, and milks. Many of the products were unspecified in the available literature. The specified products were butter, cream, and yogurt, primarily. It was not specified 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. Dry milk products, casein, non-fat dried milk, and dry infant formula were excluded from this food category. Over 40% of the samples were analyzed quantitatively. The percentage of samples with detectable contamination was about 1.1%, which is a relatively low contamination rate. Eight studies were found with contamination data, two of which were quantitative. Neither of the two studies from the U. S. was quantitative. Median contamination levels were low. Three studies were conducted after 1993 (when attention to control of *L. monocytogenes* heightened). Comparing the percentage of contaminated samples from studies conducted before and after 1993 showed a

small decrease (Appendix 7, Table 7-1). This could lead to a small overstatement of the relative risk attributed to this food category.

The factors affecting *L. monocytogenes* growth, particularly product pH, were diverse in this category. A fast growth rate of 0.24 logs/day at 5°C was reported for cream, while declining numbers were observed in yogurt and buttermilk. This is likely due to the low pH in yogurt and buttermilk, since they are fermented products. The range in the growth rate parameter used in this risk assessment allows for both growth and decline, and the mean growth rate was –0.014 logs/day at 5°C, indicating an overall decline. The storage times for this category can be long. The assumed distribution had a most likely time of 6 to 10 days and a maximum time of 15 to 45 days.

The predicted median per serving relative risk rankings for the Miscellaneous Dairy Products category were thirteenth for the perinatal and elderly subpopulations and twelfth for the intermediate-age subpopulation. The range for the per serving ranking distribution for Miscellaneous Dairy Products is moderately wide (Figure V-16a), indicating that there is a reasonable degree of certainty associated with the per serving ranking for the Miscellaneous Dairy Products category. The predicted median per annum relative risk rankings for the Miscellaneous Dairy Products category were fifth for the perinatal and intermediate-age subpopulations and fourth for the elderly subpopulation. The range for the per annum ranking distribution is somewhat narrower (Figure 16b) 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 Miscellaneous 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 if this food category were subdivided.

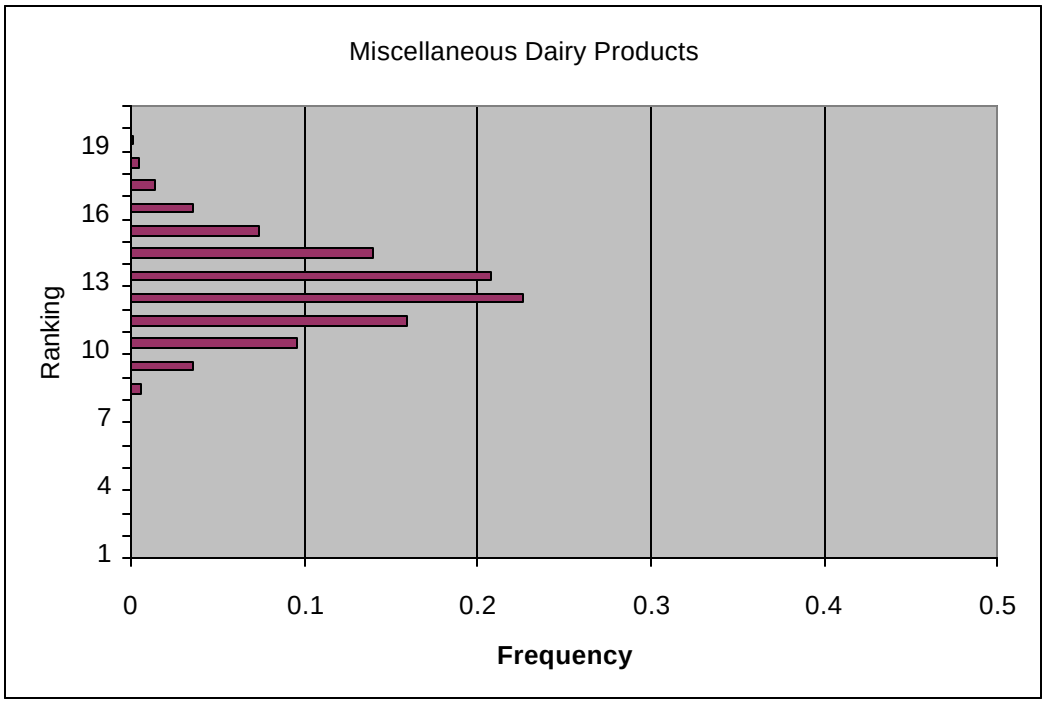

Figure V-16a. Rankings of total predicted listeriosis cases per serving for Miscellaneous Dairy Products

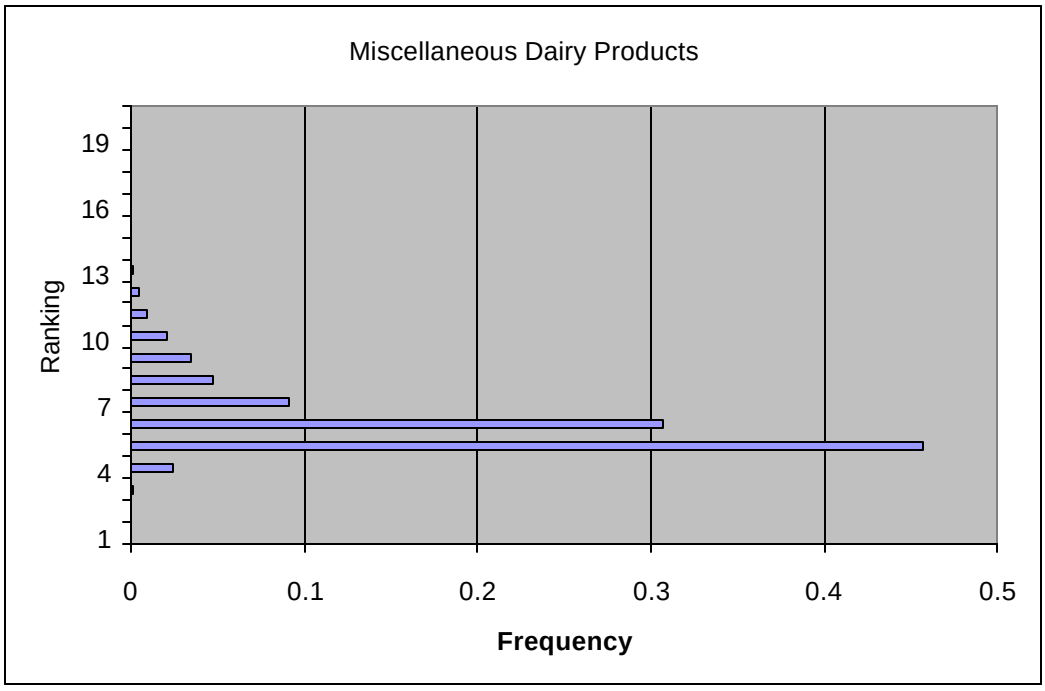

Figure V-16b. Rankings of total predicted listeriosis cases per annum for Miscellaneous Dairy Products

Food Category: Frankfurters

Frankfurters had a high predicted relative risk of causing listeriosis in the U. S. on a per serving basis. There have been two outbreaks in the U.S. 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. A significant reduction in contamination is assumed for the 86% to 99% of frankfurters consumed after adequate reheating (i.e., the risk assessment assumed that 1 to 14% of frankfurters are eaten without adequate reheating).

Consumption data for the frankfurter category include the meat portion of various types of frankfurters. The median amount consumed per serving for this category is 57 g (approximately 2 ounces, most likely one frankfurter), and the annual total number of servings is 6.5×10^9.

There were five contamination studies with a total of about 1,800 samples for this cooked food category. Four of the studies were conducted in the U.S. and three were conducted after 1993. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed there was a substantial decrease (Appendix 7, Table 7-1). The results of the risk assessment strongly reflect recent data; the pre-1993 data had little effect on the results.

One of the largest data sets used to develop the exposure rates for this food category was the results of FSIS analyses of product taken soon after manufacture. These results were modified to take into account the likely increase in *L. 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.

Two underlying assumptions used in estimating the relative risk associated with this product are that *L. 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.

It was not possible to differentiate frankfurters made from beef or poultry meats. The percentage of samples with detectable contamination was a moderate 7.6%. The data suggested that about 20% of the samples had greater than 10 cfu/g, but no counts higher than 100 cfu/g were reported. About 6% of the 1,800 samples were quantitatively analyzed. The predicted percentage of servings with 10^6 to 10^9 cfu at retail was low.

Four studies reported growth rates for *L. monocytogenes* in frankfurters, including beef/pork, turkey, and chicken frankfurters. The average growth rate at 5°C was 0.11 $\log_{10}$ per day. The assumed most likely storage time was 7 days and the maximum time 180 days. It is estimated that 1 to 14% of the frankfurters are not fully reheated before consumption. These assumptions, however, are based on limited observations.

The predicted median per serving relative risk rankings for the Frankfurters category were seventh for the perinatal subpopulation and eighth for the intermediate-age, and elderly subpopulations. This ranking is based on the assumption that 1% to 14% of frankfurters are consumed without reheating and the remainder are assumed to be heated before consumption (Table III-10). In an independent calculation that assumed none of the frankfurters were reheated before consumption, the risk per serving ranking (for intermediate-age population) would be 1. If all of the frankfurters received reheating according to Table III-10, the risk per serving would rank 15. The predicted median per annum relative risk rankings were fourth for the perinatal and intermediate-age subpopulations and fifth elderly subpopulation. The range for the per serving ranking distribution for Frankfurters is moderately wide (Figure V-17a) concentrated toward the lower ranks (higher risk). The range for the per annum ranking distribution for Frankfurters is quite narrow (Figure V-17b) concentrated in 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 category.

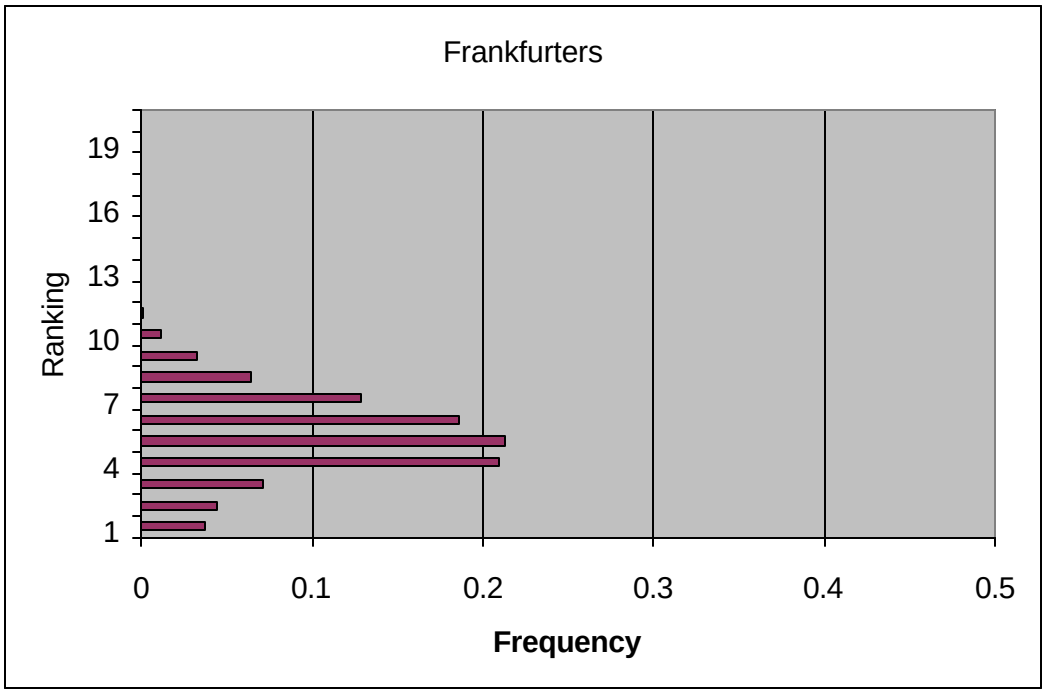

Figure V-17a. Rankings of total predicted listeriosis cases per serving for Frankfurters

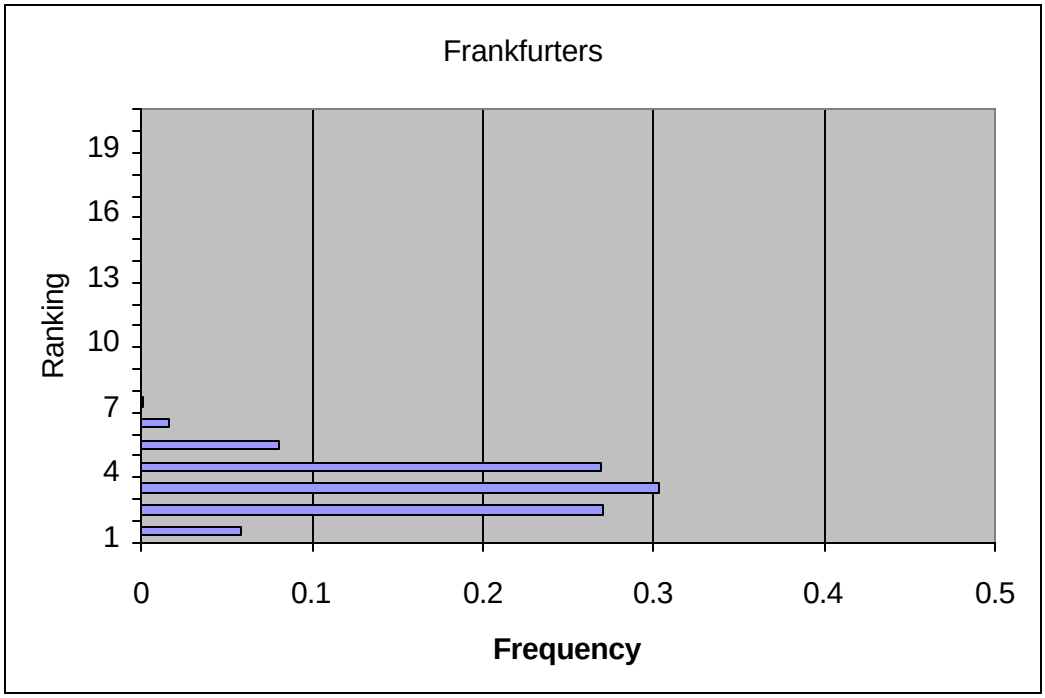

Figure V-17b. Rankings of total predicted listeriosis cases per annum for Frankfurters

Food Category: Dry/Semi-Dry Fermented Sausages

Dry/Semi-Dry Fermented Sausages, such as Lebanon bologna, mortadella, pepperoni, and salami, had a moderate predicted relative risk of causing listeriosis in the U. S. on a per serving basis. This reflects the fact that this is a no-growth category and all other factors are at a moderate level. One outbreak and one sporadic case of listeriosis in the U.S. 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, mortadella, 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 1.8×10^9.

There were 10 studies (one U.S. study) of contamination frequency with these products, including three studies conducted after 1993. Three of the studies were quantitative. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed there was a substantial increase over time (Appendix 7, Table 7-1) In addition to possible increases in contamination, this could also be the result of improved detection methods.

More than 2,400 samples of fermented sausages were analyzed, but the kind was generally unspecified, except for salami. About 30% of the samples were analyzed quantitatively. The percentage of samples with detectable contamination was 7.8%, which is in the moderate contamination range. The predicted percentage of servings with 10^6 to 10^9 cfu at retail was moderate, based on extrapolation of exposure distributions.

Inoculated pack studies show *L. monocytogenes* decreases several logs during the manufacture of these meat products and then slowly declines with additional storage. No growth was modeled for this category, but the organism can survive for extended periods of time. The organism can grow during the early phase of the fermentation or if there has been a fermentation failure. This has also been implicated in outbreaks caused by *Staphylococcus aureus* and *Salmonella* in products associated with this food category.

The predicted median per serving relative risk rankings for the Dry/Semi-Dry Fermented Sausages category were thirteenth for the perinatal subpopulation and twelfth for the intermediate-age and

elderly subpopulations. The range for the per serving ranking distribution for Dry/Semi-Dry Fermented Sausages is moderately broad (Figure V-18a) and concentrated in the middle ranks (moderate risk). This indicates that there was a moderate 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 rankings were twelfth for all three subpopulations. The range of the per annum ranking distribution was broad with an apparent bimodal distribution (FigureV-18b). This indicates that there is substantial uncertainty associated with the per annum predicted relative risk ranking, which may reflect the variability in the consumption patterns for this food category.

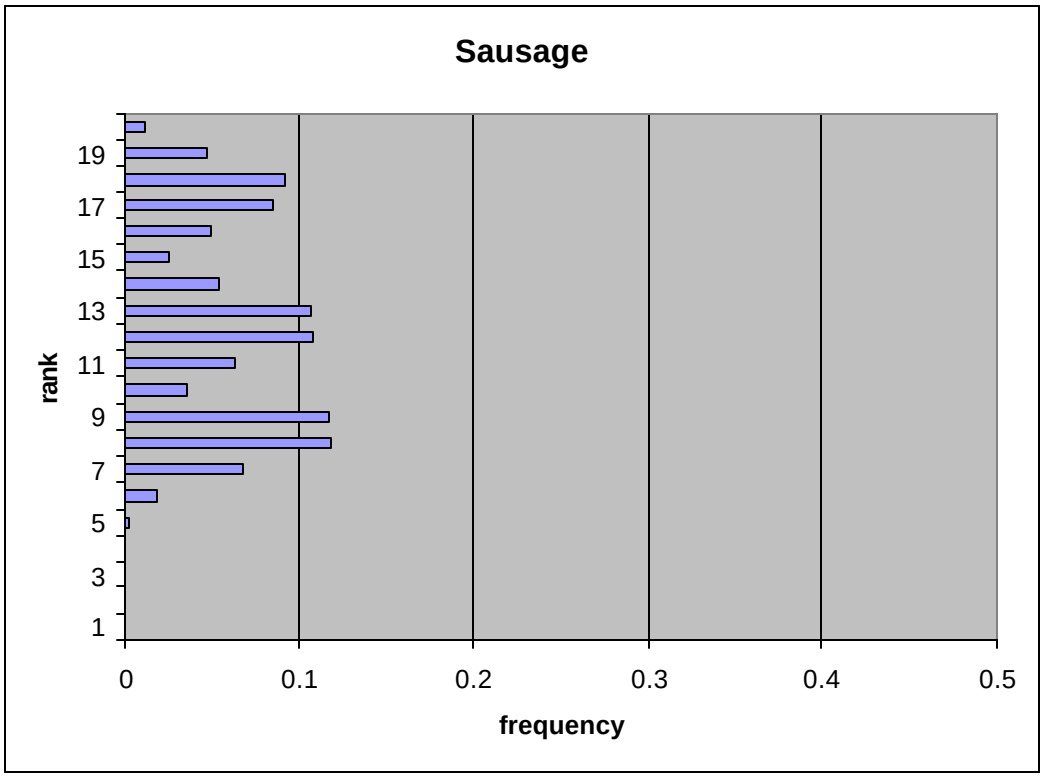

Figure V-18a. Rankings of total predicted listeriosis cases per serving for Dry/Semi-Dry Fermented Sausages

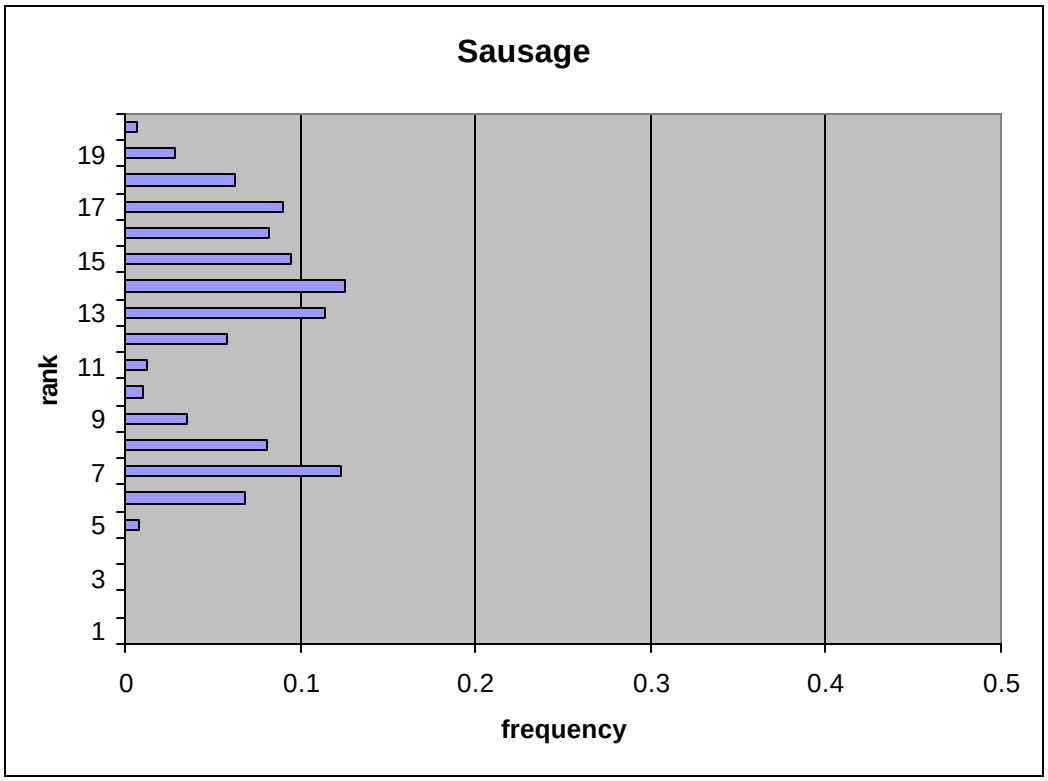

Figure V-18b. Rankings of total predicted listeriosis cases per annum for Dry/Semi-Dry Fermented Sausages

Food Category: Deli Meats

Deli Meats had a high predicted relative risk of causing listeriosis in the U. S. on a per serving basis. Though this category had a moderate contamination frequency with moderate contamination levels, moderate storage times and serving sizes, there were a high number of servings consumed and a high growth rate, which is one of the usual factors that drive listeriosis risk in foods. Deli meats have been secondarily implicated in only one U. S. outbreak (the 1998-99 outbreak that was primarily linked to frankfurters), and 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 2.1×10^{10}.

This category of products encompasses a variety of processes and compositions that can effect contamination and growth. There were five contamination studies (one U.S. study). Four were published after 1993. Eight percent of the over 10,000 samples provided quantitative data. Approximately 2.8% of the samples were contaminated and the level of contamination was moderate. The predicted percentage of servings with 10^6 to 10^9 cfu at retail was moderate.

The cooking steps that are used to produce Deli Meats are assumed to kill any *L. monocytogenes* present. It is generally assumed that *L. 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. Nevertheless, no data were available to allow these two approaches to the marketing of Deli Meats to be distinguished in the risk assessment.

The growth rate of *L. monocytogenes* in Deli Meats has been reported in 12 studies. The products included bologna, corned beef, ham, roast beef, poultry loaf, and breaded chicken fillets. Growth rates varied with product composition (salt) and packaging (aerobic/vacuum). The average was 0.244 logs per day at 5°C, a rapid rate of growth. The most likely storage time was 5 to 7 days, with a maximum of 20 to 30 days.

The predicted median per serving relative risk rankings for the Deli Meats category were fourth for each of the three subpopulations. The range for the per serving ranking distribution for Deli Meats is moderately narrow and normally distributed (Figures V-19a). This suggests a low degree of uncertainty associated with the per serving predicted relative risk ranking for the Deli Meats category. The predicted median per annum relative risk rankings were first for all three subpopulations. The range for the per annum ranking distribution was quite narrow (Figure V-19b). The increase in the per annum ranking over the per serving ranking likely reflects the frequent consumption of the product.

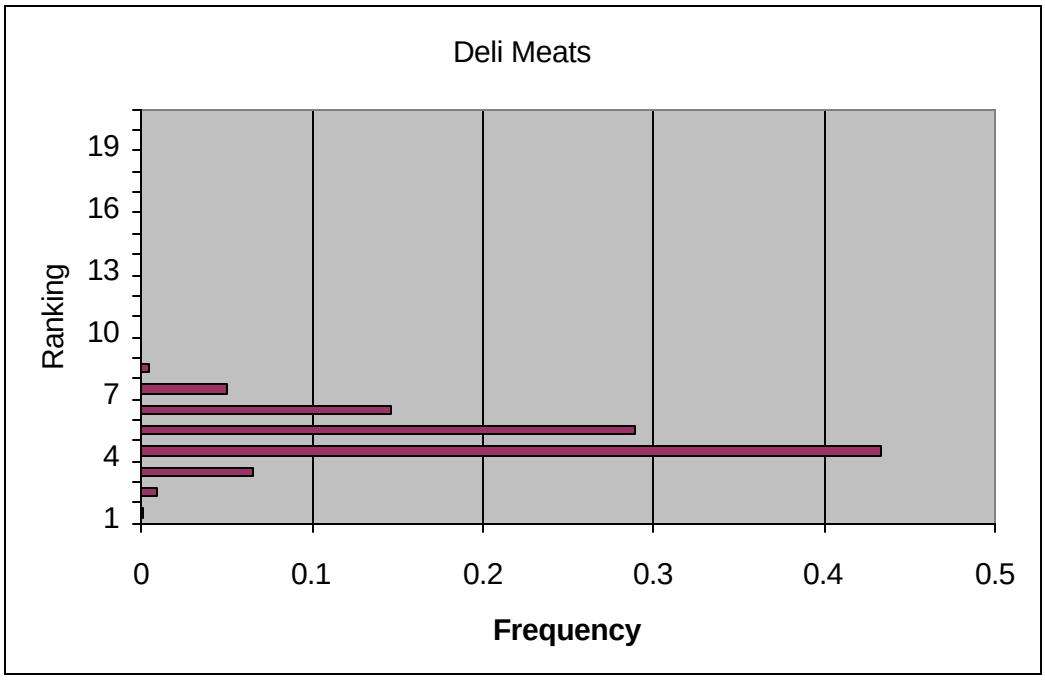

Figure V-19a. Rankings of total predicted listeriosis cases per serving for Deli Meats

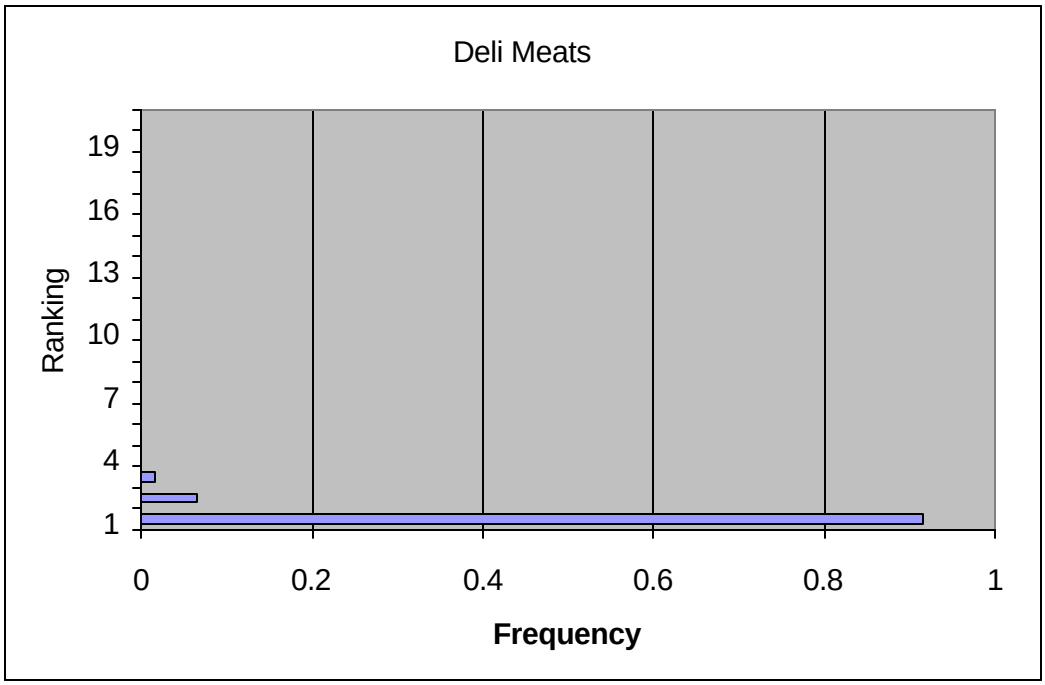

Figure V-19b. Rankings of total predicted listeriosis cases per annum for Deli Meats

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 U. S. on a per serving basis. Although the foods in this category generally were consumed on a relatively infrequent basis, and median serving size, retail contamination frequency and retail contamination levels were moderate, the growth rates and storage times were high. Outbreaks in the U. K., France, and Western Australia have been linked to consumption of pâté (Ryser, 1999a; Goulet *et al.*, 1998).

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.

Contamination data for this category included pâté (e. g., liver pâté) and meat spreads. The percentage of samples with detectable contamination was about 5.6%, which is in the moderate contamination range. The highest reported counts were greater than 10^6 cfu/g, with about 1% of samples having more than 100 cfu/g. There were seven studies (five after 1993) with a total of about 5,000 samples. One of the studies was conducted in the U.S. Contamination levels in about 4,400 samples were quantified. Comparison of the percentage of contaminated samples from studies conducted before and after 1993 showed a relatively substantial decrease over time (Appendix 7, Table 7-1) . This could lead to an overestimation in the relative risk predicted by the risk assessment, but the large number of samples that were analyzed post-1993 offsets this.

The predicted percentage of servings with 10^6 to 10^9 cfu at retail was moderate. Post-retail levels are likely to increase prior to consumption due to a significant predicted post-retail growth. Pâté and Meat Spreads supported growth at 5°C at 0.25 log/day. Storage times were estimated to be long, with 6 to10 and 15 to 45 days for most likely and maximum times, respectively.

The predicted median per serving relative risk rankings for the Pâté and Meat Spreads category were second for the perinatal and elderly subpopulations, and first for the intermediate-age subpopulation. The range for the per serving ranking distribution for Pâté and Meat Spreads is relatively narrow (Figure V-20a) 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 were eighth for the perinatal and intermediate subpopulations and seventh for the elderly subpopulation. The range of the per annum ranking distribution was moderately wide, indicating increased uncertainty associated with the predicted per annum ranking (Figure V-20b). The broadening of the distribution of the per annum rankings likely reflects the variability and uncertainty associated with the annual consumption of this food category.

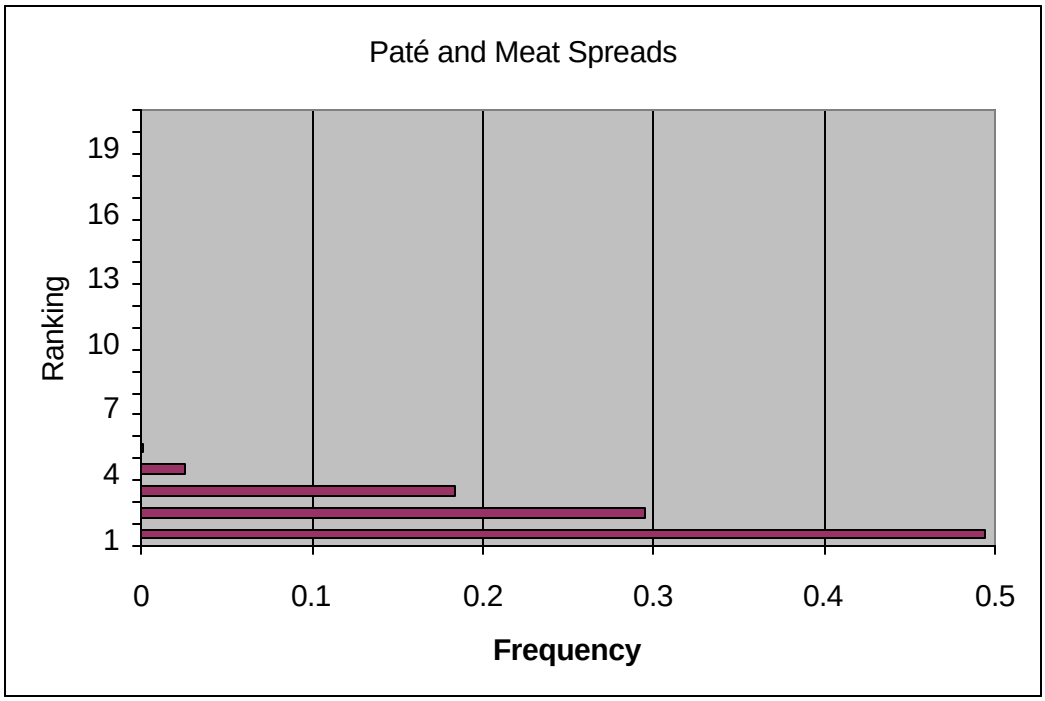

Figure V-20a. Rankings of total predicted listeriosis cases per serving for Pâté and Meat Spreads

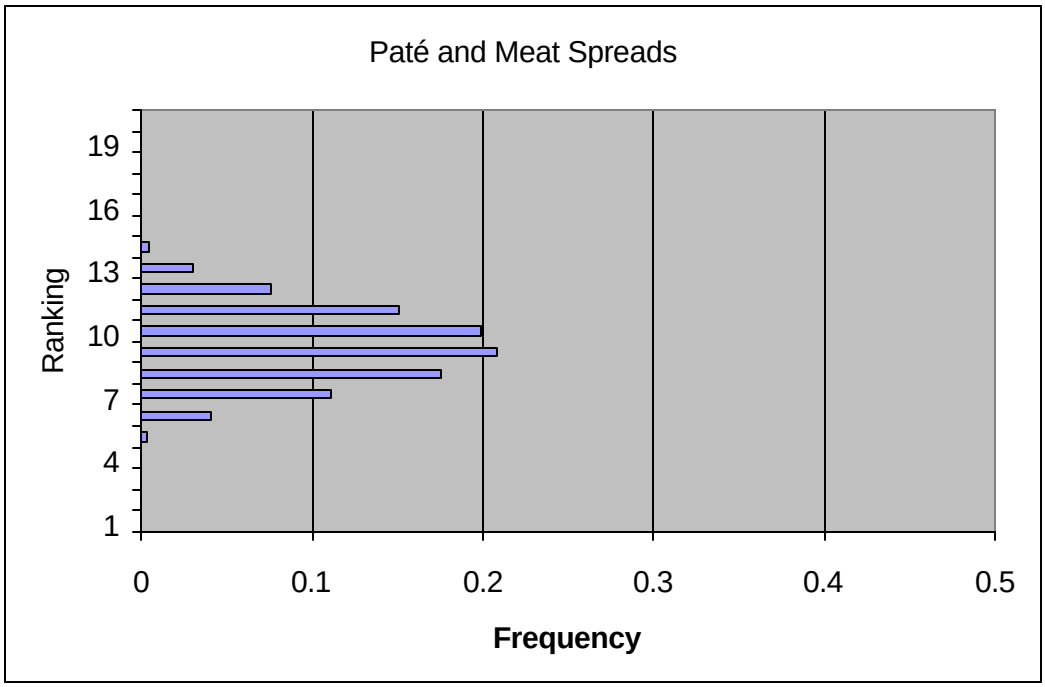

Figure V-20b. Rankings of total predicted listeriosis cases per annum for Pâté and Meat Spreads

Food Category: Deli Salads

Foods in the Deli Salads category, such as meat, seafood, egg, and pasta salads, had a high predicted relative risk of causing listeriosis in the U. S. on a per serving basis. This can be attributed to the moderate number of servings per year, a moderate proportion of the population consuming the products, a moderate contamination frequency, but a large serving size. Also, since no reports quantifying the growth rate of *L. monocytogenes* in these products were found, the growth rate for the Deli Meats category was used to estimate growth in Deli Salads. This may have increased the relative risk associated with Deli Salads. Although some Deli Salads may contain acidic components that suppress microbial growth, microenvironments remain within the chunks of meat, poultry, and seafoods that would permit growth at the rate occurring in the meats alone. Storage times were relatively short, but in the moderate range. 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 *L. monocytogenes*.

This category includes consumption data for a wide variety of meat, seafood, egg, and pasta salads, as well as the salad portion of sandwiches. It does not include vegetable and fruit salads, which were grouped with the Vegetables and Fruits categories. The median amount consumed per serving for meat, seafood, egg, and pasta salads is 104 g (i.e., a little less than 4 ounces), and the total annual number of servings is 5.6×10^9.

Only seven studies (two U.S. studies) provided contamination data for this food category. All the samples were salads with cooked or ready-to-eat animal protein ingredients. Only two studies were conducted post-1993 and they reported an increased rate of contamination (Appendix 7, Table 7-1). Thus, the inclusion of the pre-1993 data is not likely to have inflated the relative risk associated with this food category. Three of the seven studies provided quantitative data (1,182 of the nearly 3,200 samples analyzed). The percentage of samples with detectable contamination was 9.9%, which is at the upper end of the moderate contamination range. The predicted percentage of servings with 10^6 to 10^9 cfu at retail and consumption was moderate. The most likely storage time was 3 to 4 days with a maximum of 8 to 12 days.

The predicted median per serving relative risk rankings for the Deli Salads category were eighth, fifth, and sixth for perinatal, intermediate-age, and elderly subpopulations, respectively. The range

for the per serving ranking distribution for Deli Salads was reasonably narrow (Figure V-21a) and tended to concentrate in the lower ranks (higher risk). The predicted median per annum relative risk rankings were third for the perinatal and elderly subpopulations and second for the intermediate-age subpopulation. The range for the per annum ranking distribution for Deli Salads was slightly wider and appeared to be normally distributed (Figures V-21a and V-21b). Overall, there was a relatively low degree of uncertainty associated with both the predicted per serving and per annum rankings.

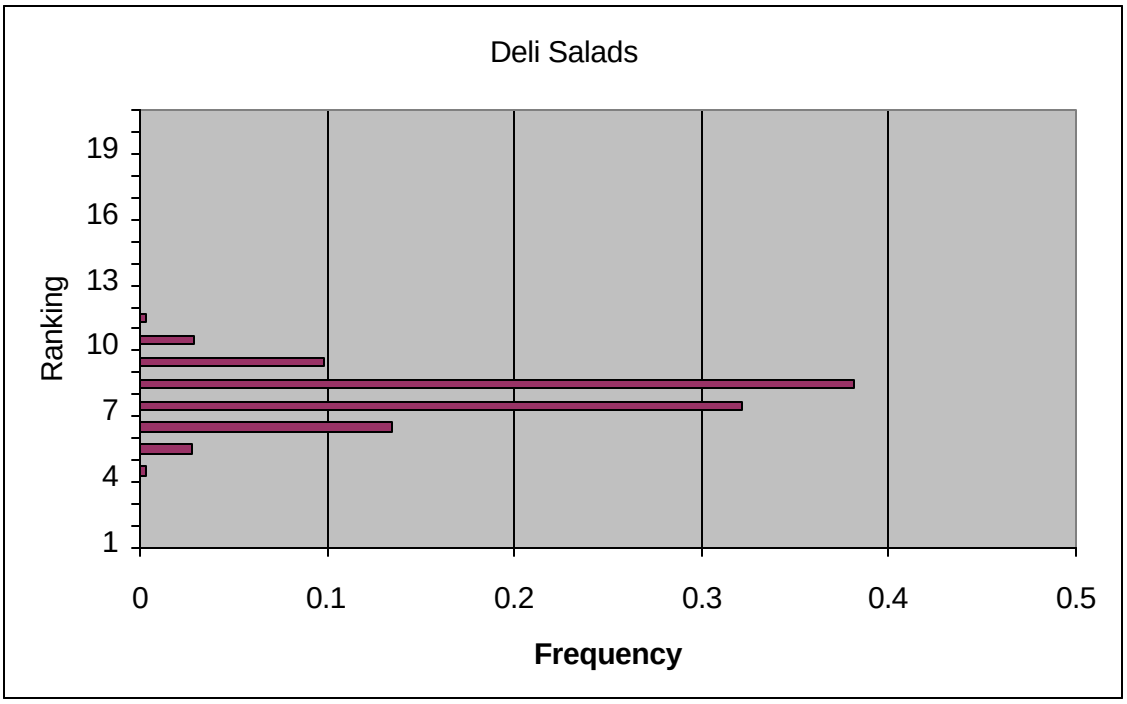

Figure V-21a. Rankings of total predicted listeriosis cases per serving for Deli Salads

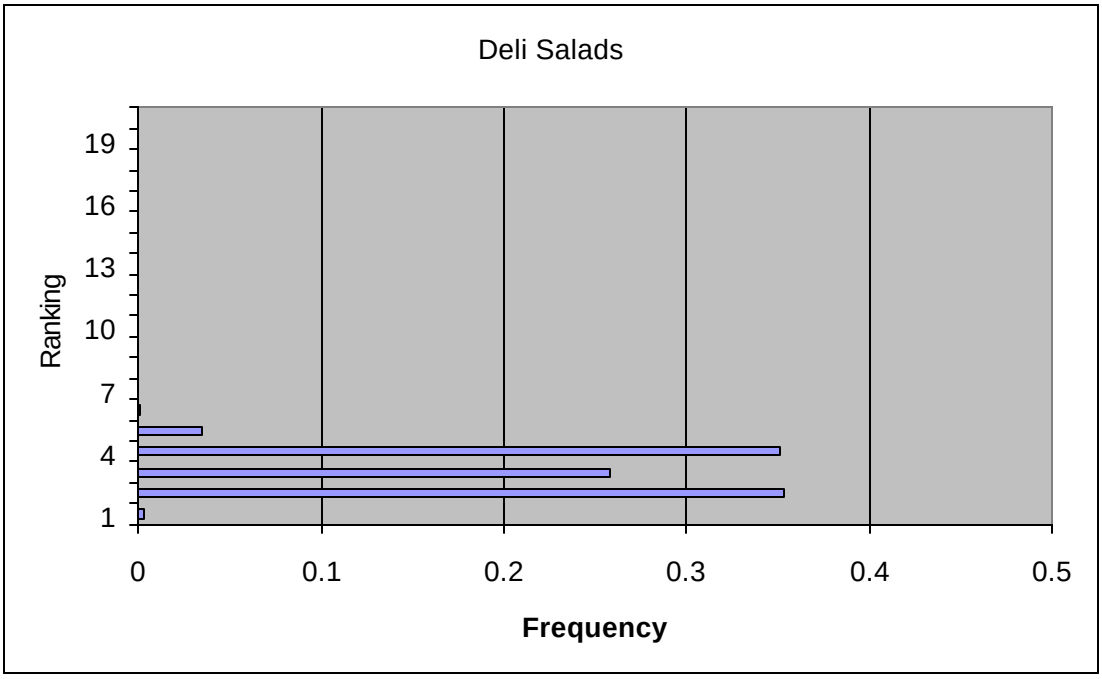

Figure V-21b. Rankings of total predicted listeriosis cases per annum for Deli Salads