III. EXPOSURE ASSESSMENT

Exposure to foodborne *L. monocytogenes* can be described in two primary ways. The first is by characterizing the range of likely pathways by which foods become contaminated with *L. monocytogenes*. The second addresses the likely consumption levels of the contaminated food. Unlike other recently completed microbiological risk assessments, this risk assessment does not consider the contamination pathway or the effects of preventive interventions and controls on the likely consumption levels. Two exceptions are efforts to model growth during refrigeration and thermal destruction during home cooking or reheating. Because the goal of this risk assessment was to provide information needed to focus risk management strategies among a variety of foods that could be potentially contaminated with *L. monocytogenes*, the emphasis of the exposure assessment for this risk assessment is to model the consumption of foods that have a potential for *L. monocytogenes* contamination.

Exposure is a function of the amount of a food consumed and the level of contamination in that food. Hence, it was necessary to develop estimates of the quantity of contaminated foods likely to be consumed in the U. S., as well as the *L. monocytogenes* levels in those foods. However, limitations inherent in food consumption data and the paucity of contamination data for certain foods made certain assumptions necessary to develop the estimates. These limitations and assumptions are discussed later in this document.

Foods that were included in the risk assessment were identified either through a comprehensive review of the recall, microbiological and epidemiological literature. Each food was placed in one of 20 food categories. Using distributions of contamination and consumption data, estimates of exposure to *L. monocytogenes* in the various foods were derived.

Food Category Identification

The first step in the exposure assessment was to consider appropriate foods to include in the risk assessment model. As the risk assessment progressed, foods and food categories were continually reevaluated and modifications were made based on new information, such as the results of growth models or new microbiological or epidemiological literature. Foods that have a significant potential for *L. monocytogenes* contamination were identified. They represent a subset of foods that comprise

an individual's total diet. Foods that have not been linked to *L. monocytogenes* contamination were not included, for example, grain products (*e. g.,* bread, cookies, cakes), soft drinks, canned fruits, and cooked mixed dishes (*e. g.,* lasagna, soups). Furthermore, foods that have limited association with *L. monocytogenes* contamination (*e. g.,* cream-filled pastries) were not included because neither contamination level data nor appropriate data to serve as a substitute were available. It was also presumed that some foods that are cooked just prior to consumption (*e. g*., most meats and seafoods) present a very low likelihood of containing *L. monocytogenes* when consumed and were not included in this risk assessment.

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

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

The next step in selecting foods for the risk assessment was a review of contamination data that were available for the foods. Food contamination data were compared with the available food consumption data, and food categories were created when both types of data were available. (See Appendix 4 for additional background information and a listing of selected references used for food category identification.) In some instances, food consumption data and/or growth rates did not exist for all foods linked to listeriosis or *L. monocytogenes* contamination (*e. g.,* pork tongue in jelly). In other cases, contamination data were limited or not available. Proxy data from similar foods were used for those foods.

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

The identified foods were sorted into categories based upon overall similar food characteristics, use, and the potential for growth of *L. monocytogenes*. For example, the Cooked RTE Crustaceans food category contains peel-and-eat shrimp, steamed and boiled shrimp, and steamed crabs – foods that may be refrigerated and eaten chilled or allowed to cool after cooking, thus allowing for re-contamination and growth. The Vegetable food category includes many raw, dried, and pickled vegetables, as well as vegetable salads. Vegetable salads contain raw vegetables and vegetables that have been cooked and allowed to cool, such as potatoes in potato salad. The Fruits food category includes many raw and dried fruits, fruit salads, and combinations of nuts, dried fruits, and seeds.

Table III-1 lists the 20 food categories that were used in this risk assessment. The food categories fall into five general groups: Seafood, Produce, Dairy, Meat, and Combination Foods. See Appendix 5 for a detailed listing of the foods included in each food category.

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

SEAFOOD
Smoked Seafood (finfish and mollusks)
Raw Seafood (finfish and mollusks)
Preserved Fish (dried, pickled, and marinated finfish)
Cooked Ready-to-Eat Crustaceans (shrimp and crab)
PRODUCE
Vegetables (raw, dried, and vegetable salads)
Fruits (raw, dried, fruit salads, and nuts)
DAIRY
Soft Mold-Ripened and Blue-Veined Cheese
Goat, Sheep, and Feta Cheese
Fresh Soft Cheese [a] (e.g., queso fresco)
Heat-Treated Natural Cheese and Process Cheese (mozzarella, cottage, cream cheese, and cheese spreads)
Aged Cheese (hard, semi-hard, and semi-soft cheese)
Pasteurized Fluid Milk[b]
Unpasteurized Fluid Milk[b]
Ice Cream and Frozen Dairy Products
Miscellaneous Dairy Products (butter, yogurt, cream)
MEAT
Frankfurters
Dry/Semi-Dry Fermented Sausages
Deli Meats (cooked, ready-to-eat)
Pâté and Meat Spreads
COMBINATION FOODS
Deli Salads (cooked seafood, meat, poultry, egg, and cheese and/or pasta as primary salad ingredients.)

[a]Contamination data for soft-ripened cheese made from unpasteurized milk were used in the modeling to define the shape of the distribution of contamination data for the Fresh Soft Cheese food category.
[b] All available data from North America and Europe were used in the modeling to characterize the distribution of contamination data for these milk food categories, but only the data from North America were used in the characterization of the prevalence of the contamination.

Food Consumption

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

- Two 24-hour recalls of foods eaten during two nonconsecutive days (with the interview for the second day conducted 3 to 10 days after the interview for the first day, but not on the same day of the week).

- Sample weights for weighting the data so that they will more closely reflect consumption by the non-institutionalized U. S. population.
- A sample of 16,103 respondents, including:

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

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

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

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

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

- Oversampling of young children, older persons, black persons, and Mexican Americans.
- A U. S. Population Parameter of 251,097,003, appropriate for 1988-1994.

Consumption data from the CSFII 94-96 survey were used for 18 of the 20 food categories. CSFII data were used preferentially because they are newer and account for up to two days of eating per respondent. However, NHANES III data were used for two food categories (Raw Seafood and Preserved Fish) for which there are fewer than 30 eating occasions (servings) in the CSFII survey. The surveys contain consumption data for many foods and each food has an associated food code. Over 7,200 food codes were reviewed and the codes matching the foods in the various food categories were selected for inclusion. The following information was extracted from the databases for each food category:

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

Several limitations of the food consumption surveys had an impact on their use for risk assessment purposes. For some foods, it was difficult to determine consumption. Surveys sometimes listed particular foods under several category codes, such as ham consumed alone or ham in a ham sandwich. The proportion of a particular food (such as ham) in a mixed ingredient product (such as ham sandwich) was determined using a generic recipe, and the amount of the product (ham) consumed was calculated. For this risk assessment, sandwiches were broken down into individual ingredients. In the case of frankfurters, dry semi/dry fermented sausages, deli meats, pâté and meat spreads, and deli salads, the actual consumption of meat or deli salad product consumed alone, as well as the proportion used in sandwiches was used. For combination foods that contain cottage cheese, such as cottage cheese with gelatin dessert and fruit, the proportion of cottage cheese in the food was used. In the case of vegetable and fruit salads in which fruits and vegetables were the major component, however, the entire salad was used, rather than the component ingredients.

The consumption surveys do not collect information from consumers to determine whether the milk they drank was pasteurized or unpasteurized. Although federal law requires milk in interstate commerce to be pasteurized, some states allow unpasteurized milk to be sold and consumed within the state. Results of a 1995 FDA/CDC survey of all 50 states, Puerto Rico, and the District of Columbia, showed that 28 states (54%) permit the sale of unpasteurized fluid milk. However, it is estimated that unpasteurized milk accounts for less than 1% of the total volume of milk sold in these states (Headrick *et al.*, 1998). Because consumption surveys did not list "drinking occasions" (servings) of unpasteurized fluid milk, the consumption of this food category was modeled by estimating it as 0.5% of the amount consumed per serving of pasteurized milk (54% x 1%). Neither

of these surveys reports the consumption of unpasteurized fluid milk; therefore, the reported serving sizes for pasteurized fluid milk were used as surrogate data.

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

The food consumption surveys did not collect demographic information delineating consumers who are immunocompromised. Furthermore, the surveys did not measure consumption by the elderly who are living in nursing homes or other forms of assisted living outside of the home, nor did they contain a large enough sample of pregnant women to generalize consumption to all pregnant women. Thus, the available consumption data did not allow the determination of comprehensive estimates of food consumption for each individual susceptible subpopulation. Consumption among the subpopulations was compared. Specifically, nonparametric statistical analyses were conducted to determine if there were significant differences between the distributions of the amount eaten in each serving (expressed as weighted percentiles) for the elderly and women of childbearing age as a group versus all eaters. Fifteen of the 20 food categories had sufficient consumption data to permit these analyses. There were no statistically significant differences in consumption patterns for 14 of the examined 15 food categories. Thus, for the purpose of estimating the distribution of serving sizes, the food consumption data representing all eaters were applied to all three subpopulations.

Annual Number of Servings of Foods

In order to estimate the number of servings of the foods in each food category eaten in a year, some key data assumptions were necessary. First, it was assumed that the weighted number of servings for one (NHANES III) or two days (CSFII) of consumption of the foods in a specific food category could be extrapolated to the number of servings of those foods eaten by the population on an annual basis. Second, it was assumed that the weighted number of eaters of a food per day would represent the number of eaters of the food over 365 days. Obviously, there are some foods that individuals are more likely to eat each day (*e. g.,* vegetables, milk) and others that they eat frequently (*e. g*., fruits, deli meats) or occasionally (*e. g*., frankfurters, cottage cheese). Some foods are seasonal and are not

available year round (*e. g.*, some fruits and vegetables), and people may not be likely to purchase more costly items (*e. g.*, shrimp, crabmeat) for regular consumption. Thus, it is important to note that when estimating the consumption of foods on an annual basis, all foods reported in food consumption surveys during a one- or two-day period are not likely to be eaten in the same frequency by the same people over an entire year. Table III-2 provides the annual number of servings of food consumed in the U.S. for each of the 20 food categories.

Serving Size Distributions in the Model

Empirical distributions were used to describe the serving sizes (grams of food eaten per serving) in the 20 food categories. These distributions are expressed as a series of population percentiles of the amount of food eaten per serving, weighted to reflect the consumption survey demographics. There were no uncertainties presented for these food categories because empirical distributions were used. The uncertainties associated with the serving size distributions would be relatively small, compared to other uncertainty distributions in this risk assessment for three reasons. First, even the smallest data sets used to characterize the serving size distributions are large relative to other parts of the *L. monocytogenes* risk model. Second, although the data may not be completely representative of the current behavior of the U.S. population, the data come from surveys that were explicitly designed for that purpose. Third, the variability in intake covers a smaller range (two logs) than many other parts of the model.

Table III-3 shows the 50^{th}, 75^{th}, 95^{th} and 99^{th} percentiles of the weighted distributions of serving size. For Smoked Seafood, for example, these percentiles are and 57, 75, 136 and 142 g/serving, respectively.

Table III-2. Annual Servings of Foods Consumed in the U.S. by Subpopulation and Food Category

Food Category[b]	Intermediate-Age Population	Perinatal Population[a]	Elderly Population	Total Population
SEAFOOD				
Smoked Seafood	1.63×10^{8}	3.07×10^{5}	4.13×10^{7}	2.05×10^{8}
Raw Seafood	1.82×10^{8}	2.74×10^{5}	5.73×10^{5}	1.82×10^{8}
Preserved Fish	8.27×10^{7}	1.58×10^{5}	2.24×10^{7}	1.05×10^{8}
Cooked Ready-to-Eat Crustaceans	4.70×10^{8}	8.28×10^{5}	8.13×10^{7}	5.52×10^{8}
PRODUCE				
Vegetables	9.55×10^{10}	1.76×10^{8}	2.18×10^{10}	1.17×10^{11}
Fruits	3.78×10^{10}	7.55×10^{7}	1.25×10^{10}	5.03×10^{10}
DAIRY				
Soft Mold-Ripened and Blue-Veined Cheese	2.06×10^{8}	3.67×10^{5}	3.88×10^{7}	2.44×10^{8}
Goat, Sheep, and Feta Cheese	2.06×10^{8}	3.83×10^{5}	4.90×10^{7}	2.55×10^{8}
Fresh soft cheese (e.g., queso fresco)	1.29×10^{8}	2.02×10^{5}	5.27×10^{6}	1.34×10^{8}
Heat-Treated Natural Cheese and Processed Cheese	1.56×10^{10}	2.73×10^{7}	2.60×10^{9}	1.82×10^{10}
Aged Cheese	1.21×10^{10}	2.08×10^{7}	1.70×10^{9}	1.38×10^{10}
Pasteurized Fluid Milk	7.23×10^{10}	1.31×10^{8}	1.49×10^{10}	8.72×10^{10}
Unpasteurized Fluid Milk[c]	3.61×10^{8}	6.54×10^{5}	7.47×10^{7}	4.36×10^{8}
Ice Cream and Frozen Dairy Products	1.18×10^{10}	2.23×10^{7}	3.07×10^{9}	1.49×10^{10}
Miscellaneous Dairy Products	2.26×10^{10}	4.22×10^{7}	5.46×10^{9}	2.81×10^{10}
MEATS				
Frankfurters	5.90×10^{9}	9.79×10^{6}	6.29×10^{8}	6.52×10^{9}
Dry/Semi-Dry Fermented Sausages	1.54×10^{9}	2.68×10^{6}	2.47×10^{8}	1.79×10^{9}
Deli Meats	1.78×10^{10}	3.10×10^{7}	2.84×10^{9}	2.07×10^{10}
Pâté and Meat Spreads	9.71×10^{7}	1.77×10^{5}	2.08×10^{7}	1.18×10^{8}
COMBINATION FOODS				
Deli Salads	4.47×10^{9}	8.44×10^{6}	1.16×10^{9}	5.63×10^{9}

[a] For the purposes of estimating rates of listeriosis per serving, the values for the perinatal group were calculated by adjusting the number of annual servings for the total population for the annual birth rate: The annual birth rate as a fraction of the total population (1.5 %) was multiplied by the number of servings for the total population and then divided by 12 (to estimate the number of pregnant women in the last month of pregnancy).

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

[c] Consumption of Unpasteurized Fluid Milk is based on 0.5% of pasteurized milk.

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

Food Categories	Weighted Percentiles (grams per serving)[a]			
	50th	75th	95th	99th
Seafood				
Smoked Seafood	57	75	136	142
Raw Seafood	16	28	77	136
Preserved Fish	70	125	130	250
Cooked Ready-to-Eat Crustaceans	50	96	256	345
Produce				
Vegetables	28	55	135	248
Fruits	118	138	272	570
Dairy				
Soft Mold-Ripened and Blue-Veined Cheese	17	34	69	87
Goat, Sheep, and Feta Cheese	26	38	88	113
Fresh soft cheese (e.g., queso fresco)	34	73	185	246
Heat-Treated Natural Cheese and Processed Cheese	21	42	113	226
Aged Cheese	27	43	85	142
Pasteurized Fluid Milk	244	245	488	732
Unpasteurized Fluid Milk	244	245	488	732
Ice Cream and Frozen Dairy Products	132	186	330	454
Miscellaneous Dairy Products	15	61	254	490
Meats				
Frankfurters	57	114	171	285
Dry/Semi-Dry Fermented Sausages	46	69	161	161
Deli Meats	56	75	113	196
Pâté and Meat Spreads	57	85	128	454
COMBINATION FOODS				
Deli Salads	104	177	338	531

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

Food Contamination

Over the last fifteen years, numerous studies have been published that report on foods contaminated with *L. monocytogenes* in a variety of countries and locations. Contamination data included in this risk assessment were reported from the U. S. and other countries on six continents. Most of the studies were from the industrialized countries of Western Europe and North America. Many studies did not identify imported foods or indicate whether imports were excluded from the study.

Data were initially collected on food contamination by all *Listeria* species. However, data for all *Listeria* species were not used because there were adequate *L. monocytogenes* occurrence and quantitative data for most food categories. In any case, there are few published reports of the ratio of non-*L. monocytogenes* to *Listeria monocytogenes*, and some experts expressed doubts about the use of all *Listeria* as surrogates for *L. monocytogenes*. Contaminant serotype information was not considered because the food contamination studies did not usually identify the serotypes.

Data sources included the published scientific literature, published and unpublished official government documents, and data obtained from the private sector. Two types of data describing the levels of *L. monocytogenes* contamination in food were identified:

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

Both qualitative and quantitative studies were used in the assessment (Table III-4). Data from presence/absence studies (qualitative data) were converted to numerical data and included in the model by assigning the lowest possible contamination level that can be detected by current laboratory methods that use a 25-g sample (0.04 cfu/gram of food). Thus, both qualitative and quantitative data were used in the construction of the cumulative distribution curves of *L. monocytogenes* levels in food.

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

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

Food Category	Number of Studies[a]					Number of Samples[b]		Percent Positive Samples
	Total	U.S.	Post 1993	Total Quant	U.S. Quant	Qual.	Quant.	
SEAFOOD								
Smoked Seafood	12	2	5	4	1	2596	1026	15.2
Raw Seafood	31	7	11	3	1	13248	363	7.1
Preserved Fish	11	0	5	4	0	694	620	10.2
Cooked Ready-to-Eat Crustaceans	8	3	3	3	2	3460	179	2.8
PRODUCE								
Vegetables	22	3	9	6	0	2028	1363	7.8
Fruits	4	1	1	1	0	482	43	10.7
DAIRY								
Soft Mold-Ripened and Blue-Veined Cheese	8	1	4	3	0	674	1089	5.7
Goat, Sheep, and Feta Cheese	5	1	1	3	0	97	734	7.0
Fresh soft cheese (e.g., queso fresco)[c]	6	1	3	2	0	148	49	17.3
Heat-Treated Natural Cheese and Processed Cheese	5	1	2	1	0	300	366	1.2
Aged Cheese	8	1	2	2	0	2348	1018	1.9
Pasteurized Fluid Milk[d]	25	2	8	2	0	10373	107	0.4
Unpasteurized Fluid Milk[d]	38	7	7	3	0	12065	961	4.4
Ice Cream and Frozen Dairy Products	13	3	6	1	0	24262	68	0.7
Miscellaneous Dairy Products	8	2	3	2	0	1144	199	1.7
MEAT								
Frankfurters	6	4	3	2	2	1717	157	7.6
Dry/Semi-Dry Fermented Sausages	10	1	3	3	0	1782	745	7.8
Deli Meats[e]	5	1	4	1	0	10166	879	2.8
Pâté and Meat Spreads	7	1	5	5	0	623	4406	5.6
COMBINATION FOODS								
Deli Salads	7	2	2	3	0	1936	1182	9.9

[a] See Appendix 5 for the reference citation for each study.

[b] Total number of samples equals qualitative (Qual.) plus quantitative (Quant.) samples for each category. Percent value times total, divided by 100 = number positive samples.

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

[d] All available data from North America and Europe were used in the modeling to characterize the distribution of contamination data for these milk food categories, but only the data from North America were used in the characterization of the prevalence of the contamination. The percent positives for samples collected in North America are 0.12% for pasteurized milk and 2.9% for unpasteurized milk.

[e] Includes one study that used a <20 cfu/g detection limit. This value was considered to approximate the presence/absence detection limit of 0.04 cfu/g.

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

The analytical methods used in the food contamination studies to determine the presence of *L. monocytogenes* were generally well known and were approximately equal in sensitivity at about 1 cfu per 25 g sample (0.04 cfu/g). However, for enumeration methods of analysis, the sample size was usually less than 25 g. Typically, the samples obtained for analysis were from non-composited samples of food. An exception, however, was unpasteurized fluid milk obtained from bulk tanks.

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

The available data on *L. monocytogenes* levels had some limitations that affected the distributions for levels of *L. monocytogenes* in foods. First, there are relatively few data points above the limit of detection (0.04 cfu/g). This is because the occurrence of detectable levels of *L. monocytogenes* in food is rare and because most surveys of the occurrence of *L. monocytogenes* in food did not quantify the levels in positive samples. Second, some of the data are not from the U. S. and, despite the assumption that contamination distributions for food in the U.S. do not vary significantly from those in other countries, the data may not always be representative of food and food processing procedures in the U. S. In the case of Fluid Pasteurized Milk and Fluid Unpasteurized Fluid Milk, these differences were sufficient to warrant relying on Noth American data for the frequency of contamination. However, insufficient quantitative data were available to use only North American data for the distribution of contamination levels, and international data were used to derive those distributions. Third, there was a wide degree of variation between studies in the occurrence of high levels of *L. monocytogenes*. The extent to which this variation reflects true variation in a particular food, is not known.

Many of the studies found in the published literature were conducted in the late 1980s and early 1990s. The extent to which improved sanitation and other control measures implemented by the food industry have reduced the frequency and level of contamination since 1993 (when the earlier research was conducted) is difficult to determine from published literature. A comparison of the results of studies conducted before and after 1993 was done. This comparison provided an indication of whether the studies conducted before or after 1993 would affect the estimations of contamination data used in the risk assessment, and therefore would constitute a critical bias factor (Table III-4). While some food categories showed a decline in contamination post-1993 others showed an increase or little change. Therefore, all data were used. A detailed analysis of the levels of *L. monocytogenes* in foods from studies pre- and post-1993 is provided in tabular form in Appendix 7 (Table A7.1).

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

Modeling: *L. monocytogenes* Levels in Food at Retail

Quantitative data on *L. monocytogenes* contamination are presented as colony forming units per gram of food (cfu/g) and negative presence/absence data are converted to a level of <0.04 cfu/g. The frequency distribution of *L. monocytogenes* levels in appropriate concentration categories was calculated on one-half logarithmic unit ranges. The cumulative frequency of occurrence versus the $\log_{10}$ of the levels (cfu/g) was plotted. The resulting data points were fit with curves corresponding to Lognormal, Weibull-Gamma, and Beta-Poisson distributions. Occurrence data are also presented as the number of positive samples per number of samples of the food examined.

Distributions of *L. monocytogenes* levels for each food category were generated by fitting statistical distribution equations to the data. Because most of the data points were <0.04 cfu/g, the equations were fit to the upper tail. Of twelve distribution equations examined, only three, the Lognormal, Weibull-Gamma, and Beta equations, could accommodate the extreme ranges of *L. monocytogenes* levels encountered. A graph showing the cumulative frequencies of contamination and the fits of three mathematical models (Lognormal, Weibull-Gamma, and Beta) is provided in Appendix 5 for each food category. The values of the three models were optimized using a weighted least squares goodness-of-fit criterion. The weight accorded to a particular study was proportional to the number

of samples in the study. Greater weight was given to data points at higher levels. Unless this weighting was done, the preponderance of data points at the level of detection (0.04 cfu/g) often prevented the sparser number of data points at higher levels from influencing the model fit. There was no representation of sampling error included in the uncertainty analysis for the distribution of *L. monocytogenes*.

As an example, the process by which contamination levels were estimated can be illustrated using data for *L. monocytogenes* in the Smoked Seafood category (see Appendix 5). Figure A5.1.2 (see Appendix 5) is a cumulative frequency graph where the x-axis is the contamination level (cfu/g) and the y-axis is the fraction of data points with that value or lower values. The y-axis ranges from 0.6 to 1.0. Different statistical distributions were fitted to the cumulative frequency distribution with the residual sums of squares for each frequency distribution used to weight the distributions. The probability column in Table A5.1.4 (see Appendix 5) indicates the weights for the three distributions. In this example the Weibull-Gamma and Beta distributions have 45 and 35% of the weight, respectively.

Table III-5 shows the modeled distributions for *L. monocytogenes* contamination for the 20 food categories at retail. The table presents the predicted percentage of servings contaminated with increasing levels of *L. monocytogenes*. The predicted median of the fraction of servings having less than one cfu of *L. monocytogenes* per serving ranged from 70.6 to 99.2% for the various food categories. In other words, 1 to 29% of the servings had one or more *L. monocytogenes* cfu per serving, regardless of the food category. Although servings of all food categories are likely to be contaminated, to some degree, at the retail level, servings of certain food categories (*e. g.,* Smoked Seafood, and Deli Salads) were the most likely to be contaminated.

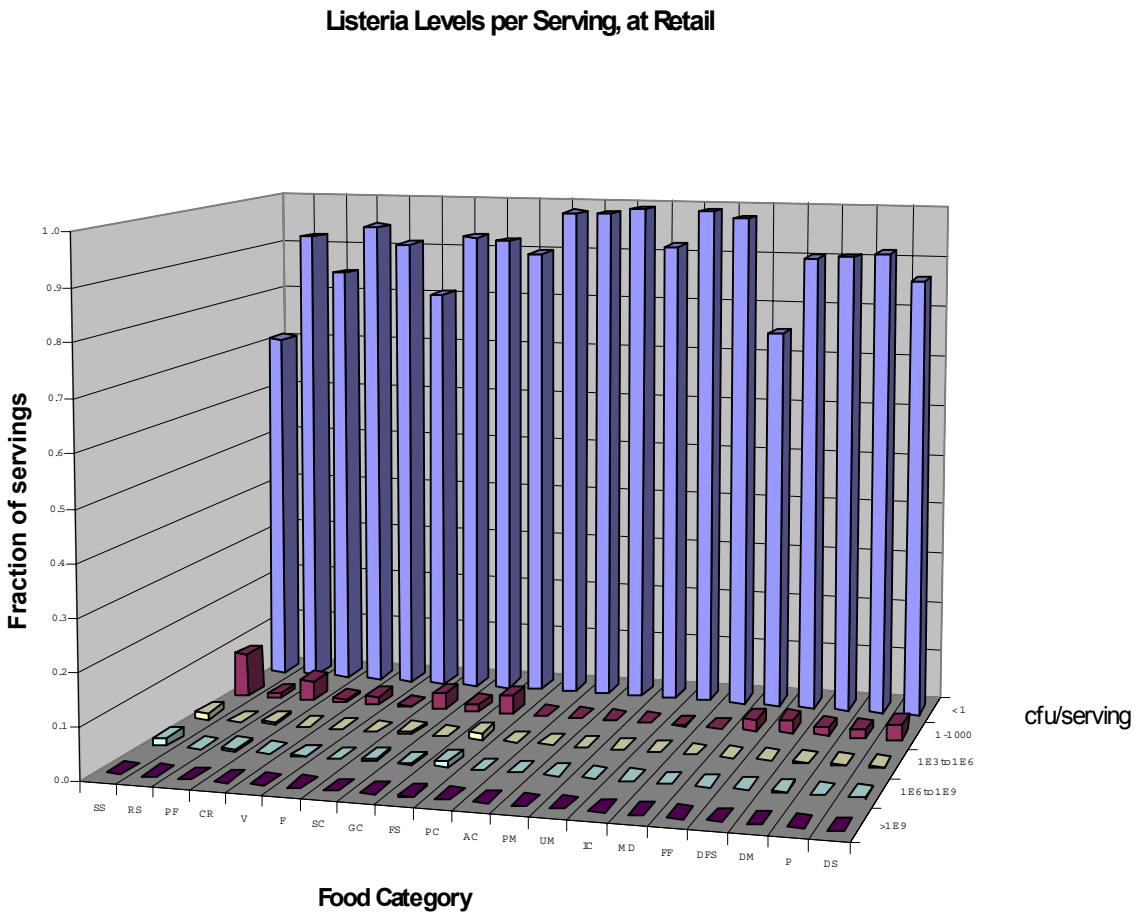
The bar chart in Figure III-1 provides a graphic depiction of the modeled distributions. Most of the servings for each food category are in the <1 cfu/serving level (back row of bars). As the level of contamination per serving rises (moving into the front rows of bars), the fraction of servings decreases markedly for most of the food categories. For the Fresh Soft Cheese and Smoked Seafood food categories, the fractions of servings at higher levels of contamination decrease less rapidly than for most categories. Thus, for the Fresh Soft Cheese category, the fraction of servings at <1, 1 to 10^3, 10^3 to 10^6, 10^6 to 10^9, and >10^9 cfu/serving are about 89.7, 5.2, 4.0, 1.2 and 0.1% of servings, respectively.

The median values show that higher levels of contamination are a decreasing proportion of the servings within any food category. This distribution of median values is an estimate of the variation in contamination levels. Table III-5 groups the contaminated servings by 10^3 fold ranges, the actual modeling used 0.5 log ranges. The percentiles indicate the uncertainty about the median values.

Table III-5. Modeled Percentage Distribution of Food Servings Contaminated with *Listeria monocytogenes* at Retail

Food Category	Median Percentage of Servings Contaminated at Different Levels									
	<1 cfu/serving		1 - 1000 cfu/serving		10^3 - 10^6 cfu/serving		10^6 - 10^9 cfu/serving		> 10^9 cfu/serving	
	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]
Seafood										
Smoked Seafood	70.6	70.4, 76.2	18.7	11.9, 21.2	8.5	6.8, 11.0	1.4	0.9, 2.0	0.1	0.0, 0.2
Raw Seafood	92.0	92.0, 92.7	7.2	5.3, 7.2	0.8	0.7, 2.0	0.0	0.0, 0.0	0.0	0.0, 0.0
Preserved Fish	84.8	82.9, 88.2	10.4	6.3, 13.4	3.9	3.2, 5.3	0.5	0.2, 0.9	0.0	0.0, 0.0
Cooked Ready-to-Eat Crustaceans	94.5	93.3, 96.1	5.0	1.6, 6.4	0.5	0.2, 1.5	0.0	0.0, 0.8	0.0	0.0, 0.0
Produce										
Vegetables	91.0	90.1, 91.8	7.3	5.6, 8.8	1.6	1.1, 2.6	0.0	0.0, 0.0	0.0	0.0, 0.0
Fruits	80.7	80.6, 86.0	19.2	12.5, 19.4	0.1	0.0, 1.5	0.0	0.0, 0.0	0.0	0.0, 0.0
Dairy										
Soft Mold-Ripened and Blue-Veined Cheese	92.8	90.0, 92.8	3.5	3.5, 7.7	3.2	2.0, 3.2	0.5	0.2, 0.5	0.0	0.0, 0.0
Goat, Sheep, and Feta Cheese	92.2	90.9, 92.5	6.3	5.7, 7.5	1.4	1.2, 2.1	0.1	0.0, 0.2	0.0	0.0, 0.0
Fresh soft cheese (e.g., queso fresco)	89.7	89.1, 90.3	5.2	3.8, 6.2	4.0	3.3, 5.0	1.2	1.1, 1.3	0.1	0.0, 0.2
Heat-Treated Natural Cheese and Processed Cheese	98.0	98.0, 98.6	1.8	1.4, 2.0	0.1	0.0, 0.3	0.0	0.0, 0.0	0.0	0.0, 0.0
Aged Cheese	98.0	97.9, 98.0	2.0	1.0, 2.0	0.0	0.0, 0.9	0.0	0.0, 0.3	0.0	0.0, 0.0
Pasteurized Fluid Milk	99.2	98.9, 99.6	0.8	0.4, 1.1	0.0	0.0, 0.0	0.0	0.0, 0.0	0.0	0.0, 0.0
Unpasteurized Fluid Milk	91.9	90.0, 95.9	7.9	3.5, 9.5	0.2	0.0, 0.6	0.0	0.0, 0.0	0.0	0.0, 0.0
Ice Cream/Frozen Dairy Products	99.0	99.0, 99.0	0.5	0.4, 0.9	0.0	0.0, 0.3	0.0	0.0, 0.3	0.0	0.0, 0.0
Misc. Dairy Products	97.9	97.8, 98.5	2.1	1.5, 2.2	0.0	0.0, 0.0	0.0	0.0, 0.0	0.0	0.0, 0.0
Meats										
Frankfurters	75.2	73.4, 85.7	22.8	11.2, 24.3	2.6	2.0, 3.1	0.0	0.0, 0.0	0.0	0.0, 0.0
Dry/Semi-Dry Fermented Sausages	90.3	90.2, 92.3	6.8	4.3, 8.3	2.4	1.3, 3.4	0.1	0.1, 0.5	0.0	0.0, 0.0
Deli Meats	90.7	89.0, 91.2	7.7	6.9, 9.1	1.6	1.6, 1.7	0.2	0.0, 0.2	0.0	0.0, 0.0
Pâté and Meat Spreads	91.5	91.4, 94.0	6.7	3.5, 7.2	1.6	1.3, 2.4	0.1	0.0, 0.2	0.0	0.0, 0.0
Combination Foods										
Deli Salads	86.3	83.0, 90.1	9.9	5.3, 15.1	3.2	1.8, 4.4	0.2	0.1, 0.6	0.0	0.0, 0.0

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



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

Figure III-1. Modeled Distribution of *Listeria monocytogenes* Contamination Levels in Food Servings at Time of Retail

Growth Between Retail and Consumption

Most of the contamination data used in this risk assessment were from samples taken during retail or storage prior to retail. Because *L. monocytogenes* can grow slowly at refrigeration temperatures and more rapidly at higher temperatures, a growth module was incorporated into the exposure assessment. The growth model provides an estimate of likely growth and thus a better estimate of the numbers of *L. monocytogenes* consumed for each food category.

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

Some of the presence/absence data points were determined on samples taken after production or in the warehouse, not at retail. To adjust those values a simple growth model was used. The temperature ranges and storage times for the food categories are in Table III-6. These values were based on data received from the industry and other sources related to the times and temperatures likely to be encountered between manufacture and retail. The uniform distribution for temperature is used to determine exponential growth rate (see section titled, Modeling: Exponential Growth Rates). The exponential growth rate is multiplied by the storage time, also a uniform distribution, to estimate the amount of growth. A Monte Carlo simulation is run for each food category to determine a mean amount of growth. This point value is used to adjust the presence/absence data. If, for example, the estimated growth was 0.5 logs prior to retail, a study with 5% positive at 0.04 cfu/g at manufacture would become 5% positive at 0.13 cfu/g at retail.

Table III-6. Estimated Storage Temperature and Duration Between Manufacture and Retail

Food Category	Temperature Range (°C)	Storage Time Range (days)
SEAFOOD		
Smoked Seafood	1 to 5	1 to 30
Raw Seafood	1 to 5	1 to 3
Preserved Fish	**Not applicable**[a]	
Cooked RTE Crustaceans	1 to 5	1 to 3
PRODUCE		
Vegetables	1 to 5	1 to 5
Fruits	1 to 5	1 to 5
DAIRY		
Soft Mold-Ripened and Blue Veined Cheese	1 to 5	1 to 30
Goat, Sheep and Feta Cheese	1 to 5	1 to 45
Fresh Soft Cheese	1 to 5	1 to 5
Heat-Treated Natural Cheese and Processed Cheese	1 to 5	1 to 5
Aged Cheese	1 to 5	1 to 45
Pasteurized fluid milk	1 to 5	1 to 3
Raw fluid milk	1 to 5	1 to 3
Ice Cream and Frozen Dairy Products	**Not applicable**[a]	
Miscellaneous Dairy Products	1 to 5	1 to 30
MEATS		
Frankfurters	1 to 5	1 to 30
Dry/ Semi-Dry Fermented Sausage	**Not applicable**[a]	
Deli Meats	1 to 5	1 to 30
Pâté and Meat Spreads	1 to 5	1 to 7
COMBINATION FOODS		
Deli Salads	1 to 5	1 to 3

[a] No *Listeria monocytogenes* growth expected in these foods during storage.

Modeling: Exponential Growth Rates

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

$$\sqrt{EGR} = a(T - T_0) \qquad \text{Equation [1]}$$

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

Different storage temperatures were used in the studies from the published literature that reported growth of *L. monocytogenes* in various foods. Therefore, using the data from these studies, equivalent EGRs ($\log_{10}$ cfu/day) at 5°C were calculated. The equation for this ratio is presented as Equation 2 and is a rearrangement of Equation 1.

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

where $\mathbf{EGR_5}$ is the converted growth rate at 5°C, $\mathbf{EGR_{lit}}$ is the growth rate from the inoculated pack study, $\mathbf{T_5}$ is set to 5°C to standardize the EGRs, and $\mathbf{T_{lit}}$ is the temperature used in the literature.

A summary of the converted growth rate data for the 20 food categories is presented in Table III-7. A list of references and literature data that were included in each food category can be found in Appendix 8. Significant differences in composition and processes are present within many of the food categories. Within the Smoked Seafood food category, for example, there were hot and cold smoked fish, various salt levels, both aerobic and vacuum packaging, and different fish species. The modeling process used a cumulative table of the actual data points, not the means and standard deviations presented in the summary. If a category had five or more data points, the cumulative distribution was fitted by different equations for the variation, and the uncertainty was estimated by the different values obtained from the different equations (Appendix 5).

For categories with fewer than five data points, a Triangular distribution defined by the minimum, most frequent (mode), and maximum values was used. For those categories with only two points, a rectangular distribution was used with the two points being the minimum and the maximum of the distribution. In some food categories, the *L. monocytogenes* levels declined, usually at a slow rate. The rate of decline was modeled with the same square root model (Equation 1) as for growth with a

negative slope (**a**) and a negative EGR. Negative EGR values from the literature were combined with positive data to create one distribution, which was fitted to the growth models as explained earlier. The rate of decline was adjusted for temperature, after being converted to a positive value, by the same ratio method of Equation 2. Increasing the storage temperature above 5°C increases the rate of decline and conversely temperature decreases below 5°C decrease the rate of decline. This approach agrees with the USDA Pathogen Modeling Program (USDA, 1997) which predicts faster rates of decline at higher storage temperatures. This relatively simple approach to modeling growth versus decline (survival) sufficiently accounted for the relatively slow rates of declines encountered in this risk assessment.

As an example, data from the Smoked Seafood food category (see Appendix 5) will be used to illustrate how the exponential growth rate of *L. monocytogenes* was calculated. Briefly, the data sets are placed in order of ascending magnitude. Figure A5.1.3 (see Appendix 5) entitled Cumulative Distribution for the Exponential Reference Growth Rate (5 °C) is a cumulative frequency graph where the x-axis is the EGR in $\log_{10}$ cfu/day and the y-axis is the fraction of data points from the literature with that value or lower values from Appendix 8. The y-axis ranges from 0.0 to 1.0. Different statistical distributions are fitted to the cumulative frequency distribution with the residual sums of squares for each frequency distribution used to weight the distributions. The probability column Table A5.1.7 (see Appendix 5) indicates the weights for the four best-fitting distributions. In this example, the Lognormal and Gamma distributions have 36 and 31% of the weight, respectively. The Triangular and Beta distributions had poorer fits and carried relatively little weight. The probability of each growth model dictates the frequency of selection of each distribution for use in each uncertainty iteration during a Monte Carlo simulation (Cassin, *et al*., 1998; Vose, 1998). The variation predominantly reflects the shape(s) of the most heavily weighted statistical distribution. There is no theoretical support for one distribution to be more appropriate than any other distribution. Therefore, the uncertainty reflects the range of values generated by the different statistical distributions and they are used in proportion to their weights.

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

Table III-7. Mean Exponential *Listeria monocytogenes* Growth Rates and Total Number of Samples From Growth Rate Studies for Each Food Category

Food Categories	Growth Rate at 5 °C		Number of Samples
	Mean (log_{10} cfu/g per day)	Standard Deviation	
SEAFOOD			
Smoked Seafood	0.155	0.100	25
Raw Seafood	0.152	0.126	5
Preserved Fish		**No Growth**	
Cooked Ready-to-Eat Crustaceans	0.383	0.110	3
PRODUCE			
Vegetables	0.065	0.094	22
Fruits	0.041	NA[a]	1
DAIRY			
Soft Mold-Ripened and Blue-Veined Cheese	0.058	0.068	7
Goat, Sheep, and Feta Cheese	- 0.008	0.008	3
Fresh soft cheese (e.g., queso fresco)	0.142	NA	1
Heat-Treated Natural Cheese and Processed Cheese	0.105	0.289	28
Aged Cheese	- 0.031	0.080	8
Pasteurized Fluid Milk[b]	0.262[b]	0.115	10
Unpasteurized Fluid Milk[b]	0.262[b]	0.115	10
Ice Cream and Frozen Dairy Products		**No Growth**	
Miscellaneous Dairy Products	- 0.014	0.192	11
MEATS			
Frankfurters	0.125	0.058	4
Dry/Semi-Dry Fermented Sausage		**No Growth**	
Deli Meats	0.244	0.137	17
Pâté and Meat Spreads	0.250	0.156	2
Combination Foods			
Deli Salads[c]	0.244[c]	0.137[c]	17[c]

[a] NA = Not applicable
[b] Pasteurized and unpasteurized milk were combined for analysis of exponential growth rate of fluid milk.
[c] No data; growth rate for deli meats was used as a surrogate for this food category.

Refrigeration Temperatures

Data for home refrigerator temperatures were obtained from a 1999 survey conducted by Audits International (Audits International, 1999). Nine hundred thirty nine refrigerators in the U. S. were included in the survey and 26% of the refrigerators exceeded 5°C (Table III-8). The refrigeration temperatures were modeled with an empirical distribution where values were interpolated from the table of percentages provided by Audits International.

Table III-8. Frequency Distribution of Home Refrigerator Temperatures

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

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

Post-Retail Storage Times

The storage times were multiplied by the EGR to provide an estimate of the amount of *L. monocytogenes* growth occurring between retail purchase of the food and its consumption. Some foods are consumed on the day of purchase whereas others remain in the home refrigerator for lengthy periods of time. This is a major source of variability in the estimate of growth. Except for frankfurters and deli meats, no data were found on the storage of foods in the home; therefore, storage time, including variation and uncertainty, were estimated (Table III-9) based on the expert judgments of individuals familiar with the production and use of the various foods. The variation in storage time was described using a modified BetaPert distribution. The BetaPert was modified by increasing the weight for the central value from 4 to 7. This modification reduced the frequency of values in the extended tails, Figure III-2. The two values for both the most likely and maximum

storage times are for the negative conclusion with high and low refrigeration temperatures, respectively (see following section). The storage times were not considered for foods where *L. monocytogenes* does not grow.

The uncertainty was also described using a ±20% uniform distribution for the most frequent value and a ±50% uniform distribution for the maximum value, with a 100% correlation between the two distributions. These times were compared to recommended storage times. However, foods are often kept beyond recommended storage times. This risk assessment models estimated consumer food practices, not necessarily the recommended practices.

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

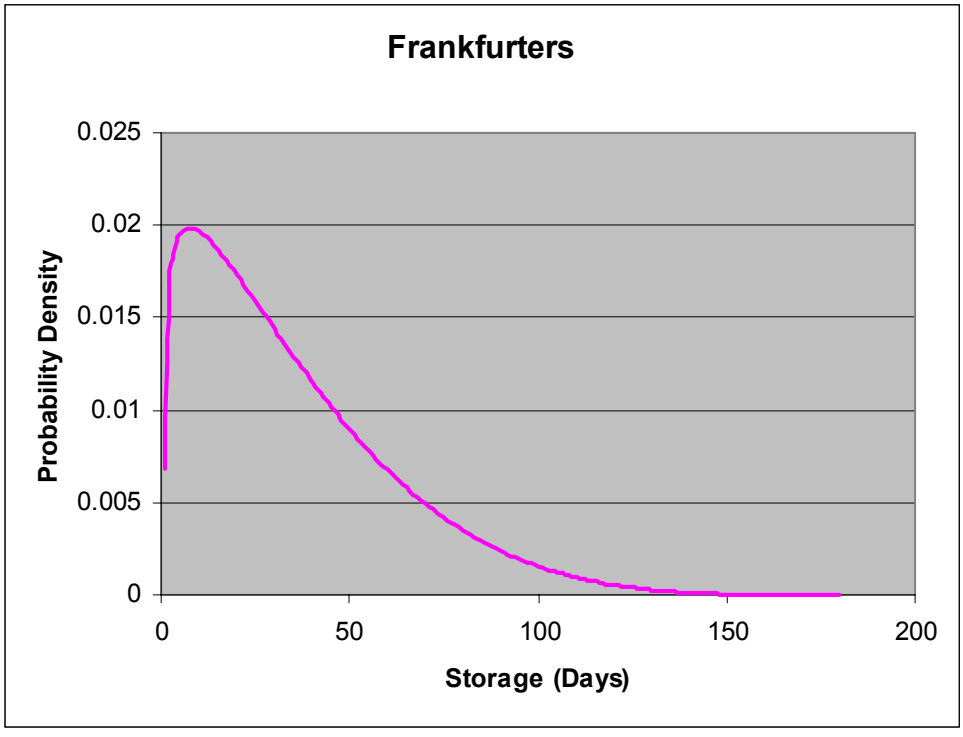


Figure III-2. Example of a Modified BetaPert Distribution

Table III-9. Variation in Post-Retail Storage Times Assigned to the Food Categories

Food Categories	Storage time (days)[a]		
	Minimum	Most Likely	Maximum
SEAFOOD			
Smoked Seafood	0.5	6 to 10	15 to 45
Raw Seafood	0.5	1 to 2	10 to 20
Preserved Fish		**Not Applicable[b]**	
Cooked Ready-to-Eat Crustaceans	0.5	1 to 2	10 to 20
PRODUCE			
Vegetables	0.5	3 to 4	8 to 12
Fruits	0.5	3 to 4	8 to 12
DAIRY			
Soft Mold-Ripened and Blue-Veined Cheese	0.5	6 to 10	15 to 45
Goat, Sheep, and Feta Cheese	0.5	6 to 10	15 to 45
Fresh soft cheese (e.g., queso fresco)	0.5	6 to 10	15 to 45
Heat-Treated Natural Cheese and Processed Cheese	0.5	6 to 10	15 to 45
Aged Cheese	0.5	6 to 10	90 to 180
Pasteurized Fluid Milk	0.5	3 to 5	10 to 15
Unpasteurized Fluid Milk	0.5	3 to 4	6 to 10
Ice Cream and Frozen Dairy Products		**Not Applicable[b]**	
Miscellaneous Dairy Products	0.5	6 to 10	15 to 45
MEATS			
Frankfurters	0.5	5 to 7	90 to 180[c]
Dry/Semi-Dry Fermented Sausages		**Not Applicable[b]**	
Deli Meats	0.5	5 to 7	20 to 30[c]
Pâté and Meat Spreads	0.5	6 to 10	15 to 45
COMBINATION FOODS			
Deli Salads	0.5	3 to 4	8 to 12

[a] The values represent a temperature-dependent range of storage times where the length of storage is negatively correlated with temperature. Higher storage temperatures have the short times. Uncertainty was represented with a uniform distribution corresponding to ±20% of the nominal most frequent value and ±50% of the nominal maximum value. A modified BetaPert model was used to create the distribution where the most frequent value was given a weight of 7 times that of the tails. The selected storage intervals were based on the expert opinion of the risk assessment team, in consideration with agency recommended storage times, except as noted for frankfurters and deli meats.

[b] No *Listeria monocytogenes* growth expected in these foods during storage.

[c] Provided by FSIS based on preliminary survey data (Wachsmuth, 2000).

Interaction of Storage Times and Temperatures

Increases in the levels of *L. monocytogenes* were calculated as the product of the EGR (which is dependent on the refrigeration temperature) and storage time. The Monte Carlo simulation program randomly selects different values from each calculated distribution. Both temperature and time distributions are concentrated toward the center of their ranges, 4°C and 8 days, respectively for

Smoked Seafood. As a result, the most frequent estimates of growth would reflect these conditions. The simulation process would also select, at a lower frequency, the combination of low refrigeration temperatures and short storage times. Such combinations would result in relatively little growth. Similarly, the process could select high refrigeration temperatures and long storage times, 10°C and 45 days, which would result in extensive growth. However, this combination of temperatures and times would likely result in the food showing obvious spoilage and hence would not be consumed. Modeling the refrigeration temperature and storage time distributions as independent distributions was not believed to be appropriate. Therefore, the uncertainties in the mode and maximum storage times were negatively correlated to the temperature. For example, for Smoked Seafood, this means the mode ranged from 6 to 10 days. When refrigeration temperature was 10°C, the time was 6 days and when the temperature was 0°C the time was 10 days. The maximum storage time similarly ranged from 15 to 45 days for 10°C and 0°C storage, respectively.

Maximum Growth Levels

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

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

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

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

Thermal Inactivation

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

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

that at least one household member has eaten frankfurters directly from the package (Wachsmuth, 2000). Therefore, an estimated range of 1 to 14% of frankfurters were assumed to be eaten non-reheated (i.e., directly from the package). A triangular distribution with a minimum of 1, a maximum of 14, and a most likely value of 3.3 was used to model the consumption of non-reheated frankfurters.

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

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

$$\log_{10} \text{survivors} = 20.53 - 0.12\ T \qquad \text{Equation [3]}$$

The maximum cooking temperature to calculate the decrease (T) is in degrees Fahrenheit. Because the initial contamination was 6.6 logs, the equation can be rearranged to calculate the decrease in

contamination and applied to any initial level of contamination. The temperature was also converted into degrees Celsius:

$$\log_{10} \text{ reduction} = 0.216 (T - 46.4) \qquad \text{Equation [4]}$$

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

Reductions in *L. monocytogenes* levels were calculated by estimating a distribution of cooking temperatures with a triangular distribution having a minimum of 54 ºC, most frequent temperature in the range of 69 to 73 ºC, and a maximum of 77 ºC. The four-degree range for the most frequent temperature represents uncertainty in the cooking temperature distribution. Table III-10 contains the resulting cumulative distribution in log reductions for the frankfurters that were given some reheating, the remainder had no reduction in *L. monocytogenes* after the growth modeling.

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

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

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

Modeled Contamination at Consumption

The estimated levels of *L. monocytogenes* at consumption are presented on Table III-11. This table has the same format as the table for *L. monocytogenes* contamination at retail (Table III-5), and may be directly compared to it to observe the shift in levels of *L. monocytogenes* after storage and/or heating. The median percentage of servings that fall within designated ranges of *L. monocytogenes* levels per serving are presented. The actual simulation modeling was at narrower levels (every logarithm and half-logarithm cfu/serving). The 5 and 95% values for the distributions for *L. monocytogenes* levels in each food are also given. These distributions indicate the uncertainty in the value for each median. The distribution observed with the values across a row gives the variation in *L. monocytogenes* levels expected for each food category. Because these medians are from skewed uncertainty distributions and because of rounding errors, a row may not sum to exactly 1.00.

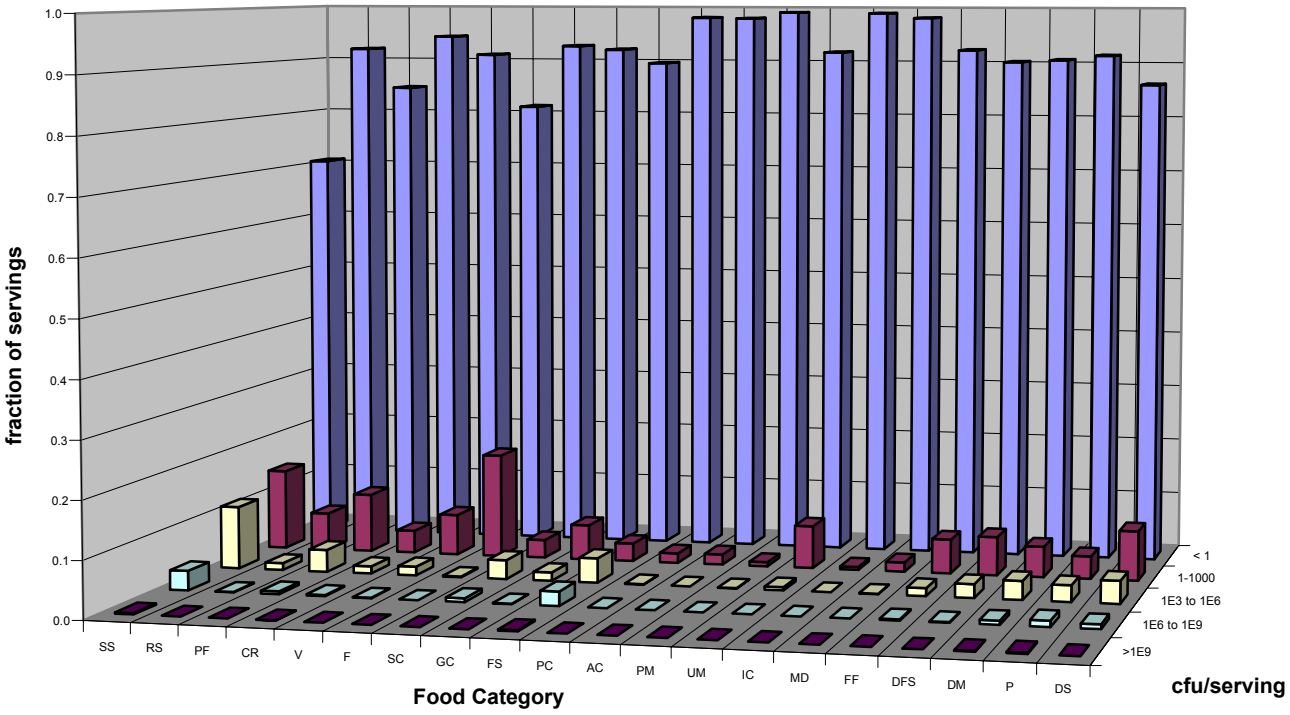
The table column with 10^6 to 10^9 *L. monocytogenes* per serving is the level where the occurrence of listeriosis would be expected to be most likely. Fresh Soft Cheese, Smoked Seafood, and Pâté and Meat Spreads categories comprise a group of foods estimated to have the greatest likelihood of containing 10^6 to 10^9 *L. monocytogenes* per serving. Soft Mold-Ripened and Blue Veined Cheese, Deli Salads, Deli Meats and Preserved Fish food categories form a second group that is next most likely to contain high levels of *L. monocytogenes.* These levels are illustrated in Figure III-3. The row in the rear represents the fraction of servings with <1.0 cfu *L. monocytogenes*. Over three-quarters of the food categories each have more than 90% of their servings in this contamination range. In contrast, Smoked Seafood has only slightly more than 70% of its servings in the <1.0 cfu per serving contamination range. The rows have increasing levels of contamination toward the front of the figure.

Comparing corresponding values in Tables III-10 and III-5 allows prediction of the effect of storage conditions on ultimate levels of *L. monocytogenes* at retail. Fresh Soft Cheese and Smoked Seafood have some of the most dramatic changes. For example, at retail, 1.2% of Fresh Soft Cheese servings would be in the 10^6 to 10^9 cfu/serving group. This increases to 2.5% at the time of consumption. Frankfurters have an increase in the 10^6 to 10^9 cfu/serving group from *L. monocytogenes* growth in the small portion of franks not reheated. The overall reduction in *L. monocytogenes* from reheating is evident in the <1, 1-1000 and 10^3 to 10^6 cfu/serving groups.

Table III-11. Modeled Percentage Distribution of Food Servings Contaminated with *Listeria monocytogenes* at Time of Consumption

Food Category	Median Percentage of Servings Contaminated at Different Levels[a]									
	<1 cfu/serving		1 - 1000 cfu/serving		10^3 - 10^6 cfu/serving		10^6 - 10^9 cfu/serving		> 10^9 cfu/serving	
	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]	Median	Percentiles[a]
Seafood										
Smoked Seafood	70.6	70.4, 76.2	14.3	8.1, 17.6	11.1	9.2, 11.4	3.4	2.6, 4.3	0.2	0.1, 0.3
Raw Seafood	92.0	92.0, 92.7	6.7	4.6, 7.0	1.2	1.0, 2.7	0.1	0.0, .11	0.0	0.0, 0.0
Preserved Fish	84.8	82.9, 88.2	10.4	6.3, 13.4	3.9	3.2, 5.3	0.5	0.2, 0.8	0.0	0.0, 0.1
Cooked Ready-to-Eat Crustaceans	94.5	93.3, 96.1	4.0	1.1, 6.0	1.3	0.8, 1.5	0.2	0.0, 1.2	0.0	0.0, 0.1
Produce										
Vegetables	91.1	90.2, 91.9	7.2	5.6, 7.2	1.5	1.0, 2.5	0.0	0.0, 0.1	0.0	0.0, 0.0
Fruits	81.4	80.8, 86.5	18.5	12.0, 19.1	0.1	0.1, 1.5	0.0	0.0, 0.0	0.0	0.0, 0.0
Dairy										
Soft Mold-Ripened and Blue-Veined Cheese	92.8	90.0, 92.8	3.2	3.0, 7.2	3.3	2.3, 3.8	0.7	0.3, 0.8	0.0	0.0, 0.0
Goat, Sheep, and Feta Cheese	92.2	90.9, 92.5	6.2	5.7, 7.5	1.5	1.2, 2.1	0.1	0.0, 0.2	0.0	0.0, 0.0
Fresh Soft Cheese	89.7	89.1, 90.3	3.2	2.1, 4.5	4.3	4.2, 4.5	2.5	2.0, 3.0	0.2	0.1, 0.2
Heat-Treated Natural Cheese and Processed Cheese	98.2	98.1, 98.6	1.7	1.3, 1.8	0.1	0.0, 0.1	0.0	0.0, 0.0	0.0	0.0, 0.0
Aged Cheese	98.0	98.0, 98.1	1.8	1.0, 1.9	0.0	0.0, 0.9	0.0	0.0, 0.2	0.0	0.0, 0.0
Pasteurized Fluid Milk	99.2	98.9, 99.6	0.7	0.3, 1.1	0.0	0.0, 0.1	0.0	0.0, 0.0	0.0	0.0, 0.0
Unpasteurized Fluid Milk	91.9	90.5, 95.9	7.6	3.0, 9.4	0.6	0.2, 1.0	0.0	0.0, 0.0	0.0	0.0, 0.0
Ice Cream/Frozen Dairy Products	99.0	99.0, 99.0	0.5	0.4, 0.9	0.0	0.0, 0.3	0.0	0.0, 0.3	0.0	0.0, 0.0
Misc. Dairy Products	98.2	98.1, 98.8	1.6	1.1, 1.8	0.1	0.0, 0.1	0.0	0.0, 0.0	0.0	0.0, 0.0
Meats										
Frankfurters	92.4	90.0, 94.5	6.1	4.5, 7.4	1.4	0.7, 2.2	0.2	1.0, 0.4	0.0	0.0, 0.1
Dry/Semi-Dry Fermented Sausages	90.3	90.2, 92.3	6.8	4.3, 8.3	2.4	1.3, 3.4	0.1	0.1, 0.5	0.0	0.0, 0.0
Deli Meats	90.7	89.0, 91.2	5.4	4.7, 7.2	3.3	2.7, 3.7	0.7	0.3, 1.1	0.1	0.0, 0.2
Pâté and Meat Spreads	91.5	91.4, 94.0	4.0	1.7, 5.0	2.9	2.7, 3.1	1.0	0.7, 1.4	0.2	0.1, 0.3
Combination Foods										
Deli Salads	86.3	83.0, 90.1	8.8	4.3, 14.2	4.0	2.6, 4.7	0.8	0.2, 1.0	0.0	0.0, 1.0

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



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

Figure III-3. Three Dimensional Graph of the Modeled Distribution of *Listeria monocytogenes* Levels of Contamination at the Time of Consumption for the Food Categories