



NOVIGEN  
SCIENCES, INC.  
*International*

UNITED STATES  
1730 Rhode Island Avenue NW  
Ste. 1100, Washington, DC 20036  
T (202) 293-5374 F (202) 293-5377  
info@novigensci.com

UNITED KINGDOM  
75 Graham Road  
Malvern, Worcs, WR14 2HR  
T (+44) 1684-588444 F (+44) 1684-588445  
info@novigensci.co.uk

**USDHHS-FDA-CFSAN'S AND USDA-FSIS'S "DRAFT ASSESSMENT OF  
THE RELATIVE RISK TO PUBLIC HEALTH FROM FOODBORNE  
LISTERIA MONOCYTOGENES AMONG SELECTED CATEGORIES OF  
READY-TO-EAT FOODS": A REVIEW PREPARED FOR MEMBERS OF  
THE L. M. WORKING GROUP**

**PREPARED BY:**

Barbara Petersen, Ph.D.  
Leila Barraaj, Ph.D.  
Nancy Rachman, Ph.D.  
Joanne Watters, M.P.H.  
Novigen Sciences, Inc.  
1730 Rhode Island Avenue  
Suite 1100  
Washington, DC 20036

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# **USDHHS FDA-CFSAN'S AND USDA-FSIS'S "DRAFT ASSESSMENT OF THE RELATIVE RISK TO PUBLIC HEALTH FROM FOODBORNE LISTERIA MONOCYTOGENES AMONG SELECTED CATEGORIES OF READY-TO-EAT FOODS": A REVIEW PREPARED FOR MEMBERS OF THE L. M. WORKING GROUP**

## **A REVIEW**

### **I. EXECUTIVE SUMMARY**

Members of the *Listeria monocytogenes* Working Group ("L. M. Working Group") asked Novigen to critically review each component of USDHHS-FDA-CFSAN's and USDA-FSIS's "Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods", January 2001 ("Draft Risk Assessment" or "FDA-FSIS"). Specifically, Novigen was asked to systematically examine each component of the assessment, determine those that contribute the most to the final outcome, explore the impact of different assumptions, and explain critical uncertainties.

The stated purpose of the Draft Risk Assessment is to provide a tool that "food safety regulatory agencies will consider using to evaluate the effectiveness of current policies, programs and regulatory practices to minimize the public health impact of this pathogen." (FDA-FSIS, p. iii.)

FDA and FSIS are to be complimented on their development of a comprehensive and creative approach to characterizing risk given the available data and information. The approach and the mathematical models developed for the risk assessment provide a valuable initial framework for the systematic evaluation of risk factors and risk reducing measures and strategies.

The assessment is comprehensive, meticulous in its logic, and creative in its approach, attempting to fully use the wide array of diverse and often limited data and information on the variables involved in potential exposure to *L. monocytogenes* (*L. m.*) in (ready-to-eat) RTE foods. Distributions for key variables were used, rather than point estimates. Data variability, many uncertainties (missing data or information) and areas where critical research is needed were identified explicitly and quantitatively. This facilitates a determination of how confident one can be in the final risk rankings. Despite its enormous complexity, the assessment model is also reasonably transparent (to the technical professional) and amenable to detailed review, evaluation and even scenario and hypothesis testing.

Novigen Sciences, Inc. (Novigen) reviewed the Draft Risk Assessment with the aim of understanding how key inputs, assumptions, and statistical and modeling approaches used affect the risk per serving for the various food categories. Since the purpose of the draft assessment is to serve as a foundation for determining data needs and risk management interventions, we looked at the "responsiveness" of the overall exposure model to changes in data inputs and assumptions relating to *L. m.* levels or post-retail growth for selected food categories, and

consumer practices for deli meats and frankfurters. Novigen examined various parameters of the exposure assessment in order to determine how data inputs and key assumptions influence the exposure distributions for intake per serving and intake per year (colony-forming-units [cfu]/gram of food), and in certain cases, also risk per serving.

Our review also touches briefly on fundamental uncertainties in dose-response and hazard characterization. Limitations of the mouse model for predicting human foodborne listeriosis are widely acknowledged, including by FDA-FSIS. Given the available information, FDA-FSIS's use of the mouse data is credible. However, as is true for risk assessments of toxic chemicals, the issues of variability in the available data and uncertainty (lack of data on key variables) are significant with respect to the dose-response curves, particularly in the low dose ranges.

Another challenge to assessing *L. m.* risk at this time is that the available contamination data do not specify strain and therefore may not be predictive of human risk of listeriosis. These fundamental uncertainties with respect to infectivity and virulence of *L. m.* and human susceptibility to infection can only be remedied by more research, not by revisions to this draft risk assessment in the short-term.

Novigen's review suggests that certain aspects of the exposure assessment may contribute to overestimation of the risk associated with certain food categories. While combining foods into categories and using data for a particular food as "proxy" for other foods may be unavoidable at this point because of limitations in the available data, the approach does not highlight characteristics of foods, or processing or retail practices, that may have bearing on risk factors. Recognizing and understanding these characteristics is very important for effective *L. m.* control strategies.

Novigen's analysis yielded the following specific observations:

Criteria for grouping foods and for selecting contamination data to use as proxy data for a food category should also include similarities between the proxy food and the food in the category with respect to food and/or processing characteristics known to be associated with *L. m.* risk. Using several different approaches to grouping foods could highlight important risk factors and research needs critical to the food industry.

Novigen found some inconsistencies between published data on contamination cited in the Draft Risk Assessment and the cumulative distributions used by FDA-FSIS.

By assigning each contamination study a weight proportional to the number of samples included in that study, FDA-FSIS gave more weight to the larger, and presumably more reliable, studies. However, FDA-FSIS also gave greater weights to the higher percentiles of concentration. This could give smaller, less precise studies more weight, or could give some data points undue importance.

When data are sparse, use of parametric distributions to represent the data can introduce a large amount of uncertainty. While FDA-FSIS's model provided relative rankings of the distributions used based on goodness of fit, it did not provide estimate of how well each distribution fit the data. Thus, a measure of the goodness-of-fit of the parametric functions used to represent the data would provide an estimate of how close the distribution fits the data observations and provide users of the model with an estimate of the uncertainty introduced by the use of parametric distributions.

With few exceptions, no support was provided in the Draft Risk Assessment for the assumption that contamination distributions for food in the US do not vary significantly from those in other countries. If processing methods differ in other countries, data from those countries should be evaluated, at least qualitatively, for relevance to the US food supply before using them to assess risk to US consumers.

FDA-FSIS reported that for some food categories (e.g., cooked ready-to-eat crustaceans, soft mold-ripened cheese and frankfurters), contamination levels are lower in post-1993 data than in pre-1993 data. For certain food categories, FDA-FSIS noted the existence of such differences. Therefore, by using both pre- and post-1993 data, FDA-FSIS may overestimate risks.

It would be informative for the purpose of developing risk management strategies to group foods and attempt to examine associated risks according to what is known about the influence of the food matrix and processing and packaging methods, i.e., characteristics of the food that affect the survival and growth of *L. m.* Foods that do not support growth would not pose a risk during their specified shelf life if *L. m.* is present at a low level and the foods are handled properly.

High quality data on consumer behavior (storage time and percent eaten without reheating), recently commissioned by the American Meat Institute Foundation (AMI), significantly affected the exposure and risk estimates for frankfurters.

The model combines a large number of input variables and assumptions into various components (e.g., growth model, exposure model, dose-response model, etc.) and an estimate of the uncertainty introduced by using various parametric distributions can be derived from the model. However, the model does not include a way to readily perform sensitivity analyses. Such analyses provide the risk manager with information as to which of the input variables or assumptions contribute the most to the risk estimate or to what extent the uncertainty in a specific input impacts the uncertainty of the estimated risk. Sensitivity analyses are important tools in developing effective risk management approaches.

Novigen applauds FDA's and FSIS's willingness to continue to refine the risk assessment and to share its detailed components. We acknowledge the challenges that FDA and FSIS will face in maintaining transparency and consistency as new data or methods are incorporated into the draft assessment, and into their risk management plans, over time. We trust the Agencies will continue to meet this challenge.

## **II. INTRODUCTION AND BACKGROUND**

### **A. Scope of Novigen's Review**

Members of the L. M. Working Group asked Novigen to critically review each component of USDHHS-FDA-CFSAN's and USDA-FSIS's "Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods", January 2001 ("Draft Risk Assessment" or "FDA-FSIS"). Specifically, Novigen was asked to systematically examine each component of the assessment, determine those that contribute the most to the final outcome, explore the impact of different assumptions, and explain critical uncertainties.

Novigen reviewed the Draft Risk Assessment with the aim of understanding how key inputs, assumptions, and statistical and modeling approaches used affect the risk per serving for the various food categories. Since the purpose of the draft assessment is to serve as a foundation for determining data needs and risk management interventions, we looked at the "responsiveness" of the overall exposure model to changes in inputs and assumptions relating to *L. m.* levels or post-retail growth for selected food categories, and consumer practices for deli meats and frankfurters. Novigen looked at the effects of changing these various parameters on concentration distributions (cfu/gram), intake per serving and intake per year. In certain cases, we also combined the exposure measures with the dose-response distribution to calculate risk per serving (risk = exposure x dose-response). Because each risk calculation using the program provided by FDA requires considerable computer time, we did not express our results in terms of risk in every case.

We discuss our evaluations and the concerns they raise in this report.

### **B. Overview of the FDA-FSIS Draft Risk Assessment**

#### **1. Exposure Assessment**

The Draft Risk Assessment focuses on ready to eat (RTE) foods. FDA-FSIS used published literature and unpublished data on listeriosis outbreaks and contamination of foods to identify foods with significant potential for contamination. Foods likely to be cooked before eating were generally eliminated from consideration. The foods included were then grouped into twenty categories according to similarities in primary origin, composition, processing, available data on *Listeria* prevalence and epidemiological information (FDA-FSIS, p. viii). Because contamination data are not available for all the selected foods, the available data were used as "proxy" data for certain other foods and categories of foods. The US population was divided into 3 groups based on susceptibility to listeriosis: perinatal (fetuses and neonates, from exposures during pregnancy), the elderly (age 60 and above), and the intermediate age groups (all others). Exposures to each food category, and risk rankings for the categories, were estimated in 2 ways: per serving, and per annual number of servings.

## **2. Dose Response**

The Draft Risk Assessment incorporated dose-response models to predict mortality for 3 aged-based subpopulations: perinatal, the elderly, and the intermediate age population. As is true for the exposure assessment, the approach to dose-response assessment was creative and comprehensive. There are 3 main variables involved in *L. m.* dose-response, pathogen virulence, host susceptibility and the effects of the food matrix (Draft Risk Assessment, p.57). The draft assessment included consideration of virulence and host susceptibility. Distributions were modeled in an attempt to deal explicitly with the uncertainty and variability in the available data for these variables.

The mouse model was used to establish the shape of the dose-response curve, i.e., the spread of the dose range associated with illness and death. The doses that cause human illness were taken from human epidemiological data.

When the dose-response relationship based on the mouse model was combined with the estimated food-borne exposures to *L. m.* to predict the incidence of lethal infections in humans, the resulting estimate greatly exceeded the observed number of deaths, based on the epidemiological data, by a factor of a million or more (Draft Risk Assessment, p. 71). Therefore, FDA-FSIS applied an adjustment factor to the mouse dose-response data, to reduce the predicted number of illnesses to the range predicted by CDC based on epidemiological data.

## **III. EXPOSURE ASSESSMENT**

### **A. General Observations**

The exposure assessment is comprehensive, meticulous in its logic, and creative in its approach, attempting to use the wide array of diverse and often limited data and information on the variables involved in potential exposure to *L. m.* in RTE foods. FDA-FSIS used distributions for key variables, rather than point estimates. Data variability and uncertainty (missing data or information) and areas where critical research is needed were identified explicitly and quantitatively. This facilitates a determination of how confident one can be in the final risk rankings. Despite its enormous complexity, the assessment model is reasonably transparent technically, and amenable to detailed review and manipulation.

### **B. Novigen Review**

Novigen manipulated various aspects and parameters of the exposure assessment in order to determine how data inputs and key assumptions influence the risk per serving outcome. In the course of this work, we have identified several issues, which we discuss in more detail in this section. In general, we found that certain aspects of the exposure assessment may contribute to mischaracterization or overestimation of the risk associated with certain food categories. While combining foods into categories and using data for a particular food as “proxy” for other foods

may be unavoidable in risk assessment at this point because of limitations in the available data, the approach does not highlight characteristics of foods, or processing or retail practices, that may have bearing on key risk factors. Recognizing and understanding these characteristics may be very important for effective risk management interventions.

Novigen's review brought into focus certain types of issues that will be discussed in detail in this report. These are:

- Transparency/reproducibility of FDA-FSIS's calculations.
- Lack of specificity of food microbiological data as to *L. m.* strain.
- Food contamination - food microbiological data quality and data usage issues.
- Foods included in the assessment, grouping of foods into categories, and specificity/representativeness of proxy microbiological data.
- Use of available food consumption data.
- Consumer behavior – storage and cooking practices.
- Statistical and modeling issues – including questions as to how data were statistically treated, how distributions were modeled and combined.

### **C. Transparency/Reproducibility of FDA-FSIS's Calculations**

Some information was provided on the CD and in Appendix 6 (“Software”) to the Draft Risk Assessment on how to run the software. However, no assumptions can be changed, and how the various spreadsheets produced by the various components of the software can be related is not documented. Based on direct communication with FDA, Novigen was able to use the software provided by FDA to estimate intake per serving, and to run the various “what if scenarios” using different input distributions to the exposure component of the software. However, this would not have been possible without the information obtained from FDA through this direct communication. Thus, a significant amount of information needs to be added to Appendix 6 of the Draft Risk Assessment, and to the instructions provided with the software to make the model usable. The additional information needed includes: instructions on how to run the programs in the various spreadsheets; how to link the outputs generated from these spreadsheets; how to modify the assumptions in the spreadsheets; and which default settings can be changed in the spreadsheets directly, and which can only be changed by changing the software code.

The model combines a large number of input variables and assumptions into various components (e.g., growth model, exposure model, dose-response model, etc...), and an estimate of the uncertainty introduced by using various parametric distributions can be derived from the model. However, the model does not include sensitivity analyses that provide users, including risk managers, with information as to which of the input variables is most associated with the risk estimate or to what extent the uncertainty in a specific input variable impacts the uncertainty of the estimated risk. For instance, an important application of such a model should be to be able to answer questions of the type “which components and inputs to the model affect the risk estimate most” and “by how much should this component change to result in, say, a 50%

reduction in the risk estimate.” With the current model structure these answers can only be arrived at through a series of time intensive “what if scenarios,” where changes are introduced to the various components and the resulting estimated risks are then compared. Sensitivity analyses are important in developing effective risk management approaches.

#### **D. Lack of Specificity of Food Microbiological Data with Respect to *L. m.* Strain**

Not all strains of *L. m.* are equally virulent. There are some serotype data available and cited in the risk assessment, but they demonstrate only that the distribution of serotypes among human cases is different than the distribution of serotypes in foods that people consume.

Inasmuch as markers that distinguish between high and low virulence strains are generally lacking, the only possible approaches at this time are to (1) use association with human disease to help distinguish which foods are likely to cause disease when they are contaminated with *L. m.*, or to (2) not explicitly consider strain and virulence differences. Since the available data on *L. m.* in foods, for the most part, do not specify the strain, it is understandable that FDA used the latter approach.

Although FDA did attempt to account for virulence ranges in the dose-reponse models, the limitation in the contamination data means that estimated exposures may be overstated and mischaracterized, to the extent that the contamination data includes strains that have poor disease-producing potential. The extent to which this is so cannot presently be predicted. Therefore, until virulence markers become available, there is no alternative but to assume that all strains are the same with respect to causing listeriosis.

#### **E. Food Contamination - Food Microbiological Data Quality and Data Usage Issues**

The contamination data used in the draft risk assessment come from diverse sources, may be out of date with respect to food processing and handling practices, are largely non-quantitative, and do not specify the variables in handling, such as duration of time held at retail or during distribution (and under what conditions), before sampling. There is considerable variability between studies with respect to the prevalence of high contamination levels. FDA acknowledged the limitations in the available data, and attempted to compensate for some of them.

Novigen has examined the food contamination data used for all food categories. The following potential issues were explored with respect to their impacts on the risk results for the various categories. Illustrative examples are discussed.

##### FDA-FSIS approach:

The contamination data used by FDA-FSIS were compiled from several sources (some published and others unpublished). For the most part, the data were for food samples collected at retail. Two types of data describing the levels of *L. m.* contamination in food were used:

- Presence/absence (qualitative) data (*i.e.*, the number of positive samples relative to the total sample collection). Data from these studies were converted to numerical values by assigning to positive samples the lowest possible contamination level that can be detected by current laboratory methods that use a 25g sample, 0.04 cfu/gram of food.
- Enumeration (quantitative) data (*i.e.*, the number of cfus of *L. m.* that were measured and recorded from a sample).

FDA-FSIS compiled the data from the various studies into “cumulative” distributions, *i.e.*, distributions that list the concentration level and the proportion of samples with contamination levels at or below the listed contamination levels. FDA-FSIS combined all the cumulative distributions for a given food category into a single distribution. In each case, three parametric distributions (lognormal, Weibull and Beta) were assumed to fit the data and the parameters of these distributions were estimated using the combined data.

We think it is important for the underlying data to be available for review and evaluation. Accordingly, we show in Appendix A, Tables A.1 through A.20, the contamination data used by FDA-FSIS in their Draft Risk Assessment, extracted from the CD ROM provided by FDA. For this review, the data in the tables were reported by country of origin and study. Tables A1 to A20 share a similar format. For purposes of illustration, we describe here Table A2, which summarizes the concentration data used for the “Cooked Ready-to-Eat Crustaceans” food category (see The Draft Risk Assessment, p. 245).

The first column in Table A.2 lists the study and the second column lists the country in which the samples were collected. In this table the data were compiled from 8 studies, conducted in 5 countries (Canada, France, Iceland, United Kingdom, and the United States). The total number of samples in each study is listed in the third column. The cumulative frequency of positives at the various concentration levels is summarized in the fourth and fifth columns. Note however that the numbers of samples that were positive at each contamination level were not included in the tables. We could not always discern this information from the FDA-FSIS spreadsheets.

Referring to Table A.2, data on 49 samples of shrimp were extracted from Farber, 1991b. Of these 49 samples, 45 were reported at <0.04 cfu/gram, while 3 had contamination levels between 0.04 and 0.3 cfu/gram and one sample had a contamination level between 0.3 cfu/gram and 10 cfu/gram (Farber, 1991). FDA-FSIS summarized these data in the following cumulative distribution:

<u>Contamination level (cfu/g)</u>	<u>Relative frequency</u>
<0.04	$45/49 = 0.918$
<0.3	$(45+3)/49 = 48/49 = 0.978$
<10	$(45+3+1)/49 = 49/49 = 1$

The cumulative frequencies may not total 1 for studies in which only presence/absence data (i.e., percent positives) were available. FDA-FSIS assumed all such positive samples to contain  $\leq 0.04$  cfu/g *L. m.*

#### Novigen analysis and comments:

Looking at Tables A.1-A.20, there appear to be some inconsistencies in the summary concentration data used by FDA-FSIS. For instance in Table A.1, data from Greenwood et al., (1991) were reported used for aged cheeses. Two different numbers were listed for the number of samples from this study (66 and 65). A similar inconsistency was observed for data from Teufel and Bendzulla (1991), also in Table A.1, where two different numbers of samples were reported (34 and 38).

There also were some inconsistencies between the published data and the cumulative distributions used by FDA-FSIS. For instance in Table A.4, data from Wilson (1996) on pre-packed sandwiches were reported used for deli salads. Of the 725 samples reported in Wilson, 431 contained salads. The number of samples listed by FDA-FSIS was 316. Novigen could not determine the reason for the discrepancy. Only two of the salad-containing sandwiches (both sandwiches were reported containing chicken and salad) were reported contaminated with *L. m.* (one at 100 cfu/gram, the other at  $6.3 \times 10^4$ ). In addition, in FDA-FSIS's spreadsheets, 314 of the 316 samples were listed as having concentrations  $< 0.04$  cfu/gram, and  $< 100$  cfu/gram, while 315 were reported as having concentrations  $< 1,000$  cfu/gram and  $< 10,000$  cfu/gram. While summarizing the data in this manner is not computationally incorrect, it may affect the parametric distributions that were fitted to these data. Specifically, because of the weighted method used by FDA-FSIS in deriving the parameters of these distributions (see below), excess influence may be given to artificial points at the upper tail of the distribution.

The scope of Novigen's review did not include examining all the individual references and studies cited by FDA-FSIS and comparing the concentration distributions used by FDA-FSIS with the original sources, so it is not known whether other inconsistencies were present. However, the above examples illustrate the need for a clear explanation of the study data and how FDA-FSIS interpreted and used the data.

### **1. Estimated concentrations at retail**

#### FDA-FSIS approach:

Data from presence/absence studies 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 25g sample (0.04 cfu/gram of food) when *L. m.* was present and  $< 0.04$  when *L. m.* was absent. FDA-FSIS reports that in a few instances the data available were from samples collected pre-retail and a simple growth model was used to adjust those values. The temperature ranges and storage times 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. A simple growth model was used.

### Novigen analysis and comments:

For example, if the estimated growth was 0.5 logs prior to retail, a study with 5% positive samples at 0.04 cfu/gram at manufacture would become 5% positive at 0.13 cfu/gram at retail. FDA-FSIS did not provide a listing of which studies collected samples pre-retail, however, it is possible to identify these studies from an examination of the concentration data listed in the spreadsheets used by FDA-FSIS<sup>1</sup>. For instance the concentration value listed for pasteurized milk (0.07 cfu/g) for seven studies (Appendix A, Table A.12) resulted from the multiplication of 0.04 (the detection limit for the samples pre-retail) by  $10^{0.25}$ , based on the assumption of an 0.25 log growth between manufacture and retail. Similarly, data from Rawles et al., (1995) were reported used for cooked, ready to eat crustaceans (Appendix A, Table A.2). The concentration levels used by FDA-FSIS were 0.10 ( $=0.04 \times 10^{0.41}$ ), 25.70 ( $=10 \times 10^{0.41}$ ), 128.52 ( $=50 \times 10^{0.41}$ ), 257.04 ( $=100 \times 10^{0.41}$ ), 2570.40 ( $=1000 \times 10^{0.41}$ ), and 5140.79 ( $=2000 \times 10^{0.41}$ ). This treatment of the data may have artificially inflated estimates of concentration levels at retail, for samples collected pre-retail. This, in turn, may have resulted in artificially inflated risk estimates for certain food groups. In fact, FDA compared the prevalence of *L.m.* in samples collected at production and at retail, and concluded that “prevalence at retail is not consistently higher than at production.”

Novigen assessed the impact of assuming that the at-retail concentrations in pasteurized milk for the seven studies for which FDA used a growth factor to account for potential growth between production and retail, were 0.04 cfu/g rather than 0.7 cfu/g. The same two-stage intake estimation approach as that used by FDA-FSIS was used, namely the data from all studies were first used to estimate the parameters of the three distributions, and the distributions were then re-fit using only the US data, and adjusted the scale parameter only. The exposure model was then run using 1000 population iterations and 100 uncertainty iterations and the estimated per-serving intakes were inputted in the risk assessment component of the dose-response model for the intermediate population to estimate the annual number of listeriosis deaths and of serious listeriosis illnesses associated with each food group and corresponding ranks, as well as the number of per-serving serious listeriosis illnesses and associated ranks. The estimated risks and associated rankings are compared to the estimated risks and rankings derived by FDA-FSIS in Table 1. The per-serving risk (number of listeriosis illnesses) estimated by FDA-FSIS in the case of pasteurized milk is 4000 times higher than that estimated using the “unadjusted” concentration data. The relative rank for pasteurized milk changed from 10 to 18 on a per serving basis, and from 3 to 17 on a per-annum basis. The small differences in the estimated number of illnesses for the other food groups is due to the fact that Novigen’s assessment used fewer iterations than FDA-FSIS’s assessment (1000 versus 4000).

These findings highlight the importance of assumptions about growth and the need to estimate *L. m.* levels reliably.

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<sup>1</sup> The concentration levels for samples collected by these studies were included as “formulas” instead of absolute values in the spreadsheets.

## 2. Effects of weighting the upper tails of the distributions

### FDA-FSIS approach:

Distributions of *L. m.* levels for each food category were generated by fitting statistical distributions to the data. The parameters of the distributions were estimated 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.

### Novigen analysis and comments:

- “Between-studies” weighting: By assigning each study a weight proportional to the number of samples included in that study, FDA-FSIS gave more weight to the larger, and therefore presumably more reliable, studies. However, sample size is only one factor of many (e.g., sample design, collection method, representativeness, analytical method) affecting study reliability. It isn’t clear if FDA considered these factors in the evaluation of the studies included in the assessment.
- “Within-study” weighting: Giving greater weights (proportional to the concentration level) to the higher percentiles, could give the less precise studies more weight or could give some data points undue importance due to a single sample. For instance, if one study reported the results as the number of samples with concentrations in the following bins: {<0.04, 0.04 – 10, 10-100, 100-1000}, while another study used coarser bins, e.g., {<0.04, 0.04 – 100, 100-10,000}, then the results at the upper tail in the second, less precise, study would be given more weight. Further, by arbitrarily using a weight proportional to the concentration level, the weights assigned to the upper tails were as much as 25,000,000 times larger than those assigned to the samples at the lower tail of the distribution. For instance, in the case of goat and feta cheese (Appendix A, Table A.8), FDA-FSIS used data on 46 samples (McLaughlin et al., 1990). The upper limits of the bins used by FDA-FSIS to summarize the results of this study were: {<0.04, 10, 100,000 and 1,000,000}. Based on FDA-FSIS’s spreadsheets, 19 of the 46 samples had concentrations < 0.04 cfu/gram, and one sample had concentrations between 100,000 and 1,000,000 cfu/gram. This would give the data point resulting from that single sample a weight 25,000,000 (= 1,000,000 / 0.04) times larger than the weight assigned to the 19 samples that did not show any concentrations.

Novigen assessed the impact of assigning upper percentiles of the distribution weights proportional to the concentration level at these percentiles by comparing the upper percentile estimates of the fitted distributions derived with and without this weight assignment. The results of selected comparisons are summarized in Tables 2 and 3 for frankfurters and fruits, respectively. The tables summarize the parameters of the three parametric distributions under both methods (FDA-FSIS and “no weight”), the estimated percentiles of these distributions, and the ratio of the percentiles derived using FDA-FSIS’s method to those derived without weighting.

For instance in the case of fruits (Appendix A, Table A.7), FDA-FSIS used data from 4 studies. All samples except one had concentrations below 0.04 cfu/gram. One sample had a concentration level between 0.04 and 20 cfu/gram. The estimated 99th percentile of the fitted Weibull distribution derived by giving more weight to the upper percentiles was 19 times higher than that derived assuming equal weights to all percentiles within a given study (Table 3). Similar differences (although smaller) were observed at the other percentiles and for the other distributions.

Risk estimates derived using the concentration distributions based on FDA-FSIS's weighted approach thus may be much higher than those derived using distribution based on the non-weighted approach.

### **3. Problems associated with assuming distributions for small data sets**

#### FDA-FSIS approach:

FDA-FSIS used parametric distributions to represent most of the variables in the risk assessment. For instance, the contamination distributions were assumed to be either Lognormal, Weibull or Beta distributions. Similarly, the cumulative distribution of the exponential growth rates was modeled using a uniform or triangular distribution depending on whether there were two or three to four data points. If the category had five or more data points, the cumulative distribution was fitted by different equations. If more than one distribution was used to represent the data, sampling from the various distributions was done proportionately to how well (relative to the other distributions used) the distributions fit the observed data.

#### Novigen analysis and comments:

- When data are sparse, use of parametric distributions to represent the data can introduce a large amount of uncertainty. A measure of the goodness of fit of the parametric function used to represent the data provides an estimate of how close the fitted distribution is to the observed data. FDA-FSIS's assessment did not provide estimates of goodness of fit either for the lognormal, Weibull or Beta distributions used to represent the food contamination data, or for the cumulative distributions of the exponential growth rates. The assessment provided, instead, "rankings" of the distributions used for a given food category and the associated probabilities of selection from the various distributions were based on a comparison of the distributions versus each other. That is, the "probabilities" listed for each distribution in the model provide only a relative ranking of the selected distribution. For example, in Table A5.5.7 of the Draft Risk Assessment, the exponential growth rate for vegetables was represented by a triangular distribution 98% of the time, a logistic distribution 1% of the time and a normal distribution 1% of the time. This indicates

that the triangular distribution fitted the data much better than the other two distributions, but does not provide any information about how well the triangular distribution fitted the data, and thus does not provide information about the potential uncertainty introduced by using the fitted distributions.

- The parametric distributions were fitted to the data using either EXCEL functions or a special software developed by FDA-FSIS (ParamFit). FDA-FSIS provided a limited description of ParamFit. However, it is not clear how ParamFit derives the parameters of some of the distributions it uses. For instance, the rectangular (or uniform) distribution was one of the distributions used to model exponential growth for soft-ripened cheese and aged cheese. It appears (from the Draft Risk Assessment Tables A5.7.7 and A.5.11.7 and Figures A.5.7.3 and A.5.11.3) that the algorithm used by ParamFit does not use all the data. Specifically, for aged cheese, based on the data plotted in Figure A.5.11.3, the empirical cumulative distribution of the data is:

<u>X</u>	<u>Cumulative Distribution</u>
-0.228	0
-0.053	0.2
-0.003	0.4
0	0.6
0	0.8
0.015	1

However, the rectangular distribution that was fitted to the data had parameters: - 0.007 (minimum) and 0.003 (maximum). The Draft Risk Assessment should provide information about such potential uncertainty introduced by using the fitted distributions.

#### **4. Impacts of including data from outside the US**

##### FDA-FSIS approach:

- Contamination levels at consumption were modeled with the assumption that contamination distributions for a given food in the US do not vary significantly from those in other countries.
- In the case of milk, FDA-FSIS concluded that there were sufficient differences between the North American data and the data from other countries to warrant relying on the North American data for the frequency of contamination. However, since insufficient quantitative data were available from the North American studies, FDA-FSIS used the distribution of contamination levels from international data to estimate the variability in the distribution.

Novigen analysis and comments:

- The assumption that contamination distributions for food in the US do not vary significantly from those in other countries should be evaluated in each case with respect to processing conditions. If processing is substantially different in the US and the country where the data were developed, the data may not be relevant to the US food supply, or, they may need to be adjusted to reflect the impact of the differences.
- FDA-FSIS did differentiate between US and non-US studies for two food categories (pasteurized and unpasteurized milk). This differentiation was, however, restricted to the detection rate and the average contamination level. The variability in the distribution for these foods was assumed to be similar to that derived from data for other countries. FDA-FSIS's approach was driven by the limited data available, but the assumption of similar variability may not be supportable, given the differences in pasteurization methods in different countries.
- In Appendix A, Tables A.1 to A.20, the studies used by FDA-FSIS are listed by country, and can be used for a qualitative evaluation of FDA-FSIS's assumption that the distributions do not vary. Some differences can be detected between the data from the various countries for some food categories. For instance, in the case of aged cheese, FDA-FSIS reported eight studies; only one of these was for the US. Of the 116 samples in the US study, none had quantifiable contamination levels. One of the studies used by FDA-FSIS (providing 4 data points of the total of 12 data points for aged cheese) reported concentrations as high as 1000 cfu/gram, while another reported concentrations as high as 500 cfu/gram. Also, in the case of goat and feta cheese, FDA-FSIS used data from 5 studies. Two of the studies reported high detection rates (59% (UK) and 33% (Spain), respectively), while all other studies, including one from the US, had detection rates ranging from 0% to 5.4%. The impact of excluding the two non-US studies (Sanchez-Rey et al., 1993 and McLauchlin et al., 1990) that do not "match" the US data from the assessment is illustrated in Table 4, which compares the percentiles of the fitted distributions used by FDA-FSIS for goat and feta cheese and those derived excluding these two studies. The estimates of the upper percentiles derived using FDA-FSIS's distributions are orders of magnitude higher than those derived excluding these two studies.
- For some food categories, all the data used were from countries other than the US (e.g., fresh cheese) or included data from countries where the climate is significantly different than in the US (e.g., raw seafood where data from Egypt and India were included). The relevance of these data to the US food supply should be explicitly considered and discussed.
- Overall, there was a wide degree of variation between studies in the occurrence of high levels of *L. m*. The extent to which this variation reflects true variation in a particular food or in a particular country is not known. This variation reflects for example, the differences in processing methods and handling practices that exist between countries. This variation contributes uncertainty to the risk characterization. To the extent that processing and handling in the US are more stringent than in countries where the data originate, this uncertainty tends to overestimate risk to the US consumer.

## 5. Impacts of pre-1993 data as compared to post-1993 data

### FDA-FSIS approach:

Several of the studies used by FDA-FSIS were conducted in the late 1980s and early 1990s. FDA-FSIS compared the results of studies conducted before and after 1993 and concluded that while some food categories showed a decline in contamination post-1993 others showed an increase or little change. FDA-FSIS, therefore, used the entire dataset.

### Novigen analysis and comments:

FDA-FSIS's assessment compared the data in studies published before and after 1993 (some of the studies published post 1993 included data collected earlier). For instance, the data in Appendix A, Table A.12) from Kozak, et. al. (1996) are for samples collected in the late 1980's.

The apparent increase in the frequency of detection, and problem awareness, could be related to improvements in the detection methods, and is not necessarily an indication of higher incidence of *L. m.* in the food supply. In fact, FDA-FSIS reported that for some food categories, e.g., cooked ready to eat crustaceans, soft-mold ripened cheese, and frankfurters contamination levels are lower in post-993 studies. This would suggest that risk for these foods may be lower than that calculated by FDA-FSIS.

Novigen compared the percentiles of the distributions used by FDA-FSIS to represent contamination levels with those derived using only the post-1993 data, to determine whether including the pre-1993 data affected the fitted distributions. Table 5 illustrates this comparison for frankfurters. The estimated 99<sup>th</sup> percentile of the lognormal distribution derived using all the data is 5.6 times higher than that derived using the post-1993 data only. Similar differences (although smaller) were observed for the other percentiles and other distributions. Thus, in the case of frankfurters, risk estimates derived using the post-1993 data are likely to be lower than those derived based on all the data used by FDA-FSIS. The relative rankings of the food categories would therefore likely change.

## 6. Impacts of new data

The National Food Processors Association Research Foundation recently developed new data on contamination levels in samples collected at retail for deli meats and salads ("NFPA Research Foundation *Listeria monocytogenes* Contamination Data"). NFPA prioritized sliced luncheon meats and prepared "deli" salads for testing by using the following criteria:

- The foods may reasonably be expected to contain *L. m.* based on the literature, information from regulatory agencies and information from outbreaks.
- *L. m.* in the food can reasonably be expected to remain the same or to grow between time of purchase and time of consumption.
- The food is held refrigerated or frozen, and is then consumed without (re)heating.

- Consumption pattern information is in the FSIS Continuing Survey of Food Intakes by Individuals (CSFII).

In this study, when a sample tested positive for *L. m.*, a retained sample was enumerated. The enumeration range for the study was 0.3-60,000 cfu/g. 99.7% of the 5,597 samples of deli meat contained <0.4 cfu/g. The highest level found was 1000 cfu/g, in only one sample.

NFPA data on deli meat provided to Novigen are summarized in Appendix B. Novigen compared the effects on risk per-serving using the FDA-FSIS data set and the new NFPA data. Specifically, FDA-FSIS's approach was used to estimate the parameters of the three parametric distributions that were fitted to the concentration data. These distributions were then used in the risk assessment component of FDA-FSIS's model, using 1000 population iterations and 100 uncertainty iterations. The estimated per-serving intakes were used in the risk assessment component of the model for the elderly population to estimate the annual number of listeriosis deaths and of serious listeriosis illnesses associated with each food group, and corresponding ranks, as well as the number of per-serving serious listeriosis illnesses and associated ranks. The estimated risks and associated ranks are compared to the estimated risks and rankings derived by FDA-FSIS in Table 6. The per-serving risk (number of listeriosis illnesses) estimated by FDA-FSIS in the case of deli meats is 400 times higher than that estimated using NFPA's concentration data. The relative rank changed from 4 to 16 on per serving basis, and from 1 to 13 on a per-annum basis. The small differences in the estimated number of illnesses for the other food groups is due to the fact that Novigen's assessment used fewer iterations than FDA-FSIS's assessment (1000 versus 4000).

#### **F. Foods Included in the Assessment, Grouping of Foods into Categories, and Specificity/Representativeness of Proxy Microbiological Data**

Some of the food categories are not uniform. They contain foods that stand apart from the rest of the category from the standpoint of inherent characteristics, processing or handling methods, or dietary consumption characteristics. An example is the vegetables category, which contains various salads with vinegar dressings, and also meat substitutes (meatless bacon, frankfurter, sausage, meatball and soyburger) as well as raw and cooked vegetables. Low pH, and acetic acid in particular are known to kill *L. m.* (Sorrells *et al.*, 1989). Meat substitutes are typically heated before eating. Grouping diverse foods into a category without considering such differences may tend to obscure factors associated with *L. m.* risk or risk reduction. Applying proxy data from a limited number of foods in a category to the broader, more diverse grouping may further compound the introduction of uncertainties.

Novigen examined the food categories from the standpoint of identifying non-uniformities, i.e., foods or food codes that do not appear to match other foods in the category to which FDA-FSIS assigned them. We evaluated the impact of removing or reclassifying such non-uniform items on the estimated frequency of consumption and amounts of foods consumed for the category. These analyses are summarized in this section.

## **1. Aged cheeses**

The “aged cheeses” category illustrates non-uniformity of consumption patterns. FDA-FSIS used a median serving size of 27g. However, this approach does not reflect the significant differences in consumption patterns for total amount consumed and frequency of consumption for the cheeses in this group, as reported in the CSFII. Figures 1 to 3 display the disparate consumptions for cheddar, Swiss, and Parmesan cheese, all included in the “aged cheeses.” For example, Parmesan cheese is consumed 5 times more often than Swiss and 17 times more often than cheddar; however, both Swiss and cheddar are consumed in amounts almost 4 times higher than Parmesan when they are consumed.

It is interesting that in the Risk Characterization for the aged cheeses category (as for several others), FDA-FSIS noted the bimodal nature of the risk-per-serving and risk-per-annum ranking distributions. FDA-FSIS suggested that this bimodality reflects the available contamination data since there were a large number of samples in which *L. m.* was not detected. However, this is unlikely the reason, since the percent of samples with no *L. m.* was large for all the food groups considered. Other factors that contribute to the non-uniformity of the category, such as the dietary consumption differences illustrated here, can affect the risk distribution and must be explicitly considered.

## **2. Vegetables and fruits**

Acetic acid is an effective inhibitor of *L. m.* growth. However, there was minimal impact of removing from the vegetables and fruits categories items pickled in vinegar on the estimated annual number of servings of these foods (Table 7). Similarly, there was little effect from removing items that have different characteristics than the rest of the category, e.g., potato salads and other such foods. However, putting foods such as these, that may not support *L. m.* growth, into a separate category for risk assessment purposes is recommended from the standpoint of gaining a better understanding of uncertainties and highlighting data needs important for risk management (see below).

### **G. Post-Retail Growth of *L. m.***

#### **1. General observations**

FDA-FSIS concluded that some food categories represent substantially less relative risk than others because of inherent characteristics associated with the food or processing methods. Whether or not a food supports growth of *L. m.* is a factor critical to determining consumer risk. While understanding of food matrix and processing effects on *L. m.* survival and growth is still developing, more current knowledge could have been incorporated in the Draft Risk Assessment. The selection and application of proxy data on *L. m.* survival and growth should be evaluated critically in this regard.

In looking for examples of how use of growth data affected the risk assessment results, Novigen focused on only a few food categories: deli meats, frankfurters, smoked seafood and fresh soft cheese. We limited our analyses to these groups because FDA-FSIS's calculations did not predict that post-retail growth appeared to be a significant factor, except for these categories (compare Tables III-5, and Table III-11, on p. 40 and p. 55, respectively, of the Draft Risk Assessment).

## **2. Characteristics of foods that do not support growth**

It would be informative for the purpose of developing risk management strategies, to group foods and attempt to examine the associated risks according to what is known about the influence of the food matrix, i.e., characteristics that affect the survival and growth of *L. m.* For example, *L. m.* is unlikely to initiate growth in food products having pH = 5.0 (Lou and Yousef, 1999). However, *L. m.* may remain viable and can grow at pH <5.0 under certain conditions (Parrish and Higgins 1989). Contact of *L. m.* cells with juice in chopped tomatoes or ketchup resulted in death (Beuchat and Brackett 1991). At a given pH, acetic acid is more effective than lactic, citric and hydrochloric acids in killing *L. m.*

Freezing food inhibits growth of *L. m.* Although the organism may survive freezing, if a frozen food such as ice cream is temperature-abused to the extent that it allows for growth of surviving *L. m.*, the product is typically no longer edible or acceptable to the consumer. FDA-FSIS acknowledged this in the Draft Risk Assessment. Ice cream and frozen dairy foods ranked very low with respect to *L. m.* risk. In addition, many frozen foods must be heated before serving. Even though specific data may be lacking, it is reasonable to expect that frozen foods of all types (in all the FDA-FSIS) categories would rank low in risk.

If the level of contamination is below that which poses a health hazard, and the foods are handled properly, foods that do not support *L. m.* growth are not expected to pose a risk during their specified shelf life. While the available information on food characteristics and matrix effects may not yet be conclusive, categorizing foods according to relevant matrix and processing characteristics for purposes of risk assessment would highlight uncertainties and research needs that are highly significant to the food industry.

## **3. Storage time**

Consumer storage time is a critical variable in the growth model. We deal with storage time issues below, in Section H., Consumer behavior.

## **H. Consumer Behavior – Storage and Cooking Practices**

There are 2 variables relating to consumer behavior post-retail that Novigen believes may exert significant influence on the risk results: home refrigeration temperature and storage time. FDA-FSIS were faced with very limited data for both variables, and assumptions had to be made. To the extent that these assumptions do not correspond to actual consumer practices for the foods in a given category, the risk for that category is mischaracterized.

For example, for fresh soft cheeses, FDA-FSIS used a post-retail storage time distribution with a minimum of 0.5 days, a mode of 6 to 10 days and a maximum of 15 to 45 days. Cheeses in this category are date-coded, perishable products, sold fresh. According to the National Cheese Institute, the typical storage time after purchase is 1 to 5 days, and the maximum is less than 30 days (C. Frye, personal communication). Using these values in the storage distribution reduces the estimated risk per serving from this food category for the elderly population by a factor of 9. This result illustrates the impact of a small change in the assumptions used by FDA-FSIS and highlights the need for an assessment of the impact of the uncertainty in each input parameter on the uncertainty of the derived risk estimates.

New data have become available for frankfurters and deli meats. Using these new data in the risk assessment results in different conclusions.

### **1. FDA-FSIS assumed that refrigerator temperature and storage time are not independent**

#### FDA-FSIS approach:

FDA-FSIS used data for home refrigerator temperatures from a 1999 survey of 939 refrigerators in the U.S. FDA-FSIS used the expert judgments of individuals familiar with the production and use of the various foods to model storage duration for all foods where *L. m.* is expected to grow, except frankfurters and deli meats. The variation in storage time was described using a BetaPert distribution, modified by increasing the weight for the central value and thus reducing the frequency of values in the extended tails. The most likely and maximum storage times were modeled to be negatively associated with high and low refrigeration temperatures, respectively.

In the case of frankfurters and deli meats, preliminary data from a study on storage durations conducted for FSIS were used. Figure III.2 of the Draft Risk Assessment displays the BetaPert distribution used by FDA-FSIS for frankfurters.

#### Novigen analysis and comments:

The assumption of negative correlation between storage duration and temperature that was used by FDA-FSIS makes intuitive sense. However, FDA-FSIS does not have data to support the actual model used to correlate the two distributions. The correlation level used in FDA-FSIS's model was arbitrary. In addition, although the most likely storage duration for

frankfurters was modeled to be between 5 and 7 days, 88% of the modeled storage durations (based on the data summarized in FDA-FSIS's Figure III-2) were longer than 7 days (Figure 4). In fact, the mean and median storage durations were 35 and 28 days, respectively.

New data on storage durations for deli meats and frankfurters collected for the AMI Foundation (Wirthlin 2001) show that the distribution used by FDA-FSIS is overly conservative (see below).

## **2. New AMI data on consumer storage time for frankfurters and deli meats**

In the draft risk assessment, FDA-FSIS assumed that the likely storage time is as much as 180 days and that as much as 14% of frankfurters are consumed without reheating. FDA-FSIS pointed out that these assumptions were based on limited observations.

AMI recently provided new data on consumer practices for deli meats and frankfurters (Wirthlin 2001). The data, from a telephone survey of 1000 US adults 18 or older (including adults over 60), include:

- number of days people store pre-packed deli meats and frankfurters in their refrigerators
- number of days people store custom-sliced deli meats in their refrigerator
- number of people who eat frankfurters right from the package without heating
- frequency of eating prepackaged frankfurters without reheating.

Table 8 summarizes the storage duration data collected by this study for pre-packed deli meats and frankfurters. Based on these data, 84% of the respondents reported storing their pre-packed deli meats and frankfurters in the refrigerator for 7 or less days, i.e., only 16% of the reported storage durations were greater than 7 days. Novigen used the storage time data derived from the survey to estimate the *L. m.* concentration distributions in frankfurters after storage. Specifically, the BetaPert distribution used by FDA-FSIS in the exposure model was replaced by the distribution summarized in Table 8. FDA-FSIS's exposure model was then re-run using this distribution, and the *L. m.* concentration data at-retail was compared to the *L. m.* concentration data after consumer storage. The difference in these distributions was compared to the difference observed using FDA-FSIS's storage distributions. Figure 5 summarizes the comparisons for frankfurters. Similar analyses were conducted for deli meats but showed a less significant impact on the resulting distributions because the storage time distribution used by FDA-FSIS for deli meats was less extreme than that used for frankfurters.

In addition, Novigen assessed the impact of using the newly generated storage time data on the estimated risk for frankfurters. Specifically, FDA-FSIS's exposure model for frankfurters was re-run using the new storage data and the estimated exposure distribution was used in the risk assessment component of the model for the intermediate population to estimate the annual number of listeriosis deaths and of serious listeriosis illnesses associated with each food group. Corresponding ranks, as well as the number of per-serving serious listeriosis illnesses and associated ranks. The estimated risks and associated rankings are compared to the estimated

risks and rankings derived by FDA-FSIS in Table 9. The per-serving risk (number of listeriosis illnesses) estimated by FDA-FSIS in the case of frankfurters is 27 times higher than that estimated using AMI's data. The relative rank changed from 8 to 15 on per serving basis, and from 4 to 11 on a per-annum basis. The small differences in the estimated number of illnesses for the other food groups is due to the fact that Novigen's assessment used fewer iterations than FDA-FSIS's assessment (1000 versus 4000).

### **3. New AMI data on frankfurters eaten without reheating**

In the case of frankfurters, FDA-FSIS relied on data from a USDA telephone survey and assumed that between 1-14% of frankfurters are eaten directly from the package without reheating. Of the respondents in the new AMI survey, 72% reported never consuming raw frankfurters and fewer than 1% reported always consuming raw frankfurters. The remaining 27% reported eating raw frankfurters on occasion. Based on these data, Novigen estimated the average probability of consuming frankfurters without reheating as 7% (See Appendix C for further discussion of these calculations).

Considering 7% of frankfurters are consumed without reheating and there are 6.52E+09 annual servings of frankfurters, based on consumption estimates in the 1994-96 CSFII, on a total US population basis there are approximately 4.57E+08 servings annually at risk of *L. m.* contamination (see Table 10).

Another factor important for *L. m.* exposure assessment may be in what location frankfurters are eaten. It is reasonable to assume that the likelihood of consuming frankfurters without reheating would be highest in the home (as opposed to restaurants or foodservice establishments). Based on data in the CSFII, almost 40% of frankfurters are consumed or prepared outside the home (Table 11). We recommend that frankfurters consumed/prepared outside the home not be included in the calculation of the percentage of frankfurters eaten without reheating.

#### **I. Statistical and Modeling Issues**

Data from multiple studies were combined into single distributions to represent the contamination data. The data were assumed to be representative of the various foods in the category. For each food group, 3 parametric distributions were fitted and the assessment sampled from the 3 distributions, proportionately to how well the distributions fit the original data (the actual data points reported in the studies) relative to each other. However, no information was provided on the goodness of fit of each of the distributions, that is, FDA-FSIS's assessment did not provide estimates of how well the parametric distributions represent the empirical data or how different the results might be if the empirical distributions were used rather than the parametric distributions. There may be substantial uncertainty introduced by using the distributions in this way.

#### **IV. HAZARD CHARACTERIZATION (DOSE-RESPONSE MODEL)**

##### **A. Transparency/Reproducibility Issues**

The dose response model combines intake estimates from the exposure model with dose response curves fitted to the mouse data to estimate the number of listeriosis deaths and illnesses associated with each food for each of the populations considered. In addition, the model included a factor to adjust the estimated risk numbers to make them comparable with the CDC data on estimated listeriosis cases. A separate program was used by FDA-FSIS to fit the dose response curves to the mouse data and was provided on the CD, together with the risk assessment software. However, limited information was provided on the algorithms and assumptions used by this program, as well as on how to relate the output of this program to the dose-response model. Further, although Novigen was able to run the exposure and dose-response parts of the model, this would not have been possible without information obtained directly from FDA-FSIS. Thus, a significant amount of information needs to be provided to the user to make the model usable. The additional information needed includes: instructions on how to run the programs in the various spreadsheets; how to link the outputs generated from these spreadsheets; how to modify the assumptions in the spreadsheets; and which default settings can be changed in the spreadsheets directly and which can only be changed by changing the software code. Because each risk calculation using the program provided by FDA-FSIS requires considerable computer time, and the scope of this review did not include software modifications [we did not express our results in terms of risk in every case.]

##### **B. Mouse Model**

FDA-FSIS's use of the mouse data is credible given the available information. However, as is true for risk assessments of toxic chemicals, the issues of variability in the available data and uncertainty (lack of data on key variables) are significant with respect to the dose-response curves, particularly in the low dose ranges. Arguably, the mouse model and its relevance to human listeriosis is one of the greatest sources of uncertainty in the Draft Risk Assessment.

FDA-FSIS applied an adjustment factor to the mouse dose-response relationship to reduce the predicted number of human illnesses to the range of CDC estimates based on epidemiological data. When using animal data, some adjustment is typically necessary to account for differences in susceptibility between humans and experimental animals. In assessing chemical risk for example, humans are assumed to be ten to one hundred times more susceptible than experimental rats or mice. Generally for chemicals, human epidemiology data for direct comparisons are lacking. The magnitude of the adjustment factor used in the Draft Risk Assessment (up to  $10^8$ ,  $10^{11}$ , and  $10^{12}$  for the perinatal, elderly and intermediate subpopulations, respectively) is such that it raises questions about the mouse model, and also suggests that the risk estimates may be subject to additional sources of significant uncertainty.

Limitations of the mouse model for predicting human foodborne listeriosis are widely acknowledged, including by FDA-FSIS. The infective dose in the mouse studies is determined by isolating *Listeria* from normally sterile tissues of the animal's body. The relevance of this to human illness is not really known, although it is assumed. Stillbirths and neonatal infections seen in humans cannot be produced in the mouse model.

With new research currently underway, these uncertainties should be reduced significantly in the future. Lecuit *et al.* (2001) recently reported the development of a mouse model for orally acquired listeriosis. They have produced a transgenic mouse whose gut epithelial cells overexpress the human gene for E-cadherin, the intestinal transmembrane protein that binds the *Listeria* surface protein internalin, enabling *Listeria* expressing internalin to penetrate the intestinal barrier in humans. In addition, progress was recently reported by USDA scientists in sequencing the genome of the serotype 4b strain of *L. m.*, which is responsible for most outbreaks of foodborne listeriosis as well as half of the sporadic cases of human illness (USDA ARS June 7 announcement). Research is also underway in pregnant rhesus monkeys that may provide a better dose-response model for the perinatal/pregnant women subpopulation.

Another challenge to characterizing *L. m.* hazard at this time is that the available contamination data do not specify *L. m.* strain and therefore may not be relevant to predicting human risk of listeriosis. While some serotype data are available and cited in the risk assessment, they only demonstrate that the distribution of serotypes among human cases may be different from the distribution of serotypes in foods that people consume. Since the prevalence of *L. m.* is high, but the number of documented cases remains low (and falling), many food isolates irrespective of serotype may be able to be consumed by most persons (of whatever host risk category) without much risk of disease. In the absence of virulence markers to distinguish strains that cause disease from those that do not, there is no alternative but to try to use association with human disease to help distinguish specific foods that when contaminated with *L. m.*, may cause illness. Assuming all strains are equal with respect to virulence overestimates the risk of disease.

These fundamental challenges with respect to infectivity of *L. m.* and human susceptibility to infection can only be remedied by more research.

## **V. DISCUSSION**

### **A. General Observations**

The Draft Risk Assessment approach accommodates lack of data and biological variability in human and microbial populations in a reasonable, albeit conservative, and relatively transparent manner. The background information, including access to underlying data within many of the tables and graphs, is particularly valuable. The models are well documented and various components are, in general, readily available for review. The use of available data is described and the model fully uses most of this data. Nonetheless, there are important uncertainties that may affect the risk rankings.

## **B. Dose-Response Model and Lack of Specificity in Contamination Data**

Novigen did not perform a systematic and quantitative evaluation of all the elements in the comprehensive assessment. However it is our judgment, based on working with the models and the data, that the largest uncertainties in the Draft Risk Assessment are (1) the questionable relevance of the dose-response model based on the mouse to human food borne listeriosis, and (2) the lack of specificity in the contamination data with respect to virulence. These uncertainties can only be addressed by more research. Thus, FDA and FSIS should accelerate the pace of the relevant research, and assure that the Draft Risk Assessment is revised as soon as new information becomes available. Recent developments (a transgenic mouse that may yield more relevant dose-response data and the sequence of the genome of an *L. m.* serotype associated with illness) suggest that these uncertainties may be reduced substantially in the next few years. It is conceivable that the new results will indicate that new risk management approaches, for example focusing on susceptible subpopulations, would lead to better risk characterization and optimal risk reduction. As noted throughout this review, other inputs can be improved with additional data and/or with refinements to the model and model components.

## **C. Uncertainties Due to Data Quality Issues**

We have shown that high-quality data on prevalence and on consumer behavior, such as those provided by NFPA on contamination level found in samples collected at retail and by AMI on consumer practices can produce significant impacts on the exposure and risk estimates. We have also illustrated problems with the use of proxy data. Better data would enable FDA and FSIS to move beyond a relative risk ranking approach, which does not provide important details for the development of effective control strategies.

## **D. Uncertainties Associated with Use of Distributions**

The Draft Risk Assessment does not specifically address the uncertainty associated with the selection of particular distributions to represent the variables. Although FDA and FSIS compared the distributions to each other, a goodness-of-fit evaluation of each distribution with respect to the underlying data used is recommended. Again, additional data would also facilitate the selection of appropriate distributions and possibly identify additional factors to be incorporated into the risk assessment.

## **E. Limitations Related to Food Categories**

The risk assessment approach itself introduces sources of uncertainty that FDA and FSIS should better characterize and seek to reduce. First, different approaches to grouping foods into categories should be included in the exposure assessment. The current categories may appear to contain “similar foods,” but they combine foods dissimilar with respect to both matrix and processing characteristics. For example, pickled vegetables and potato salad are combined with raw vegetables when they are more similar to deli salads in matrix and processing characteristics. Grouping also affects how proxy data are selected and applied. While the effects of food

matrices and processing methods on *L. m.* survival and growth are not yet completely understood, the “hypothesis testing” of grouping foods according to these characteristics could shed additional light on specific uncertainties and data needs that are critically important to the food industry.

#### **F. Limitations of the Risk Ranking Approach**

As FDA and FSIS observed, a relative risk ranking approach to risk assessment may be the best procedure when data are limited. However, data quality issues, grouping and other uncertainties affect risk rankings. They have limited utility for control strategy purposes. For example, rankings are unstable. If additional data are developed for a food category leading to reduced uncertainty and lower risk for that category, the relative ranking of categories changes. Effective control strategies for specific foods or food categories can only be assured when risks associated with those foods or categories are individually characterized.

#### **G. Facilitation of Sensitivity Analyses**

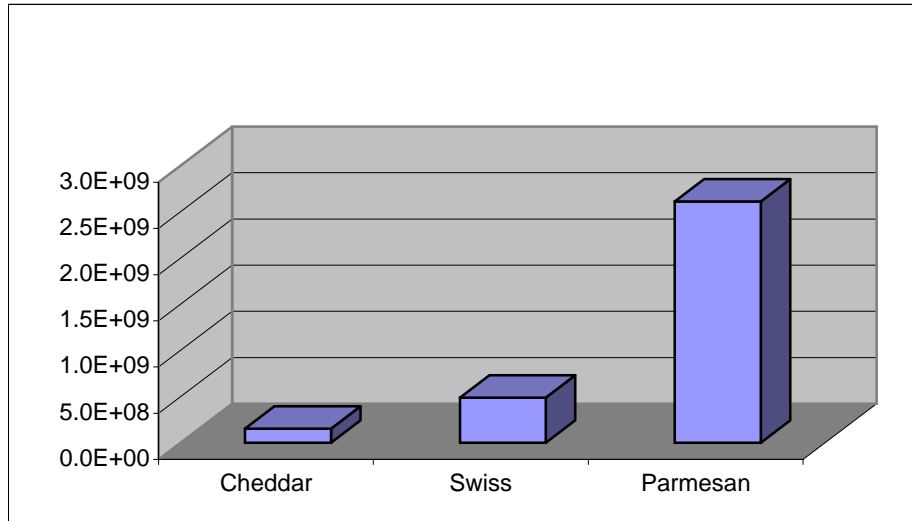
The model combines a large number of input variables and assumptions into the various model components (e.g., growth model, exposure model, dose-response model, etc.) and an estimate of the uncertainty introduced by using various parametric distributions can be derived from the model. However, the model does not include a method to readily perform sensitivity analyses. Sensitivity analyses provide the risk assessors and managers with information as to which of the input variables or assumptions contribute the most to the risk estimate and to what extent the uncertainty in a specific input impacts the uncertainty of the estimated risk. Sensitivity analyses are important tools in developing effective risk management approaches.

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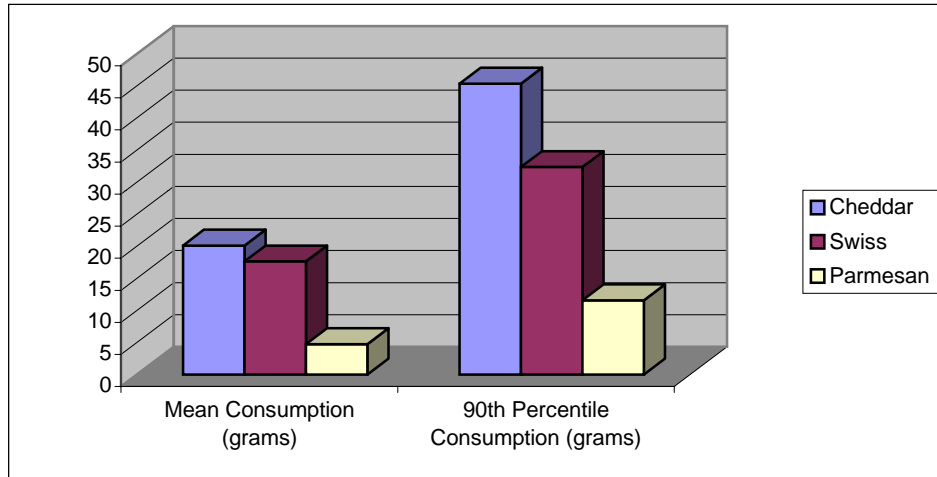
**FIGURE 1**

**NUMBER OF ANNUAL SERVINGS FOR AGED CHEESES, US POPULATION  
(DATA FROM USDA CSFII, 1994-1996)**



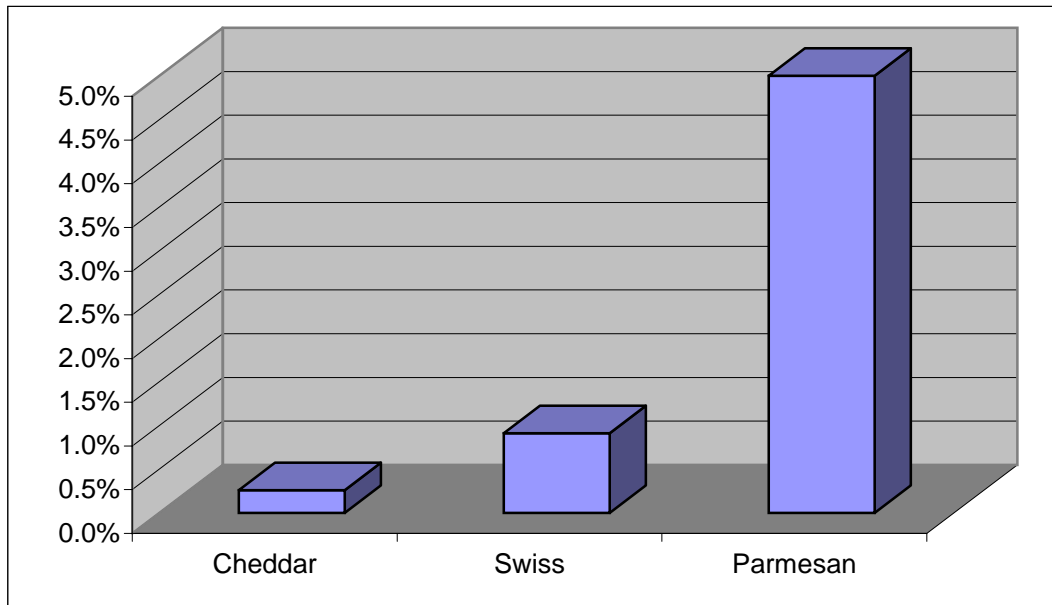
**FIGURE 2**

**PER-USER CONSUMPTION OF AGED CHEESES, PER EATING OCCASION  
(DATA FROM USDA CSFII, 1994-1996)**



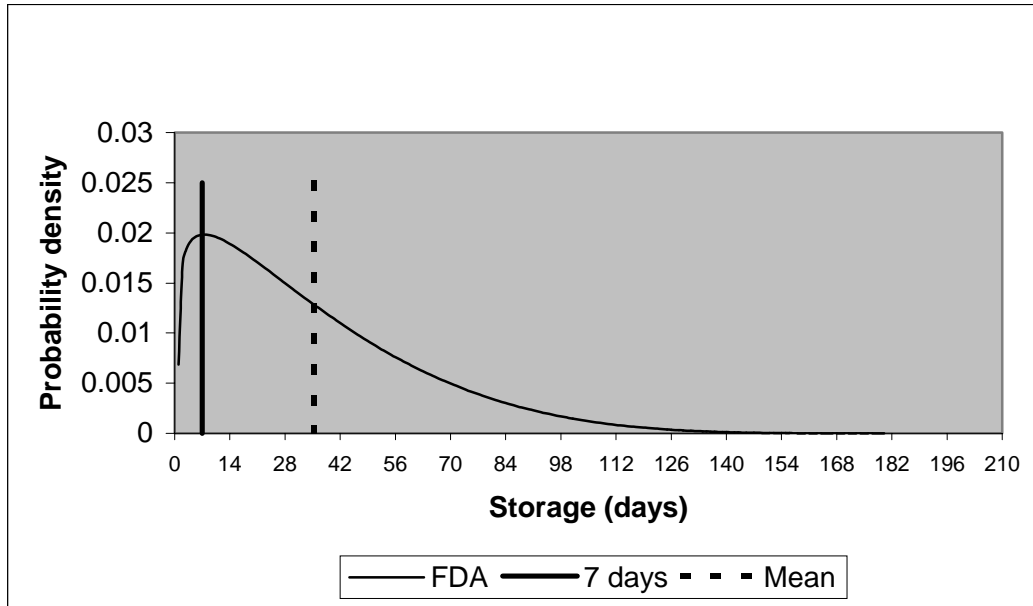
**FIGURE 3**

**PERCENTAGE OF TOTAL US POPULATION CONSUMING AGED CHEESES  
(DATA FROM USDA CSFII, 1994-1996)**



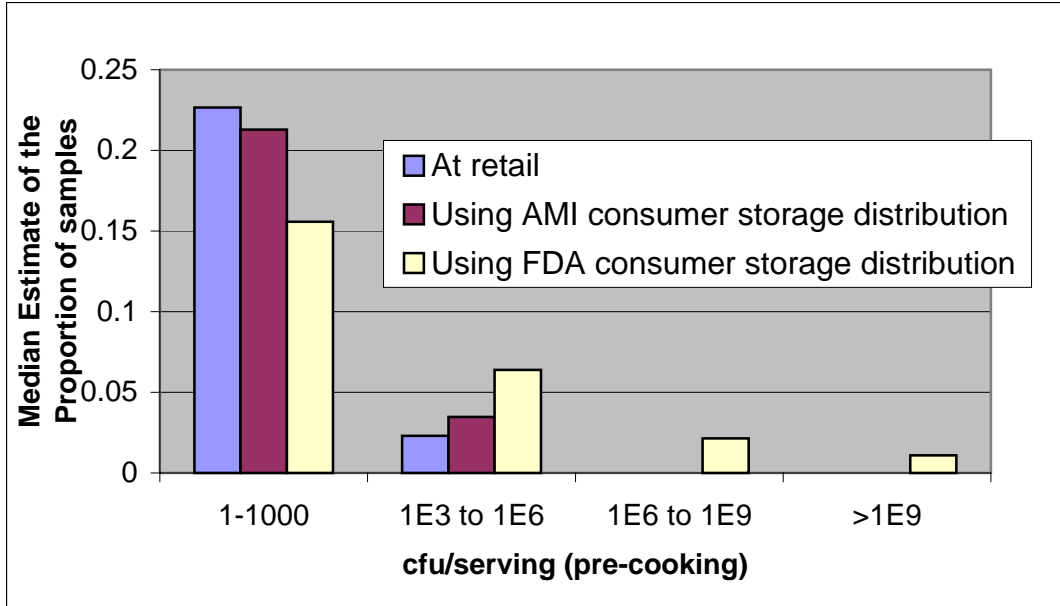
**FIGURE 4**

**STORAGE TIME DISTRIBUTION USED BY FDA (FRANKFURTERS)**



**FIGURE 5**

**IMPACT OF THE STORAGE TIME DISTRIBUTION (FRANKFURTERS)<sup>1</sup>**



<sup>1</sup> Excluding servings with <1 cfu/serving.

**TABLE 1**  
**IMPACT OF USING UNADJUSTED CONCENTRATION DATA FOR PASTEURIZED MILK**  
**ON THE ESTIMATED RISK FOR THE INTERMEDIATE POPULATION**

Food Group	Estimated Median Number of Listeriosis Cases per Serving		Per-serving Relative Ranking		Per-Annum Relative Ranking	
	FDA	Scenario I <sup>1</sup>	FDA	Scenario I	FDA	Scenario I
Smoked Seafood	5.3E-08	5.1E-08	3	3	6	5
Raw Seafood	5.6E-10	5.3E-10	14	13	17	16
Preserved Fish	7.5E-09	6.4E-09	7	7	13	13
Cooked Ready-to-Eat Crustaceans	1.2E-08	1.1E-08	6	6	9	8
Vegetables	4.1E-11	4.0E-11	17	16	11	10
Fruits	1E-11	1.4E-11	18	17	16	12
Soft Mold-Ripened and Blue-Veined Cheese	2.5E-09	2.5E-09	9	9	14	14
Goat, Sheep and Feta Cheese	5.6E-11	5.8E-11	16	15	18	18
Fresh Soft Cheeses	5.8E-08	5.8E-08	2	2	7	6
Heat-Treated Natural Cheese and Processed Cheese	3.3E-10	3.3E-10	15	14	10	9
Aged Cheeses	3.2E-13	2.8E-13	19	19	19	19
Pasteurized Fluid Milk	<b>1.6E-09</b>	<b>3.8E-13</b>	<b>10</b>	<b>18</b>	<b>3</b>	<b>17</b>
Unpasteurized Fluid Milk	1.1E-09	1.0E-09	11	10	15	15
Ice Cream/Frozen Dairy Products	1.2E-13	1.1E-13	20	20	20	20
Miscellaneous Dairy Products	8.7E-10	8.0E-10	12	12	5	4
Frankfurters	5.9E-09	5.9E-09	8	8	4	3
Dry/Semi-Dry Fermented Sausages	8.1E-10	9.1E-10	13	11	12	11
Deli Meats	2.6E-08	2.5E-08	4	4	1	1
Pâté and Meat Spreads	6.6E-08	6.4E-08	1	1	8	7
Deli Salads	1.4E-08	1.4E-08	5	5	2	2

<sup>1</sup> In this scenario, the concentration levels for the samples collected pre-retail were not inflated by assuming an 0.25 log growth model, as in FDA's assessment.

**TABLE 2**  
**CONCENTRATION DATA: FRANKFURTERS**  
**IMPACT OF REMOVING WEIGHTS ON UPPER PERCENTILES**

<b>Distribution</b>	<b>Lognormal</b>		<b>Weibull</b>		<b>Beta</b>	
<b>Parameters</b>	<b>FDA report</b>	<b>No weight</b>	<b>FDA report</b>	<b>No weight</b>	<b>FDA report</b>	<b>No weight</b>
<b>1</b>	2.23E-04	3.49E-04	1.37E-01	1.50E-01	1.60E-02	4.35E-02
<b>2</b>	5.50E+00	5.17E+00	6.15E-04	1.06E-03	6.16E+06	9.46E+06
<b>3</b>					1.00E+09	5.67E+07
<b>Percentiles</b>	<b>FDA</b>	<b>No weight</b>	<b>FDA</b>	<b>No weight</b>	<b>FDA</b>	<b>No weight</b>
<b>50%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>75%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>90%</b>	2.57E-01	2.63E-01	2.66E-01	2.78E-01	1.29E-01	3.26E-01
<b>95%</b>	1.89E+00	1.72E+00	1.81E+00	1.61E+00	3.85E+00	1.31E+00
<b>97.5%</b>	1.07E+01	8.77E+00	8.23E+00	6.45E+00	2.16E+01	2.99E+00
<b>99%</b>	8.03E+01	5.83E+01	4.14E+01	2.84E+01	7.37E+01	5.98E+00
<b>Ratio of FDA percentile to new percentile</b>	<b>FDA</b>	<b>No weight</b>	<b>FDA</b>	<b>No weight</b>	<b>FDA</b>	<b>No weight</b>
<b>50%</b>	NA <sup>1</sup>	No Change <sup>2</sup>	NA	No Change	NA	No change
<b>75%</b>	NA	No Change	NA	No Change	NA	No Change
<b>90%</b>	NA	0.98	NA	0.96	NA	0.39
<b>95%</b>	NA	1.10	NA	1.12	NA	2.94
<b>97.5%</b>	NA	1.22	NA	1.27	NA	7.23
<b>99%</b>	NA	1.38	NA	1.46	NA	12.31

<sup>1</sup> NA: Not applicable

<sup>2</sup> No change: Both estimates were < 0.04 cfu/gm

**TABLE 3**  
**CONCENTRATION DATA: FRUITS**  
**IMPACT OF REMOVING WEIGHTS ON UPPER PERCENTILES**

Distribution	Logonormal		Weibull		Beta	
<b>Parameters</b>	<b>FDA report</b>	<b>No weight</b>	<b>FDA report</b>	<b>No weight</b>	<b>FDA report</b>	<b>No weight</b>
<b>1</b>	1.98E-03	3.26E-02	2.34E-01	5.49E+00	1.90E-02	2.24E-02
<b>2</b>	2.41E+00	1.42E-01	1.27E-03	3.36E-02	3.94E+07	9.36E+07
<b>3</b>					1.00E+09	9.89E+08
<b>Percentiles</b>	<b>FDA</b>	<b>No weight</b>	<b>FDA</b>	<b>No weight</b>	<b>FDA</b>	<b>No weight</b>
<b>50%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>75%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>90%</b>	4.34E-02	<0.04	4.47E-02	<0.04	5.62E-02	5.48E-02
<b>95%</b>	1.04E-01	4.11E-02	1.37E-01	4.10E-02	1.01E+00	6.48E-01
<b>97.5%</b>	2.23E-01	4.30E-02	3.34E-01	4.26E-02	4.50E+00	2.41E+00
<b>99%</b>	5.38E-01	4.53E-02	8.62E-01	4.44E-02	1.35E+01	6.51E+00
<b>Ratio of FDA percentile to new percentile</b>	<b>FDA</b>	<b>No weight</b>	<b>FDA</b>	<b>No weight</b>	<b>FDA</b>	<b>No weight</b>
<b>50%</b>	NA <sup>1</sup>	No Change <sup>2</sup>	NA	No Change	NA	No Change
<b>75%</b>	NA	No Change	NA	No Change	NA	No Change
<b>90%</b>	NA	>1 <sup>3</sup>	NA	>1	NA	1.03
<b>95%</b>	NA	2.53	NA	3.35	NA	1.56
<b>97.5%</b>	NA	5.17	NA	7.84	NA	1.87
<b>99%</b>	NA	11.88	NA	19.43	NA	2.08

<sup>1</sup> NA: Not applicable

<sup>2</sup> No change: Both estimates were < 0.04 cfu/gm

<sup>3</sup> The estimated percentile based on FDA's distributions is > 0.04 cfu/g, while the estimated percentile derived without the weight is <0.04 cfu/g.

**TABLE 4**

**CONCENTRATION DATA: GOAT AND FETA CHEESE  
IMPACT OF REMOVING NON-SIMILAR NON-US DATA**

<b>Distribution</b>	<b>Lognormal</b>		<b>Weibull</b>		<b>Beta</b>	
<b>Parameters</b>	<b>FDA report</b>	<b>US only<sup>1</sup></b>	<b>FDA report</b>	<b>US only</b>	<b>FDA report</b>	<b>US only</b>
<b>1</b>	1.47E-07	1.00E-10	7.07E-02	7.07E-02	8.03E-03	3.78E-03
<b>2</b>	9.00E+00	9.00E+00	2.83E-08	1.00E-08	1.08E+06	1.20E+06
<b>3</b>					1.00E+09	1.25E+09
<b>Percentiles</b>	<b>FDA</b>	<b>US only</b>	<b>FDA</b>	<b>US only</b>	<b>FDA</b>	<b>US only</b>
<b>50%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>75%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>90%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>95%</b>	3.95E-01	<0.04	1.55E-01	5.48E-02	8.74E-01	<0.04
<b>97.5%</b>	6.73E+00	<0.04	2.94E+00	1.04E+00	2.28E+01	7.23E-01
<b>99%</b>	1.82E+02	1.24E-01	6.77E+01	2.39E+01	1.79E+02	4.27E+01
<b>Ratio of FDA percentile to new percentile</b>	<b>FDA</b>	<b>US only</b>	<b>FDA</b>	<b>US only</b>	<b>FDA</b>	<b>US only</b>
<b>50%</b>	NA <sup>2</sup>	No Change <sup>3</sup>	NA	No Change	NA	No Change
<b>75%</b>	NA	No Change	NA	No Change	NA	No Change
<b>90%</b>	NA	No Change	NA	No Change	NA	No Change
<b>95%</b>	NA	>1 <sup>4</sup>	NA	2.83	NA	>1
<b>97.5%</b>	NA	>1	NA	2.83	NA	31.49
<b>99%</b>	NA	1468.79	NA	2.83	NA	4.19

<sup>1</sup> Includes only US data and European data that are similar to the US data.

<sup>2</sup> NA: Not applicable

<sup>3</sup> No change: Both estimates were < 0.04 cfu/gm

<sup>4</sup> The estimated percentile based on FDA's distributions is > 0.04 cfu/g, while the estimated percentile derived without the weight is <0.04 cfu/g.

**TABLE 5**

**CONCENTRATION DATA: FRANKFURTERS  
IMPACT OF USING POST 1993 DATA ONLY**

<b>Distribution</b>	<b>Lognormal</b>		<b>Weibull</b>		<b>Beta</b>	
<b>Parameters</b>	<b>FDA report</b>	<b>Post-93</b>	<b>FDA report</b>	<b>Post-93</b>	<b>FDA report</b>	<b>Post-93</b>
<b>1</b>	2.23E-04	1.77E-03	1.37E-01	2.01E-01	1.60E-02	1.37E-02
<b>2</b>	5.50E+00	3.87E+00	6.15E-04	4.30E-03	6.16E+06	6.01E+06
<b>3</b>					1.00E+09	9.63E+08
<b>Percentiles</b>	<b>FDA</b>	<b>Post-93</b>	<b>FDA</b>	<b>Post-93</b>	<b>FDA</b>	<b>Post-93</b>
<b>50%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>75%</b>	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
<b>90%</b>	2.57E-01	2.53E-01	2.66E-01	2.72E-01	1.29E-01	4.07E-02
<b>95%</b>	1.89E+00	1.03E+00	1.81E+00	1.01E+00	3.85E+00	2.16E+00
<b>97.5%</b>	1.07E+01	3.49E+00	8.23E+00	2.84E+00	2.16E+01	1.57E+01
<b>99%</b>	8.03E+01	1.44E+01	4.14E+01	8.55E+00	7.37E+01	6.16E+01
<b>Ratio of FDA percentile to new percentile</b>	<b>FDA</b>	<b>Post-93</b>	<b>FDA</b>	<b>Post-93</b>	<b>FDA</b>	<b>Post-93</b>
<b>50%</b>	NA <sup>1</sup>	No Change <sup>2</sup>	NA	No Change	NA	No change
<b>75%</b>	NA	No Change	NA	No Change	NA	No Change
<b>90%</b>	NA	1.02	NA	0.98	NA	3.17
<b>95%</b>	NA	1.84	NA	1.79	NA	1.78
<b>97.5%</b>	NA	3.07	NA	2.90	NA	1.38
<b>99%</b>	NA	5.57	NA	4.84	NA	1.20

<sup>1</sup> NA: Not applicable

<sup>2</sup> No change: Both estimates were < 0.04 cfu/gm

**TABLE 6**

**IMPACT OF USING NFPA CONCENTRATION DATA FOR DELI MEATS  
ON THE ESTIMATED RISK FOR THE ELDERLY POPULATION**

Food Group	Estimated Median Number of Listeriosis Cases per Serving		Per-serving Relative Ranking		Per-Annun Relative Ranking	
	FDA	Scenario II <sup>1</sup>	FDA	Scenario II	FDA	Scenario II
Smoked Seafood	4.4E-07	4.6E-07	3	3	6	5
Raw Seafood	5.0E-09	4.6E-09	14	13	20	20
Preserved Fish	7.9E-08	6.5E-08	7	6	13	14
Cooked Ready-to-Eat Crustaceans	1.0E-07	9.7E-08	5	5	8	7
Vegetables	3.4E-10	3.4E-10	17	17	9	8
Fruits	1.0E-10	1.4E-10	18	18	14	12
Soft Mold-Ripened and Blue-Veined Cheese	2.1E-08	2.2E-08	9	8	15	15
Goat, Sheep and Feta Cheese	5.5E-10	5.7E-10	16	15	17	17
Fresh Soft Cheeses	8.1E-07	8.1E-07	1	1	11	10
Heat-Treated Natural Cheese and Processed Cheese	2.8E-09	2.8E-09	15	14	10	9
Aged Cheeses	3.0E-12	2.6E-12	19	19	18	18
Pasteurized Fluid Milk	1.5E-08	1.5E-08	10	9	2	1
Unpasteurized Fluid Milk	1.0E-08	9.7E-09	11	10	16	16
Ice Cream/Frozen Dairy Products	1.1E-12	1.1E-12	20	20	19	19
Miscellaneous Dairy Products	7.5E-09	7.2E-09	13	12	4	3
Frankfurters	5.0E-08	5.1E-08	8	7	5	4
Dry/Semi-Dry Fermented Sausages	8.4E-09	9.6E-09	12	11	12	11
Deli Meats	<b>2.2E-07</b>	<b>5.4E-10</b>	<b>4</b>	<b>16</b>	<b>1</b>	<b>13</b>
Pâté and Meat Spreads	5.8E-07	5.9E-07	2	2	7	6
Deli Salads	9.4E-08	1.2E-07	6	4	2	3

<sup>1</sup> In this scenario, the contamination data collected by NFPA were used for deli meats.

**TABLE 7**

**EFFECT ON ANNUAL NUMBER OF SERVINGS OF EXCLUDING FOODS WITH CERTAIN CHARACTERISTICS FROM CATEGORIES**

<b>A. Excluding Pickled Foods</b>		
<b>Food Category</b>	<b>Annual Number of Servings</b>	
	<b>Original Grouping</b>	<b>Excluding Pickled Foods</b>
Deli Salads	5.63E+09	5.63E+09
Fruits	5.03E+10	5.03E+10
Vegetables	1.17E+11	9.47E+10

<b>B. Excluding Foods Served Hot</b>		
<b>Food Category</b>	<b>Annual Number of Servings</b>	
	<b>Original Grouping</b>	<b>Excluding Foods Served Hot</b>
Deli Meats	2.07E+10	1.92E+10
Vegetables <sup>1</sup>	1.17E+11	1.09E+11

<b>C. Excluding Tomatoes &amp; Foods Served Hot</b>			
<b>Food Category</b>	<b>Annual Number of Servings</b>		
	<b>Original Grouping</b>	<b>Excluding Tomatoes</b>	<b>Excluding Tomatoes and Foods Served Hot</b>
Vegetables	1.17E+11	9.20E+10	8.35E+10

<sup>1</sup> Foods served hot included in the Vegetables category are “Meatless Meatball,” “Soy-burger,” “Breakfast link, patty or slice,” and “Bacon strip, meatless.”

**TABLE 8**

**DISTRIBUTION OF STORAGE TIMES IN THE REFRIGERATOR  
FOR PRE-PACKED DELI MEATS AND FRANKFURTERS  
(DATA COLLECTED FOR THE AMI FOUNDATION)**

<b>Duration (days)</b>	<b>Percent</b>	<b>adjusted percent<sup>1</sup></b>
<b>1 to 3</b>	<b>32</b>	<b>39</b>
<b>4 to 7</b>	<b>37</b>	<b>45</b>
<b>8 to 10</b>	<b>6</b>	<b>7</b>
<b>11 to 14</b>	<b>4</b>	<b>5</b>
<b>15 to 21</b>	<b>1</b>	<b>1</b>
<b>22 to 30</b>	<b>1</b>	<b>1</b>
<b>31 to 60</b>	<b>1</b>	<b>1</b>
<b>61 or more</b>	<b>0</b>	<b>0</b>
<b>total</b>	<b>82<sup>2</sup></b>	<b>100</b>

---

<sup>1</sup> The percentages were adjusted to reflect only the answers of the respondents who consume and store their pre-packed deli meats and frankfurters in the refrigerator.

<sup>2</sup> The remaining 18% of the respondents either refused to answer (2%), reported that they do not consume pre-packed deli meats and frankfurters (13%), or that they always freeze them (3%).

**TABLE 9**

**IMPACT OF USING NEW CONSUMER STORAGE DATA FOR FRANKFURTERS  
ON THE ESTIMATED RISK FOR THE INTERMEDIATE POPULATION**

Food Group	Estimated Median Number of Listeriosis Cases per Serving		Per-serving Relative Ranking		Per-Annum Relative Ranking	
	FDA	Scenario III <sup>1</sup>	FDA	Scenario III	FDA	Scenario III
Smoked Seafood	5.3E-08	5.4E-08	3	3	6	5
Raw Seafood	5.6E-10	5.8E-10	14	13	17	17
Preserved Fish	7.5E-09	8.7E-09	7	7	13	13
Cooked Ready-to-Eat Crustaceans	1.2E-08	1.2E-08	6	6	9	8
Vegetables	4.1E-11	4.3E-11	17	17	11	10
Fruits	1.0E-11	8.9E-12	18	18	16	16
Soft Mold-Ripened and Blue-Veined Cheese	2.5E-09	2.6E-09	9	8	14	14
Goat, Sheep and Feta Cheese	5.6E-11	5.1E-11	16	16	18	18
Fresh Soft Cheeses	5.8E-08	6.0E-08	2	2	7	6
Heat-Treated Natural Cheese and Processed Cheese	3.3E-10	3.5E-10	15	14	10	9
Aged Cheeses	3.2E-13	2.5E-13	19	19	19	19
Pasteurized Fluid Milk	1.6E-09	1.7E-09	10	9	3	3
Unpasteurized Fluid Milk	1.1E-09	1.1E-09	11	10	15	15
Ice Cream/Frozen Dairy Products	1.2E-13	1.0E-13	20	20	20	20
Miscellaneous Dairy Products	8.7E-10	9.0E-10	12	11	5	4
<b>Frankfurters</b>	<b>5.9E-09</b>	<b>2.2E-10</b>	<b>8</b>	<b>15</b>	<b>4</b>	<b>11</b>
Dry/Semi-Dry Fermented Sausages	8.1E-10	8.1E-10	13	12	12	12
Deli Meats	2.6E-08	2.5E-08	4	4	1	1
Pâté and Meat Spreads	6.6E-08	6.8E-08	1	1	8	7
Deli Salads	1.4E-08	1.4E-08	5	5	2	2

<sup>1</sup> In this scenario, the storage data collected for the AMI foundation for pre-packed frankfurters were used for frankfurters.

**TABLE 10**

**ESTIMATED NUMBER OF FRANKFURTER SERVINGS AT RISK OF *L. m.***

<b>Annual No. Servings</b>	<b>Maximum Percent Assumed Consumed w/o Heating<sup>1</sup></b>	<b>Number of Servings/Yr at Risk of <i>L. monocytogenes</i><sup>2</sup></b>
6.52E+09	7%	4.57E+08

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<sup>1</sup> Percentage consumed without reheating based on AMI data.

<sup>2</sup> These numbers are for illustration purposes and do not correspond to numbers in the risk assessment. FDA's calculations also incorporate other variables.

**TABLE 11**

**FRANKFURTER CONSUMPTION AT HOME AND OUTSIDE THE HOME**

<b>Total Annual Number of Frankfurters Consumed</b>	<b>Annual Number of Frankfurters Consumed or Prepared at Home<sup>1</sup></b>	<b>Annual Number of Frankfurters Not Consumed at Home</b>
6.52E+09	4.14E+09	2.38E+09

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<sup>1</sup> This category includes foods in the CSFII reported to be consumed at home and also foods prepared at home, but consumed elsewhere.

**APPENDIX A**

**FOOD CONTAMINATION DATA USED IN THE DRAFT RISK ASSESSMENT**

**APPENDIX A**

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## APPENDIX A

### FOOD CONTAMINATION DATA USED IN THE DRAFT RISK ASSESSMENT

**TABLE A.1**

#### CONCENTRATION DATA USED BY FDA FOR AGED CHEESE

Aged Cheese				
Study	Country	Number of Samples Tested	Concentration Level (cfu/g)	Relative Cumulative Frequency <sup>1</sup>
Teufel and Bendzulla, 1993	Germany	34 or 35	0.04	0.882353
			1	0.868421
			100	0.970588
			1000	1
Weber <i>et al.</i> , 1988	Germany	4	0.04	1
Pinto and Reali, 1996	Italy	45	0.04	1
Breer and Schopfer, 1989	Switzerland	293	0.04	0.986348
Greenwood <i>et al.</i> , 1991	UK	66 or 65	0.04	0.984848
			500	1
West and North Yorkshire Joint Working Group, 1991	UK	74	0.04	1
McLauchlin and Gilbert, 1990	UK	448	0.04	0.986607
Oregon State Dept. of Agriculture, 1999	USA	116	0.04	1

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.2**

**CONCENTRATION DATA USED BY FDA FOR COOKED READY-TO-EAT  
CRUSTACEANS**

<b>Cooked RTE Crustations</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Farber, 1991b	Canada	49	0.04	0.918367
			0.3	0.979592
			10	1
Ravomanana et al., 1993	France	35	0.04	0.885714
Hartemink and Georgsson 1991	Iceland	22	0.04	0.954545
Valdimarsson et al., 1998	Iceland	3331	0.10	0.978385
Richmond, 1990	UK	40	0.04	1
Degnan et al., 1994	USA	4	0.04	0.25
			10	0.75
			100	1
Rawles et al., 1995	USA	126	0.10	0.920635
			25.70	0.904762
			128.52	0.952381
			257.04	0.992063
			2570.40	0.992063
5140.79	1			
Weagant et al., 1988	USA	32	0.04	0.71875

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.3**

**CONCENTRATION DATA USED BY FDA FOR DELI MEATS**

<b>Deli Meats</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Uyttendaele et al., 1999	Belgium	879	0.04	0.9294653
			10	0.9908987
Qvist and Liberski, 1991	Denmark	160	0.04	0.84375
			100	1
Lahellec et al., 1996	France	45	0.04	0.9777778
Ng and Seah, 1995	Singapore	17	0.04	0.8235294
Levine, 2000	USA	9864	11.27	0.976987

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

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<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be  $\leq 0.04$  cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.4**

**CONCENTRATION DATA USED BY FDA FOR DELI SALADS**

<b>Deli Salads</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Uyttendaele et al., 1999	Belgium	673	0.04	0.7132244
			10	0.9702823
Teufel and Bendzulla 1993	Germany	252	0.04	0.9563492
			358	0.04
		358		100
			358	10000
Hartemink and Georgsson 1991	Iceland	37		0.04
West and North Yorkshire Joint Working Group, 1991	UK	149	0.04	0.8590604
			20	0.885906
			100	0.9328859
			1000	0.9328859
Wilson 1996	UK	316	0.04	0.9936709
			100	0.9936709
			1000	0.9968354
			10000	0.9968354
			100000	1
Buchanan et al., 1989	USA	2	0.04	1
Levine, 2000	USA	1645	0.07	0.968997

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.5**

**CONCENTRATION DATA USED BY FDA FOR FRANKFURTERS**

<b>Frankfurters</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Qvist and Liberski, 1991	Denmark	64	0.04	0.875
			100	0.96875
			100	0.96875
			1000	0.984375
			10000	1
Ng and Seah, 1995	Singapore	78	0.744835	0.9358974
Hayes et al. 92	USA	61	0.04	0.8032787
			0.3	0.9508197
			10	0.9672131
			100	1
Levine, 2000	USA	1593	0.744835	0.94
Wang and Muriana, 1994	USA	117	0.04	0.7948718
			10	1
Wenger et al., 1990	USA	46	0.744835	0.5434783

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.6**

**CONCENTRATION DATA USED BY FDA FOR FRESH CHEESE**

Fresh Cheese <sup>1</sup>				
Study	Country	Number of Samples Tested	Concentration Level (cfu/g)	Relative Cumulative Frequency <sup>2</sup>
Loncarevic <i>et al.</i> , 1995	Europe	31	0.04	0.5806452
			100	0.8709677
			1000	0.9032258
			10000	0.9677419
			100000	0.9677419
Beckers <i>et al.</i> , 1988	Netherlands	18	0.04	0.4444444
			1000	0.4444444
			1000000	1
Weber <i>et al.</i> , 1988	Germany	22	0.04	0.909091
Gelosa, 1990	Italy	17	0.04	1
Ubach <i>et al.</i> , 1991	Spain	91	0.04	0.923077
Oregon Dept of Agriculture, 1999	USA	18	0.04	0.888889

**NOTE: The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.**

<sup>1</sup> Data from Loncarevic *et al.*, 1995 and Beckers, 1988, are for soft-ripened cheese made from unpasteurized milk. They were used to describe the shape of the distribution curve only. The fitted distributions for the remaining four studies were "shifted" by 80% to make the fraction of the contaminated samples in the fitted distributions consistent with the fresh soft cheese data.

<sup>2</sup> "Relative cumulative frequency" denotes the proportion of samples with concentrations at or below the level indicated in the "Concentration level (cfu/g)" column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be  $\leq 0.04$  cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.7**

**CONCENTRATION DATA USED BY FDA FOR FRUIT**

<b>Fruit</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Teufel & Bendzulla93	Germany	8	0.04	1
McLauchlin and Gilbert, 1990	UK	289	0.04	0.916955
WNYJWG91abc	UK	43	0.04	0.9767442
			20	1
Heintz, 1999	USA	185	0.04	0.8324324

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

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<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be  $\leq 0.04$  cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.8**

**CONCENTRATION DATA USED BY FDA FOR GOAT AND FETA CHEESE**

<b>Goat and Feta Cheese</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Teufel and Bendzulla, 1993	Germany	74	0.04	0.9459459
			100	0.9864865
			1000	1
Sanchez-Rey <i>et al.</i> , 1993	Spain	15	0.04	0.6666667
Greenwood <i>et al.</i> , 1991	UK	617	0.04	0.9627229
			500	0.9983793
			10000	0.9983793
			100000	1
McLauchlin <i>et al.</i> , 1990	UK	46	0.04	0.4130435
			10	0.8695652
			1.00E+05	0.8695652
			1.00E+06	0.8913043
Oregon State Dept of Agriculture, 1999	USA	79	0.04	1

**NOTE: The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.**

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.9**

**CONCENTRATION DATA USED BY FDA FOR HEAT TREATED  
AND PROCESSED CHEESE**

<b>Heat Treated and Processed Cheese</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Greenwood <i>et al.</i> , 1991	UK	366	0.04	0.989071
			500	1
West and North Yorkshire Joint Working Group, 1991	UK	74	0.04	1
McLauchlin and Gilbert, 1990	UK	137	0.04	1
Pinto and Reali, 1996	UK	29	0.04	0.862069
Oregon State Dept of Agriculture, 1999	USA	60	0.05	1

**NOTE: The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.**

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**  
**TABLE A.10**

**CONCENTRATION DATA USED BY FDA FOR ICE CREAM**

Ice Cream				
Study	Country	Number of Samples Tested	Concentration Level (cfu/g)	Relative Cumulative Frequency <sup>1</sup>
Arnold and Coble, 1995	Australia	166	0.04	0.8614458
Farber <i>et al.</i> , 1989	Canada	496	0.04	0.9939516
Monge <i>et al.</i> , 1994	Costa Rica	50	0.04	0.98
Maifreni <i>et al.</i> , 1993	Germany	396	0.04	1
Teufel and Bendzulla, 1993	Germany	68	0.04	1
Ng and Seah, 1995	Singapore	61	0.04	1
Ciftcioglu <i>et al.</i> , 1992	Turkey	50	0.04	0.9
Greenwood <i>et al.</i> , 1991	UK	150	0.04	0.98
WNYJWG91abc	UK	68	0.04	0.9558824
			20	1
McLauchlin and Gilbert, 1990	UK	274	0.04	0.9379562
Heintz, 1999	USA	294	0.04	0.9183673
IDFA, 1999	USA	19320	0.01	0.9995342
		1744	0.04	0.9822248
Kozak <i>et al.</i> , 1996	USA	1109	0.04	0.9477006

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.11**

**CONCENTRATION DATA USED BY FDA FOR MISCELLANEOUS DAIRY**

<b>Miscellaneous Dairy</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Teufel and Bendzulla, 1993	Germany	116	0.04	0.9568966
		19	100	1
Ng and Seah, 1995	Singapore	160	0.04	1
Greenwood <i>et al.</i> , 1991	UK	268	0.04	0.9738806
			1000	0.9962687
			10000	1
West and North Yorkshire Joint Working Group, 1991	UK	45	0.04	1
McLauchlin and Gilbert, 1990	UK	327	0.04	1
Heintz, 1999	USA	303	0.04	0.9867987
Kozak <i>et al.</i> , 1996	USA	124	0.04	1

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.12**

**CONCENTRATION DATA USED BY FDA FOR PASTEURIZED MILK**

<b>Pasteurized Milk<sup>1</sup></b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>2</sup></b>
Laciar <i>et al.</i> , 1999	Argentina	80	0.04	1
Arnold and Coble, 1995	Australia	33	0.04	1
Greenaway and Drew, 1990	Australia	77	0.04	1
Venables, 1989	Australia	206	0.07	0.9951456
Casarotti <i>et al.</i> , 1994	Brazil	20	0.04	1
Moura <i>et al.</i> , 1993	Brazil	220	0.07	1
Farber <i>et al.</i> , 1989	Canada	14	0.04	1
Mickova, 1991	Czechoslovakia	30	0.07	1
Teufel and Bendzulla, 1993	Germany	443	0.04	0.997743
		41	0.04	0.95122
		41	100	1
Ibrahim <i>et al.</i> , 1992	Hungary	160	0.04	0.95625
Gelosa, 1990	Italy	7	0.04	1
Tiscione <i>et al.</i> , 1994	Italy	50	0.07	1
Beckers <i>et al.</i> , 1988	Netherlands	41	0.04	1
Gilmour and Harvey, 1990	Northern Ireland	95	0.04	0.989474
Rola, 1988	Poland	73	0.04	1
Roy, 1992	Scotland	115	0.04	0.965217
Fernandez Garayzabal <i>et al.</i> , 1986	Spain	28	0.07	0.785714
Ahrabi <i>et al.</i> , 1997	Turkey	20	0.04	0.95
Sharif and Tunail, 1991	Turkey	22	0.04	1
Gohil <i>et al.</i> , 1995	UA Emirates	182	0.04	1

<sup>1</sup>The data from all studies were used to derive a distribution of contamination data for these milk food categories. The distributions were then refit using the US data only and adjusting only the scale parameters (e.g. the mean) to make the distribution consistent with U.S. prevalence data.

<sup>2</sup>“Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.12 (CONT'D)**

**CONCENTRATION DATA USED BY FDA FOR PASTEURIZED MILK**

<b>Pasteurized Milk<sup>3</sup></b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>4</sup></b>
Greenwood <i>et al.</i> , 1991	UK	1039	0.04	0.989413
West and North Yorkshire Joint Working Group, 1991	UK	67	0.04	0.985075
			20	1
McLaughlin and Gilbert, 1990	UK	469	0.04	1
IDFA, 2000	USA	5519	0.04	0.999819
		285	0.04	1
Kozak <i>et al.</i> , 1996	USA	1145	0.07	0.993886

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>3</sup>The data from all studies were used to derive a distribution of contamination data for these milk food categories. The distributions were then refit using the US data only and adjusting only the scale parameters (e.g. the mean) to make the distribution consistent with U.S. prevalence data.

<sup>4</sup>“Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be  $\leq 0.04$  cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.13**

**CONCENTRATION DATA USED BY FDA FOR PATE AND MEAT SPREADS**

<b>Pate and Meat Spreads</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Uyttendaele <i>et al.</i> , 1999	Belgium	462	0.04	0.9588745
			10	0.995671
Anderson & Norrung <sup>95</sup>	Denmark	341	0.04	0.9765396
Lahellec <i>et al.</i> , 1996	France	110	0.04	0.8727273
Morris and Ribeiro, 1989	UK	73	0.04	0.5068493
			20	0.7534247
			100	0.8219178
			1000	0.8767123
			10000	0.9178082
			100000	0.9726027
Nichols <i>et al.</i> , 1998	UK	2834	0.04	0.9738885
			200	0.9940014
			1000	0.9957657
			10000	0.9968243
			1.00E+05	0.9985886
			1.00E+06	0.9989414
McLauchlin <sup>90</sup>	UK	696	0.04	0.8333333
Levine, 2000	USA	513	0.15	0.9707602

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.14**

**CONCENTRATION DATA USED BY FDA FOR PRESERVED FISH**

<b>Preserved Fish</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Anderson and Norrung, 1995	Denmark	335	0.04	0.8955224
			10	0.9492537
			100	0.9820896
Jorgensen and Huss, 1998	Denmark	91	0.04	0.7472527
			10	0.8021978
			100	0.9120879
			1000	0.967033
El-Shenawy and El-Shenawy, 1995	Egypt	11	0.04	0.9090909
Teufel and Bendzulla, 1993	Germany	119	0.04	0.8907563
		186	0.04	0.9946237
			100	1
Hartemink and Georgsson, 1991	Iceland	28	0.04	0.7857143
Fuchs and Surendran, 1989	India	11	0.04	1
Fuchs and Sirvas, 1991	Peru	32	0.04	0.90625
Ericsson <i>et al.</i> , 1997	Sweden	8	0.04	0.375
			100	0.75
			1000	0.875
			1.00E+06	0.875
Loncarevic, 1996	Sweden	58	0.04	0.7931034
Jemmi, 1990	Switzerland	89	0.04	0.741573
McLauchlin and Gilbert, 1990	UK	346	0.04	0.9653179

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.15**

**CONCENTRATION DATA USED BY FDA FOR RAW SEAFOOD**

<b>Raw Seafood</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Degnan <i>et al.</i> , 1994	Australia	4	0.04	0.75
Hofer and Ribeiro, 1990	Brazil	45	0.04	0.9111111
Farber, 1991b	Canada	66	0.04	0.9242424
Anderson and Norrung, 1995	Denmark	232	0.04	0.8577586
			10	0.9698276
			100	0.9956897
El-Shenawy and El-Shenawy, 1995	Egypt	78	0.04	0.8846154
Ravomanana <i>et al.</i> , 1993	France	17	0.04	0.8823529
Teufel and Bendzulla, 1993	Germany	318	0.04	0.9811321
			0.04	0.9649123
		57	100	0.9824561
			10000	1
Hartemink and Georgsson, 1991	Iceland	7	0.04	0.8571429
Fuchs and Surendran, 1989	India	24	0.04	1
Jeyasekaran <i>et al.</i> , 1996	India	65	0.04	0.8615385
Karunasagar <i>et al.</i> , 1992	India	200	0.05	1
Manoj <i>et al.</i> , 1991	India	70	0.04	1
Decastelli <i>et al.</i> , 1993	Italy	285	0.05	1
Iida <i>et al.</i> , 1998	Japan	781	0.04	0.9871959
Masuda <i>et al.</i> , 1992	Japan	613	0.04	0.9820555
Ryu <i>et al.</i> , 1992	Japan	109	0.04	0.9357798
Hudson <i>et al.</i> , 1992	New Zealand	24	0.04	1
Rorvik and Yndestad, 1991	Norway	24	0.04	0.8333333
Ng and Seah, 1995	Singapore	37	0.04	0.9189189
de Simon <i>et al.</i> , 1992	Spain	40	0.04	0.925
Ferrer and de Simon, 1993	Spain	75	0.04	0.9466667

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.15 (CONT'D)**

**CONCENTRATION DATA USED BY FDA FOR RAW SEAFOOD**

<b>Raw Seafood</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>2</sup></b>
Wong <i>et al.</i> , 1990	Taiwan	57	0.04	0.8947368
McLauchlin and Gilbert, 1990	UK	46	0.04	0.6304348
Buchanan <i>et al.</i> , 1989	USA	14	0.04	0.8571429
Draughon <i>et al.</i> , 1999	USA	74	0.04	0.4864865
			20	0.8918919
			100	1
Heintz, 1999	USA	9495	0.05	0.9258557
Kaysner <i>et al.</i> , 1990	USA	35	0.04	1
Motes, 1991	USA	149	0.05	0.9463087
Weagant <i>et al.</i> , 1988	USA	244	0.04	0.8770492
Monfort <i>et al.</i> , 1998		120	0.05	0.9083333
Pullela <i>et al.</i> , 1998		140	0.04	1

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>2</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.16**

**CONCENTRATION DATA USED BY FDA FOR SAUSAGES**

<b>Sausages</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Breer and Schopfer, 1989	Australia	63	0.04	0.9365079
Uyttendaele <i>et al.</i> , 1999	Belgium	308	0.04	0.8409091
			10	0.9577922
Farber <i>et al.</i> , 1989	Canada	30	0.04	0.8
Qvist and Liberski, 1991	Denmark	80 or 79	0.04	0.9
			100	1
			1000	0.9875
			10000	1
Lahellec <i>et al.</i> , 1996	France	161	0.04	0.757764
Teufel and Bendzulla, 1993	Germany	850	0.04	0.9482353
			0.04	0.9289941
		338	100	0.9911243
			10000	1
Trüssel, 1989	Germany	99	0.04	0.959596
			20	1
Cantoni <i>et al.</i> , 1988	Italy?	225	0.04	0.9733333
Levine, 2000	USA	352	0.04	0.9517045
Buncic, 1991	Yugoslavia	21	0.04	0.8095238

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.17**

**CONCENTRATION DATA USED BY FDA FOR SMOKED SEAFOOD**

<b>Smoked Seafood</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Garland, 1995	Australia	285	0.94	0.9964912
Dillon <i>et al.</i> , 1994	Canada	258	0.04	0.9534884
Farber, 1991b	Canada/etc	32	0.94	0.6875
Jorgensen and Huss, 1998	Denmark	420	0.94	0.6119048
			234.42	0.8404762
			2344.23	0.947619
			23442.29	0.9880952
Teufel and Bendzulla, 1993	Germany	71	0.04	0.9295775
		309	0.04	0.9288026
			100	0.97411
			1000	0.987055
Hartemink and Georgsson, 1991	Iceland	31	0.04	0.9677419
Cortesi <i>et al.</i> , 1997	Italy	165	0.94	0.8060606
			7.03	0.8969697
			468.85	0.9818182
			2344.23	0.9818182
			23442.29	0.9878788
			234422.88	1
Hudson <i>et al.</i> , 1992	New Zealand	26	0.04	0.4615385
Guyer and Jemmi, 1990	Switzerland	64	0.94	0.9375
Jemmi, 1990	Switzerland	820	0.04	0.8926829
Eklund <i>et al.</i> , 1995	USA	61	0.94	0.2131148
Heinitz and Johnson 1988	USA	1080	0.94	0.8601852

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.18**

**CONCENTRATION DATA USED BY FDA FOR SOFT RIPENED CHEESE**

<b>Soft Ripened Cheese</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Loncarevic <i>et al.</i> , 1995	Europe	333	0.04	0.9399399
			1000	0.987988
			100	0.984985
			10000	0.996997
			100000	0.996997
			1000000	1
Rodler and Korbler, 1989	Hungary	10	0.04	0.8
Beckers <i>et al.</i> , 1988	Netherlands	69	0.04	0.8550725
			1000	0.8550725
			1000000	1
De Boer and Kuik, 1987	Netherlands	20	0.04	0.9
Breer and Schopfer, 1989	Switzerland	466	0.04	0.9763948
Greenwood <i>et al.</i> , 1991	UK	769	0.04	0.9180754
			500	0.9687906
			1000	0.970091
			10000	0.9908973
			100000	0.9960988
			1000000	1
Pinto and Reali, 1996	UK	58	0.04	0.9482759

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.19**

**CONCENTRATION DATA USED BY FDA FOR UNPASTEURIZED FLUID MILK**

<b>Unpasteurized Fluid Milk</b>				
<b>Study</b>	<b>Country</b>	<b>Number of Samples Tested</b>	<b>Concentration Level (cfu/g)</b>	<b>Relative Cumulative Frequency<sup>1</sup></b>
Davidson <i>et al.</i> , 1989	Canada	256	0.07	0.984375
Farber <i>et al.</i> , 1988	Canada	445	0.07	0.9865169
Fedio and Jackson, 1990	Canada	498	0.07	0.9738956
Donnelly <i>et al.</i> , 1988	USA	939	0.07	0.9840256
Doyle and Schoeni, 1986	USA	50	0.07	1
Liewen and Plautz, 1988	USA	200	0.07	0.96
Lovett <i>et al.</i> , 1987	USA	650	0.07	0.9584615
Lund <i>et al.</i> , 1991	USA	300	0.07	0.97
Patterson <i>et al.</i> , 1989	USA	12	0.07	1
Rohrbach <i>et al.</i> , 1992	USA	292	0.07	0.9589041

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be  $\leq 0.04$  cfu/g.

**APPENDIX A (CONT'D)  
TABLE A.20**

**CONCENTRATION DATA USED BY FDA FOR VEGETABLES**

Vegetables				
Study	Country	Number of Samples Tested	Concentration Level (cfu/g)	Relative Cumulative Frequency <sup>1</sup>
Uyttendaele <i>et al.</i> , 1999	Belgium	201	0.04	0.9253731
			10	0.9900498
Farber <i>et al.</i> 89	Canada	110	0.04	1
Odumeru <i>et al.</i> , 1997	Canada	183	0.05	0.9016393
			116.14	0.9508197
Monge and Arias, 1996	Costa Rica	50	0.04	0.8
Teufel and Bendzulla, 1993	Germany	27	0.04	0.962963
Marranzano <i>et al.</i> , 1996	Italy	83	0.04	0.9518072
Ryu <i>et al.</i> , 1992	Japan	3	0.04	1
Tang <i>et al.</i> , 1994	Malaysia	28	0.04	0.9642857
Beckers <i>et al.</i> , 1988	Netherlands	25	0.04	0.56
			100	1
Salamah, 1993	Saudi Arabia	380	0.04	0.9394737
Ng and Seah, 1995	Singapore	50	0.04	0.96
de Simon <i>et al.</i> , 1992	Spain	103	0.04	0.9223301
Garcia-Gimeno <i>et al.</i> , 1996	Spain	70	0.05	0.7
Breer, 1988	Switzerland	91	0.04	0.967033
Wong <i>et al.</i> , 1990	Taiwan	49	0.04	0.877551
Sizmur and Walker, 1988	UK	60	0.04	0.9333333
Velani and Roberts, 1991	UK	150	0.04	0.9333333
			200	1
WNYJWG91abc	UK	237	0.04	0.9451477
			20	0.9704641
			100	0.9831224
			1000	0.9957806

<sup>1</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX A (CONT'D)**

**TABLE A.20 (CONT'D)**

**CONCENTRATION DATA USED BY FDA FOR VEGETABLES**

Vegetables				
Study	Country	Number of Samples Tested	Concentration Level (cfu/g)	Relative Cumulative Frequency <sup>2</sup>
McLauchlin and Gilbert, 1990	UK	567	0.04	0.8730159
			1000	0.994709
			10000	1
Heintz, 1999	USA	361	0.05	0.9445983
Heisick <i>et al.</i> , 1989	USA	500	0.04	0.956
Lin <i>et al.</i> , 1996	USA	63	0.04	0.984127

**NOTE:** The entries in this table were taken directly from the spreadsheets on the CD-ROM provided by FDA. The FDA spreadsheets sort the data according to concentration; Novigen re-grouped the entries by study.

<sup>2</sup> “Relative cumulative frequency” denotes the proportion of samples with concentrations at or below the level indicated in the “Concentration level (cfu/g)” column. Cumulative frequencies may not total 1.0 in some cases because only presence/absence information is available for these studies (i.e., percent positives). FDA-FSIS assumed all such samples to be ≤ 0.04 cfu/g.

**APPENDIX B**

**NFPA DATA ON *L. m.* CONCENTRATIONS IN DELI MEATS**

**APPENDIX B**

**NFPA DATA ON *L. m.* CONCENTRATIONS IN DELI MEAT**

<u>Number of samples tested</u>	<u>Number of positive samples</u>	<u>Number of samples successfully enumerated</u>
5597	52	26

Concentration (cfu/g)	Number of samples	Cumulative proportion
<0.3	5571 <sup>1</sup>	0.9954
0.36	9	0.9970
0.4	1	0.9971
0.92	1	0.9973
1.5	1	0.9975
2	1	0.9977
2.3	3	0.9982
4.3	1	0.9984
9.3	1	0.9986
14	1	0.9987
21	1	0.9989
60	1	0.9991
150	1	0.9993
200	2	0.9996
650	1	0.9998
1000	1	1
Total	5597	--

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<sup>1</sup> Includes the 5545 (number of samples tested – number of positive samples) negative samples, and the 25 samples that could not be enumerated (number of positive samples – number of enumerated samples).

**APPENDIX C**  
**FRANKFURTER CALCULATIONS VALIDATION**

## APPENDIX C

### FRANKFURTER CALCULATIONS VALIDATION

**TABLE C-1**

**Answers to the question:** “Within the last year, have you or has anyone else in your household ever eaten frankfurters right out of the package, without reheating them?”

<b>Ever consume hot dog without reheating?</b>	<b>Percent</b>
Yes, I have	15%
Yes, someone else in household	11%
No, we always reheat frankfurters	72%
Don't know/refused	1%
<b>Total</b>	<b>100%</b>

**TABLE C-2**

**Answers to the question:** “How often do you or someone else in your household eat frankfurters right out of the package without reheating them? Would you say...”

<b>How often?</b>	<b>Percent<sup>1</sup></b>
100% of the time	3%
75% to 99% of the time	3%
50% to 74% of the time	16%
25% to 49% of the time	14%
10% to 24% of the time	16%
9% or less	48%
Don't know/refused	0%
<b>Total</b>	<b>100%</b>

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<sup>1</sup> Among the 26% (15% + 11%) reporting ever consuming ever raw frankfurters

The data in Tables III-1 and III-2 were combined into the following table by assuming that the percentages in Table III-2 applies to all those (28% = 100%-72%) who did not report that they always reheat their frankfurters:

**TABLE C-3**

**ESTIMATE OF THE PROBABILITY OF CONSUMPTION OF RAW FRANKFURTERS**

How often?	Percent
100% of the time	1%
75% to 99% of the time	1%
50% to 74% of the time	4%
25% to 49% of the time	4%
10% to 24% of the time	4%
9% or less (but more than 0%)	13%
0%	72%
<b>Total</b>	<b>100%</b>

To characterize the distribution of the probability of consuming raw frankfurters, 10,000 random values were drawn from the above distribution. The following figure summarizes the generated distribution. The average of the distribution of the probability of consuming raw frankfurters was 7%.

**Distribution of the probability of consuming a raw hot dog**

