

**Pre-publication draft<sup>1</sup>**

**Achieving Continuous Improvement In Reductions In Foodborne Listeriosis – A Risk Based Approach**

A Report from the ILSI Risk Science Institute Expert Panel on  
*Listeria monocytogenes* in Foods<sup>2</sup>

**SUMMARY**

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### 1.0 Abstract

*Listeria monocytogenes* is a foodborne pathogen that can cause listeriosis, a severe disease whose symptoms include septicemia, meningitis, and spontaneous abortion. Ongoing efforts are needed to further reduce the incidence of listeriosis, due to its high mortality rate. The focus of this report is the use of a risk-based approach to identify strategies that will have the greatest impact on reducing foodborne listeriosis. A continuum of risk is observed in the human population for listeriosis, ranging from exquisitely sensitive groups, who are highly immunocompromised and at very high risk of listeriosis, through the normal healthy population under 65 years of age, who appear to have a minimal risk for listeriosis. In addition, unique subpopulations may exist; for example, pregnant Latina women appear to have a higher risk of listeriosis than pregnant women of other races, most likely due to consumption of contaminated soft cheeses such as queso fresco and queso blanco. Certain foods were described as “high risk” for listeriosis. High-risk foods have all of the following properties: (1) have the potential for contamination with *L. monocytogenes*; (2) support the growth of *L. monocytogenes* to high numbers (3) are ready-to-eat; (4) require refrigeration; and (5) are stored for an extended period of time. Control strategies are needed at all stages from pre-harvest to consumption to minimize the likelihood that food will become contaminated by *L. monocytogenes* and to prevent the growth of the organism to high numbers. Three main strategies were identified by the Expert Panel for ensuring continuous improvement in reducing foodborne listeriosis: (1) preventing contamination of foods with *L. monocytogenes*; (2) preventing growth of *L. monocytogenes* to high numbers in foods; and (3) science-based education messages targeted to susceptible populations and their caregivers. Of these, the Expert Panel concluded that preventing growth of *L. monocytogenes* to high numbers would have the greatest impact in reducing cases of listeriosis. Dose-response models predict that the risk of listeriosis increases as the number of organisms in a food increases and can be used as a scientific basis for a target level, below which the organism should be reduced to minimize the likelihood of listeriosis in high-risk populations. This requires implementation of effective food safety control measures and ensuring that they are consistently met. Most effective strategies to control *L. monocytogenes* in high-risk foods include: (1) Good Manufacturing Practices, sanitation standard operating procedures and HACCP programs, to minimize environmental *L. monocytogenes* contamination and to prevent cross-contamination in processing plants and at retail; (2) an intensive environmental sampling program in processing plants along with an effective corrective action plan to reduce the likelihood of contamination of high risk foods; (3) time and temperature controls throughout the entire distribution and storage period including establishing acceptable storage times of foods that support growth of *L. monocytogenes* to high numbers; (4) reformulating foods to prevent or retard the growth of *L. monocytogenes*, and (5) using post-packaging treatments to destroy *L. monocytogenes* on products. Science-based education and risk communication strategies aimed at susceptible populations and focused on high-risk foods should be delivered through health care providers or other credible sources of information. Exquisitely sensitive consumers may become ill when exposed to low numbers of *L. monocytogenes* or other opportunistic pathogens so reducing the risk to this population could be achieved by maintaining them on restricted low microbial diets during those periods when they are most severely immunocompromised. High-risk individuals (i.e., the elderly, pregnant women and most of the immunocompromised) should be provided with guidance on healthy eating, including specific information on high-risk foods that they should avoid, and strategies to reduce their risk, such as thorough cooking, avoidance of cross-contamination, and short-term refrigerated storage of cooked perishable foods. Those at low risk for listeriosis should receive information on safe food handling practices, preferably starting at a pre-school age.

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## 1.1 Introduction

*Listeria monocytogenes* is a foodborne pathogen that can cause listeriosis, a severe disease, with symptoms including septicemia, meningitis, and spontaneous abortion. *L. monocytogenes* is widespread in the environment and present at low levels in many ready-to-eat foods.

Consumption of contaminated foods is the primary means of human infection. Invasive listeriosis typically occurs in susceptible individuals who have one or more underlying conditions which predispose them to this disease. Susceptible individuals include patients with cancer or undergoing treatment with steroids or cytotoxic drugs; pregnant women or neonates; renal transplant recipients; patients with acquired immunodeficiency syndrome (AIDS); diabetics and the elderly (Gellin and Broome, 1989; Jensen *et al.*, 1994; Goulet and Marchetti, 1996; Slutsker and Schuchat, 1999).

The current level of listeriosis in the USA is estimated to be around 0.27 cases per 100,000 population per year, based on the US FoodNet surveillance data (CDC, 2003). However, the actual level is likely to be higher, due to under-reporting. An under-reporting factor of 2 was applied to estimate the rate of listeriosis in 1996-1997, based on reported cases from FoodNet and comparable sentinel site surveillance, and extrapolated to the 1997 US population, to give an estimated number of cases of listeriosis in the USA of 2,500 per year (Mead, *et al.*, 1999). Using the same methodology and under-reporting factor, the estimated number of cases for 2002 would be 1,550 per year, indicating a decrease in the overall level of foodborne listeriosis by 38% from 1996 to 2002 (CDC, 2003). Nevertheless, ongoing efforts are needed to ensure continuous reductions in the public health impact of this illness, due to its high fatality rate. A risk-based approach was used to identify strategies that will have the greatest impact on reducing foodborne listeriosis. Risk assessment data were used to identify at-risk consumers and high-risk foods. Strategies to prevent contamination of foods by *L. monocytogenes* or prevent growth in those foods that may be contaminated are described in this report. Education and risk communication messages targeted at susceptible populations are also discussed.

## 1.2 Risk Factors for Listeriosis

The key risk factors associated with contracting listeriosis are whether an individual is susceptible to listeriosis, and whether the food consumed is a high risk food.

### 1.2.1 Susceptible populations

Most cases of listeriosis occur among the elderly, pregnant women and immunocompromised individuals. Within these susceptible populations, it is possible to identify sub-populations that are more likely to become severely ill and die than others. The likelihood of severe listeriosis resulting in a fatal outcome has been shown to be dependent on the underlying condition of the individual presenting with the disease (Goulet and Marchetti, 1996; FAO/WHO 2002; Table 1.)

Exquisitely sensitive consumers are highly immunocompromised and include bone marrow transplant patients, those with blood-borne cancers and individuals with full-blown AIDS.

Exquisitely sensitive consumers may become ill when exposed to low numbers of *L. monocytogenes* although the probability appears to be low (Lyytikäinen, *et al.*, 2000; Maijala, *et al.*, 2001.) There is a group at increased risk, who have a higher risk of listeriosis than the healthy population but are less sensitive to *L. monocytogenes* than the exquisitely sensitive populations. This group includes pregnant women, diabetics, those on kidney dialysis, and the elderly with no underlying immunosuppressive conditions (Tables 1 & 2).

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Table 1. Relative susceptibilities for non-pregnant sub-populations, based on the incidences of listeriosis cases (outbreak and sporadic) in these groups in 1992 (FAO/WHO 2002).

<b>Condition</b>	<b>Relative susceptibility</b>
Transplant	2584
Cancer-Blood	1364
AIDS	865
Dialysis	476
Cancer-Pulmonary	229
Cancer-Gastrointestinal and liver	211
Non-cancer liver disease	143
Cancer-Bladder and prostate	112
Cancer-Gynecological	66
Diabetes, insulin dependent	30
Diabetes, non-insulin dependent	25
Alcoholism	19
Over 65 years old	7.5
Less than 65 years, no other condition	1

Table 2. Relative susceptibility for different sub-populations based on the incidences of listeriosis cases (outbreak and sporadic) in these groups (FAO/WHO, 2002).

<b>Condition</b>	<b>Relative susceptibility</b>
Perinatal	14
Elderly (60 years and older)	2.6
General population	1

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In addition, unique subpopulations may exist; for example, epidemiological data show that pregnant Latina women are at increased risk of listeriosis, probably due to consumption of contaminated soft cheeses such as queso fresco, made in non-commercial facilities. Healthy individuals under 65 years of age have a minimal risk of listeriosis. A better understanding of each of these groups will ensure that strategies to prevent listeriosis are appropriately focused. This requires more information on the underlying health status of patients with listeriosis.

### 1.2.2 High-Risk Foods

Certain foods pose an increased risk to consumers of being associated with listeriosis. The ILSI Risk Science Institute Expert Panel defined high-risk foods as those having all of the following properties: (1) have the potential for contamination with *L. monocytogenes*; (2) support the growth of *L. monocytogenes* to high numbers (3) are ready-to-eat; (4) require refrigeration; and (5) are stored for an extended period of time. Figures 1 & 2 show the results of a risk ranking of various foods based on the predicted cases of listeriosis associated with the foods, on a per serving and a per annum basis. On a per serving basis, deli meats, frankfurters (not reheated) and pâté and meat spreads pose a much greater risk (about 1 case of listeriosis per 10<sup>7</sup> servings is predicted) than hard cheeses, cultured milk products and processed cheeses, where the predicted level of illness is approximately 1 case of listeriosis per 10<sup>14</sup> servings.

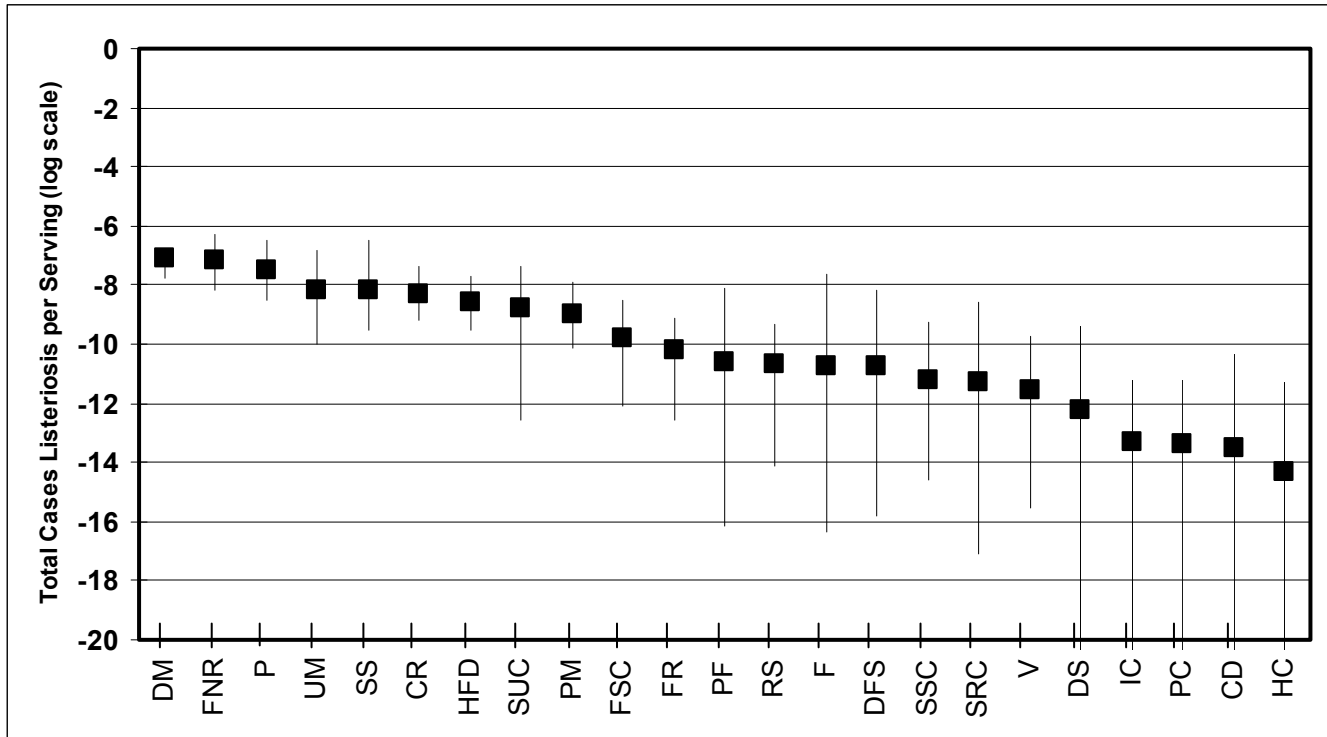
A key difference between high risk foods and low risk foods is the ability of high risk foods to support the growth of *L. monocytogenes* to high numbers. Dose response data predict that as the numbers of *L. monocytogenes* in foods increase, the likelihood of an individual developing listeriosis increases (Figure 3.) A dose-response analysis is undertaken as part of a risk assessment, to characterize the relationship between dose, infectivity and the likelihood and severity of the spectrum of adverse health effects associated with the hazard in an exposed population. A major assumption in dose-response modeling for microbial risk assessment is that a single *L. monocytogenes* cell has a very small but finite probability of causing illness (FAO/WHO, 2002; HHS/USDA, 2003). Dose-response relationships may be determined by human volunteer feeding trials, but for *L. monocytogenes*, such trials are not ethical as listeriosis is a life-threatening disease and trials may not be meaningful if conducted in healthy adults, because healthy adults are not the at-risk population and rarely contract listeriosis. Mice have been used to develop dose-response models for *L. monocytogenes*, but their utility is limited due to the uncertain correlation with the human response to the pathogen. In addition, there is considerable variation among strains of *L. monocytogenes* in their ability to cause disease, and this should be considered when developing dose-response curves. Despite these uncertainties, dose-response relationships have been derived based on studies in animal models and human illness data for both the normal healthy population and for many at risk populations (Buchanan *et al.*, 1997; Chen, *et al.*, 2003; FAO/WHO, 2002; Farber *et al.*, 1996; HHS/USDA, 2003; Lindquist and Westoo, 2000.)

Figure 3 shows a dose-response relationship derived for the neonate population (newborns infected from contaminated foods consumed by their mothers before birth). Information on the variation between strains of *L. monocytogenes* and an initial lethal dose-response model came from mouse studies, but the mortality curve was "adjusted" so that given the human consumption of *L. monocytogenes* the appropriate number of human deaths derived from epidemiological data were estimated. This technique was used because laboratory mice are much more susceptible to listeriosis than humans, so without anchoring to human data, the model would greatly overestimate the level of mortality associated with listeriosis (HHS/USDA, 2003).

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Figure 1. Predicted Cases of Listeriosis (log scale) Associated with Food Categories for the Total United States Population on a per Serving Basis (HHS/USDA 2003.)

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

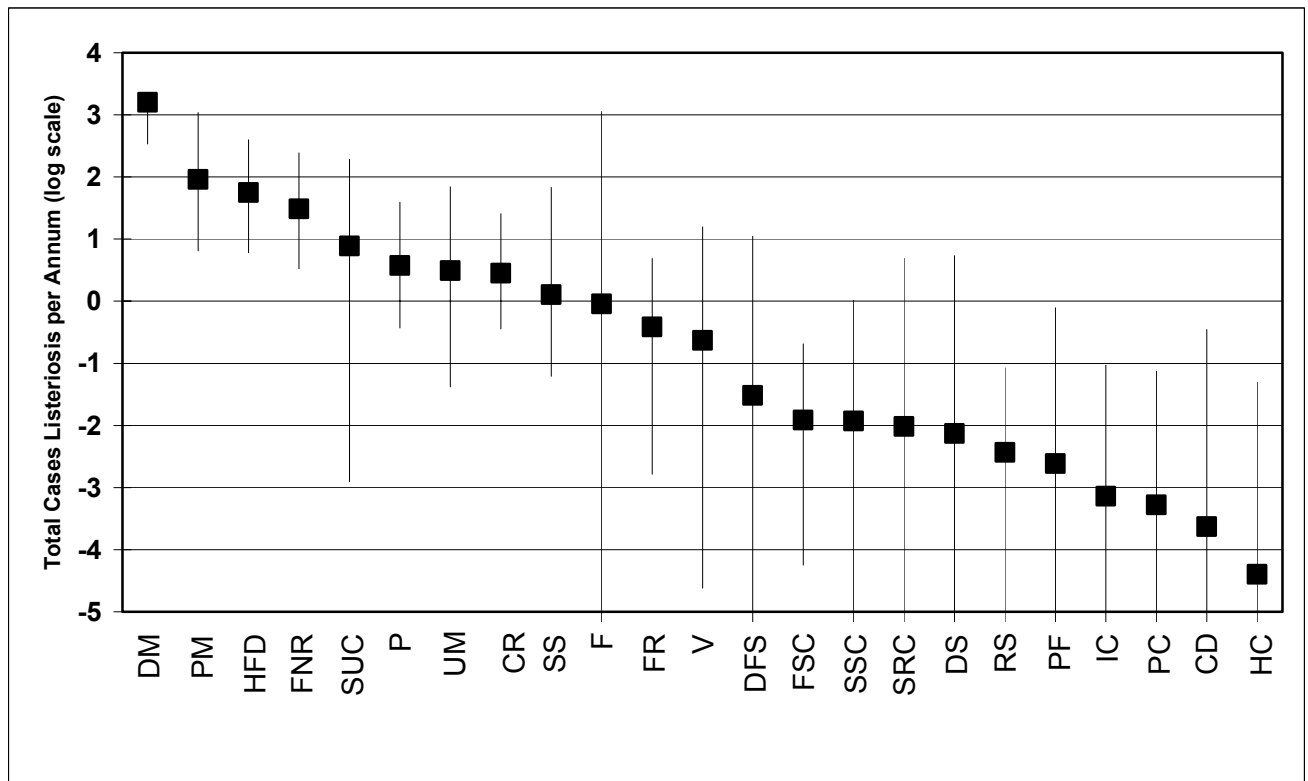


DM = Deli meats; FNR = Frankfurters (not reheated); P= Pâté and Meat Spreads; UM= Unpasteurized Fluid Milk; SS= Smoked Seafood; CR = Cooked Ready-to-eat Crustaceans; HFD = High Fat and Other Dairy Products; SUC = Soft Unripened Cheese; PM = Pasteurized Fluid Milk; FSC = Fresh Soft Cheese; FR = Frankfurters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

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Figure 2. Predicted Cases of Listeriosis (log scale) Associated with Food Categories for the Total United States Population on a per Annum Basis (HHS/USDA 2003.)

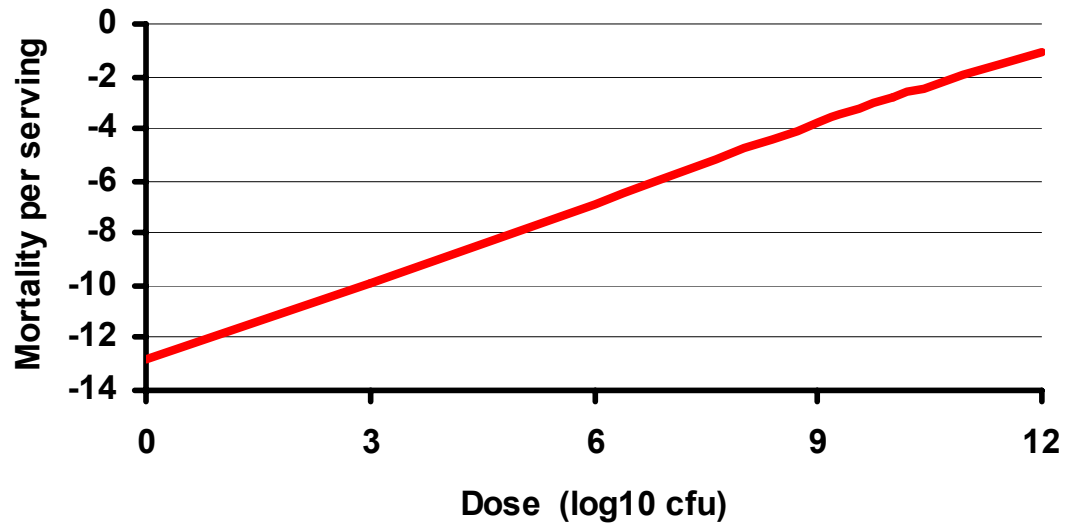
[The box indicates the median predicted number of cases of listeriosis per year in the U.S. (log scale) and the bar indicates the lower and upper bounds (i.e., the 5<sup>th</sup> and 95<sup>th</sup> percentiles. The y-axis values are presented on a log scale. For example a log of -3 is equivalent to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



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

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Figure 3. Dose-response curve for *L. monocytogenes* for neonatal populations showing the probability of mortality for a given dose (HHS/USDA , 2003.)



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The modeling process used population estimates for the numbers of individuals in the group, pathogen consumptions and illness rates to give a curve representing the "average" neonate (and similarly for other human populations) consuming a strain with average virulence. There are uncertainty estimates about this averaged value for the dose-response curve and, when evaluating a specific situation, it should be recognized that the specific strain and other characteristics of the case may not necessarily be "average." In the range of *L. monocytogenes* concentrations that would be consumed in a contaminated serving, the model predicts that a ten-fold increase in the numbers of *L. monocytogenes* consumed will increase the risk of acquiring listeriosis ten-fold. This suggests that preventing the growth of *L. monocytogenes* to high numbers will have considerable impact in reducing the incidence of listeriosis."

For specific foods, lower risk alternatives may be available, for example, fermented semi-dried deli-meats that do not support growth of *L. monocytogenes* (e.g. summer sausage) are of lower risk than cooked uncured turkey which supports prolific growth of *L. monocytogenes*; hard-aged cheeses and processed cheeses do not support growth of *L. monocytogenes* and are of lower risk than queso fresco or brie which do support growth; canned pâté is commercially sterile and therefore poses virtually no risk of listeriosis, unless it is contaminated after the can is opened. Adding inhibitors such as lactate and diacetate to hot dogs to retard the growth of *L. monocytogenes* reduces the risk of illness. Smoked seafood or deli meats may be frozen during storage and transport to reduce the associated risk, as freezing prevents growth of *L. monocytogenes* to high numbers.

### 1.3 Strategies for Reducing the Incidence of Foodborne Listeriosis

Control strategies are needed at certain stages from pre-harvest to consumption (e.g., on the farm, during processing, at retail and foodservice and in the home) to minimize the likelihood that food will become contaminated with *L. monocytogenes*, and to prevent the growth of the organism to high numbers.

Three main strategies were identified by the Expert Panel for ensuring continuous improvement in reducing foodborne listeriosis:

1. Preventing contamination of foods with *L. monocytogenes*;
2. Preventing growth of *L. monocytogenes* to high numbers in foods;
3. Science-based education messages targeted to susceptible populations and their caregivers.

Focusing on all three strategies will be most effective for reducing listeriosis (USDA FSIS, 2003,) but the Expert Panel concluded that preventing growth of *L. monocytogenes* to high numbers will have the greatest impact in reducing cases of listeriosis.

#### 1.3.1 Preventing Contamination

A small percentage of certain ready-to-eat foods are contaminated with *L. monocytogenes*, generally at very low levels (Farber and Peterkin, 1991, 1999; Gombas, *et al.*, 2003; Gram, 2003; Gravani, 1999; Hitchins, 1996; Jorgensen and Huss, 1998; Wallace *et al.*, 2003; Table 3.) Food can be contaminated from a wide variety of sources as *L. monocytogenes* is widely distributed in the environment, in food processing plants, in homes, in agricultural settings and in healthy humans and animals.

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Table 3. Prevalence and contamination levels of *L. monocytogenes* in various ready-to-eat foods sampled at retail in 2000-2001 (Adapted from Gombas *et al.*, 2003)

Product Categories	No. Positive (No. Tested)	Ranges of <i>L. monocytogenes</i> (cfu/g)							
		0.04*-0.1	>0.1-1	>1-10	>10-10 <sup>2</sup>	>10 <sup>2</sup> -10 <sup>3</sup>	>10 <sup>3</sup> -10 <sup>4</sup>	>10 <sup>4</sup> -10 <sup>5</sup>	>10 <sup>5</sup> -10 <sup>6</sup>
Deli Salads	202 (8549)	162	28	9	2	0	1	0	0
Deli Meats	82 (9199)	42	20	10	2	7	1	0	0
Fresh Soft Cheeses	5 (2931)	2	0	0	3	0	0	0	0
Bagged Salads	22 (2966)	17	1	1	2	1	0	0	0
Blue-Veined Cheeses	23 (1623)	18	3	1	1	0	0	0	0
Mold-Ripened Cheeses	14 (1347)	12	0	2	0	0	0	0	0
Seafood Salads	115 (2446)	82	19	10	2	2	0	0	0
Smoked Seafood	114 (2644)	67	11	19	8	6	1	0	2
Total	577 (31700)	402	82	52	20	16	3	0	2

\*Positive in 25 g of a sample.

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Food processors should ensure that staff are trained to understand and use various control strategies such as Good Manufacturing Practices (GMPs), sanitation standard operating procedures (SSOPs) and HACCP to minimize environmental *L. monocytogenes* contamination and to prevent cross-contamination (USDA FSIS, 2003). In many situations, processors can also apply in-package pasteurization to eliminate the pathogen (Clardy, *et al.*, 2002; Murano, *et al.*, 1999; Muriana, *et al.*, 2002; Murphy and Berrang, 2002.) Separation of cooked or ready-to-eat product from raw foods and effective sanitation can minimize the potential for cross contamination in food service, retail and home environments. *L. monocytogenes* may colonize a food processing unit and establish itself in a niche from where it may continuously or intermittently contaminate the food. Finding *L. monocytogenes* in a product – either repeatedly or sporadically – should result in a search for its niche in the processing environment. Such niches can only be detected through sampling and testing. An intensive environmental sampling program is necessary to minimize the potential for environmental contamination with *L. monocytogenes* in foods during processing, along with an effective plan to take corrective action when results indicate environmental controls are out of control. Sampling of product, e.g., during processing, may be appropriate for certain high risk products as part of the plant surveillance and analysis to verify process control. End-product testing is used by regulatory authorities or buyers at port-of-entry when no prior knowledge of the food or process controls used is available. However, as *L. monocytogenes* is typically heterogeneously distributed and at very low levels on contaminated product, most conventional sampling and testing procedures for end product testing will not guarantee detection of the organism, and therefore end product testing cannot be relied upon to ensure the safety of products if subsequent growth can occur.

### 1.3.2 Preventing growth of *Listeria monocytogenes* to high numbers

Consumers appear to be exposed frequently to low levels of *L. monocytogenes* but exposure rarely results in illness, even among highly susceptible populations (Hitchins, 1996; Chen *et al.*, 2003; HHS/USDA 2003). While low numbers of organisms may cause illness in highly susceptible individuals, the HHS/USDA (2003) risk assessment predicts that most cases of illness are associated with foods that contain elevated levels of *L. monocytogenes* (Table 4.) In addition, most outbreaks of listeriosis occurred in foods in which *L. monocytogenes* can grow to high numbers (ICMSF, 2002.) Therefore, the Expert Panel concluded that reducing the number of servings of food containing high numbers of *L. monocytogenes* will have the most significant impact in reducing foodborne listeriosis. This can be achieved by preventing growth of *L. monocytogenes* in contaminated ready-to-eat foods, for example, through time and temperature controls, including freezing, or through reformulating foods such that they retard or do not support growth of *L. monocytogenes* (Bedie *et al.*, 2001; USDA FSIS, 2003; Glass *et al.*, 2002; HHS/USDA, 2003; Islam *et al.*, 2002a,b; Mbandi and Shelef, 2002; Porto, *et al.*, 2002; Samelis, *et al.*, 2002; Seman, *et al.*, 2002.) Prevention strategies can and should be implemented in manufacturing sites, at retail and foodservice, and in the home. Storage temperature is the critical variable in determining the rate of growth; therefore increased efforts are needed to ensure that refrigerators are maintained at an appropriate temperature, both at retail and in the home (HHS/USDA 2003.) The FDA recommends that refrigerated products that support pathogen growth should be maintained at 5°C (41°F) or less (FDA, 2001.)

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Table 4. Estimated relationships between *Listeria monocytogenes* (Lm) dose per serving at the time of consumption and incidence of foodborne listeriosis in the U.S., based on the HHS/USDA (2003) risk assessment\* (Buchanan, 2003)

<b>Level of Lm in food at consumption (cfu/serving)</b>	<b>% servings annually at that level</b>	<b>% cases of listeriosis attributable to that level</b>
0.04	96.37	0.02
0.1	1.90	<0.01
1	0.91	0.01
10	0.43	0.03
100	0.21	0.13
1000	0.10	0.60
10,000	0.05	2.85
100,000	0.02	13.47
1,000,000 or greater	0.01	82.89

\* Note, the dose-response relationship is based on a model which is subject to uncertainty as described in the text.

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### 1.3.2.1 Role of Food Safety Objectives

A food safety objective is the maximum frequency and / or concentration of a hazard in a food at the moment of consumption that still provides the appropriate level of protection (ALOP). The ALOP concept was introduced in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which promotes the use of risk assessment based on objective and accurate scientific data when setting food safety standards. The ALOP is defined as the level of protection deemed appropriate by the member-country establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within a territory. The ALOP is viewed as the degree of risk that a society is willing to tolerate, or accept, and measures what is achievable before “costs” to society become too great. Costs may be human, economic, ethical, medical, legal, etc.

Food safety management systems can be based on meeting a specific public health goal if the degree of stringency of the system is related to the public health goal rather than based on “As Low As Reasonably Achievable” (ALARA). However, a major hurdle to implementing the ALOP concept is that metrics used to articulate public health goals are typically not in a form that can be employed by the food industry or food control agencies to establish the required stringency for food safety systems. The International Commission on Microbiological Specifications for Foods (ICMSF, 2002) has proposed the establishment of Food Safety Objectives (FSO) to provide a link between public health objectives and target points in the supply chain. The FSO provides a “bright line,” below which food may be considered safe for consumption. The establishment of an FSO based on a public health goal requires an understanding of risk characterization curves which relate, via an established dose-response curve, the relationship between exposure and public health outcome for the general and susceptible populations. Once an assessment of risks has been made, a public health goal can, in principle, be articulated. Following this, an FSO can be established with consideration to the dose-response relationship, and other factors (e.g., economic, societal) that the authority establishing the FSO determines appropriate. It is likely that when establishing an FSO for *L. monocytogenes* both the general and susceptible subpopulations will have to be considered. One challenge lies in adequately defining susceptible populations; at the extreme, there may be individuals (e.g., transplant patients immediately after surgery) who are so susceptible to *L. monocytogenes* and opportunistic pathogens that the only protective FSO would be the total exclusion of foodborne exposure to the pathogen until the patients once again have a reasonable level of immune function (Lyytikäinen *et al.*, 2000). In these populations, strict avoidance of foods that pose a high risk of listeriosis may be necessary, and the only practical safety strategy may be the consumption of only commercially-sterile foods.

The public health impact of setting an FSO for *L. monocytogenes* in ready-to-eat foods depends on how effectively industry can meet the FSO. If all foods in the U.S. were contaminated at 0.04 cfu/g or less at the time of consumption, (i.e., the limit of detection that defines the U.S. zero tolerance policy) the estimated number of listeriosis cases would be less than one per year (Table 5). As there were an estimated 2,500 cases per year in the USA in 1997 (Mead, *et al.*, 1999), this number is not being achieved. Table 5 shows the estimated number of cases of listeriosis per year in the USA for foods containing *L. monocytogenes* levels ranging from 0.04 to 1,000 cfu/g (FAO/WHO, 2002.) The model predicts that if levels could be reduced to < 1,000 cfu/g for every serving of food at the time of consumption, (with most servings of foods being <1 cfu/g, as shown in Table 4) the estimated number of illnesses per year in the USA would decrease from 2,500 to 25.4 (Table 5). This would provide a considerable public health benefit. Researchers

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also considered a worst-case scenario, to estimate the number of illnesses that would occur if all servings contained the highest level of *L. monocytogenes* shown in the table, rather than a range of counts, as is typically observed. For example, if all servings contained 10 cfu/g, the model predicts an increase from 2 cases per year to 118 cases per year (Tables 5 & 6). This latter scenario is unrealistic and in countries that have set microbiological standards for *L. monocytogenes* that permit low levels of the organism, no such increase in listeriosis has occurred.

Researchers considered the impact of setting a microbiological criterion of 0.04 cfu/g versus 100 cfu/g (FAO/WHO, 2002.) A what-if scenario was developed, to look at the effect of increasing the proportion of “defective” servings on the predicted number of cases of listeriosis, where a “defective” serving is one that contains  $10^6$  cfu/g *L. monocytogenes* (Table 7.) If a serving was not defective, it had a level of *L. monocytogenes* at or below the specific microbiological criterion (distributed as shown in Table 4.) In this scenario, whether the criterion is set at 0.04 cfu/g or 100 cfu/g appears to have little impact on the public health outcome; in either case, significant reductions in listeriosis is best achieved by reducing the number of servings of foods that contain high numbers of *L. monocytogenes* (Table 7.) Setting a food safety objective and designing strategies for meeting the objective are effective means for reducing foodborne listeriosis, provided that the FSO is met. Implementing effective food safety control measures, which ensure that the FSO is being met consistently, is a key factor for reducing foodborne listeriosis.

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Table 5. Predicted annual number of cases of listeriosis in the USA when the level of *L. monocytogenes* was assumed not to exceed a specified maximum value and the levels of *L. monocytogenes* are assumed to be distributed as shown in Table 4 (adapted from FAO/WHO, 2002).

Range of Lm counts in food at consumption (CFU/g)	Maximum Dose <sup>a</sup> (CFU)	Percentage of servings containing maximum dose <sup>b</sup>	Estimated number of listeriosis cases per year <sup>c</sup>
0.04	1	100	0.5 <sup>d</sup>
0.1	3	3.6	0.5 <sup>d</sup>
1	32	1.7	0.7 <sup>d</sup>
10	316	0.8	1.6
100	3,160	0.4	5.7
1,000	31,600	0.2	25.4

<sup>a</sup>Serving size of 31.6 g

<sup>b</sup>Number of servings in the highest Lm level assumed divided by  $6.41 \times 10^{10}$

<sup>c</sup>Levels of Lm per serving used to calculate predicted number of cases based on the overall distribution from the HHS/USDA 2003 risk assessment. A total of  $6.41 \times 10^{10}$  serving per year was assumed.

<sup>d</sup>Less than one per year.

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Table 6. Estimated number of cases of listeriosis per year in the USA if all servings are contaminated at the highest level shown in the table – this is an unrealistic “worst-case scenario” (Adapted from FAO/WHO, 2002).

Level of Lm in all servings of food at consumption (CFU/g)	Dose <sup>a</sup> (CFU)	Percentage of servings containing maximum dose	Estimated number of listeriosis cases per year <sup>b</sup>
<0.04	1	100	0.54 <sup>c</sup>
0.1	3	100	1
1	32	100	12
10	316	100	118
100	3160	100	1,185
1,000	31,600	100	11,850

<sup>a</sup>Serving size of 31.6 g

<sup>b</sup>A total of  $6.41 \times 10^{10}$  servings per year assumed.

<sup>c</sup>Less than one per year.

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Table 7. Estimated number of cases of listeriosis associated with increasing numbers of servings of foods that contain  $10^6$  cfu/g. The table compares the impact of setting a microbial criterion at 0.04 cfu/g versus 100 cfu/g, and estimates the number of illnesses that will occur if an increasing percentage of servings contain *Listeria monocytogenes* at a level greater than  $10^6$  cfu/g (FAO/WHO, 2002.)

Percentage of servings containing greater than $10^6$ cfu/g Lm	Estimated number of illnesses if criteria is set at 0.04 CFU/g <sup>a</sup>	Estimated number of illnesses if criteria is set at 100 CFU/g
0.00000	0.5 <sup>b</sup>	5.7
0.00001	1.7	6.9
0.00010	12.3	17.4
0.00100	119	124
0.01000	1,185	1,191
0.10000	11,837	11,848
1.00000	117,300	117,363

<sup>a</sup>For the purposes of this scenario, a standard serving size of 31.6 g was assumed. In the case of the 100 cfu/g calculations, the number of servings containing  $10^6$  cfu/g were assumed to be proportionally distributed according to the number of servings within each cell concentration bins.

<sup>b</sup>Less than one per year.

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### 1.4 Education and Risk Communication Strategies

The Expert Panel concluded that further reductions in cases of listeriosis can be realized through improved food handling practices of those who prepare and handle food consumed by at-risk individuals. This may require a change in human behavior. Strategies that address the educational needs of food handlers in both commercial and non-commercial environments may help to achieve the required behavioral changes. The following principles were identified by the Expert Panel:

- Education and communication messages should be science-based, and targeted to susceptible consumers, their health care providers and their food handlers. Messages should focus on high risk foods, with a goal of achieving the desired behavior modification.
- Food processors should provide food that has minimal risk for all consumers. Food handlers in industry need knowledge, understanding, skill and motivation to ensure that post-processing contamination is controlled.
- Food handlers who are preparing and serving food for exquisitely sensitive and high-risk populations (e.g., caregivers in the home, hospital caterers and other food retailers) should have a thorough knowledge and understanding of the food safety issues related to *L. monocytogenes* and of practical strategies to ensure the safety of the food they serve.
- Physicians, nurses, dietitians and other health care professionals should be prepared to provide appropriate food safety advice to susceptible patients and their caregivers to ensure that members of high risk groups have the knowledge, understanding, skill and motivation to ensure the safety of their food.

A key feature of an effective educational strategy is its flexibility. Static messages become obsolete as new research information becomes available, regulatory requirements change, or as new product design and formulations become available. Food handling guidance may change and sometimes this occurs long before messages ever reach the end-user; new and innovative information may never reach them if the venue for information delivery is not effective. A successful educational strategy facilitates effective communication customized for the situation and the audience, maximizes the credibility of the message, and is inherently flexible. A framework was created for use when developing educational strategies and messages, which uses a decision tree approach (Figure 4.) The first decision to consider is whether or not the consumer is susceptible to listeriosis. If so, the next question is whether the food of concern fits our definition of a high-risk food. Further questions concern whether the food has been reformulated or otherwise treated to eliminate *L. monocytogenes* or prevent it from growing to high numbers. The framework provides examples of educational messages that are appropriate for susceptible consumers and indicates where education and training programs can be used at different points in the food chain to reduce the likelihood of illness.

Messages and their delivery should be tested with the target population, as would a marketing strategy. Attention should be given to motivating factors, overcoming barriers to action, benefits of the desired outcome and the physical, social and cultural environment in which the individual exists in their work situation or daily lives. Motivating and ensuring behavior change depends

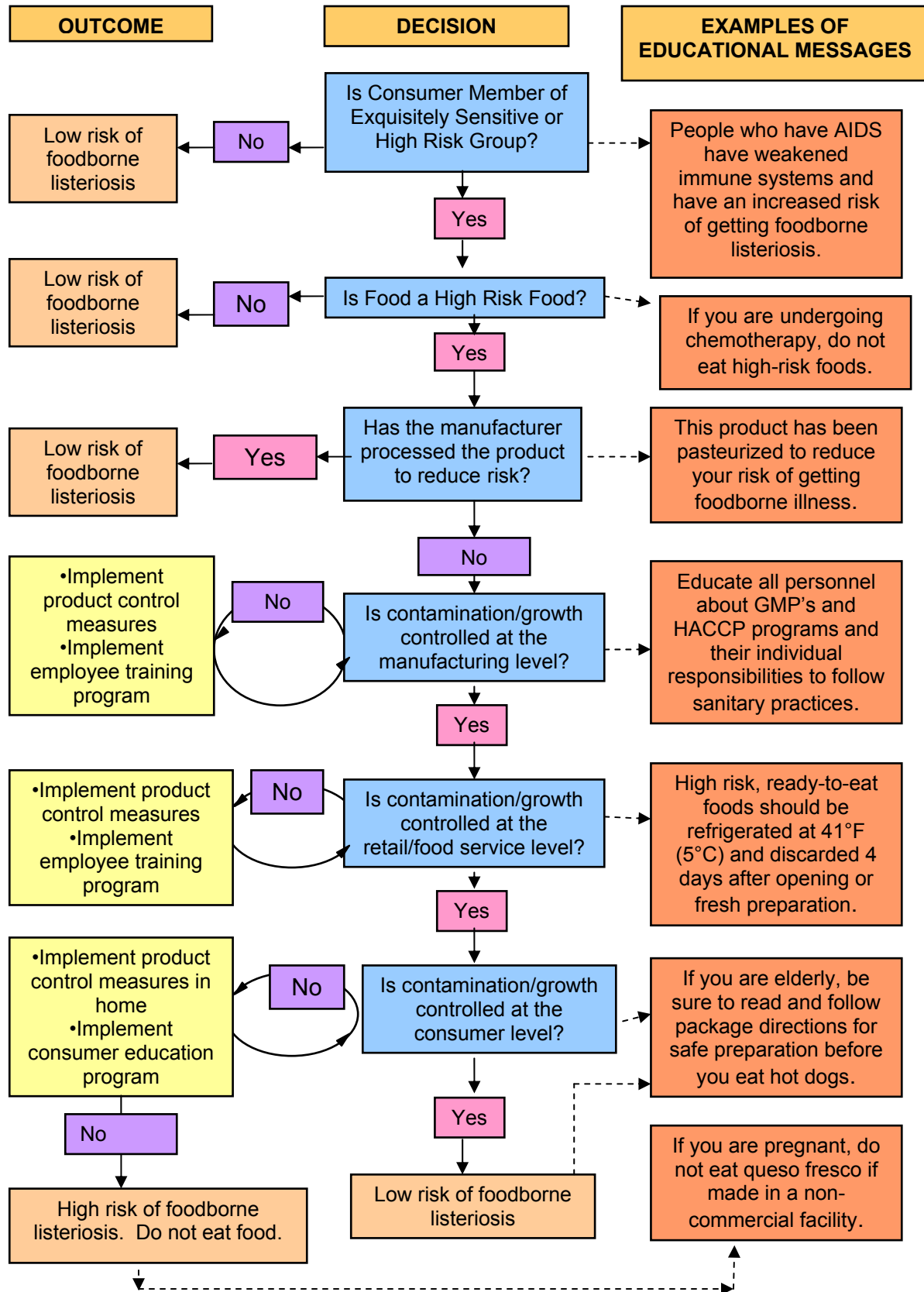
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on whether the individual is transiently susceptible to listeriosis (e.g. pregnant women, bone marrow transplant patients) or if they have lifelong susceptibility (e.g., the elderly and those with immunocompromising syndromes) possibly because maintaining safe food handling practices and avoiding certain foods is easier to do for a finite period of time.

Messages may be most effective when delivered through health care providers or other credible sources of information. For the exquisitely sensitive population, there may be no safe level of *L. monocytogenes*, and reducing the risk to this population can be achieved by maintaining them on restricted low microbial diets during those periods when they are most severely immunocompromised. This will ensure that they are not exposed to harmful or opportunistic pathogens, either of which have the potential to cause illness in highly immunocompromised populations. High-risk individuals (i.e., the elderly, pregnant women and most of the immunocompromised) should be provided with guidance on healthy eating, including specific information on high-risk foods that they should avoid, and strategies to reduce their risk, such as thorough cooking, avoidance of cross-contamination, and short-term refrigerated storage of cooked perishable foods. This group has the most cases of listeriosis, and therefore most intervention efforts should be targeted at these individuals. Specific education strategies for reaching unique subpopulations such as pregnant Latina women are encouraged. Those at low risk for listeriosis should receive information on safe food handling practices, preferably starting at a pre-school age.

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Figure 4. A decision tree for planning food safety education messages for control of *Listeria monocytogenes*.



### 1.5 Recommendations for Reducing the Incidence of Listeriosis

- Key risk factors for listeriosis include:
  1. Being an exquisitely sensitive or high-risk consumer and
  2. Consuming a high risk food
- Exquisitely sensitive consumers (i.e., highly immunocompromised individuals, including bone marrow transplant patients, those with blood-borne cancers and individuals with full-blown AIDS) may become ill when exposed to low numbers of *L. monocytogenes* and therefore should consume medically restricted foods that have been treated to destroy *L. monocytogenes*.
- High-risk individuals (i.e., the elderly, pregnant women and most of the immunocompromised) should be provided with guidance on healthy eating, including specific information on high-risk foods that they should avoid, and strategies to reduce their risk, such as thorough cooking, avoidance of cross-contamination, and short-term refrigerated storage of cooked perishable foods.
- Certain foods pose a high risk of contributing to listeriosis among exquisitely sensitive and high-risk consumers. Resources should be focused on reducing the risk associated with high risk foods, rather than treating all foods as equally risky.
- Efforts to reduce listeriosis should be focused in the manufacturing plant, at retail (both supermarket and foodservice) and in the home. Three main strategies were identified by the Expert Panel for ensuring continuous improvement in reducing foodborne listeriosis:
  1. Preventing contamination of foods with *L. monocytogenes*;
  2. Preventing growth of *L. monocytogenes* to high numbers in foods;
  3. Science-based education messages targeted to susceptible populations.
- Food processors and retailers should ensure that staff are trained to understand and use various control strategies such as Good Manufacturing Practices (GMPs), sanitation standard operating procedures (SSOPs) and HACCP to minimize environmental *L. monocytogenes* contamination and to prevent cross-contamination.
- An intensive environmental sampling program is necessary in certain processing plants to minimize contamination of ready-to-eat foods, along with an effective corrective action plan when results indicate a potential for product contamination. The plants of greatest concern are those that produce foods in which growth of *L. monocytogenes* can occur and a post-processing treatment is not applied.
- Surveillance to determine the prevalence and concentration of *L. monocytogenes* in ready-to-eat foods needs to be continued, targeted to specific high-risk foods that may be a source of high levels of *L. monocytogenes*.

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- The HHS/USDA risk assessment model suggests that most cases of illness are associated with foods that contain elevated levels of *L. monocytogenes*. This model indicates that the greatest impact for reducing listeriosis will be achieved by preventing growth of *L. monocytogenes* to high numbers. This can be achieved through:
  1. Time and temperature controls throughout the entire distribution and appropriate storage period;
  2. Reformulating foods so that they retard or do not support growth;
  3. Post- packaging treatments to eliminate *L. monocytogenes*.
- The human population varies considerably in its susceptibility to listeriosis. Science-based education messages should be targeted towards those most at risk from listeriosis and their caregivers, and should include strategies to avoid exposure to high-risk foods.
- Effective educational strategies should focus on high-risk, ready-to-eat foods known to be sources of *L. monocytogenes*, cleaning and sanitizing, storage and shelf life, and practical information to aid the end-user in selection, purchase, and preparation of foods prepared for or eaten away from home.
- Increased educational efforts are needed to ensure that refrigerators are held at the appropriate temperature, both at retail and in the home. Refrigerated products that support pathogen growth should be maintained at 5°C (41°F) or less. Use of thermometers to verify temperature is encouraged.
- Control strategies, including education materials, should be developed for small and very small processors who may have limited resources to pay for expensive control programs. This could be facilitated through university extension services and trade associations.
- The food safety education process can be enhanced by providing clear food-handling instructions on packaging. For foods that support growth of *L. monocytogenes* to high numbers, it may be useful to have date codes (e.g., use-by dates) that are validated to minimize the likelihood that growth to high numbers will occur within the time stated on the package when stored at 41F /5C.
- Food handlers serving at-risk individuals (e.g., hospital caterers and other food retailers) should have sufficient knowledge and understanding to ensure the safety of the food they prepare and serve.
- Physicians, nurses, dietitians and other health care professionals should be prepared to provide appropriate food safety advice to exquisitely sensitive and high-risk patients.

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### 1.6 Data Gaps and Research Needs

Research is needed to determine how industry can reach a higher rate of compliance with existing criteria. This includes identifying those segments that most need help and providing them with information that will lead to reductions in listeriosis.

More research is needed to better characterize the susceptible populations for listeriosis and to determine their specific risk factors. In addition, a better understanding is needed of why the attack rate for *L. monocytogenes* is low, even among the exquisitely sensitive populations.

Obtaining data from outbreaks on the likely dose consumed by patients will be critical to refining the risk assessment model.

More information is needed on sporadic cases of listeriosis. Are they mini-outbreaks or truly isolated cases? Are sporadic cases largely due to commercial foods? What is the role of the kitchen as a source? Are there harborage sites in home or foodservice kitchens and refrigerators? Can the knowledge gained from environmental testing in processing plants be used to provide guidance for cleaning and sanitizing home and foodservice kitchens?

More information is needed on the role of food service and grocery stores (e.g., deli counters) in transmitting *L. monocytogenes*.

More information is needed on transient and resident strains of *L. monocytogenes*, including their virulence properties, their ecology and whether resident strains possess unique factors that enable their establishment in food processing plants.

Research is needed to differentiate highly virulent from less virulent strains of *L. monocytogenes* and to identify strains that may be avirulent and to develop rapid, economical tests to distinguish strains. This can help target efforts to those strains that pose the greatest risk.

Research is needed to increase the number and variety of approved additives that can be used to control the growth of *L. monocytogenes* in refrigerated ready-to-eat foods. Additional predictive microbial modeling programs need to be validated to provide useful tools for formulation of products that do not support growth.

Additional research is needed to provide additional cost-effective options for preventing contamination and for listericidal treatments of packaged refrigerated ready-to-eat foods.

Continued research efforts are needed to determine whether education messages are resulting in the desired behavior changes.

Additional product – pathway risk assessment efforts are needed to identify the most effective points in the process to reduce exposure and risk.

Improved food consumption data are needed to more clearly characterize consumption and food handling practices for various segments of the population.

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