Chapter 9: Listeria in Raw Milk Soft Cheese: A Case Study of Risk Governance in the United States using the IRGC Framework

Andrew J. Knight, Food Safety Policy Center, Michigan State University, USA

Michelle R. Worosz, Food Safety Policy Center, Michigan State University, USA

Ewen C.D. Todd, Food Safety Policy Center, Michigan State University, USA

Leslie D. Bourquin, Food Science & Human Nutrition and National Food Safety and Toxicology Center, Michigan State University, USA

Craig K. Harris Department of Sociology,; Michigan Agricultural Experiment Station; and National Food Safety and Toxicology Center, Michigan State University, USA

Introduction and Background

Between 1980 and 1996 there were 30 known and reported outbreaks of foodborne illness associated with cheese consumption in the United States, Canada, Europe, and Scandinavia (Cody et al. 1999), and 16 of these outbreaks were associated with cheese produced using unpasteurised milk contaminated with one or more of the following pathogens— *Brucella sp, Escherichia coli, Listeria monocytogenes*, and *Salmonella spp.*, and *Yersinia enterocolitica* (Teuber 2000). In this chapter, we will focus on only one of these pathogens—*Listeria monocytogenes* (*Lm*). Of the above outbreaks, three were caused by *Lm*, which resulted in 284 reported illnesses and 86 deaths (Teuber 2000). Periodic outbreaks of listeriosis from cheese have continued to occur; at least another six *Lm* outbreaks in the U.S., four in Europe, and two in Canada have been associated with cheese consumption since 1996 (de Valk et al. 2005; Food Safety Network 2005; Pagotto et al. 2006; U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition [FDA CFSAN] et al. 2003).

Listeria is a genus of bacteria that includes six separate species that can be found throughout the natural environment, for example, in the feces of mammals, on vegetation, and in silage. The *Lm* strain was first identified in 1926 following an outbreak in rabbits (CFSAN 1992), but has only gained significant interest by the U.S. federal regulatory bodies in the past 20 years (Woteki and Kineman 2003). *Lm* is commonly found in the gastro-intestinal tract of several animal species and humans. It has been found in at least 37 mammal species, 17 species of birds, and both fish and shellfish; and is believed to be present in up to 10 percent of humans (CFSAN 1992). *Lm* is the primary causative agent of listeriosis. Listeriosis can be distinguished as two types: invasive and non-invasive. Invasive listeriosis is the severe form of the disease which typically has a two to three week incubation time, but can extend up to three months. Adverse outcomes can include septicemia, meningitis, encephalitis, abortion or stillbirth, endocarditis, cutaneous infections, and, though rare, it may cause focal infections, such as endophthalmitis, septic arthritis, osteomyelitis, pleural infection, and peritonitis (FDA CFSAN et al. 2003). Non-invasive listeriosis causes gastrointestinal illness, which may result in chills, diarrhea, headache, abdominal pain and cramps, nausea, vomiting, fatigue, and myalgia. The frequency of

contracting non-invasive *Lm* is unknown because most of the cases are not reported to public health officials (FDA CFSAN et al. 2003).

Although contracting listeriosis is relatively rare compared to other foodborne pathogens, it is of concern because of its high fatality rate, which has been estimated as high as 30 percent. Certain vulnerable populations (e.g., neonates, pregnant women, the elderly, and those with compromised immune systems) are particularly at risk of contracting severe cases of listeriosis. Potential food sources for *Lm* include dairy products (e.g., soft cheese), ready-to-eat meat (e.g., hotdogs, delicatessen meats), liquid whole eggs, fish and shellfish, vegetables (predominantly raw vegetables), and salads made with mayonnaise (Economic Research Service [ERS] 2000). According to the International Life Sciences Institute [ILSI] (2004), high-risk foods have five common properties: they have the potential for contamination with *Lm*; they are capable of supporting the growth of high numbers of *Lm*; they are ready-to-eat; they require refrigeration; and they are stored for an extended period of time.

There are several styles of cheese including hard (e.g., parmesan), semi-hard (e.g., cheddar), Frischkäse (e.g., cottage cheese), and soft with red smear (e.g., Münster) (Teuber 2000). We will limit this analysis to those classified as soft, meaning cheeses that have a high moisture content, that are aged for less than 60 days (e.g., Camembert, Brie), and that are made from unpasteurised milk. These types of cheese are produced around the world including, but not limited to European countries (e.g., France and the United Kingdom), and Latin America countries (e.g., Mexico). In the U.S., the production and sale of raw milk soft cheese is illegal because it is considered to be a high food safety risk. Despite this ban, there is still a small market for these varieties; raw milk soft cheese is often produced in the home, purchased in local markets and restaurants, obtained from door-to-vendors, or illegally imported into the U.S.

This chapter serves as a case study of the International Risk Governance (IRGC) risk governance framework (see Chapter 1). The risk governance system for raw milk soft cheese warrants analysis because it raises a number of issues with respect to food safety standards, values, science, cultural sensitivity, and economic development, including international trade. The organization of the chapter follows the framework outlined by IRGC.

Risk Governance Context

In the U.S., the food safety statute of most significance to our discussion is the Federal Food Drug and Cosmetic Act. It grants authority to the U.S. Food and Drug Administration (FDA) to regulate most areas of food safety and foodborne pathogens, including milk and milk products, when those foods and products are considered to be in interstate commerce or in trade with the federal government. Several other agencies are involved in the monitoring and surveillance of foodborne illness, including listeriosis, with the Centers for Disease Control and Prevention (CDC) having the primary role. Each state also has its own laws and regulations governing the production of milk and cheese, and foodborne illness is monitored by state and county health departments. The FDA banned the interstate sale of raw milk in retail packages in 1987. However, at the state level, laws and regulations governing the sale of unpasteurised milk vary because the issue of mandatory pasteurization of milk is controversial. At last count, 28 of the 50 states continue to permit the sale of unpasteurised milk, although some restrict the volume of sales (Headrick et al. 1998).

Current federal regulations governing the use of raw, heat-treated, and pasteurized milk for cheesemaking were promulgated in 1949 (Donnelly 2005). Under these regulations, cheesemakers have two options to meet food safety requirements. First, the standard practice is that milk destined for

cheesemaking is pasteurized. Second, raw milk can be used for cheese manufacture as long as the resulting cheese is held at a temperature of not less than $35^{O}F/1.7^{O}C$ for a minimum of 60 days. Although raw milk is often heat treated at a slightly lower temperature than pasteurization to prevent spoilage, it is still considered to be raw for legal purposes. Aging cheese under the temperature and time conditions above is believed to destroy foodborne pathogens (Teng et al. 2004:580). Since soft and fresh cheeses are aged less than 60 days, they are required under U.S. federal regulations to be made from pasteurized milk.

At the international level, there is currently no agreement on a standard for *Lm*. According to Todd (2007), some countries have a zero tolerance policy for *Lm*, but most others believe "zero" is not only unattainable, but serves as an international trade barrier. The Foods Standards Programme of the Codex Alimentarius Commission is currently charged with developing an international standard for food that protects human health and ensures fair trade (Todd 2007). Under present regulation, raw milk soft cheese cannot be imported into the U.S.

Pre-Assessment

Problem Framing

The overall frame within which we will discuss the management of the hazard of *Lm* in raw milk soft cheese is defined by two alternative principles, illness prevention versus consumer sovereignty (shown in Table 1). This overarching frame is composed of four subframes: standardization versus choice, unsafe versus safe, zero tolerance versus tolerance, and general population versus susceptible populations. The illness prevention principle argues that one of the proper functions of the state is to protect consumers from avoidable harms by insuring that food is as safe as possible. Under this principle, regulations requiring the pasteurization of milk and banning raw milk soft cheese are necessary to protect consumers from high-risk foods that might contain potentially lethal foodborne pathogens. Consumer sovereignty is associated with autonomy or freedom of choice and implies that sufficiently well-informed consumers should have the opportunity to acquire, without excessive transaction costs, whatever goods or services they desire, including fresh raw milk soft cheese. This principle implies, in turn, that producers, distributors, and marketers must have the freedom to respond to this demand, and that consumer demand will determine the market for raw milk soft cheese. It should be noted that this overall framing of the *Lm* management issue is not intended to represent a dichotomy between two opposing extremes. Instead, it is designed to capture the arguments underlying the current regulatory structure and those advocating for change and highlight the underlying issues of governance, science, and values.

Table 1. Management Framework for *Lm* and Raw Milk Cheese.

Illness Prevention	Consumer Sovereignty
§ Standardization	§ Choice
§ Unsafe	§ Safe
§ Zero tolerance	§ Tolerance
§ General population	§ Susceptible populations

Standardization versus choice

The illness prevention principle promotes the standardization of regulations and practices. To protect the public, raw milk soft cheese is banned. The consumer sovereignty principle argues that current regulations are too restrictive and limit choice. Issues like preservation of culture, quality, and economic development underlie this position. In some cases, consumption of raw milk soft cheese is not simply a preference for taste, but is part of a complex collection of culturally based preferences that include notions of family and tradition. It can also be viewed as a method to preserve "traditional" cheese-making methods (Reed and Bruhn 2003).

Most artisan cheese producers in the U.S. use pasteurized milk because they believe it increases safety by decreasing the bacteria and yeast that may spoil the flavor or produce an undesirable gas (Teng et al. 2004:580). Some artisan cheese producers, however, prefer cheese made with unpasteurised milk because they believe pasteurization would mean the extinction of the "best" cheeses. They argue that pasteurizing the milk prior to use decreases the flavor and lengthens the time for ripening (Teng et al. 2004). Moreover, it is believed that the pasteurization of milk results in an increased homogeneity of cheese products.

Quality is an important marketing mechanism for many small and specialty cheese producers. Studies have found that consumers intentionally seek out raw milk soft cheeses because they are perceived to be fresher, more natural, as well as more interesting with respect to both the complexity of their flavor and their story—consumers are interested in the cheese-maker, the farm of origin, and cheesemaking practices (Reed and Bruhn 2003; Teng et al. 2004). Some consumers also express socioeconomic and/or political goals in their purchasing behavior. Rather than supporting a transnational food manufacturer and/or a retail giant (e.g., Kraft and Wal-Mart), they are interested in the origin and process of production (e.g. local, organic, and family owned operations) (Reed and Bruhn 2003). Those favoring the consumer sovereignty principle point out that the pasteurization requirement limits the production and sale of some cheeses; U.S. cheese producers are not allowed to sell their products in other states nor access international markets. Cheese producers in other countries are also unable to sell their products in the U.S.

Unsafe versus safe

Under the illness prevention principle, raw milk soft cheese is unsafe. From a regulatory perspective, the sale of raw milk soft cheese (e.g., Panela, Camembert, Feta, Brie, and blue-veined) is simply too risky (FDA CFSAN et al. 2003). Raw milk soft cheese is considered high-risk, particularly because of the higher risk of contamination from raw milk. Even though outbreaks may be rare, *Lm* in soft cheese made from unpasteurised milk was implicated in at least six outbreaks in the U.S. in 1985, 2000-2001, 2001, 2003, and 2005. It is a public health issue, particularly for the Hispanic population which tends to consume specific types of these cheeses in much higher quantities than the rest of the U.S. population (Shiferaw et al. 2000).

Under the consumer sovereignty principle, the regulation and control of raw soft milk cheese are seen as "*Listeria* Hysteria" (Shaw 2000); the argument is that foodborne illness from raw milk cheese is simply too infrequent to cause concern and to warrant regulation. Reviews of all outbreaks of foodborne illness in the U.S. by Altekruse et al. (1998) identified only 32 cheese-associated outbreaks between 1973 and 1992, and Johnson et al. (1990) identified only six cheese-related outbreaks from 1948-1988. Critics of the current regulations that ban raw milk soft cheese tend to view the risk of foodborne illness from consuming raw milk cheese relative to risk associated with the ingestion of other foods. For example, the highest degree of risk of contracting listeriosis is from consumption of uncooked delicatessen meat and

unheated frankfurters (FDA CFSAN et al. 2003). Some view the risk associated with raw milk cheese as similar to non-food risks like smoking and alcohol, which are not banned but require warning labels; Stein (2001) writes that "we can only hope that [FDA] will decide to put a warning label on all cheese—pasteurized and raw—as it does for alcohol and tobacco, instead of lowering the curtain on that luscious Fourme d'Ambert."

Zero tolerance versus tolerance

Debates within this subframe center around the issues of what are the appropriate levels of food safety and when should the regulatory triggers take effect[1]? The FDA has had a "zero tolerance" policy for *Lm* since the mid 1980s. Thus, the FDA has defined the appropriate level of food safety to be zero tolerance and have set the regulatory trigger at this value. This policy was reaffirmed by a U.S. District Court decision, United States v. Union Cheese Co., in 1995 (Todd 2007:26). On the basis of that decision, *Lm* was defined as an "adulterant," which gave the FDA authority to regulate it. The FDA has specified the zero tolerance standard to be the absence of *Lm* in 25 grams (<1 cfu in 25 g) in the food under consideration. Advocates for tolerance raise questions about whether this zero tolerance standard is realistic and based on science. For instance, Donnelly (1989) points out that that detection limits for *Lm* vary by the detection methodology and because of limitations in detection, these tests may result in a false negative. Thus, advocates of tolerance argue that the regulatory trigger is set too low for the appropriate level of risk.

General population versus susceptible populations

Most people are not at risk of contracting severe listeriosis. However, particular sub-sets of the general population are more susceptible (e.g., pregnant women, neonates, the elderly, and those with compromised immune systems). Because FDA rules prohibit the manufacturing and sale of soft cheese made from raw milk, the questions posed in this subframe are: 1) "Why should raw milk soft cheese be banned if the risk associated with severe listeriosis is high for only a segment of the population, especially if this standard is not applied to other high-risk products like alcohol and tobacco?", and 2) "Should the regulatory trigger be enacted to prevent potential illness to minority vulnerable populations or the majority population who is not high-risk?" The response in the context of the illness prevention principle is that the entire population should be protected; under the consumer sovereignty principle, the response would likely be that the most vulnerable should be accorded the greatest protection and that the ideology of protecting everyone should not be consistently applied to all products.

Monitoring and Early Warning

[1] An appropriate level of food safety refers to acceptability of the risk of human illness. The regulatory trigger is the point at which government sets the regulation and can take action based on this regulation. In this context, there is debate over what is an appropriate level of risk (e.g. could be 0, 100 cfu/g, or even higher depending who is at risk), but the government sets a particular trigger or value (in U.S. 0 cfu/g, Canada and some European countries 100 cfu/g). Thus, the trigger can be below or above what is considered to be an appropriate level of risk. In the case of the U.S., critics of zero tolerance argue that the regulatory trigger is set too low for the appropriate level of risk, at least for majority of the population

Monitoring, surveillance, and enforcement activities are carried out by a combination of state and federal agencies and across several program areas. Listeriosis is one of many infectious diseases that the CDC tracks. When a case is confirmed it is reported to the CDC via the National Notifiable Diseases Surveillance System (NNDSS) (Hopkins et al. 2005). The CDC publishes statistics on all reported and confirmed incidences of listeriosis in the Morbidity and Mortality Weekly Report. The CDC also uses the Foodborne Diseases Active Surveillance Network (FoodNet), which is part of CDC's Emerging Infections Program (EIP), to determine the burden of 10 pathogens (including *Lm*), to monitor trends, to attribute the burden to specific foods, and to assess interventions. Currently, microbiological data are collected from 650 laboratories in ten regions across the U.S., representing approximately 15.3 percent of the total population. The Pulsed-Field Gel Electrophoresis Network (PFGE) (PulseNet) is the CDC's program for DNA "fingerprinting" of certain pathogens, including *Lm*. The intent of this program is to assist epidemiologists by subtyping the pathogen, identifying case clusters, and facilitating source identification.

A *Listeria* surveillance program in the U.S. dairy industry has been in place since the mid 1980s. In response to the 1985 *Lm* outbreak, the FDA established a Dairy Safety Initiative, which was "designed to correlate sample collection of finished product with a physical plant inspection" (Kozak et al. 1996:217). Between April 1986 and September 1988, 1,370 milk plants were inspected and thousands of samples were collected. These inspections found less than three percent of the plants had a finished product that was contaminated with *Lm*, and the contamination level that was found was quite low (i.e., <10 colony forming units per milliliter [cfu/ml]). In 90 percent of the positive samples, the contamination was traced to the production environment (i.e., not to the raw milk itself). As a consequence, the FDA, the States, the National Conference on Interstate Milk Shipments (NCIMS), and the dairy industry created a joint *Listeria* Prevention Program for improving production and handling practices for milk.

Early warning indicators of the potential for listeriosis outbreaks come from both programs that monitor the potential presence of prohibited milk products in the market place (e.g. confiscation of raw milk soft cheese, surveillance of homes, stores, and door-to-door vendors making or selling raw milk soft cheese) and from medical monitoring efforts (e.g., surveillance of illnesses and stool cultures to detect *Lm* outbreaks). The California Department of Food and Agriculture, for example, conducts periodic seizures of illegal cheeses and some of these contain *Lm*. An early warning indicator of a listeriosis outbreak is when two or more persons are reported to a local health agency with symptoms consistent with foodborne diseases and with recent histories of consuming one or more common foods (foods in common?, foods associated with Lm?). After confirmation of diagnosis (i.e., microbiological laboratory test), these cases are reported to the CDC and included in the Morbidity and Mortality Weekly Report. In the case of an outbreak, the affected individuals could be reported through more than one health department.

Institutional Pre-Screening

Once a foodborne disease outbreak is suspected, attempts are made by local health officials to determine its cause (i.e., the pathogen or other hazard that is the etiologic agent) and its source (i.e., the food). Patients suspected of suffering from a foodborne illness are administered a questionnaire by a public health professional. The CDC produced a foodborne outbreak investigation toolkit for public health professionals to help diagnose the causative agent, to administer the questionnaire, and to collect samples. The Bacterial Analytical Manual outlines "standard methodology, and permitted alternative rapid methodologies, to be used by FDA laboratories for detection and isolation of *Listeria monocytogenes"* (Hitchins 2003). If tests are positive for *Lm*, then further tests are conducted to quantify the level of contamination. However, in most instances, because the incubation time of listeriosis can vary from 1 to

90 days, the food item associated with the outbreak is not available for testing. Moreover, non-invasive listeriosis is unlikely to be reported or detected.

Scientific Conventions

The scientific conventions governing input to decisions about management of *Lm* comprise epidemiological testing and outbreak data, as well as risk communication that is geared toward educating both the general and high-risk populations about the risks associated with consuming raw milk soft cheese. Once an outbreak has been acknowledged, risk management strategies involve containment. Occasionally, microbial testing and risk assessments may be conducted to revisit current regulations. When microbial testing showed that pathogens in raw milk cheese could survive more than 60 days, for instance, the FDA conducted a review to consider whether the use of pasteurized milk should be required for all cheeses (Donnelly 2005).

Risk Appraisal

Under the IRGC risk governance framework, risk appraisal comprises two parts: (a) risk assessment which focuses on the "generation of knowledge linking specific risk agents with uncertain but possible consequences" (IRGC 2005) and (b) concern assessment which is the scientific assessment of the concerns or perceptions of relevant stakeholders regarding a particular risk.

Risk assessment

The following section presents an overview of risk assessment of *Lm* in soft cheeses. It is broken down into three sections recommended by the IRGC framework: hazard identification and estimation, exposure and vulnerability assessment, and risk estimation.

Hazard identification and estimation

Three risk assessments of *Lm* in soft cheeses—FDA CFSAN et al. (2003), Bemrah et al. (1998), and Sanaa et al. (2004)—were identified and will be referenced in this report. The FDA CFSAN et al. (2003) risk assessment comprised 23 ready to eat foods, including various soft cheeses, and predicted risks for the U.S. population. Both Bemrah et al. (1998) and Sanaa et al. (2004) focused on risk assessments for France. Bemrah et al.'s (1998) study examined soft cheese made from raw milk, and Sanaa et al. (2004) looked at Camembert and Brie made from raw milk. It should be noted that the assumptions and methods employed in each of these three risk assessments are different and that none of the three addressed raw milk cheese made in the home.

Hazard identification describes the adverse effects of a particular substance, organism or other entity. In addition, the relationship between exposure level (dose) and frequency of illness is evaluated, often by some biological endpoint, like infection, morbidity, or fatality (FDA CFSAN et al. 2003). Three factors affect the dose-response relationship for *Lm* and its adverse outcomes: the environment (i.e., food matrix), pathogen virulence (i.e., the virulence of the particular strain of *Lm*), and the host (i.e., susceptibility of contracting listeriosis and the ability of immune system to respond to a *Lm* infection). In the case of *Lm*, the relationship between dose and likelihood of severity of illness is not well understood. Because *Lm* has a high fatality rate, human trials have not been completed. Instead, dose levels have been calculated using animal, particularly mice, data and/or epidemiological data (Chen et al. 2003). A limitation of animal studies is that the relationship between *Lm* infection in mice and illness in humans is

not well understood, particularly at lower doses, so the FDA CFSAN et al. (2003) risk assessment used mortality as the endpoint..

While contracting a severe case of listeriosis is relatively rare in humans, its consequences are often severe. For instance, U.S. data shows that *Lm* led to higher rates of hospitalization than any other foodborne pathogen and was responsible for over one-third of all reported deaths associated with foodborne pathogens in 2000. The infection rate of *Lm* in the U.S. is estimated to be 3.4 infections per 1,000,000 population, with the overall number of listeriosis cases estimated to be 2,500 per annum (FDA CFSAN et al. 2003). The infection rate in the U.S. is similar to those in other developed countries such as Canada and France (Bemrah et al. 1998).

There are several high-risk groups for contracting listeriosis. Susceptible populations often have immature or compromised immune systems. A precise number of susceptible individuals is difficult to calculate because they include diverse groups such as the elderly, cancer and transplant patients, and persons with immunosuppressive diseases (FDA CFSAN et al. 2003). A further limitation is that since an immunocompromised state is based on qualitative or circumstantial criteria, the criteria may apply to some, but not all members of a particular group. Despite these limitations, high-risk subpopulations can be separated into non-perinatal and perinatal groups. Non-perinatal groups include the elderly (over the age of 60); perinatal groups include pregnant women and neonates.

Most of what is known about the epidemiology of listeriosis has been derived from outbreak data. As mentioned in the introduction, several outbreaks in the U.S. have been associated with raw milk soft cheese. According to FDA CFSAN et al. (2003:23), "Outbreaks due to dairy products were most often the result of raw milk being present in a product such as soft (fresh and mold-ripened) cheese, or from post-pasteurization contamination."

The first outbreak occurred in 1985 when consumption of California-made Jalisco-brand Hispanic soft cheese contaminated with *Lm* serotype 4b was linked to 142 listeriosis cases in Los Angeles County with a mortality rate of 34 percent (Linnan et al. 1988). The total number taken ill in the U.S. was estimated at 300, mainly Hispanics. Factory records indicated that raw milk might have been illegally added to pasteurized milk used in cheese making. The epidemic strain was also widespread in the factory environment, suggesting ample opportunity for post-pasteurization contamination. It was also found that the cheese was kept in cold storage for a period of weeks which, as discussed later, can increase risk of listeriosis by allowing any *Lm* present to multiply (ECHCP 1999).

In a second outbreak in 2001, consumption of a homemade Hispanic soft cheese was directly linked to 12 cases of listeriosis in North Carolina (CDC 2001). All 12 victims—11 women (10 pregnant, one postpartum) and a 70-year-old immunocompromised man—were of Hispanic origin. This outbreak resulted in five stillbirths, three premature deliveries, two infected newborns and two cases of meningitis. Fourteen *Lm* isolates from patients, the implicated cheese, and the dairy supplying the milk all belonged to the same PFGE type (or 'fingerprint'), which confirmed that the source of the outbreak was homemade raw milk cheese sold illegally by street vendors or by several small Hispanic grocery stores.

A third outbreak in 2001 occurred when three pregnant Hispanic women in the state of Washington reported purchasing unlabeled *queso fresco* two from a door-to-door vendor and one through a friend (Stewart 2002). During 2003 and 2004, at least five additional listeriosis cases in pregnant Hispanic women were linked to the purchase of illegal Hispanic soft cheeses from door-to-door street vendors in California (Food Safety Network 2004a), North Carolina (Food Safety Network 2004b), and Texas (Food Safety Network 2003). Also in 2003, 13 cases of listeriosis were reported in the state of Washington with three deaths; risk factors included immunodeficiency, ingestion of soft homemade cheese and traveling in Mexico. In 2005, another outbreak occurred in Texas affecting three Hispanic

pregnant women, two newborns, and one Hispanic elderly woman. While the source was not identified, it was suggested to be unpasteurised soft Hispanic cheese purchased at a flea market (Food Safety Network 2005).

A complication with using epidemiological data from outbreaks to assess dose-response relationships is that the incriminated food is rarely available because of *Lm*'s long incubation period (1 to 90 days) (ECHCP 1999). That is, the original dose received by the affected individuals is often unknown. In foods, *Lm* is usually present in relatively low numbers (<100 cfu/g), and the outbreak and sporadic cases data suggest that high doses are required for infections through food (>100 cfu/g). However, the ECHCP (1999 :7-8) report states that the "possibility of infection from low numbers of *L. monocytogenes* especially among the immunocompromised cannot be discounted." The World Health Organization and the Food and Agriculture Organization of the United Nations [WHO/FAO] (2004) technical report attempted to shed more light on this issue by estimating the annual number of listeriosis cases in the susceptible population in the U.S. with varying dose levels. Table 2 shows that the number of estimated listeriosis cases increases rather substantially with levels greater than 100 cfu/g.

Table 2. Predicted Annual Number of Listeriosis Cases in the Susceptible Population at Different Dose Levels.

Level (cfu/g)	Max. Dose[1] (cfu/g)	% of Servings at Max. Level[2]	# Cases/ Year[3]
0.04	1	100	0.5
0.10	3	3.6	0.5
1.00	32	1.7	0.7
10.00	316	0.8	1.6
100.00	3,160	0.4	5.7
1,000.00	31,600	0.2	25.4

[1] Serving size of 31.6 g.
[2] Number of servings in the highest *L. monocytogenes* level assumed divided by 6.41×10^{10} times 100.
[3] Levels of *L. monocytogenes* per serving used to calculate predicted number of cases based on the overall distribution from the FDA et al. risk assessment (2001). A total of 6.41×10^{10} servings per year was assumed.
Source: WHO/FAO (2004)

Exposure and vulnerability assessment

The risk of *listeriosis* associated with consumption of raw milk products to any given population is a function not just of the virulence of the pathogen itself, but of exposure to the pathogen, where exposure is a function of the quantity of food consumed and the level of contamination in that food. The exposure

assessment component of the risk assessment therefore typically contains data on food consumption, food contamination, pathogen growth, and prevalence of the pathogen.

Food consumption data is often used to determine the quantity of food consumed. In the case of raw milk soft cheese these estimates are rather problematic for various reasons. First, consumption surveys in the U.S. do not collect information on unpasteurised milk; estimates are based on pasteurized milk. Second, cheese portions tend to have a small number of servings, and can be considered snack items rather than meal components, all of which may cause estimates to be less reliable statistically. Third, demographic information delineating consumers who are immunocompromised and the elderly in nursing homes or assisted living outside of the home are not collected in food consumption data, nor do the food consumption data contain a large sample of pregnant women. Fourth, the number of servings is generally reported over a one or two day period, requiring yearly estimates to assume that foods are consumed in the same frequency over the entire year.

The risk assessment estimates for the total number of annual servings of various cheeses consumed by the intermediate-age, perinatal, elderly, and total populations in the U.S. are presented in Table 3. The FDA CFSAN et al. (2003) risk assessment is based on serving sizes of 31 grams (g) for fresh soft cheese, 29 g for soft unripened cheese, and 28 g for soft ripened and semi-soft cheeses. The fresh soft cheese category comprises high moisture (>50%) cheeses such as traditional Hispanic-style soft cheeses (i.e., panela, *queso de crema*, *queso fresco*, and *queso de puna)*. Soft unripened cheeses include high moisture cheeses such as ricotta, cottage, cream, baker, and Neufchatel. Soft ripened cheeses include high moisture cheeses, such as Brie and Camembert, and pickled or white-brined cheeses, like feta and mozzarella. Semi-soft cheeses include cheeses with a moisture content of between 39 and 50 percent such as Blue, Brick, Edam, Gouda, Havarti, Limburger, Monterrey Jack, and Provolone.

Table 3. Estimates of the Total Number of Annual Servings of Cheese Consumed in the United States by Population

Cheese	Intermediate-age	Perinatal	Elderly	Total
Fresh soft	6.9×10^7	4.08×10^5	1.3×10^6	7.1×10^7
Soft unripened	3.4×10^9	2.3×10^7	1.0×10^9	4.4×10^9
Soft ripened	1.7×10^9	1.2×10^7	1.8×10^8	1.9×10^9
Semi-soft	1.6×10^9	1.12×10^7	1.5×10^8	1.8×10^9

Source: FDA CFSAN et al. (2003)

Bemrah et al. (1998) also found that accurate data on individual consumption patterns of raw milk soft cheese were not available, so they used data from the Centre Interprofessionel de Documentation et d'Information Laitières and estimated that the consumption of ripened soft cheeses of any type made from raw milk would be 50 servings of 31 grams per capita per year in France. In addition, they presented three scenarios based on different consumption estimates (10, 20, and 50 servings).

Contamination data can be calculated in two ways. First, qualitative data measure whether a pathogen is present or absent in a particular food. Second, quantitative data enumerate the presence of a pathogen in a particular food, usually expressed as the number of colony forming units (cfu) in a gram. A review of prevalence studies shows that 4.6 percent of soft, mold-ripened cheese samples tested positive

for *Lm* (27 studies)*;* 5.1 percent of raw milk soft, mold-ripened cheese samples tested positive (11 studies); and 25.6 percent of smear-surface cheese tested positive (10 studies). In 23 studies that investigated the prevalence of *Lm* in soft cheese, but type not identified, 2.5 percent tested positive (ILSI 2004). A review for the FDA CFSAN et al. (2003) risk assessment found that 1.4 percent of fresh soft cheese samples tested positive, compared to 3.9 percent of soft unripened cheeses, 3.8 percent of soft ripened cheeses, and 3.1 percent of semi-soft cheeses. It should be noted, however, that these studies may have utilized different levels of detection and that a positive test would not necessarily result in someone developing listeriosis. It simply means that *Lm* was detected at some level.

Several other prevalence studies have been completed that were not captured in the previous review. Genigeorgis et al. (1991b) recovered *Lm* from 2 of 100 Hispanic soft cheeses in California, both of which had a pH >6.2 and were positive for the phosphatase test, indicating that they were likely prepared from raw milk. More recently, Gombas et al. (2003) detected *Lm* in 5 of 2,931 (0.2%) retail Hispanic soft cheeses purchased in Maryland and California at levels as high as 100 cfu/g. Sagoo and Little (2004) tested 8 samples of unripened soft cheeses made from raw or thermized milk from production establishments in the United Kingdom and did not detect any *Listeria*. In addition, 8 samples of ripened soft cheeses tested negative, and of seven semi-hard samples, one tested positive at >199 cfu/g. Sagoo and Little (2004) also tested cheeses made from raw or thermized milk from retail premises. Only 1 sample of 62 tested positive for *Lm* in unripened soft cheese at <100 cfu/g. *Lm* was only detected in 1 percent of the ripened cheese samples (8 of 806) with all 8 being acceptable (<100 cfu/g). Similarly, *Lm* was only detected in less than 1 percent of the semi-hard cheese samples (8 of 943) with only one positive test resulting in an unsatisfactory rating (>100 cfu/g). An FDA study of 57 Mexican personal cheese importations confiscated during a blitz at the Mexican border showed that 68 percent of cheeses were made with raw milk and 8 percent contained *Lm* (FDA/CFSAN/CDCP, 2005)).

The FDA CFSAN et al. (2003) risk assessment assumed that contamination levels at consumption of a given food did not vary significantly from the contamination distributions observed in Western Europe and other developed countries. Similarly, it was assumed that all foods had a similar pattern of contamination and virulence with all *Lm* present having the potential to cause human illness. However, *Lm* is frequently consumed in small amounts by the general population without apparent ill effects. Because previous studies were conducted in the late 1980s and early 1990s, the effect of improved sanitation and other control measures implemented by the food industry since 1993 were not included. For this reason, recent data were given greater weight in the food contamination calculations than older data.

Bemrah et al. (1998) took a different approach in their exposure assessment by estimating the cumulative effect of contamination at various points in the cheese making process (see Figure 1). Using data from a French study on the origin of raw bovine milk contamination by *Lm*, they estimated that the concentration of *Lm* in milk from infected cows and environmental sources before cheese processing to be 0 to 32.68 cfu/ml with a mean of 1.29 and a median of 0.32 cfu/ ml. This model predicted that 67 percent of raw milk would be contaminated with any concentration of *Lm*. However, the contamination was predicted to generally be of low concentration, with only 2.5 percent having a concentration of at least 10 cfu/ml and less than 0.01 percent having a concentration of at least 100 cfu/ml. The simulations in their model predicted that the contamination in 250 g of cheese could range from 0 to 259.6 cfu/g. They estimated that 1.4 percent of 250 g raw milk cheese samples could have a contamination level greater than 100 cfu/g.

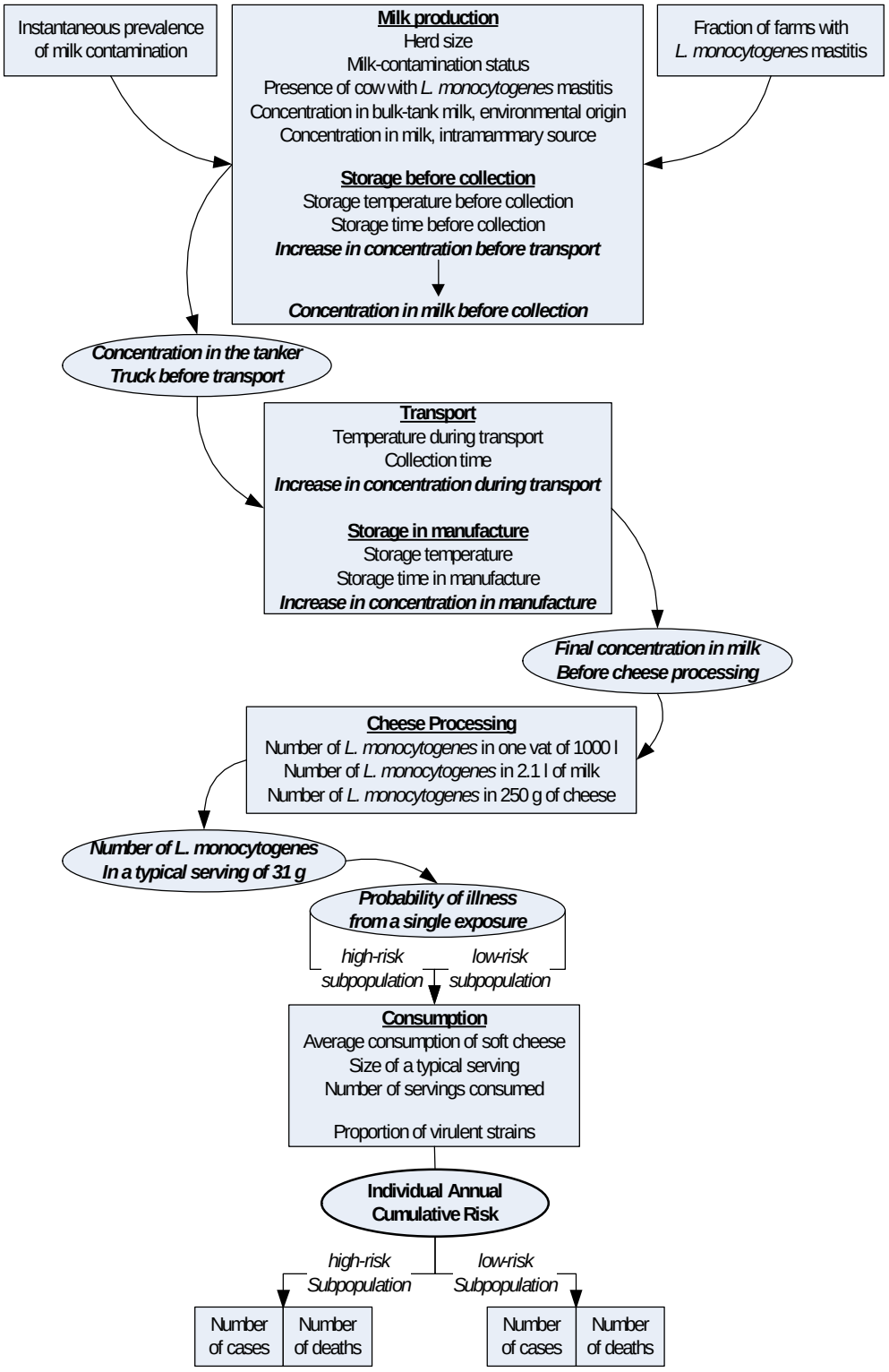

Figure 1. Commodity Chain Risk Assessment for Raw Milk Cheese (Bemrah et al. 1998).

Sanaa et al. (2004) collected actual *Lm* contamination data for milk samples obtained from two regions in France. A 50-ml sample of milk was taken from each bulk tanker that arrived at the dairy and tested for the presence of *Lm* for an entire year. While the contamination level varied for each month, the percentage of positive tests ranged from about 2 percent to about 6 percent for milk tankers at Camembert cheese plants in Normandy, and from 0 to just over 3 percent for milk tankers at Brie cheese plants in Meaux.

Growth data of *Lm* is a function of storage time, storage condition, and rate of growth in specific foods. *Lm* is particularly problematic because it has the ability to survive the manufacturing and ripening of many types of cheeses, and is capable of surviving even after refrigeration, freezing, surface dehydration, and simulated spray-chilling (ECHCP 1999). Growth is highly dependent on temperature, pH, type of food, and presence of microflora (ECHCP 1999). The key factors in determining the exposure of *Lm* are the initial numbers of bacteria present, temperature, and storage time (ECHCP 1999). In the FDA CFSAN et al. (2003) risk assessment, storage times were multiplied by the rate of *Lm* growth to provide an estimate of the level of *Lm* growth that would be expected to occur between retail sale of the food and its consumption. As data did not exist on the storage of foods in the home, storage time estimates were calculated based on expert judgment of the risk assessment team and others such as the Food Marketing Institute and external experts. Storage times for fresh soft cheeses were calculated to be about 1 to 5 days (15 to 30 days maximum storage), and 6-10 days (15-45 days maximum) for other types of soft cheeses. Bemrah et al.'s (1998) risk assessment estimated that the growth of *Lm* in raw milk stored in farm bulk tanks, transported in tanker trucks, and stored again in cheese manufacturers' silos would follow the curves of Peeler and Bunting (1994). They assumed that there was no net growth of *Lm* during the first month after milk curdling, that contamination did not occur during processing and post-processing, and that temperature abuse did not occur at the distribution and consumption stages.

Although Genigeorgis (1991a) reported that *Lm* populations increased over three logs[2] in inoculated retail Hispanic soft cheese during storage at 4 to 30°C, we know little about food handling practices among consumers of Hispanic fresh, soft cheese that may allow temperature abuse and growth of the pathogen in these cheeses. *Lm* can reportedly increase 1.4 logs in *queso blanco* after 14 days of storage at 4°C and attain a maximum population of 7.9 log cfu/g (Glass et al. 1995). Bolton and Frank (1999) applied several probabilistic models to predict the effects of salt, pH, and moisture content on the fate of *Lm* in Hispanic soft cheeses stored for 21 or 42 days at 10°C. They tested a binary logistic regression model to predict the probabilities of growth or no growth (i.e., only two possible outcomes), and an ordinal logistic regression model to predict the probabilities of growth, stasis, or death (i.e., three possible outcomes). By validating their models with independent data, they showed that this approach accurately predicted pathogen behavior in Hispanic soft cheese. Therefore, storage of this type of cheese either at retail or in the home will cause a gradual increase in the *Lm* population if the species is present.

Risk estimation

The risk estimation or risk characterization step of a risk assessment integrates data acquired during the hazard identification and exposure assessment steps to estimate the adverse effects likely to occur in a given population. For foodborne illness, it is often calculated in two ways: risk per serving and/or number of cases per annum. The FDA CFSAN et al. (2003) risk assessment calculated both using the approaches outlined in Figure 2.

[2] Logs are based on 10, meaning the logs increased by 10, i.e. 1 log = 10, 2=100, 3=1000, etc., so 7.9 is close to 100,000,000.

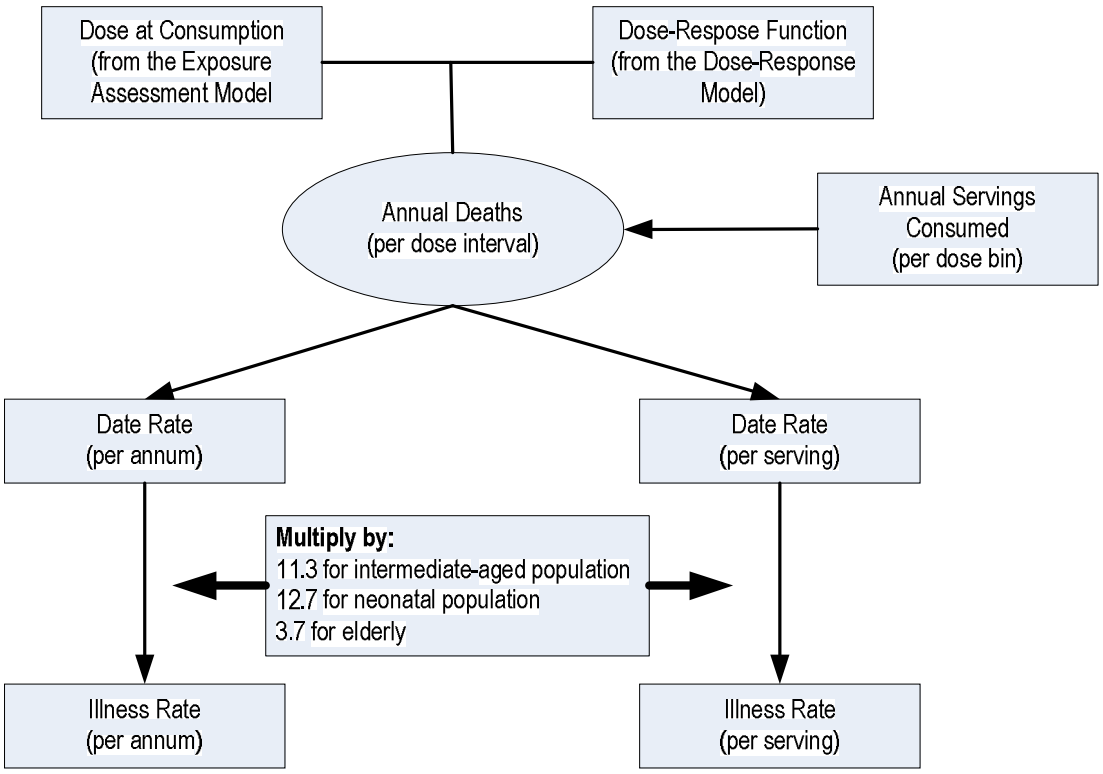

Figure 2. Components of a Risk Characterization Model (FDA CFSAN et al. 2003).

Several limitations of *Lm* risk estimations are mentioned in the FDA CFSAN et al. (2003) risk assessment. First, it is not possible to separate the risk attributable to sporadic and outbreak cases[3]. Second, outbreaks typically result from a breakdown in food production, manufacturing, or distributing systems that result in contamination. The prediction of system failure is usually beyond the scope of risk assessment. The estimated median number of cases of listeriosis per serving and the estimated median number of cases of listeriosis for various soft cheeses in the FDA CFSAN et al. (2003) risk assessment are presented in Table 4.

As demonstrated in Table 4, the risk of contracting listeriosis from cheese is rather low. Out of the 23 ready-to-eat foods assessed by FDA CFSAN et al. (2003), fresh soft cheese ranked 8th on an illness per serving basis, and 5th in the total number of cases it could cause each year in the U.S. While this places fresh soft cheese in the moderate risk category, this standing is based on data derived from cheese purchased at retail stores made with pasteurized milk. In addition to these estimates, FDA CFSAN et al. (2003) also defined a "what-if" scenario to estimate the risk from consuming fresh soft cheese made from unpasteurised milk. This scenario assumed that 50% of queso fresco cheeses would test positive for *Lm*. According to the assessment, "(t)he risk per serving was 43 times greater for the perinatal population and 36 times greater for the elderly population" than the healthy adult population or intermediate aged population (FDA CFSAN et al. 2003:221). These risk estimates are considered high-risk. The percentage of contaminated cheeses would be expected to be substantially higher for soft cheese purchased from door-to-door vendors or from home producers because they would likely be made with raw milk under less sanitary conditions (Gombas et al. 2003). Although most *Lm*-positive fresh cheese servings would be

[3] A sporadic case is defined as a single unrelated case where as an outbreak is a defined as a cluster of cases with a common source.

expected to contain very low levels of *Lm*, a small percentage is predicted to contain more than 10^6 cfu/g, which would be sufficient to cause illness in susceptible populations. Ready-to-eat products of greatest risk to consumers include those that are particularly prone to contamination, support the growth of *Lm*, and are kept refrigerated for long periods of time – particularly at elevated temperatures (e.g., 5-9°C).

Table 4. Estimated Median Number of Cases of Listeriosis Per Serving and Per Annum.

Type of cheese	Intermed. age	Elderly	Perinatal	Total
Median Cases per Serving				
Fresh soft cheese	1.2×10^{-10}	1.0×10^{-9}	4.2×10^{-8}	1.7×10^{-10}
Soft unripened cheese	5.8×10^{-10}	4.9×10^{-9}	2.0×10^{-7}	1.8×10^{-9}
Soft ripened cheese	2.1×10^{-12}	2.2×10^{-11}	1.3×10^{-9}	5.1×10^{-12}
Semi-soft cheese	2.9×10^{-12}	3.0×10^{-11}	1.6×10^{-9}	6.5×10^{-12}
Median cases per Annum				
Fresh soft cheese	<0.1	<0.1	<0.1	<0.1
Soft unripened cheese	2.0	5.1	0.5	7.7
Soft ripened cheese	<0.1	<0.1	<0.1	<0.1
Semi-soft cheese	<0.1	<0.1	<0.1	<0.1

Source: FDA CFSAN et al. (2003)

Bemrah et al.'s (1998) risk assessment predicted the probability of illness associated with one soft cheese serving. The risk ranged from 0 to 3.373×10^{-4} with a median of 1.86×10^{-8} for a high-risk sub-population, and from 0 to 1.96×10^{-8} with a median of 9.74×10^{-13} for a healthy population. In a country of 50 million inhabitants, it was estimated that the mean number of *Lm* annual cases would be 57 and the mean number of annual deaths would be 12. For the low risk healthy population, the estimated number of clinical listeriosis cases would range from zero to four, with zero to three deaths annually. Sanaa et al.'s (2004) risk assessment estimated that the percentage of servings (27 g) containing more than 100 cell/g of *Lm* would be 0.03 percent for Camembert and 0.22 percent for Brie. For 100 million servings, the number of severe listeriosis cases would be 3.46×10^{-3} for Brie and 5.11×10^{-4} for Camembert or less than 0.001 percent of servings for both cheeses combined.

Concern assessment

"It doesn't matter if food is safe if consumers think that it is not."
Brewer, Sprouls and Russon (1994) (p 64)

Regardless of regulations, practices, technology, and assurances that foods are safe to eat, if consumers ultimately do not believe that the foods they eat are safe, those foods are considered unsafe. Previous food safety scares, such as Alar[4] on apples and Mad Cow Disease in Europe, have demonstrated that even if the risk is low, the perception that foods are unsafe may lead to reduced consumption of certain foods, and demands for increased regulation, trade restrictions, or other actions.

Consumer risk perceptions are also important because consumers play a large role in food safety, particularly when dealing with how foods are cooked, handled, prepared, and stored. While contamination of foods may occur at various points in the food chain (e.g., farms, processors, restaurants, and retailers), in the case of *Lm* in cheese, most outbreaks are the result of homemade cheeses. If consumers' perceptions affect their food purchasing and handling practices, understanding these links can be important in both predicting risks and introducing appropriate measures to reduce risk.

Another reason for understanding risk perceptions is the fact that most people who become ill from foodborne diseases do not report their illness to a health care provider or a food safety agency (Mead et al. 1999). Thus, most foodborne illnesses remain undetected and thus not captured in official statistics. In other words, a misperception of the prevalence and risk of foodborne illness can result in under-reporting of cases thereby interrupting a potentially important feedback loop to food safety agencies and consumers. .*Lm*, however, is the most likely foodborne pathogen to be reported because of its severe consequences (Mead et al. 1999).

Risk perceptions

Previous studies have continually shown that consumers have high levels of concern about food safety. In particular, microbial contamination or disease consistently ranks as one of the top food safety concerns (Priest 2000). In comparison to other foodborne pathogens, *Listeria* is not very well known by consumers. For example, only 32 percent of respondents were aware of *Listeria* compared to 94 percent for *Salmonella* and 90 percent for *E. coli* (Lin et al. 2005). Altekruse et al. (1995) reported that only 9.6 percent of respondents were aware of *Listeria* and only 0.4 percent knew of a food vehicle that transmitted *Listeria*. The psychometric risk literature indicates that *Listeria* appears in the quadrant labeled familiar and dreaded (Knight and Warland 2005), where the effects of *Listeria* are somewhat known but its consequences are dreaded.

Concern about food safety risks vary by socio-demographics. A consistent finding in the food safety literature is that females have higher levels of concern about food safety issues than men (e.g. Dittus and Hillers 1996; Knight and Warland 2005; Lin 1995; Williams and Hammitt 2001). The significance of other socio-demographic variables have varied among studies with race, age, education, presence of children, and income sometimes being related to concern about food safety issues. Lin et al. (2005) found that risk perceptions, awareness of other food safety issues, contracting a foodborne illnesses, meal preparer, income, household size, presence of child, education, race, and age were related to awareness of *Listeria*. Respondents who believed that microbial contamination was a serious problem,

[4] Trade name for daminozide, a chemical designed to delay ripening of fruit.

were more likely to be aware of other food safety issues, to have someone in the household who had experienced a foodborne illness, to be the principle meal preparer, to have higher incomes, to have households with more than four persons, to have at least a college degree, and to be black or of a race other than white. Those between the ages of 30-49 had a higher awareness of *Listeria*. Frewer, Shepherd, and Sparks (1994) state that optimistic bias occurs when individuals believe that negative events are more likely to happen to other people than to themselves. This is important considering that respondents typically state that food safety risks are greater for others than themselves.

Anecdotal evidence from U.S. outbreak data and newspaper reports suggests that two groups in particular—Hispanics and "yuppies"—may be at greater risk of contracting listeriosis because their consumption of raw milk and raw milk cheese is higher than that of the general U.S. population. Hispanics, particularly immigrants from Latin America, are disproportionately represented in outbreak data. "Yuppies," or young urban affluent professionals, are also more likely to be consumers of raw milk products, as are members of the organic and natural foods movement. While there are no studies on raw milk soft cheese consumers, studies have been conducted on consumer preferences for specialty cheeses. In a study on consumer preferences among farmer's market consumers, Teng et al. (2004) found that consumers purchased cheese at farmer's markets because of selection (60%), freshness (28%), flavor (28%), price (10%), and origin (2%). These consumers also purchased soft, semi-soft, and hard cheeses about equally. Reed and Bruhn (2003) found that consumers purchased specialty cheeses because of perceived health benefits (94%), they were direct from farm (79%), they were locally produced (76%), they were organically produced (73%), and they were produced using sustainable methods (65%).

In a California consumer survey of specialty food stores, 38 percent of respondents said that they purchased raw milk cheese and did not have any health related concerns, while 45 percent did not know if they had or had not purchased raw milk cheese (Reed and Bruhn 2003). Bell, Hillers, and Thomas (2000) found that 78 percent of Hispanic participants they surveyed believed consuming raw milk *queso fresco* cheese posed a health risk. Despite awareness of the risks, almost half of the participants reported that they made *queso fresco* cheese with raw milk. Even though pasteurized milk *queso fresco* cheese could be purchased in supermarkets, the making of raw milk *queso fresco* has continued at home. In this instance, the desire to continue the tradition of making *queso fresco* at home outweighed the possible risks of becoming ill. Survey data from the same collaborators also found that half of the respondents did not know if the *queso fresco* cheese was made from raw milk, and 40 percent did not believe this cheese could cause illness; an additional 25 percent were unsure (Hillers et al. 2002). Half of the respondents indicated that they purchased or received *queso fresco* from a family member, neighbor, or a door-to-door vendor.

Social concerns

Obvious social concerns surrounding *Lm* and raw milk cheese are illness and outbreaks, and the high mortality rate associated with *Lm*, especially among vulnerable populations. While relatively large outbreaks garner some media attention, the concern demonstrated about raw milk soft cheese by the public and affected parties remains unclear because there is lack of data on this subject. As the sale of raw milk cheese is relatively rare and outbreaks have been largely localized, affecting only particular groups, these outbreaks do not appear to have resulted in widespread "food scares."

Debates surrounding raw milk and raw milk soft cheese have reflected the basic divide between principles of consumer sovereignty and illness prevention. Sovereign consumers believe that they have a right to make or purchase raw milk products regardless of governmental regulations and will probably continue to seek them or make them at home. The debate between consumer sovereignty and illness prevention proposes some interesting questions concerning food safety, the role of the state, values, and

risk in general. For instance, should consumer preferences, such as taste and texture, be taken into consideration when determining food safety policy? Does the public want a zero-tolerance policy? Or is the public willing to assume some risk for particular products? Is unpasteurised cheese relatively safe? Is it safe when made under certain conditions?

Socio-economic impacts

The total estimated economic costs related to all *Lm* contamination problems is $2.3 billion (Frenzen et al. 2000). This estimate includes medical costs, productivity losses from missed work, and the estimated value of lives lost to premature death. The estimate does not include other factors such as travel costs in obtaining medical care, lost leisure time, loss of work to care for sick children, pain and suffering, and the costs of other chronic complications. The proportion of these economic costs that are due to raw milk soft cheese consumption are unknown.

Although current U.S. regulations restricting the sale of raw milk cheeses may reduce the economic costs due to illness, they also have potential economic impacts on farmers. According to the Oldways[5] website the demand for raw milk cheese is increasing. To meet this demand, specialty food stores and farmer markets have increased their selection of cheeses. The website argues that because raw milk cheeses are high-end products, farmers are able to receive a premium price, which aids the sustainability of small farms and cheese producers. As demonstrated in the survey results of Reed and Bruhn (2003), production methods and support for local farmers play a large role in consumer purchase intentions. Thus, the current practice of banning raw milk soft cheese prevents farmers and cheese manufacturers from producing a potentially profitable product.

United States regulations requiring pasteurization also have international trade implications. Currently, European nations and Canada allow the importation and sale of raw milk soft cheese if it is produced under acceptable manufacturing conditions. Cheese producers in these countries are unable to sell their products in the U.S., and U.S. cheese producers are unable to access those international markets which allow the sale of raw milk soft cheese.

Because of its flavor, smell, and texture, raw milk soft cheese is highly valued in many cultures; it is often deeply rooted in cultural and community traditions. The Oldways website claims that cheese has been made with raw milk for 3,000 years. Raw milk soft cheese not only sustained American ancestors, but helped shape the Western diet. While raw milk soft cheese consumers may represent a tiny fraction of the population, they appear to be loyal to these products, and consumption of these cheeses is part of their quality of life. For instance, Hispanic soft cheeses, particularly *queso fresco*, are part of the Hispanic culture, and the making and sharing of raw milk cheese is often a communal event.

5. Tolerability & Acceptability Judgment

A review of the anecdotal and academic literatures suggests that a small minority will seek out raw milk soft cheese regardless of restrictions imposed by the government. Survey data show that people may not be aware of the risks associated with the consumption of raw milk cheese, which makes it difficult to gauge public opinion. Whether the public finds the risk of contracting listeriosis from raw milk soft cheese unacceptable or acceptable remains largely unknown as data on this topic are very sparse. It is probably safe to assume that the most people remain unaware of the safety debate surrounding the consumption of raw milk soft cheese. However, previous research has shown that people

[5] Oldways is a food issues 'Think tank.' Website: http://www.oldwayspt.org/

dread the consequences of listeriosis and, because of that, there is likely to be support for its reduction and/or elimination in foods.

It appears that the public's definition of tolerability and acceptability might depend on risk communication strategies and whether the public believes there is much of a risk from consuming raw milk soft cheese. As the survey data indicate, there is a segment of the population that does not believe that raw milk poses much of a risk. These individuals are likely to find the risks associated with consuming raw milk soft cheese to be at an acceptable level because they believe the risks to be small or similar to those associated with other foods such as fresh fruits and vegetables. In addition, people who believe in consumer choice are also likely to have high levels of acceptability and tolerability. These people might support the consumer's right to purchase raw milk cheese regardless of the risk, even if they may themselves choose not to eat it.

Risk characterization

The risk characterization step compiles scientific evidence based on the risk appraisal phase and contains three components: (a) risk profile, (b) judgment of the seriousness of the risk, and (c) and identification of risk reduction options.

Risk profile

Consumption of unpasteurised milk and milk products is a significant public health concern for Hispanics and "yuppies" in the U.S. In particular, consumption of Mexican-style soft cheese made from unpasteurised milk has been responsible for multiple outbreaks, including outbreaks of multidrug-resistant *Salmonella* Typhimurium DT104 (Cody et al. 1999), and *Lm* (Linnan et al. 1988). An analysis of active surveillance data shows that the incidence of listeriosis among Hispanic females of 15-39 years of age is 11 times higher than non-Hispanic females in this age group (Lay et al. 2002). In addition to Hispanics, populations at high-risk for contracting invasive listeriosis from raw milk soft cheese consumption include pregnant women, neonates, elderly, and people with immunocompromised systems. The WHO/FAO (2004) technical report calculated the relative susceptibility to listeriosis for different populations. Table 5 shows that groups suffering from immune-compromising diseases or treatments have the greatest susceptibility to listeriosis.

Judgment of the seriousness of risk

Risk assessments on contracting invasive listeriosis from consuming raw milk soft cheese are variable. For example, the FDA CFSAN et al. (2003) risk assessment estimated that the risks are high, although this is based on a "what-if" scenario, assuming a large *Lm* contamination prevalence rate. Bemrah et al. (1998) and Sanaa et al. (2004) found the risk to be much lower. However, there are differences in the seriousness of rates for different populations. For the general population, the risk is probably low. On the other hand, for pregnant women, neonates, elderly, and people with immunocompromised systems, the risk is rather high, although there are questions surrounding at what dose *Lm* would make people ill. Survey data collected by the Food Safety Policy Center in 2005 and 2006 illustrate that in the U.S., the public expects the foods they eat to be safe, and that they are dissatisfied with the current number of foodborne illnesses; these data suggest the public might favor more stringent food safety regulations. Hispanics and "yuppies" (sovereign group), however, will likely continue to consume these cheeses regardless of regulations and may be at increased risk of consuming contaminated cheeses that tend to be produced under unsanitary conditions.

Table 5. Relative Susceptibility of Contracting Listeriosis for Different Populations.[a]

Condition	Relative susceptibility
Transplant	2,584.0
Cancer – Blood	1,364.0
AIDS	865.0
Dialysis	476.0
Cancer – Pulmonary	229.0
Cancer – Gastrointestinal and liver	211.0
Non-cancer liver disease	143.0
Cancer – Bladder and prostate	112.0
Cancer – Gynaecological	66.0
Diabetes, insulin dependent	30.0
Diabetes, non-insulin dependent	25.0
Alcoholism	18.0
Perinatal	14.0
Elderly (over 65 years old)	7.5
Less than 65 years, no other condition (reference population)	1.0

Source: WHO/FAO (2004)

a. Relative susceptibility values were calculated by "taking the total number of listeriosis cases for a subpopulation and dividing it by the estimated number of people in the total population that have that condition. This value is then divided by a similar value for the general population" (WHO/FAO 2004: 141).

Several questions have been raised about what causes contamination and where does contamination occur. Dairy safety experts see the problem of cheese contamination as starting with the cow, as cows carry a number of bacteria including *Lm*, which they acquire "naturally" from their environment—grazing and pasturing. Therefore, dairy safety experts believe the use of raw milk poses a high-risk of contamination in cheesemaking, and needs to be prevented because the end-product has a high likelihood of *Lm* contamination solely because of the use of raw milk. Thus, pasteurization is the

only method assured of eliminating foodborne pathogens in the resulting soft cheeses. Soft cheeses are considered to be a particular food safety risk because they are favorable to pathogen growth due to their higher "water activity" and pH (Teng et al. 2004). Furthermore, recent evidence suggests that *Lm* and other foodborne pathogens can even survive beyond the 60 days of aging incorporated into regulations (Donnelly 2001).

Published reviews of illness outbreaks associated with cheese consumption (Altekruse et al. 1998; Donnelly 2001; Johnson et al. 1990) show, on the other hand, that the presence of pathogens is most often due to environmental contamination, such as unsanitary practices at the farm or pasteurization or post-pasteurization errors during manufacturing. Donnelly (2001:16) concluded that "in the majority of instances, confounding parameters other than use of raw milk contributed to pathogens being present in the product at the time of consumption." Some of these confounding parameters include use of pasteurized milk versus raw milk in cheesemaking trials; inadequate development of acidity during cheesemaking; low salt levels; contamination by sick employees during manufacturing; temperature abuse of milk designated for cheese production; or environmental contamination during cheesemaking. Fletcher (2006), in an article analyzing the myths surrounding raw milk and raw milk cheese, also points out that outbreaks are most commonly associated with improper pasteurization, contamination after pasteurization, or cheeses prepared under non-commercial conditions. She states that the risk of contracting *Lm* from raw cheeses aged at least 60 days at 35 degrees Fahrenheit or above, as described by law, is minute even for pregnant women, and it would make more sense for pregnant women to avoid higher risk foods such as fruits, vegetables, and deli meats.

The risk reduction strategy that follows from this second argument is one that focuses on the safety of the processes in which raw milk is used, rather than on prevention of the use of raw milk. This view holds that the safety of raw milk cheese and cheese in general can be achieved by using proper milk screening procedures, following good manufacturing practices (GMP), and following Hazard Analysis and Critical Control Point (HACCP) procedures. France is an example of a country that allows raw milk soft cheese to be produced and sold, but has been able to reduce the incidence of invasive listeriosis through improved milking hygiene, rapid detection and elimination of cows excreting *Lm*, and requiring farms that produce milk to adopt the highest level of hygiene (Sanaa et al. 2004). Critics of pasteurization also point out that there is no compelling data to indicate that mandatory pasteurization will lead to a safer product (Donnelly 2001:24). Proponents of raw milk cheese also argue that these cheeses pose little risk of contamination in comparison to other foods. While recognizing that soft and semi-soft cheeses made from unpasteurised milk do pose potentially greater risks than hard cheeses aged for 60 days, Donnelly (2005) states that environmental contamination poses a far greater risk to cheese safety.

Conclusions & risk reduction options

Based on the information gathered for this analysis, five risk reduction options have been identified and are presented in Table 6. Option 1, banning the retail sale of soft cheese made from raw milk cheese that is aged less than 60 days, is the current U.S. regulation. The advantage of this option is that it prevents the manufacture and sale of potentially harmful products and reduces the likelihood of *Lm* outbreaks from raw milk soft cheese. The risk and concern assessments, however, show disaffection with the current regulation. From a food safety perspective, the regulation is not entirely effective: outbreaks, though rare, still occur, especially with raw milk soft cheeses made in the home or bought from door-to-door vendors. From a socio-economic perspective, the regulation limits economic development; even though there is likely to be consumer demand for these products, they cannot be produced or sold legally and costs are incurred as border agents and public officials seize these products. From a cultural perspective, the regulation interferes with traditional social practices associated with the making and distribution of raw milk soft cheese.

Option 2, allowing the retail sale of specific raw milk soft cheese commodities, is similar to the first option except rather than banning all varieties of raw milk cheeses, it allows the retail sale of particular varieties that are deemed to be low risk through a review of existing manufacturing practices, regulations, and microbial testing. Under this option, specific varieties of raw milk soft cheese that are deemed to be low risk may be imported into the U.S. for retail sale, perhaps can be produced domestically under certain conditions. Risk assessments have shown that Camembert and Brie would both be low risk, with Camembert being a lower risk than Brie (Sanaa et al. 2004). However, Hispanic or Mexican-style soft cheese may be a higher risk (Gombas et al. 2003). Advantages of this option are that it would allow consumers to purchase some varieties of raw milk soft cheese; it might allow domestic production of particular varieties of raw milk soft cheeses under certain conditions; and it would be more consistent with regulations in other countries. This option is consistent, for example, with the Australian and New Zealand position on French Roquefort cheese, which is considered safe after storage for 90 days before sale, even though it is made using raw milk. At the same time, this option provides a scientific level of food safety and protects the public from the manufacture and sale of high-risk products. However, raw milk soft cheese varieties deemed to be low risk may not coincide with the preferences of particular groups, and may not eliminate the desire for particularly high-risk varieties.

Option 3 requires the use of warning labels. This option offers several potential advantages: it allows consumers to make informed choices; it could contain or reduce the number of outbreaks by making illegal cheese products less prominent; and it could allow contaminated cheeses to be identified through microbial testing and recalled. In an event of an outbreak, the source of contamination could be more easily traced back to its origin. This option may also result in increased economic opportunities for cheese producers and the preservation of social cultures engaged in the making of traditional cheeses. However, it may carry potential public health costs, since raw milk soft cheeses would be accessible to the general population, including high-risk groups. Producers would have to assume at least some of the costs associated with labeling, and increased competition from larger producers might drive smaller local cheesemakers out of business. Finally, additional public costs would be incurred by the enforcement of labeling laws and the inspection of imported cheese.

Option 4 involves changing the *Lm* tolerance standards. The most frequent alternative to a zero tolerance policy (defined as <1 cfu in 25 g of food (cfu/g)) is <100 cfu/g. Chen et al. (2003) argue that foods containing low levels of *Lm* (<100 cfu/g) pose very little risk, since prevention of higher concentrations would eliminate >99% of listeriosis cases. Thus, control efforts should focus on reduction of higher concentrations of *Lm* in ready-to-eat foods. This same argument can be derived from the FAO/WHO (2003) risk assessment, which showed that it is the increase in contaminated servings that drive the number of cases up, not the tolerance level. The question then becomes: at what point in time does raw milk soft cheese becomes a high-risk product? Since a tolerance level can only be set at production or retail, any actions by the consumer may increase the risk. In the case of soft cheese, it supports growth of *Lm* even when stored at refrigeration temperatures over time, and no practical method exists for decontaminating it before it is eaten. Thus, any concentration of *Lm* in soft cheese at purchase could result in *Lm* levels that could increase the risk of illness.

Countries such as Germany, the Netherlands, and France, have adopted the higher tolerance level for a number of years and they have about the same frequency of listeriosis per capita as the U.S. Canada and the European Union have a mixed tolerance standard where some foods are subjected to zero tolerance and others to a <100 cfu/g standard (Todd 2007). Since January 2006, the European Union has promulgated a new standard for all member states. This standard requires zero tolerance in ready-to-eat foods prepared for infants and for special medical purposes. For other foods, the zero tolerance standard applies before the food has left the immediate control of the food producer or manufacturer, is the higher tolerance standard, <100 cfu/g, must be met at purchase (European Union 2005). The advantages of this

option are that it allows consumers to purchase raw milk soft cheese, and it is consistent with the regulations of other countries, while at the same time providing a science based level of food safety.

Option 5 would require the implementation of HACCP programs. This option as several possible advantages: it allows consumer choice, may increase public safety by reducing the potential for contamination, and might reduce the production, importation, and sale of illegally produced cheeses. Other benefits include an increased ability to identify where contamination occurred, facilitation of the recall of contaminated cheeses, increased economic development opportunities, and the preservation of traditional cheesemaking cultures. The potential limitations of this risk reduction option are that cheeses produced under these procedures would be available to the entire population, including high-risk populations, substantial costs might be incurred by dairy producers and cheesemakers to comply with HACCP requirements, and the government would have to inspect and enforce these standards throughout the product chain. A sixth option in which raw milk soft cheese would not be regulated was not presented because it is not a risk reduction strategy and this option has not been advocated by either proponents or opponents of current regulations regarding raw milk soft cheese.

Risk evaluation

The risk evaluation assesses broader value-based issues that also influence the judgment. It comprises two parts: (a) judging the tolerability and acceptability of risks, and (b) the need for risk reduction measures.

Judging the tolerability and acceptability

The U.S. has adopted a zero tolerance policy, which requires the absence (< 1 cfu in 25 g) of *Lm* in 25 grams of foods. Risk assessments suggest that this stringent tolerance level may be unnecessary and could be substituted with a limit of <100 cfu/g at consumption. Outbreak data suggest that outbreaks of *Lm* in raw milk cheese have occurred because the milk used in production derived from animals that were infected (e.g., had mastitis, or were asymptomatic carriers) or was stored under unsanitary or improper storage conditions, and not because of the use of raw milk *per se*. These suggest that proper practices surrounding the production of cheese, rather than prohibition of raw milk might reduce this risk.

Table 6. Options for Risk Reduction

Option	Possible Advantages	Possible Disadvantages
1. Ban the retail sale of all raw milk soft cheese (RMSC) (aged <60 days)	§ Limits exposure to RMSC and consumption of potentially harmful product especially by vulnerable groups § Reduces the likelihood of outbreaks associated with raw milk and RMSC in the future § Lower costs associated with care and treatment of listeriosis	§ Loss of traditional cheese making culture § Does not affect levels of current "illegal" production in homes or importation of RMSC § May result in traditional local sales (i.e. to friends and neighbors) being pushed further underground § Consumers of illegal RMSC at risk because milk and cheese are not subjected to microbiological sampling § Does not allow consumers of RMSC to make informed choice about risk § Costs of enforcement (inspections and seizures)
2. Allow the retail sale of commodity specific RMSC (aged <60 days)	§ Limits exposure to some RMSC and consumption of potentially harmful product especially by vulnerable groups § Reduces the likelihood of outbreaks associated with some raw milk and RMSC in the future § May lower costs associated with care and treatment of listeriosis § May reduce illegal importation of RMSC § Allows some microbiological testing § Legal unsafe products can be recalled § Can trace legal contaminated products to source § Increases selection of cheeses available for purchase § May increase economic development as RMSC producers could sell their products across	§ May result in loss of traditional cheese making culture § May not affect levels of current "illegal" production in homes or importation of RMSC § May result in traditional local sales (i.e. to friends and neighbors) being pushed further underground § Consumers of illegal RMSC at risk because milk and cheese are not subjected to microbiological sampling § Does not allow consumers of RMSC to make informed choice about risk § Costs of enforcement (inspections and seizures) § If outbreaks occur, FDA may be blamed for allowing unsafe products on the market

Option	Possible Advantages	Possible Disadvantages
	states and on international markets	
3. Warning labels required for RMSC	§ Allows customers to make an informed choice about whether to consume RMSC or not § May reduce incidence of foodborne illness among high-risk populations § May reduce RMSC production in homes as cheese can be purchased in retail outlets § May reduce illegal importation of RMSC § Allows microbiological testing § Unsafe products can be recalled § Can trace contaminated products to source § Increases selection of cheeses available for purchase § May increase economic development as RMSC producers could sell their products across states and on international markets § Preservation of traditional culture	§ Limited public health benefits – will not prevent anyone consuming RMSC, potentially increasing risk of foodborne illness § Some cost to producers in implementing new labeling requirement § May heighten competition leaving local producers unable to compete § Enforcement of labeling laws and inspection of imported RMSC § If outbreaks occur, FDA may be blamed for allowing unsafe products on the market § Costs of enforcement (inspections and seizures) § Costs of microbial testing § Consumers may not notice label or take action based on label
4. Change in tolerance levels	§ Scientifically based tolerance level § Allows customers to make an informed choice about whether to consume RMSC or not § Consistent with some countries, enabling trade § May reduce RMSC production in homes as cheese can be purchased in retail outlets § May reduce illegal importation of RMSC § Allows microbiological testing § Unsafe products can be recalled § Can trace contaminated products to source § Increases selection of cheeses	§ Limited public health benefits – will not prevent anyone from consuming RMSC, potentially increasing risk of foodborne illness § May heighten competition leaving local producers unable to compete § Costs of enforcement (inspections and seizures)

Option	Possible Advantages	Possible Disadvantages
	available for purchase § May increase economic development as RMSC producers could sell their products across states and on international markets § Preservation of traditional culture	
5.Implementation of HACCP and/or best management practices	§ Allows consumer choice § May increase public health protection by reducing pre- and post-contamination § May reduce RMSC production in homes as cheese can be purchased in retail outlets § May reduce illegal importation of RMSC § Increases economic development of raw milk farmers and artisan cheesemakers by creating new markets § Allows microbiological sampling § Unsafe products can be recalled § Can trace contaminated products to source § Increase selection of cheeses available for purchase § May increase economic development as RMSC producers could sell their products across states and on international markets (open new markets) § Preservation of traditional culture	§ Limited public health benefits – will not prevent anyone consuming RMSC, potentially increasing risk § Cost to producers in implementing HACCP § May heighten competition leaving local producers unable to compete § Inspection and enforcement of farms, transport vehicles, production facilities, and retail stores § Inspection of imported cheese

RMSC: Raw milk soft cheese.
HACCP: Hazard Analysis and Critical Control Point

While risk estimates predict a low risk of contracting invasive listeriosis for the general population, susceptible populations are at higher risk and precautions should be taken, preferably avoiding consumption of raw milk soft cheese. Because there is little data that can inform policymakers on what the public deems to be an acceptable risk, it is difficult to judge the tolerability and acceptability of raw milk soft cheese. One possibility is that the availability of commercially made raw milk soft cheeses under HACCP guidelines may act as a substitute for homemade or imported products. Bell, Hillers, and Thomas (2000), however, suggest that some Hispanic Americans will continue to make *queso fresco*

cheese until an alternative is presented. What we do know is that consumer demand persists for raw milk soft cheese amongst a relatively small, but dedicated proportion of the population, and that current regulations have not prevented outbreaks affecting these people.

Need for risk reduction measures

Ideally, a zero risk scenario would be preferred, but this goal is not realistic. The need for risk reduction measures is made evident by examining the outbreak data. The five options presented in Table 6 offer different benefits and risks. The current U.S. regulation bans the sale of raw milk soft cheese, and has been in place for over 50 years. It is conceivable that with proper guidelines in place, this policy could be changed. One possible scenario would be to allow raw milk soft cheese production using HACCP, or other similar procedures, and to require a warning label be applied to the packaging. Another scenario would be to allow the importation of particular raw milk cheese varieties from specific countries that can insure that these varieties are low risk and contain a warning label on the packaging. The risks assumed under either of these options would be similar to those of other countries, like Canada, France, and Australia, and are congruent with the interests of the sovereign frame.

Risk Management

Risk management involves recommending and implementing actions and remedies to deal with risks with an aim to avoid, reduce, or transfer them. It involves two steps: decision making and implementation.

Decision making

Based on a reconsideration of the knowledge gained in the risk appraisal phase and the options evaluated in the tolerability and acceptability judgment phase, the decision making process involves the selection of a risk management strategy.

Option identification and generation

Table 6 outlined five risk management options. The current risk management strategy practiced in the US is Option 1 (banning the retail sale of raw milk soft cheese). The assumption of this strategy is that raw milk soft cheese represents a high food safety risk, because it is conducive to the presence and growth of *Lm* pathogens. Because it is considered a dangerous food, the risk management strategy is to make the production and sale of raw milk soft cheese illegal, thereby reducing the exposure to the population. The issue is complicated by rules and regulations surrounding the sale of raw milk. Federal law prohibits the interstate sale of raw milk, and most states either prohibit or limit its sale. However, there is a small but persistent consumer demand for raw milk soft cheese, particularly among the Hispanic population and "yuppies." Several outbreaks of listeriosis and other foodborne illnesses have occurred because these cheeses are made in the home, imported illegally for personal consumption, and purchased from retail stores and door-to-door vendors. An argument for maintaining the ban on the sale of raw milk soft cheese is that, in comparison to other foods, there have been few outbreaks suggesting that the status quo is working.

Should risk management options be based on a rather substantial high-risk susceptible population (an estimated 20 percent of the general population) or based on a larger low risk population? If the goal is to

protect the high-risk population, then the current risk management strategy is probably the best. If the goal is the latter, then other risk management strategies may be more desirable. Chen et al. (2003) state that the level of risk deemed acceptable is ultimately decided by society. In this case, a question is who constitutes society? Is it food safety experts, politicians, regulators, cheese artisan industry, farmers, and/or the public? In the U.S., the FDA is primarily responsible for food safety and would probably require substantial scientific data to overturn existing legislation, especially since it has been in effect for over 50 years.

Option assessment.

While education programs are suggested for all five risk management options, they become more prominent if raw milk soft cheese production becomes legalized, as susceptible populations would have greater access to these products. Consumers, particularly susceptible groups, would have to be educated about the dangers associated with consuming these cheeses. However, as discussed previously, there are scientific and cultural arguments for legalization of at least some varieties of raw milk cheese, including the fact that outbreaks have occurred primarily because of pre- or post-contamination practices; the source of outbreaks can be established and perhaps reduced through microbiological testing; economic development opportunities can be explored; consumers would have greater choice; and traditional cultures can be maintained. To reduce the risk of listeriosis, a HACCP program would have to be introduced for raw milk soft cheese production. A risk management strategy banning the production and importation of high-risk raw milk soft cheese varieties, manufacturing low risk varieties under HACCP, and placing warning labels on all raw milk soft cheese products might be an acceptable compromise to all parties, including both sovereign and illness prevention groups. A similar approach has been proposed by The Institute of Food Science & Technology [IFST] (1998) in the United Kingdom.

Option evaluation & selection

Evaluating and selecting the best option for the production of raw milk soft cheese is difficult because of the lack of data in risk and concern assessments. Risk assessments with realistic data need to be conducted on each type of raw milk soft cheese, and concern assessments need to be completed on how consumers and stakeholders determine trade-offs between preferences and food safety. As well, microbiological testing procedures need to be improved to determine the actual risk levels for different populations. Once this additional information is gathered, the information can be provided to the public, interest groups, and stakeholders to participate in the decision-making process.

Implementation

This section comprises the implementation of the risk management design with particular emphasis on option realization, monitoring and control, and feedback from the risk management process.

How might a HACCP program for the raw milk soft cheese industry operate? There should be an overall framework to help managers develop a consistent approach, to include all relevant inputs, and make consistent decisions. These components are also important for regulatory authorities to better balance risks and benefits across society in an acceptable way, and to make the decision-making process more explicit by being more open and consistent. The WHO/FAO approach to risk assessment is to have four steps: risk evaluation, option assessment, option implementation, monitoring and review. With *Lm* the complication is that different strains of the pathogen may enter at different steps in the process, and though it may be rare, contamination of the product in the processing plant may be the most critical. ILSI's expert panel (ILSI 2004) states that

Control strategies are needed at all stages from pre-harvest to consumption to minimize the likelihood that food will become contaminated by *LM* and to prevent the growth of the organism to high numbers. The panel recommends five control strategies: 1. Good Manufacturing Practices, sanitation standard operating procedures and HACCP programs, to minimize environmental *LM* 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 *LM* to high numbers; 4. reformulating foods to prevent or retard the growth of *LM*, and 5. using post-packaging treatments to destroy *LM* on products.

In the U.S., there are already voluntary HACCP programs in place for milk. However, the dairy industry in the U.S. is not subject to HACCP regulations, but rather is subject to regulation by individual states according to procedures published in the "Grade A Pasteurized Milk Ordinance." The FDA NCIMS HACCP Pilot Program suggests that every milk producer, milk distributor, bulk milk hauler/sampler, milk tank truck, milk transportation company and each milk plant, receiving station, transfer station, milk tank truck cleaning facility operator must hold a valid permit to produce and transport milk. Also, each entity in the milk chain is subject to inspection and/or audit by the appropriate regulatory agency if the milk is to be used for consumption.

Dairy farms and milk tank cleaning facilities are inspected at least every 6 months, and milk plants are inspected at least every 3 months. Inspectors are particularly concerned that proper pasteurization is taking place and that there are no violations with regards to cross-contamination. In addition to inspections, bulk milk haulers are to collect representative samples from each farm bulk tank so that the milk samples can undergo microbial testing (FDA CFSAN et al. 2003). However, tests do not appear to include testing for *Lm*. An additional requirement would be the testing of unpasteurised milk destined for cheese production for foodborne pathogens, including *Lm* at the farm level. As well, rapid detection methods would have to be implemented at the farm level so that cows excreting *Lm* can be identified and eliminated, and a selection and sorting system would have to be established to insure the production of milk to the highest level of hygiene (Sanaa et al. 2004).

In France, if milk is found to test positive for *Lm*, or other foodborne pathogens, like *Salmonella*, *E. coli*, and *Staphylococcus*, it is checked for hygienic practices. If, despite corrective hygienic procedures, the contamination persists, the milk of individual cows is tested and those with somatic cell counts higher than 300,000/mL are tested for mastitis caused by *Listeria*. A positive test results in the cow being slaughtered. Microbial testing is also completed in cheese samples before they are released. If the samples test positive, the lot is withdrawn (Sanaa et al. 2004).

Based on the regulations and practices in place in France, Food Standards Australia and New Zealand (FSANZ 2005) recently conducted a scientific evaluation of Roquefort raw milk cheese made in France to determine whether this variety of cheese can be legally imported for commercial sale in Australia and New Zealand. The scientific evaluation comprised 3 stages: (1) a scientific valuation of the safety of the cheese; (2) a review of the safety control measures implemented by producers and enforced by the French government; and (3) an on-site audit of control measures. This evaluation concluded that the risk of the prevalence and growth of 7 pathogens that cause foodborne illnesses, including *Lm*, were low, and that regulatory control was demonstrated. Thus, it was recommended that Roquefort cheese from France to be permitted for sale in Australia with the following requirements: compliance with French Ministerial Orders; test raw milk for *Lm*; monitoring of pH, salt concentration and moisture; minimum storage period of no less than 90 days; must meet microbiological limits in the Food Safety Code; and the packaging requires labeling. While Roquefort cheese cannot be considered soft because of

the 90 days storage requirement, it does provide an option of how an importation process might be implemented for raw milk soft cheese.

While it may be impossible to insure that raw milk is free from potential pathogens, IFST (1998) suggested four measures in the production of raw milk cheese. First, raw milk should be collected and maintained in good hygienic conditions. Second, if the raw milk is not used immediately, it should be refrigerated to minimize pathogen growth. Third, risk assessments should determine high-risk products, and those products should undergo full pasteurization. Fourth, good conditions of hygiene should be maintained throughout the cheese manufacture, ripening, distribution, sale, and storage until consumption to prevent contamination. Thermization of raw milk, where raw milk is heated below pasteurization temperatures, may also be utilized to reduce the growth of pathogens (Donnelly 2005). Pritchard (2005) advocates that pre-requisite programs as well as HACCP procedures should be in place that detail cleaning and sanitation procedures. Furthermore, there should be an understanding of microbiology and factors that suppress or promote the growth of organisms, and good agricultural practices. While the HACCP process may be daunting and labor intensive for a small cheesemaking facility, Pritchard (2005:151) states that "The time taken to develop a hazard analysis and to identify areas of special interest in a manufacturing process is time well spent, if for no other reason than gaining a better understanding of the principles behind the process of cheesemaking."

Risk Communication

This risk governance framework has identified two problem frames and five risk reduction options. The two problem frames comprise scientific, economic, cultural, and value debates surrounding current regulations requiring the pasteurization of milk and the production of raw milk soft cheese. The first step of risk communication may be to determine if risk professionals, regulators, and politicians are aware of these debates. If deemed necessary, a risk communication strategy may be to bring risk professionals, regulators, politicians, stakeholders, media, and the public together to understand the breath of these debates to insure that credence is given to political, scientific, economic, and cultural considerations, and that the most effective risk management approach can be formulated and communicated. Once this is accomplished, the FDA must make a decision whether current regulations need to kept or changed.

ILSI's expert panel (ILSI 2004) recognized the need for a science-based approach to risk communication, and data from risk assessments show that some interventions work better than others. The challenge of risk communicators is to educate various target groups about the effects of *Lm* and practices to lessen the risk. Consumer practices are especially important as long-term storage in refrigerators can make a large impact on growth of the pathogen at home. ILSI's expert panel (ILSI 2004) stated that science-based education and risk communication strategies should be aimed at susceptible populations and focused on high-risk foods. Information should be delivered through health care providers or other credible sources of information. Campaigns are most successful if the audience is segmented, based on risk factors, demographics and other factors, and the messages are carefully targeted and tailored for audience members (Rimal and Adkins 2003). Because consumption patterns of raw milk soft cheese vary by ethnicity, socio-economic status, and consumer preferences, messages need to be tailored to these specific target groups. Risk communication strategies should also be tailored to specific vulnerable populations such as pregnant women, the elderly, and the immunocompromised.

Conventional wisdom suggests that many of the raw milk cheese consumers are simply unaware of the risks associated with its consumption and unaware of proper handling practices. Following a 2001 outbreak among Hispanic women in Washington, it was found that none of them was aware of the risks of

consuming soft cheese during pregnancy, nor were they aware that unpasteurised milk is typically used to make *queso fresco* (Stewart 2002). However, lack of knowledge and/or concern about *Listeria* and risks associated with raw milk cheese are not limited to Hispanics. Educational strategies to increase awareness of the risks associated with raw milk soft cheese must take into account the possibility of optimistic bias or the perception that others are a greater risk of contracting listeriosis than themselves. A particular problem for risk communicators is that efforts to educate the U.S. Hispanic population about the risks of *queso fresco* consumption have been hampered by their transient nature.

Passive education strategies have generally been adopted as the main approach for reducing the incidence of listeriosis among Hispanics in the U.S. who consume raw milk soft cheese. After the first two listeriosis cases were identified in the 2001 Washington outbreak, for example, public health officials visited the neighborhood where the cases resided and to near-by health care providers and distributed Spanish-language fact sheets describing the potential risks associated with consuming *queso fresco* (Public Health Seattle and King County 2002). The Texas Department of Health has included warnings about listeriosis in its Nutrition Fact Sheet: A Quick Consumer Guide To Safe Food Handling. It states that *Lm* has been found in unpasteurised milk, imported soft cheese, hot dogs, luncheon meats and spreads. It suggests a number of control strategies including recommendations to avoid soft cheeses such as Mexican style cheeses.

A more active approach to risk communication has been the Abuela ("Grandmother") project, which was designed and implemented in the state of Washington (Bell et al. 1999). After an outbreak of *Salmonella* Typhimurium associated with raw milk soft cheese in 1997, a multi-agency intervention was developed. An element that sets this approach apart from others is its inclusion of the local Hispanic population in the design of the intervention. The center piece of the intervention focused on workshops, which introduced a pasteurized-milk *queso fresco* recipe. In addition to the workshops, a mass media campaign about the risks of consuming raw milk cheese was implemented, and newsletter articles warning about the risks of selling or giving away raw milk were aimed at dairy producers. The goal of the intervention was to reduce the incidence of *Salmonella* while maintaining the traditional, nutritious food in the Hispanic diet.

Dairy scientists at Washington State University modified a local *queso fresco* pasteurized milk recipe to inhibit undesirable microbial growth, increase shelf life, and improve the ease of preparation. Members of the Hispanic community tested the recipe to insure that flavor and texture were satisfactory. Fifteen older Hispanic women, abuelas or grandmothers, from the Hispanic community were recruited to participate in workshops that provided training on safe production of traditional cheeses (Bell et al. 1999; Medeiros et al. 2001). Each abuela educator signed a contract to teach at least 15 additional members in the community on how to safely make *queso fresco* from pasteurized milk. Pamphlets containing instructions for making the cheese were also distributed at these workshops and made available to others. A mass media campaign followed the workshops with radio public service announcements, newspaper articles, posters, and medical alerts to physicians to raise awareness of the risks associated with raw milk and raw milk soft cheese consumption. Data from the Abuela project indicate that this intervention had a significant impact on behaviors related to making Hispanic soft cheese with a significant number of participants subsequently using pasteurized rather than unpasteurised milk to make their cheese. However, the impacts from this project were not sustained over time, probably due to the transient nature of the Hispanic population in this area, and the fact that the mechanisms were not in place for community sustainability of the intervention. Although this intervention was a success in many respects, additional strategies are required.

8. Conclusions

The current approach of the U.S. government (illness prevention) to *Lm* in raw milk soft cheese is rather simple in that the management strategy is rather routine, the appropriate instruments for risk reduction are rather "traditional," and there is no need for stakeholder participation or revision of current legislation. However, a more thorough analysis using the IRGC framework illustrates that looks can be deceiving. This review of risk governance of *Lm* in raw milk soft cheese shows that there is much uncertainty as well as ambiguity with the *status quo*. First, an analysis of the risk assessments reveals that a fair amount of uncertainty exists in risk assessment models. One particular issue of scientific debate is the establishment of an appropriate *Lm* tolerance level. What initially appears to be simple (tolerance defined as absence of *Listeria in 25 g*), actually becomes rather complicated (tolerance defined as <1 cfu in 25 g at manufacture or as <100 cfu/g at consumption). Similarly, other debates surround the dose response and the amount of cheese that needs to be eaten to contract listeriosis. In hindsight, risk assessments on cheese tend to have a relatively high level of uncertainty in their models. Second, while the current legislation suggests that raw milk soft cheese cannot be produced safely, it appears that other countries have achieved a similar level of food safety with less restrictive regulations. Third, debates surrounding values are ambiguous. The two frames—illness prevention and consumer sovereignty—identified in this research represent different values. For example, illness prevention focuses on consumer protection whereas consumer sovereignty focuses on consumer choice.

The IRGC framework was particularly useful in conceptualizing the range of stakeholders throughout the commodity system, as well as the range of positions that any one group may or may not have with respect to raw milk soft cheese governance. It is possible that each stakeholder group may devise a very different range of governance options not otherwise considered. Moreover, it opens up the possibility to question the ethics of any one decision. The use of the model also draws our attention to how little is known about risk decision-making at the regulatory level! The IRGC framework sheds light on what we believe may be a set of entrenched organizational dynamics. At the federal level these dynamics appear to lack foresight and reflexivity, as well as institutional memory. As a consequence, it is unclear why such a strict reactionary standard was created for *Lm* in raw milk soft cheese (aside from reaction to raw milk outbreaks), and how this standard was justified (i.e., if *Lm* is ubiquitous, how it could be determined to be an adulterant?). Understanding how and why these decisions were made is one step in the process of developing efficient and effective statutory and regulatory standards. Another advantage of the IRGC framework is that it makes risk governance more transparent. It forced us to conceptualize risk management options not currently employed, identify inconsistencies across regulations and risk management procedures, identify uncertainty in risk assessment and risk perception data, incorporate social science and public perception into risk management, to identify contentious issues surrounding raw milk soft cheese, identify stakeholders, and provide an understanding of different stakeholder views.

In conducting this project, we also encountered several problems using the framework. In particular, we found that the definitions of the concepts are not well defined. Second, we chose a pathogen/commodity pair that is, relatively speaking, heavily regulated. Regardless of the issues we raised in our analysis, it is unlikely that there will be any major changes to the current U.S. regulations. Third, we found the intent of the framework to be unclear (i.e., the deliverables). Is the purpose: 1) to develop a risk communication strategy? 2) to recommend policy? 3) to be a guideline during the policy formation process? and/or 4) to develop criteria from which to evaluate policy? Because of these questions we were unsure if the risk judgment and management sections were to focus on what had already been done or if the intent was for us to provide our own analysis of what had been done and to raise alternative management options.

It seems intuitive that a framework incorporating social science would be an improvement to existing risk governance procedures and decision-making. However, examining concern assessment with

anecdotal evidence may lead to a position that a particular frame has more public support than it actually does. In addition to public concern assessments, it would be beneficial to understand the concerns of risk professionals and regulators. In the case of the U.S., regulatory proposals or changes are usually reactive and involve placement in the federal register where the public and interest groups may comment if they are aware of the issues. The system does not actively engage public opinion. Science based regulation is the key phrase, so why should experts engage the opinion of the public when they are the experts who know best? In other words, should regulations be based on science or values or a combination of both? This seems to be a fundamental question underlying the IRGC framework.

References:

Altekruse, S.F., D.A. Street, S.B. Fein, and A.S. Levy. 1995. "Consumer Knowledge of Foodborne Microbial Hazards and Food-Handling Practices." *Journal of Food Protection* 59:287-294.

Altekruse, S.F., B.B. Timbo, J.C. Mowbray, N.H. Bean, and M.E. Potter. 1998. "Cheese-Associated Outbreaks of Human Illness in the United States, 1973 to 1992: Sanitary Manufacturing Practices Protect Consumers." *Journal of Food Protection* 61:1405-1407.

Bell, R.A., V.N. Hillers, and T.A. Thomas. 1999. "The Abuela Project: Safe Cheese Workshops to Reduce the Incidence of *Salmonella typhimurium* From Consumption of Raw-Milk Fresh Cheese." *American Journal of Public Health* 89:1421-1424.

Bell, R., V. Hillers, and T. Thomas. 2000. "The Abuela Project: A Community-Based Food Safety Intervention."

Bemrah, N., M. Sanaa, M.H. Cassin, M.W. Griffiths, and O. Cerf. 1998. "Quantitative risk assessment of human listeriosis from consumption of soft cheese made from raw milk." *Preventive Veterinary Medicine* 37:129-145.

Bolton, L.F. and J.F. Frank. 1999. "Defining the growth/no-growth interface for *Listeria monocytogenes* in Mexican-style cheese based on salt, pH, and moisture content." *Journal of Food Protection* 62:601-609.

Brewer, M.S., G.K. Sprouls, and C. Russon. 1994. "Consumer attitudes towards food safety issues." *Journal of Food Safety* 14:63-76.

Center for Food Safety and Applied Nutrition. 1992, "The *Bad Bug Book*: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook", Retrieved March 02, 2006 (http://vm.cfsan.fda.gov/~mow/intro.html).

Centers for Disease Control and Prevention. 2001. "Outbreak of Listeriosis Associated With Homemade Mexican-Style Cheese — North Carolina, October 2000–January 2001." *Morbidity and Mortality Weekly Report* 50:560-562.

Chen, Y., W.H. Ross, V.N. Scott, and D.E. Gombas. 2003. "Listeria monocytogenes: Low Levels Equal Low Risk." *Journal of Food Protection* 66:570-577.

Cody, S.H., S.L. Abbott, A.A. Marfin, B. Schulz, P. Wagner, K. Robbins, J.C. Mohle-Boetani, and D.J. Vugia. 1999. "Two Outbreaks of Multidrug-Resistant Salmonella Serotype Typhimurium DT104

Infections Linked to Raw-Milk Cheese in Northern California." *Journal of the American Medical Association* 28:1805-1810.

de Valk, H., C. Jacquet, V. Goulet, V. Vaillant, A. Perra, F. Simon, JC Desenclos, and P. Martin. 2005. "Surveillance of Listeria Infections in Europe." *Eurosurveillance* 10:251-255.

Dittus, K.L. and V.N. Hillers. 1996. "Attitudes about the nutritional benefits and pesticide-exposure risks from fruit and vegetable consumption." *Family and Consumer Sciences Research Journal* 24:406-421.

Donnelly, C. 1989. "Listeria safety and government regulation of cheese."

—. 2005. "The pasteurization dilemma." Pp. 173-196 in *American farmstand cheese: The complete guide to making and selling artisan cheeses*, edited by P.S. Kindstedt and the Vermont Cheese Council. White River Junction, VT: Chelsea Green Publishing.

Donnelly, C. W. 2001. "Factors Associated with Hygienic Control and Quality of Cheeses Prepared from Raw Milk: A Review." *IDF Bulletin* 369:16-27.

Economic Research Service. 2000, "Economics of foodborne disease: *Listeria monocytogenes*" *Briefing Room*, Retrieved March 01, 2006 (http://www.ers.usda.gov/briefing/foodborneDisease/listeria/).

European Commission Health and Consumer Protection Directorate-General (ECHCP). 1999. "Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on *Listeria Monocytogenes*." Pp. 44, edited by M. o. S. C. I. Scientific Health Opinions: European Commission Health & Consumer Protection Directorate-General.

European Union. 2005. "Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs." Pp. 26, edited by The Commission of the European Communities.

Fletcher, J. 2006, "The Myths about Raw-Milk Cheese" *Specialty Food Magazine*, Retrieved March 1, 2006 (http://www.specialtyfood.com/do/news/ViewNewsArticle?id=1841).

Food Safety Network. 2003, "Health warning issued for illegally sold white cheese", Retrieved October 4, 2006 (http://archives.foodsafetynetwork.ca/fsnet/2003/8-2003/fsnet_august_26.htm#CHEESE).

—. 2004a, "Listeriosis, neonatal", Retrieved October 4, 2006 (http://archives.foodsafetynetwork.ca/fsnet/2004/3-2004/fsnet_march_8.htm#story0).

—. 2004b, "Listeriosis, North Carolina", Retrieved October 4, 2006 (http://archives.foodsafetynetwork.ca/fsnet/2004/6-2004/fsnet_june_4-2.htm#story3).

—. 2005, "City fears potential outbreak of bacterial illness: Health officials see 6 listeriosis cases in a month", Retrieved October 4, 2006 (http://archives.foodsafetynetwork.ca/fsnet/2005/8-2005/fsnet_aug_23-2.htm#story0).

Food Standards Australia New Zealand (FSANZ). 2005. "Final Assessment Report Application A499 to Permit the Sale of Roquefort Cheese," Retrieved October 24, 2006

(http://www.foodstandards.gov.au/_srcfiles/A499_Roquefort_FAR_FINALv2.pdf#search=%22roquefort%22).

Frenzen, P. and J. Buzby. 2000, "ERS Updates Foodborne Illness Costs" *Food Safety*, v. 23, 1.3. Retrieved March 1, 2006 (http://www.mindfully.org/Food/Foodborne-Illness-Costs-USDA.htm).

Frewer, L.J., R. Shepherd, and P. Sparks. 1994. "The interrelationship between perceived knowledge, control and risk associated with a range of food-related hazards targeted at the individual, other people and society." *Journal of Food Safety* 14:19-40.

Genigeorgis, C., M. Carnicui, D. Dutulescu, and T.B. Farver. 1991a. "Growth and survival of *Listeria monocytogenes* in market cheeses stored at 4 to 30°C." *Journal of Food Protection*:662-668.

Genigeorgis, C., J.H. Toledo, and F.J. Garayzabal. 1991b. "Selected Microbiological and chemical characteristics of illegally produced and marketed soft Latino-style cheeses in California." *Journal of Food Protection* 54:598-601.

Glass, K.A., B. Prasad, J.H. Schlyter, H.E. Uljas, N.Y. Farkye, and J. B. Luchansky. 1995. "Effects of acid type and ALTATM2341 on *Listeria monocytogenes* in a Queso Blanco type of cheese." *Journal of Food Protection* 58:737-741.

Gombas, D. E., Y. Chen, R.S. Clavero, and V.N. Scott. 2003. "Survey of Listeria monocytogenes in ready-to-eat foods." *Journal of Food Protection* 66:559-569.

Headrick, M.L., S. Korangy, N.H. Bean, F.J. Angulo, S.F. Altekruse, M.E. Potter, and K.C. Klontz. 1998. "The epidemiology of raw milk-associated foodborne disease outbreaks reported in the United States, 1973 through 1992." *American Journal of Public Health* 88:1219-1221.

Hillers, V., R. Bell, and T. Thomas. 2002. "The Abuela Project: A Community Based Food Safety Intervention involving Queso Fresco, a Raw-Milk Cheese." in *Thinking Globally - Working Locally: A Conference on Food Safety Education*. Orlando, FL: FSIS/USDA.

Hitchins, A.J. 2003. "Detection and Enumeration of Listeria monocytogenes in Foods." *Bacteriological Analytical Manual*, edited by U.S. Department of Health and Human Services and U. S. Food and Drug Administration Center for Food Safety & Applied Nutrition.

Hopkins, R.S., R.A. Jajosky, P.A. Hall, D.A. Adams, F. J. Connor, P. Sharp, W.J. Anderson, R.F. Fagan, J.J. Aponte, G.F. Jones, D.A. Nitschke, C.A. Worsham, N. Adekoya, and M. Chang. 2005. "Summary of Notifiable Diseases -- United States, 2003." Division of Public Health Surveillance and Informatics, Epidemiology Program Office, Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention, Atlanta, GA.

Institute of Food Science and Technology (IFST). 1998, "IFST: Current hot topics. Food safety and cheese", Retrieved March 14, 2006 (http://www.ifst.org/hottop15.htm).

International Life Sciences Institute (ILSI). 2004. "Achieving Continuous Improvement In Reductions In Foodborne Listeriosis - A Risk Based Approach." A report from the ILSI Institute Working Group on *Listeria monocytogenes* in Foods.

Johnson, E. A., J. H. Nelson, and M. Johnson. 1990. "Microbiological safety of cheese made from heat-treated milk, Part II." *Journal of Food Protection* 53:519-540.

Knight, A.J. and R. Warland. 2005. "Determinants of food safety risks: A multi-disciplinary approach." *Rural Sociology* 70:253-275.

Kozak, J., T. Balmer, R. Byrne, and K. Fisher. 1996. "Prevalence of *Listeria monocytogenes* in foods: Incidence in dairy products." *Food control* 7:215-221.

Lay, J., J. Varma, R. Marcus, T. Jones, S. Tong, C. Medus, M. Samuel, P. Cassidy, F. Hardnett, C. Barden, and EIP FoodNet Working Group. 2002. "Higher incidence of Listeria infections among Hispanics: FoodNet, 1996-2000." in *International Conference on Emerging Infectious Diseases.* Atlanta, GA.

Lin, C.T. Jordan. 1995. "Demographic and socioeconomic influences on the importance of food safety in food shopping." *Agricultural and Resource Economics Review* 24:190-198.

Lin, C.J., K.L. Jensen, and S.T. Yen. 2005. "Awareness of foodborne pathogens among US consumers." *Food Quality and Preference* 16:401-412.

Linnan, M.J., L. Mascola, X.D. Lou, V. Goulet, S. May, C. Salminen, D.W. Hird, M.L. Yonekura, P. Hayes, R. Weaver, and et al. 1988. "Epidemic listeriosis associated with Mexican-style cheese." *New England Journal of Medicine* 319:823-828.

Mead, P.S., L. Slutsker, V. Dietz, L.F. McCaig, J.S. Bresee, C. Shapiro, P.M. Griffin, and R.V. Tauxe. 1999. "Food-Related Illness and Death in the United States." *Emerging Infectious Diseases* 5:607-625.

Medeiros, L., V.N. Hillers, P. Kendall, and A. Mason. 2001. "Food safety education: What should we be teaching to consumers?" *Journal of Nutrition Education* 33:108-113.

Oldways. n.d., "Food Issues Think Tank", Retrieved October 4, 2006 (http://www.oldwayspt.org/).

Pagotto, F., L.K. Ng, C. Clark, J. Farber, and Canadian Public Health Laboratory Network. 2006. "Canadian Listeriosis Reference Service." *Foodborne Pathogens and Disease* 3:132-137.

Peeler, J.T. and V.K. Bunning. 1994. "Hazard assessment of *Listeria monocytogenes* in the processing of bovine milk." *Journal of Food Protection* 57:689-697.

Priest, S.H.. 2000. "US public opinion divided over biotechnology?" *Nature Biotechnology* 18:939-942.

Pritchard, T. 2005. "Ensuring safety and quality I: Hazard Analysis Critical Control Point and the cheesemaking process." Pp. 139-152 in *The Complete Guide to Making and Selling Artisan Cheeses*, edited by P. S. Kindstedt and Vermont Cheese Council. White River Junction, VT: Chelsea Green Publishing.

Public Health Seattle and King County. 2002. "Listeriosis in pregnant women linked to consumption of queso fresco." in *Epi-Log Newsletter*, vol. 42.

Reed, B.A. and C. Bruhn. 2003. "Sampling and farm stories prompt consumers to buy specialty cheeses." *California Agriculture* 57:76-80.

Rimal, R.N. and A.D. Adkins. 2003. "Using computers to narrowcast health messages: The role of audience segmentation, targeting, and tailoring in health promotion." in *Handbook of Health*

Communication, edited by T. L. Thompson, A. M. Dorsey, K. I. Mller, and R. Parrott. Mahwah, NJ: Lawrence Erlbaum Associates.

Sagoo, S.K. and C.L. Little. 2004. "European Commission Co-ordinated Programme for the official control of foodstuffs for 2004: Microbiological examination of cheeses made from raw or thermised milk from establishments of production and retail in the United Kingdom."

Sanaa, M., L. Coroller, and O. Cerf. 2004. "Risk Assessment of Listeriosis Linked to the Consumption of Two Soft Cheeses Made from Raw Milk: Camembert of Normandy and Brie of Meaux." *Risk Analysis* 24:389-399.

Schmidt, D. n.d. "Food Safety: A risk approach to informing the public."

Shaw, S.A. 2000, "Cheesy does it: Getting your hands on great cheese in the U.S. means circumventing an archaic FDA regulation" *Travel & Food*, Retrieved March 02, 2006 (http://www.salon.com/travel/food/feature/2000/01/28/cheese/).

Shiferaw, B., S. Yang, P. Cieslak, D. Vugia, R. Marcus, J. Koehler, V. Deneen, F. Angulo, and The Foodnet Working Group. 2000. "Prevalence of High-Risk Food Consumption and Food - Handling Practices among Adults: A Multistate Survey, 1996 - 1997." *Journal of Food Protection* 63:1538-1543.

Stein, N. 2001. "Would You Like Cheese With That? You may have to settle for Kraft. Nicholas Stein questions the FDA's investigation into whether unpasteurised cheese poses a health threat." *Fortune*, April 2, pp. 199-200.

Stewart, L. K. 2002. "Listeriosis in pregnant women linked to consumption of Queso Fresco." *Communicable Disease and Epidemiology News* 42:2.

Teng, D., A. Wilcock, and M. Aung. 2004. "Cheese quality at farmers markets: Observation of vendor practices and survey of consumer perceptions." *Food Control* 15:579-587.

Teuber, M. 2000. "Fermented milk products." in *The Microbiological Safety and Quality of Food*, edited by B. M. Lund, T. C. Baird-Parker, and G. W. Gould. Gaithersburg, Md.: Aspen Publishers.

Todd, E. 2007. "*Listeria*: Risk assessment, regulatory control and economic impact." Pp. Chapter 17 in *Listeria, Listeriosis, and Food Safety*, edited by E. T. Ryser and E. H. Marth. New York: Marcel Dekker.

U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, U.S. Department of Agriculture Food Safety and Inspection Service, and Centers for Disease Control and Prevention. 2003. "Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods." Pp. 1-523: United States Department of Agriculture.

U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, and Centers for Disease Control and Prevention. 2005. "Current FDA Activities Related to the Listeria monocytogenes ActionPlan." Retrieved May 24, 2007 (http://www.foodsafety.gov/~dms/lmr2pla2.html)

Williams, P.R.D. and J.K. Hammitt. 2001. "Perceived risks of conventional and organic produce: pesticides, pathogens, and natural toxins." *Risk Analysis* 21:319-330.

World Health Organization and Agriculture Organization of the United Nations (WHO/FAO). 2004. "Risk assessment of Listeria monocytogenes in ready-to-eat foods: Technical Report." Geneva, Switzerland.

Woteki, C.E. and B.D. Kineman. 2003. "Challenges and approaches to reducing foodborne illness." *Annual Review of Nutrition* 23:315-44.