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PAPER

US position on *Listeria monocytogenes* in foods

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Public health and regulatory agencies in the USA have established a zero tolerance for Listeria monocytogenes *in cooked, ready-to-eat food. This policy is science-based: the organism causes human illness, can grow at refrigeration temperatures and the infectious dose is unknown. The US response to listeriosis has included emphasis on Good Manufacturing Practices and Hazard Analysis Critical Control Point systems for processing, recommendations for sanitation and other measures for retail handling, and consumer education targeted to populations at highest risk for listeriosis. Published by Elsevier Science Ltd.*

Keywords: *Listeria monocytogenes*; ready-to-eat; policy

INTRODUCTION

Federal agencies responsible for public health and protection of the food supply in the USA have established a zero tolerance for *Listeria monocytogenes* in cooked, ready-to-eat foods. Food in the USA is regulated by two federal agencies: the US Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), which is responsible for the regulation of meat, poultry and egg products; and the Food and Drug Administration (FDA) of the Department of Health and Human Services (DHHS), which is responsible for other foods, including seafood. A third agency, the Center for Disease Control and Prevention (CDC) of the DHHS, is responsible for epidemiologic investigations and disease surveillance in the USA. CDC supplies both food regulatory agencies with foodborne illness data. FDA, USDA/FSIS, and CDC are individually and collectively working to understand better the epidemiology of listeriosis and to learn more about the virulence, general physiology, and ecology of *L. monocytogenes*. FDA works cooperatively with USDA/FSIS to better control *L. monocytogenes* throughout the food chain. USDA and FDA individually develop policy and control strategies but have generally coordinated these efforts. Both agencies provide technical and educational support and materials to food processors, retailers, and consumers, advising what must be done by each to minimize the risk of listeriosis.

Since the first reported foodborne outbreak of listeriosis in 1980–81, US policy has been shaped by our increasing knowledge of the epidemiology of outbreaks and sporadic cases of human listeriosis and of the characteristics of the organism. Because outbreaks of listeriosis initially alerted us to the potentially severe public health consequences associated with this pathogen, epidemiologic data from outbreak investigations and sporadic illness occurring in the last 15 years is briefly described below.

OUTBREAKS

L. monocytogenes has been known as an animal pathogen, primarily affecting sheep and cattle, since 1926 (Murray *et al.*, 1926 and Blenden and Szatalaowicz, 1967). Listeriosis was first described as a human pathogen in 1929 (Nyfeldt, 1929) and was first linked with perinatal disease in 1933 (Burn, 1933).

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Table 1 Summary of selected foodborne listeriosis outbreaks

Year	Outbreak site	Cases	Deaths	Food implicated	Food isolate
1980–81[a]	Nova Scotia	41	18	Coleslaw	Yes
1983[b]	Boston	49	14	Pasteurized milk	No
1985[c]	Los Angeles	142	48	Mexican-style cheese	Yes
1983–87[d]	Vaud, Switzerland	122	33	Vacherin cheese	?
1992[e]	France	279	?	Jellied pork tongue	Yes
1994[f]	US Picnic	52	None	Chocolate milk	Yes (10^9/ml)

[a]Schlech *et al.*, 1983.
[b]Fleming *et al.*, 1985.
[c]Linnan *et al.*, 1988.
[d]Bille and Glauser, 1988.
[e]Jacquet *et al.*, 1995.
[f]Dalton *et al.*, 1995.

The first foodborne outbreak of human listeriosis reported in North American medical literature occurred in 1980–81 in Nova Scotia, Canada (Schlech *et al.*, 1983) (*Table 1*). There were 41 cases, including seven adult and 34 (83%) perinatal cases, and 18 deaths (two adult and 16 fetal or newborn). Coleslaw was epidemiologically implicated as the probable source of *L. monocytogenes* in this outbreak. The outbreak strain was grown from the coleslaw in a patient's refrigerator. The coleslaw had been made from cabbage grown in a field fertilized with manure from *L. monocytogenes*-infected sheep.

In 1983, a second foodborne listeriosis outbreak was reported (Fleming *et al.*, 1985); it occurred in Boston, Massachusetts. There were 49 cases: 42 in immunosuppressed adults and 7 (14%) in newborn infants. Of these, 12 adults and 2 babies died. Pasteurized milk was epidemiologically linked as the vector for transmission of *L. monocytogenes*, although the organism was not cultured from the suspect brand of milk.

In 1985, a third and larger foodborne outbreak of listeriosis occurred in Los Angeles, California (Linnan *et al.*, 1988). There were 142 cases, including 49 non-pregnant adults and 93 (83%) pregnant women or their offspring. There were 48 deaths: 18 adult deaths and 30 fetal or newborn deaths. Of the 49 non-pregnant adults, 48 (98%) had a predisposing factor. A Mexican-style soft, white cheese (queso blanco), manufactured with contaminated milk, was the vehicle implicated. Laboratory study confirmed the presence of *L. monocytogenes* 4b of the epidemic phage type in the Mexican-style cheese.

From 1983 to 1987, 122 cases of foodborne listeriosis were identified during a prolonged outbreak in the Canton of Vaud, Switzerland with 33 deaths (Bille and Glauser, 1988). The food vehicle was determined to be Vacherin cheese.

In 1992, a foodborne listeriosis outbreak in France included 279 cases (Jacquet *et al.*, 1995): 92 were pregnancy related, and 187 were not related to pregnancy. Results from a case control study and typing of *L. monocytogenes* strains isolated from foods sampled at various stages (process, transport, distribution and patients' refrigerators) implicated jellied pork tongue as the major vehicle of the outbreak (Goulet *et al.*, 1993). No jellied pork tongue was found in patients' refrigerators because the product is rapidly consumed. In general, the 2–3 week incubation from consumption of contaminated food to the subsequent diagnosis of the infection, means that foods are no longer available in the patient's refrigerator (Jacquet *et al.*, 1995).

A 1994 outbreak of gastrointestinal listeriosis occurred among attendees at a picnic in the USA (Dalton *et al.*, 1995). Fifty-two of 64 otherwise healthy individuals developed gastrointestinal illness. Chocolate milk was identified both epidemiologically and by culture as the vehicle of infection. The gastrointestinal illness was mild, and not similar to the more commonly recognized, and potentially fatal invasive disease noted in other outbreaks. The chocolate milk had been temperature abused, and was found to contain approximately 10^9 cells per ml (Dalton, personal communication). This outbreak was unusual in that the median incubation time was only 20 h, much shorter than the often weeks long incubation time seen in patients thought to have consumed lower levels of *L. monocytogenes*.

EPIDEMIOLOGICAL STUDIES

In response to the foodborne listeriosis outbreaks of the early 1980s, CDC, through an interagency agreement with FDA and the cooperation of state and local public health officials, initiated an active surveillance programme for invasive disease (ie bacteremia/meningitis not diarrhoea). For the 1986–87 study, a 34 million population base in six states was surveyed (Schwartz *et al.*, 1988; Broome *et al.*, 1990; Gellin *et al.*, 1991). Based on the number of cases identified, the investigators estimated the annual incidence of listeriosis in the USA to be 1600 cases, with over 400 deaths (*Table 2*). This programme also included a case-control study for food preference patterns and found an association between sporadic listeriosis and the consumption of uncooked hot dogs and undercooked chicken.

During 1988–90, an 18 million population base was used for the active surveillance programme, and the case control studies were expanded to gather more

Table 2 Foodborne sporadic listeriosis in the USA

Years	Cases[a]	Deaths[a]	Implicated food
1986–87[b]	1600	400	Uncooked hotdogs Undercooked chicken
1988–90[c]	1850	425	Mexican-style cheese Delicatessen foods
1989[d]	1965	481	Not studied
1993[d]	1092	248	Not studied

[a]US estimated annual.
[b]Schwartz *et al.*, 1988; Broome et al., 1990; Gellin *et al.*, 1991.
[c]Schuchat *et al.*, 1992.
[d]Tappero *et al.*, 1995.

detailed information on food histories and underlying diseases or conditions of patients (Schuchat *et al.*, 1992). Again, the estimated annual incidence of listeriosis in the USA was 1850 cases and 425 deaths. These data confirmed that, although foodborne listeriosis is rare, the associated mortality rate is high among those at-risk. Case control studies found sporadic listeriosis was associated with soft, Mexican-style white cheeses and foods purchased from store delicatessen counters. Compared to matched controls, people with highly immunosuppressed conditions, who consumed undercooked chicken had a three times higher risk of listeriosis.

Although the association of listeriosis with eating uncooked hot dogs was found in the earlier (1986–87) study, the 1988–90 case-control study did not confirm the finding. One notable exception was the intensive investigation of a fatal case of listeriosis in 1989 when a trace back found culture positive turkey frankfurters in the patient's refrigerator and product, unopened, at retail (Barnes *et al.*, 1989). CDC epidemiologists postulated that increased agency monitoring actions and industry efforts to decrease contamination following the reported illness from turkey franks was responsible for the absence of increased risk associated with uncooked hot dogs and decrease in isolation rate from hot dogs (Schuchat *et al.* 1992).

The most recent report based on this active surveillance program (Tappero *et al.*, 1995) used a population base of over 19 million and compared 1989 incidence data to those found in 1990–93. The estimated annual incidence rate decreased over 40% from 1965 cases and 481 deaths in 1989 to 1092 cases and 248 deaths in 1993. Tappero *et al.* (1995) suggest that the decline in numbers of cases of listeriosis may be attributed to increased industry and government regulatory agency emphasis on prevention during food processing and food handling, and increased public awareness due to targeted educational efforts of CDC, USDA and FDA.

In addition to active surveillance for human disease, surveys of dairy products were initiated by FDA and a programme was developed specifically for cheese products. These surveys found that 3% of dairy based products tested contained *L. monocytogenes* (NACMCF, 1991). The organism appears to be widely distributed in the environment and can be isolated from meat, poultry, seafood and vegetables (NACMCF, 1991). Published food surveys have shown that 15 of 57 (26%) imported and domestic seafood samples tested were positive for *L. monocytogenes*. The positive samples included raw and cooked shrimp, crabmeat, lobster tails, squid, finfish, and surimi analogs (Weagent *et al.*, 1988). Buchanan *et al.* (1989) reported 9 of 21 fresh meat samples positive for *L. monocytogenes*. These samples included sausage, pork sausage, hamburger, ground veal, and lamb. Genigeorgis *et al.* (1989, 1990) reported 13% of raw chicken parts and 15% of turkey parts positive for *L. monocytogenes*. Hesick *et al.* (1989) reported 19 of 70 potato samples and 25 of 68 radish samples positive for *L. monocytogenes*. A review by the NACMCF (1991) states that 'It is assumed that numbers of *L. monocytogenes* are low' in vegetables, but '...the bacterium can multiply during storage particularly in damaged vegetables...'

PUBLIC HEALTH RESPONSE

The US response to outbreaks of human listeriosis has been multifaceted and has been accomplished through the efforts of three federal agencies and the cooperation of state and local health officials. FDA produced *Food Code 1993* which recommends employee practices, sanitization, protection from cross-contamination, and times and temperatures for cooking, cooling and holding food to prevent the occurrence and/or spread of *L. monocytogenes* during retail food preparation and production. FDA and FSIS jointly produced recommendations to delicatessen operators and posters describing safe food handling procedures for use at retail. Posters reinforcing these provisions were developed by the agencies when delicatessen foods were found to be associated with sporadic listeriosis.

Much of the US food safety education is general, and for all consumers. However, occurrence of listeriosis in easily identifiable populations has allowed FDA, USDA and CDC to target brochures and posters to at-risk populations, such as Hispanic pregnant women and people with AIDS. Educational materials for consumers are developed and provided by DHHS through the FDA Office of Public Affairs and District Public Affairs offices, the FDA Center for Food Safety and Applied Nutrition, and the CDC National Center for Infectious Diseases. USDA provides background information on *L. monocytogenes* through FSIS, the Cooperative Extension Service state and local network, and the Meat and Poultry Hotline.

National programmes have centred on the production of food using preventive measures: clean and sanitary plants, use of good manufacturing practices, and the use of Hazard Analysis Critical Control Point (HACCP) by industry. Knowledge gained through

epidemiologic studies has allowed US agencies to focus regulatory compliance on those food product categories known to be associated with cases of listeriosis. FDA has also been able to obtain injunctions against food manufacturers that are manufacturing or distributing food that is contaminated with *L. monocytogenes*. It has focused educational efforts on food handlers and those known to be at highest risk for illness or death from listeriosis.

Following the outbreaks of listeriosis in Nova Scotia and Boston, FDA and FSIS recognized that existing methodology for culturing and typing *L. monocytogenes* were too time consuming and cumbersome to be useful in epidemiologic and other studies. Both agencies focused on methods development for detection and identification of *L. monocytogenes* in food. Short-term incubation methods were developed in 1983–85 (McClain and Lee, 1988) to replace the weeks-long cold enrichment method used previously (Gray *et al.* 1948). In 1986, FSIS developed the lithium chloride-phenylethanol-moxalactam (LPM) medium that is used by both USDA and FDA for isolation of the bacterium (Lee and McClain, 1986). In 1987, USDA presented its methodology for meats (McClain and Lee, 1988). In 1985, FDA established a policy for *L. monocytogenes* in food, based on a method for detection using a 250 g sample. In 1987, FDA reduced the sample size required for isolation of the organism to two 25 g samples and the following year FSIS adopted FDA's sampling plan. Methods continue to be improved for rapidity of detection, enumeration and differentiation, incorporating polymerase chain reaction and DNA probes, for example. Rapid serological and ribotyping methods for strain differentiation have improved the accuracy of epidemiologic investigations which compare patient isolates of *L. monocytogenes* to those isolates from suspected food vehicles.

The US public health response to *L. monocytogenes* outbreaks is summarized in the following sections.

Current policy: USDA/FSIS policy for meat and poultry products

FSIS policy is the same as that of FDA and is based on the definition of adulteration: *L. monocytogenes* in ready-to-eat foods is considered an added agent (Definitions, 9 CFR 301.2). Ready-to-eat products testing positive for the organism are considered to be adulterated and are subject to seizure, condemnation or other appropriate action.

In 1987, FSIS considered there to be a strong possibility that meat and poultry products could contain *L. monocytogenes* although these products had not been reported in human outbreaks. Therefore, FSIS expanded its testing/monitoring program (52 FR 7464) for *L. monocytogenes* in meat and poultry products to emphasize cooked and ready-to-eat products such as dry-cured pork products, fermented sausages, and cooked lunch meats. The USDA notice stated that processors need to ensure that current procedures for handling raw materials, and for processing, packaging and storage of product will not contribute to the growth of *L. monocytogenes*, that any existent *L. monocytogenes* is destroyed during processing and the possibility of recontamination is eliminated.

In 1989, FSIS intensified its programme for surveillance and recall of processed meat and poultry products due to the conclusive link of turkey franks with a case of human listeriosis (Barnes *et al.*, 1989). The new policy (54 FR 22345) requires action to be taken on lots for which monitoring samples of intact, retail packages are found to be positive for *L. monocytogenes*. Action includes recall of current lots until test results are known and the agency is assured that corrective action has been successfully implemented as well as sampling of other products at the establishment. For positive samples from larger, wholesale-type packages (such as an entire round of cooked beef), samples from subsequent lots of intact product are held and tested. With FSIS's changes in compliance policy, the sampling procedure was also intensified by increasing the size and number of samples analysed.

In 1995, USDA/FSIS published (60 FR 6775) a pathogen reduction programme in response to widely disseminated outbreaks of illness due to *Escherichia coli* 0157:H7 and a proposed rule for HACCP to reduce the incidence of foodborne illness associated with the consumption of meat and poultry products. FSIS is accepting comments on their proposal until 5 July, 1995.

Current policy: FDA policy for foods

In 1985 FDA established a policy for *L. monocytogenes*: detection of the organism in a ready-to-eat food by the FDA method is a violation of the Federal Food, Drug and Cosmetic Act, section 402(a) (1) and (4). This act prohibits the distribution in the USA, or importation into the USA, of foods that are adulterated. These sections of the act state that a food is adulterated

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; ... or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

The Federal Food, Drug and Cosmetic Act does not define 'added' as found in section 402(a) (1). The definition given in 21 C.F.R. section 109.3 (c) and (d) can be used:

(c) A *naturally occurring poisonous or deleterious substance* is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.
(d) An *added poisonous or deleterious substance* is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

L. monocytogenes is a human pathogen which may be injurious to health and is considered an added substance. This interpretation was recently affirmed by a US District Court (USA *v* Union Cheese Co, 1995). Therefore, if the organism is detected in a ready-to-eat-food, the food is considered to be adulterated.

Since 1985, Class I recalls have been imposed on ready-to-eat foods contaminated with *L. monocytogenes* including cheeses, ice cream, milk, fish prepared salads, sandwiches, crab meat, smoked fish, and bakery products. A Class I recall (21 CFR 7.3(m)(1)) is initiated when there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. The degree of hazard is determined by FDA's Health Hazard Evaluation Board. During 1987–92, there were recalls on 970 ready-to-eat products from 109 firms because of contamination with the organism (Tappero *et al.*, 1995). Currently, FDA requests recall of any ready-to-eat food in which *L. monocytogenes* is detected using present methodology, if it is determined that the cooking or heating instructions would not provide for lethality ('zero tolerance' for these foods).

FDA also takes regulatory action against product that 'has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health' (Section 402(a) (4) of the Act). FDA requires that foods be produced using proper sanitation and other measures and has codified these in 21 C.F.R. 110, Current Good Manufacturing Practices (CGMPs). In many instances, foods testing positive for *L. monocytogenes* are produced in plants with deviations from the food CGMPs. In such cases, the organism is often found in food environmental samples taken in the processing plant.

SUMMARY OF CURRENT UNITED STATES POLICY

The current policy considers the detectable presence of *L. monocytogenes* in ready-to-eat foods to be a hazard to health. (The limit of sensitivity of the analytical method is actually 0.4 organisms per gram.) The following are some issues that need to be addressed when considering changes to the existing policy:

- There is very limited scientific evidence to define the quantitative level of concern, ie, a non-zero number, of *L. monocytogenes* organisms that can be safely consumed. This is especially important for susceptible populations (pregnant women, immunocompromised).
- *L. monocytogenes* can reproduce at refrigeration temperatures and therefore, foods that begin with very low levels may, after time, contain levels sufficient to cause illness.
- Continued regulatory pressure to achieve 'zero' has resulted in great improvement in the sanitary conditions in a number of industries.
- CDC has published the results of a new sentinel study showing a dramatic (40%) decline in listeriosis in the US (Tappero *et al.*, 1995). A case can thus be made that current regulatory pressure has been very successful in protecting the public health and that relaxing the strict standards might be unwise and risky.

Public health and regulatory agencies in the USA have established a zero tolerance for *L. monocytogenes* in cooked and ready-to-eat food. Good Manufacturing Practice regulations are enforced and sanitary inspections are conducted. Discretionary enforcement authority is used to selectively sample and test for *L. monocytogenes*. Active surveillance for listeriosis is pursued and all outbreaks of listeriosis thoroughly investigated.

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NOTE ADDED IN PROOF

In December, 1995, FDA published (60 FR 65096) a rule requiring the use of HACCP in the processing of fish and fishery products. In July, 1996, USDA/FSIS published (61 FR 38806) a mandatory pathogen reduction and HACCP rule for the processing of meat and poultry products. The most updated version of FDA's Food Code is the *Food Code 1995*.