Microbiological criteria for *Listeria monocytogenes* in foods under special consideration of risk assessment approaches

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**Abstract**

This paper shortly summarizes data related to risk assessment of *Listeria monocytogenes*. From available data on risk assessment, it is concluded that the levels of *L. monocytogenes* consumed is an important factor affecting the incidence of listeriosis. Foods that do not support the growth of *L. monocytogenes* are unlikely to be a source of listeriosis, whereas foods that support the growth to high levels, should be the target of risk management efforts. Based on current epidemiological information from several countries, a concentration of *L. monocytogenes* not exceeding 100/g of food at the time of consumption is of low risk to the consumers. In order not to exceed these levels at the point of consumption, lower levels may need to be applied at the port of entry, for those foods in which growth can occur within the shelf life. In order to establish such levels, knowledge of the shelf life and behaviour of *L. monocytogenes* in the food during prevailing storage and distribution conditions is needed.

**Keywords**: *Listeria monocytogenes*; Microbiological criteria; Risk assessment; Food safety

**1. Introduction**

In several countries, criteria or recommendations for tolerable levels of *Listeria monocytogenes* in ready-to-eat (RTE) foods, have been established (Gravani, 1999). Some countries, for example, the USA and Italy, require absence of *L. monocytogenes* in 25 g of foods (zero tolerance) while other European countries (e.g., Germany, The Netherlands and France) have a tolerance of below 100 cfu *L. monocytogenes*/g at the point of consumption. Finally, some countries, e.g., Canada and Denmark, have a tolerance of below 100/g for some foods and a zero tolerance for others, especially those which are supportive of growth and with extended shelf-lives. Several countries have concluded that a complete absence of *L. monocytogenes* for certain RTE foods is an unrealistic and unattainable requirement, that limits trade without having a positive impact on public health and consequently might detract resources from other potentially more efficient measures against *L. monocytogenes*. Therefore, there is a need for international microbiological criteria for *L. monocytogenes* in foods, with special consideration for risk assessment approaches. With this in mind,
Germany hosted a Codex drafting group meeting on February 15 and 16, 1999 where a background document on microbiological criteria for *L. monocytogenes* in foods was drafted. In the present paper, data related to risk assessment of *L. monocytogenes* will be summarized. Furthermore, some of the considerations of the risk assessment will be briefly mentioned and the criteria, which presumably will be proposed by the Codex drafting group, will be described in more detail. It is important to caution against any further use of these criteria as related to Codex until they have undergone a full Codex review.

2. Hazard identification

*Listeria monocytogenes* is a bacterial pathogen which can cause serious illness such as septicaemia and meningitis, in humans. Although listeriosis occurs infrequently, at an incidence rate below 10 cases per million, the fatality rate is high, up to 75% in highly susceptible individuals, such as immunocompromised individuals suffering from cancer, AIDS, etc. In contrast, the fatality rate is often low in persons without predisposing factors. In general, the case fatality rate ranges between 20 and 30% (Gellin and Broome, 1989). Although other modes of transmission exist, foods have been clearly identified as a primary source of infection. The high prevalence of *L. monocytogenes* in foods in general, together with the high mortality rate from listeriosis, suggest that *L. monocytogenes* represents an important hazard to human health. Consequently, the occurrence, spread, growth and survival of *L. monocytogenes* in foods and food environments has to be controlled.

3. Hazard characterization

Serotyping distinguishes 13 different serotypes of *L. monocytogenes*, but cases of human listeriosis are caused mainly by only three serotypes (4b, 1/2a and 1/2b). Most human epidemics and a great percentage of the sporadic cases have been caused by serotype 4b for a reason not yet understood. In contrast, serogroup 1/2 strains seem to be more often recovered from food (Lovett et al., 1987; Pini and Gilbert, 1988). For example, 64% of the clinical isolates occurring in the UK are serotype 4b, whereas only 4–6% of the isolates found in the environment are of this serotype (Kerr et al., 1995). No studies have been able to explain why serotype 4b accounts for most cases of human listeriosis and at the same time is seldom found in foods.

Although from time to time, some non-virulent mutants lacking certain virulence properties have been isolated from foods and the environment (Tabouret et al., 1991; Strom, 1998), no general correlation between origin (human, animal, category of food, environment) or typing characteristics (serotype, phage type, ribo-type, etc.) and virulence has been established. Thus, as extensive investigations have failed to find systematic differences in virulence between food isolates that have not been implicated in listeriosis, and clinical isolates, all *L. monocytogenes* strains should be considered pathogenic.

Virulent strains of *L. monocytogenes* may invade the gastrointestinal epithelium and enter phagocytic host cells, where the bacteria are able to survive and multiply, thereby permitting access to the brain or the fetus in pregnant women. The incubation period varies from about 1 day to 6 weeks. Serious cases are manifested by septicaemia and meningitis and may result in death. The highest incidence is among individuals at increased risk due to alterations or deficiencies in the normal immune response as a result of immunosuppressive drugs, cancer, AIDS, etc. The very young and the very old may also be affected and the unborn child is particularly at risk, because listeriosis may lead to abortion, stillbirth or septicaemia and meningitis in neonates. Cases of gastrointestinal illness following ingestion of the organism have recently been documented (Salamin et al., 1996; Dalton et al., 1997; Aureli, 1998).

There is no experimental dose response data on humans available for *L. monocytogenes*, i.e., the minimum infective dose of *L. monocytogenes* for humans is unknown. However, analysis accompanying epidemiological investigations have indicated that foods implicated in both sporadic cases of listeriosis and outbreaks, typically have had elevated levels of the pathogen. Furthermore, foods which have been implicated in human outbreaks of listeriosis, have always been foods which are known to support growth of the pathogen. In addition, most people regularly ingest foods containing low num-
bers of \textit{L. monocytogenes} without becoming ill and there is little suggestion that an accumulative effect is significant. From animal experiments we know that \textit{Listeria} infections are dose dependent and that the ID$_{50}$ is rather high, above $10^3$ in different models for intragastrial inoculation (Schlech III et al., 1993; Notermans et al., 1998). However, we do not know exactly how to extrapolate these data to humans. New approaches using dose–response models based on probability distributions have been introduced (Farber et al., 1996; Buchanan et al., 1997) but it should be kept in mind that such models are also based on assumptions of infective dose and consumption patterns rather than on scientific data (see Section 5).

4. Exposure assessment

\textit{Listeria monocytogenes} is widespread in nature and can be found as a transient resident of the intestinal tract of humans and animals and in fish, meat, milk, vegetables, etc. It can survive and grow on food production lines and in the production environment, especially in difficult-to-clean equipment and production areas. In addition, surveys indicate that \textit{L. monocytogenes}, to some extent, is present in a variety of ready-to-eat (RTE) foods, including smoked fish, soft cheeses, lightly preserved meat products, heat treated meat products, etc.

\textit{Listeria monocytogenes} can grow in the presence or absence of air and in foodstuffs at pH values between 4.5 and 9.2, at water activities above 0.92 and at temperatures between 0 and 45°C, when other conditions in the food are optimal for growth. \textit{L. monocytogenes} is also able to grow in the presence of high salt concentrations. Growth rate of \textit{L. monocytogenes} in foods can be calculated using different predictive modeling programs, such as, “Food MicroModel” from the UK or the US Department of Agriculture’s Pathogen Modeling Program. \textit{L. monocytogenes} is relatively heat resistant, but the organism is killed by a normal pasteurization process. The organism may survive for long periods of time in frozen or dried foods.

In the last few years, several surveys have provided knowledge of both the qualitative and quantitative presence of \textit{L. monocytogenes} in a wide variety of foods (Teufel and Bendzulla, 1994; Andersen and Nörrung, 1995). However accurate data on individual consumption patterns for many RTE foods are generally not available. Disappearance data exist for a number of foods and has been used in health risk assessments of \textit{L. monocytogenes} (Farber et al., 1996).

5. Risk characterization

In conclusion, scientific information currently available indicates that foodborne listeriosis is associated with products in which initial levels of the pathogen have increased due to conditions supporting growth. There is little evidence that consumption of low levels ($< 100 / g$) of the organism in foods pose a health risk even in susceptible individuals.

To date, a formal risk assessment has not been carried out to establish the relationship between risk of foodborne listeriosis and the levels of \textit{L. monocytogenes} in various products. Furthermore, risk assessment is complicated as human volunteer feeding studies are not available. As an alternative approach, Van Schothorst (1996) used German data on the levels of \textit{L. monocytogenes} in smoked fish (Teufel and Bendzulla, 1994) to estimate the risk of foodborne listeriosis in individuals with increased risk in Germany. It was assumed that all cases of listeriosis in Germany (estimated 300 cases of listeriosis for a population of 83 million) were attributable to ready to eat smoked fish containing $> 10000$ cfu \textit{L. monocytogenes} /g, that the normal serving size is 100 g, and that up to 20% of the population may be immunocompromised at any time. Based on these assumptions Van Schothorst (1996) estimated the risk of an immunocompromised individual acquiring listeriosis from such a heavily contaminated portion of smoked fish at 1 in 6000. The corresponding estimated risk for a product containing $< 100$ cfu /g would be 1 in 100 000. Buchanan et al. (1997) felt that this latter value was overly conservative due to the exponential character of dose–response relations, and that based on the same assumptions as Van Schothorst, the probability of acquiring listeriosis from a serving of smoked fish containing 100 cfu /g was less than 1 in 1 000 000. It should be noted that both estimates of risk are based on a series of conservative assumptions and that the actual risk of
acquiring listeriosis is likely to be even less by one or more orders of magnitude.

6. Consideration of risk assessment results

The criteria for *L. monocytogenes* in foods, as they presumably will be proposed in Codex, can be seen in Fig. 1.

From available data on risk assessment, it is concluded that the levels of *L. monocytogenes* consumed is an important factor affecting the incidence of listeriosis. Foods that do not support the growth of *L. monocytogenes* are unlikely to be a source of listeriosis, whereas foods that support the growth to high levels, should be the target of risk management efforts. There is very little data to suggest that low levels of *L. monocytogenes* in foods cause listeriosis.

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**Fig. 1. Listeria monocytogenes criteria for foods in international trade (proposal).**
High numbers may, however, pose an unacceptable risk even to healthy persons. Based on current epidemiological information from several countries, a concentration of *L. monocytogenes* not exceeding 100/g of food at the time of consumption is of low risk to the consumers. In order not to exceed these levels at the point of consumption, for those foods in which growth can occur lower levels may need to be applied at the port of entry. In order to establish such levels, knowledge of the shelf life and behavior of *L. monocytogenes* in the food during prevailing storage and distribution conditions is needed.

References


