codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 390 6 57051 Telex: 625825-625853 FAO I Email codex@fao.org Fax: 39 06 5705.4593

Agenda Item 10 **CX/FH 99/10**

October, 1999

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-second Session
Washington, D.C., USA, November 29 – December 4, 1999

DISCUSSION PAPER ON MANAGEMENT OF *LISTERIA MONOCYTOGENES* IN FOODS[1]

(Prepared by the Delegation of Germany with assisstance of Austria, Denmark, France, Japan, Norway, the United Kingdom, the European Commission and International Commission on Microbiological Specifications for Foods (ICMSF)

Background Information

The issue on various aspects of control of *Listeria monocytogenes* had been on the Provisional Agenda of the Committee on Food Hygiene (CCFH) since its 23rd Session when it had requested the delegations of the Federal Republic of Germany and the Netherlands to prepare a paper of existing recommendations made by various expert groups on *Listeria monocytogenes* in Foods for review by the Committee (ALINORM 89/13, para 96.) The 24th Session of the CCFH agreed to issue a Circular Letter to gather information on *Listeria monocytogenes* with intention to prepare a working paper (ALINORM 91/13, para. 103).

The 25th Session of the Codex Committee on Food Hygiene (ALINORM 93/13, paras 72-76) considered the national and expert recommendation on the control of *Listeria monocytogenes* and applicable quantitative tolerances in foods. The Secretariat summarized the control strategies for *Listeria monocytogenes.* There was considerable discussion within the Committee on the appropriateness of establishing quantitative tolerances for *Listeria* in food. It requested that member countries provide the allowed national tolerances for *Listeria* in foods and sampling plans and methodologies which were used for consideration at the Committee's next Session.

The 26th Session of the Committee (ALINORM 93/13A, paras 81-86) noted that the member country's allowable tolerances for *Listeria* in foods ranged from zero in ready-to-eat foods to low levels in foods that did not support its growth. It also noted that some member countries have set the tolerance for *Listeria* based on the type of food and "use by date" on the labels of the food. The Committee concluded that there is insufficient data and inadequate scientific consensus to establish quantitative tolerances for *Listeria*. The Committee also noted the ICMSF paper entitled "Decision Tree Approach to the Control of *L. monocyotoges"* and decided to circulate it. Additionally, the Committee requested governments to make specific proposals to control *Listeria* in foods that are

---

[1] Prepared for the consideration on the Proposed Draft Recommendations for the Control of *Listeria monocytogenes* in Foods in International Trade

traded internationally. It also requested member countries to provide measures that they have taken at the national level to reduce *Listeriosis*.

At the 27th Session (ALINORM 95/13, para 86-94), as per Committee's request, ICMSF presented a revised paper entitled "Decision Tree Approach to the Control of *L. monocyotoges* ." Some Delegations disagreed with steps proposed in the "decision tree" approach also the concern was expressed regarding the establishing separate levels of protection for different groups of consumers. The Committee noted significant variations in the national allowable tolerances for *Listeria which* in ready-to-eat foods ranged from zero to 100 cfu/gm. Several delegations as a matter of concern raised the reliability of test methods for enumeration of the organism. Some delegations expressed their disappointment that the Committee was unable to accept ICMFS decision tree approach. The Committee requested the ICMSF to revise the discussion paper based on the views expressed by the delegates. In addition, the Committee requested the ICMSF to address trade issues and various national tolerances for *Listeria,* and to incorporate a harmonized HACCP based approach to control *Listeria* in food.

At the 28th Session of the Committee (ALINORM 97/13, paras 46-50), ICMSF presented a revised paper to address the Committee recommendations presented at the 27th Session. The revised paper included a harmonized approach on the certification of HACCP based procedures for use in trade for the control of *Listeria monocytogenes*. Some of the issues identified at this Session were: the inappropriateness of a tolerance level of 100 cfu/gm for *Listeria,* and the lack of definition of foods that have potential to support *Listeria* growth. It was expressed concern that the paper did not address the issue of how to assess safety of imported foods of unknown history. It was pointed out that the sampling plan specified in the paper did not provide a high confidence level in the detection of *Listeria*. The Committee requested ICMSF to redraft the document and to include background papers on criteria (tolerances in foods) for *Listeria monocytogenes, Salmonella* with special reference to *S. entreditis*, C*ampylobacter* and entero-haemorrhagic *E. coli*.

At the 29th Session, while considering the Establishment of Sampling Plans for Microbiological Safety Criteria for Foods in International Trade, ICMSF presented the paper that included the Committee's recommendations on the inclusion of other pathogens. The Committee at the same Session later reversed itself and agreed to elaborate a document addressing issues on *Listeria* and not to include other food pathogens in this text. The Committee agreed to ask the Delegations of Germany, with assistance from Denmark and the United States, to finalize the Section of the document on *Listeria monocytogenes* and to circulate under an appropriate title for comments by governments with the understanding that the document would provide a model format to followed to address the other pathogens (ALINORM 97/13A, para 52).

The Committee did not discuss the revised text on the control of *Listeria monocytogenes* at its 30th Session because of lack of time and/or the unavailability of the document for circulation. At the 31st Session of the Committee the Delegation of Germany informed the Committee that it was prepared to continue to develop a discussion paper including some elements of risk assessment and recommendations for the control of *Listeria monocytogenes.* The Committee noted that the Delegation of Denmark had presented a paper on this issue under CRD 3 and was prepared to assist in this work.

The current text is prepared with the intention that it may serve as a model text for future work on other food-borne pathogens.

The Committee is invited to consider the discussion paper and the opportunity of placing it in the formal Codex Step procedure (see Annex).

Annex

MANAGEMENT OF *LISTERIA MONOCYTOGENES* IN FOODS

1 INTRODUCTION

Listeria monocytogenes (L. monocytogenes) is a bacterium that occurs widely in both the agricultural (soil, plants and water) and food processing environment. The bacterium is resistant to various environmental conditions such as high salt or acidity (Ryser and Marth, 1991). *L. monocytogenes* grows at low oxygene conditions and refrigeration temperatures, and survives for long periods in the environment, on foods, in the processing plant, and in the household refrigerator. Although frequently present in raw foods of both plant and animal origin, it also can be present in cooked foods due to post-processing contamination. *L. monocytogenes* has been isolated in such foods as raw and pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice-cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types) and raw and smoked fish (Farber and Peterkin, 1991; Ryser and Marth, 1991). Even when *L. monocytogenes* is initially present at a low level in a contaminated food, the organism can multiply during storage, including storage at refrigeration temperatures.

It is well established that ingestion of *L. monocytogenes* can cause serious human illness, i.e., listeriosis (Rocurt and Cossart, 1997; Farber and Peterkin. 1991; Ryser and Marth, 1991). Although serious, listeriosis is a relatively rare foodborne illness. Most cases of listeriosis occur in pregnant women or individuals with a predisposing disease (such as alcoholism, diabetes, cirrhosis of the liver) or an impaired immune system resulting from either a disease (such as AIDS) or immuno-suppressive treatment for a malignancy or an organ transplant (Rocurt and Cossart, 1997).

Based upon the known characteristics of the microorganism and the disease some countries (USA, Italy) maintain a policy of „zero-tolerance“ for *L. monocytogenes* in ready-to-eat foods. Because the documented prevalence of *L. monocytogenes* in people and in commonly eaten foods is much higher than the documented incidence of listeriosis, some experts believe that the ingestion of low levels of *L. monocytogenes* may not result in illness and thus, may not constitute a general public health hazard (Farber et al, 1996; ICMSF, 1994). Several countries have concluded that while a complete absence of *L. monocytogenes* (zero tolerance) may be a commendable goal, for certain foods it is an unrealistic and unattainable requirement, that limits trade without having a positive impact on public health. A WHO expert panel came to the same conclusion (WHO, 1988). The levels of *L. monocytogenes* associated with “unavoidable” contamination of these products are typically low, and the risks are minimal if multiplication does not, or cannot, occur during storage, distribution and preparation.

Therefore, a slightly different approach to *L. monocytogenes* contamination is taken by other countries. Relying upon their interpretation of the existing scientific data, countries such as Canada and Denmark have a „non-zero-tolerance“ for *L. monocytogenes* for some classes of foods (ICMSF, 1994). For example, in Canada ready-to-eat foods that have not been associated with an outbreak and do not allow any growth of *L. monocytogenes* during a 10-day period of refrigerated storage may contain up to 100 *L. monocytogenes* per gram without being considered unlawful. But a zero tolerance is required for such food supporting growth of *L. monocytogenes* within an extended shelf life. Denmark has 6 classes of foods that have to meet different criteria for *Listeria monocytogenes*. For example, in raw ready-to-eat foods, 2 of 5 samples can contain between 10 and 100 organisms per gram, but no sample has to exceed 100 organisms per gram (Denmark, 1998).

The different approaches towards the evaluation of Listeria require an agreement on microbiological criteria for *L. monocytogenes* in foods in international trade under special considerations of risk assessment.

2 LINKAGE

This background paper on management of *L. monocytogenes* in foods is linked to following documents:

(a) Documents of the Codex Committee on Food Hygiene:

- Report of the 31st Session of the Codex Committee on Food Hygiene (ALINORM 99/13A)
- Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment (at step 8 of the procedure)
- Danish Government: discussion paper for the Codex Committee on Food Hygiene on „The Control of *Listeria monocytogenes* in Foods“ (28th August 1998)
- Discussion paper on recommendations for the management of microbiological hazards for foods in international trade, prepared by France (edited by the CCFH secretariat, CX/FH 97/10, August 1998)
- „Establishment of sampling plans for microbiological safety criteria for foods in international trade“. Document prepared by the ICMSF for the Codex Food Hygiene Committee (September 1996)
- Annex to Codex document on Establishment of sampling plans for *Listeria monocytogenes* in international trade (submitted by the ICMSF secretariat to the Codex FH Committee, September 1996)

(b) „Risk management and food safety“. Report of a joint FAO/WHO Consultation, Rome, Italy, 27 to 31 January 1997. FAO Food Nutrition Paper 65, Rome 1997

3 SCOPE

The document gives guidelines for the management of *L. monocytogenes* in foods in [international] trade based on considerations of risk assessment and risk management options and will recommend microbiological criteria.

4 MICROBIOLOGICAL RISK EVALUATION

4.1 IDENTIFICATION OF A SPECIFIC FOOD SAFETY PROBLEM

Available epidemiological data show single cases and outbreaks of listeriosis. During recent years, the incidence of listeriosis in most countries has not increased, and in a number of countries the incidence appears to have decreased (Tappero et al., 1995; Rocourt, 1996). In most countries, the reported incidence is 2 to 7 cases per million inhabitants. Transitory increases in incidence rates have been noted in several countries. These have been associated typically to foodborne outbreaks attributed to specific foods, often from specific manufacturers (Gilbert et al., 1993; McLauchlin, 1991; McLauchlin et al., 1991). Even at the height of such outbreaks, listeriosis is still a relative rare

disease, having an attack rate of 0.8 to 2 cases per 100,000 people (Broome et al., 1990). The incidence rates for listeriosis returned to prior baseline values after the causative food was removed from the market and consumers received effective public health information pertaining to appropriate food choices and handling practices (Roberts, 1994).

Apparent reductions in the baseline levels of listeriosis have been observed during the past several years. This likely reflects the world-wide efforts of industry and governments (a) to implement GMPs and apply HACCP to reduce the frequency and extent of Listeria in industrially processed foods, (b) to improve the integrity of the cold chain to reduce the incidence of temperature abuse conditions that foster the growth of *L. monocytogenes*, and (c) to enhance risk communication, particularly for consumers at increased risk of listeriosis (ICMSF, 1996).

Listeriosis is recognized as a foodborne disease. The connection with consumption of food is well established. Several types of foods have been implicated in foodborne disease cases or outbreaks, such as packaged coleslaw mix (Canada, 1982), Mexican style cheese (USA, 1985), pate (United Kingdom, 1987-88), cheese (Switzerland, 1983-87), pork tongue delicatesse (France, 1992), pork „rillettes“ (France, 1993), smoked mussels (Australia, 1991, New Zealand, 1992) and hot dogs (USA, 1998).

Analyses accompanying epidemiological investigations have indicated that foods implicated in both sporadic cases and outbreaks have typically had elevated levels of the pathogen due to the growth of the microorganism in the food at some time prior to the food being consumed (ICMSF, 1996). Public health agencies have concluded that the levels of *L. monocytogenes* consumed is an important factor affecting the incidence of listeriosis (Pinner et al., 1992). Foods that do not support the growth of *L. monocytogenes* are unlikely to be a sources of listeriosis, whereas foods that support the growth to high levels, should be the target of risk management efforts (Pinner et al., 1992). There is very little data to suggest that low levels of *L. monocytogenes* in foods, particularly in foods that do not support its growth, cause listeriosis.

The contention that foodborne listeriosis is associated with the consumption of foods with elevated levels of *L. monocytogenes* is supported by studies with animal models.

4.2 CONSIDERATION OF RISK INFORMATION

4.2.1 Hazard identification

L. monocytogenes is a facultative intracellular bacterial pathogen of both human and animals. It causes listeriosis in humans, with a variety of symptoms including mild diarrhoea, meningitis, and septicaemia (Marth, 1988). Epidemiological evidence suggest that most exposure is foodborne (Ciesielski et al., 1988; Broome et al., 1990; Farber and Peterkin, 1991; McLauchlin, 1993). Although listeriosis occurs infrequently at somewhere between 2 and 7 cases per million of the population, between 20 and 30% of both epidemic and sporadic cases are fatal (McLauchlin, 1993; Rocourt, 1994). The fatality rate is higher (up to 38 - 45%) in highly susceptible individuals, such as immunosuppressed people, including pregnant women, newborns, immunocompromized patients and the elderly people, whereas it is lower in persons without predisposing factors (Büla et al., 1995). In addition, *L. monocytogenes* is found in many different foods (Farber and Peterkin, 1991; Archer, 1996, Gilbert, 1995; Pinner et al., 1992; Teufel und Bendzulla, 1993).

Serotyping distinguishes 13 serovars of *L. monocytogenes*, but cases of human listeriosis are caused mainly by only three serotypes (4b, 1/2a and 1/2b). Most outbreaks of human listeriosis and a great percentage of the sporadic cases have been caused by the serovar 4b. In contrast, serogroup 1/2

strains seem to be more often recovered from food (Pini and Gilbert, 1988; Schoenberg et al., 1989; Kerr et al., 1995).

This broad based prevalence in the food system, together with a high mortality rate of listeriosis, suggests that *L. monocytogenes* represents an important emerging hazard threat to human health.

4.2.3 Hazard characterization

Serious cases are manifested by septicaemia and meningitis, and may result in death. The highest incidence is amongst individuals at increased risk due to alterations or deficiencies in the normal immune response as a result of immunosuppressive drugs, cancer, AIDS, etc. Data collected in France indicated that patients at higher risk among non-pregnancy related cases are organ-transplantation recipients (200 cases/100,000 recipients), patients suffering from cancer (13/100,000 patients) and individuals aged more than 65 years without known underlying diseases (14/100,000 individuals). Data of U.S.A. indicated incidence of listeriosis among HIV-infected patients with 52 cases per 100,000 and among AIDS-patients with 115 cases per 100,000 patients (Jurado et al., 1993).

The very young and the very old human beings may also be affected, and the unborn child is particularly at risk, because listeriosis may lead to abortion, stillbirth, or septicaemia and meningitis in the neonate. The incidence of pregnancy-related listeriosis has been reported as 4.7 to 30 cases per 100,000 live birth (Jones et al., 1994; Nolla-Salas et al., 1993).

Cases of mild gastrointestinal illness following the ingestion have recently been documented. The actual number is unknown, but mild diarrhoea-type episodes can occur, as evidenced by several recent outbreaks outside Canada (Riedo et al., 1994; Proctor et al., 1995).

Virulent strains may invade the gastrointestinal epithelium and enter phagocytic host cells, where the bacteria are able to survive and multiply. Their intracellular presence permits access to the brain and probably to the fetus in pregnant women. The incubation period varies from about 2 days to 6 weeks.

The role of healthy carriers in the epidemiology of listeriosis has not been elucidated. It may be excreted by patients suffering on listeriosis during the long incubation period or by certain individuals where the pathogen may persist without clinical symptoms leading to continued risk of spread and infection. As noted, although the incidence of listeriosis is relatively low and the consequence of an infection may be severe, an estimated 2 to 6 percent of the healthy population harbours *L. monocytogenes* in their intestinal tract without signs of illness (Rocourt and Cossart, 1997). A microbiological examination of stool-samples of food handlers in Switzerland indicated that 13 out of 1730 stool-samples (= 0.75%) were positive for *Listeria spp.* (Stefan and Untermann, 1998).

All *L. monocytogenes* strains should be considered as potentially pathogenic for humans. No correlation between origin (human, animal, food, environment) or typing characteristics (serovar, lysotype, ribovar, DNA macrorestriction patterns etc.) and virulence has been established (WHO, 1995).

Differences in virulence are observed. Serotype 4b contains more virulent and the serotypes 1/2a and 1/2b contain less virulent strains. To date, nothing is known about changes in virulence of these pathogens due to interaction with the host and the environment or due to transfer of genetic material between microorganisms. Virulence factors like haemolysis gene are known but do not reflect the pathogenicity of *L. monocytogenes* conclusively. In addition, up to date virulence factors identified in animal models are not suitable to differentiate *L. monocytogenes* strains with respect to infectivity or

severity of disease. Due to this unresolved problems all *L. monocytogenes* strains are assumed to be pathogenic, and the following calculations are done on this conclusion. Special food attributes that may alter the microbial pathogenicity of *L. monocytogenes* are not known.

4.2.3.1 Dose-response assessment

There are no experimental dose response data for humans available, i.e., the minimum infective dose (MID) of *L. monocytogenes* for humans is unknown. However, analyses accompanying epidemiological investigations have indicated that foods implicated in both sporadic cases and outbreaks have typically had elevated levels of the pathogen in the food at some time prior to consumption (**table 1**, ICMSF 1996). Furthermore, foods that have been implicated in human listeriosis outbreaks have always been foods in which the growth of *L. monocytogenes* during storage is supported.

In addition, widespread occurence of *L. monocytogenes* in foods harbouring low numbers of *L. monocytogenes* indicate that many people ingest a lot of such food without getting ill.

There is no information, whether accumulating effects exist, when different contaminated foods are consumed.

Animal experiments show, that the listeria infection is dose-depending and that the ID_{50} is rather high, above 10^5, in different models for intragastral inoculation (Amtsberg, 1980; Schlech et al., 1993; Notermans, 1995). However, extrapolation of mouse data to the human situation is tenuous, at best.

New approaches using dose-response models based on probability distributions have been introduced, but it should be kept in mind that also such models are based on assumptions of infective dose and consumption patterns.

Three groups of investigators have constructed dose-response relationships for *L. monocytogenes* (Bemrah et al., 1998):

- the Weibull-Gamma (WG) model for a susceptible population (Farber et al., 1996), assuming reference ID_{10} and ID_{50} levels of response of 10^5 and 10^7 CFU, respectively,
- the exponential model based on data for a susceptible population (Buchanan et al., 1997), combining epidemiological data with food survey data on *L. monocytogenes* in foods and
- the Beta-Poisson (BP) model of infectivity fit to data from mouse feeding studies (Haas, 1998).

4.2.4 Exposure assessment

L. monocytogenes is widespread in nature and can be found in soil, silage, sewage and the faeces of humans and animals. 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, microbiological surveys indicate that *L. monocytogenes* is present in a variety of foods, including meat products, smoked fish products, milk, cheese and "ready to eat" products. There is a high exposure of people with *L. monocytogenes* and other *Listeria spp.* .

L. 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 degrees Celsius, when other conditions in the food are optimal for growth. *L. monocytogenes* is able to grow in the presence of high salt-concentrations (up to 10% NaCl). It may also survive for long periods of time

in frozen or dried foods. Conclusively, high numbers of *L. monocytogenes* occur after growth in certain foods during storage.

Exposure assessment comprises data about prevalence or levels of *L. monocytogenes* in foods and consumption data of these foods. Specific food consumption databases give information on type and amounts of products eaten, gender, age etc. of the population and individuals depending on the depth of surveys. Surveys on the prevalence or levels of *L. monocytogenes* in foods reveal products of concern in particular those which promote the growth of *L. monocytogenes* during storage, distribution and sale. These data are supplemented by general data on the potential fate of *L. monocytogenes* in a specific commodity.

In summary, the available data fulfil to a large extent the requirements for a risk assessment as layed down in ALINORM 99/13, Appendix III.

4.2.5 Risk characterization in relation to specific food groups

In conclusion, scientific information currently available indicates that foodborne listeriosis is a disease associated with products in which initially low levels of the pathogens have increased due to conditions supporting growth. There is little evidence that consumption of low levels (<100/g) of the microorganism in foods that do not support its growth cause listeriosis. Further, estimates based on available data indicate that the risks associated with such products are low, even for the immunosuppressed segments of the population.

To date, a formal risk assessment has not been carried out to establish the relationship between risk of foodborne listeriosis and the levels of *L. monocytogenes* in various products. This reflects the fact that there have not been, nor are there likely to be, human volunteer feeding studies with this microorganism. As an alternative approach, smoked fish data (Teufel und Bendzulla, 1993) were used to estimate the risk of foodborne listeriosis in individuals with increased risk in Germany (Van Schothorst, 1995). 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 >10,000 cfu *L. monocytogenes*/g, that the normal serving size is 100g, and that up to 20% of the population may be immunosuppressed at any time. Based on these assumptions van Schothorst (1995, 1996) estimated the risk of an immunosuppressed 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 over-conservative due to the exponential character of dose-response relations, and that 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 the actual risk of acquiring listeriosis is likely to be even less by one or more orders of magnitude.

A more detailed evaluation in Germany, based on additional consumption and demographic data support these calculations.

4.3. CONSIDERATION OF RISK ASSESSMENT RESULTS

Many of the foods on the market (such as those containing raw ingredients or which are subjects to some form of portioning or maturation process after processing) will, from time to time, contain low numbers of *L. monocytogenes*. Many such foods will be cooked during preparation for consumption, so there will be no health concern. Moreover, epidemiological evidence indicates that the ingestion of low numbers of *L. monocytogenes* does not pose a significant health risk to the general public. High numbers may pose an unacceptable risk even to healthy persons. The criteria for

L. monocytogenes in foods, as they presumably are proposed in this document (**figure 1**) will reflect these facts and considerations. In addition, efficient management strategies should include guidelines for the selection and safe handling of foods by highly susceptible individuals.

5 MICROBIOLOGICAL RISK MANAGEMENT OPTIONS ASSESSMENT

[According to the French discussion paper on recommendations for the management of microbiological hazards for foods in international trade (edited by the CCFH secretariat, CX/FH 97/10, August 1998] there are many different approaches to managing microbiological risks for people at risk such as:

- avoiding foods with a substantiated history of contamination;
- preventing contamination and/or introduction of *L. monocytogenes* at any stage in the food chain;
- introducing measures to reduce the level of specific *L. monocytogenes* in primary production;
- preventing growth of pathogens by the combined action of extrinsic factors (e.g. chilling or freezing) and/or intrinsic factors (e.g. adjusting pH and a_w; adding preservatives; orientating microbiological competition);
- destroying *L. monocytogenes* (e.g. cooking, high pressure);
- establishing microbiological standards or other criteria and enforcing compliance;
- establishing regulatory requirements and/or creating incentives for changes in attitude that will contribute to risk reduction, for instance by developing food safety assurance schemes (e.g. HACCP), by allowing operators to trade among themselves the stringency of such schemes and the microbiological quality of the products they buy or sell;
- educating / informing the population at large or affected sub-groups about the steps they can take to reduce risks.

Most of the time, a combination of options will be more effective in reducing risks.

GENERAL PRINCIPLES OF FOOD HYGIENE AND HACCP

Application of the "International Code of Practice-General Principles of Food Hygiene" (CAC/RCP 1-1969, Rev. 3 (1997)) and in particular the HACCP principles "from farm to fork", as Annexed to the "General Principles of Food Hygiene" are the most effective means to control *L. monocytogenes* and hence to prevent listeriosis. Timely action, taken in case of a deviation at a critical control point (CCP) will reduce the risk that defective products reach the consumer. Analyzing samples of end-products may provide some additional information concerning the microbiological status of the product but will not guarantee safety. Thus, health authorities and industry should base control of *L. monocytogenes* on the proper application and verification of HACCP and GHP.

MICROBIOLOGICAL CRITERIA

Imported foods should in principle be treated in the same manner as those produced in the domestic market. As stated above, the safety of products should be assured by application and implementation of the HACCP principles and GHP in the country of origin. Moreover, codes developed for regulating the import and export of foods should be adhered to. However, when there is no assurance that the HACCP principles and GHP were correctly applied and implemented, inspection and analysis of imported lots may be indicated. In this instance the following criteria could be applied.

Microbiological criteria should be developed according to the "Principles for the Establishment and Application of Microbiological Criteria for Foods" (CAC/GL 21 - 1997). Based on current epidemiological information from several countries (see annex), a concentration of *L. monocytogenes* not exceeding 100/g of food at the point of consumption is of low risk to the consumers. However, for a food specifically intended for consumption by clearly identifiable vulnerable groups (high risk groups) e.g. geriatric foods, baby foods, enteral foods absence in 25g in a certain number of sample units should be achieved. 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. In order to establish such levels, knowledge of the behaviour of *L. monocytogenes* in the food at the prevailing storage and distribution conditions is needed; the use of predictive models may be helpful (Buchanan and Philips, 1990).

In order to determine the number of sample units within a lot that should comply with these limits, the recommendations prepared by ICMSF (1997) for Codex purposes have been applied. These considerations have been used to construct a decision tree (**figure 1**). The criteria proposed should be achievable by products produced according to good hygienic practices (GHP) and under a system for control based on HACCP.

6 IMPLEMENTATION

These general recommendations are in line with Codex and the requirements of international trade.

7 MONITORING AND REVIEW

For appropriate monitoring and review of *L. monocytogenes* it is important to focus on the whole food chain from farm to table. When producing data from foods it is important to relate these data to quality assurance in the laboratories. The use of stated different methods is also of concern. Only validated methods of enumeration of *L. monocytogenes* should be used (e.g. ISO 11290-1:1996 and ISO 11290 -2:1998).

During recent years, the incidence of listeriosis in most countries has not increased, and in a number of countries the incidence appears to have decreased. In most countries, the reported incidence is 2 to 7 cases per million inhabitants. This rate is similar for countries that have a “zero” tolerance and those that have adopted quantitative criteria. Transitory increases in incidence rates have been noted in several countries. These have been associated typically to foodborne outbreaks attributed to specific foods, often from specific manufacturers. Even at the height of such outbreaks, listeriosis is still a relative rare disease, having an attack rate of 0.8 to 2 cases per 100,000. The incidence rates for listeriosis returned to prior baseline values after the causative food was removed from the marketplace and consumers received effective public health information pertaining to appropriate food choices and handling practices.

The control measures taken to reduce the incidence of listeriosis have apparently had an effect, regardless whether a „zero-tolerance“ or a less stringent policy was applied. In the light of this fact and other considerations mentioned in this report, it is recommended to review this policy, because it has caused unnecessary recalls and trade restrictions.

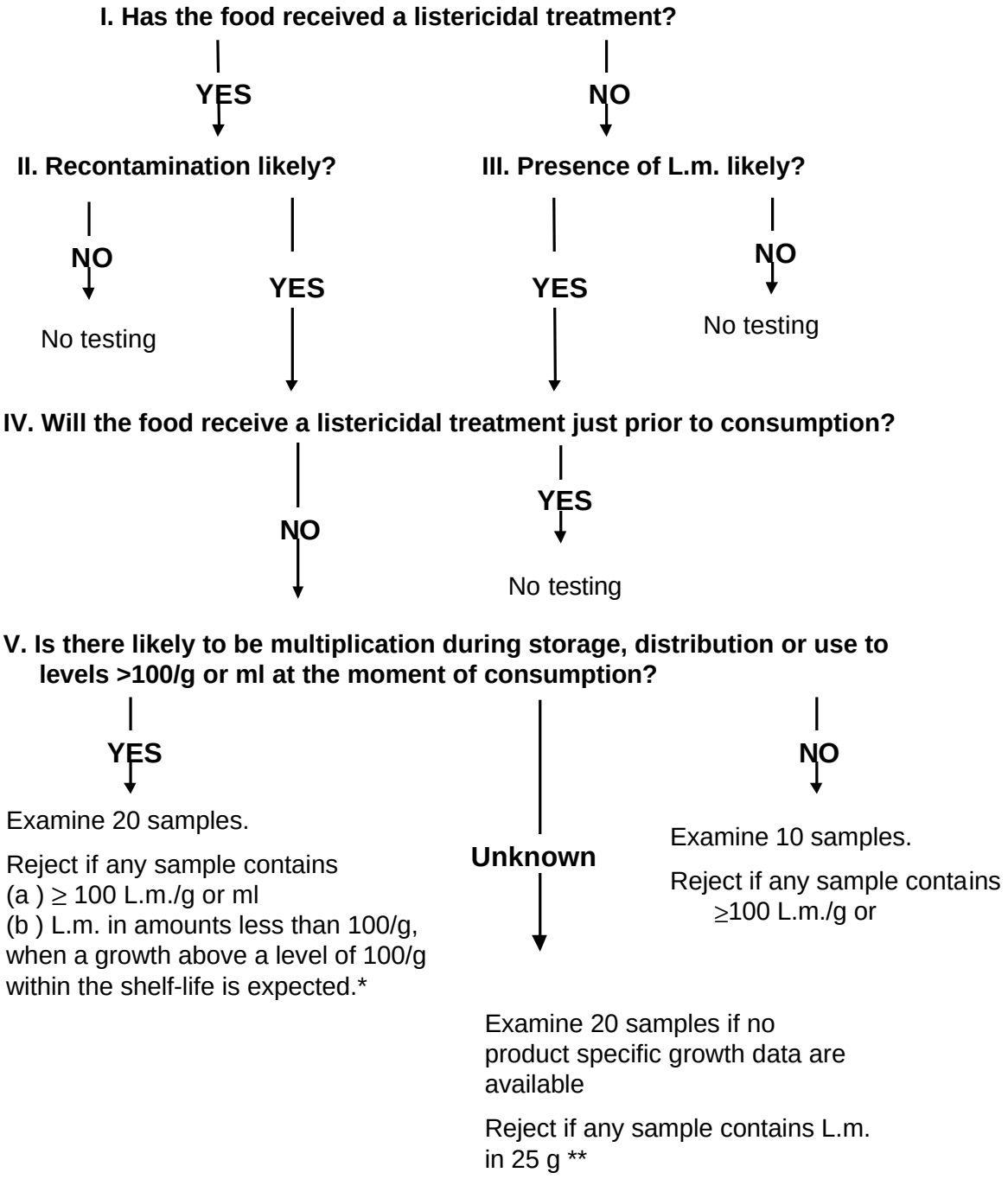
Analyses accompanying epidemiological investigations have indicated that foods implicated in both sporadic cases and outbreaks have typically had elevated levels of the pathogen due to the growth of the microorganism in the food at some time prior to the food being consumed. Public health agencies have concluded that the level 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, particularly in foods that do not support its growth, cause listeriosis.

Table 1:Levels of *Listeria monocytogenes* in foods causing listeriosis (ICMSF, 1996)

Country, year	No. of cases	Food	L.m./g	Sampling point *	Ref.
Switzerland, 1983-87	122	cheese	10^4 - 10^6	R	9, 37
United States, 1985	142	cheese	10^3 - 10^4	R	31
United Kingdom, 1988	1	cheese	10^7	R	7, 33
United Kingdom, 1987-88	> 300	paté	> 10^3	R	19, 35, 37
France, 1992	279	pork tongue, delicatessen	10^4 - 10^6 <10^2 - 10^4	R R	22, 46
France, 1993	39	pork “rillettes”	<10^2 - 10^4	R	3, 46
Finland, 1988	1	salted mushrooms	10^6	P	28
United States, 1988	1	turkey frank	> 10^3	P	57
Italy, 1988	1	sausage	10^6	P	14
Australia, 1991	2	smoked mussels	10^7	P	38
New Zealand, 1992	3	smoked mussels	10^3	P	37
United States, 1994	48	chocolate milk	10^8	P	24, 52

*** R : food from retailer, P : food from patient’s refrigerator**

Figure 1:*Listeria monocytogenes* (L.m.) : Sampling plans for foods in international trade



* this refers to the situation where product specific growth data indicate that the number of L.m. found in a sample might increase during the remaining shelf-life to amounts of =100/g;

** this refers to the situation where amounts of = 100/g at the moment of consumption are likely to be reached

NB: If the food is specifically intended for highly susceptible individuals, the number of samples should be increased from 10 to 30, and from 20 to 60; reject if any sample contains L.m. in 25 g.

REFERENCES

1 Amtsberg, G. (1980): Listerien. in: „Handbuch der bakteriellen Infektionen bei Tieren“, Vol. II, S. 345-410 (eds. Blobel, H. und Schliesser, T.) Gustav-Fischer-Verlag, Stuttgart, New York, 1980.

2 Anonymus: Establishment of sampling plans for microbiological safety criteria for foods in international trade. Document prepared by the ICMSF for the Codex Food Hygiene Committee.

3 Anonymous (1993). Epidémie de listériose à lysovar 2671/108/312 en France - Résultats préliminaires de l’enquête épidémiologique coordonnée par le Réseau National de Santé Publique. Bull. Epidémiol. Hebdom. 34, 157-158

4 Anonymus: International Standard ISO 11290-1:1996. Microbiology of food and animal feeding stuffs-Horizontal method for the detection and enumeration of *Listeria monocytogenes*. Part 1: Detection method.

5 Anonymus: International Standard ISO 11290-1:1996. Microbiology of food and animal feeding stuffs-Horizontal method for the detection and enumeration of *Listeria monocytogenes*. Part 2: Enumeration method.

6 Archer, D. (1996). Zero tolerance for Listeria in ready-to-eat food products: Can it be changed? Proceedings of the 22nd Annual ABC Research Technical Seminar. February 1996. Gainesville, Florida, U.S.A.

7 Azadian, B.S., Finnerty, G.T., and Pearson, A.D. (1989). Cheese-borne *Listeria meningitis* in immunocompetent patient. Lancet, February 11th, 322-323.

8 Bemrah, N., Sanaa, M., Cassin, M.H., Griffiths, M.W. and Cerf, O. (1998): Quantitative risk assessment of human listeriosis from consumption of soft cheese made from raw milk. Prev. Vet. Med. 37, 129-145.

9 Bille, J. (1989). Anatomy of a foodborne listeriosis outbreak. In: Foodborne Listeriosis (Proceedings of a Symposium on September 7, 1988 in Wiesbaden, FRG). B. Behr’s GmbH & Co., Hamburg. 29-36.

10 Broome, C.V., Gellin, B. and Schwartz, B. (1990). Epidemiology of listeriosis in the United States.
In: „Foodborne Listeriosis“. A.J. Miller, J.L. Smith and G.A. Somkuti (eds.), Foodborne Listeriosis. Society for Industrial Microbiology. Elsevier, Pub. Co. Amsterdam. 61-65.

11 Buchanan, R.L. and Phillips, J.G. (1990). Response Surface Model for Predicting the Effects of Temperature, pH, Sodium Chloride Content, Sodium Nitrite Concentration and Atmosphere on the Growth of *Listeria monocytogenes*. J. Food Prot. 53, 370-376.

12 Buchanan, R.L., Damert, W.G., Whitung, R.C. and van Schothorst, M. (1997). Use of epidemiologic and food survey data to estimate a purposefully conservative dose-response relationship for *Listeria monocytogenes* and incidence of listeriosis. J.Food Prot. 60. 918-922.

13 Büla, C.J., Bille, J., Glauser, M.P. (1995). An epidemic of food-borne listeriosis in Western Switzerland: description of 57 cases involving adults. Clin. Infect. Dis., 20, 66-72.

14 Cantoni, C., Balzaretti, C., and Valenti, M. (1989). Episodipo di listeriosi da consumo di insaccato. Arch. Vet. Ital. 40(2). 141-142.

15 Ciesielski, C.A., Hightower, A.W., Parsons, S.K. and Broome, C.V. (1988). Listeriosis in the

United States, 1980-1982. Arch. Intern. Med. 148, 1416-1419.

16 Farber, J.M. and Peterkin, P.I. (1991). Listeria monocytogenes, a food-borne pathogen. Microbiol. Rev. 55, 476-511.

17 Farber, J.M., Ross, W.H. and Hartwig, J. (1996). Health risk assessment of *Listeria monocytogenes* in Canada. Int. J. Food Microbiol. 30. 145-156.

18 Gellin, B.G. and Broome, C.V. (1989) Listeriosis. J. Am. Med. Assoc. 261, 1313-1320.

19 Gilbert, R.J., McLauchlin, J. and Velani, S.K. (1993). The contamination of paté by *Listeria monocytogenes* in England and Wales in 1989 and 1990. Epidemiol Infect. 110. 543-551.

20 Gilbert, R.J. (1995). Zero tolerance for *Listeria monocytogenes* in foods - is it necessary or realistic? in: Proceedings of the XII International Symposium on Problems of Listeriosis. Perth, Western Australia, 2-6 October 1995.

21 Gravani (1999) "Listeria in Food-Processing Facilities - Status of *Listeria monocytogenes* in Foods" in Listeria, Listeriosis and Food safety, edited by Ryser and E.H. Marth 1999. Marcel Dekker, Inc. New York

22 Goulet, V., Lepoutre, A., Rocourt, J., Courtieu, A.L., Dehaumont, P., Veit, P. (1993). Epidémie de listériose en France - Bilan final et résultats de l'enquête épidémiologique. Bull. Epidémiol. Hebdom. 4, 13-14.

23 Haas, C.N. (1998) A quantitative risk assessment model for *Listeria monocytogenes* and Escherichia coli O157:H7, Abstr. Pg 28, ILSI Symposium Series, Trends and Perspectives in Microbial Food Safety, IAMFES Annual Meeting, Nashville, TN.

24 Hayes, P. (1996). Personal Communication. Centers for Disease Control and Prevention.

25 International Commission on Microbiological Specifications of Foods (ICMSF): Annex to the Codex document on Establishment of sampling plans for *Listeria monocytogenes* in international trade (Submitted by the ICMSF secretariat to the Codex FH Committee, September 1996).

26 International Commission on Microbiological Specifications of Foods (ICMSF) (1994): Choice of sampling plan and criteria for *Listeria monocytogenes*. Int. J. Food Microbiol. 22, 83-96.

27 Jones, E.M. McCulloch, S.Y., Reevest, D.S. and MacGowan, A.P. (1994). A 10 year survey of the epidemiology and clinical aspects of listeriosis in a provincial English city. J Infect., 29, 91-103.

28 Junttila, J., Brander, M. (1989). *Listeria monocytogenes* septicaemia associated with consumption of salted mushrooms. Scand. J. Infect. Dis., 21, 339-342.

29 Jurado, R.L., Farley, M.M., Pereira, E., Harvey,R.C., Schuchat, A., Wenger, J.D. and Stephens, D.S. (1993). Increased risk of meningitis and bacteriemia due to *Listeria monocytogenes* in patients with human immunodeficiency virus infection. Clin. Infect. Dis., 17, 224-227.

30 Kerr, K.G., Kite, P., Heritage, J. and Hawkey, P.M. (1995). Typing of epidemiologically associated environmental and clinical strains of *Listeria monocytogenes* by random amplification of polymorphic DNA. J. Food Protec., 58, 609-613.

31 Linnan, M.J., Mascola, L., Lou, X.D., Goulet, V., May, S., Salminen, C., Hird, D.W., Yonekura, M.L., Hayes, P., Weaver, R., Audurier, A., Plikaytis, B.D., Fannin, S.L., Kleks, A., Broome, C.V. (1988). Epidemic listeriosis associated with Mexican-style cheese. New Engl. J. Med. 319, 823-828.

32 Marth, E.H. (1988) Disease characteristics of *Listeria monocytogenes*. Food Technol. 42, 165-168.

33 McLauchlin, J., Greenwood, M.H., and Pini, P.N. (1990). The occurrence of *Listeria monocytogenes* in cheese from a manufacturer associated with a case of listeriosis. Int. J. Food Microbiol. 10. 255-262.

34 McLauchlin, J. (1991). The epidemiology of Listeriosis in Britain. In „Proceedings of the International Conference on *Listeria* and Food Safety". Laval, France, June 13-14, 1991. A.Amgar, ed. ASEPT. 38-47.

35 McLauchlin, J., Hall, S.M., Velani, S.K. and Gilbert, R.J. (1991). Human listeriosis and paté - A possible association. Brit. Med. J. 303, 773-775.

36 McLauchlin, (1993) Listeriosis and *Listeria monocytogenes.* Environ. Policy Pract. 3, 201-214.

37 McLauchlin, J. (1995). The relationship between *Listeria* and listeriosis. Presented at: Listeria, the state of the science, Rome, June 1995.

38 Mitchell, D.L. (1991). A case cluster of listeriosis in Tasmania. Comm. Dis. Intel. 15, 427.

39 Nolla-Salas, J., Anto, J.M., Almela, M., Coll, P., Gasser, I., Plasencia,A. and the collaborative study group of listeriosis of Barcelona (1993). Eur. J. Clin. Microbiol. Infect. Dis., 12, 157-161.

40 Notermanns, S. (1995). Quantitative Risk Assessment Studies on Infections with *Listeria monocytogenes*. Presented at the XII International Symposium on Problems of Listeriosis. Perth, Western Australia, 2-6 October 1995.

41 Pini, P.N. and Gilbert, R.J. (1988). The occurence in the U.K. of *Listeria* species in raw chickens and soft cheeses. Int. J. Food Microbiol. 6, 317-326.

42 Pinner, R.W., Schuchat, A. Swaminathan, B. Hayes, P.S. Deaver, K.A., Weaver, R.E. Plikaytis, B.D., Reeves, M., Broome, C.V., Wenger, J.D. and the Listeria Study Group (1992): Role of foods in sporadic listeriosis. II. Microbiological and epidemiological investigation. J. Amer. Med. Assoc. 267. 2046-2050.

43 Proctor, M.E., Brosch, R., Mellen, J.W., Garrett, L.A., Kaspar, C.W., and Luchansky, J.B. (1995) Use of pulsed-field gel electrophoresis to link sporadic cases of invasive listeriosis with recalled chocolate. Appl. Environ. Microbiol. 61, 3177-3179.

44 Riedo, F.X., Pinner, R.W., Tosca, M.D., Cartter, M.L., Graves, L.M., Reeves, M.W., Weaver, R.E., Plikaytis, B.D. and Broome, C.V. (1994). A point-source foodborne listeriosis outbreak, Documented incubation period and possible mild illness. J. Infect. Dis., 170, 693-696.

45 Rocourt, (1994) *Listeria monocytogenes*, the state of the science. Dairy Food Environ. Sanit. 14,70-82.

46 Rocourt, J. (1996). Personal communication.

47 Rocourt, J. and Cossart, P. (1997): *Listeria monocytogenes*. In Doyle, M.P., Beuchat, L.R. and Montville, T.J. eds. Food Microbiology, Fundamentals and Frontiers. ASM Press, Washington, DC.

48 Ryser, E.T. and Marth, E.H. (1991): Listeria, listeriosis and food safety. Dekker, NY.

49 Schlech III, W.F., Chase, D.P. and Badley, A. (1993). A model of foodborne *Listeria monocytogenes* infection in Sprague-Dawley rat using gastric inoculation: development and

effect of gastric acidity on infective dose. Int. J. Food Microbiol. 18, 15-24.

50 Schönberg, A., Teufel, P. and Weise, E. (1989). Serovars of *Listeria monocytogenes* and *Listeria innocua* from food. Acta Microbiol. Hung. 36, 249-253.

51 Schroeter, A., Sommerfeld, G., Klein, H. and D. Hübner (1999). Warenkorb für das Lebensmittel-Monitoring in der Bundesrepublik Deutschland. Bundesgesundheitsbl., Gesundheitsforsch-Gesundheitsschutz, 42, 77-84.

52 Shank, F. (1995). United States Position on *Listeria monocytogenes* in foods. Presented at: Listeria, the state of the science, Rome, June 1995.

53 Stephan, R., Kühn K. and Untermann, F. (1998) Prevalence of *Salmonella* spp., *Campylobacter* spp., *Yersinia* spp., verotoxinogenic *Escherichia coli* and *Listeria* spp. in staff stool samples of food producing companies. in: Proceedings of the 4th World Congress on Foodborne Infections and Intoxications. Berlin, Germany, 7-12 June 1998.

54 Teufel, P. and Bendzulla, C. (1993). Bundesweite Erhebung zum Vorkommen von *L.monocytogenes* in Lebensmitteln. Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV).

55 Van Schothorst, M. (1995). Sampling Plans for *Listeria monocytogenes*. Presented at: "*Listeria*, the state of the science", Rome, June 1995.

56 Van Schothorst, M. (1996). Setting of Criteria for *Listeria monocytogenes* based on risk assessment.
In "Food Safety 1996", A. Amgar (ed.), ASEPT. Laval, 4 -6 June, France, 157-168.

57 Wenger, J.D., Swaminathan, B., Hayes, P.S. et al. (1990). *Listeria monocytogenes* contamination of turkey franks: Evaluation of a production facility. J. Food Protect. 53. 1015-1019.

58 WHO Report of the consultation on Emerging Foodborne Diseases, Berlin, Germany, 20-24 March 1995.