codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *Listeria Monocytogenes* IN FOODS[τ]

(Document prepared by Germany)

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.

[τ] **Secretriat's Note: Due to time constraints, written comments are not requested on the document.**

The 26th Session of the Committee (ALINORM 93/13A, paras 81-86) noted that the member country's allowable tolerances for *Listeria monocytogenes 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 monocytogenes* 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 monocytogenes*. 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 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 monocytogenes* 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 ICMSF 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 monocytogenes*, and to incorporate a harmonized HACCP based approach to control *Listeria monocytogenes* 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 monocytogenes* 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 monocytogenes*. 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. enteritidis*, *Campylobacter* 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 monocytogenes* 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 requested document was elaborated with assistance of Austria, Denmark, France, Japan, Norway, the United Kingdom and experts of the European Commission and the International Commission on Microbiological Specifications for Foods (ICMSF). It was at the 32nd session discussed and the Committee agreed to proceed with the elaboration of the document in two directions, as suggested by the Representatives of FAO and WHO, and supported by several countries: the matter (i.e. of *L. monocytogenes* in Ready to Eat foods) would be referred to the FAO/WHO Expert Consultation on risk assessment and the Delegation of Germany would prepare the Proposed Draft Guidelines for the Control of Listeria monocytogenes in Foods in accordance with the Principles and Guidelines for the conduct of Microbiological Risk assessment (i.e. Management, CX/FH 00/6) for circulation at Step 3 and for consideration by the next session of the Committee (ALINORM 01/13, para 121). Member countries and interested international organizations were invited to submit their comments.

Replies were received by two countries (Switzerland, Canada), these and the outcome of the FAO/WHO Expert Consultation on Risk Assessment were taken into consideration in drafting the present document. Although the document was not to be assigned to include a formal Risk Assessment it should consider Risk Assessment aspects. The document was meant to deal with the control of *L. monocytogenes* in foods with specific recommendations regarding Microbiological Criteria for *L. monocytogenes* in foods in international trade. In drafting this document it was assumed that the Risk Assessment of *L. monocytogenes* in Ready To Eat foods would add data to the sections dealing with the various aspects of Risk Assessment and that estimations of the risks of the consumption of low numbers of *L. monocytogenes* might become available, but that the CCFH still had to decide whether such risks would be acceptable (tolerable) or not. Moreover, the Risk Assessors would most probably not propose microbiological criteria, including sampling schemes, because establishing such criteria is a Risk Management activity to be decided upon by the Risk Managers in the CCFH. Consequently, the progress of this document is not directly related to the progress made by the FAO/WHO Expert Consultation on Risk Assessment.

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *Listeria Monocytogenes* IN FOODS[t]

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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 oxygen 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. 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 when the food supports growth. It is well established that ingestion of *L. monocytogenes* can cause serious human illness, i.e., listeriosis with potentially fatal consequences for susceptible categories of the population. Therefore, actions shall be taken to lower the risk of human listeriosis from food consumption.

Based upon the known characteristics of the microorganism and the disease some countries maintain a policy of „zero-tolerance“ for *L. monocytogenes* in ready-to-eat foods. 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. 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 was taken.

These different approaches towards the management of *L. monocytogenes* requires may lead to trade barriers that can and should be avoided, if the foods do not endanger a country's appropriate level of protection. This document provides data on which the CCFH and countries or regions can decide whether the presence of low numbers of *L. monocytogenes* in certain categories of food would be tolerable (acceptable) and proposes Microbiological Criteria that should prevent in the context of the WTO/SPS Agreement the establishment of unnecessary or unjustified trade barriers.

1 SCOPE

The document gives guidelines for the control of *L. monocytogenes* in foods in [international] trade based on considerations of risk assessment and lists a number of risk management options. Moreover Microbiological Criteria are proposed, if their establishment is decided upon.

2 DOCUMENTS USED

During the elaboration of these guidelines for the control of *L. monocytogenes* in foods the following documents were considered:

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

- Report of the 32nd Session of the Codex Committee on Food Hygiene (ALINORM 01/13)
- Principles and Guidelines for the Conduct of Microbiological Risk Assessment (ALINORM 99/13A, Appendix II)
- Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)

- Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Annex to CAC/RCP 1-1969, Rev. 3 1997).

- Danish Government: discussion paper for the Codex Committee on Food Hygiene on „The Control of *Listeria monocytogenes* in Foods“ (28th August 1998)

- Proposed Draft Principles and Guidelines for the conduct of microbiological risk management, CX/FH 00/6 July 2000

- „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

(c) Report of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. Rome, 17-21 July 2000.

3 DEFINITIONS

Microbiological Food Safety Objective –A statement [based on risk analysis] expressing the level of microbiological hazard in a food that is tolerable in relation to an appropriate level of protection [1].

Risk Management – The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed selecting appropriate prevention and control options [2].

[Management Options - different approaches to managing microbiological risks.]

Microbiological Criterion – A microbiological criterion for food defines the acceptability of a product or a lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot[3].

4 INVOLVEMENT OF STAKEHOLDERS

[The management of *L. monocytogenes* in foods needs to involve parties along the whole food chain, i.e. food producers, processors, distributors, retailers, people in food service and consumers. The degree to which a single party gets involved depends on the steps to consider in the Risk As-

[1] This definition is taken from the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management, CX/FH 00/6

[2] This definition is taken from the Procedural Manual of the Codex Alimentarius Commission, Eleventh Edition.

[3] This definition is taken from CAC/GL 21 - 1997

sessment of *L. monocytogenes* in foods of concern. If there is a listericidal step within the production process, the control of *L. monocytogenes* is focussed at the processing level and food processors are mainly involved. When no listericidal step is included several control measures may need to be taken to achieve the appropriate level of protection, and thus more parties have to be involved in the management process. Within CCFH, governments and interested parties have the possibility to participate, however, sometimes participation of particular stakeholders may be specifically encouraged.]

5 GUIDELINES FOR THE CONTROL OF LISTERIA MONOCYTOGENES IN FOODS

5.1 INITIAL RISK MANAGEMENT ACTIVITIES

[5.1.1 Identification of Risk Managers

The primary responsibility for the production of safe food production is with the food operator. He may, however, need to be guided regarding the level of safety to be achieved. Within the context of Codex Alimentarius it is the CCFH who has the responsibility to establish such levels, as an Appropriate Level of Protection (or Tolerable Level of Risk), a Microbiological Food Safety Objective (MFSO) or a Microbiological Criterion. The CCFH has in the past developed, and will in the future develop, Codes of Practice, which contain many control measures that will be helpful to ensure the safety of a product.

At the national level, the national food authorities act as Risk Managers. They hold a pivotal position in management of *L. monocytogenes* in the whole food chain "from farm to fork" (primary production, food-processing establishments, food distribution, retail and professional preparation). In order to arrive at effective risk management decisions frequent and transparent interactions between governmental risk managers and responsible business managers along the food chain as well as consumers is needed. When food choice, storage, handling and preparation of the food by the consumer are important control measures, the public should be aware of this and be involved in the decision making process.

[5.1.2 Identification of the 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. 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. 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. 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.

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 GHP 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. 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 are 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.

[5.1.3 Risk Profile

5.1.3.1 Present information on 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. Epidemiological evidence suggests that most exposure is foodborne. 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. The fatality rate is higher (up to 38 - 45%) in highly susceptible individuals, such as immunosuppressed people, including pregnant women, new-borns, immunocompromized patients and the elderly people, whereas it is lower in persons without predisposing factors. In addition, *L. monocytogenes* is found in many different foods.

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.

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

5.1.3.2 Present information on 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.

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.

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.

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 from 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).

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.

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 take account of this conclusion. Special food attributes that may alter the microbial pathogenicity of *L. monocytogenes* are not known.

5.1.3.3 Present information on 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 occurrence of *L. monocytogenes* in foods harbouring low numbers of *L. monocytogenes* indicate that many people ingest frequently 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 questionable.

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.

[More information can be found in the Risk Assessment report]

5.1.3.4 Present information on 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 assessments of specific foods should comprise data about prevalence or levels of *L. monocytogenes* in foods and consumption data of these foods. Specific food consumption databases should contain 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 should reveal products of concern in particular those, which promote the growth of *L. monocytogenes* during storage, distribution and sale. These data will be supplemented by general data on the potential fate of *L. monocytogenes* in a specific commodity.

The presently available data indicate that the population worldwide is frequently exposed to varying levels of *L. monocytogenes*. This is, for the moment, sufficient to consider which Risk Management Options are available to decrease the number of illnesses, or as a minimal requirement, keep it at the same level.

[5.1.4 Defining Goals

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 Microbiological Criteria for *L. monocytogenes* in foods, as proposed in this document (**Figure 1**), reflect these facts and considerations. The main emphasis is on reduction of higher levels of *L. monocytogenes* in food at the moment of consumption. Control measures to achieve this will most probably have an influence on the frequency of occurrence of low levels as well. In addition, efficient management strategies should include guidelines for the selection and safe handling of foods by highly susceptible individuals. These actions are aimed at reducing the risk of human listeriosis from food consumption.

[The Risk Assessors could be asked to estimate the effectiveness of these measures.]

[5.1.5 ***[5.1.5. Scope, range and risk assessment policy, to be established by CCF***

[5.1.6 Commissioning of microbiological risk assessment

[A Risk Assessment of in Ready To Eat food has been commissioned and the outcome needs to be reflected in this document. CCFH should consider, based on these guidelines, which other questions need to be addressed by the Risk Assessment Experts].

[5.1.7 Consideration of the process and results of the microbiological risk assessment

To date, no formal risk assessment has been carried out to establish the relationship between risk of foodborne listeriosis and the levels of *L. monocytogenes* in various products. However, the data mentioned in this document suffice to advance the Risk Management process in the Codex system. The 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. High numbers may pose an unacceptable risk even to healthy persons. 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.

[This needs to be confirmed, or not, by the Risk Assessment currently undertaken]

[5.1.8 Identifying of tolerable level of risk (TLR)

At present it is accepted, that the TLR can be assumed as the level of *L. monocytogenes* below 100/g food at the point of consumption.

[The decision may need to be revised according to the outcome of the currently undertaken Risk Assessment for Ready To Eat foods.]

[5.1.9 Regional considerations

The problem of *L. monocytogenes* can not be regionalised. Indeed, data on the occurrence of *L. monocytogenes* in ice cream indicate no regional differences in exposure. For other foods there are insufficient data concerning prevalence in foods at the moment of consumption in various regions of the world available, and their effect on human health in different regions is insufficiently known.

5.2 RISK MANAGEMENT OPTIONS ASSESSMENT

[5.2.1 Identification of available options

There are many different approaches to control *L. monocytogenes* at the various steps of the food chain. Most of the time, a combination of options (control measures) will be more effective in reducing risks.

5.2.1.1 Microbiological Food Safety Objective (MFSO)

A maximum contamination level of less than 100/g *L. monocytogenes* in food at the time of consumption can be defined as the MFSO for this food safety hazard.]

5.2.1.2 Precautionary principle

When the first outbreak of listeriosis occurred in 1985 not much was known concerning risk factors involved. As a precaution some countries established a general "zero tolerance" for *L. monocytogenes* in food, a measure which is recommended to be reviewed in the light of current knowledge.]

[5.2.2 Selection of preferred microbiological risk management options

The application of the "General Principles of Food Hygiene" (CAC/RCP 1-1969, Rev. 3, 1997) and in particular the HACCP principles "from farm to fork" (Annex to CAC/RCP 1-1969, Rev. 3, 1997) are the most effective means to control *L. monocytogenes* and hence to prevent listeriosis.

5.2.2.1 Primary production and food harvesting

The management for preventing contamination and/or introduction of *L. monocytogenes* should start at primary production level with approaches such as:

- introducing measures to reduce the level of specific *L. monocytogenes* in specific kinds of primary production;
- specific hygienic measures related to harvesting of fish and fishery products, meat, milk, salads, sprouts

[To be elaborated]

5.2.2.2 Food processing and distribution

Timely action, taken in case of a deviation at a critical control point (CCP) will reduce the risk that defective products reach the consumer. Analysing 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.

Some approaches for managing *L. monocytogenes* are:

- Preventing contamination and/or introduction of *L. monocytogenes* into the food processing plant
- 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 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;

- establishing microbiological standards or other criteria and enforcing compliance;

[To be elaborated? - How far should we go to outline technical details?]

5.2.2.3 Use of Microbiological Criteria

Imported foods should be treated in the same manner as those produced in the domestic market. 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 (References to CCFICS documents). 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 Microbiological Criteria could be applied.

The proposed Microbiological Criteria were developed according to the "Principles for the Establishment and Application of Microbiological Criteria for Foods" (CAC/GL 21 - 1997). Based on the considerations mentioned above, 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.

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.

When analysing foods it is important to adhere to adequate quality assurance procedures in the laboratories and the use of validated methods of detection and enumeration of *L. monocytogenes* (e.g. ISO 11290-1:1996 and ISO 11290 -2:1998).

5.2.2.4 Consumer education

Communication programmes should be implemented to inform consumers about potential risks and how to avoid foodborne listeriosis to lower the risk of human listeriosis from food consumption such as

- for people at risk avoiding foods with a substantiated history of contamination;

- informing the population at large or affected sub-groups about the steps they can take to reduce risks: [to be elaborated]

[5.2.3 Final management decisions

CCFH has to decide on whether the approach taken in this document is acceptable for the management of *L. monocytogenes* in foods in international trade. At a national or regional level, Food Control authorities have to decide whether the decisions made are appropriate for the protection of the consumers under their jurisdiction. If not, they have to per-

form a risk assessment and justify their deviation from the Codex recommendation(s) in order to be in line with the WTO/SPS Agreement.]

6 GUIDELINES FOR IMPLEMENTATION OF RISK MANAGEMENT DECISIONS FOR CONTROL OF LISTERIA MONOCYTOGENES

[Once CCFH has taken a decision on the Risk Management options to be implemented, this section can be elaborated further.]

7 MONITORING AND REVIEW

Monitoring of human listeriosis during recent years has shown that 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.

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.

8 REFERENCES

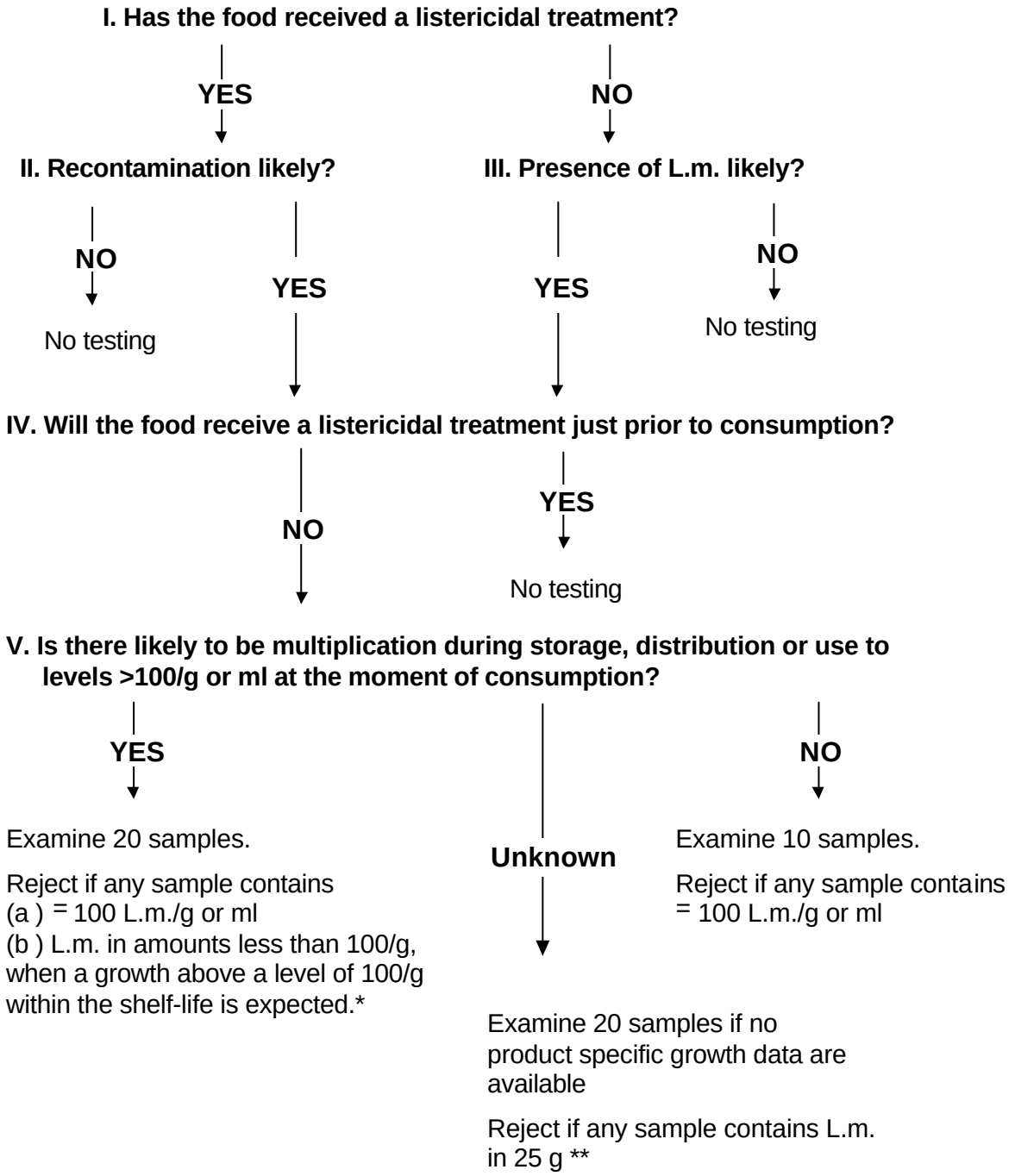
9 ANNEXES

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

Country, year	No. of cases	Food	L.m./g	Sampling point *
Switzerland, 1983-87	122	cheese	10^4 - 10^6	R
United States, 1985	142	cheese	10^3 - 10^4	R
United Kingdom, 1988	1	cheese	10^7	R
United Kingdom, 1987-88	> 300	paté	> 10^3	R
France, 1992	279	pork tongue, delicatessen	10^4 - 10^6 <10^2 - 10^4	R R
France, 1993	39	pork "rillettes"	<10^2 - 10^4	R
Finland, 1988	1	salted mushrooms	10^6	P
United States, 1988	1	turkey frank	> 10^3	P
Italy, 1988	1	sausage	10^6	P
Australia, 1991	2	smoked mussels	10^7	P
New Zealand, 1992	3	smoked mussels	10^3	P
United States, 1994	48	chocolate milk	10^8	P

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

9.2. Figure 1: Decision tree for application of 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.