codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session
Orlando, Florida, USA, January 27 – February 1, 2003

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *Listeria monocytogenes* IN FOODS (at Step 3 of the Procedure)

Prepared by Germany with assistance of Austria, Canada, China, Czech Republic, Denmark, France, Hungary, Japan, Norway, Phillipines, the United Kingdom, the United States of America, the European Commission and the International Commission on Microbiological Specifications for Foods (ICMSF)

Governments and interested international organizations are invited to submit comments or information on the attached Proposed Draft Guidelines at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Twelfth Edition*, pages 19-20) **to**: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by FAX +39-06-5705-4593 or email codex@fao.org **by December 15, 2002.**

Background

The issue on various aspects of control of *Listeria (L.) monocytogenes* had been on the Provisional Agenda of the Committee on Food Hygiene (CCFH) since its 23rd Session. The Committee considered the national and expert recommendation on the control of *L. monocytogenes* and applicable quantitative tolerances in foods (ALINORM 93/13, paras 72-76) and there was considerable discussion within the Committee on the appropriateness of establishing quantitative tolerances for Listeria in food.

There are significant variations in the national allowable tolerances for *L. monocytogenes*. 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. Some CCFH member countries have set the tolerance for *L. monocytogenes* based on the type of food and "use by date" on the labels of the food. The levels of *L. monocytogenes* associated with “unavoidable” contamination of these products are typically low, particularly if multiplication does not, or cannot, occur during storage, distribution and preparation.

These different approaches towards the management of *L. monocytogenes* may lead to trade barriers that can and should be avoided, if the foods do not endanger a country's appropriate level of protection. To set the quantitative approach on a risk assessment basis the 32nd session the Committee agreed to proceed with the elaboration of the topic in two directions: 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 *L. monocytogenes* in Foods in accordance with the Draft Principles and Guidelines for the conduct of Microbiological Risk Management (CX/FH 00/6).

The document on the management of Listeria in foods 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.

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 help lowering the risk of human listeriosis and prevent in the context of the WTO/SPS Agreement the establishment of unnecessary or unjustified trade barriers.

This revision of the paper is based on the document CX/FH 01/6 and the outcome of the last Drafting Group Meeting held in Berlin from 12-14 June 2002. During the drafting group meeting all received comments made by CCFH member states to the ALINORM 03/13, Appendix IV were discussed and a revised paper was elaborated.

Some of the salient feature of the revised document are: modified structure of the paper, the clarified scope, incorporation of the risk assessment results, precise chapter on risk management options and a separate chapter on guidelines for managing Listeria in food production. Additionally, the revised document includes a new chapter 6 which was elaborated by the US at the request of the drafting group. It includes general aspects from the former annexes (i.e. common aspects of guidelines for milk products, meat products and fishery products). Therefore, the former annexes are redundant and were deleted from the revised document. The new annexes are now about the initial risk management activities and the explanation of the decision tree. In Addition, an explanatory note for establishing sampling plans is given.

The Committee is invited to consider the revised Proposed Draft Guidelines in the light of comments to be submitted to the 35th session of the CCFH.

Appendix

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS (AT STEP 3 OF THE PROCEDURE)

TABLE OF CONTENTS

INTRODUCTION

L. monocytogenes is a bacterium that occurs widely in both the agricultural (soil, vegetation, silage, faecal material, sewage, water) and food processing environment. There is evidence to suggest that it is a transitory resident of the intestinal tract in humans, with 2 to 10% of the general population being carriers of the organism without any apparent health consequences. [8)] The bacterium is resistant to various environmental conditions such as high salt or acidity. *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.

L. monocytogenes causes illness by penetrating the lining of the gastrointestinal tract and then infecting normally sterile sites within the body. The likelihood that *L. monocytogenes* will invade the intestinal tissue depends upon a number of factors, including the number of organisms consumed, host susceptibility, and virulence of the specific isolate ingested. All strains of *L. monocytogenes* appear to be pathogenic but their virulence, as defined in animal studies, varies substantially. Listeriosis is an opportunistic infection that most often affects those with severe underlying disease, pregnant women, unborn or newly delivered infants and the elderly. The bacterium most often affects the pregnant uterus, the central nervous system or the bloodstream, and manifestations of listeriosis include but are not limited to bacteremia, meningitis, encephalitis, endocarditis, meningoencephalitis, miscarriage, neonatal disease, premature birth, prodromal illness in pregnant women, septicemia and stillbirth. Incubation periods prior to individuals becoming symptomatic can be from a few days up to three months. *L. monocytogenes* can also cause mild febrile gastroenteritis in otherwise healthy individuals. The public health significance of this type of listeriosis is much lower than that of invasive listeriosis. [8)]

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. Invasive listeriosis is a relatively rare but often severe disease with incidence rates typically of about 4 to 8 cases per 1,000,000 individuals and fatality rates of 20 to 30% among hospitalized patients. [7)] 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. 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 efforts of industry and governments (a) to implement Good Hygiene Practice (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,

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8) FAO (2000): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. FAO, Food and Nutrition Paper No. 71.

7) FAO and WHO (2001): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterization of Salmonella spp. in eggs and broiler chickens and *L. monocytogenes* in ready-to-eat foods. FAO, Food and Nutrition Paper No.72.

particularly for consumers at increased risk of listeriosis. However, further actions shall be taken to lower the risk of human listeriosis from food consumption world wide.

1 SCOPE

These guidelines provide a framework for the management of *L. monocytogenes* in foods. They are aimed predominantly at governments and relate to both management at the national level and the facilitation of international trade. However, they also provide information that may be of use to the food industry, consumers and other interested parties.

The primary purpose of the guidelines is to minimise the likelihood of illness arising from the presence of *L. monocytogenes* in foods. In providing risk management options to achieve this aim, the guidelines take account of the output from risk assessment activities and available knowledge on the control of this organism in foods. The guidelines are applicable throughout the food chain, from primary production to the final consumer. However, they concentrate mainly on the management of *L. monocytogenes* in ready to eat foods as these are the products that are most associated with illness.

In producing these guidelines account has been taken of the of the Principles and Guidelines for the Conduct of Microbiological Risk Management. [6)] The use of these has identified that governments need to consider two main aspects in order to manage *L. monocytogenes* in food. The setting of the Appropriate Level of Protection (and subsequent Food Safety Objectives) and the application of appropriate hygiene practices in the food chain. While the basis for the latter is contained within the CODEX ALIMENTARIUS Food Hygiene Basic Texts, additional information specific to *L. monocytogenes* is provided in this document.

The safety of foods should be assured by the application and implementation of HACCP and GHP in the country of origin. However, it is recognised that in international trade there may be occasions when there is limited information on how a food has been produced and in such instances it might be appropriate to apply microbiological criteria. These guidelines provide information on how such criteria could be used. As imported foods should be treated in the same manner as those produced on the domestic market, these criteria may also be of use at the national level.

2 DOCUMENTS USED

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

1. Report of the 34 Session of the Codex Committee on Food Hygiene (ALINORM 03/13).

2. Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999).

3. Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

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

5. Danish Government: Discussion paper for the Codex Committee on Food Hygiene on „The Control of *L. monocytogenes* in Foods“ (28th August 1998)

[6)] Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management, CX/FH 00/6 July 2000

6. Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management, CX/FH 00/6 July 2000

7. FAO and WHO (2001): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterization of Salmonella spp. in eggs and broiler chickens and *L. monocytogenes* in ready-to-eat foods. FAO, Food and Nutrition Paper No.72.

8. FAO (2000): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. FAO, Food and Nutrition Paper No. 71.

9. WHO (2000): The Interaction between Assessors and Managers of Microbiological Hazardsin Foods. Report of a WHO Expert Consultation, Kiel, Germany, 21-23 March, 2000.

10. WTO/SPS Agreement on the Application of Sanitary and Phytosanitary Measures

11. Codex Alimentarius Procedural Manual, Joint FAO/WHO Food Standards Programme, Twelth Edition, 2001.

12. "Microorganisms in Foods: Volume 2, Sampling for Microbiological Analysis: Principles and Specific Applications," 2nd edition, International Commission on Microbiological Specifications for Foods, University of Toronto Press, Toronto, Canada, 1986.

13. FAO and WHO (2000): Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. Report of a FAO/WHO Consultation, Kiel, Germany, 18-22 March 2002, Draft.

3 DEFINITIONS

[**Food Safety Objective (FSO):** The maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of health protection.] [6)]

Acceptable Level of Protection (ALOP): Level of protection deemed appropriate by the member (country) establishing a sanitary measure to protect human health within its territory. [10)]

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. [11)]

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)]

[**Performance Criterion**: The required outcome of one or more control measures at a [specified] step or combination of steps that contribute to assuring the safety of a food.] [6)]

[**Process Criterion**: The process control parameters (e.g. time, temperature, dose,...) at a specified step, or combination of steps, that can be applied to achieve a performance criterion.] [6)]

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6) Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management, CX/FH 00/6 July 2000

10) WTO/SPS Agreement on the Application of Sanitary and Phytosanitary Measures

11) Codex Alimentarius Procedural Manual, Joint FAO/WHO Food Standards Programme, Twelfth Edition, 2001.

3) Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)

[Product Criterion: A parameter of a food that can contribute to assuring that a food safety objective is met.]

4 CONSIDERATION OF THE RESULTS OF THE MICROBIOLOGICAL RISK ASSESSMENT

The initial risk management activities and the results of the interaction between Risk assessors and Risk managers are given in the **Annex 1**.

The Joint FAO/WHO Expert consultation on Risk Assessment of Microbiological Hazards in Foods [8)] concluded that questions pertaining to international food safety issues can be addressed by expanding and/or adapting components of risk assessment done at a national level. They showed also that pre-existing models and data sets can serve as a basis for a quantitative risk assessment efforts. The group identified also a number of areas where data gaps exist and indicated the need for improved data acquisition for prevalence and growth of *L. monocytogenes* in foods and the incidence of foodborne listeriosis. The risk characterization was based on exposure assessment for six ready-to-eat foods from initial prevalence and concentration at the retail level to final concentration in contaminated servings. Risk characterizations based on the exposure profile of *L. monocytogenes* at consumption and dose-response models were used to attempt to estimate-predicted cases of listeriosis per serving for each of the six foods.

Regarding regional considerations, the Joint WHO/FAO expert consultation on Risk Assessment considered that quantitative data on levels of *L. monocytogenes* contamination of foods and prevalence of listeriosis should be obtained in various regions of the world. This information should be developed to determine if seasonality and/or regional differences exist and the influence of climate and season in different regions in the world. Therefore, there is no indication for referring regional considerations.

Due to the identification of an error in the simulation model the expert consultation decided that these findings should not be reported until the models used in assessing exposure have been subjected to a more extensive review and revised if necessary.

However, despite the fore mentioned difficulties gaps in data and various caveats the consultation gave valuable conclusions which are used as very preliminary data in this document.

In summary, the questions posed by the 33rd CCFH meeting were answered as follows: [7)]

i. Estimate the risk for consumers in different susceptible population groups (elderly, infants, pregnant women, and immunocompromised patients) relative to the general population.

Based on epidemiological data from France and the US the relative susceptibility of populations at risk was calculated. The estimated R-value [14)] varied within a particular susceptibility subpopulation depending on assumed maximum dose. Thus for the most susceptible group (transplant patients), the estimated R-values varied from 5.8×10^{-10} (estimated log dose 7.5) to 2.3×10^{-11} (estimated log dose 10.5). In comparison, similar R-values estimates ranged from 2.23×10^{-13} to 7.45×10^{-15} . Setting the susceptibility of non-immunocompromised population to 1, those people having received organ

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8) FAO (2000): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. FAO, Food and Nutrition Paper No. 71.

7) FAO and WHO (2001): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterization of Sa*L. monocytogenes*onella spp. in eggs and broiler chickens and *L. monocytogenes* in ready-to-eat foods. FAO, Food and Nutrition Paper No.72.

14) The R-value is a reflection of the host/microorganism interaction probability, and is the probability of the ingested organisms being individually capable of causing an infection to a specific consumer. (See reference number 7 of section 2 "Documents used")

transplants are 2584fold more susceptible when they are challenged with a infective dose of log 7.5. Elderly people (above 60 years) may be 1.6-7.5 fold more susceptible than younger, non-immunocompromised people.

ii. Estimate the risk from *L. monocytogenes* in food when the number of organisms ranges from absence in 25 g to 1000 colony-forming units (cfu) per gram, or does not exceed specified levels at the point of consumption.

The experts tried to answer question by developing an example using the most conservative dose-response relationship derived in the hazard characterization in conjunction with the FDA/USDA-FSIS exposure assessment. By using the most conservative dose-response curve the total predicted number of cases/year in the United States is 2130, if log 7.5 cfu/serving is set as the maximum log dose at consumption. Data are presented in **Table 1** [7)].

TABLE 1: THE NUMBER OF CASES PREDICTED IF VARIOUS CRITERIA FOR CFU/SERVING COULD BE REALIZED AT 100% EFFECTIVENESS

Maximum log dose at consumption (log cfu/serving)	**Predicted number of cases**
Baseline distribution (log $10^{7.5}$ cfu/serving)	2130
4.5	24.9
3.5	5.3
2.5	1.1
1.5	0.2
0.5	0.06
-0.5	0.02
-1.5	0.01

iii. Estimate the risk from *L. monocytogenes* in foods that support growth and foods that do not support growth under specific storage and shelf life conditions.

The expert group reports: “The question concerning the relative risk associated with foods that do and do not support growth can also be considered broadly by using the example above. The key consideration is whether a correction factor needs to be applied when comparing levels at time of retail versus at time of consumption. For foods that support growth, increases in *L. monocytogenes* cell numbers between retail and consumption would have to be assumed and there is a significant likelihood that the hypothetical criteria analyzed above would be exceeded. However, this would not be the case for foods that do not support growth. Thus, for foods that do not support growth of *L. monocytogenes*, the predicted number of cases in relation to maximum dose level at retail would be the same as those depicted above for doses at time of consumption. Again, more rigorous modeling of other factors that could influence the differential in risk of severe listeriosis between foods that do and do not support the growth of *L. monocytogenes* are currently underway and the results of that activity are expected shortly. However, these are not likely to alter the large differential in risk between food that do and do not support the growth of *L. monocytogenes* to high levels that is suggested by the current “best-case” analysis.”

In summary the FAO/WHO Expert Consultation give a preliminary basis for the management of the Listeria in food. It can be concluded :

- that by eliminating higher dose levels ($>10^{3.5}$) the number of predicted cases would be reduced by more than 99% ;

- that ingestion of low levels (<100/g) of the microorganism in foods is associated with a low risk.

However, considering :

- the primary goal of Codex which is to lower the risk of listeriosis,

- the extend of the public health (severity of the disease, high case-fatality rate) and *L. monocytogenes* characteristics (especially the ability to grow at refrigerated temperatures),

- the absence of the final risk assessment requested by CCFH,

the conclusion based on the preliminary Risk Assessment that setting an FSO of less than 100 L.m./g at the time of consumption for high risk foods (food which allows *Listeria* growth) may need to be reconsidered when the final Risk Assassment data become available.

5 RISK MANAGEMENT OPTIONS

5.1 ACCEPTABLE LEVEL OF PROTECTION (ALOP)

The Codex is not responsible for setting an ALOP, however, it is certainly recommended to reduce the number of listeriosis in most countries around the world. For this reason, an FSO is set based on the calculated reduction the chosen FSO would achieve.

5.2 FOOD SAFETY OBJECTIVE (FSO)

Setting of FSOs is also principally the responsibility of individual governments, but based on the FAO/WHO risk assessment, a recommendation can be made. **Table 1** (point 4) shows clearly that a 99% reduction in the number of illnesses will be obtained by setting a FSO at <100 *L. monocytogenes* per gram of food at the moment of consumption.

5.3 PERFORMANCE CRITERIA

Performance criteria (expressing the level of *L. monocytogenes* at a point in the food chain) for ready to eat foods not supporting growth, would be the same as this FSO. For foods that receive a listericidal treatment before consumption, this performance criterion could be set at a higher value. This value would depend on the decimal reduction obtained with this treatment. For foods that would allow growth during distribution sale etc. and that do not receive a listericidal treatment, the performance criterion would be lower than the FSO (<100/g). The value would depend on the characteristics of the food and the conditions (shelf life and temperature) during shelf life.

5.4 MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES*

5.4.1 Microbiological Criteria for *L. monocytogenes* for foods in international trade.

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. Moreover it may be of advantage to verify that foods were produced according to GHP and HACCP and in this instance Microbiological Criteria could be applied.

These Microbiological Criteria were established according to Codex [3)]. The sampling plans were selected according to ICMSF [12)] as referred to in the Codex document (see **Explanatory Note**). The limit of 100 *L. monocytogenes* per gram was based on the FSO as described in 5.2. 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.

However, the proposed microbiological criteria are not intended to be used for clearly identifiable food, specifically intended for consumption by clearly identifiable vulnerable groups (high risk groups) e.g. geriatric foods, baby foods, enteral foods.

For the selection of the appropriate sampling plan the decision tree presented in **Figure 1** is recommended, an explanation is given in **Annex 2.** An example on how the microbiological criterion may vary according to the point in the food chain and how the stability of a product may be evaluated are presented in the same Annex.

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).

5.4.2 Microbiological Criteria for *L. monocytogenes* for foods produced domestically

Much of what has been described in 5.4.1 applies also to foods produced domestically. However, sampling plans may be different, because more information concerning the conditions during production, distribution and sale may be available. Still it is recommended that the same FSO would be met, unless regional differences would indicate that another FSO would be more appropriate. In establishing these sampling plans, the same principles as described in 5.3. for performance criteria should be applied. In short, sampling plans for foods that allow growth of *L. monocytogenes*, should be more stringent than for foods that are not or that receive a listericidal treatment before consumption.

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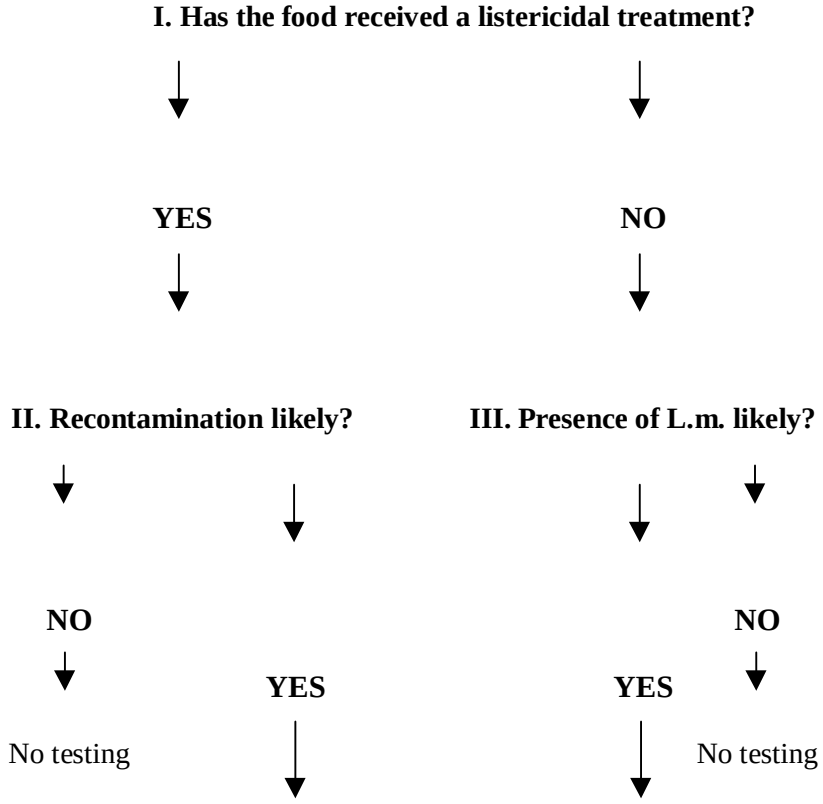
3) Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)

12) "Microorganisms in Foods: Volume 2, Sampling for Microbiological Analysis: Principles and Specific Applications," 2nd edition, International Commission on Microbiological Specifications for Foods, University of Toronto Press, Toronto, Canada, 1986.

FIGURE 1: DECISION TREE FOR MICROBIOLOGICAL CRITERIA FOR FOODS IN INTERNATIONAL TRADE



↓	↓
Examine 20 samples.	Examine 10 samples.
REJECT IF ANY SAMPLE CONTAINS	**REJECT IF ANY SAMPLE CONTAINS**
(a) > 100 L.m./g or ml	> 100 L.m./g or ml
(b) > N* L.m/g or ml when product specific growth data indicate that such a number may increase during the remaining shelf-life to > 100/g or ml at the moment of consumption	
[(c) L.m in 25g or ml when no product specific growth data are available**]	

* N depends on the time of examination before consumption and the growth rate of *L. monocytogenes* in the product under the prevailing shelf-life conditions

[** This is an exceptional situation because reliable growth rates can be predicted with available models when parameters such as pH, a_w , temperature are known.]

*** This value may change when new data would indicate that another value would be more appropriate for this purpose

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. monocytogenes* in 25 g.

5.5 PRIMARY PRODUCTION AND FOOD HARVESTING

Raw meat and poultry, raw milk, raw seafood, and raw produce may contain *L. monocytogenes*, although the frequency of occurrence and the levels vary widely. Ingredients likely to contain *L. monocytogenes* should be handled as if they are contaminated.

Practices such as Good Agricultural Practices (GAPs) should be put in place to minimize the microbiological food safety hazards associated with raw agricultural ingredients from primary production through distribution of finished products. Ingredients should be subjected to thermal or other effective processing methods either prior to mixing into final foods or in the final preparation of a finished food product.

5.6 FOOD PROCESSING AND DISTRIBUTION

Some of the key options/control measures that specifically is known to be effective against *L. monocytogenes* should be identified and preferably be subject to focused risk assessment/validation.

L. monocytogenes can cause problems that should be managed by using hygienic measures. Thus, health authorities and industry should base control of *L. monocytogenes* on the proper application and verification of Good Hygienic Practice (GHP) and HACCP.

Specific aspects of managing *L. monocytogenes* in meat and poultry, fish and cheese processing are given in **chapter 6.**

Some general approaches for managing *L. monocytogenes* are:

- Selecting raw materials and ingredients (e.g. the use of ingredients, which received a listericidal treatment), if necessary use of microbiological criteria and testing to accept or reject incoming material.
- Preventing contamination and/or introduction of *L. monocytogenes* into the food processing plant
- Combating multiplication, and spread of *L. monocytogenes* in the food processing plant, use of an environment management and monitoring program;
- Inactivation of *L. monocytogenes* (e.g. pasteurization, sterilization, cooking, high pressure etc.);
- Preventing recontamination between cooking and packaging e.g. separation of raw from cooked product;
- Reducing the levels in cooked products after packaging e.g. applying a commercially feasible in-pack pasteurization.
- Preventing an increase in levels between packaging and preparation for serving. Controlling the increase of *L. monocytogenes* during storage and distribution that may occur when food was recontaminated. Examples are. the use of adding safe, accepted additives, the use of improved chill chain management or freezing of the product; and furthermore the implementation of code-dating practices
- Removing *L. monocytogenes* from products e.g. the use of validated washing regimes on fresh-cut salads and vegetables as a pathogen reduction step;
- Establishing regulatory requirements and/or creating incentives for changes in attitude that will contribute to risk reduction, for instance by developing food safety assurance systems (e.g.

HACCP), by allowing operators to establish themselves the stringency of such schemes and the microbiological quality of the products they buy or sell;

- Establishing microbiological standards, performance, process, product or other criteria and enforcing compliance (see **Explanatory Note**).

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 information concerning the microbiological status of the product. However, analysis of samples taken from the line and line-environment is a more useful tool to check the effectiveness of control measures.

5.7 CONSUMER EDUCATION

Setting up communication programs on food hazards should be principally the responsibility of individual governments since each country has specific consumption habits. These programs are instrumental in the risk management of listeriosis. These programs

- should be directed to consumers with high risks of contracting listeriosis, such as pregnant women and immunocompromised persons, e.g., by means of health professionals (e.g. specialists in public or private hospital, local or general health services).

- should be implemented to inform consumers how to avoid food products that are most frequently contaminated and how to respect some practices during food handling and preparation.

Recommendations are linked to the nature of the bacterium *L. monocytogenes*, its habitat and its resistance to various environmental conditions:

- *L. monocytogenes* is resistant to cold temperatures but not to heat:
  Among the most frequently contaminated foods, some are consumed without final cooking. The consumption of ready-to-eat products that have undergone no treatment allowing the destruction of *L. monocytogenes* (e.g., by cooking) must be avoided, as well as the consumption of ready-to-eat foods having undergone a cooking during the manufacturing process but that are normally not reheated before consumption (such products may have been contaminated by the environment after heat treatment, e.g. during the manufacturing process, the transport, the storage or the slicing in the retail point).

- *L. monocytogenes* is a bacterium present in the environment and therefore has access to any external area of a food:
  Some measures are sufficient to eliminate pathogens present on the food surface, such as washing carefully raw vegetables and aromatic herbs, cooking the raw foods of animal origin (meat, fish, raw pork products like diced bacon) or removing the crust of the cheeses. Grind meats (for which the notion of surface contamination cannot be taken into account) must be medium cooked.

  Other measures allow to reduce the risk of cross-contamination, such as storing raw foods (meat, vegetables, etc.) separately from the cooked or ready-to-eat foods, or washing hands and kitchen utensils after handling of raw foods.

Use all appropriate and available means (e.g. mass media, distribution of informative cards by retailers, supermarkets or consumer associations) to allow high-risk consumers to be able to recognise those foods on the packaging and to help them distinguish these specific products from other categories of foods.

Educate the population about food hygiene as soon as possible. For example, beyond basic measures as "cleaning hands" left-over foods and cooked dishes must be carefully reheated before immediate consumption. It is recommended:

- to wash frequently and disinfect after with bleach water the household refrigerator;
- to reduce the refrigerator's temperature at 4°C
- to respect for dates written on food labelling (in particular the use-by-date) and avoid the special offers sold near the end of the shelf life.

6 GUIDELINES FOR MANAGING OF *L. MONOCYTOGENES* IN FOOD PRODUCTION

This section provides guidance to food producers and processors on how they can minimize *L. monocytogenes* contamination in foods. While the guidelines focus on refrigerated foods that support the growth of *L. monocytogenes*, they can be applied to other foods to minimize contamination in the processing environment. The guidelines recommend controls to reduce contamination from ingredients likely to contain *L. monocytogenes* and to minimize growth in the food. In addition, the guidelines provide guidance on facility and equipment design and GHP, including sanitation, to minimize post-process contamination. This guidance should also help reduce the risk of contamination with pathogenic and spoilage organisms in foods in addition to *L. monocytogenes.*

GHP, including sanitation and equipment and facility design, are important controls to reduce the risk of *L. monocytogenes* contamination. These programs are referred to as Prerequisite Programs and are the foundation of a successful food safety program. Departure from the pre-requisite program recommendations should result in correction by the plant. The following recommended prerequisite programs are directed towards minimizing *L. monocytogenes* post-process contamination that may originate from multiple sources in the plant environment, including those referenced in **Table 2**.

6.1 ESTABLISHMENT: DESIGN AND FACILITIES

The design, construction, and operation of the processing plant should minimize the risk of contamination of the product with *L. monocytogenes* . The following guidance is provided:

6.1.1. Plant Design

The plant layout should ensure separation of finished product areas from raw food processing areas, raw material storage, equipment washing facilities, microbiological laboratories, maintenance areas, waste areas, offices, and toilet facilities to prevent contamination via air, aerosols, water, employees, or equipment traffic. Separation of raw and finished areas can be accomplished in a number of ways including linear product flow (raw to finished) with filtered airflow in the opposite direction (finished to raw) or physical partitions. This goal may be achieved by building partitions with linear flow of product through the operation from the raw ingredients to the finished product.

Positive air pressure should be maintained on the finished side of the operation relative to the "raw" side (e.g., maintain lower air pressures in raw areas and higher pressures in finished areas). Proper air balance should be achieved by consulting with engineering experts to determine the number, size, and location of intake and exhaust fans.

Room air should not provide a source of microbial contamination. In rooms where finished foods are exposed, the plant make-up air should be filtered to minimize microbiological contamination. At a minimum, the final filter should have an efficiency of 90-95% at 1 micron. Air intake should not be located adjacent to the air exhaust to minimize recontamination of the intake air. This may be achieved

by filtering plant make-up air for finished areas through High Efficiency Particle Attenuation (HEPA) filters (99.97-99.99% at 0.3 micron) to remove bacteria, yeasts, and molds.

Water systems should be designed and maintained to ensure no cross-connections exist between treated and untreated water.

Exhausting vapors from cooking operations, using dehumidifiers, and providing adequate ventilation can prevent condensate formation.

Sewer lines should not be located above exposed food, food contact surfaces, or food packaging materials.

The washing areas for finished food equipment should be located in a separate room from the finished processing area and the raw equipment cleaning area.

Drains should be accessible for cleaning and function to prevent the accumulation of standing water in or around the drain. Drains should conform to the applicable plumbing codes and be designed and constructed so they do not flow from the "raw" area to the finished areas. Existing open floor drains should be equipped for automatic flushing (preferred: whenever possible, eliminate trench drains in finished areas and replace with enclosed plumbing to a floor drain).

Floors should be sloped to the drains at least ¼ inch per foot.

Overhead fixtures and piping in the food production areas should be accessible for cleaning.

6.1.2. Plant Construction

The construction of the building should minimize potential for *L. monocytogenes* contamination. The following guidance is provided:

The facility should be free of cracks, holes, and openings that would allow nesting or entry of pests. Vents, fans, and windows that can be opened should be adequately screened to prevent pest entry. All exterior doors and entrances should remain closed and should form a seal when closed. All walls, ceilings, windows, doors, floors, drains, and overhead fixtures (e.g. pipes, air vents, lights) should be in good condition and constructed so that they are easily cleanable, resist deterioration by product or cleaning chemicals, and prevent microbial harborage. Water drainage from the roof should be effective and not allow leakage into the facility. Windows should not be able to be opened in the finished product areas. Wood construction materials should be avoided in finished product areas and other wet processing areas in the facility to prevent microbial harborage and cross-contamination.

6.1.3. Equipment Design, Construction And Maintenance

Equipment should be designed, constructed and maintained to minimize contamination of the food. The following guidance is provided:

Processing equipment should be designed and constructed to facilitate cleaning and to minimize sites where microbial multiplication and harborage can occur. Food contact surfaces should be smooth, non-absorbent, sealed, easily cleanable, sloped to drain freely, and made of durable, non-corrosive and non-toxic materials. They should also be smoothly bonded, e.g., free of pits, folds, cracks, crevices, open seams, cotter pins, exposed threads and piano hinges. Junctures should be covered. Acceptability of equipment design should be reviewed from a microbiological and sanitation standpoint for existing, modified, and new equipment. Either the equipment manufacturer or you may perform this review. Catwalks and stairs of open grating should not be positioned over exposed food or food contact surfaces. Ladders and stairs in these locations should have kick plates. Equipment in the finished

product area, e.g. catwalk framework, table legs, conveyor rollers, racks should not be designed such that water can collect and harbor *L. monocytogenes*.

Lubricants, e.g. chain, valve, and seal lubricants, can become contaminated with product residue and become a niche for *L. monocytogenes*. Such lubricants should contain additives (e.g., sodium benzoate) that are listericidal.

Food contact surfaces including conveyors should be elevated sufficiently above the floor to prevent contamination from floor splash.

Stationary equipment should not be installed over floor drains to prevent contamination of the equipment and to allow accessibility of drain for cleaning. Overhead conveyors should be designed to be easily accessible for cleaning (preferred: avoid overhead conveyors).

Racks used for transporting exposed product should have cleanable cover guards over the wheels to prevent contamination of the food from wheel spray.

Condensate from refrigeration unit pans should be directed to a drain via a hose. Care should be taken to ensure that the hose does not become blocked (preferred: condensate should be hard plumbed with an anti-siphon device to a sanitary sewer whenever an air gap is not present).

Heat exchangers, where raw product is used to cool finished product, should have higher pressure on the finished side than on the raw side.

Piping used to convey finished foods should have no dead ends or cross-connections between raw and finished foods.

6.2. CONTROL OF OPERATION

Plant operation should minimize the potential for post process contamination of the food with *L. monocytogenes*. The following guidance is provided:

Traffic flow patterns for employees, food products, and equipment should be controlled between raw processing and storage area(s) and finished area(s) to minimize *L. monocytogenes* transfer.

Wood pallets should not be used in finished areas and other wet processing and storage areas. Pallets should be easily cleanable and in good condition. Non-wood pallets and wheels of transport equipment (e.g. carts, forklifts, and mobile racks) entering the food production room should be cleaned and sanitized before entry (preferred: dedicate a set of carts, forklifts, mobile racks, and pallets to the raw area and dedicate a different set to the finished product area to minimize cross-contamination).

Product, rework, and waste containers in food product areas should be labeled and easily distinguishable. Containers should be dedicated by function and specific to the finished product area. They should be easily cleanable (preferred: color-coded containers may be used to identify in process products, rework and waste).

Portable food contact equipment such as utensils, racks, and totes should be dedicated to the finished product area and should be easily distinguishable from non-finished equipment (preferred: color-coding may be used to identify portable equipment in finished product areas and non-finished areas, e.g. red handled utensils in raw area).

Continuous use brines and recycled process water used in direct contact with finished product should be discarded or decontaminated (e.g. chlorination, heat treatment, or some other effective treatment) with sufficient frequency to ensure control of *L. monocytogenes*. Treatment frequency may be based on the results of microbiological monitoring.

Compressed gases used directly in or on food, or on food contact surfaces, should be filtered at the point of use and the filters maintained. A filter of <0.3 micron is recommended.

Water that contacts food and food contact surfaces should be from a safe supply, e.g. meets EPA microbial standards for drinking water. Water treatment systems should be properly maintained and inspected to prevent them from becoming a source of microbial contamination. Mixed hot and cold water should be available at hand washing stations.

Ice used in or on food should be made of water from a safe supply, e.g. meets EPA microbial standards for drinking water. Ice should be handled and stored to protect it from contamination.

6.3. ESTABLISHMENT: MAINTENANCE AND SANITATION

6.3.1. Equipment Maintenance

Breakdowns during production increase the risk of *L. monocytogenes* contamination. Therefore, equipment should be properly maintained to minimize breakdowns and the risk of contamination during repair. The following guidance is provided:

A preventive maintenance program should be in place (preferred: the program should be written and should include a defined maintenance schedule)

Preventative maintenance should include periodic examination and maintenance of equipment such as valves, gaskets, o-rings, pumps, screens, filters, and heat exchanger plates. Air filters for plant air (intake air) should be examined and changed based on manufacturer's specification or more frequently based on pressure differential or microbiological monitoring. Only tools dedicated to the finished area should be used for maintenance of finished product equipment in the finished area. Such tools should be washed and sanitized prior to use. Maintenance personnel in the finished area should comply with the same hygiene requirements as the finished product production employees. Finished product equipment food contact surfaces should be cleaned and sanitized after maintenance work and prior to production use. Equipment that could have become contaminated during maintenance work on facility utilities, e.g. air system, water system, etc., or remodeling should be cleaned and sanitized prior to use.

6.3.2. Sanitation

Sanitation programs should be developed to minimize *L. monocytogenes* contamination of ready to eat food and ready to eat food contact surfaces. The following guidance is provided:

A written sanitation standard operating procedure (SSOP) including a sanitation maintenance schedule should be in place for food areas and food contact surfaces. The SSOP should be available to those responsible for cleaning. Adherence to the SSOP should be monitored. Sanitation procedures should identify equipment to be cleaned; equipment disassembly; frequency; type and concentration of cleaning compounds and sanitizers; time/temperature of cleaning solutions; and cleaning solution flow rate (velocity) if applicable.

Cleaning and sanitizing should include the following steps: (1) remove heavy debris from floors, with brooms or shovels, and from the equipment, if needed, (2) pre-rinse the equipment, (3) foam and scrub the equipment with an effective cleaner, (4) rinse the equipment, (5) clean debris from floor, (6) rinse floor with water using a low pressure/low volume hose, (7) use a dedicated brush or floor scrubber to scrub floor with an effective cleaner applying water as needed, (8) thoroughly rinse floors using a low pressure/low volume hose, (9) sanitize the equipment and floors, and (10) remove excess water from floors if needed.

Some equipment may require disassembling prior to cleaning and sanitizing, and may need to be re-sanitized after reassembling.

After being cleaned and sanitized, food product contact surfaces should be visually inspected for product residue as a verification of sanitation efficacy. The concentrations of cleaning solutions and sanitizers for clean-in-place (CIP) and clean-out-of-place (COP) systems should be monitored. Other verification activities may be necessary for CIP systems e.g. verify flow rate and temperature. In addition to visual inspection, cleaning efficacy may be verified by the producer conducting routine microbiological testing after cleaning via conventional or rapid methods e.g. total count, coliform counts, or bioluminescence.

Wet cleaning of equipment, e.g. down lines, storage and spiral coolers, spiral freezers should not be conducted in the same room as exposed food. Do not rely on covering the product with plastic or paper. Remove all exposed food from the room before beginning to clean. Exposed food should be removed from the cooler prior to cleaning coolers, refrigeration condenser units or condensate drip pans and hoses.

When assembling cleaned and sanitized equipment (e.g., pump impellers, pipes), the equipment should not be placed directly on the floor. Water from the floor or unclean equipment must not be splashed onto clean equipment. Multi-use CIP systems should be dedicated for either finished product equipment or for raw equipment. As an alternative, a common CIP system may be used if the alkaline cleaning solution temperature is maintained at or above 71°C (160°F). COP units, e.g. wash tanks, should be dedicated for either finished product equipment or raw equipment.

All wipes should be disposable and discarded after each use on food contact surfaces. Scouring pads should be discarded daily. When scouring pads are not in use during the day, they should be kept dry or placed in a sanitizer solution.

The equipment used for cleaning, e.g. brushes, mops, floor scrubbers, and vacuum cleaners should be maintained and cleaned so they do not become a source of contamination. The cleaning equipment should be dedicated either for raw areas or finished areas, and easily distinguishable (preferred: color-coded cleaning tools).

Recommended Routine Cleaning and Sanitation Schedules:

<table>
<tr><th>FOOD PRODUCTION AREAS</th><th colspan="2">FREQUENCY</th></tr>
<tr><td rowspan="3">a. Food Contact Surfaces including utensils, tubs, containers, racks.</td><td colspan="2">Clean at a frequency that allows no more than 1 log[1] increase of L. monocytogenes or other pathogens of concern and, unless otherwise validated, should not exceed 24 hours. For batch operations, the following cleaning schedule may be suitable:</td></tr>
<tr><td>Room Temp</td><td>Min. Cleaning Frequency</td></tr>
<tr><td><5°C (41°F)</td><td>24 hours</td></tr>
</table>

[1] ***HHS/USDA Draft Assessment of the Relative Risk to Public Health From Foodborne L. monocytogenes Among Selected Categories of RTE Foods*** **(http://vm.cfsan.fda.gov/~dms/*L. monocytogenes*risk.html).**

[2] **United States Food and Drug Administration, Food Code 2001.**

[3] **Tompkin, R.B., V.N. Scott, D.T. Bernard, W.H. Sveum and K.S. Gombas. 1999. Guidelines to prevent post-processing contamination from *L. monocytogenes*. Dairy, Food and Environmental Sanitation, 19: 551-562.**

	5-7.2°C (41-45°F)	20 hours
	7.2-10°C (45-50°F)	16 hours
	10-12.7°C (50-55°F)	10 hours
	>12.7°C (55°F)	4 hours
b. Non-Food Contact Surfaces3:		
Surfaces with a potential for becoming a niche for *L. monocytogenes* contamination, e.g. where moisture or potential product residue build-up may occur; employees contact equipment during operation	Daily	
Drains and Floors	Daily	
Non-wood pallets	Daily	
Waste containers	Daily	
Cleaning tools, e.g. mops, brushes	Daily	
Motor housings, overhead piping, external surfaces of enclosed processing systems	Monthly	
Ceilings and Walls	Monthly unless they meet conditions described in b. above then daily	
Condensate drip pans	Weekly	
Freezers containing exposed product, e.g. spiral, blast, tunnel	Semi-annually or more frequently based on the freezer manufacturer's recommendations.	
Ice Makers interior	Semi-annually or more frequently as recommended by the manufacturer	

Note: *Increased frequency may be warranted when equipment and environmental monitoring results indicate a need or as recommended by the equipment manufacturer.*

6.3.3. Drain Cleaning

Floor drains should be cleaned and sanitized in a manner that prevents contamination of other surfaces in the room. Floor drain brushes should be at least ¼ inch smaller than the diameter of the drain opening or a splashguard should be used to prevent splashing during cleaning. Utensils for cleaning drains should be easily distinguishable, and be dedicated to that purpose to minimize the potential for contamination (preferred: color-coded drain cleaning utensils).

Floor drains should not be cleaned during production. High-pressure hoses should not be used to clear or clean a drain, as aerosols may be created that may spread contamination throughout the room.

If a drain backup occurs and water flows back into finished areas,

- production should stop
- uncovered food product should be removed from the affected area and evaluated for microbiological contamination
- the drain should be cleared
- the affected area should be cleaned with an effective cleaner, rinsed, and sanitized and
- excess water removed from the floor.

Splashing equipment during the entire above mentioned process steps should be avoided. Employees who have been cleaning drains should not clean food contact surfaces without changing clothes, washing and sanitizing hands. Bactericidal drain rings may be used if they are monitored and replaced as necessary to maintain effectiveness.

6.3.4. Sanitizers And Sanitization

Quaternary ammonium compounds (QAC) have been found to be effective against *L. monocytogenes*, and leave a residual germicidal effect on surfaces. In addition, peroxyacetic acid sanitzers have been shown to be effective against biofi*L. monocytogene*s containing *L. monocytogenes*. Rotating sanitizers may provide for greater effectiveness. Temperature, pH, and water hardness can influence sanitizer effectiveness, and your sanitizer supplier should provide recommended limits.

Area	**Sanitizer**	**Recommended Level for *L. monocytogenes* Control**
Food Contact Surfaces	QAC	200 ppm
	Iodine/ Iodophors	25 ppm
	Chlorine	200 ppm
	Hot Water/ Steam	Achieve an equipment surface temperature of >160 °F (71 °C)
	Peroxyacetic acid	200 ppm
	Acid anionic	400 ppm
Non-food Contact Surfaces	QAC	400 ppm
Cleaning Tools, scouring pads, mops	QAC	600-1000ppm
Footbaths	QAC	400 – 800 ppm
Drains	QAC	400 ppm
Floors	QAC	400 ppm
Walls / Ceilings	QAC	400 ppm

Solid forms of sanitizers (e.g., blocks of QAC) should be placed in the drip pan of refrigeration units to control microbial growth.

6.4. ESTABLISHMENT: PERSONAL HYGIENE

Employee hygiene practices should minimize the potential for post-process contamination of the food with *L. monocytogenes*. The following guidance is provided:

All persons should wash their hands before entering food production areas. Employees should not touch exposed foods, food contact surfaces, or food packaging material with bare hands. Employees should use suitable utensils such as spatulas, tongs, or gloves. When gloves are used, employees should wash their hands before putting on gloves. Multi-use gloves should be washed and sanitized, after the employee touches any non-product contact surface. Single use gloves should be discarded and replaced after the employee touches any non-product contact surface. Gloves worn outside the food production area, such as to the restroom should be discarded before returning to the food production area. Gloves worn by food handling employees in food production areas should be made of impermeable material, in good repair, easily cleanable or disposable and used only in food production areas.

Footwear worn by employees should be made of impermeable material, in good repair, easily cleanable or disposable and used only in food production areas. Cleated footwear should only be worn when necessary for employee safety purposes because it may collect large particles of dirt/plant waste. Employees should use footbaths containing sanitizer when entering food production areas. Sanitizer concentrations for footbaths are recommended in section D3, Sanitizers/Sanitization. This goal may be achieved using an automated sprayer of foam disinfectant on the floor where people, carts, forklifts, etc. enter the area.

Street clothes should not be worn unless adequately covered above the knees with a clean smock. Smocks for employees should be worn only in the food production area and adjacent vestibule. Smocks should be laundered or disposed of daily. This goal may be achieved by having employees change into a clean uniform before entering food production areas, by providing different color coded smocks according to work area and by task (production, maintenance, etc.), and by providing separate locker areas, break areas, and cafeteria areas for raw and finished area employees.

Hose nozzles should be kept off of the floor at all times to prevent nozzles and employee hands from becoming contaminated. Sections of hose that touch the floor or other unclean surface should not make contact with food, food contact surfaces, or packaging material. This goal may be achieved by installing automatically retractable hoses or fixed length hoses that do not touch the floor.

Employees should not use high-pressure water hoses in food areas during production or after equipment has been cleaned and sanitized to prevent aerosols from contacting food, food contact surfaces and food packaging materials. At other times, high-pressure hoses can be used as needed.

Employees who handle trash, offal, floor sweepings, drains, production waste, or scrap product should not handle food, and should not touch food contact surfaces or food packaging material, unless they change their smock, wash and sanitize hands, wear clean new gloves and don and sanitize footwear.

6.5. TRANSPORTATION

Transportation vehicles should be inspected for structural integrity, cleanliness, and overall suitability when unloading ingredients and prior to loading finished products. Temperature control of incoming ingredients and outgoing finished food products should be effective and monitored.

Dedicated tankers should be used to transport ingredients and finished products.

6.6. TRAINING

A training program, covering GHP including controls addressing sanitation and cross-contamination, should be in place to provide necessary information to employees prior to performing job activities. GHP training should be conducted for all employees and contractors (e.g. production, maintenance, quality assurance, quality control, warehousing, temporary and seasonal employees) entering production and storage areas. Also, annual refresher training on GHP, and additional GHP training as warranted by the occurrence of poor employee practices, should be given to all employees entering food production areas.

TABLE 2: POTENTIAL SOURCES OF *L. MONOCYTOGENES*

A. Ingredients	
• **Raw meat/poultry**	• **Raw seafood**
• **Raw milk**	• **Raw produce**
B. Processing Aids	
• Compressed air	• Brine solutions used in chilling food
• Ice	
C. Plant Environment	
• Ceilings, overhead structures, catwalks	• Floors
• Rubber seals around doors especially in coolers	• **Vacuum Cleaner contents**
• **Drains**	• **Condensate**
• Wet insulation in walls or around pipes and cooling units	• Walls
• **Standing water**	• **Wash areas (sinks)**
D. Product contact surfaces	
• Fibrous or porous type conveyor belts	• **Spiral freezers/blast freezers**
• **Filling or packaging equipment;**	• Slicers, dicers; shredders, blenders
• Belts, peelers, collators	• Ice makers
• Containers, bins, tubs, or baskets	• Utensils

• **Equipment cleaning tools (brushes, scouring pads)**	• **Gloves and aprons**
E. Non product contact surface	
• **In-floor weighing equipment**	• Cracked hoses
• **Hollow rollers for conveyors**	• Equipment framework
• **Trash cans and other such ancillary items**	• **Wet rusting or hollow framework**
• **Open bearings within equipment**	• **Poorly maintained compressed air filters**
• **Condensate drips pans**	• **Motor housings**
• **Maintenance tools (wrenches, screw drivers, etc.)**	• Forklifts, hand trucks, trolleys, racks
• **On/off switches**	• **Vacuum cleaners and floor scrubbers**

NOTE: *Some of the sources listed should be eliminated in a properly designed plant but may be present in existing facilities. When such sources exist, environmental monitoring may be warranted.*

[7 MONITORING OF *L. MONOCYTOGENES* IN FOODS AND SURVEILLANCE OF LISTERIOSIS]

(to be elaborated , coming out with the Kiel-report of 2002 [13)])

[13)] FAO and WHO (2000): Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. Report of a FAO/WHO Consultation, Kiel, Germany, 18-22 March 2002, Draft.

ANNEXES

ANNEX 1: INITIAL RISK MANAGEMENT ACTIVITIES

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.

1.2 Identification of the problem

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.

Available epidemiological data show single cases and outbreaks of listeriosis (Table 1 and Table 2 of Annex 1). 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 delicatessen (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.

1.3 Risk Profile

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 diarrhea, meningitis, and septicemia. 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, newborns, immunocompromised 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.

1.3.2 Present information on hazard characterization

Serious cases are manifested by septicemia 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 septicemia 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 diarrhea-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 harbors *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 homeless 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.

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 and Table 3 of Annex 1). 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 harboring 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.

1.3.4 Present information on exposure assessment

L. monocytogenes is widespread in nature and can be found in soil, silage, sewage and the faces 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 data bases 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.

ANNEX 1, TABLE 1: FOODBORNE OUTBREAKS OF HUMAN LISTERIOSIS

Country	**Year**	**Number of cases (deaths)**	**Food implicated**	**Level of L.m./g**
USA	1976	20 (5)	?Raw salad*	
New Zealand	1980	20 (5)	?Shell or raw fish*	
Canada	1981	41 (18)	Coleslaw	
USA	1983	49 (14)	?Milk*	
USA	1985	142(48)	Soft cheese	10^3-10^4 (R)
Switzerland	1983-7	122(34)	Soft cheese	10^4-10^6 (R)
UK	1987-9	>350 (?)	Pâté	10^2-10^6 (R)
Denmark	1989-0	26 (6)	Hard and Blue cheese	
Australia	1990	9 (6)	Pâté	10^3 (R & P)

Australia	1991	4	Smoked mussels	10^7 (R)
New Zealand	1992	4 (2)	Smoked mussels	
France	1992	279(85)	Pork tongue in aspic	10^4-10^6 (R)
France	1993	33	Pork rillettes	10^2-10^4 (R)
Italy	1993	18?	Rice salad	
USA	1994	45†	Chocolate milk	10^9 (R)
Sweden	1994-5	8 (2)	Smoked fish	10^2-10^6 (R)
France	1995	33 (4)	Soft cheese	
Australia	1996	4 (1)	Cooked chicken	
Italy	1997	748	Corn meal	10^6 (R)
USA	1998-9	100(>10)	Hot dogs and deli meats	
Finland	1998-9	18 (4)	Butter	10^1-10^4(R & P)

* = Epidemiological association only, without recovery of the implicated strain from the specific foot item

† = Predominantly pyrexial and gastrointestinal illness

R = Food from retailer, usually unopened

P = Food from patients home, usually opened

ANNEX 1, TABLE 2: SPORADIC CASES OF FOODBORNE HUMAN LISTERIOSIS

Country	Year	Patient died	Food implicated	Level of L.m./g
USA	1985	No	Turkey frankfurters	10^3 (P)
England	1986	No	Soft cheese	'High' (P)
USA	1987	NK	Raw milk	
England	1988	No	Soft cheese	10^7 (P)
England	1988	Yes	Cooked chicken	
England	1988	Yes	Rennet	
Canada	1989	Yes	Alfalfa tablets	
USA	1989	No	Sausage	
Finland	1989	No	Salted mushrooms	10^6 (P)
Italy	1989	NK	Sausage	10^6 (P)
Italy	1989	No	Fish	
Denmark	1989	NK	Smoked cod roe	
Canada	1989	No	Soft cheese	
Belgium	1989	No	Fresh and ice cream	10^3-10^6 (P)
Sweden	1993	No	Mettwurst	
Italy	1994	NK	Pickled olives	

NK = Not known

P = Food from patients home, usually opened

ANNEX 1, TABLE 3: LEVELS OF *L. MONOCYTOGENES* IN FOODS CAUSING LISTERIOSIS (ICMSF, 1996)

Country, year	**No. of cases**	**Food**	***L. monocytogenes*/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**

ANNEX 2: EXPLANATION OF THE *L. MONOCYTOGENES* DECISION TREE

***Question I:* HAS THE FOOD RECEIVED A LISTERICIDAL TREATMENT ?**

The answer should be YES for all sterilised, pasteurised, cooked, fried, extruded etc. products. In this case, Question II has to be answered.

***Question II:* IS RECONTAMINATION LIKELY ?**

The answer is NO for all products that received the treatment after packaging, or that were aseptically packed, filled etc.. In this case, no testing is recommended, because testing resources could be better used for other purposes.

If the answer is YES, because no in-pack treatment was applied and experience has shown that the product has been found contaminated in the past, or such information is not available, Question IV needs answered.

***Question IV:* WILL THE FOOD RECEIVE A LISTERICIDAL TREATMENT JUST PRIOR TO CONSUMPTION ?**

The answer depends on the normal preparation practices and instructions given by the manufacturer. If the heating can be relied upon as an adequate listericidal treatment, the answer is YES, and no testing is recommended. For all products eaten raw the answer is obviously NO, and question V has to be answered.

Question IV needs also to be answered when Question I was answered with NO, i.e., the food did not receive a listericidal treatment, and when

***Question III*, i.e. IS THE PRESENCE OF *L. MONOCYTOGENES* LIKELY,**

was answered with YES. If Question III is answered with NO, again no testing is recommended. This is the case for many dry products, produced in dry (warm) environments and many other products where *L. monocytogenes* has not found a (cold) niche for multiplication.

***Question V:* IS IT LIKEKLY THAT MULTIPLICATION TO LEVELS OF > 100/G OR ML AT THE MOMENT OF CONSUMPTION WILL TAKE PLACE DURING THE INTENDED CONDITIONS OF STORAGE, DISTRIBUTION AND USE?**

The acceptance of low numbers of *L. monocytogenes* (L.m.) in foods is closely related to the stability of foods against growth of L.m. Such stability can be achieved by the use of a combination of several hurdles, which inhibit the growth of L.m. The application of this concept is named hurdle technology, barrier technology or food preservation by combined processes. Therefore, in order to answer this question knowledge concerning intrinsic and extrinsic factors controlling the growth of *L. monocytogenes* in the product is necessary (see below listed **Guidelines for evaluation of the stability of a product against growth of *L. monocytogenes*):**

If the a_w is below 0.90, or the pH below 4.5 or other values when combinations of such hurdles are used together with temperature control during the shelf life, the answer can be NO. In this case it is recommended to examine 10 samples, and to reject the lot when any sample contains >100 *L. monocytogenes* /g or ml.

When it is not known whether *L. monocytogenes* can multiply in the product under the prevailing conditions of storage and distribution, or how rapidly they can multiply it is recommended to examine 20 samples. This reflects to concept of taking a more precautionary approach. Clearly the lot should be rejected if any sample contains >100 *L. monocytogenes* /g or ml.

In any case where the stabilization of foods can be evaluated as being marginal or questionable it can be necessary to require documentation from the manufacturer that his product is stabilized against growth of L.m. To provide such documentation it can be necessary over a period of time to carry out repeated shelf life studies on products found positive for L.m. If natural contaminated material is not available challenge tests may be carried out. Also predictive modelling programs can be useful for research in this area or data are available from the safety records (market experience) of the product.

If these data concerning the multiplication rate in the product during the time and temperature conditions are available, the level of *L. monocytogenes* at the moment of examination can be calculated, which would ensure that no sample could reach the limit at the moment of consumption.

Although it is suggested, for instance by the delegation of Denmark, to examine 25g samples for the presence of L. monocytogenes when Question V is answered with YES or UNKNOWN, this proposal is in this version of the document not retained. The report of the FAO/WHO risk assessment shows that reducing the levels of L. monocytogenes below 100/g or ml will have an enormous impact on the incidence of listeriosis. High levels of L. monocytogenes are a consequence of inadequate temperature and time control. Intervention measures should therefore directed at improving the temperature conditions of storage and distribution and adjusting the shelf life time where necessary. Keeping the limit of L. monocytogenes at < 100/g or ml at the moment of consumption in the microbiological criterion would support the intervention strategy and prevent that products may be rejected for reasons that are scientifically not justified.

GUIDELINES FOR EVALUATION OF THE STABILITY OF A PRODUCT AGAINST GROWTH OF L. MONOCYTOGENES:

The evaluation of the stability of foods against growth of *L. monocytogenes* is important for food manufacturers and food controlling authorities. In this respect the following guidelines can be used.

Stability achieved without limitation in shelf life	Freezing pH < 4,5 pH < 5,0 + chilled storage aw < 0,90 aw < 0,92 + chilled storage aw < 0,95 + pH < 5,5
Stability achieved with limitation in shelf life	Lactate 2% + chilled storage (max 4 weeks shelf life) Lactate 2% + nitrite 150 ppm + chilled storage (max 5 weeks shelf life) Lactate 2% + glucone-delta-lactone + chilled storage (max 5 weeks storage)

Foods are complex eco-systems and experience has shown that interactions among known and unknown hurdles can provide stability against growth of *L. monocytogenes* without fulfi *L. monocytogenes* and of above mentioned criteria. Factors of significance in this respect can be modified atmosphere, smoke ingredients, bacteriocins, bacterial competition, available nutrients etc.

EXPLANATORY NOTE:
Establishment of sampling plans for microbiological safety criteria for foods in international trade

(according to Document prepared by the ICMSF for the Codex Food Hygiene Committee and discussed in 1996 at its 29th meeting)

1. Introduction

For certain foods Codex Alimentarius has developed microbiological criteria, but for many other foods such criteria do not exist. However the "Principles for the Establishment and Application of Microbiological Criteria for Foods", (ALINORM 97/13 Appendix III) describe how such Criteria should be developed. The text clearly describes the principles, but it lacks details concerning sampling plans and their interpretation. This document is intended to provide further guidance and discussion of sampling plans for *L. monocytogenes*.

2. Establishment of microbiological criteria

According to the "Principles for the Establishment and Application of Microbiological Criteria for Foods", consideration should be given to:

- evidence of actual or potential hazards to health,
- the microbiology of raw materials,
- effect of processing,
- likelihood and consequences of contamination and growth during handling, storage and use,
- the category of consumers at risk,
- the cost/benefit ratio of the application and
- the intended use of the food.

These considerations are of a very general nature and apply to all foods. When dealing with specific foods, decisions must be made where criteria are to be applied in the food chain and what would be achieved by applying them.

3. Sampling plans

In ALINORM 97/13 Appendix III, in developing sampling plans, the severity of the hazard and assessment of the likelihood of its occurrence must be considered. A scientific rationale for the development of sampling plans has been developed and published by the ICMSF (1986).

The ICMSF approach distinguishes three categories of hazards based upon the relative degree of severity :

- severe hazards,
- moderate hazards, potentially extensive spread,
- moderate hazards, limited spread.

This categorization and the examples presented in Table 1 were based on the best epidemiological data available at the time of publication. Those categories may need to be revised as a result of new risk assessment procedures.

Table 1. Categories of hazards

Severe :	**C. botulinum** **V. cholera 01** **S. typhi**
Moderate, potentially extensive spread :	**Salmonella (non typhi)** **Enterotoxigenic E. coli** **Shigella (non dysenteriae I)**
Moderate, limited spread :	**S. aureus** **V. parahaemolyticus** **B. cereus**

The other factor to be considered is the likelihood of occurrence, taking account of the anticipated conditions of use. Here the ICMSF again recognizes three categories:

- situations where the hazard would decrease,
- situations where the hazard would increase and
- situations where the hazard would remain the same.

Combining the three levels of severity with the categories of likelihood of occurrence, leads to different levels of concern called "cases" by the ICMSF, case 7 being of lowest concern to food safety and case 15 of the highest.

Taking into account the severity of the hazard, cases 9, 12 and 15 represent the highest levels of concern because they refer to situations where pathogens can multiply in the food under expected conditions of handling, storage, preparation and use. Cases 7, 10 and 13 represent the lowest levels of concern, because they refer to intermediate situations of concern where the degree of the hazard is likely to be reduced before consumption, for instance during preparation. Cases 8, 11 and 14 refer to situations where the degree of the hazard would remain the same between the time of sampling and the time of consumption.

Based on these nine cases, the ICMSF developed 2-class sampling plans in which "n" indicates the number of sample units to be tested and "c" the number of defective sample units which can be accepted. These sampling plans are summarized in Table 2. The plans direct more of the available resources for analysis towards those situations with a high level of concern. In most cases the weight of the analytical unit is 25 g, but the stringency of the sampling plan can be changed further by using other weights or volumes.

Table 2. Plan stringency (Case) in relation to degree of health hazard and conditions of use

Type of Hazard	Conditions in which food is expected to be handled and consumed after sampling in the usual course of events.		
	Reduce Degree of Hazard	**Cause No Change in Hazard**	**May Increase Hazard**
Health hazard moderate, direct, limited spread	Case 7 n = 5, c = 2	Case 8 n = 5, c = 1	Case 9 n = 10, c = 1
Health hazard moderate, direct, potentially extensive spread	Case 10 n = 5, c = 0	Case 11 n = 10, c = 0	Case 12 n = 20, c = 0
Health hazard Severe, direct	Case 13 n = 15, c = 0	Case 14 n = 30, c = 0	Case 15 n = 60, c = 0

n = the number of sample units tested,
c = the number of defective sample units which can be accepted

Although, for instance, examining 60 sample units may seem to be a high number; in practice, analytical sample units can be composited to reduce considerably the workload.

At a given % defectives, the number of sample units examined determines the probability of detecting lots of foods that are contaminated. The limitation of sampling is that it is neither practical nor cost-effective to attempt to detect, with a high degree of confidence, low levels of contamination in processed or prepared food. It must be realized that only positive results are meaningful, while negative results provide the level of confidence set by the number of sample units tested, assuming that there is a homogeneous distribution of the pathogen in the lot. For example, finding no defectives after testing 5 sample units gives 95% confidence that a lot is less than 50% contaminated, 30 samples that the lot is less than 10% contaminated; and 300 samples that the lot is 1% contaminated. This is a significant limitation of using microbiological testing of samples to assure food safety or to verify the effective implementation of HACCP.

Sampling plans must be included in the microbiological criteria inserted in the Codex documents. Those criteria should be regarded as minimum requirements to be met (safety objectives). Once the criteria have been established, the ICMSF emphasizes that routine testing of all imported foods is impractical, unnecessary, and not recommended. The decision to test must be made by regulatory authorities if it is not possible to judge the acceptability of the food on the basis of other factors.

Examples of factors that may influence whether or not to test an imported food for which microbiological criteria have been established are:

- Supplier's history of compliance with:

  GMP

HACCP

Criteria, including microbiological criteria

- New information linking the food commodity with foodborne illness
- Whether the food is:

  commonly involved in disease

  primarily destined for sensitive population
- The country of origin is:

  known to exercise control over the food

  not in an area with endemic disease of importance to food safety
- Practical considerations such as:

  cost/benefit

  the statistical limitations of the sampling plan for differentiating acceptable from unacceptable lots, particularly when a low level of defective units is expected.