codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE [CONTROL] OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

Prepared by Germany, with assistance of Austria, Canada, China, Denmark, Finland, France, Greece, Hungary, Italy, Japan, Norway, the United Kingdom, Uruguay, the United States of America and experts from the European Commission, the International Commission on Microbiological Specifications for Foods (ICMSF), the International Dairy Federation (IDF), and the Institute of Food Technologists (IFT).

Governments and interested international organizations are invited to submit comments on the attached Draft Code 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*) **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 email codex@fao.org or fax: +39-06-5705-4593 **by I5 February 2005.**

Background

The former Listeria-document *"Proposed Draft Guidelines on the application of General Principles of Food Hygiene to the [Management] of Listeria monocytogenes in Foods"* was presented at the 36th CCFH session in Washington 2004 under agenda item 7. The Committee emphasized the practical information and guidance in controlling Listeria in foods provided by the document. Due to the scope of the document, it was suggested to revise the title of the document to "Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods". It was also suggested that the Scope should focus on Ready-to-Eat foods that support the growth of *Listeria monocytogenes.*

The Committee decided not to discuss the proposed draft Guidelines in detail and focussed its discussions on major issues to be considered by the drafting group, so as to provide general guidance to the drafting group (ALINORM 04/27/13, para 93) [1].

[1] Alinorm 04/27/13 Report of the Thirty-Sixth Session of the Codex Committee on Food Hygiene, 29 March - 3 April 2004, para 91-100

Due to the decision reached on the definitions of Food Safety Objective (FSO), Performance Objective, and Performance Criterion (see ALINORM 04/27/13, paras. 75-76), it was agreed to initiate work on the establishment of FSOs and related performance objective and performance criteria, including microbiological criteria, and to include this information in an Annex to the Listeria-guidelines. The concepts included in the „*Principles and Guidelines for the Conduct of Microbiological Risk Management*" (CX/FH 04/6) should be applied in this Annex. In this regard, it was noted that the report of the FAO/WHO Expert Consultation on risk assessment of *L. monocytogenes* in ready-to-eat food would provide data for this work.[2] In order not to delay the further development of the Listeria-guidelines, it was agreed to proceed on the parallel development of the main guideline document and the Annex.

The Committee returned the former proposed draft guidelines to step 2 and agreed that a drafting group led by Germany with the assistance of Austria, Canada, China, Denmark, Finland, France, Greece, Hungary, Italy, Japan, Norway, the United Kingdom, Uruguay, the USA, EC, ICMSF, IDF and IFT would revise the proposed draft guidelines based on the written comments received and the discussion of the 36th CCFH session. In addition, the Committee agreed that a sub-group of the drafting group with the participation of the above listed countries and organisations plus Sweden, Switzerland, FAO and WHO would prepare an annex to the guidelines on the establishment of FSO's and related performance objectives and criteria, including microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods. The revised document, including the annex to be elaborated, has to be circulated for comments at Step 3 and for further consideration at the next CCFH session in 2005 (ALINORM 04/27/13, para 100).

On behalf of the head of the German CCFH delegation a CCFH drafting group meeting took place in Berlin from 21.- 24. September 2004. The meeting aimed at the revision of the former *"Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the [Management] of L. monocytogenes in Foods"* on the basis of comments (ALINORM 04/27/13, para 94-99) and at the elaboration of the annex to the guidelines on the establishment of FSO's and related criteria for Listeria. The meeting focussed on the finalisation of the revision of the main guideline document; including ANNEX I „*Recommendations for an environmental monitoring program for L. monocytogenes in processing areas*". In addition, the meeting aimed at the transition of data of risk assessment studies into FSO's and related performance objectives and criteria, including microbiological criteria and at drafting the specific amendments (FSO and related objectives and criteria) for *L. monocytogenes* in ready-to-eat foods as related to the revised main guideline document in a separate annex, named ANNEX II:

The enclosed main guideline document "*Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the [Control] of Listeria monocytogenes in Ready-To-Eat Foods*", including ANNEX I, has been elaborated by the drafting group according to the outcome of the drafting group meeting in Berlin 2004. Herewith we would like to submit this document for circulation, comments at step 3 and further consideration at the next CCFH meeting.

The enclosed ANNEX II „*Deriving microbiological limits and sampling plans in microbiological criteria from food safety objectives; example: Listeria monocytogenes in ready-to-eat food products*" is a preliminary draft elaborated subsequently mainly by a sub-group of the drafting group according to the outcome of the meeting. ANNEX II intends to illustrate how microbiological limits and sampling plans as components of a microbiological criterion (MC) for *Listeria monocytogenes* can be established using food safety objectives (FSOs) and derived performance objectives (POs) as a basis. This paper is intended for circulation, as a discussion basis and for further consideration at the next CCFH meeting.

[2] FAO/WHO, 2004. Risk assessment of *Listeria monocytogenes* in ready-to-eat foods. Technical Report. Microbiological Risk Assessment Series, No. 5.

Appendix

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE [CONTROL] OF *LISTERIA MONOCYTOGENES* IN FOODS

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INTRODUCTION

Listeria (L.) monocytogenes is a Gram-positive bacterium that occurs widely in both agricultural (soil, vegetation, silage, faecal material, sewage, water), aquacultural, and food processing environments. *L. monocytogenes* is a transitory resident of the intestinal tract in humans, with 2 to 10% of the general population being carriers of the microorganism without any apparent health consequences.[1] In comparison to other non-spore forming, foodborne pathogenic bacteria (e.g., *Salmonella* spp., enterohemorrhagic *Escherichia coli*), *L. monocytogenes* 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, sporadic cases or outbreaks of listeriosis are generally associated with ready-to-eat, refrigerated foods, and often involves the post-processing recontamination of cooked foods.

L. monocytogenes has been isolated from foods such as raw vegetables, raw and pasteurised fluid milk, cheeses (particularly soft-ripened varieties), ice cream, butter, fermented raw-meat sausages, raw and cooked poultry, raw and processed meats (all types) and raw, preserved and smoked fish. Even when *L. monocytogenes* is initially present at a low level in a contaminated food, the microorganism may multiply during storage in foods that support growth, even at refrigeration temperatures.

L. monocytogenes causes invasive listeriosis wherein the microorganism penetrates the lining of the gastrointestinal tract and then establishes infections in normally sterile sites within the body. The likelihood that *L. monocytogenes* can establish a systemic infection is dependent on a number of factors, including the number of microorganisms consumed, host susceptibility, and virulence of the specific isolate ingested. Almost all strains of *L. monocytogenes* appear to be pathogenic though their virulence, as defined in animal studies, varies substantially. Listeriosis is an infection that most often affects individuals experiencing immunosuppression including individuals with chronic disease (e.g., cancer, diabetes, AIDS), foetuses or neonates (assumed to be infected *in utero*), the elderly and individuals being treated with immunosuppressive drugs (e.g., transplant patients). The bacterium most often affects the pregnant uterus, the central nervous system or the bloodstream. Manifestations of listeriosis include but are not limited to bacteremia, septicaemia, meningitis, encephalitis, miscarriage, neonatal disease, premature birth, 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 gastro-enteritis in otherwise healthy individuals. The public health significance of this type of listeriosis appears to be much lower than that of invasive listeriosis.

Available epidemiological data show invasive listeriosis occurs both as sporadic cases and outbreaks, with the former accounting for the majority of cases. Invasive listeriosis is a relatively rare, but often severe disease with incidences typically of 3 to 8 cases per 1,000,000 individuals and fatality rates of 20 to 30% among hospitalised patients.[2] During recent years, the incidence of listeriosis in most countries has remained constant, with a number of countries reporting declines in the incidence of disease. These reductions likely reflect the efforts in those countries by industry and governments (a) to implement Good Hygienic Practice (GHP) and apply HACCP to reduce the frequency and extent of *L. monocytogenes* in ready-to-eat foods, (b) to improve the integrity of the cold chain through processing, distribution, retail and the home 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. However, further actions are needed to achieve continuous improvement of public health by lowering the incidence of human foodborne listeriosis worldwide. Periodically transitory increases in incidence have been noted in several countries. These have been

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

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

associated typically with foodborne outbreaks attributable to specific foods, often from specific manufacturers. In such cases, the incidence of 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.

Listeriosis has been recognised as a human disease since the 1930's, however, it was not until the 1980's, when there were several large outbreaks in North America and Europe, that the role that foods play in the transmission of the disease was fully recognised. Foods are now considered to be the major vehicle for *L. monocytogenes*. A variety of specific foods have been implicated in outbreaks and sporadic cases of listeriosis (e.g., processed meats, soft cheeses, smoked fish, butter, milk, coleslaw). The foods associated with listeriosis have been overwhelmingly ready-to-eat products that are typically held for extended periods at refrigeration or chill temperatures.

The large number of ready-to-eat foods in which *L. monocytogenes* is at least occasionally isolated has made it difficult to effectively focus food control programs on those specific foods that contribute the greatest risk to foodborne listeriosis. As a means of addressing this and a number of related questions, several formal quantitative risk assessments have been undertaken to address issues related to the relative risks among different ready-to-eat foods and the factors that contribute to those risks. Available governmental risk assessments currently include (1) a comparative risk assessment of 23 categories of ready-to-eat foods conducted by the U.S. Food and Drug Administration and the Food Safety and Inspection Service (FDA/FSIS, 2003)[3], (2) a comparative risk assessment of four ready-to-eat foods conducted by FAO/WHO JEMRA at the request of the Codex Committee on Food Hygiene[4], and (3) a product/process pathway analysis conducted by the U.S. Food Safety and Inspection Service for processed meats[5], which examined the risk of product contamination from food contact surfaces.

Each of these assessments articulates concepts that countries can use to identify and categorise those ready-to-eat products that represent a significant risk of foodborne listeriosis. Five key factors were identified as contributing strongly to the risk of listeriosis associated with ready-to-eat foods:

- Amount and frequency of consumption of a food
- Frequency and extent of contamination of a food with *L. monocytogenes*
- Ability of the food to support the growth of *L. monocytogenes*
- Temperature of refrigerated/chilled food storage
- Duration of refrigerated/chilled storage

A combination of interventions is generally more effective in controlling the risk rather than any single intervention (FDA/FSIS, 2003).

In addition to the factors above, which influence the number of *L. monocytogenes* present in the food at the time of consumption, the susceptibility of an individual is important in determining the likelihood of listeriosis.

The risk assessments that have been conducted have consistently identified the impact that the ability of a food to support the growth of *L. monocytogenes* has on the risk of listeriosis. Those foods that are able to support growth during the normal shelf life of a product increase substantially the risk that the food will contribute to foodborne listeriosis. Control of growth can be achieved by several different approaches, including reformulation of the product such that one or more of the parameters influencing

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[3] FDA/FSIS, 2003. Quantitative assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods at www.cfsan.fda.gov

[4] FAO/WHO, 2004. Risk assessment of *Listeria monocytogenes* in ready-to-eat foods. Technical Report. Microbiological Risk Assessment Series, No. 5.

[5] FSIS Rule Designed to Reduce Listeria monocytogenes in Ready-to-Eat Meat & Poultry at http://www.fsis.usda.gov/factsheets/fsis_rule_designed_to_reduce_listeria/index.asp

the growth of the bacterium (e.g., pH, water activity, presence of inhibitory compounds) is altered so the food no longer supports growth. Alternatively, strict control of temperature so that ready-to-eat foods never exceed 6°C (and preferably do not exceed 2° - 4°) and/or shortening the duration of the product refrigerated/chilled shelf life are other means for assuring that growth to any significant degree does not occur before the product is consumed.

Many of the ready-to-eat products that are associated with foodborne listeriosis include a step in their production that is listericidal. Thus, the frequency and level of contamination of these products with *L. monocytogenes* is typically associated with the recontamination of the product prior to final packaging or from subsequent handling during marketing or home use. Thus, another strategy to control foodborne listeriosis is to reduce recontamination of the product and/or to introduce an additional mitigation treatment after final packaging. Control of the frequency and level of contamination is likely to be influenced strongly by factors such as attention to the design and maintenance of equipment and the integrity of the cold chain, the latter clearly being identified as a risk factor (i.e., the temperature of refrigerated/chilled storage).

Some ready-to-eat foods do not include a listericidal treatment. Product safety in those instances is dependent on steps taken during primary production, processing, and subsequent distribution and use to minimise or reduce contamination/recontamination and to limit growth through maintaining the cold chain and limiting the duration of refrigerated storage.

The FAO/WHO risk assessment also clearly indicated that in order for food control programms to be effective, they must be capable of consistently achieving the degree of control required; the risk of listeriosis is largely associated with failures to meet current standards for *L. monocytogenes*, be they at 0.04 or 100 CFU/g. The analyses conducted within that risk assessment clearly indicate that the greatest risk associated with ready-to-eat products is the small portion of the products with high contamination levels of *L. monocytogenes.* Thus, a key component of a successful risk management program is assurance that control measures (e.g., preventing contamination and growth of the pathogen) can be achieved consistently.

SECTION I - Objectives

These guidelines provide advice to governments on a framework for the [control] of *L. monocytogenes* in ready-to-eat foods, with a view towards protecting public health and facilitating trade. Their primary purpose is to minimise the likelihood of illness arising from the presence of *L. monocytogenes* in foods. The guidelines also provide information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II - SCOPE

2.1 Scope

These guidelines are applicable throughout the food chain, from primary production through consumption. However, based on the results of the FAO/WHO risk assessment, other available risk assessments and epidemiological evaluations, these guidelines will focus on control measures that can be used, where appropriate, to prevent the contamination and/or the growth of *L. monocytogenes* in ready-to-eat foods, which are the foods predominantly associated with sporadic cases or outbreaks of listeriosis. These guidelines highlight key control measures that affect key factors that influence the frequency and extent of contamination of ready-to-eat foods with *L. monocytogenes* and thus the risk of listeriosis. In many instances, these control measures are articulated in a general manner in the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997, Amd. (1999)) as part of the general strategy for control of foodborne pathogens. In providing these guidelines, it is assumed that these General Principles of Food Hygiene are being

implemented. Those principles that are restated reflect the need for special attention for the control of *L. monocytogenes.*

2.2 Definitions

Definitions of the "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management" apply.

Ready-to-eat food – Any food (including beverages) which is normally consumed in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form which is normally consumed without further processing. [6]

SECTION III - PRIMARY PRODUCTION

Many ready-to-eat foods receive one or more treatments during processing or preparation that inactivate *L. monocytogenes*. For these foods animal health and general application of good agricultural practices should be sufficient to minimise the prevalence of *L. monocytogenes* at primary production.

In those ready-to-eat foods that are manufactured without a listericidal treatment, extra attention at primary production is needed to assure specific control of the pathogen (e.g., control of *L. monocytogenes* mastitis in dairy cattle and sheep where the milk will be used to make raw milk cheeses, frequency of *L. monocytogenes* in raw milk as related to the feeding of inadequately fermented silage, high levels of *L. monocytogenes* in pork for fermented sausages resulting from wet feeding systems, faecal contamination of fresh produce), including increased focus on personal hygiene and water management programs at the primary production sites.

Analysis of raw material for *L. monocytogenes* can be, where appropriate, an important tool for verifying that the control measures at the primary production level are adequately limiting the frequency and level of contamination to that needed to achieve the required level of control during subsequent manufacturing.

3.1 Environmental Hygiene

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

3.2 Hygienic Production of Food Sources

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

3.3 Handling, Storage and Transport

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

3.4. Cleaning, Maintenance and Personnel Hygiene at Primary Production

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

[6] Guidelines for the Design of Control Measures for street-vended foods in Africa. CAC/Gl 22 – 1997, (Rev. 1-1991); for the purposes of this document "further processing" is considered to include only listericidal steps (e.g. cooking)"

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Objectives:

Equipment and facilities should be designed, constructed and laid out to ensure cleanability and to minimise the potential for *L. monocytogenes* harbourage sites, cross-contamination and recontamination.

Rationale:

- The introduction of *L. monocytogenes* into the ready-to-eat processing environment has resulted from inadequate separation of raw and finished product areas and from poor control of employees or equipment traffic.
- Inability to properly clean and disinfect equipment and premises due to poor layout or design and areas inaccessible to cleaning has resulted in biofilms containing *L. monocytogenes* and harbourage sites that have been a source of product contamination.
- The use of spray cleaning procedures that aerosolize the microorganism has been linked to the spread of the *L. monocytogenes* in the processing environment.
- Inability to properly control ventilation to minimise condensate formation on surfaces in food processing plants may result in the occurence of *L. monocytogenes* in droplets and aerosols which can lead to product contamination.

4.1 Location

4.1.1 Establishments

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.1.2 Equipment

Whenever possible, equipment should be designed and placed in a manner that facilitates access for efficient cleaning and disinfection, and thus avoid the formation of biofilms containing *L. monocytogenes* and harbourage sites.

4.2 Premises and Rooms

4.2.1 Design and Layout

Whenever feasible, premises and rooms should be designed to separate raw and finished ready-to-eat product areas. This 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. 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).

Where feasible, the washing areas for food equipment involved in the manufacture of the finished product should be located in a separate room from the finished product processing area. This latter area should be separate from the raw ingredient handling area and the cleaning area for equipment used in the handling of raw ingredients in order to prevent recontamination of equipment and utensils used for finished products. Rooms where ready-to-eat products are exposed to the environment should be designed so that they can be maintained as dry as possible; wet operations often enhance the growth and spread of *L. monocytogenes*.

4.2.2 New construction/renovations

Due to the ability of *L. monocytogenes* to survive in the plant environment for long periods of time, disturbances caused by construction or modification of layouts can cause reintroduction of *L. monocytogenes* from harbourage sites to the environment. Where appropriate, care should be taken to isolate the construction area, to enhance hygienic operations and to increase environmental monitoring to detect *Listeria* spp. during construction/renovation (see 6.3).

4.2.3 Temporary/mobile premises and vending machines

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.3 Equipment

4.3.1 General

Due to the ability of *L. monocytogenes* to exist in biofilms and persist in harbourage sites for extended periods, processing equipment should be designed, constructed and maintained to avoid, for example, cracks, crevices, rough welds, hollow tubes and supports, close fitting metal-to-metal or metal-to-plastic surfaces, worn seals and gaskets or other areas that cannot be reached during normal cleaning and disinfection of food contact surfaces and adjacent areas.

Racks or other equipment used for transporting exposed product should have easily cleaned cover guards over the wheels to prevent contamination of the food from wheel spray.

Cold surfaces (e.g., refrigeration units) can be sources for any psychrotrophic bacteria, especially *L. monocytogenes*. Condensate from refrigeration unit pans should be directed to a drain via a hose or drip pans should be emptied, cleaned and disinfected on a regular basis.

Insulation should be designed and installed in a manner that it does not become a harbourage site for *L. monocytogenes* .

4.3.2 Food control and monitoring equipment

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.3.3 Containers for waste and inedible substances

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.4 Facilities

4.4.1 Water supply

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.4.2 Drainage and waste disposal

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.4.3 Cleaning

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.4.4 Personnel hygiene facilities and toilets

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.4.5 Temperature control

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.4.6 Air quality and ventilation

Control of ventilation to minimise condensate formation is of particular importance in *L. monocytogenes* control, since the organism has been isolated from a wide variety of surfaces in food processing plants. Wherever feasible, facilities should be designed so that droplets and aerosols from condensates do not directly or indirectly contaminate food and food contact surfaces.

4.4.7 Lighting

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

4.4.8 Storage

Where feasible and appropriate for the food product, and where food ingredients and products support growth of *L. monocytogenes,* storage rooms should be designed to maintain a temperature as low as possible (below 6°C and preferably below 2° - 4°C) to minimise growth during holding. Raw materials should be stored separately from finished, processed products.

SECTION V - CONTROL OF OPERATION

Objectives:

Processing operations should be controlled to reduce the frequency and level of contamination in the finished product, to minimise the growth of *L. monocytogenes* in the finished product and to reduce the likelihood that the product will be recontaminated and/or will support the growth of *L. monocytogenes* during subsequent distribution, marketing and home use.

Rationale:

For many ready-to-eat products listericidal processes[7] can ensure appropriate reduction in risk. However, not all ready-to-eat products receive such a treatment and other ready-to-eat products may be exposed to the environment and thus may be subject to potential recontamination. Prevention of cross-contamination, strict control of time and temperature for products in which *L. monocytogenes* can grow and formulation of products with hurdles to *L. monocytogenes* growth can minimise the risk of listeriosis.

5.1 Control of the food hazard

Control of *L. monocytogenes* for many ready-to-eat products will typically require a stringent application of Good Hygienic Practice and other supportive programs. These prerequisite programs, together with HACCP provide a successful framework for the control of *L. monocytogenes*.

The factors and attributes described below are components of Good Hygienic Practice programs that will typically require elevated attention to control *L. monocytogenes* and may be identified as critical control points in HACCP programs where *L. monocytogenes* is identified as a hazard.

[7] any appropriate treatment that kills Listeria

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

The risk assessments done by the U.S. FDA/FSIS and FAO/WHO on *L. monocytogenes* in ready-to-eat foods demonstrated the tremendous influence of storage temperature on the risk of listeriosis associated with ready-to-eat foods that support *L. monocytogenes* growth. Therefore, monitoring and controlling refrigerated storage temperatures such that the product temperature does not exceed 6°C (and preferably 2° - 4°C) is typically a key control measure when these foods are likely to contain *L. monocytogenes.*

The length of the shelf-life is an another important factor contributing to the risk associated with foods that support *L. monocytogenes* growth. The shelf-life of such foods should be consistent with the need to control the growth of *L. monocytogenes.* Since *L. monocytogenes* is able to grow under refrigeration temperatures, the length of the shelf-life should be based on appropriate studies that assess the growth of *L. monocytogenes* in the food. Shelf-life studies and other information are important tools facilitating the selection of the length of shelf-life. If they are conducted, they should account for the fact that appropriate low temperatures may not be maintained throughout the entire food chain until the point of consumption and that temperature abuse may occur.

5.2.2 Specific process steps

Listericidal processes should be validated to ensure that the treatments are effective and can be applied consistently (see Section V of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.3 -1997, Amd. (1999)).

In some products single parameters, such as a pH less than 4.0, a water activity less than 0.92 or freezing, may be relied upon to prevent *L. monocytogenes* growth. In other products a combination of parameters is used. Validation should be undertaken to ensure the process effectiveness in situations where combinations of parameters or bacteriostatic conditions are used.

In products supporting growth of *L. monocytogenes*, that may become recontaminated before final packaging, additional control measures may be necessary, e.g., freezing the product, shortening the shelf life, reformulation of the product so that it no longer supports *L. monocytogenes* growth or the application of a post-packaging listericidal treatment, i.e. heating, high pressure treatment, irradiation.

5.2.3 Microbiological and other specifications

currently under development

5.2.4 Microbiological cross-contamination

Microbiological cross-contamination is a major issue with respect to *L. monocytogenes.* It can occur through direct contact with raw materials, personnel, aerosols and contaminated utensils, equipment, etc.. Cross-contamination can occur at any step where the product is exposed to the environment, including processing, transportation, retail and in the home.

Traffic flow patterns for employees, food products, and equipment should be controlled between raw processing, storage area(s) and finished area(s) to minimise the transfer of *L. monocytogenes*. For example, automated foam sprayers can be an effective alternative to footbaths where people, carts, forklifts and other portable equipment must enter an area where ready-to-eat foods are exposed. Another example is to use a colour coding system to identify personnel assigned to different areas of the plant.

Utensils, pallets, carts, forklifts and mobile racks should be dedicated for use in either the raw area or the finished product area to minimise cross-contamination. Alternatively, they should be cleaned and disinfected before entry into the finished product area.

Reused 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*.

Ready-to eat foods that do not support the growth of *L. monocytogenes* but may have low levels of this pathogen should not be a source of contamination to other ready-to-eat foods that may support the growth of this pathogen. Consideration should be given to the fact that some ready-to-eat foods with special handling requirements (for example ice cream), that are handled after opening may present lower risk for being a vector for cross contaminating other ready-to-eat foods, because specially handled product is rapidly consumed. Other ready-to-eat products, however, with special formulation (for example dry fermented sausage), that are handled after opening may present higher risk for being a vector for cross contaminating other ready-to-eat products because neither ready-to-eat products may be rapidly consumed.

5.2.5 Physical and chemical contamination

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.3 Incoming material requirements

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.4 Packaging

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.5 Water

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.5.1 In contact with food

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.5.2 As an ingredient

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.5.3 Ice and steam

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.6 Management and supervision

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.7 Documentation and records

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

5.8 Recall Procedures

Based on the determined level of risk associated with the presence of *L. monocytogenes* in a given food product, a decision may be taken to recall the contaminated product from the market. In some instances, the need for public warnings should be considered.

5.9 Monitoring of effectiveness of control measures for *L. monocytogenes*

An effective environmental monitoring program is an essential component of a Listeria control program, particularly in establishments that produce ready-to-eat foods that support growth and may contain *L. monocytogenes*.

Recommendations for the design of an environmental monitoring program for *Listeria monocytogenes* in processing areas are given in ANNEX 1.

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

Objectives:

To provide specific guidance on how preventive maintenance and sanitation procedures, along with an effective environmental monitoring program can reduce contamination of food with *L. monocytogenes*, particularly when the foods support growth of *L. monocytogenes*:

Well structured cleaning and disinfection procedures should be targeted against *L. monocytogenes* in food processing areas where ready-to-eat foods are exposed to reduce

- the likelihood that the product will be recontaminated after processing,
- the level of contamination in the finished product.

Rationale:

Basic cleaning and disinfection programs are critical to assuring control of *L. monocytogenes.* An environmental monitoring program for Listeria in processing areas where ready-to-eat foods are exposed is necessary to assess control and, therefore, the likelihood of contamination of the food.

6.1 Maintenance and Cleaning

6.1.1 General

Establishments should implement an effective, scheduled preventive maintenance program to prevent equipment failures during operation and the development of harbourage sites. Equipment failures during production increase the risk of *L. monocytogenes* contamination as equipment is being repaired. The preventive maintenance program should be written and include a defined maintenance schedule.

The preventive maintenance program should include scheduled replacement or repair of equipment before it becomes a source of contamination. Equipment should be inspected periodically for parts that are cracked, worn or have developed spaces where food and moisture accumulate (i.e., harbourage sites). Preventive maintenance should include periodic examination and maintenance of equipment such as support structures for equipment, conveyors, filters, gaskets, pumps, slicers, filling equipment, and packaging machines and support structures for equipment. Air filters for bringing outside air into the plant should be examined and changed based on manufacturer's specification or more frequently based on pressure differential or microbiological monitoring.

Wherever possible, tools used for maintenance of equipment to which ready-to-eat foods are exposed should be dedicated to the finished product area. Such tools should be washed and disinfected prior to

use. Maintenance personnel in the finished product area should comply with the same hygiene requirements as the finished product production employees. Equipment food contact surfaces should be cleaned and disinfected after maintenance work, prior to production use. Equipment that could have become contaminated during maintenance work on facility utilities, e.g. air system, water system, etc., or remodelling, should be cleaned and disinfected prior to use.

6.1.2 Cleaning procedures and methods

Experience indicates that over-reliance on the chemicals alone for cleaning can lead to increased levels of microbial contamination. The chemicals must be applied at the recommended use-concentration, for sufficient time, at the recommended temperature and with sufficient force (i.e., turbulence, scrubbing) to remove soil and biofilms. Instances of *L. monocytogenes* contamination have been linked, in particular, to insufficient manual scrubbing during the cleaning process.

Research and experience further indicates that *L. monocytogenes* does not possess an unusual ability to resist disinfectants or attach to surfaces.

Solid forms of disinfectants (e.g., blocks of quarternary ammonium compounds (QAC)) can be placed in the drip pan of refrigeration units and solid rings containing disinfectants can be placed in drains to help control *L. monocytogenes* in drains. Granulated forms of disinfectants such as QAC, hydrogen peroxide and peroxyacetic acid can be applied to floors after routine cleaning and disinfecting.

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 (e.g., colour-coded cleaning tools).

To prevent aerosols from contacting ready-to-eat foods, food contact surfaces and food packaging materials, high-pressure water hoses should not be used during production or after equipment has been cleaned and disinfected.

It has been shown that *L. monocytogenes* can become established and persist in floor drains. Therefore, drains should be cleaned and disinfected in a manner that prevents contamination of other surfaces in the room. Utensils for cleaning drains should be easily distinguishable and be dedicated to that purpose to minimise the potential for contamination.

Floor drains should not be cleaned during production. High-pressure hoses should not be used to clear or clean a drain, as aerosols will be created that spread contamination throughout the room. If a drain backup occurs in finished product areas, production should stop until the water has been removed and the areas have been cleaned and disinfected. Employees who have been cleaning drains should not contact or clean food contact surfaces without changing clothes, and washing and disinfecting hands.

6.2 Cleaning Programs

The effectiveness of sanitation programs should be periodically verified and the programs modified as necessary to assure the consistent achievement of the level of control needed for a food operation to prevent *L. monocytogenes* contamination of ready-to-eat food and ready-to-eat food contact surfaces.

6.3 Pest control systems

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

6.3.1 General

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

6.3.2 Preventing access

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

6.3.3 Harbourage and infestation

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

6.3.4 Monitoring and detection

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

6.3.5 Irradication

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

6.4 Waste management

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

6.5 Monitoring effectiveness

Environmental monitoring (see 5.9) can also be used to verify the effectiveness of sanitation programs such that sources of contamination of *L. monocytogenes* are identified and corrected in a timely manner. Recommendations for the design of an environmental monitoring program in processing areas are given in ANNEX 1.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

Objectives:

To prevent workers from transferring *L. monocytogenes* from contaminated surfaces to food or food contact surfaces.

Rationale:

Workers can serve as a vehicle for cross-contamination and should be aware of the steps that need to be taken to manage this risk.

7.1 Health status

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

7.2 Illness and injuries

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

7.3 Personal cleanliness

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

7.4 Personal behaviour

Employee hygienic practices play an important role in preventing contamination of exposed ready-to-eat foods with *L. monocytogenes*. For example, employees who handle trash, floor sweepings, drains, packaging waste or scrap product, should not touch the food, touch food contact surfaces or food

packaging material, unless they change their smock or outer clothing, wash and disinfect hands, and wear clean new gloves for tasks requiring gloves. Adequate training and supervision should be provided to assure hygienic practices are accomplished.

7.5 Visitors

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

SECTION VIII – TRANSPORTATION

Objectives:

Measures should be taken where necessary to:

- protect food from potential sources of contamination including harbourage sites for *L. monocytogenes* in transportation equipment and to prevent the co-mingling of raw and ready-to-eat product;
- provide an adequately refrigerated environment (should not exceed 6°C and ideally be <2°C - 4°C) that minimises the growth of *L. monocytogenes* in foods that support growth.

Rationale:

Food may become contaminated during transportation if not properly protected**.**

Food may support growth to higher levels if refrigeration is inadequate.

8.1 General

Transportation is an integral step in the food chain and should be controlled, particularly temperature which should not exceed 6°C (ideally it would be <2°C - 4°C) to prevent the growth of *L. monocytogenes* in ready-to-eat foods that support growth.

Transportation vehicles should be regularly inspected for structural integrity, cleanliness, and overall suitability when unloading ingredients and prior to loading finished products. In particular, the structural integrity of transportation vehicles (e.g., tanker trucks) should be monitored for stress cracks that act as harbourage sites for *L. monocytogenes* under pressure. Tankers should be dedicated to transport either ingredients or finished products.

8.2 Requirements

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

8.3 Use and Maintenance

Food transportation units, accessories, and connections should be cleaned, disinfected (where appropriate) and maintained to avoid or at least reduce the risk of contamination. It should be noted that different commodities may require different cleaning procedures. Where necessary, disinfection should be followed by rinsing unless manufacturer's instruction indicates on a scientific basis that rinsing is not required.[8] A record should be available that indicates when cleaning occurred.

[8] Code of Hygienic Practice for the transport of food in bulk and semi-packed food (CAC/RCP 47-2001)

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

Objectives:

Consumers should have enough knowledge of *L. monocytogenes* and food hygiene such that they:

- understand the importance of shelf-life, sell-by or use-by dates written on food labels;
- can make informed choices appropriate to the individual's health status and concomitant risk of acquiring foodborne listeriosis;
- prevent contamination and growth or survival of *L. monocytogenes* by adequately storing and preparing ready-to-eat foods.

Health care providers should have appropriate information on *L. monocytogenes* in foods and listeriosis to give advice to consumers and in particular susceptible populations

Rationale:

Consumers (in particular, the susceptible populations), health care providers, need to be informed about ready-to-eat foods supporting growth of *L. monocytogenes,* food handling, preparation practices and avoidance of certain foods by susceptible populations.

9.1 Lot identification

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

9.2 Product information

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

9.3 Labelling

Countries may give consideration to labelling of certain ready-to-eat foods so that consumers can make an informed choice with regard to these products. Where appropriate, product labels may include information on safe handling practices and/or advice on the time frames in which the product should be consumed.

9.4 Communication Programs

Since each country has specific consumption habits, communication programs pertaining to *L. monocytogenes* are most effective when established by individual governments.

Programs for consumer information should be directed:

- at consumers with increased susceptibility to contracting listeriosis, such as pregnant women, the elderly and immunocompromised persons;
  to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate consumption of certain ready-to-eat foods that have been identified in national risk assessment studies, taking into consideration the specific regional conditions and consumption habits;
- to consumers to educate them on household practices and behaviours that would specifically keep the numbers of *L. monocytogenes* that may be present in foods, to as low a level as possible by

- setting refrigerator temperatures so that product temperatures should, wherever possible, not exceed 6°C, since the growth of *L monocytogenes* is considerably reduced at temperatures below 6°C;
- frequently washing and disinfecting the household refrigerator since *L. monocytogenes* can be present in many foods and grow at refrigerator temperatures, and thus contribute to cross-contamination;
- respecting the shelf-life dates written on ready-to-eat foods.

Programs for health care providers should - additionally to consumer information - be designed to provide them with guidance that

- facilitates rapid diagnosis of foodborne listeriosis;
- provides means to rapidly communicate information on preventing listeriosis to their patients, particularly those with increased susceptibility

SECTION X - TRAINING

Objectives:

Those engaged in production and handling of ready-to-eat foods should be trained in the control of *L. monocytogenes*. to the extent appropriate for their responsibilities.

Rationale:

Controls specific to *L. monocytogenes.* are generally more stringent than routine Good Hygiene Practices.

10.1 Awareness and responsibilities

Industry (primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations have an important role in providing specific training for control of *L. monocytogenes*.

10.2 Training programs

Personnel involved with the production and handling of ready-to-eat food should have appropriate training in:

- the nature of *L. monocytogenes*, its harbourage sites, and its resistance to various environmental conditions to be able to conduct a suitable hazard analysis for their products;
- control measures for reducing the risk of *L. monocytogenes* associated with ready-to-eat foods during processing, distribution, marketing, use and storage;
- the means for verifying effectiveness of control programs, including sampling and analytical techniques;

10.3 Instruction and supervision

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

10.4 Refresher Training

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

ANNEX I: RECOMMENDATIONS FOR AN ENVIRONMENTAL MONITORING[9] PROGRAM FOR *LISTERIA MONOCYTOGENES* IN PROCESSING AREAS

(Should be linked to section 5.9 and 6.5)

Manufacturers of ready-to-eat foods should consider the potential risk to consumers in the event their products contain *L. monocytogenes* when they are released for distribution. The necessity for an environmental monitoring program is highest for ready-to-eat foods that support *L. monocytogenes* growth and that are not given a post-packaging listericidal treatment. Recontamination has led to many of the recognised outbreaks of listeriosis. One effective element of managing this risk is to implement a monitoring program to assess control of the environment in which ready-to-eat foods are exposed prior to final packaging.

A number of factors (a – i) should be considered when developing the sampling program to ensure the program's effectiveness:

a) Type of product and process/operation

The need[10] for and extent of the sampling program should be defined according to the characteristics of the RTE foods (supporting or not supporting growth), the type of processing (listericidal or not) and the likelihood of contamination or recontamination (exposed to the environment or not). In addition, consideration also needs to be given to elements such as the general hygiene status of the plant or the existing history of *L. monocytogenes* in the environment.

b) Type of samples

Environmental samples consist of both food contact and non food contact surface samples. Food contact surfaces, in particular those after the listericidal step a prior to packaging, present a higher risk of directly contaminating the product, while for non food contact surfaces the risk will depend on the location.

Raw materials may serve as a source of environmental contamination and may therefore be included in the monitoring program.

c) Target organisms

While this document addresses Lm, effective monitoring programs may also involve testing for *Listeria* spp; their presence is a good indicator of conditions supporting the potential presence of *Listeria monocytogenes*. Where appropriate and shown to be valid, other indicator organisms may be used.

d) Sampling locations and number of samples

The number of samples will vary with the complexity of the process and the food being produced.

Information on appropriate locations can be found in published literature, can be based on process experience or expertise or in plant surveys. Sampling locations should be reviewed on a regular basis. Additional locations may need to be sampled depending on special situations such as major maintenance or construction or when new or modified equipment has been installed.

[9] Environmental monitoring is not to be confused with monitoring as defined in the HACCP.
[10] Products such as in pack pasteurised foods which are not further exposed to environment may not necessarily require a formal monitoring

e) Frequency of sampling

The frequency of sampling would be based primarily on the factors outlined under sub-heading "Type of product and process/operation". It should be defined according to existing data on the presence of *L. monocytogenes* in the environment of the operation under consideration.

In the absence of such information sufficient suitable data should be generated to correctly define the appropriate frequency. These data should be collected over a sufficiently long period as to provide reliable information on the prevalence of *L. monocytogenes* and the variations over time.

The frequency of sampling may need to be increased as the result of finding *L. monocytogenes* in environmental samples. This need will depend on the significance of the finding (e.g. risk of direct contamination for the product).

f) Sampling tools and techniques

It is important to adapt the type of sampling tools and techniques to the type of surfaces and sampling locations. For example sponges may be used for large flat surfaces, swabs may be more appropriate for cracks and crevices or scrapers for hard residues.

g) Analytical methods

The analytical methods used to analyse environmental samples should be suitable for the detection of *L. monocytogenes* and of other defined target organisms. Considering the characteristics of environmental samples it is important to demonstrate that the methods are able to detect the target organisms. This should be documented appropriatelly.

Under certain circumstancies it may be possible to composite (pool) certain samples without loosing the required sensitivity. However, in the case of positive findings additional testing will be necessary to determine the location of the positive sample.

Fingerprinting isolates by one or more of the available genetic techniques (e.g., pulsed field gel electrophoresis, ribotyping) can provide very useful information about the source(s) of *L. monocytogenes* and pathway(s) that lead to contamination of the food.

h) Data management

The monitoring program should include a system to record the data and their evaluation, e.g. performing trend analyses. A long-term review of the data is important to revise and adjust monitoring programs. It can also reveal low level, intermittent contamination that may otherwise go unnoticed.

i) Actions in case of positive results

The purpose of the monitoring program is to find *L. monocytogenes* or target organisms if present in the environment. Generally manufacturers should expect to find them occasionally in the processing environment. Therefore an appropriate anticipated action plan should be designed to adequately respond to positive findings.

The manufacturer should react to each positive result; the nature of the reaction will depend upon the risk of contaminating the product.

The plan should define the specific action to be taken and the rationale. This could range from no action (no risk of recontamination), to intensified cleaning, to source tracing (increased environmental testing), to review of hygienic practices up to holding and testing of product.

ANNEX II. DERIVING MICROBIOLOGICAL LIMITS AND SAMPLING PLANS IN MICROBIOLOGICAL CRITERIA FROM FOOD SAFETY OBJECTIVES; EXAMPLE: *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOOD PRODUCTS

Table of content

Preamble

On behalf of the head of the German CCFH delegation a drafting group meeting on the CCFH Listeria document took place in Berlin from 21.- 24. September 2004. The meeting aimed at the revision of the former *"Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the [Management] of L. monocytogenes in Foods"* on the basis of comments and at the elaboration of a new document as on the establishment of Food Safety Objectives /FSO's) and related criteria for Listeria (ALINORM 04/27/13, para 91-100). The drafting group meeting discussion focussed on the transition of data of risk assessment studies into FSO's and related Performance Objectives and criteria, including Microbiological Criteria and at drafting the specific amendments for *L. monocytogenes* in ready-to-eat foods. Generally, the new elaborated document is intended to be an additional part (ANNEX II) of the main guideline document in the future. The ANNEX II should be understood as an preliminary draft to show the procedure on how to calculate Performance Objectives, Microbiological limits and sampling plans based on a assumed Food Safety Objective, which is based on the risk assessment outcomes. The herewith drafted procedure can be seen as a decision tool and as the way of choice for setting the objectives and criteria. Hence, the ANNEX II outlines how the Food Safety Objective can serve as the translation between a public health goal (e.g. cases of listeriosis) and microbiological limits for *L. monocytogenes.*

The calculated results may be taken as a support for the consideration of setting Microbiological Criteria. Therefore, no specific recommendations for Microbiological Criteria for *L. monocytogenes* were given in the document as this depends largely on the setting of a Food safety Objective. The ANNEX II describes in general four food commodities of different risk categories as examples to describe the relation between a Food Safety Objective and the Performance Objective. In addition, one example is described to calculate a Microbiologial criterium for a specific food commodity.

1. INTRODUCTION

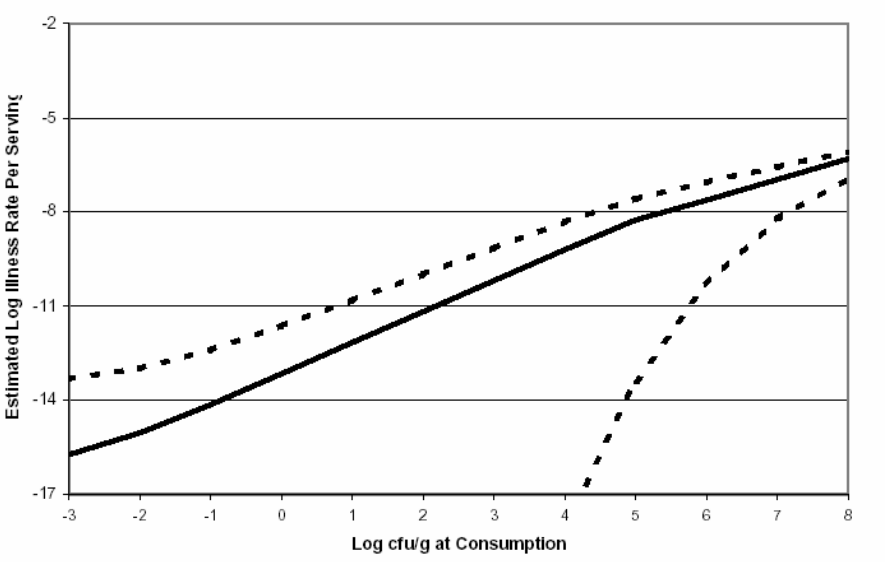
This risk assessment on *Listeria (L.) monocytogenes* in ready-to-eat (RTE) foods (WHO/FAO 2004) was undertaken to (i) respond to the request of the Codex Committee on Food Hygiene (CCFH) for sound scientific advice as a basis for the development of guidelines for the control of *L. monocytogenes* in foods; and (ii) address the needs expressed by Member countries for adaptable risk assessments that they can use to support risk management decisions and to conduct their own assessments. The present Annex II uses the information from the risk assessment mentioned to illustrate how microbiological limits and sampling plans as components of a Microbiological Criterion (MC) for *L. monocytogenes* can be established using Food Safety Objectives (FSO's) and derived performance objectives (PO's) as a basis. This is done using four food commodities as examples. These examples also cover situations where setting and using MCs is not a feasible way of verifying that a food lot meets the FSO or PO as appropriate.

1.1 The risk assessment

The risk assessment on *L. monocytogenes* focused on four ready-to-eat foods in order to provide examples of different risk categories. The risk was calculated on a per serving basis and on a population basis. An example of a risk characterization curve is presented in figure 1 where the per serving risk of contracting listeriosis for a particular risk group (the elderly) from a particular food (deli meat) as a function of the dose consumed is given.

Figure 1.

Cases of listeriosis (per serving) for the elderly population as a function of *Listeria monocytogenes* concentration per gram at consumption in Delicatessen meats (FDA/FSIS 2003)



1.2 Appropriate level of protection, food safety objective and performance objective

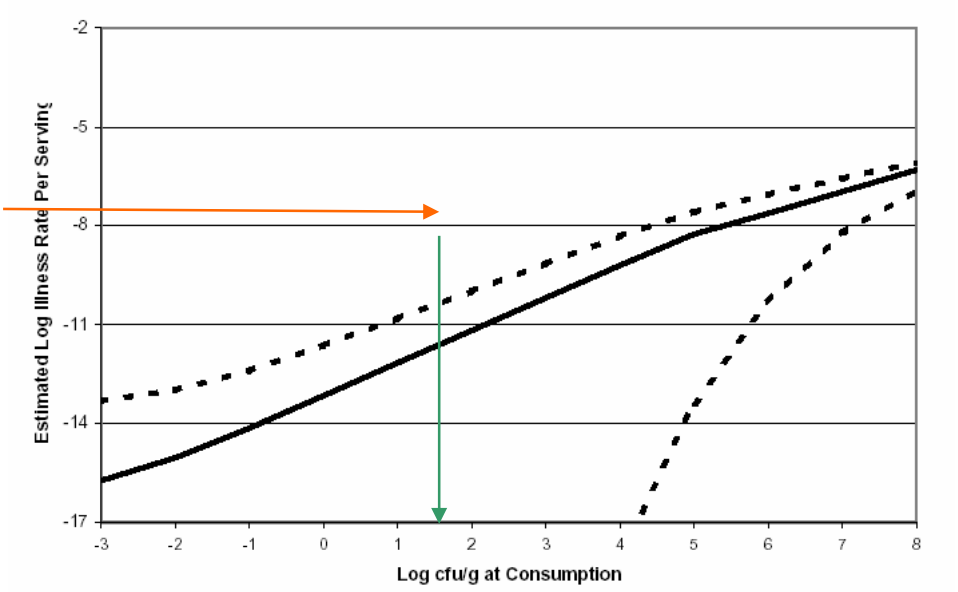
A government will typically express public health targets, i.e. its appropriate level of protection (ALOP), for its food safety policy in goals related to the incidence of disease. For instance, a government could aim for a 50% reduction of the number of people getting sick from listeriosis associated with ready-to-eat foods. Such expressions do not provide food processors, producers, handlers, retailers or trade partners with information as to how to achieve this goal or how to change/improve in their operations. To be actionable, the targets for food safety set by governments must be converted into parameters that can be controlled by food producers, and potentially verified by government agencies. Therefore, the concepts of "food safety objective" (FSO) and “performance objective” (PO) have been proposed.

An FSO translates the number of cases of foodborne illness a society is prepared to tolerate to the level and/or frequency of the pathogenic microorganisms in the food at the time of consumption. No national government actually regulates food safety at the moment of consumption and an equivalent term, the PO, may be set at a specific step or steps earlier in the food chain. The term is used to define the maximum frequency and/or concentration of the pathogenic microorganism that could be present in the food at particular earlier steps that enables the FSO to be met.

In simple graphic terms, the ALOP may be expressed on the Y-axis of the risk characterization curve and the FSO the corresponding X-axis-value (figure 2).

Figure 2.

Cases of listeriosis (per serving) for the elderly population as a function of *Listeria monocytogenes* concentration at consumption in Delicatessen meats (FDA/FSIS 2003)



1.3 Microbiological criteria

FSO's and PO's are not microbiological criteria (MCs), although they are also expressed in quantitative terms. A MC requires amongst others that the food product, the analytical size and method, the sampling plan and the microbiological limits are defined. MCs may be used as acceptance criteria for a food lot , especially in situations where no prior knowledge on processing conditions is available. In contrast, the PO or FSO is the target level (frequency and concentration) of a hazard at specific point during processing or at consumption which will ensure that a specific public health goal is obtained. They do not specify sampling plans and are not designed to be verified by microbiological testing. As illustrated by the examples below, the FSO or PO can in certain situations be translated into an MC following also the general guidelines from Codex documents (ref). Microbiological limits in an MC are for instance the level of microorganisms that should not be exceeded in any sample, expressed as a number (for example 100 per gram) or absence in an analytical unit (for example 25 gram) given a particular number of samples.

1.3.1 Nature of sampling plans

We assume that microorganisms are homogeneously distributed in food products and normally it is anticipated that they follow a log-normal distribution. This means that when the arithmic numbers are transformed in log10 units a mean log number and its standard deviation (s.d.) can be calculated (figure 3).

Figure 3 Log normal distribution around a mean log count with two s.d.	To be completed

The ability of a sampling plan to distinguish between "acceptable" and "non-acceptable" lots is highly influenced by this standard deviation.. In order to understand the performance of a sampling plan (indicating the number of analytical units and criteria for acceptance or rejection) an 'operating characteristic' (OC) curve can be used. For a two-class plan which uses one microbiological limit (see figure 4) this curve has two scales. The X-axis shows a measure of lot quality like the fraction or percentage of positive ('defective') units in the lot being tested. The vertical scale gives the probability of acceptance. When used for a lot which has a specified proportion of 'defectives', the value on the OC curve gives the probability that such a lot will be accepted when tested according to the sampling plan. The probability that such a lot will be rejected is given on the OC curve, by 1 minus this value.

The stringency of a sampling plan in making decisions can be increased by increasing number of samples. This should be distinguished from a shift of the OC curve that is achieved by decreasing the acceptance number *c* or changing the microbiological limit.

Figure 4. Operating characteristic curve	To be completed

In an example given below, the sampling plan is n=10, c=0 and m=100 bacteria per gram. Figure 5 starts with the OC curves for such a sampling plan with two different standard deviations.; 0.2 and 0.8, respectively. In the first case, lots will be rejected with 95% probability when the mean concentration is 1.87 log units. If the s.d. is 0.8 log units, the same sampling plan will reject lots with 95% probability when the mean concentration is 1.48 log units.

The values given above will typically be the operation of government control, however, in order to meet such a MC the industry has to target their mean concentration to ensure acceptability with 95% probability which will result in a much lower mean value.

When the distribution of the microorganism in a lot is known (mean microbiological limit and standard deviation) the MC the so-called performance of the sampling plan can be assessed, i.e. how sure one can be that faulty lots are rejected and non-faulty lots accepted. A processor would in parallel ask how sure he/she can be that acceptable lots are indeed accepted. A spread sheet enabling evaluation of sampling plans can be found at http://www.foodscience.afisc.csiro.au/icmsf/samplingplans.htm.

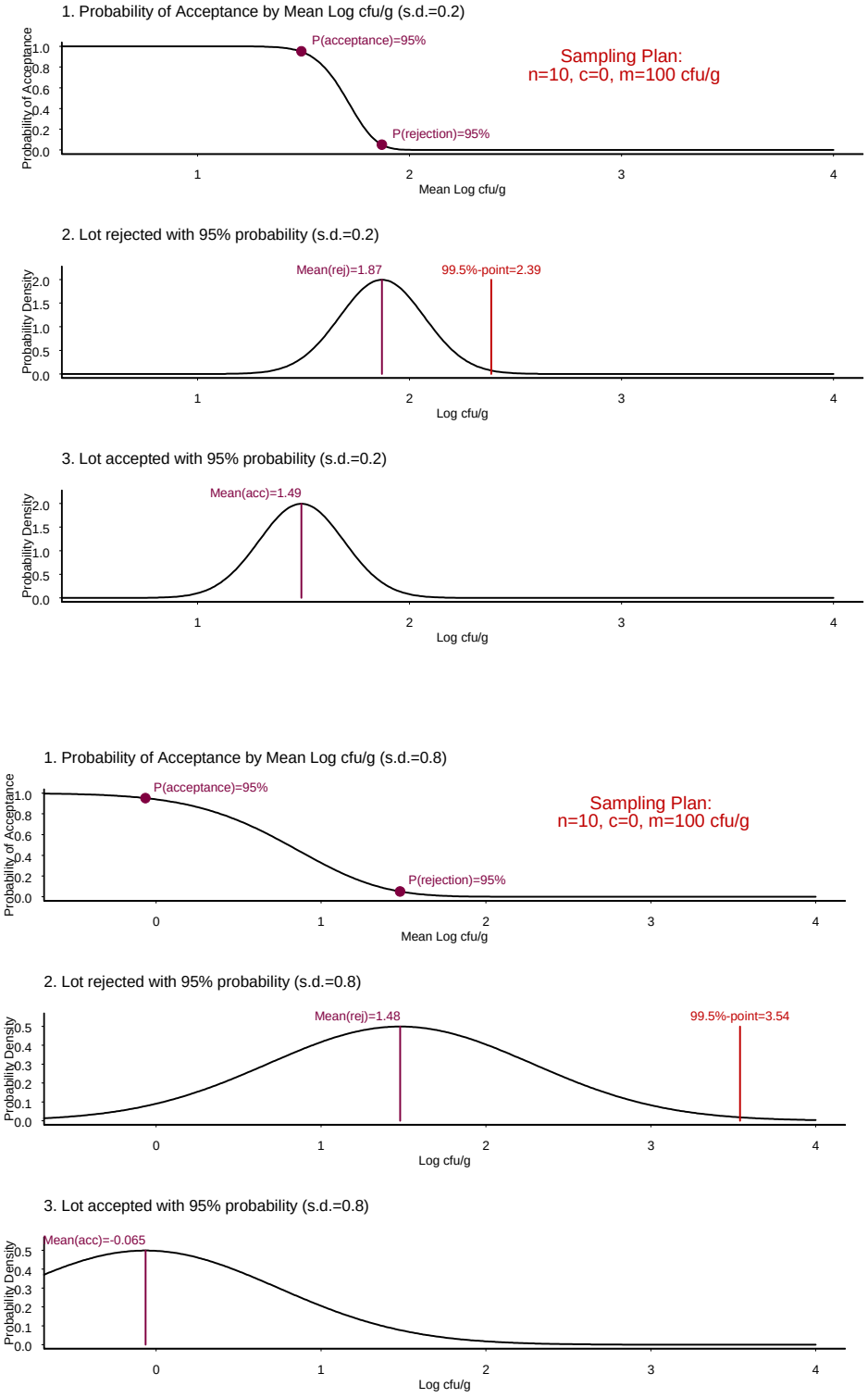


Figure 5. Probability of acceptance and rejection of a lot by mean log cfu per grams and different standard deviations

1.4 Setting a microbiological limit and choosing a sampling plan based on Food Safety Objective or Performance Objective

1.4.1 Terms and definitions

The elaboration of microbiological limits and sampling plans based on FSO's needs the following parameters:

Performance Objective (PO):

The PO is the target level of the hazard at steps earlier in the food chain than at consumption. This can be e.g. at retail, at manufacture or at harvest. If a microbiological criterion is developed from a PO, the point of sampling has to be specified. (see Codex Alimentarius *"Principles for the establishment and application of microbiological criteria for foods"*). The fate of *L. monocytogenes* between the point of sampling and final consumption has to be analysed. Essentially it is the summary of log values of all potential increases or decreases of *L. monocytogenes* working back from the FSO. The PO is found by adding or subtracting events between the particular PO and the FSO. PO can be smaller equal or bigger than the FSO depending on the processes in between. In the examples given below, point estimates are used but when developing the PO it should be realised that it is a function of a mean and standard deviations and a decision must be made about the stringency when setting the PO.

Mean value of maximally accepted concentration distribution (μ_{po}) and standard deviation (s.d.):

When developing a microbiological criterion from the PO, it is statistically seen as the upper limit of a frequency distribution around a mean log count (as depicted in Figure 3). It is a risk management decision how far from the mean log count, the PO should be, e.g., with what probability a given sampling plan should reject (or accept) faulty (or acceptable) lots. In the examples below, the mean value (μ_{po}) is defined as the PO minus three times the standard deviation (s.d.). The value μ_{po} is the mean value of the maximally acceptable concentration distribution (in log cfu/g) and s.d. is the assumed standard deviation of this distribution. The standard deviation may be derived from baseline studies on a specified food item. If the s.d. is not known, one commonly assumed that it is 0.8. This value is based on previous experiments and includes also the variance of the method. To show the influence of varying s.d. values on the number of samples taken, a scenario was calculated for three sd values: 0.2, 0.4 and 0.8.

Probability of rejecting non conforming lots (p_{rej}):

The required probability of rejecting a non-conforming lot has to be specified. Non-confirming corresponds to a mean value that exceeds $\mu_{po.}$ This value is set according to risk considerations and is often 95%. However, for very serious risks, a higher rejection probability may be chosen – or a lower FSO.

Microbiological limit (m):

To specify the sampling plan the microbiological limit *m* needs to be defined. This value is defined on the basis of the method used to detect the microorganism, i.e., presence-absence testing or quantitative techniques such as plate count or MPN. The value for m should never be below the detection limit of the method to be used. For *L. monocytogenes*, testing 25 gram for presence/absence is equal to 0.04 cfu/gram (or -1.39 log units). Testing by 10-fold-dilution and using MPN based techniques, the lower limit of detection is 0.3 equal to –0.52 log units. Direct plating of a 10-fold diluted suspension has a lower detection limit of 100 cfu/g; or 2 log units. For practical reasons m should be set between the mean value of a concentration (μ_{po}) and the value for the performance objective. It should be noted that

"m" has a slightly different meaning in some 3-class sampling plans where it is the level that distinguishes marginally acceptable form non-acceptable levels.

Maximum allowable number of positive samples (c) :

The maximum allowable number of sample units yielding unsatisfactory test results is given in "c". It depends essentially on the pathogen to be detected and the seriousness of the resulting disease. For pathogens c is frequently set to zero. If c is greater than 0, then the number of samples for the same stringency will be greater.

Final calculation

The probability that a single sample yields a positive result (>m) together with the probability of rejection are taken to calculate the number of samples (n) needed to find with 95% probability at least one positive sample unit in a defective lot. Together with the other information given in the example the sampling plan can be expressed and incorporated in the total set of information needed to express a microbiological criterion. In the smoked fish example below, a table exemplifies how the limits and the sampling plans can be set given a particular FSO and a particular PO.

2. CATEGORIZATION OF FOOD

The risk assessment on *L. monocytogenes* in ready-to-eat foods covered several types of ready-to-eat products and the risk form individual types of commodities differed depending on a set of characteristics:

- growth of *L. monocytogenes* was or was not possible in the product
- quantities consumed
- population that consumed

Products that supported growth of the organism carried a much higher risk than products that did not support growth. Some products had a very low per serving risk (e.g. pasteurised milk) but where consumed in large quantities – others had a high per serving risk (e.g. smoked fish) but were consumed by only few people. Four food categories are listed in table 1. The foods were classified according to their

- treatment by the manufacturer (heat treatment or other stabilizing procedures (yes/no), use of preservatives (yes/no), portioning or other treatment steps with recontamination potential after the end of the manufacturing process (yes/no), type and date of packaging;
- indications with respect to storage conditions and marketability (shelf-life or best-before date),
- use (suitability for defined consumer groups, requirement of heat treatment before consumption: yes/no) and
- product characteristics with respect to the capacitiy of multiplication of *L. monocytogenes*.

The examples chosen in the following chapter have been selected to illustrate different risk categories.

3. SIMPLIFIED EXAMPLES OF DETERMINING PERFORMANCE OBJECTIVES AND MICROBIOLOGICAL LIMITS DERIVED FROM FOOD SAFETY OBJECTIVES AND DECIDING ON A SAMPLING PLAN

The following examples were developed to help to illustrate underlying principles that influence the establishment of PO's from FSO's. Also, a few selected examples illustrate how the PO can be used to determine the limit (m) number of samples in a 2-class sampling plan. To achieve this goal the examples were derived using a number of simplifying assumptions that are described below. The actual calculation of these values at different points in the food chain would require the replacement of the simplifying assumptions with specific production data related to the details and distributions associated with raw ingredients, products, processes, marketing practices, consumer practices, and sampling plans. The key general assumptions include:

- Point estimates were used when developing PO's from FSO's. Ultimately a real calculation of PO's would require inclusion of the variability of the products and processes and the level of confidence required by the food authority.
- Assuming that FSO's are established on the basis of the number of *L. monocytogenes* in a serving of food (e.g., 1000 CFU/serving), then the FSO on a "per g" or "per ml" basis would be determined by the FSO divided by the serving size (e.g., FSO on per serving basis = 1000 CFU with a 10 g serving = 100 CFU/g)
- The PO at different points is derived by subtracting the amount of growth expected (or adding the amount of reduction) as compared to the point of consumption.
- A probability of rejection of 95% was set for the sampling plans and limits developed

Note:

In developing these examples, no attempt was made to relate the various FSO's to an incidence of disease, however, this could be done using available risk assessments in combination with information on consumption rates and degree of compliance with performance targets.

3.1 Pasteurized milk

3.1.1 Description of the product and its production

This product has a very low contamination rate, a high consumption rate, a large serving size, and supports the rapid growth of *L. monocytogenes*. For the purposes of this example, the production is assumed to involve the following steps that are critical for control of *L. monocytogenes*:

- Raw milk
- Pasteurization
- Filling
- Refrigerated storage (at 5°C)
- Home use

3.1.2 Product/process specific assumptions

The product would be expected to have no *L. monocytogenes* immediately following pasteurization. However, the product may become recontaminated during filling or other intervening steps that occur post-pasteurization but prior to sealing of the final package. This occurs about once every 4500 containers (FDA/FSIS 2003). Although recontamination may take place in the home (at an unknown frequency), this is not dealt with in this example. With respect to the calculations, it is assumed that:

- The serving size is 100 ml
- Shelf life from date of manufacture: 1 week
- Growth rate of *L. monocytogenes* at 5ºC: 1 log per day

3.1.3 Selection and calculation of PO's and other limits

One PO was selected for this example, at end of packaging. This was derived at by taking the FSO (examples in table 2) and subtracting the expected increase of *L. monocytogenes* numbers during one week of refrigerated storage. For example, if an FSO is set at 10.000 CFU per serving, then for a 100 ml serving size the FSO per ml is 100 CFU (2.0 $\log_{10}$ CFU/ml). If the growth expected during the products one week shelf life is 7 logs (1.0 log/day), then the PO that would be needed to ensure that the FSO is not exceeded would be calculated as:

$$PO = 2.0 – 7.0 = -5.0.$$

This would be equivalent to 1 CFU per 100.000 ml, or, the equivalent of one1-liter container in one hundred containers being contaminated with a single cell of *L. monocytogenes*. Examples of the PO's for different FSO's are provided below

Table 2: Pasteurized milk: Examples of the PO's for different FSO's

Log (cfu/serving)	Log (cfu/ml)			
FSO	FSO	PO (home)	PO (retail)	PO (manufacturing)
7.0	5.0			-2.0
6.0	4.0			-3.0
5.0	3.0			-4.0
4.0	2.0			-5.0
3.0	1.0			-6.0
2.0	0.0			-7.0
1.0	-1.0			-8.0
0.0	-2.0			-9.0

3.1.4 Conclusions

For a product such as pasteurized milk that supports the growth of *L. monocytogenes*, it is not feasible to set a microbiological criterion. No practical sampling plan would be able to detect this level of contamination. Since contamination with *L. monocytogenes* is mainly an issue of post-process contamination, control measures would need to rely on ensuring good hygienic processing practices and elimination of the organism in the filling area.

3.2 Cold smoked Fish

3.2.1 Description of the product and its production

This product has high contamination levels, low consumption rates (although this varies among countries), a small serving size, and supports a moderate growth of *L. monocytogenes.* The production of this product class involves the following steps:

- Raw Fish
- Salting
- Smoking
- Chilling
- Slicing
- Final packaging
- Refrigerated Storage
- Home Use

At retail, the typical rate of contamination is 2 to 6% with most contaminated samples having less than 100 CFU *L. monocytogenes* per g.

3.2.2 Product/process specific assumptions

The incoming raw fish may be sporadically contaminated with *L. monocytogenes* which may survive at some level the salting and cold-smoking practices. However, in most smoke houses, the major source of product contamination is after smoking; during slicing. There are no additional bactericidal treatments between slicing and consumption and the primary determinant of *L. monocytogenes* levels is the temperature and duration of refrigerated storage. Also, levels of lactate, if added, and lactic acid bacteria influence the growth of *L. monocytogenes*. Assumptions made include:

- The serving size is 50 g
- Total shelf life (at 5ºC) from packaging: 3 weeks.
- Time between manufacture and retail sale: 1 week
- Home storage before consumption: 2 weeks
- Growth rate of *L. monocytogenes* at 5ºC: There is substantial variation within this product group in relation to the rate and extent of growth. As a means of considering this difference, two assumptions were considered: a) growth rate = 1.0 log per week and b) growth rate = 0.3 log per week

3.2.3 Selection and calculation of PO's and microbiological limits

Two PO's were selected based on likely points for inspection or analysis. These were immediately after final packaging (where 3 weeks refrigerated storage life is assumed) and the finished product at point of retail sale (where 2 weeks of refrigerated storage life is assumed to remain). For a specified FSO expressed as a log number, the corresponding PO is calculated by subtracting the increase resulting from growth during 2 or 3 weeks:

- PO (manufacturer) = FSO – expected growth between production and consumption = FSO - (growth rate x 3 weeks)
- PO (retail) = FSO – expected growth between sale and consumption = FSO – (growth rate x 2 weeks).

Table 3: Cold smoked fish: Examples of the PO's for different FSO's assuming different growth rate at 5ºC:

growth rate of 1.0 log per week:

Log (cfu/serving)	Log (cfu/g)		
FSO	FSO	PO (retail)	PO (manufacturing)
7.0	5.3	3.3	2.3
6.0	4.3	2.3	1.3
5.0	3.3	1.3	0.3
4.0	2.3	0.3	-0.7
3.0	1.3	-0.7	-1.7
2.0	0.3	-1.7	-2.7
1.0	-0.7	-2.7	-3.7
0.0	-1.7	-3.7	-4.7
PO (manufacturer) = FSO – 3 x growth rate = FSO – 3; PO (retail) = FSO – 2 x growth rate = FSO – 2.			

growth rate of 0.3 log per week:

Log (cfu/serving)	Log (cfu/g)		
FSO	FSO	PO(retail)	PO(manufacturing)
7.0	5.3	4.7	4.4
6.0	4.3	3.7	3.4
5.0	3.3	2.7	2.4
4.0	2.3	1.7	1.4
3.0	1.3	0.7	0.4
2.0	0.3	-0.3	-0.6
1.0	-0.7	-1.3	-1.6
0.0	-1.7	-2.3	-2.6
PO (manufacturer) = FSO – 3 x growth rate = FSO – 0.9; PO (retail) = FSO – 2 x growth rate = FSO – 0.6			

3.2.4 Conclusions

These scenarios clearly illustrate how growth rate during refrigerated storage has a major impact on setting PO's. It is also shown that by limiting the growth rate, the stringency of the control measures of manufacture and/or retail can be reduced yet it still achieves the same FSO. Since distribution of the bacterium in the food (and hence the standard deviation around the mean log count) does not change, the difference between the PO and the microbiological limit is not affected by growth rate.

3.3 Pre-cut leafy vegetable (shredded lettuce)

3.3.1 Description of the product and its production

For this example, these products will be assumed to have moderate levels and frequencies of contamination, medium frequency of consumption, medium serving size and support the moderate growth of *L. monocytogenes.* The production of this product class involves the following steps:

- Harvest from the field
- Wash
- Slice (Shred)
- Wash with acidulant, and chill
- Remove excess water
- Package
- Distribute refrigerated
- Home storage

3.3.2 Product/process specific assumptions

The main source of contamination is in the field and for ease of calculation the frequency of contamination of raw materials is assumed to be 10%, e.g. 1 in 10 heads of lettuce. Also, the level of contamination of the heads is assumed to be 100 CFU/g (or 2.0 log10 units).

- Serving size: 100 g
- Total shelf life (from end of manufacturing): 3 weeks
- Time between manufacture and retail sale: 1 week
- Home storage before consumption: 2 weeks
- Growth rate of *L. monocytogenes* in this product at 5°C: 1 log per week
- Acidulant treatment reduces the level of *L. monocytogenes* by 2 log units

3.3.3 Selection and calculation of PO's and microbiological limits

This example illustrates how a manufacturer or control authorities may set PO's not just at the end of manufacturing or at retail but also further back the food production chain. Four potential PO's were selected based on the key steps in the process:

- PO (retail). FSO minus expected growth (in log units) during the 2 weeks of assumed retail storage.
- PO (end of manufacturer) after acidulant wash. At this stage, the product has been shredded and thoroughly mixed and any contamination is evenly distributed. As in the smoked fish example, this PO would be the FSO minus expected growth (in log units) during the 3 weeks of time from end of

manufacturing to consumption. In contrast to the smoked fish example, the acidulant treatment is assumed to reduce the level during processing with 2 log units.

- PO (after shredding and before acidulant washing). This PO reflects the overall level of contamination just prior to the only listericidal treatment. This PO is, in turn, dependent on the level of *L. monocytogenes* and extent of contamination in the raw ingredient which is distributed throughout the product during shredding.
- PO (raw material - heads of lettuce). This PO has both a frequency value and a maximum concentration of *L. monocytogenes* cells. Both factors must be considered since contamination will be homogeneously distributed when both contaminated and uncontaminated heads are combined during shredding and initial washing. Thus, the level of *L. monocytogenes* in the product after shredding would be calculated by multiplying the $\log_{10}$(CFU/g) in the contaminated heads by the % of heads that are contaminated (e.g., 2.0 $\log_{10}$(CFU/g)/contaminated head X 10% contaminated heads = 1.0 $\log_{10}$(CFU/g) in the shredded product).

The four PO's are then calculated according to the following manner:

- PO (retail) = FSO – expected growth during the 2 weeks of storage = FSO – 2.
- PO (end of manufacture) equals FSO minus increase during 3 weeks = FSO – 3. This is also the PO at retail minus 1.
- PO (after shredding before washing) can be calculated from the PO (manufacturer) based on the effectiveness of the *Listeria* reduction step i.e. the acidulant treatment. Thus, if the acidulant treatment provides a 2.0 $\log_{10}$(CFU/g) decrease, then in this scenario the PO (after shredding) is **higher** than the PO at end of manufacturing: PO (shredding) = PO(manufacturer) + 2.
- PO (raw material) is calculated from the PO (shredded material) based on the level of *L. monocytogenes* post-shredding but pre-acidulant treatment, and is the frequency and extent of contamination of the raw ingredient (lettuce heads) that cannot be exceeded in order to not exceed the capability of the acidulant treatment, and thus achieve the PO_{PAW}. Potentially, there are different combinations of initial contamination rates and levels that would allow PO'S to be met. For example, if the FSO was 3.0 $\log_{10}$(CFU/g) and the corresponding PO (retail), PO (manufacturer), and PO (shredding) were 1.0, 0.0, and 2.0, respectively, then the level of *L. monocytogenes* should not exceed 3.0 $\log_{10}$(CFU/g) on contaminated heads of lettuce if 10% of the heads were contaminated or 4.0 $\log_{10}$(CFU/g) if the frequency of contamination was 1%.

Table 4: Pre-cut leafy vegetable (shredded lettuce): Examples of the PO's for different FSO's and various scenarios

Log (cfu/serving)	Log (cfu/g)				
FSO	FSO	PO (retail)	PO (manufacturer)	PO (shredding)	PO (raw heads)[1]
6.0	4.0	2.0	1.0	3.0	0.1; 4.0
5.0	3.0	1.0	0.0	2.0	0.1; 3.0
4.0	2.0	0.0	-1.0	1.0	0.1; 2.0
3.0	1.0	-1.0	-2.0	0.0	0.1; 1.0
2.0	0.0	-2.0	-3.0	-1.0	0.1; 0.0
1.0	-1.0	-3.0	-4.0	-2.0	0.1; -1.0
0.0	-2.0	-4.0	-5.0	-3.0	0.1; -2.0
1. Also indicated is the maximum frequency of contaminated heads allowed (here 10%)					

3.3.4 Conclusions

The PO for the shredded lettuce after shredding but before the acid wash may be detectable using techniques for large sample sizes and feasible using standard methods Direct examination of individual heads of lettuce as the raw material will be of limited practical usefulness if the frequency of contamination is below 20% due to the large number of samples to provide sufficient sampling confidence with this defect rate.

3.4 Dry fermented sausages

3.4.1 Description of the product and its production

These products are made from ingredients that will likely contain *L. monocytogenes* and may support the growth of *L. monocytogenes* during initial manufacturing if the fermentation is slow or inadequate. After fermentation and drying, these products do not support growth. Additional recontamination during slicing is possible, particularly in a deli or food service environment, but the microorganism would not be expected to grow. However, the process discussed in this example is for product to be sold without slicing. These products have moderate contamination, moderate consumption, and relatively small serving size. The process is:

- Raw meats
- Mixing of ingredients
- Adding spices and starter culture
- Filling casings
- Fermentation
- Drying
- Retail sale without slicing
- Home storage and use

3.4.2 Product/process specific assumptions

As mentioned, there is no growth during the shelf life period, and counts may even decline in some products. However, for this example no change in bacterial levels is assumed – as a conservative assumption.

- Serving size: 50 g
- Shelf life: can be months
- The extent of growth during the initial steps of production does not exceed 1.0 $\log_{10}$ CFU/g.

3.4.3 Selection and calculation of PO's and microbiological limits

Three PO's were selected based on likely points in the food chain where the product might be examined.

- PO (retail). Since the levels in this product do not change after manufacture, the PO (retail) = FSO
- PO (manufacturer). The level of *L. monocytogenes* in the finished product at the point of manufacturer. Since the levels in this product do not change, the PO (manufacturer) = FSO
- PO (raw ingredients). After mixing raw ingredients into the final batter, just prior to stuffing, fermentation and drying. A *L. monocytogenes* growth of 1 log unit is assumed during stuffing, fermentation, and drying and this PO is therefore the FSO minus 1.0 $\log_{10}$(CFU/g). Thus, PO (raw ingredients) = FSO – 1.

Table 5: Dry fermented sausages: Examples of the PO's for different FSO

Log(cfu/serving)	Log (cfu/g)			
FSO	FSO	PO (retail)	PO (manufacturer)	PO (raw batter)
6.0	4.3	4.3	4.3	3.3
5.0	3.3	3.3	3.3	2.3
4.0	2.3	2.3	2.3	1.3
3.0	1.3	1.3	1.3	0.3
2.0	0.3	0.3	0.3	-0.7
1.0	-0.7	-0.7	-0.7	-1.7
0.0	-1.7	-1.7	-1.7	-2.7

3.4.5 Conclusions

It is likely that a microbiological criterion be feasible for some of the PO's

3.5 Setting a microbiological limit and deciding on a sampling plan based on FSO and PO

The following examples develop a series of limits and sampling plans at retail for cold-smoked salmon. The assumptions mentioned above (50 g serving size, 0.3 log units of growth per week at 5ºC and a two-week storage between consumption and retail)

Step	**Example: smoked salmon**	**Explanatory notes**
1	FSO (per 50g serving) = 4.0, 5.0 or 6.0 (log units) per 50g FSO on consumption per annum basis = 2.3, 3.3 or 4.3 cfu/g	A government has decided on an FSO of 10,000 cfu *L. monocytogenes* from a serving of cold smoked salmon.
2	PO is set at retail level – this is also the sampling point.	The point of sampling has been specified according to Codex principles. This has been set at retail.
3	Under refrigeration at 5°C the expected growth rate is 0.3 log per week, a shelf life of 2 weeks is assumed	Assumptions made to derive a PO from the FSO
4	PO (retail) =2.3 – 2 x 0.3 = 1.7 cfu/g PO (retail)=3.3 – 2 x 0.3 = 2.7 cfu/g PO (retail)=4.3 – 2 x 0.3 = 3.7 cfu/g	The PO in this example is a point estimate and is calculated by subtracting the expected growth of *L. monocytogenes* during retail storage from the FSO
5	μ_{po} = 1.7 - 3 x 0.2, μ_{po} = 1.1 cfu/g μ_{po} = 1.7 - 3 x 0.4, μ_{po} = 0.5 cfu/g µpo = 1.7 - 3 x 0.8, μ_{po}= - 0.7 cfu/g μp_o = 2.7 - 3 x 0.2, μ_{po}= 2.1 cfu/g µpo = 2.7 - 3 x 0.4, μ_{po}= 1.5 cfu/g	The PO is the upper limit of a frequency distribution (statistically seen). The mean value μ_{po} is defined by subtracting from the PO three times the standard deviation (sd) around the mean log count. s.d. may be derived from baseline studies on a specified food item. If no prior knowledge is available, s.d. of 0.8 is commonly used. This value is based on previous

	μ_{po} = 2.7 - 3 x 0.8, μ_{po} = 0.3 cfu/g μ_{po} = 3.7 - 3 x 0.2, μ_{po} = 3.1 cfu/g μ_{po} = 3.7 - 3 x 0.4, μ_{po} = 2.5 cfu/g μ_{po} = 3.7 - 3 x 0.8, μ_{po} = 1.3 cfu/g	experiments and includes also the variance of the method. To show the influence of varying sd values on the number of samples taken, a scenario was calculated for three sd values: 0.2, 0.4 and 0.8.
6	Rejection probability : 95%	The rejection probability has to be decided upon. This is a risk manager decision. It indicates the probability by which faulty lots will be rejected by the sampling plan/criterion. In this example a value of 95% is chosen. This value is usually set according to certain risk considerations and widely in use.
7	assumptions for m: a) presence/absence in 25g:m = 0.04 *L. monocytogenes* per g (log -1.39) b) quantitative method: MPN m=0.3 *L. monocytogenes* per g (log -0.52) c) quantitative method: plate m=100 *L. monocytogenes* per g (log 2.0)	To specify the sampling plan, the microbiological limit "m" needs to be defined. This value is defined on the basis of the method used to detect the microorganism, i.e., presence/absence testing or quantitative techniques such as plate count or MPN. The value for m should never be below the detection limit of the method to be used.
8	assumptions for c: c = 0	c is the maximum allowable number of sample units yielding unsatisfactory test results. It depends essentially on the pathogen to be detected and the seriousness of the resulting disease. Normally it is set to zero. If c greater than 0, then the number of samples for the same stringency will be greater
9	Number of samples (n) calculated on the basis of the above assumptions – see detailed table below	The probability that a single sample yields a positive result (>m) together with the probability of rejection are taken to calculate the number of samples (n) needed to find with 95% probability at least one positive sample unit. Together with the other information given in the example the sampling plan can be expressed and incorporated in the total set of information needed to express a microbiological criterion.
10		

FSO / PO	log (cfu/g)		number of sampling units (n) when m is		
log(cfu/g)	σ (s.d.)	μ_{po}	0.04 cfu/g	0.3 cfu/g	100 cfu/g
2.3 / 1.7	σ = 0.2	1.1	1	1	-
	σ = 0.4	0.5	1	1	-
	σ = 0.8	-0.7	2	6	-
3.3 / 2.7	σ = 0.2	2.1	1	1	3
	σ = 0.4	1.5	1	1	27

	$\sigma = 0.8$	0.3	1	2	177
4.3 / 3.7	$\sigma = 0.2$	3.1	1	1	1
	$\sigma = 0.4$	2.5	1	1	2
	$\sigma = 0.8$	1.3	1	1	15

(rejection probability: 95%)

If levels of *L. monocytogenes* are distributed in the sample with a standard deviation of 0.2 log units, then a single sample using presence/absence test would ensure with 95% probability that the PO of 2.3 log units is not exceeded. If the standard deviation is 0.8, then 2 negative presence/absence tests are required to give the same probability. Using a method with m = 100 cfu/g does not give meaning when the PO is less than 100 (e.g. 1.7 cfu/g).

4. REFERENCES

(to be completed)

Table 1: Food categories and examples of products in the individual category with respect to the control of *Listeria monocytogenes*

No.	Name of the food category	Examples of food products
I	**Ready-to-eat foods whose production ensures a cilling of *L. monocytogenes* and whose recontamination must not be possible**	- Foods for babies and infants; - foods intended specifically for pregnant women, diseased and immunocompromized persons
II a	**Ready-to-eat foods which may be contaminated with *L. monocytogenes* and permit its multiplication**: - heat-treated and not otherwise stabilized * foods	- Cooked meat products, e.g. fryed products, Frankfurter type and boiled sausages (in particular sliced products) - Cooked fishery products, e.g. hot smoked fish, shrimps and crab meat (without preservatives) - Hors d'oeuvres and desserts prepared in a hot state and to be served in a cold state, e.g. pudding, mousse au chocolat and other cream dishes; - Liquid egg products and heat-treated delicatessen products, e.g. liquid egg, mayonnaise, dressings, salads made from meat, crabs, eggs and potatoes (without preservatives); - Pastry products with completely heated but easily perishable filling or layer; - Soft cheese, fresh cheese and fresh cheese preparations, mixed milk drinks.
II b	**Ready-to-eat foods which may be contaminated with *L. monocytogenes* and <u>permit its multiplication</u>:** Non heat-treated, non-stabilized* foods	- Raw meat products, e.g. minced meat, carpaccio, fermented sausage (in particular products with a short maturing period such as Mettwurst), fermented ham (provided that water activity is sufficient for multiplication of organisms); - Raw, marinated and/or cold smoked fishery products, e.g. sushi, white herring or herring with herbs, graved salmon, smoked salmon; - Pastry products with non-completely heated and easily perishable filling or layer; - Raw products, in particular pre-cut salads, but also, in principle, other vegetables and fruits; - Non-heat-treated delicatessen products, e.g. dressings, salads made from meat, herring,

		crabs, eggs, cabbage and potatoes (without preservatives); - Desserts prepared in a cold state and to be served in a cold state, e.g. tiramisu, cream dishes and fruit salads; - Non-heat-treated egg-containing products; - Raw milk cheese (soft and fresh cheese); - Certified milk.
III a	**Ready-to-eat foods which may be contaminated with *L. monocytogenes* and do not permit multiplication of *L. monocytogenes*** Heat-treated, stabilized* foods	- Cooked meat products with a very low pH value or very low water activity, e.g. jellified products and other non-perishable products; - Shrimps, crab meat (with preservatives); - Frozen and deep-frozen foods, e.g. ready-to-eat bakery and pastry products; - Ice cream - Marmelades and preserves; - Joghourt and other sour milk products; - Hard cheese, sliced cheese (produced with pasteurized milk)
III b	**Ready-to-eat foods which may be contaminated with *L. monocytogenes* and do not permit multiplication of *L. monocytogenes*** Non-heat-treated but otherwise stabilized* foods	- Raw meat products such as fermented sausages, air-dried ham and meat, e.g. Bündner meat; - Fishery products treated with preservatives or strongly salted, sweetened or acidified, e.g. salted fillets of pollack (salmon substitute), sardelles, anchoses, "Swedish bites", rolled pickled herring, Bismarck herring; - Other delicatessen (with preservatives); - Frozen and deep-frozen products such as deep-frozen minced meat, deep-frozen cold smoked fish (on the production and wholesale level) and deep-frozen bakery products with non-completely heated filling or layer; - Honey; - Eggs for human consumption (shell contamination);

		- Hard cheese, sliced cheese (produced with raw milk)
IV	**Foods not ready to eat which, in accordance with their intended use, are heated prior to consumption**	- Fresh meat and poultry meat; - Fresh fish, other sea and freshwater fish (fresh); - Snails and other molluscs; - Meat preparations, e.g. frying sausage, Hamburgers, marinated products such as meat plate and gyros, - ready-to-cook dishes, e.g. deep-frozen dishes, cooled noodles with stuffing; - Milk at farm level.

***** Those products are to be considered as "stabilized" in which a low *L. monocytogenes* level has been established and there has been no multiplication of *Listeria monocytogenes* reaching levels of a set objective during the period fixed by the manufacturer for consumption or as minimum shelf-life ("best before").