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, malnutrition, 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 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.

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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.

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)[3].

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 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 (preferably 2°C- 4°C) 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.

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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

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 programmes 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 the health of consumers and ensuring fair practices in food trade. Their primary purpose of these guidelines is to minimise the likelihood of illness arising from the presence of *L. monocytogenes* in ready-to-eat 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 intended for ready-to-eat foods and 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 minimize and/or prevent the contamination and/or the growth of *L. monocytogenes* in ready-to-eat foods. 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) as part of the general strategy for control of foodborne pathogens in all foods. 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.*

Good Hygienic Practices (GHPs) as specified in the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and other applicable codes of hygienic practice should be suitable to control *L. monocytogenes* in non ready-to-eat foods. However, the additional measures described in the following guidelines should be consulted and implemented, as necessary to control *L. monocytogenes* in ready-to-eat foods.

2.2 DEFINITIONS

For the purpose of these Guidelines, the following definitions apply:

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

Ready-to-eat food – Any food which is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form which is normally eaten without further listericidal steps.

SECTION III - PRIMARY PRODUCTION

Many ready-to-eat foods receive one or more treatments during processing or preparation that inactivate or inhibit the growth of *L. monocytogenes*. For these foods animal health and general application of good agricultural practices, including animal husbandry, 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 validating and 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 (CAC/RCP 1-1969).

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

3.3 HANDLING, STORAGE AND TRANSPORT

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

3.4. CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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 occurrence 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 (CAC/RCP 1-1969).

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 Section 6.5).

4.2.3 Temporary/mobile premises and vending machines

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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 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 (CAC/RCP 1-1969).

4.3.3 Containers for waste and inedible substances

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

4.4 FACILITIES

4.4.1 Water supply

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

4.4.2 Drainage and waste disposal

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

4.4.3 Cleaning

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

4.4.4 Personnel hygiene facilities and toilets

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

4.4.5 Temperature control

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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 (CAC/RCP 1-1969).

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 so that a product temperature should not exceed 6°C, (preferably 2°C - 4°C). 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[6] 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.

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. It is therefore necessary to control the time/temperature combination used for storage.

Monitoring and controlling refrigerated storage temperatures are key control measures. The product temperature should not exceed 6°C (preferably 2°C - 4°C). Temperature abuse that may occur supporting the growth of *L. monocytogenes* could result in a reduction of product shelf life.

The length of the shelf-life is 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. Temperature abuses may allow the growth of *L. monocytogenes*, if present, unless appropriate intrinsic factors are applied to prevent such growth. This should be taken into account when establishing shelf life.

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).

In some products single parameters, such as a pH less than 4.4, 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 effectiveness of these parameters in situations where combinations of parameters or bacteriostatic conditions are relied upon.

Products supporting the growth of *L. monocytogenes* that have undergone a listericidal treatment may be contaminated/recontaminated before final packaging. In these cases, additional control measures may be applied if necessary, (e.g., freezing the product, shortening the shelf life, reformulation of the product) to limit the extent of or prevent *L. monocytogenes* growth. Alternatively, a post-packaging listericidal treatment may be necessary (e.g. heating, high pressure treatment, irradiation, where accepted).

[6] Any appropriate treatment that kills listeria.

In raw, ready-to-eat food (e.g. lettuce), that support the growth of *L. monocytogenes*, that may be contaminated, specific control measures may be applied if necessary to limit the extent of or prevent the growth of *L. monocytogenes* (e.g. acid wash).

5.2.3 Microbiological and other specifications

Refer to the *RecommendedInternational Code of Practice-General Principles of Food Hygiene(CAC/RCP 1-1969) and Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1979).*

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, catering, 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, a change of footwear or 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 specific 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. Where this is not practical, 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 for recycled water, 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 a lower risk for being a vector for cross contaminating other ready-to-eat foods, because such 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 a higher risk of being a vector for cross contaminating other ready-to-eat products if neither ready-to-eat product is rapidly consumed.

5.2.5 Physical and chemical contamination

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.3 INCOMING MATERIAL REQUIREMENTS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.4 PACKAGING

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.5 WATER

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.5.1 In contact with food

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.5.2 As an ingredient

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.5.3 Ice and steam

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.6 MANAGEMENT AND SUPERVISION

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.7 DOCUMENTATION AND RECORDS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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*. Testing of food products can be another component of verification that control measures for *L. monocytogenes* are effective (see Section 5.2.3).

Recommendations for the design of an environmental monitoring program for *L. 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 contaminated 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 the effectiveness of control measures 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 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. Food contact surfaces on equipment 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 biofilm. 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. However, it is noted that *L. monocytogenes* has the ability to form biofilms on a variety of 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 development of antimicrobial resistance should be considered in the application and use of disinfectants.

The equipment used for cleaning, e.g. brushes, bottle 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 (CAC/RCP 1-1969).

6.3.1 General

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

6.3.2 Preventing access

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

6.3.3 Harbourage and infestation

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

6.3.4 Monitoring and detection

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

6.3.5 Eradication

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

6.4 WASTE MANAGEMENT

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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 (CAC/RCP 1-1969).

7.2 ILLNESS AND INJURIES

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

7.3 PERSONAL CLEANLINESS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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 (CAC/RCP 1-1969).

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 (so that product temperature should not exceed 6°C, preferably 2°C - 4°C).

Rationale:

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

If refrigeration is inadequate, food may support the growth of *L. monocytogenes* to higher levels..

8.1 GENERAL

Transportation is an integral step in the food chain and should be controlled, particularly the product temperature which should not exceed 6°C (preferably2°C - 4°C).

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*. 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 (CAC/RCP 1-1969).

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.[7] A record should be available that indicates when cleaning occurred.

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 label;
- 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 (CAC/RCP 1-1969).

9.2 PRODUCT INFORMATION

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

9.3 LABELLING

Countries should 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 should include information on safe handling practices and/or advice on the time frames in which the product should be eaten.

9.4 CONSUMER EDUCATION

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 relevant risk assessment and other studies, taking into consideration the specific regional conditions and consumption habits;

[7] Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CAC/RCP 47-2001).

- 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 not exceed 6°C (preferably 2°C - 4°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;
    - using of thermometers inside home refrigerators.

Programs for health care providers should, in addition to information provided to consumers, 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

Objective:

Those engaged in food operation who come directly or indirectly in contact with ready-to-eat foods should be trained and/or instructed in the control of *L. monocytogenes* to a level appropriate to the operations they are to perform..

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 instruction and 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 (CAC/RCP 1-1969).

10.4 REFRESHER TRAINING

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

ANNEX I: RECOMMENDATIONS FOR AN ENVIRONMENTAL MONITORING[8] PROGRAM FOR *LISTERIA MONOCYTOGENES* IN PROCESSING AREAS

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[9] for and extent of the sampling program should be defined according to the characteristics of the ready-to-eat 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 and prior to packaging, have a higher probability of directly contaminating the product, while for non food contact surfaces the likelihood will depend on the location and practices.

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 *L. monocytogenes*, 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[10].

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.

e) Frequency of sampling

The frequency of environmental 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 *Listeria* spp. and/or *L. monocytogenes* in the environment of the operation under consideration.

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8 Environmental monitoring is not to be confused with monitoring as defined in the HACCP.

9 Products such as in pack pasteurised foods which are not further exposed to environment may not necessarily require a monitoring.

10 Attributes contributing to the scientific support of the use of an indicator organism in view of a specific pathogen include: similar survival and growth characteristics; a shared common source for both organisms; direct relationship between the state or condition that contributes to the presence of the pathogen and the indicator organism; and practical, isolation, detection or enumeration methods for the potential indicator organism.

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 *Listeria* spp. and/or *L. monocytogenes* and the variations over time.

The frequency of environmental sampling may need to be increased as a result of finding *Listeria* spp. and/or *L. monocytogenes* in environmental samples. This will depend on the significance of the findings (e.g. *L. monocytogenes* and a risk of direct contamination of 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, with acceptable sensitivity, the target organisms. This should be documented appropriately.

Under certain circumstances 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 other target organisms if present in the environment. Generally manufacturers should expect to find them occasionally in the processing environment. Therefore an appropriate action plan should be designed and established to adequately respond to positive findings. A review of hygiene procedures and controls should be considered.

The manufacturer should react to each positive result; the nature of the reaction will depend upon the likelihood of contaminating the product and the expected use of the products.

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: MICROBIOLOGICAL CRITERIA FOR *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

1. INTRODUCTION

The microbiological criteria presented in this Annex are intended as advice to governments within a framework for control of *L. monocytogenes* in ready-to-eat foods with a view towards protecting the health of consumers and ensuring fair practices in food trade. They also provide information that may be of interest to industry.

This Annex references and takes into account the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997) and uses definitions, e.g. for microbiological criterion, as included in these principles. The provisions of this Annex should be used in conjunction with *Annex II: Guidance on Microbiological Risk Management Metrics of the Principles and Guidelines for the Conduct of Microbiological Risk Management* **(**CAC/GL 63-2007).

The risk assessments referenced in the introduction to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Food* (CAC/GL 61-2007) have indicated that food can be categorized according to the likelihood of *Listeria monocytogenes* being present and its ability to grow in the food. Available risk assessments have been taken into account in the development of the microbiological criteria in this Annex. In addition, factors that might impact upon the ability of governments to implement these microbiological criteria such as methodological limitations, costs associated with different types of quantitative testing, and statistics-based sampling needs were taken into account.

2. SCOPE

These microbiological criteria apply to specific categories of ready-to-eat foods, as described herein. The competent authority should consider the intended use and how specific ready-to-eat foods are likely to be handled during marketing, catering, or by consumers to determine the appropriateness of applying the microbiological criteria. Governments may apply these criteria, where appropriate, to assess the acceptability of ready-to-eat foods in international trade for imported products, at end of manufacture (finished product) for domestic products, and at point of sale for at least the expected shelf life[11] under reasonably foreseeable conditions of distribution, storage and use.

The microbiological criteria may be used as the basis for the development of additional criteria (e.g. process criteria, product criteria) within a food safety control system[12] to ensure compliance with these guidelines.

Different criteria or other limits may be applied when the competent authority determines that the use of such an approach provides an acceptable level of public health or when the competent authority determines a more stringent criterion is necessary to protect public health.

3. USE OF MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS

There are various applications for microbiological criteria. As described, microbiological testing by lot can be used as a direct control measure, i.e., sorting of acceptable and unacceptable lots[13]. In this instance, microbiological criteria are implemented for those products and/or points of the food chain when other more

[11] See definition in the Code of Hygienic Practice For Milk and Milk Products (CAC/RCP 57–2004).
[12] See: Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008).
[13] See: Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

effective tools are not available and where the microbiological criteria would be expected to improve the degree of protection offered to the consumer.

A microbiological criterion defines the acceptability of a product or food lot based on the absence or presence or number of microorganisms in the product. Testing for compliance with a microbiological criterion may be conducted on a lot by lot basis when there is little information about the conditions under which the product has been produced. Where there is information about the conditions of production, testing of lots for verification purposes may be conducted less frequently.

In addition, the application of the Hazard Analysis and Critical Control Point (HACCP) System describes how microbiological testing against a criterion can be used as a means of verifying the continuing effectiveness of a food safety control system[14]. Typically, such applications involve testing on less than a lot by lot basis and may be formalized into a system of process control verification testing (see Annex III).

Where possible and practicable, the risk-based approach to development of microbiological criteria as described in the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL-63-2007) can be used to assure or contribute to the assurance, that a food control system will achieve the required level of consumer protection.

The competent authority should use a risk-based approach to sampling for *L. monocytogenes* such as that found in the Codex General Guidelines on Sampling (CAC/GL 50 – 2004). It may consider modifying the frequency of testing for process control verification based on additional consideration of the likelihood of contamination, characteristics of the food, product history, conditions of production and other relevant information. For example, testing against microbiological criteria may have limited utility immediately following certain processing steps or if the level of *L. monocytogenes* in a ready-to-eat food is consistently well below the limit of detection taking into account practical limits for sample sizes.

In particular, testing against microbiological criteria for *L. monocytogenes* may not be useful for:

(a) products that receive a listericidal treatment after being sealed in final packaging that ensures prevention of recontamination until opened by the consumer or otherwise compromised,

(b) foods that are aseptically processed and packaged[15] , and

(c) products that contain a listericidal component that ensures rapid inactivation of the pathogen if recontaminated (e.g., products that contain > 5 % ethanol)

Competent authorities may define other categories of products for which testing against microbiological criteria are not useful.

Different types of food present different risks from *L. monocytogenes*, hence different microbiological criteria could apply for the following categories of foods:

(a) ready-to-eat foods in which growth of *L. monocytogenes* will not occur, and

(b) ready-to-eat foods in which growth of *L. monocytogenes* can occur.

3.1 Ready-To-Eat foods in which growth of *L. monocytogenes* will not occur

Ready-to-eat foods in which growth of *L. monocytogenes* will not occur would be determined based on scientific justification[16], including the inherent variability of factors controlling *L. monocytogenes* in the

[14] See: Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).
[15] See: Code of Hygienic Practice For Aseptically Processed And Packaged Low-Acid Foods (CAC/RCP 40-1993).

product. Factors such as pH, a_w, are useful in preventing growth. For example, *L. monocytogenes* growth can be controlled in foods that have:

- a pH below 4.4,
- an $a_w < 0.92$,
- a combination of factors (pH, a_w ,), e.g. the combination of pH < 5.0 with $a_w < 0.94$.

Such growth can also be controlled by freezing (during that period when the product remains frozen).

In addition, inhibitors can control the growth of *L. monocytogenes* and synergy may be obtained with other extrinsic and intrinsic factors that would result in no growth.

Demonstration that *L. monocytogenes* will not grow in a ready-to-eat food can be based upon, for example, food characteristics, the study of naturally contaminated food, challenge tests, predictive modelling, information from the scientific literature and risk assessments, historic records or combinations of these. Such studies would generally be conducted by food business operators (or by the appropriate product board, sector organizations or contract laboratories) and must be appropriately designed to validate that *L. monocytogenes* will not grow in a food[17].

The demonstration that *L. monocytogenes* will not grow in a ready-to-eat food should take into account the measurement error of the quantification method. Therefore, for example, for practical purposes, a food in which growth of *L. monocytogenes* will not occur will not have an observable increase in *L. monocytogenes* levels greater than (on average) 0.5 log CFU/g[18] for at least the expected shelf life as labelled by the manufacturer under reasonably foreseeable conditions of distribution, storage and use, including a safety margin.

For foods intended to be refrigerated, studies to assess whether or not growth of *L. monocytogenes* will occur should be conducted under reasonably foreseeable conditions of distribution, storage and use.

National governments should provide guidance on the specific protocols that should be employed to validate the studies demonstrating that growth of *L. monocytogenes* will not occur in a food during the expected shelf life.

If information is lacking to demonstrate that *L. monocytogenes* will not grow in a ready-to-eat food during its expected shelf life, the food should be treated as a ready-to-eat food in which growth of *L. monocytogenes* can occur.

3.2 Ready-to-eat foods in which growth of *L. monocytogenes* can occur

A ready-to-eat food in which there is greater than an average of 0.5 log CFU/g[118] increase in *L. monocytogenes* levels for at least the expected shelf life under reasonably foreseeable conditions of distribution, storage and use is considered a food in which growth of *L. monocytogenes* can occur.

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[16] References that have been addressed for identifying properties of ready-to-eat foods which will categorize them as foods in which growth of *L. monocytogenes* will not occur, or as foods in which growth of the pathogen can occur, include *Microorganisms in Foods 5 – Characteristics of Microbial Pathogens* (ICMSF, 1996) and *Microbiological Risk Assessment Series 4 and 5: Risk assessment of Listeria monocytogenes in ready to eat foods: Interpretative Summary and Technical Report* (FAO/WHO, 2004).

[17] See: Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008).

[18] 0.5 log is two times the estimated standard deviation (i.e. 0.25 log) associated with the experimental enumeration using viable counting/plate counts.

4. MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS

Microbiological criteria for *L. monocytogenes* in ready-to-eat foods are described.

Another procedure for establishing microbiological criteria for *L. monocytogenes* other than the criteria at specified points in the food chain that are described below, would be through the application of risk-based metrics (e.g., Food Safety Objective (FSO), Performance Objective (PO)) according to the general principles established in the *Annex II: Guidance on Microbiological Risk Management Metrics of the Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

4.1 Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* will not occur

The criterion in Table 1 is intended for foods in which *L. monocytogenes* growth will not occur under the conditions of storage and use that have been established for the product (see Section 3.1).

This criterion is based on the product being produced under application of the provisions of the general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods with appropriate evaluation of the production environment and process control and validation that the product meets the requirements of a food in which growth of *L. monocytogenes* will not occur (see Section 3.1).

If the factors that prevent growth cannot be demonstrated, the product should be evaluated based on criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur (see Section 4.2).

Another approach can also be used (see Section 4.3).

Table 1:

Microbiological criterion for ready-to-eat foods in which growth of *L. monocytogenes* will not occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	*Listeria monocytogenes*	5 [a]	0	100 cfu/g [b]	2 [c]

Where n = number of samples that must conform to the criterion; c = the maximum allowable number of defective sample units in a 2-class plan;. m=a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots.

[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[b] This criterion is based on the use of the ISO 11290-2 method.

Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

[c] Assuming a log normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 93.3 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected based on any of the five samples exceeding 100 cfu/g *L. monocytogenes*. Such a lot may consist of 55% of the samples being below 100 cfu/g and up to 45% of the samples being above 100 cfu/g, whereas 0.002% of all the samples from this lot could be above 1000 cfu/g. The typical actions to be taken where there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption, (2) recall the

product if it has been released for human consumption, and/or (3) determine and correct the root cause of the failure.

4.2 Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur

The criterion in Table 2 is intended for foods in which *L. monocytogenes* growth can occur under the conditions of storage and use that have been established for the product (see Section 3.2).

This criterion is based on the product being produced under application of general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods with appropriate evaluation of the production environment and process control (see Annex III).

The purpose of this criterion is to provide a specified degree of confidence that *L. monocytogenes* will not be present in foods at levels that represent a risk to consumers.

Another approach can also be used (see Section 4.3).

Table 2:

Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	*Listeria monocytogenes*	5 [a]	0	Absence in 25 g (< 0.04 cfu/g) [b]	2 [c]

[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[b] Absence in a 25-g analytical unit. This criterion is based on the use of ISO 11290-1 method. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

[c] Assuming a log normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 0.023 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected if any of the five samples are positive for *L. monocytogenes.* Such a lot may consist of 55% of the 25g samples being negative and up to 45% of the 25 g samples being positive. 0.5 % of this lot could harbour concentrations above 0.1 cfu/g.

The typical actions to be taken where there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption, (2) recall the product if it has been released for human consumption, and/or (3) determine and correct the root cause of the failure.

4.3 Alternative approach

Further to the approaches described in sections 4.1 and 4.2 competent authorities may choose to establish and implement other validated limits for the *L. monocytogenes* concentration at the point of consumption or at other points that provide an acceptable level of consumer protection for foods in which *L. monocytogenes* will not grow as well as foods in which *L. monocytogenes* growth can occur.

Due to the large diversity among ready-to-eat food products in which growth of *L. monocytogenes* can occur, this approach would primarily be applied for specific categories or subcategories of ready-to-eat foods being

produced under application of the provisions of the general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods and that have a limited potential of growth over a specified shelf life.

In establishing such limits for *L. monocytogenes*, the competent authority needs to clearly articulate the types of information required of food business operators to ensure that the hazard is controlled and to verify that these limits are achieved in practice. Information needed by competent authorities should be obtained through validation studies or other sources, and may include

- specification for physicochemical characteristics of the products, such as pH, a_w, salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf life[19] including a safety margin, and

- consultations of available scientific literature and research data regarding the growth and survival characteristics of *L. monocytogenes*.

When appropriate on the basis of the above mentioned studies, additional studies should be conducted, which may include:

- predictive mathematical modelling established for the food in question, using critical growth or survival factors for *L. monocytogenes* in the product,

- challenge tests and durability studies to evaluate the growth or survival of *L. monocytogenes* that may be present in the product during the shelf life under reasonably foreseeable conditions of distribution, storage and use including seasonal and regional variations.

[19] See footnote 2 : Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57–2004).

ANNEX III: RECOMMENDATIONS FOR THE USE OF MICROBIOLOGICAL TESTING FOR ENVIRONMENTAL MONITORING AND PROCESS CONTROL VERIFICATION BY COMPETENT AUTHORITIES AS A MEANS OF VERIFYING THE EFFECTIVENESS OF HACCP AND PREREQUISITE PROGRAMS FOR CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

Introduction

These recommendations are for use by competent authorities if they intend to include environmental monitoring and/or process control testing as part of their regulatory activities. It is also anticipated that the annex will provide guidance that the competent authority can provide to industry. The recommendations provide an elaboration of the concepts in Sections 5 and 6 of the main text of this Code.

Guidance within Codex regarding microbiological testing is often restricted to the testing of end products using traditional lot-by-lot testing. However, the guidance provided in the main text of this Code emphasizes the criticality of enhanced control of sanitation, including the appropriate use of environmental monitoring. This is further elaborated in Annex I: *Recommendations for an Environmental Monitoring Program for Listeria monocytogenes in Processing Areas,* which provides recommendations to industry on implementation of environmental monitoring programs. The *Recommended International Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969) emphasizes the need to apply control measures in a systematic manner using HACCP or other food safety control systems, including the testing of in-line or finished product samples for process control verification. This annex provides general recommendations on how competent authorities can use microbiological testing to verify the effectiveness of (a) general hygiene programs in the food operation environment and (b) control measures in facilities employing HACCP or other food safety control systems.

The two types of microbiological testing programs described below can be an important part of the ability of competent authorities to verify the effectiveness of *L. monocytogenes* control programs over time (see Section 5.9). In developing these recommendations, no attempt is made to establish specific decision criteria for the two types of microbiological testing or the specific actions that should be taken to re-establish control. Establishment of such specific criteria and actions is more appropriately the responsibility of competent authorities due to the diversity in products and manufacturing technologies.

a) Environmental Monitoring

In certain instances, competent authorities may incorporate the testing of the environment (food contact and/or non-food contact surfaces) for *L. monocytogenes* (or an appropriate surrogate microorganism (e.g., *Listeria* spp.)), as part of their regulatory requirements or activities. This can include sampling by a competent authority as part of its inspection activities or sampling performed by the individual food business operator that the competent authority can review as part of its verification of the business operator's controls (see Section 5.9). The aim of conducting and/or reviewing environmental testing programs by a competent authority is to verify, for example, that a manufacturer has successfully identified and controlled niches and harbourage sites for *L. monocytogenes* in the food plant and to verify that sanitation programs have been appropriately designed and implemented to control contamination by *L. monocytogenes*.

In developing environmental testing programs and the decision criteria for actions to be taken based on the results obtained, competent authorities should clearly distinguish between sampling of food contact surfaces and non-food contact surfaces. For example, sampling locations for competent authorities may be similar to those used by food business operators (See Annex I). In evaluating facilities that produce multiple products where at least one can support growth of *L. monocytogenes*, competent authorities should consider the importance of environmental sampling as a means of verifying that there is no cross contamination between the products (see Section 5.2.4). In the design of an environmental verification program, the competent authority should articulate the testing and sampling techniques that would be employed, including size, method and frequency of sampling, analytical method to be employed, locations where samples should be

taken, decision criteria, and actions to be taken if a decision criterion is exceeded (similar to recommendations in Annex I).

The competent authority should establish decision criteria that include specific conditions (e.g., specific number of positive samples) that will initiate follow-up actions (including additional testing) when an environmental sample is positive for *L. monocytogenes* or *Listeria* spp. The competent authority should also establish actions that the food business operator should anticipate if the criteria are exceeded. Detection of positive environmental samples by the competent authority exceeding the decision criteria should lead to an investigation by the food business operator and/or the competent authority to identify the source of contamination and action that should be taken by the food business operator to correct the problem. In reporting results of their analyses to food business operators, competent authorities should provide advice on the possible inferences the data provide in order to assist the food business operator in finding and correcting the source of contamination. For example, the competent authority could point out that the repetitive isolation of a specific subtype of *L. monocytogenes* is indicative of a harbourage site that current sanitation activities are insufficient to control.

Overall, sampling techniques and testing methods should be sufficiently sensitive for the decision criteria established and appropriate for the surface or equipment being evaluated. Methods used should be appropriately validated for the recovery of *L. monocytogenes* from environmental samples.

b) Process Control Verification

Business operators ensure the effectiveness of HACCP and other programs for the control of *L. monocytogenes* in their operating facilities. Further, business operators validate the food safety control systems they have in place. Competent authorities verify that the controls are validated and being implemented as designed, through activities such as monitoring of records and activities of production personnel.

For a well-designed food safety control system, a competent authority may consider establishing microbiological process control testing and decision criteria for products to identify trends that can be corrected before decision criteria are exceeded. When undesirable trends occur or decision criteria are exceeded, the food business operator will investigate the food safety control system to determine the cause and take corrective action(s). The competent authority verifies that appropriate actions are taken when criteria are exceeded. For example, the decision criteria for process control testing could be the frequency of contamination that would be indicative of a process no longer in control and likely to produce ready-to-eat foods that do not meet the microbiological criteria established in Annex II.

In addition to verifying that the process controls within the food safety control system are validated and operating as designed, process control testing of finished product (sometimes referred to as cross-lot or between-lot testing) has been used by business operators and/or competent authorities to detect changing patterns of contamination, which allows distinction between occasional 'in control' positive samples and an emerging loss of control. Process control testing of finished product contributes to the assessment of the continuing performance of a food safety control system and helps to ensure that corrective actions are implemented before microbiological criteria are exceeded. The competent authority verifies that the food safety control system remains 'in control' or ensures that the food business operator has taken corrective actions to prevent loss of control, which could include immediate corrections or changes to the food safety control system itself. The presence of *L. monocytogenes* in finished product can also indicate the lack of control of *L. monocytogenes* in the processing environment.

In certain instances, competent authorities may find it useful to establish an industry-wide process control-based criterion for *L. monocytogenes* for the purpose of ensuring that specific ready-to-eat foods undergo a consistent approach for verification of HACCP or other food safety control systems. This can include sampling by competent authorities as part of their inspection activities or sampling performed by the business operator that the competent authority can review as part of its verification of the food business operator's records.

As with other forms of verification via microbiological testing, the use of process control testing involves the establishment of decision criteria, specification of analytical methods, specification of a sampling plan, and actions to be taken in case of a loss of control. Details of process control testing principles and guidelines are beyond the scope of this annex, but are available through standard references.