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 [MANAGEMENT] OF *LISTERIA MONOCYTOGENES* IN FOODS

Prepared by Germany, with assistance of Austria, Canada, China, Denmark, 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 Proposed Draft Guidelines at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Twelfth Edition,* pages 19-20) **to**: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by February 1, 2004.**

Background

The previous *Listeria (L.) monocytogenes* document *"Proposed Draft Guidelines for the Control of Listeria monocytogenes in Foods"* was presented at the 34th CCFH session in Orlando under agenda item 7. On the basis of the discussions to the "Reports of the ad hoc expert consultations on risk assessment of microbiological hazards in food and related matters" (agenda item 5), especially to the topic "General Considerations of Risk Management Papers" (see paras 39-41) it was proposed by the committee to review the Listeria document. Furthermore, it was indicated that until an agreement on Food Safety Objectives (FSOs) and other related definitions was reached, the elaboration of microbiological specifications for *L. monocytogenes* in foods was premature (para 104). Therefore, it was proposed by Germany in the session

to split the current guidelines into two new documents: a guideline document to manage *L. monocytogenes* in foods and another document on the specific microbiological criteria on *L. monocytogenes*. After a lengthy discussion about the parallel development of two papers there was no consensus. It was concluded by the committee that the development of a document on microbiological criteria could be considered at a future meeting (see para 108). The 34th session decided that the drafting group should redraft the current *L. monocytogenes* document to develop a general applicability guideline document to manage *L. monocytogenes* in foods. It was pointed out that the best approach was to follow the structure of the Recommended "International Code of Practice - General Principles of Food Hygiene" and to only elaborate provisions that were specific to this pathogenic microorganism. It was also agreed that the results of the FAO/WHO Expert Consultation on Risk Assessment of *L. monocytogenes* in ready-to-eat food should be taken into account.

The Committee agreed (34th CCFH-session in Orlando, ALINORM 03/13, para 99-110) that the drafting group led by Germany, and with the assistance of Austria, Canada, China, Denmark, 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) should revise the proposed draft guidelines at Step 2 for circulation, comments and further consideration at its next meeting.

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE [MANAGEMENT] 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 associated typically with foodborne outbreaks attributable to specific foods, often from specific manufacturers. In such cases, the incidence of

[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 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), (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, and (3) a product/process pathway analysis conducted by the U.S. Food Safety and Inspection Service for processed meats, 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. Six key factors that were identified as contributing strongly to the risk of listeriosis associated with ready-to-eat foods are:

- Amount and frequency of consumption of a food
- Frequency 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
- Number of *L. monocytogenes* present in the food at the time of consumption

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 (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 identified that in addition to being effective, food control programs 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 that 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 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. [3]

SECTION III - PRIMARY PRODUCTION

Many ready-to-eat foods receive one or more treatments that inactivate *L. monocytogenes*. As such, general application of good agricultural practices and animal health should be sufficient to control the prevalence of *L. monocytogenes* at primary production. [For example, risk factors related to the introduction of *L. monocytogenes* in pig facilities were particularly identified for wet feeding farms.]

In those ready-to-eat foods that are manufactured without a listericidal treatment, extra attention at primary production may be needed to assure specific control of the pathogen (e.g., control of *L. monocytogenes*

[3] Guidelines for the Design of Control Measures for street-vended foods in Africa. CAC/GI 22 – 1997, (Rev. 1-1991)

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, 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.

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.

In addition to the guidance provided in Section IV of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.3 -1997, Amd. (1999)), the following areas are particularly important for the proper control of *L. monocytogenes* in the plant environment.

4.1 LOCATION

4.1.1 Equipment

Whenever possible, overcrowding of equipment should be avoided in order to permit 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 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 harbouring 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).

4.3 EQUIPMENT

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 cleanable 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 in a manner that it does not become wet and does not allow for the growth of *L. monocytogenes* .

4.4 FACILITIES

4.4.1 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.

4.4.2 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[4] 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,

[4] any appropriate treatment that kills Listeria

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 often require a more stringent application of Good Hygienic Practice and other supportive programs as compared to other foodborne pathogens. Together with HACCP, these programs can provide a successful framework for the control of *L. monocytogenes* .

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

The risk assessment done by the U.S. FDA/FSIS 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 pH, water activity or inhibitors of microbial growth, may ensure that *L. monocytogenes* growth is prevented or minimised. In other products a combination of factors are relied upon. In both cases the effectiveness of these control measures should be validated to ensure that they are consistent.

Where recontamination cannot be avoided in products supporting growth of *L. monocytogenes*, additional control measures may be necessary, e.g., freezing the product, 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

To be addressed later

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*.

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*.

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.

5.3 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.

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* to:

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

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

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 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 MONITORING EFFECTIVENESS

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*. The purpose of environmental monitoring is to verify the effectiveness of sanitation

programs such that sources of contamination are identified and corrected in a timely manner. Recommendations for the design of an environmental monitoring program for *Listeria* spp. 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 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.

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 an unacceptable increase in *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 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.[5] A record should be available that indicates when cleaning occurred.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AND INDUSTRY 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 to provide to susceptible patients and identify and treat patients with human listeriosis in a timely manner.

Industry and trade associations should have enough information on:

- 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, including means for verifying effectiveness of control programs.

Rationale:

Consumers (in particular, the susceptible populations), health care providers, processors, retailers and foodservice/institutional establishments 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 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;

[5] 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, wherever possible, not exceed 6°C, since the growth of *L. monocytogenes* is considerably reduced at temperatures below 6°C;
    - frequency 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 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.

Programs for processors, retailers and foodservice/institutional establishments that manufacture, distribute, market, store or prepare ready-to-eat foods that provide practical guidance on means to

- reduce the frequency and level of *L. monocytogenes* contamination in ready-to-eat foods;
- minimise the growth of *L. monocytogenes* prior to consumption;
- reduce the likelihood that the product will be recontaminated and/or will support the growth of *L. monocytogenes* during subsequent marketing and home use.

9.2 LABELLING

Countries may give consideration to labelling of certain ready-to-eat raw 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.

ANNEX 1: RECOMMENDATIONS FOR AN ENVIRONMENTAL MONITORING PROGRAM FOR *LISTERIA* SPP. 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.

In-plant contamination has led to many of the recognised outbreaks of listeriosis at both the national and international levels. One effective strategy for 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 should be considered when developing the sampling program to ensure the program's effectiveness. The worst possible scenario is one in which a sampling program is incapable of detecting contamination and facility management believes the environment is in control.

An example of a sampling program could involve collecting samples during production on a weekly basis from established sites. The day of the week and time of sample collection are randomised to reflect different conditions that occur during production. The locations are based on experience and previous successes in detecting contamination and solving problems. The majority of samples can consist of sponge samples from selected surfaces (e.g., product contact, support structures, floors) since this has been found to be an effective technique for detecting contamination. The analytical method must be sensitive, provide a timely result and be reasonable in cost. The method can be qualitative and yield a presence/absence result that enables management to respond more quickly and minimise product contamination. 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.

The number of samples will vary with the complexity of the process and the food being produced. Sample site selection can be best resolved by answering the following question. Which sites would yield the best assessment of control and the potential for product contamination? This is particularly important if available funds limit the number of samples at each sampling interval. When a facility has a favourable record of control, it may be possible to composite certain samples and reduce the analytical cost. Samples from drains can yield information about the diversity and persistence of *L. monocytogenes* in the drains and, to some degree, the processing environment. There is considerable disagreement, however, on how to interpret the relationship between a positive drain and the potential for product contamination. The interpretation may depend on the type of food and the processing conditions. Considering the limited number of samples that most manufacturers can afford on a routine basis, samples from drains are likely to be lower in priority than product contact surfaces.

The monitoring program should include tabulation and reporting at frequent intervals (e.g., weekly) to provide a short-term assessment of control. The report should include previous results so trends and patterns can be observed. A quarterly or annual report provides a longer-term review of the data and can reveal low level, intermittent contamination that may otherwise go unnoticed. Experience has demonstrated that the sampling program should become more stringent (e.g., more sample sites and/or frequent samplings) during periods when construction is occurring and when new or modified equipment has been installed.