CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

**Agenda item 9** **CRD06**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FOOD HYGIENE**

**Fifty-fifth Session**

**Nashville, Tennessee, United States of America**

**15 - 19 December 2025**

# PROPOSED DRAFT REVISION OF THE *GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF LISTERIA MONOCYTOGENES IN FOODS* (CXG 61-2007)

**Based on written comments received**

(Revised by the Electronic Working Group Chair, the United States of America, and co-chairs, Canada, France, and China)

The United States of America, Canada, France, and China appreciate the comments submitted in response to the proposed draft revision of *Guidelines on the Application of the General Principles of Food Hygiene to the Control of* Listeria monocytogenes *in Foods* (CXG 61-2007) at Step 4 (CX/FH 25/55/9). To facilitate an efficient discussion of this agenda item at the plenary session, we provide our response to some of the more substantive comments received and a new version of the proposed draft revision (appendix 1) with tracked changes for the Committee's consideration.

Definition of "Ready-to-eat food" (para 27)

In the revised guidelines, we have proposed to define "ready-to-eat (RTE) food" to mean "any food (raw or processed) for which it is normally, or reasonably foreseeable that it will be, eaten without further listericidal treatment." This definition expands RTE foods to include those foods for which it is reasonably foreseeable that the food will be eaten without a listericidal treatment. Comments received ranged from support for the addition of "reasonably foreseeable", requests for additional clarity on the practical application of the "reasonably foreseeable" concept, and a comment suggesting deletion of the "reasonably foreseeable" concept from the RTE food definition.

The *General Principles of Food Hygiene* (CXC 1-1969) states the fundamental question for each FBO in every case is: "what is necessary and appropriate to ensure the safety and suitability of food for consumption?" FBOs should ensure that consumers have clear and easily understood information to enable them to protect their food from contamination and prevent the growth/survival of foodborne pathogens by storing, handling, and preparing food correctly. Likewise, consumers should play their role by following relevant guidance and instructions for food handling, preparation, and storage and applying appropriate food hygiene measures. However, consumers do not always follow labeling instructions despite clear labeling and consumer education efforts. For example, there have been outbreaks of listeriosis in both the European Union and North America associated with some foods (e.g., certain frozen vegetables, enoki mushrooms) that were intended by the FBO to be cooked but are known to be consumed without cooking by some consumers.

CXC 1-1969 recognizes that it is important to consider unintended use of a product by consumers when determining appropriate control measures. For example, when describing the product in Step 3 of HACCP Application (Section 19.3), CXC 1-1969 states:

> "Describe the use intended by the FBO and the expected uses of the product by the next FBO in the food chain or the consumer. The description may be influenced by external information, e.g. from the competent authority or other sources on ways in which consumers are known to use the product other than those intended by the FBO."

And further in Step 6/Principle 1 of HACCP Application (Section 19.6), CXC 1-1969 notes that while conducting the hazard analysis to determine whether there are significant hazards, the intended use and/or probability of product mishandling by potential consumers that could render the food unsafe should be considered. CXC 1-1969 further states:

> "The hazard analysis should consider not only the intended use, but also any known unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without

a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan (see Annex III, Table 1 for an example of a hazard analysis worksheet)."

The expanded definition of "RTE food" in the revised guidelines (CXG 61-2007) to include those foods for which it is reasonably foreseeable that the food will be eaten without a listericidal treatment is consistent with the consideration of "known unintended use" in CXC 1-1969. With the focus of the revised guidelines on RTE foods, this expanded definition ensures that appropriate control measures will be taken for those foods for which it is reasonably foreseeable that they will be eaten without a listericidal treatment.

Additionally, paragraph 104 in the revised guidelines (see Appendix I) contains examples of how to apply the reasonably foreseeable use concept in practice as requested by several comments from members.

Updated proposed revised draft revision of *Guidelines on the Application of the General Principles of Food Hygiene to the Control of* Listeria monocytogenes *in Foods* (CXG 61-2007) considering comments in reply to CL 2025/62-FH

After reviewing the comments in reply to 2025/62-FH, the EWG cochairs have provided an updated version of the proposed draft revision of CXG 61-2007 in Appendix I below with added text in **bold** and **underlined** and deleted text in ~~strikethrough~~.

**Appendix I**

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

## 1. INTRODUCTION

1. *Listeria (L.) monocytogenes* is a ubiquitous non spore forming Gram-positive bacterium that occurs widely in ~~agricultural~~ **nature** (soil, vegetation, silage, faecal material, sewage, water), aquacultural, and food processing environments. *L. monocytogenes* can be found in the intestinal tract of humans. Faecal carriage among asymptomatic individuals has been reported to range from less than 1% to as high as 10%. Generally, *L. monocytogenes*:

- can grow in low oxygen conditions and at refrigeration temperatures;
- is more resistant to various environmental conditions (e.g. high salt or acidity) compared to other non-spore forming, foodborne pathogenic bacteria (e.g. *Salmonella* spp., enterohemorrhagic *Escherichia coli*);
- does not grow at a pH less than 4.4 or a water activity less than 0.92;
- can survive for long periods in the environment, on foods, in food processing establishments, and in the household refrigerator; and
- can form, colonise, survive in and persist in biofilms.

2. *L. monocytogenes* mainly infects humans through contaminated food. It can cause 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, the susceptibility of the host, and the virulence of the particular *L. monocytogenes* strain ingested. While almost all strains of *L. monocytogenes* are considered to be capable of causing illness, virulence among strains and lineages varies significantly as reflected in the occurrence in clinical isolate genotypes of lineage I twice as frequently as lineage II.

3. Listeriosis is an infection that most often affects susceptible populations, ~~such as~~ **including pregnant** individuals ~~experiencing pregnancy (including~~ **(and** their foetuses or neonates infected in utero or during delivery), **adults aged 65 or older, and those with** immunosuppression**—whether due to** chronic **diseases such as** cancer, diabetes, renal **or** liver failure, inflammatory **diseases**, heart disease, **or** AIDS**—** or as a result of **treatment with** immunosuppressive **drugs (e.g., transplant recipients).**The bacterium most often affects the placenta, the blood stream, or the central nervous system. Manifestations of invasive listeriosis include, but are not limited to, bacteremia, septicaemia, meningitis, encephalitis, miscarriage or stillbirth, premature birth, and neonatal disease. Long-term consequences affecting health have also been reported (e.g. chronic sequalae). Incubation periods prior to individuals becoming symptomatic can be from a few days to three months. In otherwise healthy individuals, *L. monocytogenes* can also cause mild febrile gastro-enteritis (i.e. non-invasive listeriosis), a less severe form of the disease.

4. Available epidemiological data show invasive listeriosis occurs both as sporadic cases and outbreaks, with the majority of illnesses being sporadic (i.e. not associated with an identified outbreak). Invasive listeriosis is a relatively rare, but often severe disease with incidence rates of 2 to 7 cases per 1,000,000 individuals, hospitalisation rates >90%, and case fatality rates of 15 to 30%.[1] Earlier efforts by industry and competent authorities in many countries resulted in a reduced incidence of listeriosis. Such efforts included~~:~~

- implementing Good Agriculture Practices (GAPs), Good Hygienic Practices (GHPs), and applying Hazard Analysis Critical Control Points (HACCP) to reduce the frequency, extent, and level of *L. monocytogenes* in ready-to-eat (RTE) foods,
- improving 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*,
- encouraging the use of processing aids, post-packaging treatments, and formulations that reduce levels or suppress the potential growth of *L. monocytogenes* in RTE food, and
- enhancing risk communication, particularly for consumers at increased risk of listeriosis.

However, following the initial reduced incidence of listeriosis due these early efforts by FBOs and competent authorities, the incidence of listeriosis has remained unchanged or, in some cases, increased in recent

years.

5. Transitory increases in incidence rates have also been associated with large foodborne outbreaks attributable to specific foods, often from specific food business operators (FBOs). 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.

6. Sporadic cases and outbreaks of listeriosis are generally associated with RTE foods especially, but not limited to, those held for extended periods under refrigeration temperatures. It should be noted that some foods associated with listeriosis outbreaks, such as certain frozen vegetables, were intended by the FBO to be cooked by the consumer before consumption. However, frozen vegetables (as with some other frozen foods) are palatable without cooking, and consumers do not always follow the cooking instructions on the product labels.

7. Outbreaks of listeriosis can vary greatly in size, involving as few as two cases to potentially more than a hundred cases. For example, the largest known listeriosis outbreak occurred in 2017-2018, with over 1,000 identified cases and over 200 confirmed deaths. Contaminated processed RTE meat products (i.e. polony) were identified as the cause of this outbreak.

8. *L. monocytogenes* has been isolated from a wide range of foods, including fresh, fresh-cut and frozen fruits~~/~~ **and** vegetables, raw and pasteurised fluid milk, cheeses made from unpasteurised and pasteurised milk (particularly soft-ripened varieties), ice cream, butter, fermented raw-meat sausages, raw and cooked poultry, raw and processed meats (all types), raw and processed seafood (all types), as well as plant-based foods and beverages.

**9.** The wide variety of foods from which *L. monocytogenes* has been at least occasionally isolated has made it difficult to effectively focus control programmes on those specific foods that contribute to the greatest risk to foodborne listeriosis. As a means of addressing this and other related questions, a full farm-to-table risk assessment on *L. monocytogenes* in selected foods was undertaken by the Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO) Joint Expert Meeting on Microbiological Risk Assessment (JEMRA) to review, modify, and update previous risk assessments[1,2,3]. In particular, past risk assessment models[4] addressed risk from the point of distribution to consumption, while the updated risk assessments by FAO/WHO considered diverse commodity sub-groups and all steps from primary production to consumption. **More specifically, to strengthen local risk management strategies, JEMRA's publicly accessible, open-source quantitative risk assessment models, together with the WHO-supported web-based tool[5], can be applied under relevant conditions and practices for *Listeria monocytogenes* in RTE diced cantaloupe, frozen vegetables, and RTE cold-smoked fish.**

10. These risk assessments articulate concepts that countries can use to identify and categorise foods that represent a significant risk of foodborne listeriosis. Several factors that were identified as contributing strongly to the risk of listeriosis associated with foods include:

- strain virulence;
- host susceptibility;
- amount and frequency of consumption of a food;
- frequency, extent, and level of contamination of a food with *L. monocytogenes;*
- presence of *L. monocytogenes* in the processing environment;
- potential for transfer of *L. monocytogenes* from the processing environment to RTE food;
- ability of the food to support the growth of *L. monocytogenes*;

[1] Microbiological Risk Assessment Series 38: *Listeria monocytogenes* in ready-to-eat (RTE) food: attribution, characterization and monitoring: meeting report

[2] Microbiological Risk Assessment Series 47: Risk assessment of *Listeria monocytogenes* in foods part 1: formal models

[3] Microbiological Risk Assessment Series 48: **Risk assessment of *Listeria monocytogenes* in foods part 2: risk assessment**

[4] Microbiological Risk Assessment Series 5: Risk assessment of *Listeria monocytogenes* in ready-to-eat foods: technical report

[5] **WHO Risk Estimation Tool for *Listeria monocytogenes* in Foods. Available at: https://worldhealthorg.shinyapps.io/Shiny_qraLm/**

- temperature of refrigerated~~/~~ **or** chilled food storage;
- duration of refrigerated~~/~~ **or** chilled storage; and
- consumer knowledge~~/~~ **or** behaviour and impact of non-intended use (i.e. consumer non-compliance with recommended storage, preparation and consumption practices).

In addition, these risk assessments concluded that a combination of interventions is generally more effective in controlling the risk rather than any single intervention.

11. Risk assessments have consistently identified the ability of an RTE food to support the growth of *L. monocytogenes* as a significant risk factor for listeriosis. Formulation of RTE foods can be one way to substantially reduce the risk of listeriosis, 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.

12. ~~For refrigerated RTE foods that support the growth of *L.* *monocytogenes*, contamination at low~~ **Multiplication of low numbers of *L.* *monocytogenes*** ~~to~~ levels ~~may result in its multiplication~~ **that cause illness can occur** during holding~~/~~ **and** storage**,** or distribution **of RTE foods that support the growth of *L. monocytogenes*,** even when the food is maintained at refrigeration temperatures. Strict control of temperature so that, where feasible, the food never exceeds 6°C (preferably 2°C - 4°C, as growth of *L. monocytogenes* is significantly reduced at these lower temperatures) and~~/or~~ shortening the duration of the food's refrigerated~~/~~ **or** chilled shelf-life are means of minimising the potential for growth of *L. monocytogenes* before the food is consumed.

13. The production process for many RTE foods includes a listericidal treatment. In such foods, the frequency, extent and level of contamination with *L. monocytogenes* is typically associated with contamination of the food after the listericidal treatment and before packaging. Other RTE foods may not have a listericidal treatment in their production process. In these foods, the frequency, extent and level of contamination with *L. monocytogenes* may be associated with contamination of the food (or its ingredients) at any step in the production process, including primary production. Examples of control measures that can influence the frequency, extent and level of contamination include the proper design and maintenance of facilities and equipment, effective cleaning and disinfection procedures, and maintaining the integrity of the cold chain. The latter has been clearly identified as a risk factor for listeriosis (i.e. the temperature of refrigerated~~/~~ **or** chilled storage). For some RTE foods, an additional listericidal treatment after final packaging may be introduced to further reduce the risk of listeriosis.

14. The presence of *L. monocytogenes* in the food processing environment is a major risk for contamination of RTE food. Environmental monitoring programmes (EMPs) that involve the sampling and testing of equipment surfaces (both food contact and non-food contact) and processing environment surfaces can be used to verify the effectiveness of control measures implemented to maintain hygienic conditions and prevent contamination of exposed RTE foods with *L. monocytogenes* (see Annex I).

15. RTE foods may also be contaminated with *L. monocytogenes* during distribution, marketing, and consumer use. For example, the shared use of equipment in retail operations (e.g. slicers used to cut meats or cheeses in delis) has been identified as a significant risk for transferring *L. monocytogenes* between foods, most importantly if *L. monocytogenes* were to be transferred to RTE foods that support its growth. In addition, it is important to note that the ability of a food to support growth of *L. monocytogenes* and~~/or~~ the likelihood of its consumption without further listericidal treatment can depend on consumer practices which may deviate from the intended use of the food by the manufacturer. For this reason, FAO/WHO has advised caution when classifying foods into strict categories of RTE versus non-RTE or into RTE foods that support the growth of *L. monocytogenes* versus those that do not.

16. Risk assessments (including those recently conducted by FAO/WHO) continue to indicate that in order for food control programmes to be effective, they must be capable of consistently meeting the microbiological criteria for *L. monocytogenes* in RTE foods, i.e. not detected in 25 g (0.04 CFU/g) in RTE foods in which growth of *L. monocytogenes* can occur or ≤100 CFU/g in RTE foods in which growth of *L. monocytogenes* will not occur (see Annex III). Such risk assessments clearly indicate that the greatest risk associated with RTE foods is the small ~~portion~~ **proportion** of products with high contamination levels of *L. monocytogenes*.

17. The effects of climate change (e.g. variation in temperature~~/~~ **or** humidity, increased frequency~~/~~ **or** severity of weather events) may influence the frequency, extent and level of *L. monocytogenes* contamination of ingredients and foods (e.g. increased contamination of soil, agricultural lands, ground and surface water from flooding of fields, failure to maintain the integrity of the food supply cold chain resulting

in microbial growth)[6].

**2. OBJECTIVES**

18. These guidelines provide advice to FBOs and competent authorities on a framework for the control of *L. monocytogenes* in RTE foods, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The primary purpose of these guidelines is to **provide information that will help** minimise the likelihood of illness arising from the presence of *L. monocytogenes* in RTE foods. ~~The guidelines~~ **This information may** also ~~provide information that will~~ be of interest to ~~the~~ food industry **associations**, consumers, and other interested parties.

**3. SCOPE**

19. These guidelines are intended for RTE foods and are applicable throughout the food chain, from primary production to consumption. Based on the results of the FAO/WHO risk assessments, other available risk assessments and epidemiological evaluations, these guidelines will focus on control measures that can be used, where appropriate, to minimise and~~/or~~ prevent the contamination ~~and/~~or the growth of *L. monocytogenes* in RTE foods. These guidelines focus on key control measures that affect the most significant factors that influence the frequency, extent and levels of *L. monocytogenes* contamination in RTE foods, thereby highlighting the greatest means of reducing the risk of listeriosis. **Control measures described for processing environments may apply to marketing, distribution and retail environments as well as consumer homes.** In many instances, these control measures are articulated in a general manner in the *General Principles of Food Hygiene* (CXC 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* in RTE foods.

20. GHPs as specified in the *General Principles of Food Hygiene* (CXC 1-1969) and other applicable codes of hygienic practice should be sufficient to control *L. monocytogenes* in non-RTE foods. However, the additional measures described in these guidelines could also be ~~consulted~~ **considered** and implemented, as necessary, to further control *L. monocytogenes* in non-RTE foods.

**4. USE**

21. These guidelines and their annexes are complementary to and should be used in conjunction with any relevant Codex texts, such as:

- *General Principles of Food Hygiene* (CXC 1-1969);
- *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997);
- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999);
- *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007);
- G*uidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023);
- *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008);
- *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995);
- *General Standard for the Labeling of Pre-packaged Foods* (CXS 1-1985);
- *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001);
- *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004);
- *General Guidelines on Sampling* (CXG 50-2004); ~~and~~
- *Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods* (CXC 40-1993**); and**
- ***Guidelines on the Management of Biological Foodborne Outbreaks* (CXG 96-2022).**

[6] Microbiological Risk Assessment Series 42: Prevention and control of microbiological hazards in fresh fruits and vegetables: parts 1 & 2: general principles: meeting report

**4.1 Roles of competent authorities, food business operators, and consumers**

22. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)

**5. GENERAL PRINCIPLES**

23. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)

**5.1 Management commitment to food safety**

24. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)

**6. DEFINITIONS**

25. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)

26. Refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007)

27. **Ready-to-eat food** – Any food (raw or processed) for which it is normally **eaten without further listericidal treatment**, or **for which it is** reasonably foreseeable[7] **, based on evidence of consumer habits or practices**, that it will be~~,~~ eaten without ~~further listericidal~~ **such** treatment.

28. **Listericidal treatment** – Any validated[8] treatment that reduces *L. monocytogenes* ~~sufficient~~ **sufficiently** to achieve food safety.

**GOOD HYGIENE PRACTICES**

**7. INTRODUCTION AND CONTROL OF FOOD HAZARDS**

29. Control of *L. monocytogenes* for many RTE foods will typically require application of GHPs, some to a greater degree than for non-RTE foods, and other supportive prerequisite programmes, as applicable. Prerequisite programmes, together with HACCP, provide a successful framework for the control of *L. monocytogenes.*

30. For the effective identification and implementation of GHPs for the control of *L. monocytogenes*, the following factors should be considered:

- the intrinsic parameters of the food (e.g. water activity, pH, inhibitory compounds);
- where in the process the food can be contaminated and~~/or~~ **where** contamination is removed;
- its history of contamination within the specific facility and within the food type across the international market; and
- the intended use of the food and the anticipated frequency (based on evidence) the food is used without a subsequent listericidal treatment by another manufacturer or the consumer (i.e. the reasonably foreseeable use of the food).

31. After **reviewing and** assessing~~/reviewing~~ the conditions and activities of the FBO, it may be determined that GHPs alone may be sufficient to control *L. monocytogenes*. However, it may also be determined that it is necessary to place greater attention on some GHPs that are particularly important in the control of *L. monocytogenes* in RTE foods (e.g. increased stringency for cleaning and disinfecting a slicer used for producing deli meats) or the implementation of a critical control point (CCP) consistent with HACCP principles.

**8. PRIMARY PRODUCTION**

32. Objectives: Primary production (i.e. those steps in the food chain up to and including storage and, where appropriate, transport of outputs of farming) should be managed in a way to control *L. monocytogenes* when growing crops, raising fish and animals, and harvesting plants, animals or animal products, as applicable~~, such that food is safe and suitable for its intended use~~.

33. **On-farm** primary production operations, ~~e.g. growing, harvesting, storage, handling (washing, trimming) and packaging,~~ should be controlled to reduce the likelihood ~~that food will be contaminated. Additionally, some~~ **of contamination of raw foods and ingredients with *L. monocytogenes*, and prevent growth during storage and transportation. Additional** controls at primary production (e.g.

[7] ~~Reasonably foreseeable means a frequency that can be anticipated as likely to occur because of data or other information showing habits within a population, supply chain, or region (even though such habits may not be intended for the food). Reasonably foreseeable does not mean any conceivable use (or misuse) of the food~~ **See the concept of "known unintended use" in *General Principles of Food Hygiene* (CXC 1-1969)**.

[8] **See *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).**

drying) can be used to decrease the likelihood that the food will support the growth of *L. monocytogenes* during subsequent processing.

34. Rationale: To reduce the likelihood of introducing *L. monocytogenes* into the food chain, during on-farm activities, which can be a source of contamination.

35. For RTE foods subject to one or more listericidal treatments during subsequent processing or preparation, attention to animal health and the general application of ~~good agricultural practices~~ **GAPs** and GHPs, including animal husbandry practices and use of fit-for-purpose water, is usually sufficient to help reduce the introduction of *L. monocytogenes* to raw materials (e.g. meat, fish, vegetables, fruit).

36. However, for RTE foods that are processed without a listericidal treatment (e.g. raw milk and raw milk cheeses, fresh produce), in addition to those practices described above, extra attention is needed at primary production. For example, increased focus may be needed on personal hygiene, water management programmes, control of contamination in livestock (e.g. mastitis in dairy animals), and in the environment at primary production (e.g. the feeding of inadequately fermented silage or use of wet feeding systems) to mitigate *L. monocytogenes* from known sources of contamination.

37. Primary production methods vary depending on the characteristics of the food. ~~An assessment of~~ **T**he history of *L. monocytogenes* in raw materials **(e.g. meat, fish, vegetables, fruit)** or the primary production environment, as well as factors that can impact the risk of contamination of the food with *L. monocytogenes* should be considered. Some of these factors could include:

- seasonality (e.g. microbial kinetics in soil and on the leaves of vegetables);
- **primary** production practices (e.g. cultivation in open fields, protected agriculture and hydroponic conditions for crops, harvesting practices, irrigation, fertilisation, and other on-farm management practices; harvesting in open waters (sea or fresh) or in farmed environments (aquaculture) for fish and other production activities such as rearing, feeding, milking and capturing); and
- the effects of climate change (e.g. adverse weather events such as heavy rainfall and flooding), which could, for example, increase prevalence of *L. monocytogenes* in soil, increase soil transfer to **fresh** produce or decrease agricultural water quality.

38. Where appropriate (e.g. when other more effective tools are not available and where ~~such an analysis~~ **raw material testing** would be expected to improve the degree of protection offered to the consumer), analysis of raw materials for *L. monocytogenes* can be a tool for verifying that the control measures at primary production are adequately limiting the frequency, extent and level of contamination to those needed to achieve the required level of control during subsequent processing.

**8.1 Environmental control**

39. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**8.2 Hygienic production**

40. For RTE foods that are processed without a listericidal treatment, it is of particular importance to identify activities where a high likelihood of contamination from *L. monocytogenes* exists and take specific measures to reduce the likelihood to the extent possible. The design and maintenance of equipment used for growing or harvesting food that is consumed without a listericidal treatment (e.g. fresh leafy greens, melons) should prevent the harbourage of *L. monocytogenes* that could lead to contamination of the food.

**8.3 Handling, storage and transport**

41. After harvest, RTE foods that are processed without a listericidal treatment should be held at temperatures that minimise the growth of *L. monocytogenes*, ~~where~~ **whenever** feasible and appropriate. The ~~delay~~ **period** between harvest and storage should be as short as possible.

**8.4. Cleaning, maintenance and personnel hygiene**

42. The cleaning and disinfection of equipment used for growing, harvesting, and transporting food that is consumed without a listericidal treatment should be conducted at a frequency sufficient to minimise or prevent the contamination of the food and subsequent processing areas with *L. monocytogenes*. The effectiveness of cleaning and disinfection programmes should be periodically verified and the programmes modified, as necessary, to consistently achieve the required level of control during subsequent processing. One way to verify the effectiveness of cleaning and disinfection is with an EMP (see Annex I).

**9. ESTABLISHMENT – DESIGN OF FACILITIES AND EQUIPMENT**

43. Objectives: Equipment and facilities should be designed, constructed and laid out to facilitate cleanability and to minimise the potential for *L. monocytogenes* harbourage sites and the contamination of

RTE food.

44. Rationale:

- The introduction of *L. monocytogenes* into the RTE processing environment has, at times, resulted from inadequate separation of raw and RTE food processing areas and from poor control of employee ~~and/~~or equipment traffic.
- The inability to properly clean and disinfect equipment and premises due to poor design or poor accessibility has resulted in biofilms containing *L. monocytogenes* and harbourage sites that have been a source of contamination.
- The dispersion of microorganisms in aerosols, such as by high-pressure spray during cleaning procedures, has been linked to the spread of *L. monocytogenes* in the processing environment.
- Inadequate ventilation that allows condensate to form on surfaces in food processing environments has resulted in the presence of *L. monocytogenes* in droplets and aerosols, increasing the risk of product contamination. Once *L. monocytogenes* finds harbourage in an establishment (e.g. in a biofilm or in difficult to clean areas) it can be very difficult to eradicate.

**9.1 Location and structure**

**9.1.1 Location of establishment**

45. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**9.1.2 Design and layout of food establishment**

46. Processing facilities should be designed to separate the storage and processing areas for raw and RTE food. This can be accomplished in a number of ways, including linear product flow (raw to RTE) with filtered airflow in the opposite direction (RTE to raw) or physical partitions. Positive air pressure should be maintained on the RTE side of the operation relative to the raw side (e.g. maintain lower air pressures in raw processing areas and higher pressures in RTE processing areas).

47. For RTE foods that are processed without a listericidal treatment, the entire processing area (i.e. from receiving to packaging) should be designed to prevent or minimise the potential for contamination of the RTE food with *L. monocytogenes*.

48. For RTE foods that are processed with one or more listericidal treatments, a greater focus should be placed on the design of processing areas after a listericidal treatment to prevent or minimise the potential for contamination of RTE food with *L. monocytogenes*.

49. Where feasible, the washing areas for removeable food equipment and utensils involved in the processing of RTE food should be located in a separate room from the RTE processing area. In addition, these washing areas should not be used to clean and disinfect equipment and utensils used in the handling of ingredients, particularly those that are raw.

50. Processing areas where RTE foods are exposed to the environment should be designed to avoid the accumulation of moisture on surfaces. Wet operations, especially those with excessive accumulation of moisture on surfaces, often enhance the growth and spread of *L. monocytogenes*.

**9.1.3 Internal structures and fittings**

51. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**9.1.4 Temporary/Mobile food establishments and vending machines**

52. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**9.2 Facilities**

**9.2.1 Drainage and waste disposal facilities**

53. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**9.2.2 Cleaning facilities**

54. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**9.2.3 Personnel hygiene facilities and toilets**

55. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**9.2.4 Temperature**

56. Adequate facilities should be available for controlling the temperature of RTE foods to minimise growth of *L. monocytogenes*. Control of ambient temperature during processing can also be important in the control of *L. monocytogenes*.

**9.2.5 Air quality and ventilation**

57. Where applicable, air handling systems that supply air to RTE processing areas should be designed (e.g. to include adequate filtration) such that the air does not introduce *L. monocytogenes* to the processing environment. Where possible, air handling units, including air ducts and ventilation systems, should not be located directly above RTE food equipment or blow air directly onto RTE food or RTE food contact surfaces.

58. Condensate from air handling units and ventilation systems has been an identified source of *L. monocytogenes* in RTE processing areas. The formation of condensate on such equipment and structures should be minimised; however, if it does occur, condensate should be collected in drip pans and transferred directly to a drain. Drip pans and piping~~/~~ **or** tubing used to collect and transfer condensate should be cleaned and disinfected on a regular basis such that they do not become sources of contamination by *L. monocytogenes*.

**9.2.6 Lighting**

59. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**9.2.7 Storage**

60. Adequate facilities should be available for storing refrigerated or frozen RTE foods at temperatures that minimise growth of *L. monocytogenes.* Refrigerated storage rooms should be designed so that a refrigerated product temperature, where feasible and appropriate, does not exceed 6°C (preferably 2°C - 4°C, as growth of *L. monocytogenes* is significantly reduced at these lower temperatures). Frozen storage rooms should be designed so that ~~a~~ **an appropriate** frozen product temperature is maintained ~~at -18°C or colder~~.

61. Raw materials should be stored separately from RTE food. For example, chillers for ~~unpackaged~~ cooked product should be separate from those for raw product to prevent cross-contamination.

**9.3 Equipment**

**9.3.1 General**

62. 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 sites that cannot be reached during routine cleaning and disinfection of food contact surfaces**, non-food contact surfaces,** and adjacent areas.

63. Where possible, equipment should be designed and installed in a manner that facilitates easy access for efficient cleaning and disinfection, e.g. it can be easily dismantled and thus avoid the formation of biofilms containing *L. monocytogenes* and harbourage sites.

64. Racks or other equipment used for transporting exposed products, especially RTE foods, should have easily cleanable cover guards over the wheels to prevent contamination of the food from wheel spray.

65. Cold surfaces (e.g. refrigeration and freezing units) can be sources of *L. monocytogenes*. As with ventilation systems, 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* (wet insulation has previously been identified as a source of *L. monocytogenes*).

**9.3.2 Food control and monitoring equipment**

66. In equipment used for cooling or holding~~/~~ **or** storing RTE food under refrigerated conditions, especially for RTE food that supports growth of *L. monocytogenes*, temperatures should be maintained and monitored so that, where feasible and appropriate, food is cooled below and consistently does not exceed 6°C (preferably 2°C - 4°C, as growth of *L. monocytogenes* is significantly reduced at these lower temperatures). For frozen foods, ~~temperatures~~ **an appropriate frozen temperature** should be maintained ~~at -18°C or colder~~.

67. Refrigerated and frozen storage equipment should not be filled or loaded beyond their capacity such that they cannot maintain proper temperatures of RTE food, especially RTE food that supports the growth of *L. monocytogenes*.

**10. TRAINING AND COMPETENCE**

68. Objective: Those engaged in food operations who come directly or indirectly in contact with RTE foods should be trained and instructed in **food hygiene and** the control of *L. monocytogenes* to a level appropriate to the operations they are to perform.

69. Rationale: Controls specific to *L. monocytogenes* are generally more stringent than routine GHPs.

**10.1 Awareness and responsibilities**

70. FBOs are responsible for providing specific training and ~~instruction~~ **instructions** for control of *L. monocytogenes* relevant to their products but may rely on resources from trade associations or other organisations.

**10.2 Training programmes**

71. As appropriate to their role and responsibilities (e.g. in the facility's management, design of food safety systems, production~~/~~**,** processing~~/~~**,** handling and marketing of RTE food), personnel should receive effective training in:

- the nature of *L. monocytogenes*, its typical harbourage sites in primary production and processing equipment~~/~~ **or** areas, and its resistance to various environmental conditions;
- determining whether or not the food supports the growth of *L. monocytogenes*;
- identifying processing conditions that may increase the likelihood for *L. monocytogenes* to grow and~~/or~~ spread to the food;
- evaluating the intended consumer, and the intended and reasonably foreseeable use of the food;
- control measures for reducing the risk of *L. monocytogenes* associated with RTE food during primary production, processing, distribution, marketing, use and storage;
- **effective cleaning and disinfection techniques to reduce the risk of *L. monocytogenes* - including the dilution and contact times of the chemical being used;**
- the means for verifying effectiveness of control programmes, including sampling and analytical techniques; and
- actions to be performed in order to address a *L. monocytogenes* or *Listeria* spp. positive (or presumptive positive) result obtained from an environmental sample or RTE food testing, as applicable.

**10.3 Instruction and supervision**

72. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**10.4 Refresher training**

73. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL**

74. Objectives: To provide specific guidance on how preventive maintenance as well as cleaning and disinfection procedures, along with an effective EMP can reduce contamination of RTE food with *L. monocytogenes*, especially when the food supports growth of *L. monocytogenes*. Well-structured cleaning and disinfection procedures should be targeted against *L. monocytogenes* in food processing areas where RTE foods are exposed to reduce:

- the likelihood that the food will be contaminated from *L. monocytogenes* that may be present in the processing environment; and
- the level of contamination in the finished RTE food.

75. Rationale: Cleaning and disinfection programmes are critical to control *L. monocytogenes.* An EMP for *L. monocytogenes* or**, preferably,** *Listeria* spp. in processing areas where RTE foods are exposed is necessary to assess the effectiveness of control measures and, therefore, the likelihood of contamination of the food (see Annex I).

**11.1 Maintenance and cleaning**

**11.1.1 General**

76. Establishments should implement an effective, scheduled preventive maintenance programme to prevent equipment failures during operation and the development of harbourage sites. Equipment failures

during processing increase the risk of *L. monocytogenes* contamination as equipment is being repaired. Harbourage sites for *L. monocytogenes* can be created in certain equipment parts (e.g. gaskets) when they breakdown.

77. The preventive maintenance programme should be written and include a defined maintenance schedule, including a schedule for the replacement of parts known to deteriorate over time and the repair of equipment before it becomes a source of contamination. Equipment should be inspected periodically for harbourage sites (i.e. parts that are rusted, cracked, heavily scratched~~/~~ **or** etched, worn or have developed spaces where food and moisture accumulate). Preventive maintenance should include periodic examination and maintenance of all equipment parts, including: conveyors, filters, gaskets, pumps, slicers, filling equipment, and packaging machines, cleaning equipment as well as support structures for equipment. When equipment parts have deteriorated such that they have created a potential harbourage site before their scheduled replacement, the time period for their replacement within the preventive maintenance programme should be shortened accordingly. Air filters connected to fans that bring outside air into the establishment should be examined and changed based on manufacturer's specification or more frequently based on pressure differential or microbiological monitoring.

78. Where possible, tools used for maintenance of equipment to which RTE foods are exposed should be dedicated to the RTE processing area. Such tools should be washed and disinfected prior to use. Maintenance personnel in the RTE processing area should comply with the same hygiene requirements as the RTE processing employees. Food contact surfaces should be cleaned and disinfected after maintenance work, prior to operational use. Equipment at risk of becoming contaminated during maintenance work on facility utilities (e.g. air system, water system) or during construction or remodeling activities should be cleaned and disinfected prior to use.

79. Due to the ability of *L. monocytogenes* to survive in the processing environment for long periods of time, disturbances caused by the breakdown of equipment, construction, or modification of layouts can spread *L. monocytogenes* from harbourage sites to the environment. Where appropriate, care should be taken to:

- isolate the construction area from processing areas, including ventilation and air-handling systems as needed;
- restrict the movement of processing personnel and equipment;
- enhance hygienic operations;
- increase environmental monitoring to detect *Listeria* spp. during construction~~/~~ **or** renovation; and
- verify hygienic conditions before resuming operations.

**11.1.2 Cleaning and disinfection methods and procedures**

80. 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.

81. Research and experience further ~~indicates~~ **indicate** that *L. monocytogenes* is not inherently more resistant to disinfectants or more capable of attaching to surfaces than other vegetative pathogens (e.g. *Salmonella* spp., *E. coli*, *S. aureus*). However, it is noted that *L. monocytogenes* can form biofilms and persist on a variety of surfaces. To avoid the persistence of *L. monocytogenes*, physical disruption of biofilms combined with the rotational application of disinfectants, where applicable, should be implemented.

82. Equipment used for cleaning (e.g. brushes, bottle brushes, mops, floor scrubbers, vacuum cleaners, hoses**, hose reels**) often stay wet and should be maintained, inspected, cleaned and disinfected so they do not become a source of contamination. The cleaning equipment should be dedicated for use in either raw or RTE processing areas, and their dedicated use should be easily distinguishable (e.g. colour-coded cleaning tools for different processing areas).

83. To prevent aerosols from contacting RTE foods, food contact surfaces and food packaging materials, the use of high-pressure water hoses should be avoided where possible. High-pressure water hoses should not be used during processing (including processing on lines adjacent to, or in the same room as, those being cleaned or disinfected) or after equipment has been cleaned and disinfected, or to clear or clean a drain.

84. 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. Equipment for cleaning drains should be dedicated to that purpose and be easily distinguishable (e.g. colour-coded) and stored separately from equipment for other cleaning purposes to minimise the potential for contamination. Employees who have been cleaning drains should not contact or clean food contact surfaces without changing clothes and washing and disinfecting hands.

85. Floor drains should not be cleaned during processing operations. If a drain backup occurs, processing should stop until the water has been removed and the areas have been cleaned and disinfected.

86. Solid forms of disinfectants such as blocks of quaternary ammonium compounds (QAC) can be placed in the drip pan of refrigeration and freezing units while rings can be placed in drains to help control *L. monocytogenes*. Granulated forms of disinfectants such as QAC, hydrogen peroxide and peroxyacetic acid can be applied to floors after routine cleaning and disinfecting. However, the use of solid forms of disinfectants should not replace control measures designed to prevent the entry or spread of *L. monocytogenes* within a processing environment (e.g. hygienic entry procedures, separation of raw and RTE processing areas, control of personnel and equipment traffic patterns).

**11.1.3. Monitoring of effectiveness**

87. The effectiveness of cleaning and disinfection programmes should be periodically verified and the programmes modified, as necessary. **by trained personnel. Verification activities and changes should be recorded.** The goal is to consistently achieve the level of control needed for the food operation to prevent *L. monocytogenes* contamination of RTE food and RTE food contact surfaces. Recommendations for the design of an EMP are given in Annex I.

**11.2 Pest control systems**

**11.2.1 General**

88. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**11.2.2 Prevention**

89. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**11.2.3 Harbourage and infestation**

90. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**11.2.4 Monitoring and detection**

91. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**11.2.5 Control of pest infestation**

92. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**11.3 Waste management**

**11.3.1 General**

93. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**12. PERSONAL HYGIENE**

94. Objectives: To prevent workers from transferring *L. monocytogenes* from contaminated surfaces to RTE food, food contact surfaces, or food packaging material.

95. Rationale: Workers can serve as a vehicle for *L. monocytogenes* contamination by physically transporting and transferring the organism through the facility. Workers should be aware of the steps that need to be taken to manage this risk. (e.g. handwashing, boot washes, clean clothing).

**12.1 Health status**

96. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**12.2 Illness and injuries**

97. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**12.3 Personal cleanliness**

98. Employees who touch RTE food, food contact surfaces, or food packaging material should wash and disinfect hands and change gloves any time they touch an unclean surface, including parts of their own body (e.g. nose, eyes, ears). Adequate training, instruction and supervision should be provided to be confident that hygienic practices are accomplished.

**12.4 Personal behaviour**

99. Employee hygienic practices play an important role in preventing contamination of exposed RTE foods with *L. monocytogenes*. For example, employees who handle money, trash, floor sweepings, drains, packaging waste or scrap product, should not touch RTE food, 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.

**12.5 Visitors and other persons from outside the establishment**

100. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**13. CONTROL OF OPERATION**

101. Objectives: Processing operations should be controlled to avoid contamination in RTE foods, to ~~minimise the growth of *L. monocytogenes* in RTE foods and to~~ reduce the likelihood that the RTE food will be contaminated and~~/or~~ will support the growth of *L. monocytogenes* during subsequent distribution, marketing and consumer use.

102. Rationale: For some RTE foods, listericidal treatments can appropriately reduce the risk of listeriosis. However, not all RTE foods receive such treatment. Furthermore, RTE foods that are exposed before or at packaging may be subject to *L. monocytogenes* contamination from the processing environment. Prevention of contamination, strict control of time and temperature, and formulation of RTE foods to suppress the growth of *L. monocytogenes* can minimise the risk of listeriosis.

**13.1 Description of products and processes**

103. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**13.1.1 Product description**

104. In addition to the intended use of the food, FBOs should also consider ~~how the food is used at retail and by~~ **information on ways in which the next FBO in the supply chain or** the consumer **are known to use the food other than those intended by the FBO** (i.e. reasonably foreseeable use)~~. Consumer use of some foods intended by FBOs to be non-RTE should be considered~~ when developing ~~risk management strategies (e.g.~~ **control measures. Such information can include investigational data from foodborne outbreaks or consumer surveys about food preparation or consumption habits within a population, supply chain, or region. For example, soup mixes intended to be mixed with water and cooked are known to be commonly used without a heat treatment in flavouring a dip for chips. Additionally,** certain ~~foods considered by~~ **foods that are intended to be cooked maybe used without cooking. These foods intended by** the FBO to be non-RTE may require some level of *L. monocytogenes* control to account for ~~consumer~~ **known unintended** use of the product without cooking~~)~~**. FBOs should not consider all conceivable uses or isolated reports of misuse of a food as a reasonably foreseeable use.**

105. FBOs should determine whether RTE foods will not support the growth of *L. monocytogenes* and have a written rationale. In some RTE foods, single parameters (e.g. a pH less than 4.4, a water activity less than 0.92), may be relied upon to prevent *L. monocytogenes* growth. In other RTE foods, a combination of parameters is used. Validation should be undertaken to confirm the effectiveness of these parameters in situations where combinations of parameters or bacteriostatic compounds~~/~~ **or** agents are relied upon. These parameters should be regularly monitored and results documented. If there is insufficient information to demonstrate that *L. monocytogenes* will not grow in an RTE food during its expected shelf-life under reasonably foreseeable conditions of distribution, storage and use, the food should be treated as an RTE food in which growth of *L. monocytogenes* can occur (see Annex III).

106. Although *L. monocytogenes* will not grow under frozen conditions, frozen foods that are generally not consumed in the frozen state may be handled or used at retail or by the consumer such that *L. monocytogenes* may grow (e.g. they may be thawed and held under refrigeration). When frozen conditions are used as the sole means of preventing *L. monocytogenes* growth in an RTE food, such reasonably foreseeable use of the food should be considered when classifying the RTE food as supporting growth (or not) and when developing risk management strategies.

**13.1.2 Process description**

107. Flow diagrams, which show the sequence and interaction of all processing steps in the operation, should identify any listericidal treatments. Clearly indicating the listericidal treatments on the flow diagram can allow FBOs and competent authorities to better identify those processing steps~~/~~ **or** areas after listericidal treatments, where greater focus should be placed to prevent or minimise the contamination of RTE food with *L. monocytogenes* (see section 9.1.2).

**13.1.3 Consideration of the effectiveness of GHPs**

108. Refer to the *General Principles of Food Hygiene* (CXC 1-1969). Recommendations to food business operators for an environmental monitoring programme for *Listeria monocytogenes* in **processing and** primary production ~~and processing~~ areas are given in Annex I. Recommendations to competent authorities for the use of microbiological testing as a means of verifying the effectiveness of HACCP and prerequisite programmes for the control of *Listeria monocytogenes* in RTE foods are given in Annex II.

**13.1.4 Monitoring and corrective action**

109. Refer to the *General Principles of Food Hygiene* (CXC 1-1969). See also Annex I of this guideline.

**13.1.5 Verification**

110. Refer to the *General Principles of Food Hygiene* (CXC 1-1969). Recommendations to Competent Authorities and Food Business Operators for developing and applying microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods are given in Annex III. See also Annexes I and II of this guideline.

**13.2 Key aspects of GHPs**

**13.2.1 Time and temperature control**

111. The risk assessments done by FAO/WHO and others on *L. monocytogenes* in RTE foods demonstrated the significant influence of storage temperature on the risk of listeriosis associated with RTE foods that support *L. monocytogenes* growth. It is therefore necessary to control the time~~/~~ **and** temperature combination used for storage.

112. Monitoring and controlling refrigerated storage temperatures are key control measures. Where feasible and appropriate, the product temperature should not exceed 6°C (preferably 2°C - 4°C, as growth of *L. monocytogenes* is significantly reduced at these lower temperatures). Any loss of temperature control during the storage of RTE foods that support the growth of *L. monocytogenes* should be carefully evaluated to assess potential food safety risk through the product's intended shelf-life.

113. The length of an RTE food's shelf-life is another important factor contributing to the risk associated with foods that support *L. monocytogenes* growth. In that context, the shelf-life of such foods should be consistent with the need to control the growth of *L. monocytogenes.* Since *L. monocytogenes* can grow under refrigeration temperatures, the length of the shelf-life should consider appropriate studies that assess the growth of *L. monocytogenes* in the food taking into consideration reasonably foreseeable conditions of storage, distribution, and use. Shelf-life studies and other information (e.g. scientific literature, microbiological modeling, environmental data, supplier's quality assurance) are important resources in determining the length of an RTE food's shelf-life. Appropriate temperatures for some refrigerated RTE foods may not be maintained throughout the entire food chain until the point of consumption. Temperature abuse of these foods may allow the growth of *L. monocytogenes*, if present, unless intrinsic parameters of the food prevent such growth. Potential temperature abuse, including by the consumer, should be taken into account when conducting studies to establish the shelf-life of refrigerated RTE food. Intrinsic parameters (e.g. pH, water activity, organic acid content) that are important for the shelf-life of the food should be monitored during processing at an appropriate frequency so that the food meets the conditions in the shelf-life study.

**13.2.2 Specific process steps**

114. Listericidal treatments should be validated to demonstrate that the treatments are effective and can be applied consistently (see Section 13 of the *General Principles of Food Hygiene* (CXC 1-1969)). Equipment parameters for effective listericidal treatments (e.g. temperatures, flow rates, loading capacity) should be identified and monitored to confirm **that** the ~~consistent reduction of~~ **conditions which reduce** *L. monocytogenes* **are being achieved**.

115. RTE foods that have undergone a listericidal treatment may be subject to contamination by *L. monocytogenes* from the processing environment after the listericidal treatment and before the food is contained in a sealed package. In these cases, the importance of cleaning and disinfection programmes and other programmes designed to minimise potential for contamination after a listericidal treatment, along with environmental monitoring for verification of such controls, should be emphasised. For RTE foods that support growth of *L. monocytogenes*, 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. Furthermore, a post-packaging listericidal treatment can also be applied to mitigate *L. monocytogenes* in RTE foods (e.g. heating, high pressure treatment, irradiation, where accepted).

116. RTE food that supports the growth of *L. monocytogenes* and will not undergo a listericidal treatment ~~may~~ **could** be contaminated at their source. Therefore, specific control measures ~~may~~ **should** be applied, where possible, to limit the extent of or prevent the growth of *L. monocytogenes*.

### 13.2.3 Microbiological, physical, chemical and allergen specifications

117. Refer to the *General Principles of Food Hygiene* (CXC 1-1969) and *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

### 13.2.4 Microbiological contamination

118. Contamination of RTE foods with *L. monocytogenes* can occur, for example, through direct contact with raw materials, personnel, aerosols, contaminated utensils~~/~~ **and** equipment or other unclean surfaces. Contamination can occur at any step where the food is exposed to the environment, including primary production, processing, storage, transportation, retail, catering, and consumers' homes.

119. Traffic flow patterns for personnel (e.g. all employees, visitors, and contractors), products, and equipment should be controlled between raw processing, storage areas and RTE processing areas to minimise the transfer of *L. monocytogenes*. For example, personnel should change footwear or use hygienic shoe coverings to prevent the potential transfer of *L. monocytogenes* when entering RTE processing areas that require a higher level of hygiene control (e.g. where RTE food is exposed). Another example is to use a colour coding system to identify personnel assigned to specific areas of the establishment.

120. Utensils, pallets, carts, forklifts and mobile racks should be dedicated for use in either the raw or the RTE processing area. A colour coding system can be used to identify equipment assigned to specific areas of the establishment. Where dedicated equipment is not practical, these items should be cleaned and disinfected before entering the RTE processing area. Automated foam sprayers can be an effective alternative when carts, forklifts and other portable equipment must enter an area where RTE foods are exposed.

121. Reused brines and recycled process water used in direct contact with food that will not be subjected to further listericidal treatment (including food in permeable or semi-permeable membranes, such as washed rind cheese) should be discarded or decontaminated (e.g. biocide treatment, heat treatment, or some other effective treatment) with sufficient frequency to control *L. monocytogenes*.

122. RTE foods that do not support the growth of *L. monocytogenes* (which may generally contain low levels of this pathogen) should not be a source of contamination to other RTE foods, especially those that support growth. The use of dedicated equipment for RTE food that supports the growth of *L. monocytogenes* should be considered where possible. In some cases, RTE foods that do not support growth may be processed or handled on the same equipment as RTE food that supports growth. In such a case, control measures (e.g. product sequencing, cleaning and disinfection procedures) should be implemented to prevent the contamination of RTE foods that support growth of *L. monocytogenes* with this pathogen that may be present at low levels in RTE foods that do not support its growth.

123. Some RTE foods that do not support growth of *L. monocytogenes* in their finished form (e.g. some frozen RTE foods) are processed in environments that are generally favorable for the growth of the pathogen (e.g. presence of water~~/~~ **and** temperatures that allow growth). The presence and growth of *L. monocytogenes* in the processing environment**,** and **its** subsequent transfer to the food at levels high enough to cause illness**,** have been considered contributing factors in outbreaks associated with some RTE foods that do not support the growth of the pathogen (e.g. ice cream). Therefore, appropriate control measures should be implemented in these processing environments to prevent~~/~~ **or** limit the potential harbourage, growth and transfer of *L. monocytogenes* to the RTE food, even though the pathogen may not grow in the finished food.

### 13.2.5 Physical contamination

124. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

### 13.2.6 Chemical contamination

125. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

### 13.2.7 Allergen management

126. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

### 13.2.8 Incoming materials

127. FBOs should implement appropriate supplier quality assurance activities (e.g. conducting an onsite audit of the supplier, requesting a certificate of analysis for each received incoming material lot) to prevent ingredients from being a source of *L. monocytogenes.* This is especially important when the incoming materials are used in the processing of RTE foods that support the growth of *L. monocytogenes* and there is no listericidal treatment.

**13.2.9 Packaging**

128. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**13.3 Water**

129. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

130. Refer to the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023).

**13.4 Documentation and records**

131. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**13.5 Recall procedures – removal from the market of unsafe food**

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

133. In food safety emergency situations, competent authorities should rapidly share information through formal and informal communication networks to minimise or prevent further spread of contaminated food throughout and between countries[9],**[10]**.

**14. PRODUCT INFORMATION AND CONSUMER AWARENESS**

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

- can prevent contamination and growth of *L. monocytogenes* by adequately storing and preparing RTE foods;
- understand the importance of shelf-life and how to interpret date marking written on food labels[11]; and
- can make informed food choices appropriate to the individual's health status and risk factors for acquiring foodborne listeriosis.

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

136. Rationale: Consumers (especially those in susceptible populations), their caregivers, and health care providers need to be informed about safe food handling and preparation practices as well as safe food choices (e.g. avoiding certain foods by susceptible populations or choosing safer food alternatives).

**14.1 Lot identification and traceability**

137. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**14.2 Product information**

138. Information provided to customers and consumers through pamphlets, websites, social media, or other printed or electronic media should provide consistent and clear messaging regarding the intended and safe use of food.

**14.3 Product labelling**

139. Where appropriate, labels on RTE foods should include information on safe handling practices, recommended storage temperatures and advice on the time frames in which the product should be eaten (e.g. date markings). Labels on foods for which preparation (e.g. cooking) by the consumer is needed to control *L. monocytogenes* should use terminology that clearly communicates such preparation is needed for **food safety**.

**14.4 Consumer education**

140. Since each country has specific consumption habits, communication programmes pertaining to *L. monocytogenes* are most effective when established by individual competent authorities.

141. Programmes for consumer education should be directed:

---

[9] see *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995)

**[10] see *Guidelines on the Management of Biological Foodborne Outbreaks* (CXG 96-2022)**

[11] see *General Standard for the Labeling of Pre-packaged Foods* (CXS 1-1985)

- at consumers with increased susceptibility to contracting listeriosis (individuals experiencing pregnancy, individuals experiencing immunosuppression, and adults aged 65 or older) and their caregivers;
- to help consumers make informed choices about food to purchase, including advising consumers in susceptible populations to avoid higher risk foods, where possible, or to adopt safer alternatives;
- to educate consumers on the importance of preventing contamination between raw and RTE foods (e.g. frequent cleaning of food preparation surfaces);
- to educate consumers on the proper storage of food and ~~their appropriate preparation/consumption (e.g. appropriate cooking of food before consumption when mentioned on the label) and~~ about the appropriate storage conditions and safe timeframes for keeping unused portions of packaged RTE foods after opening;
- **to educate consumers on the appropriate preparation and consumption (e.g. appropriate cooking of food before consumption when mentioned on the label);**
- to help consumers understand how they can minimise their risk of contracting listeriosis, including consideration for the specific regional conditions and consumption habits;
- to educate consumers on household practices and behaviours that would specifically keep the numbers of *L. monocytogenes* that may be present in RTE foods as low as possible by setting refrigerator temperatures, so that where feasible and appropriate, the product temperature does not exceed 6°C (preferably 2°C - 4°C, as growth of *L. monocytogenes* is significantly reduced at these lower temperatures);
- to promote the use of appropriate thermometers inside home refrigerators;
- to encourage frequent washing and disinfecting of the household refrigerator to prevent it becoming a source of *L. monocytogenes,* contributing to the contamination of RTE food stored inside;
- to educate consumers on the importance of and differences between various date markings on the labels of RTE foods; ~~and~~
- to educate consumers about the appropriate storage conditions and safe timeframes for keeping unused portions of packaged RTE foods after opening~~.~~**; and**
- **to inform and guide consumers on appropriate actions to take in response to product recalls.**

142. Programmes for health care providers should include consumer education information discussed above and be designed to provide guidance that:

- makes possible the rapid communication on preventing listeriosis, particularly to those individuals with increased susceptibility and their caregivers; and
- facilitates rapid diagnosis of foodborne listeriosis.

**15. TRANSPORTATION**

143. 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 RTE food;
- provide an adequately refrigerated environment, so that where feasible and appropriate, the temperature of refrigerated RTE food does not exceed 6°C (preferably 2°C - 4°C, as growth of *L. monocytogenes* is significantly reduced at these lower temperatures); and
- provide an adequately frozen environment, so that the temperature of frozen RTE food is maintained ~~at -18°C or colder~~.

144. Rationale: Food may become contaminated during transportation if not properly protected. If refrigeration or freezing conditions are inadequate, RTE food may support the growth of *L. monocytogenes* to higher levels and increase the risk of listeriosis.

**15.1 General**

145. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

146. Refer to the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001).

147. Transportation is an integral step in the food chain and should be controlled.

148. Transportation vehicles should be regularly inspected for structural integrity, cleanliness, and overall suitability when unloading ingredients and prior to loading finished RTE foods. In particular, the structural integrity of transportation vehicles (e.g. tanker trucks) should be monitored for stress cracks that may act as harbourage sites for *L. monocytogenes*. Tankers should be dedicated, where possible, to transport either raw materials~~/~~, ingredients or RTE foods.

**15.2 Requirements**

149. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**15.3 Use and maintenance**

150. 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[12]. A record should be available that indicates when cleaning and disinfection occurred.

**HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION**

**16. INTRODUCTION TO HACCP**

151. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**17. PRINCIPLES OF THE HACCP SYSTEM**

152. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**18. GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM**

**18.1 Introduction**

153. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**18.2 Flexibility for small and/or less developed food businesses**

154. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19. APPLICATION**

**19.1 Assemble HACCP team and identify scope (Step 1)**

155. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.2 Describe product (Step 2)**

156. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.3 Identify intended use and users (Step 3)**

157. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.4 Construct flow diagram (Step 4)**

158. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.5 On-site confirmation of flow diagram (Step 5)**

159. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.6 List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/Principle 1)**

160. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

[12] *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001).

**19.7 Determine the critical control points (CCPs) (Step 7/Principle 2)**

161. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.8 Establish validated critical limits for each CCP (Step 8/Principle 3)**

162. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.9 Establish a monitoring system for each CCP (Step 9/Principle 4)**

163. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.10 Establish corrective actions (Step 10/Principle 5)**

164. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.11 Validation of the HACCP plan and verification procedures (Step 11/Principle 6)**

**19.11.1 Validation of the HACCP plan**

165. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.11.2 Verification procedures**

166. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.11.3 Establish documentation and record keeping (Step 12/Principle 7)**

167. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**19.12 Training**

168. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

**ANNEX I**

**RECOMMENDATIONS TO FOOD BUSINESS OPERATORS FOR AN ENVIRONMENTAL MONITORING[13] PROGRAMME FOR *LISTERIA MONOCYTOGENES* IN PROCESSING AREAS AND PRIMARY PRODUCTION ~~AND PROCESSING AREAS~~**

**INTRODUCTION**

1. Outbreaks of listeriosis have been associated with contamination of RTE food that was exposed to the environment after the food received a listericidal treatment or of RTE foods that are processed without a listericidal treatment (e.g. raw milk cheeses and fresh produce). EMPs involve the sampling and testing of both food contact and non-food contact surfaces (e.g. surfaces on equipment or in the processing environment) for the presence of *L. monocytogenes* or an appropriate indicator organism, such as *Listeria* spp. (hereafter *Listeria* spp*.* is used to represent all indicators). The importance of such an EMP is greatest for equipment and processing environments used for RTE foods which are not given a post-packaging listericidal treatment and in which the growth of *L. monocytogenes* can occur.

2. EMPs are also recommended for RTE foods that do not support the growth of *L. monocytogenes*, particularly when conditions in the processing environment are favourable for its growth (e.g. wet processing environments). The presence and growth of *L. monocytogenes* in the processing environment and subsequent transfer to the food at levels high enough to cause illness have been considered contributing factors in outbreaks associated with some RTE foods that do not support the growth of the pathogen (e.g. ice cream).

3. **GAPs and** GHPs and control measures should be designed and implemented to prevent the introduction and harbourage of *L. monocytogenes* in primary production and processing environments. However, FBOs should expect to find *L. monocytogenes* occasionally in the processing environment. The purpose of the EMP is to find *L. monocytogenes* (or *Listeria* spp.) and harbourage sites. This is a proactive approach (e.g. “seek and destroy”) to minimise the risk of contamination and maintain food safety.

4. EMPs may not be appropriate for all primary production environments or situations. An effective EMP should be ~~specifically~~ designed ~~for each primary production or processing environment~~ considering the factors (A-L) listed below:

**A. TYPE OF PRODUCT AND PROCESS/OPERATION**

5. **Primary production**. The need for and extent of EMPs at primary production (e.g. during harvest, handling, and packaging) should consider:

- the characteristics of the food (i.e. supporting or not supporting the growth of *L. monocytogenes*);
- previous detections of *L. monocytogenes* or *Listeria* spp. in the food, facility, or equipment;
- the general hygienic conditions and design of equipment, especially food contact surfaces;
- whether the food will be processed with a listericidal treatment;
- the likelihood of contamination from the environment (e.g. harvesting practices, on-farm management practices, the extent of handling by operators); and
- other related factors.

6. **Processing environments**. The need for and extent of EMPs in processing facilities should consider:

- the characteristics of each of the RTE foods (i.e. supporting or not supporting the growth of *L. monocytogenes*);
- previous detections of *L. monocytogenes* or *Listeria* spp. in the raw materials, the processing environment and the RTE food;
- processing conditions (e.g. temperature, humidity, storage conditions);
- the general hygienic conditions, layout of the facility, and line configurations for each RTE food;
- the general hygienic conditions and design of equipment, especially food contact surfaces;
- whether the process flow includes a listericidal treatment (before or after packaging);
- the likelihood of contamination of RTE food from the processing environment (e.g. the extent the RTE food is exposed to the environment, the extent of handling RTE food by operators);
- traffic patterns for personnel, products and equipment within the processing environment;

[13] Environmental monitoring is not to be confused with monitoring as defined in HACCP.

- processing cycles and the frequency of sanitation;
- the intended consumers (e.g. the general population versus those populations more susceptible to listeriosis); and
- other related factors.

**B. TARGET ORGANISM**

7. The EMP should indicate when samples are tested directly for *L.* monocytogenes or *Listeria* spp. For routine environmental monitoring, it is recommended to test environmental samples for *Listeria* spp. because their presence is an appropriate indicator of conditions that would support the potential presence of *L. monocytogenes*. The detection of *Listeria* spp. prior to the start of processing indicates inadequate hygiene. Additionally, in some circumstances, *L. innocua* can outgrow *L. monocytogenes* when present in the same sample resulting in the inability to detect *L. monocytogenes*. The finding of *Listeria* spp. in the processing environment can allow actions to be taken to correct conditions that may increase the likelihood for the contamination of RTE food with *L. monocytogenes*. Where appropriate and shown to be valid, other indicator organisms may be used[14]. Biochemical assays (such as Adenosine Triphosphate (ATP) testing) or other assays to evaluate surfaces for the presence of soils are not an appropriate indicator for *Listeria* spp. or *L. monocytogenes*.

8. Testing environmental samples directly for *L. monocytogenes* may be useful when taking follow-up actions related to the positive finding of *L. monocytogenes* in a RTE food or when taking follow-up actions related to the positive finding of *L. monocytogenes* or *Listeria* spp. in the primary production or processing environment.

9. When food contact surfaces used to produce RTE foods are tested for *L. monocytogenes* and the food is not given a post-packaging listericidal treatment, FBOs should consider holding the food until the testing results are received.

**C. SAMPLING LOCATIONS**

10. The EMP should identify sampling locations that include both food contact and non-food contact surfaces. The number of sampling locations will vary with the complexity of the process, the type of food being processed, and the general conditions of the equipment/facility. Sampling locations should be identified for every processing line, line configuration and processing area in the facility where RTE food is handled or processed, especially those in which the RTE food is exposed to contamination from the environment. All equipment used for RTE foods, including infrequently made products, should be represented in the sampling program. **As part of EMP documentation, it is recommended to mark sampling locations on a detailed map of the processing facility. Additionally, the exact sampling point should be recorded in a manner that allows full traceability to the corresponding analytical results (e.g. a generic description such as, "inspection table 1" lacks precision compared to, "inner surfacer, right side of inspection table 1").**

11. FBOs should consider all surfaces that could come into direct or indirect contact with food to be food contact surfaces. Food contact surfaces can include equipment surfaces (e.g. conveyor belts, filler nozzles, hoppers, slicing machines, freezing tunnels), utensils, employee personal protective equipment (e.g. uniforms, aprons, gloves), or other surfaces from which food or other material can drip, fall, be transferred, or be drawn into exposed food or onto direct food contact surfaces (e.g. the underside lip of tables or control panels that are touched by operators who then handle food).

12. Examples of non-food contact surfaces can include equipment surfaces that are not considered direct or indirect food contact surfaces (e.g. equipment framework) and surfaces from within the processing environment (e.g. floors, walls, wheels of carts, electrical conduit, drains, evaporator plates, fans, and condensate drip pans).

13. Information on appropriate sampling locations can be found in published literature, can be obtained by consulting food safety experts with specific process experience, or can be identified by conducting sampling surveys on equipment or in processing areas. In general, surfaces on primary production equipment or in processing environments that may be harbourage sites[15] should be considered for potential sampling locations.

14. The EMP should enable (e.g. by training) and permit operators conducting environmental sampling to regularly collect a certain number of samples from locations of their choice and especially when they observe

[14] The following attributes would contribute to the scientific support for using a specific organism as an indicator of a specific pathogen: 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.

[15] Harbourage sites can include surfaces that are poorly designed, wet, worn or damaged such that they are difficult to adequately clean and disinfect.

conditions or activities within the primary production or processing environment that may have increased the risk of harbourage or spread of *L. monocytogenes*. These locations should be documented.

15. Sampling locations can be classified according to their **level of** proximity to food using a **classification** ~~zoning~~ system (e.g. **food contact surfaces, adjacent non-food contact surfaces, further remote non-food contact surfaces, outside RTE processing areas), often referred to as a "**zon**ing"** ~~es 1-4~~**approach,** for the purposes of developing sampling plans that provide adequate coverage of the surfaces on equipment or within a processing environment and for determining appropriate corrective actions should a positive (or presumptive positive) be found (see Section J ~~11~~).

16. **The EMP** ~~Sampling locations~~ should be reviewed and updated, as necessary, to include new sampling locations identified by operators, when changes are introduced (e.g. new equipment/processing lines, new product types or inputs), when there are changes to traffic patterns within the facility, or when conditions in the facility change with regard to potential harbourage sites.

**D. FREQUENCY OF SAMPLING**

17. The frequency of environmental sampling should consider the factors outlined under Section A. In general, the frequency of sampling should be higher where there is greater risk of contaminating RTE food with *L. monocytogenes* (i.e. equipment/areas where RTE food is exposed to the environment). The frequency of sampling should also reflect existing data on the presence of *L. monocytogenes* or *Listeria* spp. in the environment of the operation under consideration, especially if the same strain of *L. monocytogenes* has been identified in environmental samples over a period of time indicating that the strain is not being eliminated from the environment through routine cleaning and disinfection (i.e. a persistent strain).

18. 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 sufficient period as to provide reliable information on the prevalence of *L. monocytogenes* or *Listeria* spp. and any variations in prevalence over time (e.g. the impact of seasonality).

**E. TIMING OF SAMPLING**

19. Over time, the collection of environmental samples should be rotated between every shift of operation (e.g. 1st shift and 2nd shift in a facility that operates with two shifts) and every operating day of the week. Rotating the shifts/days during which samples are collected allows the EMP to detect contamination that may be related to differences in environmental conditions at different times.

20. Preferentially, **for** environmental **monitoring,** samples should be collected during primary production and processing at a time when any *L. monocytogenes* that may have been present in a harbourage site has had time to spread within the equipment or the environment (e.g. approximately 3 hours into processing). Environmental samples can also be collected before initiation of processing to help verify the effectiveness of cleaning and disinfection procedures, however if samples are collected from surfaces after disinfection, care ~~must~~ **should** be taken to ensure residual disinfectant does not negatively affect testing. The time of sampling and phase of operation (e.g. pre-operational after cleaning and disinfection, 3 hours into processing) should be recorded.

**F. NUMBER OF SAMPLES TO BE COLLECTED DURING EACH SAMPLING EVENT**

21. The number of samples to be collected during each sampling event depends on how many sampling locations are identified, how often sampling will be conducted (i.e. the frequency of sampling), and over what period of time a FBO wishes to test all of the identified sampling locations.

22. FBOs should consider collecting samples from both food contact and non-food contact surfaces each time samples are collected. Sampling and testing non-food contact surfaces can help detect *L. monocytogenes* or *Listeria* spp. and allow corrective actions to be taken before contamination is spread to food contact surfaces and RTE food.

**G. SAMPLING TOOLS AND TECHNIQUES**

23. The type of sampling tools and techniques should be appropriate for the type of surfaces and locations from which samples are collected. The most common sampling tools are sterile sponges, cloths and swabs. The most appropriate method for sampling should be evaluated for each unique situation. In general, sponges should be used for collecting samples of large flat surfaces, whereas swabs may be more appropriate for collecting samples from cracks, crevices, or other hard to access surfaces. **Food** residues on environmental surfaces, if present, can be loosened using a sterile scraper or other similar sterile tool to facilitate the sample collection.

24. The process of sampling should not introduce unnecessary risk. For example, if wet swabs are used to collect samples in dry processing environments, FBOs should consider immediately cleaning and disinfecting the sampled location using an alcohol-based disinfectant or other appropriate non-aqueous

solution to facilitate drying of the surface. Further, accessing food contact surfaces within enclosed processing systems for routine sampling may increase the risk of contamination, therefore FBOs may consider enhancing other routine monitoring and verification activities (e.g. finished product testing) while continuing to sample those food contact surfaces that are easily accessible.

25. Environmental surfaces that may have residual disinfectant present should be sampled using an appropriate “neutralising” solution (e.g. neutralising diluent).

26. Operators collecting environmental samples should be trained to use techniques that prevent the contamination of the sterile sampling tool (e.g. sponge or swab), including its provided storage bag/tube, with hands or other potentially contaminated surfaces. When possible, sterile gloves should be worn when collecting environmental samples.

27. Once collected, environmental samples should be cooled as soon as possible to refrigeration temperatures, then stored and transported (e.g. shipped to a testing laboratory) under refrigeration conditions. Temperatures should be maintained and monitored so that, where feasible and appropriate, samples are cooled below and consistently do not exceed 6°C (preferably 2°C - 4°C). FBOs should develop procedures to manage samples in the event of unforeseen disruptions (e.g. power outages, equipment failure). Environmental samples should not be frozen as this can reduce the likelihood of recovering *L. monocytogenes*. The delay between sampling and testing should be as short as possible. Environmental samples should be tested within 48 hours of collection to maximise the recovery of *L. monocytogenes* or *Listeria* spp., if present.

## H. SAMPLE ANALYSIS

28. The analytical methods used to analyse environmental samples should be validated for the detection of *L. monocytogenes* or *Listeria* spp. and the type of surfaces being evaluated (e.g. stainless steel, plastic, concrete). It is important to demonstrate and document that the methods are able to detect the target organisms, with acceptable reproducibility, reliability and sensitivity. In the context of international food trade, analytical methods endorsed by Codex should be considered first, when available[16]. Validated rapid detection methods can be used to identify potentially contaminated surfaces faster than conventional cultural methods. However, in the case of a positive result by rapid methods, consideration should be given to the recovery of an isolate for further characterisation. Testing laboratories should use appropriate laboratory practices[17] and, when possible, be accredited for the specific analytical methods used.

29. Under certain circumstances, it may be possible to composite environmental samples without losing the required sensitivity allowing for a more cost-effective EMP, but only when such compositing does not reduce test sensitivity when compared to testing individual analytical units. When environmental samples are composited and the composite is positive for the target organism**,** additional testing will be necessary to determine the location of the positive sample[18], or all locations represented in the composite should be considered positive. If environmental samples are to be composited, it is recommended that:

- the entire environmental sample is added to the composite (e.g. sponges are not cut or split);
- environmental samples collected from food contact surfaces should not be composited with those collected from non-food contact surfaces;
- environmental samples from different processing lines should not be composited;
- environmental samples should not be composited with product samples; and
- samples collected for quantitative analysis should not be composited.

30. Characterising isolates by one or more of the available techniques (e.g. whole genome sequencing, pulsed field gel electrophoresis, multi-locus sequencing typing, certain polymerase chain reaction-based methods) can provide useful information about whether that strain of *L. monocytogenes* has been identified in the facility before (e.g. whether it might be considered a transient or a potential persistent strain to the facility), the potential source of the strain, and potential pathway(s) for the strain to contaminate RTE food. It is recommended that *L. monocytogenes* isolates be retained and stored under appropriate frozen conditions in case further characterisation is desired.

## I. DATA REVIEW/MANAGEMENT

31. Testing laboratories should inform FBOs of presumptive and confirmed results for detection of *L.*

[16] *Principles for the use of sampling and testing in international food trade* (CXG 83-2013)
[17] *Guidelines for the Assessment of the competence of testing laboratories involved in the import and export control of food* (CXG 27-1997)
[18] In the event that a composite sample is positive and additional testing cannot identify which location in the composite was positive (i.e. the target organism is not detected in additional testing for each location), then all locations represented in the composite should be considered positive.

*monocytogenes* and *Listeria* spp. as soon as possible to facilitate prompt review and implementation of actions to mitigate the contamination.

32. The EMP should identify the timeframe within which results from analytical testing will be reviewed and the person(s) who will be responsible for reviewing them. Results from the testing of environmental samples should be reviewed promptly so that actions can be taken as soon as possible should there be a positive (or presumptive positive) sample.

33. It is recommended that actions be initiated upon receiving a presumptive positive result (e.g. a result from a rapid screening method). The time required for confirmation of a presumptive positive result can allow *L. monocytogenes* to spread further within the facility (including to harbourage sites) and potentially into RTE food.

34. The EMP should include a system to record and evaluate the data (e.g. performing trend analyses). Examples of trends that FBOs should consider include:

- changes in positivity rates over time or during different seasons;
- increased positives during the production of certain RTE foods, the handling of certain ingredients, or the use of certain equipment; and
- other potential trends, as appropriate.

**J. ACTIONS IN CASE OF POSITIVE (OR PRESUMPTIVE POSITIVE) RESULTS**

35. FBOs should react to each positive (or presumptive positive) result as soon as possible. However, the nature and extent of the reaction should generally be greater when one or more of these factors apply:

- the contaminated surface is a food contact surface;
- the RTE foods produced on contaminated food contact surfaces support the growth of *L. monocytogenes*;
- the food being produced will not be further subjected to a listericidal treatment;
- the contamination was detected on multiple surfaces during the sampling event;
- there is a history of finding *L. monocytogenes* or *Listeria* spp. in the facility; and
- the same strain of *L. monocytogenes* has been persistent in the facility after corrective actions have been taken to eliminate it.

36. Root cause investigation and other potential actions that should be considered in reaction to a positive (or presumptive positive) result can include:

- **Investigative sampling** of environmental surfaces related to the location of the positive sample in an attempt to identify the extent of contamination within equipment and the processing environment and its potential source(s). When equipment breakdown or disassembly is performed to access surfaces not normally exposed during routine cleaning and disinfection, environmental samples should be collected from these surfaces before they are cleaned and disinfected to determine if they may have been a source of the contamination and thereafter to verify the effectiveness of their cleaning and disinfection. Locations for investigative samples can include:
    - potential harbourage sites in proximity to the positive location;
    - surfaces in related high-traffic areas (e.g. floors, which may inform as to where the contamination came from and/or where it may have spread);
    - surfaces from air and cooling systems (e.g. evaporation plates and fans from which contamination may enter the facility or be spread within); or
    - other locations that may be informative about the extent or source of the contamination (e.g. surfaces within the processing area from which contamination may have been rinsed to a floor drain which tested positive).
- **Additional and/or intensified cleaning and disinfection** of equipment or the processing environment. Intensified cleaning and disinfection can involve different activities and/or practices for cleaning and disinfection such as:
    - the application of more intense physical disruption and the rotation of disinfectants;
    - the use of more powerful chemicals (e.g. the use of a stronger disinfectant or a cleaning agent formulated to remove biofilms);

- the breakdown or disassembly of equipment to access surfaces not normally exposed during routine cleaning and disinfection; or
- the disinfection of the entire processing area.

- **Follow-up sampling** of the positive location(s) to verify the effectiveness of additional and/or intensified cleaning and disinfection activities taken in reaction to the positive(s).
- **Review of hygienic practices and procedures** related to the location of the positive sample in an attempt to identify any breakdown in hygienic controls that could have contributed to the introduction or spread of the contamination. Such review may include interviewing operators, reviewing operational lines/flows, reviewing maintenance and operational records, and observing personnel for implementation of hygienic procedures.
- **Intensified environmental monitoring** to further verify that hygienic conditions on equipment or the processing environment have been restored. Intensified environmental monitoring could include actions such as temporarily increasing the frequency of sampling and/or the number of samples collected during a sampling event.
- **Holding and testing of RTE food** to verify that contamination found in environmental locations has not spread to RTE food. When verification activities already include holding and testing RTE food for *L. monocytogenes*, the frequency of testing could be increased (if not already testing every lot) and/or the number of samples collected and tested from each lot could be increased until the restoration of hygienic conditions on equipment or the processing environment has been verified.

37. When the actions taken in response to a positive (or presumptive positive) result are not effective (meaning *L. monocytogenes* or *Listeria* spp. continue to be detected after such actions), then additional actions of an escalated nature or intensity should be taken until the hygienic conditions on equipment and the processing environment have been restored.

38. Structured processes, such as root cause analysis, can be helpful in determining the likely root cause (e.g. the source) of a *L. monocytogenes* contamination event and additional actions that may prevent such contamination from recurring. Some examples of when a structured process could be considered are:

- when *L. monocytogenes* has been confirmed on a food contact surface (or in an RTE food); and
- when a strain of *L. monocytogenes* has been found to be a resident strain to the facility.

## K. SAMPLING FOR SPECIAL CIRCUMSTANCES

39. The EMP should identify special circumstances which may require a temporary increase or modification to the established environmental sampling activities. Such circumstances can include planned events (e.g. construction activities at the facility or the introduction of new equipment, products, or ingredients) or unplanned events (such as roof leaks, drain backups, or flooding of the facility due to extreme weather events).

40. For planned events (e.g. a construction project affecting part of the facility while processing of RTE food continues in other parts of the facility), environmental monitoring activities specific to the planned event should be developed separate from the routine EMP for the facility. Resources needed to support environmental monitoring for a planned event should not reduce the facility's ability to conduct appropriate environmental monitoring in the parts of the facility that continue to produce RTE food during the planned event. Additional sampling locations may need to be identified and the sampling timing/frequency may need to be adjusted depending on the nature of the planned event.

41. FBOs should consider how they could respond to unplanned events with respect to collecting environmental samples and whether to document these activities in the EMP or in procedures developed specifically for responding to such unplanned events.

## L. REVIEW OF THE EMP

42. EMPs should be reviewed and updated on a periodic basis (e.g. at least annually) so that the programme continues to be appropriately designed and implemented. Furthermore, the EMP design should be reviewed in response to any situation that could impact the effectiveness of the controls for *L. monocytogenes,* or any event involving the loss of control for *L. monocytogenes* such as repeated detection of a persistent strain.

43. The review of the EMP could include:

- A review of the sampling locations and frequencies so that the EMP is collecting data on all appropriate equipment and the processing environment in the facility at suitable intervals.

- A review of actions taken in response to positive (or presumptive positive) samples to evaluate their completeness and effectiveness.
- A review of positive (and presumptive positive) locations to determine if there are any trends or patterns in where/when *L. monocytogenes* or *Listeria* spp. has been found in the facility. Such long-term review of the data can reveal low level, intermittent contamination that may otherwise go unnoticed.
- The collection and testing of a large number of samples from food contact and non-food contact surfaces throughout the RTE processing area of the facility (including locations not identified and sampled as part of the EMP). This activity may be especially helpful if the EMP has not detected any (or very few) positive locations since the last review.

44. It may be helpful to enlist a food safety expert with specific process experience from outside the facility to participate in the review of the EMP.

**ANNEX II**

## RECOMMENDATIONS TO COMPETENT AUTHORITIES FOR THE USE OF MICROBIOLOGICAL TESTING AS A MEANS OF VERIFYING THE EFFECTIVENESS OF HACCP AND PREREQUISITE PROGRAMMES FOR THE CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

### INTRODUCTION

1. These recommendations are for competent authorities that use microbiological testing (e.g. environmental monitoring and/or process control testing) as part of their regulatory activities. It is also anticipated that this annex will provide guidance that the competent authority can provide to industry.

2. The effectiveness of HACCP, GHPs and other programmes for the control of *L. monocytogenes* in their operating facilities falls within the responsibility of FBOs. Further, FBOs must validate the food safety control systems they have in place. Competent authorities verify that the controls are validated and have been implemented as designed. Example verification activities include conducting inspections, reviewing records of CCP compliance, reviewing the results from an FBO's microbiological testing programs and observing production or processing personnel. Additionally, competent authorities may implement ~~administer~~ their own microbiological testing programmes as a **means of** verification activity **when FBOs procedures and records do not provide sufficient assurance of compliance**.

3. Guidance within Codex regarding microbiological testing is often restricted to the testing of finished RTE foods using traditional lot-by-lot testing. However, the general section of these guidelines emphasises the importance of EMPs to verify the effectiveness of GHPs and other control measures implemented to maintain hygienic conditions and prevent contamination of RTE foods with *L. monocytogenes*. This is further elaborated in Annex I: *Recommendations to Food Business Operators for an Environmental Monitoring Programme for* Listeria monocytogenes *in Primary Production and Processing Areas,* which provides recommendations to industry on the design and implementation of EMPs.

4. Microbiological test programmes can be implemented for a) environmental monitoring and b) process control verification. These programmes described below can be an important part of the ability of competent authorities to verify the effectiveness of *L. monocytogenes* control programmes over time. These recommendations do not establish specific decision criteria for programmes or 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 processing technologies.

### ENVIRONMENTAL MONITORING

5. In certain instances, competent authorities may incorporate the testing of food contact and/or non-food contact surfaces (e.g. surfaces on equipment or the processing environment) for *L. monocytogenes* or appropriate indicator organisms, such as *Listeria* spp., as part of their regulatory requirements or activities. This sampling/testing can be performed by the competent authority as part of its inspection activities or by the individual FBO (in which case the competent authority can review the testing procedures and results as part of its verification of the FBO's controls).

6. The purpose of conducting ~~and~~/or reviewing environmental testing programmes by a competent authority is to verify, ~~for example~~, that a FBO has ~~successfully~~ **appropriately** identified and controlled *L. monocytogenes* or *Listeria* spp. and potential harbourage sites within the facility.

7. In developing environmental testing programmes, competent authorities should:

- consider the importance of environmental sampling in verifying appropriate hygienic conditions in facilities that produce both RTE foods that support the growth of *L. monocytogenes* and those that do not;
- clearly distinguish between sampling of food contact surfaces and non-food contact surfaces;
- articulate the sampling plan and testing techniques (see Annex I; note that the sampling locations for competent authorities may be similar to those used by FBOs);
- establish decision criteria that will initiate follow-up actions (including additional testing) when an environmental sample is positive for *L. monocytogenes* or *Listeria* spp.;
- establish actions that the FBO should initiate when an environmental sample is positive for *L. monocytogenes* or *Listeria* spp.; and
- include a system to record and evaluate the data.

8. Competent authorities should communicate all positive findings of *L. monocytogenes* or *Listeria* spp. in environmental samples to the FBO as soon as possible. Additionally, competent authorities should consider communicating presumptive positives so that FBOs can take appropriate actions while confirmation methods

are completed. When reporting positive (or presumptive positive) results of *L. monocytogenes* or *Listeria* spp. to FBOs, competent authorities should provide any insights from their analyses that may help the FBO identify and correct the source of contamination. For example, the competent authority could point out that the repetitive isolation of a specific strain of *L. monocytogenes* can indicate a harbourage site that routine cleaning and disinfection activities are insufficient to control.

9. When *L. monocytogenes* is detected in environmental samples by the competent authority, an investigation (by the FBO and/or the competent authority) should be performed to identify:

- the source(s) of contamination;
- whether any RTE product was impacted by the positive finding; and
- specific actions that should be taken by the FBO to correct the problem and prevent its recurrence (see Annex I, section J).

10. Overall, sampling techniques and testing methods should be reproducible, reliable, and sufficiently sensitive for the type of surface being evaluated. Methods used should be appropriately validated for the recovery of *L. monocytogenes* or *Listeria* spp. from environmental samples. Testing laboratories **should use appropriate laboratory practices and** should be accredited for the specific analytical methods used.

**PROCESS CONTROL VERIFICATION**

11. For a well-designed food safety control system, **the FBO is responsible for implementing and maintaining effective controls to prevent and manage *Listeria* contamination within its premises. A** competent authority may consider establishing microbiological process control testing (e.g. testing in-process and/or finished RTE foods) and decision criteria for specific products (or groups of products) to identify trends that can be corrected before decision criteria are exceeded. When undesirable trends occur or decision criteria are exceeded, the FBO should investigate the food safety control system to determine the cause and take action to correct the problem(s) and prevent its (their) recurrence. The competent authority should verify that appropriate actions are taken when criteria for *L. monocytogenes* or *Listeria* spp. 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 RTE foods that do not meet the microbiological criteria established in Annex III.

12. In addition to verifying that the process controls within the food safety control system are valid and operating as designed, process control testing[19] of finished RTE foods should be used by FBOs 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 RTE foods contributes to the assessment of the continuing performance of a food safety control system and helps support that appropriate actions are taken to correct problems before microbiological criteria are exceeded. The competent authority should verify that the food safety control system remains 'in control' or that the FBO has taken appropriate 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 RTE foods can indicate the lack of control at primary production and/or in the processing environment.

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

14. 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.

**CHARACTERISING *L. MONOCYTOGENES* ISOLATES**

15. When competent authorities find *L. monocytogenes* as part of their inspectional activities, **characterisation of** ~~they should characterise~~ the isolate(s) by one or more of the available genetic techniques (e.g. whole genome sequencing (WGS), pulse field gel electrophoresis (PFGE), multi-locus sequencing typing (MLST), certain polymerase chain reaction-based (PCR-based) methods) ~~that~~ **is recommended. Genetic characterisation of the isolate(s)** can provide information on virulence factors, potential antibiotic sensitivity, biocide tolerance, subtyping and allow ~~the~~ genetic comparison (e.g. through subtyping) to any isolates obtained

[19] Sometimes referred to as "cross-lot" testing, which involves a limited number of tests being conducted across lots over time instead of extensive testing of each lot

and analysed by comparable methods from food, ill persons and/or from previous environmental sampling.

16. These *L. monocytogenes* isolates should be retained and stored under appropriate frozen conditions in case further characterisation is needed (e.g. WGS following an initial PFGE analysis). Furthermore, if the competent authority does not initially characterise the isolate(s), these should be retained and stored under appropriate frozen conditions in case future characterisation is needed. The availability of *L. monocytogenes* isolates and/or such characterisation data supports the development of risk assessments. **Competent authorities are encouraged to foster the timely and appropriate sharing of WGS data within and across countries. Such data plays an essential role in enabling thorough risk assessments, enhancing surveillance efforts, and reinforcing food safety systems worldwide.**

**ANNEX III**

## RECOMMENDATIONS TO COMPETENT AUTHORITIES AND FOOD BUSINESS OPERATORS FOR DEVELOPING AND APPLYING MICROBIOLOGICAL CRITERIA FOR *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

### 1. INTRODUCTION

1. The microbiological criteria presented in this Annex are intended as advice to competent authorities within a framework for the control of *L. monocytogenes* in RTE 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 FBOs (e.g. Section 3.1).

2. This Annex references and takes into account the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 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 (MRM)* (CXG 63-2007).

3. Available risk assessments have been considered in the development of the microbiological criteria in this Annex. In addition, factors that might impact the ability of competent authorities and FBOs to implement these microbiological criteria (e.g. methodological limitations, costs associated with different types of qualitative and quantitative testing, and statistics-based sampling needs) were also considered. It should be noted that microbiological testing alone cannot assure the safety of RTE food, and such testing should not be used as a substitute for appropriate and effective control measures for *L. monocytogenes*.

### 2. SCOPE

4. These microbiological criteria apply to specific categories of RTE foods, as described herein. The competent authority should consider the intended use as well as how specific RTE foods are likely to be handled during marketing, catering, or by consumers (including the reasonably foreseeable[20] use of the food) when developing risk management strategies to determine the appropriateness of applying the microbiological criteria. Competent authorities may apply these criteria, where appropriate, to assess the acceptability of RTE foods in international trade for imported products, at end of manufacture (finished RTE foods) for domestic products, and at point of sale for the expected shelf-life[21] under reasonably foreseeable conditions of distribution, storage and use.

5. 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[22] to comply with these guidelines.

6. 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 consumer protection 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 RTE FOODS

7. A microbiological criterion defines the acceptability of a food based on whether the target microorganism is detected/not detected or the number of microorganisms in the food. There are various applications for microbiological criteria for *L. monocytogenes* in RTE foods using risk-based sampling plans[23], including:

- Microbiological testing against a criterion can be used as a means of verifying the continuing effectiveness of a food safety control system (i.e. HACCP System)[24]. Typically, such applications involve testing on less than a lot-by-lot basis and may be formalised into a system of process control verification testing. However, it should be recognised that coupling environmental

[20] Reasonably foreseeable means a frequency that can be anticipated as likely to occur because of data or other information showing habits within a population, supply chain, or region (even though such habits may not be intended for the food). Reasonably foreseeable does not mean any conceivable use (or misuse) of the food.

[21] See definition in the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004).

[22] *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008)

[23] *General Guidelines on Sampling* (CXG 50-2004)

[24] *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997)

monitoring with the testing of RTE foods is a more effective approach for verifying the effectiveness of controls for *L. monocytogenes*.

- Testing for compliance with a microbiological criterion may also be used as a means of verifying the microbiological status of foods in relation to acceptance criteria specified between FBOs. Such testing may be conducted on a lot-by-lot basis when there is little information about the conditions under which the product has been produced and when other more effective control measures (e.g. listericidal treatments) are not available. Where there is information about the conditions of production/processing, testing for compliance may be conducted less frequently.
- When there is little information about the conditions under which the product has been produced and other more effective control measures are not available, microbiological testing on a lot-by-lot basis can be used as a direct control measure, i.e. sorting of acceptable and unacceptable lots. This type of testing should be limited to those products and/or points of the food chain where the microbiological criteria would be expected to improve the degree of protection offered to the consumer.

8. The frequency of testing RTE foods for *L. monocytogenes* may be modified based on the likelihood of contamination, characteristics of the food, history of the food, conditions of primary production or processing, and other relevant information.

9. Testing against microbiological criteria for *L. monocytogenes* is not necessary for foods that:

- receive a **validated** listericidal treatment after being sealed in final packaging that prevents contamination until the packaging is opened by the consumer or otherwise compromised;
- are aseptically processed and packaged[25];
- contain a component in their formulation for the rapid inactivation of the pathogen, if present (e.g. products that contain >5 % ethanol); or
- belong to other categories of RTE foods as defined by competent authorities.

10. Where possible and practicable, the risk-based approach to development of microbiological criteria[26] should be used to contribute to the assurance, that a food control system will achieve the required level of consumer protection.

11. Risk assessments have consistently identified the ability of an RTE food to support the growth of *L. monocytogenes* as a significant risk factor for listeriosis. Therefore, different microbiological criteria could apply for the following categories of foods:

- RTE foods in which growth of *L. monocytogenes* will not occur; and
- RTE foods in which growth of *L. monocytogenes* can occur.

12. If there is insufficient information to demonstrate that *L. monocytogenes* growth will not occur in an RTE food during its expected shelf-life under reasonably foreseeable conditions of distribution, storage and use, the food should be categorised as an RTE food in which growth of *L. monocytogenes* can occur.

**3.1 Recommendations for how FBOs can identify RTE foods in which growth of *L. monocytogenes* will not occur**

13. FBOs should determine if growth of *L. monocytogenes* will not occur in RTE foods. Such determination should be based on scientific justification[27], including the inherent variability of parameters controlling *L. monocytogenes* in the food. Demonstration that growth of *L. monocytogenes* will not occur in an RTE food can be based upon, for example, food characteristics, the study of naturally contaminated food

[25] *Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods* (CXC 40-1993)

[26] *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CXG 63-2007)

[27] References that have been addressed for identifying properties of ready-to-eat foods which will categorise 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).

(i.e. durability studies), challenge studies, predictive modelling, as well as information from the scientific literature, risk assessments, academic institutions and historical records of product ~~attributes~~ **characteristics** (e.g. pH, $a_w$), or combinations of these.

14. Parameters such as pH and $a_w$ can be useful in preventing growth. For example, *L. monocytogenes* growth can be controlled in foods where the following ~~attributes~~ **characteristics** can be maintained throughout the shelf-life[28]:

- a pH below 4.4;
- an $a_w < 0.92$;
- a combination of pH < 5.0 with $a_w < 0.94$; or
- other combinations of parameters validated to prevent the growth of *L. monocytogenes* in the food.

15. Growth of *L. monocytogenes* in RTE food can also be controlled by freezing the food (at least during that period when the food remains frozen). Frozen RTE foods that may be thawed and held under refrigerated conditions before consumption should be evaluated to determine if *L. monocytogenes* growth can occur in the food when it is not frozen.

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

17. When an FBO can demonstrate that the RTE food consistently meets intrinsic parameters shown to inhibit *L. monocytogenes* growth (e.g. by previous studies or microbiological models applicable to the specific RTE food), further documentation may not be needed. For all other cases, a challenge study may be conducted.

### 3.1.1 Challenge Studies

18. **For the purposes of this Annex, a challenge study is a laboratory-based study that provides information on the behaviour of *L. monocytogenes* (growth, survival, or decline) under specified storage conditions when the RTE food is artificially inoculated.** Challenge studies are the responsibility of FBOs ~~and can be conducted with appropriate industry organisations or contract laboratories~~. **They are typically carried out by a contract laboratory on behalf of an FBO but may also be conducted in collaboration with appropriate industry organisations. There are two main types of challenge studies:**

- **Growth potential (Δ) assessment**
- **Maximum specific growth rate (μmax) assessment.**

**(18-bis) Growth potential assessments should be used to determine whether the product is an RTE food in which growth of *L. monocytogenes* can occur or in which growth of *L. monocytogenes* will not occur. These assessments are critical for evaluating the adequacy of control measures for preventing the growth of *L. monocytogenes*.**

**(18 bis bis) Before initiating a challenge study, it is important that all the relevant information about the RTE food and its processing be provided to the laboratory, as the study design should accurately reflect the food's characteristics. A few key aspects to consider are:**

- **Product characteristics (e.g., pH, water activity, or inhibitory compounds);**
- **Specifications for background microbial populations;**
- **Times and temperatures at various processing steps; and**
- **Intra- and inter-batch variability for any factors that may influence the growth of *L. monocytogenes*.**

**(18 bis bis bis)** Competent authorities **may** ~~should~~ provide guidance on the specific protocols that FBOs should use to conduct studies to demonstrate that growth of *L. monocytogenes* will not occur in an RTE food.

[28] It should be noted that some food packaging (e.g. that allow for moisture exchange) may not allow these ~~attributes~~ **characteristics** to be maintained throughout the shelf-life under reasonably foreseeable conditions of distribution, storage and use.

19. Challenge studies to determine if growth of *L. monocytogenes* will not occur in an RTE food[29,30] should be appropriately designed considering the reasonably foreseeable conditions of the food's distribution, storage and use. For example:

- **Temperature**. Many refrigerated RTE foods may not be consistently held under adequate refrigerated temperatures during distribution, at retail, and/or in the home refrigerator. Therefore, such studies should be designed to evaluate the growth of *L. monocytogenes* in the food under observed (i.e. actual) temperature conditions experienced in distribution, storage and use or, in the absence of such information, under likely conditions (i.e. assuming moderate temperature abuse[31]).
- **Time**. Studies to determine if *L. monocytogenes* will not grow in an RTE food should be conducted for at least the intended shelf-life of the food (as labeled by the FBO) and potentially longer for an additional margin of safety. For example, some consumers will continue to eat certain RTE foods beyond the labeled shelf-life (i.e. the expected shelf-life). Studies to determine if *L. monocytogenes* will not grow in these RTE foods can be conducted for an additional duration of time beyond the labeled shelf-life as a safety margin to account for such consumption. The length of time used as an additional safety margin can take into account factors such as the likelihood for the food to spoil past the labeled shelf-life, or other information that may impact the likelihood for a consumer to consume the food past its labeled shelf-life.

20. When evaluating challenge study results, FBOs and competent authorities should take into account the increase in *L. monocytogenes* over the duration of the study as well as the measurement variability (standard deviation) of the quantification method, before concluding that *L. monocytogenes* will not grow in an RTE food.

21. An RTE food in which growth of *L. monocytogenes* will not occur should have an observable increase in *L. monocytogenes* levels less than or equal to (on average) 0.5 log CFU/g[32] for the expected shelf-life of the food under reasonably foreseeable conditions of distribution, storage and use.

[29] *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008)

[30] See as an example: ISO 20976-1 *Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products Part 1: Challenge tests to study growth potential, lag time and maximum growth rate*.

[31] Some studies and literature suggest 7°C to represent moderate temperature abuse. However, available data on reasonably foreseeable conditions of distribution, storage and use may suggest other temperatures to be appropriate for certain regions or points along the supply chain, including storage and use by the consumer.

[32] 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 RTE FOODS**

**22.** Microbiological criteria for *L. monocytogenes* in RTE foods are described ~~below (see~~ **in** Table 1~~)~~. The purpose of these criteria is to provide a specified degree of confidence that *L. monocytogenes* will not be present in RTE foods at levels that represent the greatest risk to consumers.

**Table 1: Microbiological criteria[a] for *L. monocytogenes* in RTE foods from the end of manufacture or port of entry (for imported products) to the point of sale**

| Type of Food | Microorganism | n | c | m | Type of Class |
|---|---|---|---|---|---|
| RTE foods in which growth of *L. monocytogenes* can occur | *Listeria monocytogenes* | 5 | 0 | Not detected in 25 g (< 0.04 CFU/g)[b] | 2[c] |
| RTE foods in which growth of *L. monocytogenes* will not occur | *Listeria monocytogenes* | 5 | 0 | 100 CFU/g[d] | 2[e] |

[a] Where n = the sample size, i.e. the number of sample units to be tested from a lot; c = the maximum number of unacceptable analytical units that can be tolerated without rejecting the lot; m = the microbiological limit that differentiates acceptable (≤m) from unacceptable (>m) microbial concentrations.

[b] 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 series).

[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 a standard deviation of 0.25 log CFU/g would be detected and rejected if any of the five sample units are positive for *L. monocytogenes*. Such a lot may consist of 55% of the 25 g 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.

[d] 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 series).

[e] 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 a standard deviation of 0.25 log CFU/g would be detected and rejected based on any of the five sample units 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.

23. The criteria in Table 1 assume appropriate application of the general principles described in these guidelines, including the recommendations for an EMP in primary production and processing areas (Annex I) and the 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 programmes for the control of *L. monocytogenes* (Annex II). Further, these criteria assume that the ability for *L. monocytogenes* to not grow in the RTE food has been determined in accordance with Section 3 of this Annex.

24. Competent authorities should provide guidance on how samples should be collected and handled, and the degree to which compositing of sample units can be employed. Sample units should not be composited when conducting enumeration assays (i.e. quantitative methods).

25. The typical actions to be taken where there is a failure to meet the criteria in Table 1 would be to (1) prevent the affected food from being released for human consumption, (2) recall the food if it has been released for human consumption, and (3) investigate and correct the root cause (or likely root cause) of the

failure, including the cleaning and disinfection of food contact surfaces used in the processing of the affected food[33].

26. Additionally, a review of the food safety system should be considered if *L. monocytogenes* is detected at less than 100 CFU/g in a RTE food in which growth of the pathogen will not occur, despite the food meeting the criteria in Table 1. This is particularly relevant if such detections occur repeatedly within short time intervals.

27. Another procedure for establishing microbiological criteria for *L. monocytogenes* other than the criteria at specified points in the food chain that are described in Table 1, 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 (MRM)* (CXG 63-2007).

**5. ALTERNATIVE APPROACH**

28. Further to the approaches described in section 4, competent authorities may choose to establish and implement other validated microbiological criteria for *L. monocytogenes* in certain RTE foods at the point of consumption (or at other points) that provide an acceptable level of consumer protection. Any microbiological criteria established further to those described in Table 1 should assume appropriate application of these guidelines, including the recommendations for an EMP in primary production and processing areas (Annex I) and the 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 programmes for the control of *L. monocytogenes* (Annex II). Such approaches should also be aligned with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

29. Due to the large number of different RTE foods in which growth of *L. monocytogenes* can occur, this alternative approach could be applied for specific categories or subcategories of RTE foods that have a limited potential of growth during the expected shelf-life (see Section 3.1.1 for a discussion of shelf-life and the duration of challenge studies used to demonstrate the limited growth potential of *L. monocytogenes* in RTE foods).

30. In establishing such limited potential for growth of *L. monocytogenes* during the expected shelf-life, the competent authority should clearly articulate the types of information required of FBOs in supporting that the hazard is controlled and to verify that such limited potential for growth is achieved in practice. Information needed by competent authorities should be obtained through validation studies and other sources, and may include:

- specification for physicochemical characteristics of the foods, such as:
  - pH,
  - $a_w$,
  - salt content, and
  - concentration of inhibitory compounds;
- the type of packaging system which may affect the oxygen content and relative humidity in the package;
- the possibilities for contamination, considering the processing conditions;
- the expected shelf-life under reasonably foreseeable conditions of distribution, storage and use; and
- consultations of available scientific literature and research data regarding the growth and survival characteristics of *L. monocytogenes*.

31. When appropriate, validation studies should be conducted based on the above-mentioned information. These studies should consider seasonal and regional variations and may include:

[33] The discussion of root cause investigation following a positive environmental sample (see Annex I) is also relevant to the actions appropriate in response to a RTE food failing to meet the criteria in Table 1.

- predictive mathematical modelling established for the food in question, using critical growth or survival factors for *L. monocytogenes* in the product;
- challenge tests, to evaluate the growth of *L. monocytogenes* artificially inoculated into the food during the expected shelf-life under reasonably foreseeable conditions of distribution, storage and use; and
- durability studies, to evaluate the growth of naturally occurring *L. monocytogenes* contamination in food, during the expected shelf-life under reasonably foreseeable conditions of distribution, storage and use. **Durability studies alone are not the most recommended validation approach when natural contaminations are rare.**

**31 bis. Once the shelf-life of an RTE food has been established and validated, it is essential to carry out verification activities to support this determination. These activities confirm that, under the reasonably foreseeable conditions of distribution, storage, and use, the presence and growth of *L. monocytogenes* remain within the established safety limits throughout the shelf-life. Verification activities may include analysis of representative batches throughout the shelf-life, for example durability studies on naturally occurring *L. monocytogenes* contamination in food.**

***es* can occur or in which growth of *L. monocytogenes* will not occur. These assessments are critical for evaluating the adequacy of control measures for preventing the growth of *L. monocytogenes*.**