Policy on *Listeria monocytogenes* in Ready-to-Eat Foods

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Food Directorate
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Identification Number: FD-FSNP 0071
Issue Date: April 1, 2011.
Effective Date: April 1, 2011.

Canada

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1 Summary

The Canadian "Policy on *Listeria monocytogenes* in ready-to-eat foods" (hereafter referred to as the *Listeria* policy) is based on Good Manufacturing Practices[1] (GMPs) and the principles of HACCP (Hazard Analysis Critical Control Point; see Appendix A). This policy was developed using a health risk assessment (HRA) approach and uses as its foundation a combination of inspection, environmental sampling[2] and end-product testing to verify control of *Listeria monocytogenes* in ready-to-eat (RTE) foods (RTE food is defined in Appendix A). Focus is given to environmental verification and control, especially in post-lethality areas, as applicable. This policy applies to RTE food sold in Canada, produced both domestically and imported. The present policy revises and replaces the Policy on *Listeria monocytogenes* in ready-to-eat foods dated October 4, 2004.

The current policy differs from the 2004 document in the following:

1) New end-product compliance criteria have been developed. These are similar to the International Codex Alimentarius Commission standards (CAC, 2009a).
2) The definitions of RTE foods in which growth of *L. monocytogenes* can or cannot occur have been modified and/or developed. Validation data to support the categorization of RTE foods (i.e., Category 2A or 2B) are to be reviewed by regulatory authorities. The list of food products implicated in listeriosis outbreaks has been updated.
3) The compliance action decision tree, including environmental testing for *Listeria* spp.[3] and end-product testing for *L. monocytogenes*, has been modified to include more details related to sampling.
4) It now states that an environmental monitoring program should be included in all plants used in the production of RTE foods, as defined in this policy.
5) It encourages the use of post-lethality treatments and/or *L. monocytogenes* growth inhibitors.
6) There is an increased focus on outreach with the federal/provincial/territorial community to increase awareness of the risks of foodborne listeriosis and to provide guidance on how to reduce the risks of acquiring listeriosis to personnel in institutions where high-risk people may be exposed.

In this policy, RTE foods have been classified into two categories, based upon health risk. **Category 1** contains products in which the growth of *L. monocytogenes* can occur (see Appendix A). These should receive the highest priority for industry verification and control, as well as regulatory oversight and compliance activities. The presence of *L. monocytogenes* in these Category 1 RTE foods will likely trigger a Health Risk 1 concern (Health Risk Categories are

[1] The term GMPs in the text is used as a generic term and includes all key conditions and control measures necessary for processors to ensure the safety and the suitability of food during manufacturing.

[2] For the purposes of this document, this includes both food contact and non-food contact surfaces.

[3] For the purposes of this document, this includes *L. monocytogenes*.

defined in Appendix A). **Category 2** contains two subgroups: 2A) RTE food products in which limited growth of *L. monocytogenes* to levels not greater than 100 CFU/g can occur throughout the stated shelf-life (e.g., durable life date shown as a "best before" date on the package); and 2B) RTE food products in which the growth of *L. monocytogenes* cannot occur throughout the expected shelf-life of that food (see Appendix A). These products should receive a lower priority with regards to industry verification and control, as well as regulatory oversight and compliance activities.

This revised policy should lead to an enhancement of the verification and control of *Listeria* spp. in the food processing environment, permit earlier identification of any potential persistent contamination of the plant environment and provide an increased ability to identify and mitigate against *L. monocytogenes* contamination of finished product. These actions will provide an early warning and permit the appropriate interventions to protect consumers.

2 Purpose and Scope

The goal of this policy is to protect the health of Canadian consumers and to provide guidance to industry and regulatory authorities regarding the verification and control of *L. monocytogenes* in RTE foods. It also provides guidance to regulatory authorities regarding oversight and compliance activities of RTE foods contaminated with *L. monocytogenes*. Consistent with the current knowledge that the risk of listeriosis is increased in RTE foods which support the growth of *L. monocytogenes* and which have extended shelf-lives, higher priority is placed on RTE foods in which the growth of *L. monocytogenes* can occur. In addition to providing guidance to other food safety regulators (e.g., the Canadian Food Inspection Agency (CFIA) and provincial/territorial governments) and decision-makers, this policy can also guide RTE food processors in their verification activities with respect to the presence of *L. monocytogenes* in both the plant environment and the finished product. In addition to what is outlined in this policy document, additional regulatory requirements specific for particular food commodities may also be applicable (e.g., the CFIA's Meat Hygiene Directives (CFIA, 2010)). Note that the information contained in this policy is based on the current state of scientific evidence and that developments are on-going.

3 Roles and Responsibilities

This policy, developed as a joint effort between Health Canada, the CFIA, and the Public Health Agency of Canada (PHAC), takes into account the roles and responsibilities of industry, government and consumers.

3.1 Industry

It is industry's role and responsibility to comply with all applicable legislative and regulatory requirements which include Sections 4 and 7 of the *Food and Drug Act* (Government of Canada, 2011a). As *L. monocytogenes* can be found in the environment of food processing plants, RTE

food processors should have an effective GMP and/or HACCP system to minimize all potential sources of food contamination. These should address *L. monocytogenes* in the environment of processing establishments. In this regard, the importance of sanitation should not be overlooked. Sanitation management can lead to intervention innovations (e.g., effective remediation) and sanitary design improvements (e.g., equipment and facility). RTE food processors should also strongly consider introducing within their food safety systems one or more validated controls for the elimination of *L. monocytogenes* from their products (e.g., use of a post-lethality treatment). Furthermore, environmental and end-product sampling schemes and the use of microbiological testing as a verification tool to demonstrate the efficacy of the control measures put in place to address *L. monocytogenes* are recommended. Food processing plants should carry out regular environmental sampling, as described in Figures 1, 2 and 3, to verify the effectiveness of their sanitation program for controlling *Listeria* spp. in the plant environment, and should increase sanitation efforts and control measures in areas where *Listeria* spp. are found.

3.2 Government

Health Canada develops food safety standards and policies to help minimize the risk of foodborne illnesses. Health Canada consults with the CFIA and provincial/territorial governments on the above. Furthermore, Health Canada's policies can serve as a basis for the development of their own internal documentation. It is the role of the CFIA and provincial/territorial governments to oversee the food industry to ensure that it meets its food safety responsibilities (Health Canada, 2010a). The role of the PHAC is to promote and protect the health of Canadians through leadership, partnership, innovation and action in public health (PHAC, 2007). The PHAC, the CFIA and Health Canada work together with public health officials and provincial/territorial ministries of health to investigate the source of any *L. monocytogenes* related illnesses when an outbreak is suspected. PHAC has already begun to play a more active role in food surveillance across the country, e.g., C-EnterNet, a multi-partner program designed to detect changes in trends in human enteric disease and in levels of pathogen exposure from food, animal and water sources in Canada (PHAC, 2009a). In addition, the three federal departments provide reference laboratory services, conduct food safety investigations, HRAs and recall actions.

It is also the role of the government of Canada to brief the medical community, public health officials, the food industry and consumers on many issues related to *L. monocytogenes* and listeriosis.

3.3 Consumers

In addition to government agencies and food industries working diligently to minimize the exposure to *L. monocytogenes*, consumers also have an important role to play. That role calls for Canadians to learn and adopt safe food handling, responsible food selection and safe preparation practices (Health Canada, 2010a, Health Canada 2010b, Health Canada 2010c, Health Canada, 2010d). Caterers and care providers for the elderly and other vulnerable populations have a

higher level of responsibility in this regard. To this end, Health Canada, the CFIA and the PHAC (and other provincial/territorial bodies) have in the past, and will continue in the future, to be committed to the development and delivery of science-based educational material to inform consumers and care providers about the hazards associated with *L. monocytogenes* in RTE food and how to minimize the risks of foodborne disease, with a particular focus on vulnerable populations and their families, as well as their care providers.

4 Background

L. monocytogenes is a bacterial pathogen that is widely distributed in nature. It has been isolated from faecal specimens of healthy animals and humans, as well as from sewage, silage, soil, fertilizer, vegetable matter and many foods (Farber and Peterkin, 1991; Farber and Peterkin, 2000; McLauchlin *et al.*, 2004). Important characteristics of this organism include its ability to grow at temperatures of -0.4 to 45 °C, pH values of 4.4 or greater and water activities (a_w) of 0.92 or higher (ICMSF, 1996).

It is estimated that up to 5 % of humans may carry *L. monocytogenes* in their intestines without ill effects. This organism, however, is recognized as the causative agent of the infection known as listeriosis. Listeriosis can manifest itself in two different forms, namely invasive and non-invasive. Invasive listeriosis usually develops in people with compromised immune systems while non-invasive listeriosis can develop in any population if large numbers of bacteria (e.g., > 10^3 CFU/g) are consumed. Several modes of transmission have been identified: mother-to-foetus infection *in utero* or infection during childbirth, infant-to-infant, animal-to-human and, most importantly, transmission to humans through consumption of contaminated food (McLauchlin, 1993; McLauchlin *et al.*, 2004).

Serious infections of *L. monocytogenes* (i.e., invasive listeriosis) are manifested by septicaemia and/or meningoencephalitis, and may result in death. The highest incidence of listeriosis is amongst pregnant women, the elderly (> 60 years of age) and immunocompromised individuals. Among the elderly, the risk increases as individuals age, i.e., as compared to healthy individuals 40 to 59 years of age, Canadian data show that persons aged 65 to 69 years of age have a 4-times increased risk, while those aged 75 to 79 years of age have nearly a 9-times increased risk (PHAC, 2009b). Infection of healthy adults is relatively rare. Symptoms are typically mild in pregnant women, however, the passage of the organism through the placenta may cause miscarriage, stillbirth, or perinatal septicaemia and meningitis in the newborn baby. *L. monocytogenes* is more likely to cause death than other bacteria that cause foodborne illness, i.e., 20-30 % of foodborne listeriosis infections in high-risk individuals may be fatal (Health Canada, 2010a). In addition, the potential health outcomes from listeriosis could be serious and/or long-lasting (Roberts *et al*., 2009).

A number of foodborne outbreaks have been documented throughout the world (see Appendix B). Listeriosis outbreaks have been attributed to RTE food products such as pâté, unacidified jellied pork tongue (i.e., in aspic), rillettes, frankfurters, certain deli-meats, chicken wraps, cheese made from either raw or pasteurized milk, pasteurized milk (including chocolate milk),

butter, frozen ice cream cake, whipping cream, coleslaw, fruit salad, RTE fish products such as smoked mussels, gravlax (aka. gravad) and cold-smoked trout, imitation crab meat, shrimp, prepackaged sandwiches, as well as rice and corn salads.

In Canada, the national reported rate of listeriosis has increased over the last several years from 2.3 cases per million population in 2000 to 4.2 cases per million population in 2007, i.e., 2.3, 2.9, 2.9, 3.4, 3.0, 3.3, 3.9 and 4.2, respectively (PHAC, 2009c; Clark *et al.*, 2009). A sharp increase in incidence was noted in 2008, with 7.2 cases per million population reported (PHAC, 2009b). This was largely attributable to two large outbreaks involving 57 and 40 confirmed cases, respectively (PHAC, 2009d; PHAC, 2010, Gaulin and Ramsay 2010). France, the United Kingdom and several other European countries have also reported increases in the incidence of listeriosis over the last several years. In these countries, the increase has been predominantly driven by an increased incidence in patients > 60 years of age. The reasons for this increase are unknown (Gillespie *et al.*, 2006; Goulet *et al.*, 2008; ACMSF, 2009).

5 Scientific Basis for *Listeria monocytogene*s Criteria in Ready-to-Eat Foods

The foods implicated in major outbreaks of listeriosis worldwide are typically those in which *L. monocytogenes* is present at or can grow to levels that could present a risk to consumers (see Appendix B). In general, the risk of acquiring foodborne listeriosis increases depending on factors such as host susceptibility, the amount and frequency of consumption of a food contaminated with *L. monocytogenes*, the frequency, distribution and level of *L. monocytogenes* in the food, the potential for growth of *L. monocytogenes* in the food during refrigerated storage, the refrigerated storage temperature and/or the duration of refrigerated storage before consumption (FAO/WHO, 2004a). Therefore, the policy considers the levels of *L. monocytogenes* in a food and the potential for growth of *L. monocytogenes* in a particular food. This is based on factors such as pH, water activity, the presence of preservatives[4] (see Appendix C) and storage conditions, e.g., temperature and shelf-life.

In all likelihood, Canadians consume foods contaminated with *L. monocytogenes* on a regular basis; however, the incidence of listeriosis remains relatively low. The incidence of *L. monocytogenes* in RTE foods ranges from 0 to 10 % (Farber and Peterkin, 2000; Gombas *et al.*, 2003; Ryser and Marth, 2007; Little *et al.*, 2009). A large US study found that the prevalence of *L. monocytogenes* in RTE products such as smoked seafood, luncheon meats, salads (seafood, bagged precut leafy vegetable and deli) and cheeses (fresh soft, blue-veined, and mold-ripened) ranged from 0.17 to 4.7 % (Gombas *et al.*, 2003). In addition, a recent UK study found that the prevalence of *L. monocytogenes* in RTE products such as RTE sliced meats, hard cheeses, sandwiches, butter, spreadable cheese, confectionery products containing ice cream and probiotic drinks ranged from 0 to 7. 0 % (Little *et al.,* 2009).

[4] A preservative acts to prolong the shelf-life of foods by protecting against deterioration caused by microorganisms or oxidation. A Class II preservative is considered to be an antibacterial agent (Health Canada, 2007).

A definitive dose-response model for *L. monocytogenes* in humans has yet to be established. However, based on current case data from around the world, the likelihood of any one food contaminated with low numbers of *L. monocytogenes* resulting in illness is considered to be remote (FAO/WHO, 2004b). Foods containing low levels of *L. monocytogenes* (e.g., < 100 CFU/g) pose very little risk (Chen *et al.*, 2003; FAO/WHO, 2004b). In fact, in instances where foods linked to listeriosis outbreaks were still available for testing, the levels of *L. monocytogenes* detected both from unopened foods and leftover foods obtained from the patients have usually been high (i.e., $>10^3$ CFU/g), and thus these outbreaks were due to non-compliant samples (European Commission Health and Consumer Protection Directorate-General, 1999). Consequently, a lower priority should be placed on products in which the organism cannot grow or, has a limited potential for growth whereby the levels do not exceed 100 CFU/g throughout the stated shelf-life (e.g., durable life date shown as a "best before" date on the package) (see Table 1).

At the international level, the Codex Alimentarius Commission and the Commission of European Communities have proposed similar microbiological criteria for the verification and control of *L. monocytogenes* in RTE foods, with a view towards protecting the health of consumers while ensuring fair practices in food trade (European Communities, 2007; CAC, 2009a). The U.S. risk assessment, which included a risk categorization of foods (FDA/FSIS, 2003), further supports the fact that RTE foods differ in their ability to support growth and being linked to listeriosis.

6 Compliance Criteria for the Control of *Listeria monocytogenes* in Ready-to-Eat Foods

6.1 Assignment of Risk Classification of Ready-to-Eat Foods According to Consumer Risk (Categories 1 and 2: see Table 1 and Appendix A)

Category 1 RTE foods:

Category 1 RTE foods are those foods which can support the growth of *L. monocytogenes*. As presented earlier, Category 1 RTE foods should receive the highest priority for industry verification and control, as well as regulatory oversight and compliance activities. The presence of *L. monocytogenes* in a Category 1 food when the specified sampling plan and analysis are applied, will be classified as a Health Risk 1, as determined in Table 1: "Sampling methodologies and compliance criteria for *L. monocytogenes* in RTE foods". A public alert and recall will likely be issued if the food has left the control of the processor (Health Risks 1 and 2 are defined in Appendix A). The implicated product may be considered to be in violation of sections 4 and 7 of the *Food and Drugs Act* (Government of Canada, 2011a). Different risk management actions may occur in cases where the food processor is able, as part of the safety evaluation, to present data which demonstrate that the growth of *L. monocytogenes* will not occur in the product, for example, the validated use of preservatives, etc.

Category 2 RTE foods:

Category 2 is subdivided into: 2A) RTE food products in which limited growth of *L. monocytogenes* to levels not greater than 100 CFU/g can occur throughout the stated shelf-life (e.g., durable life date shown as a "best before" date on the package); and 2B) RTE food products in which the growth of *L. monocytogenes* cannot occur throughout the expected shelf-life of that food.

Category 2A RTE foods:

This category is meant to include foods which are known to occasionally contain low levels of *L. monocytogenes* and do not have a kill step, and/or RTE refrigerated foods with a shelf-life of ≤ 5 days. The latter time period would not allow sufficient time, under reasonably foreseeable conditions of distribution, storage and use, for *L. monocytogenes* to grow to levels above 100 CFU/g throughout the stated shelf-life (e.g., durable life date shown as a "best before" date on the package). For these RTE refrigerated foods (i.e., with shelf-life of ≤ 5 days), no validation studies are needed. Other foods with a shelf-life greater than 5 days, e.g., refrigerated cold-smoked salmon, fresh-cut produce, although they are frequently consumed, have not been linked to large documented outbreaks of listeriosis. Notwithstanding that these foods can support the growth of *L. monocytogenes*, the growth is generally limited because of a number of factors such as short refrigerated shelf-life, a large background microflora containing anti-*Listeria* lactic acid and/or other microorganisms, etc. These Category 2A foods should receive a medium to low priority, with regards to the level of oversight and compliance activities. For these foods, processors should validate and verify their processes to ensure that the levels of *L. monocytogenes* are consistently equal to or less than 100 CFU/g throughout the stated shelf-life. In general, RTE food processors should regularly monitor their products, to ensure that they continue to meet the criteria (e.g., limited potential for growth of *L. monocytogenes* to levels not greater than 100 CFU/g throughout the stated shelf-life (e.g., durable life date shown as a "best before" date on the package)) that justify their classification in this category. If information is insufficient, inadequate or no information exists to demonstrate that there is limited growth of *L. monocytogenes* (as stated above) throughout the shelf-life, as determined by validated data, the food will be treated, by default, as a RTE food in which growth of *L. monocytogenes* can occur (i.e., Category 1). Hence, the sampling plan and method of analysis for Category 1 foods, as specified in Table 1, will be applied. If questions arise, it is the responsibility of the processor/importer to demonstrate what category the RTE food belongs to.

Category 2B RTE foods:

Since these foods do not support the growth of *L. monocytogenes*, they should receive a low priority, with regard to the level of oversight and compliance activity. In general, RTE food processors would need to monitor their products to ensure that they continue to meet the criteria (e.g., physico-chemical parameters such as pH and a_w) that justify their classification in this category. If information is insufficient, inadequate or no information exists to demonstrate that there is no growth of *L. monocytogenes* throughout the shelf-life, as determined by validated data, the food will be treated, by default, as a RTE food in which growth of *L. monocytogenes*

can occur (i.e., Category 1). Hence, the sampling plan and method of analysis for Category 1 foods, as specified in Table 1, will be applied. If questions arise, it is the responsibility of the processor/importer to demonstrate what category the RTE food belongs to.

Some frozen RTE foods, otherwise considered as Category 2B, may be temperature-abused, causing them to thaw and thereby could potentially permit the growth of *L. monocytogenes.* Additionally, some Category 2 products may be intended for use in Category 1 products (e.g., frozen smoked fish used to make a refrigerated smoked fish mousse) or, some RTE foods may be targeted for persons at high-risk, e.g., immunocompromised, elderly, pregnant, etc. A finding of *L. monocytogenes* in the above foods would lead to follow-up action(s) and hence, an HRA may be required on a case-by case basis, to be conducted by the Bureau of Microbial Hazards (BMH), Food Directorate, Health Products and Food Branch (HPFB), Health Canada, in order to determine the compliance action to be taken. These Category 2 foods may be assessed to represent a Health Risk 1 concern.

RTE foods intended to be produced for High-Risk Population Groups:

RTE foods that are intended to be produced for consumption by individuals who are known to be in the high-risk category (i.e., final distribution of such RTE products is known to be targeted specifically to pregnant women, elderly and/or immunocompromised individuals) should receive the highest priority for industry verification and control, as well as regulatory oversight and compliance activities. These RTE foods may be considered to represent a Health Risk 1 and not Health Risk 2 concern, irrespective of product type (see Table 1). In addition, specific control measures may need to be taken for these products (e.g., in the HACCP form).

6.2 Applying the Criteria to Domestic, Imported and Exported Ready-to-Eat Foods

6.2.1. Domestic facilities:

6.2.1.1. Environmental control:

The relative importance of verifying the controls for *Listeria* spp. in the processing environment depends on the risk to consumers if the food becomes contaminated. Inspectors of domestic establishments should encourage adherence to the principles of GMP and the HACCP system. If oversight reveals inadequate application of GMPs that could lead to post-lethality contamination of a RTE food, as applicable, a review of the processor's control program for *Listeria* spp. should be conducted with regulatory oversight. This review should take into account previous environmental and end-product testing results. If the review indicates that *Listeria* spp. are not being controlled, increased environmental sampling should be undertaken by the processor to determine whether *Listeria* spp. are present. If *Listeria* spp. are present, this should be taken as evidence for the need to improve control of *Listeria* spp. In addition, if food contact surface (FCS) samples are found positive at two (Category 1; see Figure 1) or more (Category 2A and 2B; see Figure 2) steps, end-product testing should be initiated to ensure that finished product is not contaminated with *L. monocytogenes*.

6.2.1.2. Product control:

Increased knowledge of the ecology of *L. monocytogenes* in RTE food products has clarified which products can or cannot support the growth of *L. monocytogenes*. This has permitted the classification of RTE foods for which specific compliance action may be needed. The nature of concern should be determined based on the information in Table 1. Sampling priority should be given to Category 1 RTE products. Although Category 2A and 2B products are of lesser concern than Category 1 RTE foods, sampling at times may still be warranted. RTE food processors, in consultation with the regulatory authority, should a) attempt to determine the source of the contamination (e.g., root cause analysis) using inspection, environmental sampling and end-product testing, and b) take the appropriate corrective actions. The actions taken need to reflect the findings of the investigation that is done when unsatisfactory results are obtained. They may include, without being limited to, the following: i) increasing and/or correcting sanitation procedures (including equipment disassembly beyond FCSs with intensified cleaning/sanitation and verification of the cleaning/sanitation process and intense cleaning/sanitation of surrounding area) and modification of equipment for improved cleanability; ii) observing GMPs during sanitation and operations to ensure compliance; iii) requiring minimum follow-up tests (Figures 1, 2 and 3); iv) obtaining additional data to confirm hypotheses when conducting root cause analysis; v) developing and implementing an enhanced sampling plan (for the affected line and possibly the product); and vi) if applicable, revisiting the HACCP system and adjusting it, if necessary. Corrective actions must be monitored to confirm their effectiveness. The whole process should be documented, as this information can be integrated into the establishment's trend analysis activities.

6.2.2. Imported RTE products:

Canadian food importers must import food products that are in compliance with relevant Canadian legislation and policies. The importer should be able to demonstrate that the food products are safe and meet these requirements. Information regarding the product(s) imported, including information about the supplier, processor or exporter is most useful, and should serve as background information to determine what verification activities are required. As well, the importer should ensure that safe food storage and handling procedures are in place at the importer's facility.

Inspection of imported RTE foods is intended to ensure an equivalent level of protection to consumers of both imported and domestic products. Canadian food regulatory agencies, however, may be unable to evaluate whether certain imported foods have been manufactured using effective GMPs and/or the HACCP system. Therefore, other verification measures such as end-product testing may be required to assess whether these products meet the criteria in Table 1. If insufficient, inadequate or no information exists regarding the 2A or 2B categorization of the imported RTE product (i.e., RTE food in which a limited potential for growth of *L. monocytogenes* to levels not greater than 100 CFU/g can occur or in which growth of *L. monocytogenes* cannot occur throughout its shelf-life, as determined by validated data), it will, by default, be considered as a RTE food in which growth of *L. monocytogenes* can occur (i.e.,

Category 1). Hence, the sampling plan and method of analysis for Category 1 foods, as specified in Table 1, will be applied. If questions arise, it is the responsibility of the importer to demonstrate what category the RTE food belongs to. Compliance action may be taken against lots that exceed the criteria.

Compliance action should be taken on a lot-by-lot basis and should not differ from that for domestic products. Importers should have a system in place to ensure that Canadian regulatory authorities will be able to differentiate individual lots based on clear product markings. If a shipment cannot be distinguished into individual lots, then the entire shipment would be considered as a single lot for oversight and compliance activities. The sampling plan should be adjusted accordingly.

6.2.3. Exported RTE products:

Canadian food exporters are responsible for exporting food products that meet the requirements of the receiving country, as well as the provisions of Section 37 of the *Food and Drug Act* (Government of Canada, 2011a).

7 Achieving Compliance with the Criteria for Ready-to-Eat Foods

7.1 Requirements for the Manufacture of Ready-to-Eat Food Products

The policy is based on a combination of manufacturing verification and control measures (by industry), oversight (by regulatory authorities), as well as environmental sampling and end-product testing that should be undertaken by both industry and regulatory authorities.

RTE food processors should implement adequate verifications and controls to ensure their products are in compliance with the criteria in Table 1. It should be assumed that some incoming raw ingredients may contain *L. monocytogenes.* Thus, when feasible, RTE food processors should apply procedures that are validated to eliminate or reduce *L. monocytogenes* in the raw materials in order to comply with the criteria for *L. monocytogenes* in RTE foods. The potential for recontamination with *L. monocytogenes* should also be controlled and is influenced by factors such as plant layout (including traffic control), infrastructure, equipment design and maintenance (e.g., equipment that require disassembly, such as slicing equipment), effectiveness of sanitation procedures and employee practices (CAC, 2007; Meat Industry *Listeria monocytogenes* Working Group, 2011).

The survival of *L. monocytogenes* can be managed through the HACCP system, which includes the use of validated critical control points (CCPs) and appropriate monitoring and verification procedures for each CCP. Procedures for validating pathogen reduction steps and strategies such as the use of additives to prevent growth have a long history of use for a variety of foodborne pathogens. The concern for recontamination is managed through the application of GMP procedures, including adequate sanitation practices, which require thorough and regular

adherence due to the prevalence of *L. monocytogenes* in the environment, ease of dispersal, and ability to grow in the RTE processing environment (Meat Industry *Listeria monocytogenes* Working group, 2011). Several documents are available for guidance (Tompkin *et al.*, 1999; NFI/NFPA, 2002; CAC, 2007; Meat Industry *Listeria monocytogenes* Working group, 2011). In addition, workshops sponsored by industry trade associations can be very effective for teaching current best practices for *Listeria* control within specific segments of industry.

Also helpful to food processors is direct on-site observation which is a valuable means to assess compliance with the GMPs that can influence the presence of *Listeria* spp. (CAC, 2007). It is not possible, however, to predict by direct on-site observation alone, the degree to which *Listeria* spp. may occur in areas where RTE foods are exposed before and during final packaging. Many existing food processing establishments were not originally designed for the control of pathogens with the unique characteristics of *L. monocytogenes*. However, each food processing establishment should be managed following best practices, recognizing that the verification and control of *Listeria* spp. is necessary for consumer protection. Modifications can often be made to control *Listeria* spp. in the environment and to reduce the risk of product contamination. An effective environmental monitoring program, supported by investigative sampling to detect sources of *Listeria* spp., should be used to identify the changes that will facilitate the control needed to ensure compliance with the criteria (Table 1). Experience indicates that environmental sampling is the most sensitive tool to assess control of the environment and risk of product contamination (Tompkin *et al.*, 1992; Tompkin, 2002).

7.2 Environmental Sampling (Figures 1, 2 and 3)

Steps for sampling FCSs and RTE foods (Figures 1 and 2) as well as non-FCSs (Figure 3) by processors and regulatory authorities are outlined in this section. Environmental sampling should be conducted according to MFLP-41 (Health Canada, 2010e). Testing should be conducted according to any method published in the Health Canada's Compendium of Analytical Methods for *Listeria* in which the "application" section is appropriate for the intended purpose (e.g., MFHPB-methods and MFLP-methods). The relative importance of verifying control of the processing environment should be reflective of the risk to consumers if the food becomes contaminated. Of highest concern are i) foods that do not contain validated inhibitors of the growth of *L. monocytogenes* (e.g., lactate, diacetate); ii) foods in which growth of *L. monocytogenes* to levels >100 CFU/g can occur during the shelf-life of the food; iii) foods which are not subjected to a listericidal treatment in the package before distribution and; iv) foods which are targeted to a high-risk population group. The same factors should be considered when establishing the frequency and extent of sampling of the environment. Particularly for foods in which *L. monocytogenes* can grow during the product's shelf-life, the monitoring and control programs should be sufficiently strong (e.g., regarding sampling selection, frequency of sampling, numbers of samples, method of sampling, etc.) to enable RTE food processors and regulatory authorities to conclude when reviewing the data that the foods being produced are not contaminated with *L. monocytogenes* (CAC, 2007; Meat Industry *Listeria monocytogenes* Working Group, 2011).

Each establishment's *Listeria* control program should be designed to reflect current knowledge and experience that *L. monocytogenes* can be reduced to a level in the environment that ensures product will not become contaminated. However, the possibility exists that *Listeria* will be re-introduced into areas in which RTE foods are exposed. These factors emphasize the need to maintain an environmental sampling program that is adequate to manage consumer risk in relation to the Category of RTE food being produced (Table 1). It is important to continually strive for negative results by responding to each positive sample with appropriate corrective actions in a timely manner.

Establishments processing RTE foods should design, implement and maintain an environmental sampling program for testing FCS and non-FCS for the presence of *Listeria* spp. It is recommended that *Listeria* spp. should be monitored in the environment as outlined in Figures 1, 2 and 3. Testing for *Listeria* spp. and reacting to positive results as if they were *L. monocytogenes* provides for a more sensitive and broader verification and control program, than would testing for *L. monocytogenes* alone (Meat Industry *Listeria monocytogenes* Working group, 2011). The purpose of the environmental sampling program is to assess the effectiveness of sanitation and other GMPs in RTE processing environments and the potential for product contamination. In addition, by detecting and responsibly responding to each positive result, consumer risk can be minimized. Environmental monitoring programs must include routine sampling of FCSs that come into contact with exposed RTE foods before final packaging. Sponge/swab samples from surface areas of equipment should be collected during production, typically after 3 hours of start up of operation. Guidance for environmental sampling can be found in the Health Canada's Compendium of Analytical methods, under MFLP-41 (Health Canada, 2010e). The number of sites (e.g., 1 – 10) will vary according to the complexity of the processing system or packaging line. The frequency and points of sampling for routine sampling should be plant and/or line specific, based on the manufacturing processes and the controls that are present (Tompkin *et al.*, 1992). An increase in sample sites (FCSs and non-FCSs) and frequency should be considered during and/or after special circumstances (e.g., construction, the installation of used or modified equipment, overhead/ceiling leaks in exposed product areas), which may provide an opportunity for control of *L. monocytogenes* to be lost.

In some situations, food in various stages of processing or product build-up can be used as additional samples to further assess the presence of *Listeria* along a processing line or system. Samples should also be collected from non-FCSs as an additional measure of verification. Recent publications (CAC, 2007; Meat Industry *Listeria monocytogenes* Working Group, 2011) can provide guidance on the establishment of an environmental sampling program.

Investigational sampling differs from the routine environmental program used to monitor control of *Listeria.* It involves collecting additional samples from sites to help identify more clearly the source(s) of contamination. Investigational sampling is a valuable tool for identifying and eliminating harbourage sites (Tompkin, 2002; CAC, 2007). The benefit of environmental sampling for products given a validated final in-package listericidal treatment is affected by the degree of inactivation delivered by the listericidal process, e.g., cook-in-bag roast beef.

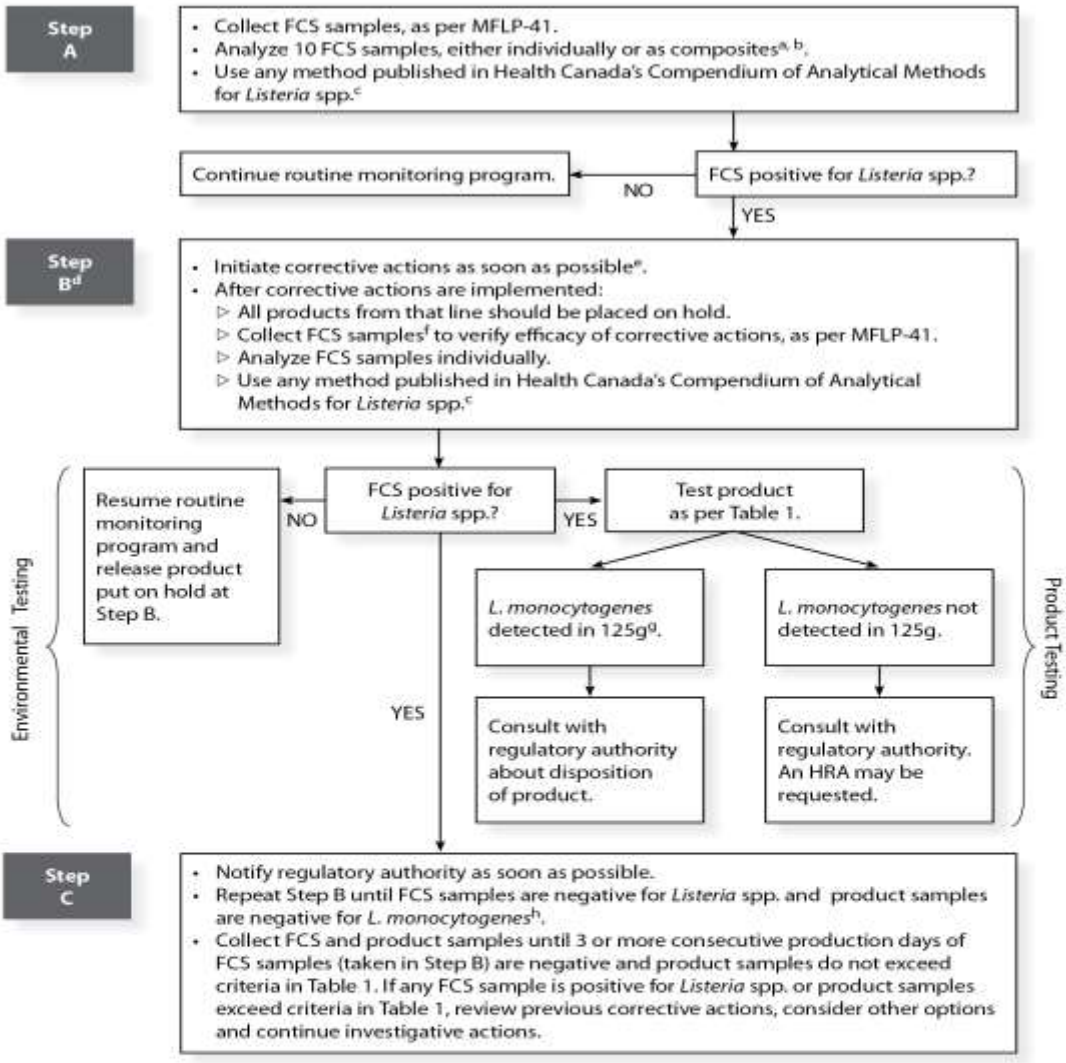
Tompkin *et al*., (1999) as well as D'Amico and Donnelly (2008) found that in general, non-FCS contamination with *Listeria* spp., including *L. monocytogenes*, usually precedes FCS contamination, thereby highlighting the importance of environmental verification and controls. Therefore, finding sources of contamination away from the production line and preventing cross-contamination, is encouraged as a fundamental principle of *Listeria* control. The guidance provided in Figures 1, 2 and 3 should be followed.

Depending on the application of the sampling program (i.e., the amount of testing being done, and the locations(s), number and frequency of positive findings), the presence of *L. monocytogenes* in a RTE food will (i.e., in Category 1 RTE foods) or would likely (i.e., in Category 2 RTE foods) indicate that the establishment's control program is not adequate to prevent product contamination. When reviewing data for trend analysis, contamination of non-FCSs with *Listeria* spp. in areas of the plant environment where RTE foods are exposed to post-lethality contamination, as applicable, could indicate that the control of *Listeria* is inadequate. It is the responsibility of processors of RTE food to react to all unsatisfactory environmental results in a timely manner and to ultimately achieve *Listeria*-negative results. A finding of *Listeria* spp. in the RTE processing environment should trigger follow-up actions, e.g., corrective actions which include intensified cleaning and sanitizing, timely re-testing of the contaminated area, testing of end-products that were potentially in contact with the positive FCS, in-depth review of the plant's food safety system, etc., as appropriate.

If two or more samples from the same production line (i.e., using the same equipment) are found positive within a short timeframe, this is considered to be evidence of persistent contamination and an indication that the *Listeria* control program could be inadequate. Persistent contamination of FCS with any *Listeria* spp. in the RTE plant environment could be an indication of inadequate GMPs and sanitation practices. Appropriate follow-up actions are necessary when unsatisfactory results are obtained, taking into account the type and/or location of the sampling sites, and the category of food (see Figures 1, 2 and 3).

All positive results for *L. monocytogenes* in a RTE food or persistent *Listeria* spp. on a FCS, should be communicated as soon as possible to the regulatory authority having jurisdiction, as per Figures 1 and 2.

Figure 1: Sampling Guidelines for FCS and Category 1 Ready-to-Eat Foods



a. The number of meaningful sampling sites (preferably 10) selected on each processing line should depend upon the complexity of the line(s).

b. If compositing more than 10 FCS sites, a protocol should be developed and validated. The number of swabs and the enrichment protocol may vary according to the processing conditions.

c. In addition, the "application" section must be appropriate for the intended purpose (e.g., MFHPB and MFLP methods).

d. Events that proceed beyond Step A should be recorded and maintained in a file that is separate from the routine monitoring program data. The records should include information on corrective actions, investigational sampling, product testing and disposition of product.

e. Investigative sampling can assist in finding and correcting the source of contamination, particularly if a harbourage site exists within equipment which leads to isolation of a *Listeria* spp. or a specific subtype of *L. monocytogenes* (CAC, 2007).

f. At a minimum, the FCS sites in the routine monitoring program should be included. The number and location of samples should be adequate to verify that the entire line is negative and under control.

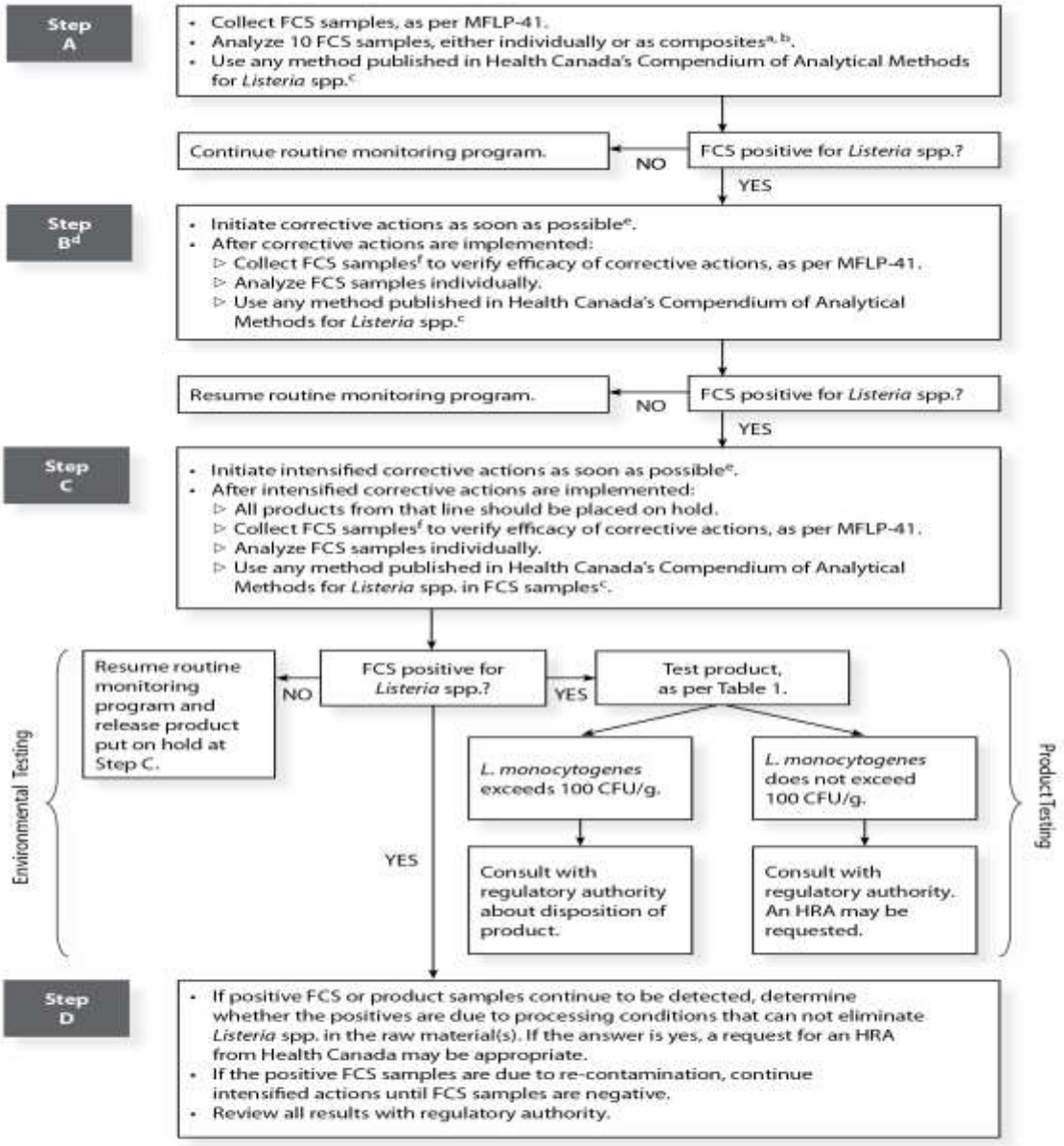
g. It is recommended that subsequent lots be held. If *L. monocytogenes* is detected on product at Step B, all subsequent lots of product should be tested.

h. After corrective actions have been implemented at Step C, it is recommended that each lot of product should be held and tested until the results demonstrate that control has been achieved.

Note 1: This policy states the minimum requirements that should be adhered to. The operator or regulatory authority can exceed these minimum requirements.

Note 2: End-product testing for *L. monocytogenes* should be performed if any *L. monocytogenes* is found on a FCS(s).

Figure 2: Sampling guidelines for FCS and Category 2 Ready-to-Eat Foods



a. The number of meaningful sampling sites (preferably 10) selected on each processing line should depend upon the complexity of the line(s).

b. If compositing more than 10 FCS sites, a protocol should be developed and validated. The number of swabs and the enrichment protocol may vary according to the processing conditions.

c. In addition, the "application" section must be appropriate for the intended purpose (e.g., MFHPB and MFLP methods).

d. Events that proceed beyond Step A should be recorded and maintained in a file that is separate from the routine monitoring program. The records should include information on corrective actions, investigational sampling, product testing and disposition of product.

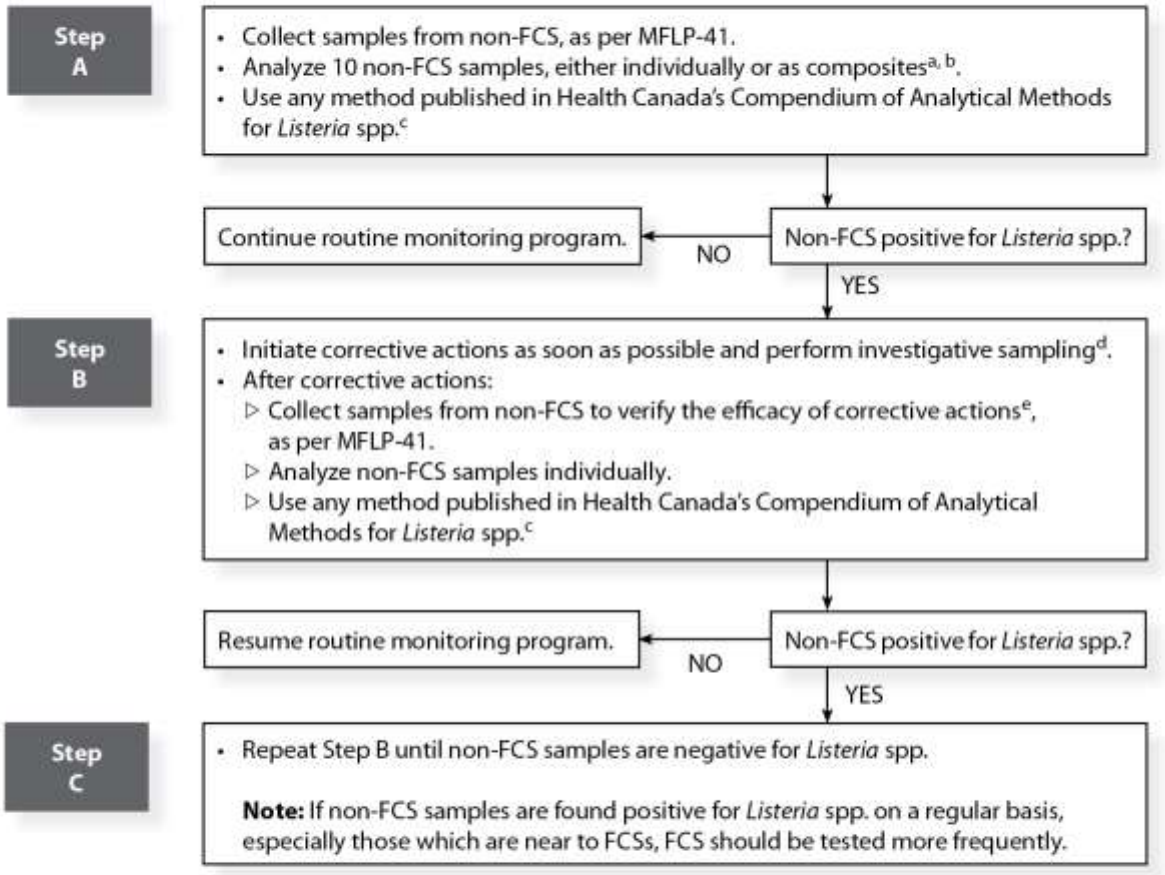
e. Investigative sampling can assist in finding and correcting the source of contamination, particularly if a harbourage site exists within equipment which leads to isolation of *Listeria* spp. or a specific subtype of *L. monocytogenes* (CAC, 2007).

f. At a minimum, the FCS sites in the routine monitoring program should be included. The number and location of samples should be adequate to verify that the entire line is negative and under control.

Note 1: This policy states the minimum requirements that should be adhered to. The operator or regulatory authority can exceed these minimum requirements.

Note 2: End-product testing for *L. monocytogenes* should be performed if any *L. monocytogenes* is found on a FCS(s).

Figure 3: Sampling Guidelines for non-FCS, especially those in proximity to FCSs, linked to RTE foods in Category 1 and 2



a. The number of meaningful sampling sites (preferably 10) selected in the plant should depend upon the complexity of the plant.
b. If compositing more than 10 non-FCS sites, a protocol should be developed and validated. The number of swabs and the enrichment protocol may vary according to the processing conditions.
c. In addition, the "application" section must be appropriate for the intended purpose (e.g., MFHPB and MFLP methods).
d. Investigative sampling will assist in finding and correcting the source of contamination. For instance, current sanitation activities may be ineffective, in which case a harbourage site may be present. This may be inferred from the isolation of a specific subtype of *L. monocytogenes* (CAC, 2007).
e. It should be noted that it is not necessarily only the same sample sites that should be tested after corrective actions. Upon re-sampling, the original or nearby sites might be negative but sampling other sites might reveal a positive, and hence be more informative in resolving the problem.

7.3 Sampling and Analysis of Finished Ready-to-Eat Foods

For most RTE products, control (i.e., by adequate sanitation and GMPs) and verification of the environment (i.e., by an appropriate environmental sampling plan) is the most desirable approach to verification and control of *L. monocytogenes.* Therefore, a better decision can be made regarding releasing end-products, rather than relying on testing individual lots. In fact, microbiological testing of food is an imprecise science and may not portray the true microbiological condition of the food. Consequently, for many foods, the relative importance of end-product testing is less than that for environmental testing. However, end-product testing is conducted for various reasons, such as customer requirements, evaluation of product contamination when FCS tests positive for *Listeria* spp. (as stipulated in Figures 1 and 2), periodic testing to determine control of process/GMPs, foreign country requirements, regulatory testing, verification of the effectiveness of the antibacterial treatments, incoming product testing, testing of marketed products as part of an investigation and trend analysis, etc. When testing end-products, RTE food processors should develop:

a) written procedures for end-product testing with details on any hold and test procedures
b) sampling procedures
c) sampling frequency and size
d) methodology and
e) proposed follow-up actions.

It is recommended that all implicated end-products be held pending results from routine testing, as per Table 1 "Sampling methodologies and compliance criteria for *L. monocytogenes* in ready-to-eat (RTE) foods". End-product testing for *L. monocytogenes* should be performed if any *L. monocytogenes* is found on a FCS(s).

Samples of all finished RTE food products submitted for the analysis of *L. monocytogenes* will consist of 5 sample units of at least 100 g each (Table 1), which are representative of the lot and the production conditions, taken at random from each lot. Sampling of imports, particularly of large shipments, should be applied to identifiable lots of the product. Where the importer is unable to provide information on the identity of different lots, then the entire shipment (e.g., per product type) would be treated as a single lot.

Category 1 RTE foods:

Analysis of Category 1 RTE foods for the presence of *L. monocytogenes* should be conducted using any method published in the Health Canada's Compendium of Analytical Methods for *L. monocytogenes* in which the "application" section is appropriate for the intended purpose (e.g., MFHPB methods and MFLP methods). An analytical sample size of 5 X 25g for this specific category of RTE product should be used for routine end-product testing. The detection of *L. monocytogenes* in a finished Category 1 RTE food requires follow-up as described in step C of Figure 1.

Category 2A and 2B RTE foods:

For the analysis of all Category 2 RTE foods, a quantitative analysis should be conducted according to Laboratory Procedure (MFLP) 74 (Pagotto *et al.,* 2011a), or any method published in the Health Canada's Compendium of Analytical Methods for *L. monocytogenes* in which the "application" section is appropriate for the intended purpose (e.g., MFHPB-methods and MFLP-methods). An analytical sample size of 5 X 10g for this specific category of RTE product should be used for routine end-product testing. This will determine the CFU/g of *L. monocytogenes* in the food. The detection of *L. monocytogenes* in a finished Category 2 RTE food requires follow-up as described in steps C and D of Figure 2. The frequent presence (i.e., occurring repeatedly at brief intervals) of *L. monocytogenes* at low levels (≤ 100 CFU/g) in a product could be an indication of inadequate application of GMPs, and/or a process that cannot ensure non-detectable levels of *L. monocytogenes*.

Follow-up actions:

The appropriate regulatory authority should be notified upon any positive end-product results, and follow-up actions should be implemented to ensure that the RTE food processor has the situation (i.e., including all implicated RTE end-products) under control. Corrective actions to be undertaken by the company and/or regulatory authorities, such as a review of the company's *Listeria* control strategy including GMPs, intensive cleaning and sanitation, as well as additional environmental and end-product testing, are all strongly recommended.

Table 1: Sampling Methodologies and Compliance Criteria for *L. monocytogenes* in Ready-to-Eat[a] Foods

Categories	Sampling	Analysis	Type of analysis	Action level for *L. monocytogenes*	Nature of concern	Level of priority for oversight[b]
1. RTE foods in which growth of *L. monocytogenes* **can** occur[c] throughout the stated shelf-life, e.g., durable life date shown as a "best before" date on the package (e.g.[d], deli-meats, soft cheeses, hot dogs, pâté).	5 sample units (min 100 g or ml each), which are representative of the lot and the production conditions, taken aseptically at random from each lot	5 x 25 g analytical units[e] are either analysed separately or composited	Enrichment only	**Detected in 125g** [f, g]	**Health Risk 1**[h]	High
2 A) RTE foods in which a **limited** potential for growth of *L. monocytogenes* to levels not greater than 100 CFU/g **can** occur[c] throughout the stated shelf-life (e.g., durable life date shown as a "best before" date on the package). A number of factors will be taken into consideration with regards to which foods may fall into this Category (see Section 6.1 – i.e., RTE foods which are known to occasionally contain low levels of *L. monocytogenes* and do not have a kill step (validation needed) and/or RTE refrigerated foods with a shelf-life of ≤ 5 days (validation not needed)). Such foods could include: refrigerated gravlax/cold-smoked rainbow trout and salmon, fresh-cut produce, etc. **2 B)** RTE foods in which growth of *L. monocytogenes* **cannot** occur[i] (i.e., < 0.5 log CFU/g increase (validation may be needed)) throughout the stated shelf-life, e.g., durable life date shown as a "best before" date on the package (e.g., ice cream, hard cheese, dry salami, dried-salted fish, varieties of prosciutto ham).	Same as above	5 x 10 g analytical units[e]	Direct plating only	**> 100 CFU/g** [J, k, l]	**Health Risk 2**[h, l]	Medium to low Low

a- For a definition of RTE foods, see Appendix A.

b- Other criteria (e.g., process, packaging, outbreak data) could also have an impact on the level of priority assigned to the RTE food products.

c- For a definition of RTE foods in which growth of *L. monocytogenes* can occur, see Appendix A.

d- These traditional examples of Category 1 foods may fall into Category 2A or 2B, if it can be demonstrated that they do not support the growth, or support limited growth of *L. monocytogenes* to levels not greater than 100 CFU/g, throughout the stated shelf-life respectively (e.g., durable life date shown as a "best before" date on the package).

e- The designated analytical unit is taken from each sample unit.

f- For example, MFHPB-30; presence or absence by enrichment only (Pagotto *et al.,* 2011b), or use any enrichment method for *L. monocytogenes* published in the Health Canada's Compendium of Analytical Methods in which the "application" section is appropriate for the intended purpose (e.g., MFHPB methods and MFLP methods).

g- Assuming a log-normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 0.023 CFU/g and an analytical standard deviation of 0.25 CFU/g would be detected and rejected if any of the five samples are positive for *L. monocytogenes* (CAC, 2009a).

h- For a definition of health risk categories, see Appendix A.

i- For a complete definition of "RTE foods in which growth of *L. monocytogenes* will not occur", see Appendix A

A RTE food in which growth of *L. monocytogenes* will NOT occur (CAC, 2009a) includes the following:

(a) pH < 4.4, regardless of a_w
(b) a_w < 0.92, regardless of pH
(c) combinations of factors (e.g., pH < 5.0 and a_w < 0.94)
(d) frozen foods

The pH and a_w should be determined for at least 3 out of 5 analytical units. The growth of *L. monocytogenes* is presumed to occur, if any one of the analytical units falls outside the range of pH and a_w values in which the growth of *L. monocytogenes* will not occur (as above).

j- For example, MFLP-74; enumeration done by direct plating onto selective agar (Pagotto *et al.,* 2011a), or use any enumeration method for *L. monocytogenes* published in the Health Canada's Compendium of Analytical Methods in which the "application" section is appropriate for the intended purpose (e.g., MFHPB methods and MFLP methods).

k- Assuming a log-normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 93.3 CFU/g and an analytical standard deviation of 0.25 log CFU/g would be detected and rejected based on any of the five samples exceeding 100 CFU/g *L. monocytogenes* (CAC, 2009a).

l- This becomes a Health 1 concern if the RTE food is intended to be produced for a high-risk population group such as the elderly, pregnant women or immunocompromised individuals (e.g., AIDS patients, transplant recipients, cancer patients, etc.), or if the product is intended for use in a Category 1 product. In addition, if counts ≤ 100 CFU/g are detected in RTE products intended to be produced for high-risk population groups such as those outlined above, an HRA may be requested, which may lead to a higher health risk concern.

Note: If insufficient, inadequate or no information exists regarding the 2A or 2B categorization of the RTE food product (i.e., domestic or imported RTE foods in which a limited potential for growth of *L. monocytogenes* to levels not greater than 100 CFU/g can occur or in which growth of *L. monocytogenes* cannot occur throughout its stated shelf-life, as determined by validated data), it will by default, be considered as a RTE food in which growth of *L. monocytogenes* can occur (i.e., Category 1). Hence, the sampling plan and method of analysis for Category 1 foods, as specified in Table 1, will be applied. If questions arise, it is the responsibility of the processor/importer to demonstrate which category the RTE food belongs to.

7.4 Importance of Trend Analysis and Quality Assurance Tools

An establishment cannot rely solely on end-product testing to verify and control *Listeria*. Its food safety management system should apply modern quality control and statistical methods to monitor its processes and detect time and/or spatial patterns (trends) suggestive of contamination sources that can be further investigated and mitigated. In addition, these trends (data) can be used comprehensively to model and predict risk and thus better target oversight and compliance activities. Where possible, quality control and statistical methods should include modern graphical techniques such as control charts, Pareto diagrams, etc., as well as appropriate descriptive and analytical statistical methods. All data and analysis results should be made available to those in the plant responsible for managing the *Listeria* control program. Responsibility for updating and disseminating the data should be assigned to one or more individuals within the establishment (e.g., quality assurance, food safety and/or HACCP coordinators). On-going review and analysis of the data for *Listeria* spp. from routine monitoring programs should be performed to detect trends before major issues develop. Such reviews also provide information on the prevalence of *Listeria* spp., their fluctuations over time and identify issues to be addressed in a timely manner. Attention should be given to the dates and locations of positive samples to determine if low level and/or sporadic positives occur at certain locations that may have gone unnoticed previously (CAC, 2007). Trend analysis should be used to achieve improved control over time as each establishment gains experience in controlling *Listeria* and makes appropriate adjustments.

8 Development of Educational Materials for Consumers and Others Involved in Food Handling and Preparation

The aim of developing educational materials is to educate, inform and increase awareness of food hazards associated with RTE foods for consumers in general, and more specifically for seniors and their caregivers, pregnant women, people with weakened immune systems and other potentially high-risk individuals about safe food handling practices, and what they can do to reduce the risk of acquiring foodborne listeriosis. While significant information already has been provided by various levels of government, collaboration between the federal and provincial/territorial and municipal governments, will ensure that consumers receive reliable and consistent information so that they can make better informed choices and/or learn how foods should be properly handled and prepared. To this end, Health Canada will seek the collaboration of the PHAC, the CFIA and the Provinces/Territories for future work in this area.

8.1 Contributions of Health Canada Scientists to Published Information Related to Foodborne Listeriosis

- Clark, C.G., Farber, J.M., Pagotto, F., Ciampa, N., Doré, K., Nadon, C., Bernard, K., Ng, L.-K. and the Canadian Public Health Laboratory Network. (2010). Surveillance for *Listeria monocytogenes* and listeriosis in Canada, 1995-2004. Epidemiol. Infect., 138: 559-572.

- Farber, J.M., Pagotto, F. and Scherf, C. (2007). Incidence and behaviour of *Listeria monocytogenes* in meat products. In: *Listeria, Listeriosis and Food Safety*. Ryser E. T. and Marth E. H. (Eds.), 3rd edition, CRC Press. Pages: 503-570.

- Pagotto, F. Corneau, N. and Farber, J.M. (2006). *Listeria monocytogenes* infections. In: *Foodborne Infections and Intoxications*. Riemann, H.P. and Cliver, D.O. (Eds.), 3rd edition, Academic Press. Pages: 313-340.

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- ILSI Expert Panel. (2005). Achieving continuous improvement in reductions in foodborne listeriosis - a risk based approach. J. Food Prot., 68:1932-1994.

- Farber, J.M., Daley, E.M., Mackie, M.T. and Limerick, B. (2000). A small outbreak of listeriosis potentially linked to the consumption of imitation crab meat. Lett. Appl. Microbiol., 31:100-104.

- Farber, J.M. and Harwig, J. (1996). The Canadian Position on *Listeria monocytogenes* in Ready-to-eat Foods. Food Control, 7: 253-258.

- Farber, J.M., Ross, W.H. and Harwig, J. (1996). Health Risk Assessment of *Listeria monocytogenes* in Canada. Int. J. Food Microbiol., 30:145-156

- Lammerding, A.M. and Farber, J.M. (1994). The Status of *Listeria monocytogenes* in the Canadian Food Industry. Dairy, Food Environ. Sanit., 14: 146-150.

- Farber, J.M. (1993). Current Research on *Listeria monocytogenes* in Foods: an Overview. J. Food Prot., 56:640-643.

Appendix A: Definitions

Durable life:

Section B.01.001 of Division 1, Part B (Foods) of the *Food and Drugs Regulations* defines "durable life" as follows: "*Durable life means the period, commencing on the day on which a prepackaged product is packaged for retail sale, during which the product, when it is stored under conditions appropriate to that product, will retain, without any appreciable deterioration, its normal wholesomeness, palatability, nutritional value and any other qualities claimed for it by the manufacturer"* (durée de conservation) (Government of Canada, 2011b).

Durable life date:

Section B.01.001 of Division 1, Part B (Foods) of the *Food and Drugs Regulations* defines "durable life date" as follows: "*Durable life date means the date on which the durable life of a prepackaged product ends*" (date limite de conservation) (Government of Canada, 2011b).

Food additives:

Section B.01.001 of Division 1, Part B (Foods) of the *Food and Drugs Regulations* defines "food additive" as follows: *"Food additive means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include: (a) any nutritive material that is used, recognized or commonly sold as an article or ingredient of food; (b) vitamins, mineral nutrients and amino acids, other than those listed in the tables to Division 16; (c) spices, seasonings, flavouring preparation, essential oils, oleoresins and natural extractives; (d) agricultural chemicals, other than those listed in the tables to Division 16; (e) food packaging materials and components thereof, and (f) drugs recommended for administration to animals that may be consumed as food*" (additifs alimentaires) (Health Canada, 2007; Government of Canada, 2011b).

Food additives are regulated in Canada under the *Food and Drug Regulations* and associated Marketing Authorizations (MAs). Approved food additives and their permitted conditions of use are set out in the Lists of Permitted Food Additives that are incorporated by reference in the MAs. If the *Regulations* and associated MAs do not allow use of a particular food additive, the processor is required to file a food additive submission in accordance with Section B.16.002 of the *Regulations* before it can be used in foods sold in Canada. Health Canada no longer issues Interim Marketing Authorizations (IMAs) for food additives, as the *Food and Drugs Act* was amended on October 25, 2012 to replace the authority to issue IMAs with the authority to issue Marketing Authorizations (MA). This MA authority was used to incorporate by reference the *Lists of Permitted Food Additives* (Health Canada, 2007; Government of Canada, 2011b).

Food Contact Surface:

A food contact surface (FCS) is any surface or object that comes into contact with the RTE product (CFIA, 2009).

Hazard Analysis Critical Control Point (HACCP):

A system that identifies, evaluates and controls hazards that are significant for food safety (CAC, 2009b).

Health risk categories:

Health Risk 1:
The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to adverse health consequences which are serious or life-threatening, or that the probability of a foodborne outbreak situation is considered high.

Health Canada Advice:
Appropriate actions should be taken immediately to prevent exposure of the population to the product, including product at the consumer level. Follow-up action should try to determine the cause of the problem, and determine if appropriate and timely corrective measures have been taken.

Health Risk 2:
The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to temporary or non-life threatening health consequences, or that the probability of serious adverse consequences is considered remote.

Health Canada Advice:
Appropriate actions should be taken in a timely manner to prevent exposure of the population to the product or to prevent further distribution of the product. Follow-up action should try to determine the cause of the problem and determine if appropriate and timely corrective measures have been taken.

Implicated RTE products:

As a minimum, all the products processed on the same line (i.e., using the same equipment) as the tested products are considered implicated when a tested lot has an unsatisfactory result. It should be noted that results from root cause analysis may also trigger the need to include additional products as part of the implicated products.

Line:

A number of pieces of equipment (e.g., slicers, tables, conveyors, packaging or filling machines) used in series in the post-lethality environment, as applicable, to prepare RTE foods for final packaging.

Lot:

A lot consists of all of the same product type processed on a given line, between two complete sanitation cycles but not exceeding one day's production. When testing this lot, the 5 sample units submitted for analysis must be representative of these products and production conditions.

Novel food/process:

The Food Directorate, Health Canada, has a legislated responsibility for pre-market assessment of novel foods and novel food ingredients as detailed in the *Food and Drug Regulations* (Division 28). As per B.28.001, a "novel food" includes, but is not limited to: a food that has been manufactured, prepared, preserved or packaged by a process that (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change, the major change being, in respect to the food, a change that places the food outside the accepted limits of natural variations for that food, with regard to microbiological and chemical safety (Government of Canada, 2011b).

Persistent:

Repetitive FCS environmental test failures, e.g., two positive results for *Listeria* spp. from the same production line (i.e., using the same equipment) in the RTE plant environment within a short timeframe.

Ready-to-eat food:

Ready-to-eat (RTE) foods are foods not requiring any further preparation before consumption, except perhaps washing/rinsing, thawing or warming.

However, only the following kinds of RTE foods are subject to the provisions of the *Listeria* policy: foods which have been subjected to some form of processing in order to render them RTE (most often cooking) and/or which have been subjected to another process to extend their shelf-life, including but not restricted to the use of heat, chemicals, reduction of pH, reduction of water activity, or special packaging. Fresh produce processed and sold as RTE are also included[5]. These foods may be shelf stable or may require refrigeration or freezing in order to assure their preservation until the time of consumption.

Under this definition, products such as dry goods (e.g., cereals, dried herbs, dried spice mixtures, dry pasta, bread, etc.), raw fruits and raw vegetables[6], any raw meat or raw fish or seafood[7], products that are fully cooked in a hermetically-sealed container and are not exposed to the environment after a validated heat treatment, e.g., canned foods, aseptic processing and

[5] RTE fresh-cut fruits and vegetables are subject to the provisions of this policy, i.e., raw fresh fruit and vegetables that have been either washed or peeled, either sliced, chopped or shredded prior to being packaged for sale and are intended to be consumed raw and not for further processing or cooking. Examples include: shredded bagged lettuce, coleslaw, fresh-cut melons or fruit salad.

[6] Non RTE fresh-cut fruits and vegetables are not subject to the provisions of this policy, i.e., raw fresh fruit and vegetables that have been either washed, peeled, sliced, chopped or shredded prior to being packaged for sale with cooking instructions on the package (e.g., mixed fresh-cut vegetables intended as pizza dressing or intended for use in preparing soup), as well as raw whole fresh fruits and vegetables, i.e., whole fresh fruit and vegetables that have only been trimmed, cleaned, brushed, washed, graded, packaged or otherwise prepared for human consumption (e.g., fresh herbs, whole or trimmed fruit or vegetables, whole leaf vegetables and berries).

[7] Exception: Sushi, which may or may not contain raw fish, as well as steak tartar and Carpaccio where the meat component is raw, are considered RTE foods and hence are subject to the provisions of this policy.

packaging, as well as cook-in-bag products which achieve a minimum 5-log reduction in numbers of *L. monocytogenes*, are excluded from the *Listeria* policy. Processed products which require cooking and which are clearly labelled with adequate cooking instructions, are also excluded from the *Listeria* policy[8].

Ready-to-eat foods in which growth *of Listeria monocytogenes* can occur (i.e., Category 1 and Category 2A):

Foods in which the growth of *L. monocytogenes* can occur and the Category which the RTE food would fall into would be determined based on scientific information. For the purpose of this policy, the growth of *L. monocytogenes* can occur in a RTE food if:

i) in a naturally-contaminated lot, the RTE food, throughout its stated shelf-life (e.g., durable life date shown as a "best before" date on the package), which has been stored under reasonably foreseeable conditions of distribution, storage and use, contains *L. monocytogenes* that:

- can be detected at levels > 100 CFU/g, as determined by direct plating (i.e., MFLP-74 (Pagotto *et al.,* 2011a), or any method published in the Health Canada's Compendium of Analytical Methods for *L. monocytogenes* in which the "application" section is appropriate for the intended purpose (e.g., MFHPB-methods and MFLP-methods)) (Category 1);

OR

ii) in a representative inoculated batch, the RTE food, throughout its stated shelf-life (e.g., durable life date shown as a "best before" date on the package), which has been stored under reasonably foreseeable conditions of distribution, storage and use, contains *L. monocytogenes* that can, as determined by the direct plating method[9]:

- increase in number by at least 0.5 log CFU/g[10]

AND

- increase in number to levels greater than 100 CFU/g
(Category 1)

OR

iii) in a representative inoculated batch, the RTE food, throughout its stated shelf-life (e.g., durable life date shown as a "best before" date on the package), which has been stored under reasonably foreseeable conditions of distribution, storage and use, contains *L. monocytogenes*

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[8] Processed products which have a cooked appearance (but are not fully cooked) may be considered RTE, and thus may be subjected to the provisions of this policy, if they only have microwave cooking instructions, or if the instructions are only to warm and serve.

[9] By a method published in the Health Canada's Compendium of Analytical Methods in which the "application" section is appropriate for the intended purpose (e.g., MFHPB-methods and MFLP-methods)

[10] 0.5 log is two times the estimated standard deviation (i.e., 0.25 log) associated with the experimental enumeration viable counting/plate counts (CAC, 2009a).

that can, as determined by the direct plating method[11]:

- increase in number by at least 0.5 log CFU/g[12]

AND

- increase in number to levels ≤ 100 CFU/g
(Category 2A; note that other factors will be taken into consideration with regards to which foods may fall in this Category. The limited growth potential (i.e., ≤ 100 CFU/g throughout the stated shelf-life of RTE foods that are known to occasionally contain low levels of *L. monocytogenes* and do not have a kill step) should be determined based on scientific validated data which will be reviewed by regulatory authorities) – see section 6.1.

Growth of *L. monocytogenes* is assumed to occur in RTE foods if the pH and a_w values fall outside the range specified in the notes included in Table 1, i.e., pH < 4.4, regardless of a_w; a_w < 0.92, regardless of pH; a combination of factors (e.g., pH < 5.0 and a_w < 0.94) etc., unless the RTE food processor/importer is able to present data, to be reviewed by regulatory authorities which demonstrates that the growth of *L. monocytogenes* will not occur, as determined by validated data, in the product which has been stored under reasonably foreseeable conditions of distribution, storage and use throughout its stated shelf-life, e.g., durable life date shown as a "best before" date on the package (CAC, 2009a). Additionally, predictive models that are validated, robust and built upon scientifically sound data can play an important role (along with other supporting information), in determining if a given product formulation or process will reduce the likelihood of *Listeria* presence or growth.

Ready-to-eat foods in which growth of *Listeria monocytogenes* will not occur as determined by validated methods (i.e., Category 2B):

Foods in which growth of *L. monocytogenes* will not occur should be determined based on scientific validated data which will be reviewed by regulatory authorities. Factors such as pH, a_w, inhibitors and storage temperature, are important parameters affecting the growth of the organism. Growth of *L. monocytogenes* is assumed not to occur in RTE foods if the pH and a_w values fall within the range specified in the notes included in Table 1, i.e., pH < 4.4, regardless of a_w; a_w < 0.92, regardless of pH; a combination of factors (e.g., pH < 5.0 and a_w < 0.94); and frozen foods, etc., under reasonably foreseeable conditions of distribution, storage and use throughout its stated shelf-life, e.g., durable life date shown as a "best before" date on the package (CAC, 2009a). For RTE foods falling in the above physico-chemical parameters, no validation studies are needed.
However, if the physico-chemical parameters of a RTE food do not consistently fall within the ranges specified above, challenge test studies involving designing, implementing and interpreting results would be required (Health Canada, 2010f). For example, the growth of *L. monocytogenes*

[11] By a method published in the Health Canada's Compendium of Analytical Methods in which the "application" section is appropriate for the intended purpose (e.g., MFHPB-methods and MFLP-methods)

[12] 0.5 log is two times the estimated standard deviation (i.e., 0.25 log) associated with the experimental enumeration viable counting/plate counts (CAC, 2009a).

can be controlled in RTE foods containing preservatives that act as antibacterial agents (e.g., food additives such as *Carnobacterium maltaromaticum* CB1, potassium lactate, sodium acetate, sodium diacetate, sodium lactate). Demonstration of no growth can be determined, for example, by experiments with naturally-contaminated food, challenge tests, information from the scientific literature, validated predictive microbiological modeling complemented with other data sources, HRAs or a combination of these[13]. The demonstration of no growth should take into account the measurement error of the validation method. For practical purposes, a food in which *L. monocytogenes* does not increase in numbers by 0.5 log CFU/g[14] throughout the stated shelf-life under reasonably foreseeable conditions of distribution, storage and use, as determined by a direct plating method (i.e., MFLP-74 (Pagotto *et al.,* 2011a), or any method published in the Health Canada's Compendium of Analytical Methods for *L. monocytogenes* in which the "application" section is appropriate for the intended purpose (e.g., MFHPB-methods and MFLP-methods)), is considered not to support growth of the organism (CAC, 2009a). If information is insufficient, inadequate or no information exists to demonstrate that there is no growth of *L. monocytogenes* throughout the stated shelf-life, as determined by validated data, the food will be treated, by default, as a RTE food in which growth of *L. monocytogenes* can occur (i.e., Category 1). Hence, the sampling plan and method of analysis for Category 1 foods, as specified in Table 1, will be applied. If questions arise, it is the responsibility of the processor/importer to demonstrate what category the RTE food belongs to.

Refrigeration:

Section B.27.001 of Division 27, Part B (Foods) of the *Food and Drugs Regulations* defines "refrigeration" as follows: *"Refrigeration means exposure to a temperature of 4°C or less, but does not mean frozen*" (réfrigéré) (Government of Canada, 2011b).

[13] For example, it has been demonstrated that shredded/sliced carrots may have anti-*Listeria* activity (Beuchat and Brackett, 1990; Nguyen-the and Lund, 1991).

[14] 0.5 log is two times the estimated standard deviation (i.e., 0.25 log) associated with the experimental enumeration viable counting/plate counts (CAC, 2009a).

Appendix B: Major Reported Foodborne Listeriosis Outbreaks:

Table 2: Listeriosis Outbreaks Related to Meat and Poultry Products

Year	Location	Invasive/ Non-invasive	Number of cases (deaths)	Foods	References
1987-1989	United Kingdom and Ireland	Invasive	355 (94)	Pâté	McLauchlin *et al.*, 1991; Farber and Peterkin, 2000
1990	Australia	Invasive	11(6)	Pâté	Watson and Ott, 1990; Kittson, 1992
1992	France	Invasive	279 (85)	Jellied pork tongue	Goulet *et al.*, 1993; Jacquet *et al.*, 1995; Salvat *et al.*, 1995
1993	France	Invasive	39 (12)	Pork rillettes (pâté-like RTE meat)	Goulet, 1995; Goulet *et al.*, 1998
1998-1999	U.S.A.	Invasive	108 (14)	Meat frankfurters	Anonymous, 1998; Anonymous, 1999; Mead *et al.*, 2006
1999	U.S.A.	Invasive	11	Pâté	Norton and Braden, 2007
1999-2000	France	Invasive	10 (3)	Rillettes (pâté-like RTE meat)	de Valk *et al.*, 2001; Swaminathan *et al.*, 2007
1999-2000	France	Invasive	32 (10)	Jellied pork tongue	Dorozynski, 2000; de Valk *et al.*, 2001; Swaminathan *et al.*, 2007
2000	U.S.A.	Invasive	30 (7)	Deli turkey meat	Hurd *et al.*, 2000; Olsen *et al.*, 2005
2000	Australia	Non-invasive	31	RTE corned beef and ham	Sim *et al.*, 2002
2001	U.S.A.	Non-invasive	16	Precooked sliced turkey	Frye *et al.*, 2002
2002	U.S.A.	Invasive	54 (8)	Sliceable turkey deli-meats	Anonymous, 2002; Gottlieb *et al.*, 2006
2008	Canada	Invasive	57 (23)	RTE deli-meats	PHAC, 2009d; PHAC, 2010

Table 3: Listeriosis Outbreaks Related to Dairy Products

Year	Location	Invasive/ Non-invasive	Number of cases (deaths)	Foods	References
1983	U.S.A.	Invasive	49 (14)	Pasteurized milk	Fleming *et al.*, 1985
1983-1987	Switzerland	Invasive	122 (31)	Soft cheese	Bille, 1990; Büla *et al.*, 1995; Farber and Peterkin, 1991
1985	U.S.A.	Invasive	142 (48)	Mexican-style fresh cheese	Anonymous, 1985; Linnan *et al.*, 1988
1989-1990	Denmark	Invasive	26 (6)	Blue mould cheese or hard cheese	Jensen *et al.*, 1994
1994	U.S.A.	Invasive	45	Chocolate milk	Proctor *et al.*, 1995; Dalton *et al.*, 1997
1995	France	Invasive	37 (11)	Raw milk soft cheese	Goulet *et al.*, 1995; Rocourt *et al.*, 1997; Lundén *et al.*, 2004
1997	France	Invasive	14	Soft cheeses	Jacquet *et al.*, 1998
1998-1999	Finland	Invasive	25 (6)	Butter made from pasteurized milk	Lyytikäinen *et al.*, 2000
2000	Canada (MB)	Invasive	7	Flat whipping cream	Pagotto *et al.*, 2006; Clark *et al*., 2010
2000-2001	U.S.A.	Invasive	13	Mexican-style fresh cheese	Boggs *et al.*, 2001; MacDonald *et al.*, 2005
2001	Sweden	Non-invasive	> 120	Fresh cheese made from raw milk in a summer farm	Carrique-Mas *et al.*, 2003; Danielsson-Tham *et al.*, 2004
2001	Japan	Non-invasive	38	Washed-type cheese	Makino *et al.*, 2005
2001	Belgium	Invasive	2	Frozen ice cream cake	Yde and Genicot, 2004
2002	Canada (BC)	Invasive	47	Cheese	Pagotto *et al.*, 2006
2002	Canada (PQ)	Invasive	17	Soft and semi-hard raw milk cheese	Gaulin *et al.*, 2003; Pagotto *et al.*, 2006
2002	Canada (BC)	Non-invasive	86	Cheese made from pasteurized milk	Pagotto *et al.*, 2006
2003	U.S.A.	Invasive	13 (2)	Mexican-style fresh cheese	Carriedo, 2003; Swaminathan and Gerner-Smidt, 2007

Year	Location	Invasive/ Non-invasive	Number of cases (deaths)	Foods	References
2005	Switzer-land	Invasive	10 (3)	Soft cheese	Bille *et al.*, 2006
2007	U.S.A.	Invasive	5 (3)	Pasteurized flavoured and non-flavoured milk	Cuming *et al.*, 2008
2008	Canada (PQ)	Invasive	40 (2)	Cheeses	Gaulin and Ramsay, 2010
2009-2010	Austria, Germany and Czech Republic	Invasive	34 (8)	Acid curd cheese "Quargel"	Fretz *et al*., 2010a; Fretz *et al*., 2010b

Table 4: Listeriosis Outbreaks Related to Fish and Seafood Products

Year	Location	Invasive/ Non-invasive	Number of cases (deaths)	Foods	References
1989	U.S.A.	Non-invasive	9 (1)	Shrimp	Riedo *et al*., 1994
1991	Australia (Tasmania)	Non-invasive	4	New Zealand produced smoked mussels	Mitchell, 1991; Misrachi *et al*., 1991; Brett *et al*., 1998
1992	New Zealand	Invasive	4 (2)	Smoked mussels	Baker *et al*., 1993; Brett *et al*., 1998
1994-1995	Sweden	Invasive	6 (1)	"Gravad" rainbow trout and cold-smoked rainbow trout	Ericsson *et al*., 1997
1996	Canada	Invasive	2	Imitation crab meat	Farber *et al*., 2000
Un-known	Finland	Non-invasive	5	Cold-smoked rainbow trout	Miettinen *et al*., 1999

Table 5: Listeriosis Outbreaks Related to Fruit and Vegetable Products

Year	Location	Invasive/ Non-invasive	Number of cases (deaths)	Foods	References
1981	Canada	Invasive	41 (17)	Coleslaw mix	Schlech *et al*., 1983
1997	Italy	Non-invasive	1566	Corn and tuna salad	Aureli *et al*., 2000
1998-1999	Australia	Invasive	6 (5)	Commercially prepared fruit salad	Rooney and Sutherland, 2001; Abelson *et al*., 2006

Table 6: Listeriosis Outbreaks Related to Other Food Products

Year	Location	Invasive/ Non-invasive	Number of cases (deaths)	Foods	References
1993	Italy	Non-invasive	23	Rice salad	Salamina *et al*., 1996; Farber and Peterkin, 2000
2003	United Kingdom	Invasive	5	Prepacked sandwiches	Dawson *et al*., 2006
2009	Australia	unknown	8	Chicken wraps	International Food Safety Authorities Network, 2009

Appendix C: Use of Food Additives, Processing Aids and/or Post-Lethality Treatments for Ready-to-Eat Foods

RTE foods exposed to the environment after their manufacturing process are at greater risk of becoming contaminated by *L. monocytogenes*. Recently, new RTE product formulations that incorporate *Listeria* inhibitors to reduce or eliminate the potential for listerial growth have been developed. Alternatively, post-lethality treatments, as applicable, can also be used to reduce or eliminate *L. monocytogenes* in RTE foods. Although voluntary, the use of food additives, processing aids and/or post-lethality treatments for *L. monocytogenes* in RTE foods, alone or in combination, is strongly encouraged for this purpose. In fact, since 2002 with the widespread use of inhibitors and robust environmental testing protocols, there has not been any listeriosis RTE meat-related outbreak in the U.S. It remains the responsibility of the industry to demonstrate its ability and willingness to reduce the potential risks associated with RTE foods. It should, however, be noted that only food additives permitted for use in Canada can be added and/or applied to RTE foods, as per the *Food and Drugs Act and Regulations* (Government of Canada, 2011a and b).

i) Food additives

The use of *Listeria* inhibitors (classified as food additives under the *Food and Drugs Act and Regulations*) is one of various steps in the overall approach to minimize the risks associated with *L. monocytogenes* in RTE foods. During RTE food production, the correct implementation of GMPs will help to prevent the introduction of microbial pathogens and minimize their potential growth. The function of an antibacterial treatment is to partially or totally destroy *L. monocytogenes* or inhibit its growth. Food processors should be aware that the degree of control in these two areas has a significant impact on the overall safety of their RTE foods. For this reason, the application of any listericidal/listeriostatic treatment that is intended to be used should be validated to ensure its effectiveness and consistency (CAC, 2009a). The scientific literature proposes different antibacterial treatments for RTE foods which can achieve different levels of *L. monocytogenes* growth inhibition and/or pathogen reduction and, therefore minimize the risks associated with these types of products. Intense research is on-going to find effective *Listeria* inhibitors that can provide growth inhibition and/or reduction in RTE foods throughout their shelf-lives. Examples of such inhibitors can include *Carnobacterium maltaromaticum* CB1, potassium lactate, sodium acetate, sodium diacetate and sodium lactate. For practical purposes, a food in which *L. monocytogenes* does not increase in numbers by 0.5 log CFU/g[15] during the expected shelf-life under reasonably foreseeable conditions of distribution, storage and use, as determined by a direct plating method, i.e., MFLP-74 (see Pagotto *et al.,* 2011a), or any method published in the Health Canada's Compendium of Analytical Methods for *L. monocytogenes* in which the "application" section is appropriate for the intended purpose (e.g., MFHPB-methods and MFLP-methods), is considered not to support growth of the organism (CAC, 2009a). The additional use of *Listeria* inhibitors in RTE foods may be reviewed by regulatory authorities, if sufficient data is provided. If information is insufficient, inadequate or

[15] 0.5 log is two times the estimated standard deviation (i.e., 0.25 log) associated with the experimental enumeration viable counting/plate counts (CAC, 2009a).

no information exists to demonstrate that there is limited or no growth of *L. monocytogenes* (i.e., Category 2A or 2B RTE food for domestic or imported RTE foods) throughout the stated shelf-life, the food will be treated, by default, as a RTE food in which growth of *L. monocytogenes* can occur (i.e., Category 1). Hence, the sampling plan and method of analysis for Category 1 foods, as specified in Table 1, will be applied. If questions arise, it is the responsibility of the processor/importer to demonstrate what category the RTE food belongs to. Currently approved food additives that can be used to potentially control the growth of *L. monocytogenes* in foods can be found on the Health Canada Website (Health Canada, 2011).

ii) Post-lethality treatments:

The use of a post-lethality treatment[16] (either classified as "novel" or "non-novel" under the *Food and Drugs Act and Regulations*), as applicable, can also be part of an overall approach to minimize the risks associated with *L. monocytogenes* in RTE foods. Such an intervention step can reduce the levels or inactivate any *L. monocytogenes* found on the surface of products due to post-lethality contamination. Examples of post-lethality treatments include surface heat pasteurization (by steam, hot water, radiant oven heating or infrared technology) and high-pressure processing. At the present time, a post-lethality treatment for RTE foods that can achieve a minimum 3-log reduction in numbers of *L. monocytogenes* is recommended. It is important to note that independent of the effectiveness of the post-lethality treatment, RTE foods should be manufactured according to Good Manufacturing/Hygienic Practices (Houben and Eckenhausen, 2006; Huang and Sites, 2008).

iii) Conclusion:

In conclusion, the use of a combination of methods, including an antibacterial treatment and/or a post-lethality treatment, as applicable, is recommended to produce a safer RTE product. It should be noted that if both strategies are used in conjunction, a synergistic effect could also potentially be achieved.

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[16] The use of novel technologies for post-lethality treatments could be subjected to a comprehensive assessment by the Food Directorate, Health Canada according to the *Guidelines for the Safety Assessment of Novel Foods* (Health Canada, 2006).

For "non-novel" post-lethality treatments, it is highly recommended that the microbiological safety and efficacy of these new or improved food processing and handling techniques proposed by the food industry (e.g., steam pasteurization, hot water treatment, radiant oven heating, infrared heating) be assessed by the BMH, Food Directorate, HPFB, Health Canada.

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