Health Canada Santé Canada

Policy on *Listeria monocytogenes* in ready-to-eat foods

Effective date:
October 1, 2023

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Également disponible en français sous le titre :
Politique sur la présence de *Listeria monocytogenes* dans les aliments prêts-à-manger

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

Publication date: March 2023

Cat.: H164-230/2023E-PDF
ISBN: 978-0-660-47322-2
Pub.: 220739

Table of contents

List of figures

List of tables

Legislative context

The *Food and Drugs Act* and *Regulations*, generally apply to all food sold in Canada, including both imported and domestically produced food traded at the interprovincial/territorial and intraprovincial/territorial level. The *Safe Food for Canadians Act* and *Regulations*, mainly apply to food that is imported, or prepared for export or interprovincial/territorial trade for commercial purposes. Together they form the legislative foundation of federal food laws.

Health Canada is responsible for administering provisions of the *Food and Drugs Act* that relate to public health, safety and nutrition. As such, Health Canada's *Listeria* policy is intended to support the interpretation and application of the *Food and Drugs Act.* In particular, the manufacturing, preparation, preservation, packaging or storage of food for sale under unsanitary conditions as well as the sale of a ready-to-eat food containing *L. monocytogenes* at levels exceeding those specified in Table 1 of the *Listeria* policy, may be considered to contravene paragraphs 4(1)(a), 4(1)(e) and section 7 of the *Food and Drugs Act.*

In addition to the administration and enforcement of the *Safe Food for Canadians Act* and *Regulations*, the Canadian Food Inspection Agency (CFIA) is responsible for the enforcement of the food-related provisions of the *Food and Drugs Act* and *Regulations*, and takes into consideration the standards, guidelines and policies established by Health Canada. As such, the relevant federal regulatory authority referred to in Health Canada's *Listeria* policy is the CFIA. The *Listeria* policy is applied in the conduct of federal food inspections. The CFIA also provides guidance to help ready-to-eat food manufacturers and importers comply with the control measure requirements set out in the *Safe Food for Canadians Regulations* in the following document based on Health Canada's *Listeria* policy: Control measures for *Listeria monocytogenes* in ready-to-eat foods (the control measures document). **Food businesses that require a licence under the *Safe Food for Canadians Regulations* should be aware that certain control measures and reporting recommendations described in Health Canada's *Listeria* policy may be regulatory requirements under the *Safe Food for Canadians Regulations* and should refer to the control measures document for further details.** Risk-based guidelines on sampling and testing frequencies are also in the control measures document.

Furthermore, as provincial/territorial food regulatory authorities may be conducting enforcement of their own food legislation, they may apply similar policy considerations in relation to the application of their laws. Hence, Health Canada's *Listeria* policy may serve as a resource for this purpose. In these cases, Health Canada's *Listeria* policy can play a complementary role, but is not intended to provide guidance on legislation that is not within Health Canada's jurisdiction or mandate.

Ultimately, it is industry's responsibility to produce safe food and to comply with all applicable Canadian legislative requirements.

To help facilitate your reading

Appendix A contains definitions of the terminology used in this policy, including relevant definitions from the *Food and Drugs Act* and *Regulations*. At the first relevant instance, terminology defined in Appendix A have been hyperlinked to facilitate reading and comprehension. Other hyperlinks direct the reader to specific sections, figures or tables. Some hyperlinks direct readers to complementary resources available on the Government of Canada's website.

1 Summary

Listeria monocytogenes is unique among foodborne pathogens. It is widespread in nature, can grow at refrigeration temperatures and can survive in the environment of food processing plants for months to years. Although rare, *L. monocytogenes* infections can result in serious and severe diseases, especially in vulnerable individuals. Foodborne outbreaks of listeriosis have mostly been linked to ready-to-eat (RTE) foods that are not normally further prepared before consumption. As such, this document sets out Health Canada's policy relating to the application, implementation and verification of control measures for *L. monocytogenes* in RTE foods.

Health Canada's "Policy on *Listeria monocytogenes* in ready-to-eat foods" (referred to as the *Listeria* policy) applies to the manufacturing and importation of RTE foods that are sold in Canada. These foods have been classified into 2 categories (see Section 6 under Principles for the control of *Listeria monocytogenes* in ready-to-eat foods) based on their potential to support the growth of *L. monocytogenes*. The *Listeria* policy takes into account the potential for the growth of *L. monocytogenes* to occur as well as the presence or levels of *L. monocytogenes* in RTE foods as factors to determine the health concern that such foods pose to consumers (Table 1). Furthermore, the intended consumers of RTE foods (for example, vulnerable populations) are also considered in determining the health concern.

The *Listeria* policy uses a risk-based approach and is based on Good Manufacturing Practices (GMPs) and the principles of Hazard Analysis Critical Control Points (HACCP). The implementation of the *Listeria* policy relies on process review, environmental sampling (includes food contact and non-food contact surfaces) and end-product testing. In an effort to manufacture RTE foods that are safe for consumption, the *Listeria* policy places an emphasis on environmental sampling in post-process areas where foods are exposed to the environment prior to packaging.

The updated *Listeria* policy replaces the "Policy on *Listeria monocytogenes* in Ready-to-Eat Foods" dated April 1, 2011. The update focuses on the following:

- presentation of concepts, including the legislative context of the *Listeria* policy, in a new order for better readability as well as their refinement for improved clarity
- the current outcome-based regulatory landscape for domestic manufacturers, importers and exporters of RTE foods
- specific food businesses, activities and foods for which the *Listeria* policy does not apply (updated with more detail, see Section 2 under Purpose and scope)
- the definition of RTE foods (modified to include more detail, see Section 2 under Application of the policy)
- a decision tree to facilitate the categorization of RTE foods (Figure 1)
- more detail on foods specifically produced for consumption by vulnerable populations

2 Purpose and scope

The *Listeria* policy is intended to assist in the application and verification of activities for *L. monocytogenes* in RTE foods to protect the health and safety of Canadians. The implementation of the *Listeria* policy should permit the early identification of the persistence of *Listeria* species (*Listeria* spp., including *L. monocytogenes*) in the food processing environment and allows for the assessment of the effectiveness of control measures put in place to address *L. monocytogenes* in RTE foods. In this specific context, the *Listeria* policy guides industry on ways to comply with federal food legislation and may be used as a resource for the relevant regulatory authority for such enforcement. Details regarding risk-based frequencies of sampling, verification and compliance are left to the discretion of the relevant regulatory authority (CFIA, 2023).

In accordance with the *Listeria* policy, RTE foods should be produced under conditions that will minimize or prevent the introduction and/or growth of *L. monocytogenes*. This may be accomplished by:

- adhering to Good Agricultural Practices (GAPs) and/or GMPs
- following a HACCP plan or preventive control plan (PCP)
- conducting environmental sampling for *Listeria* spp. in the plant
- controlling processing steps that eliminate or reduce numbers of *L. monocytogenes* during manufacturing
- preventing the introduction of *L. monocytogenes* in post-process areas where foods are exposed to the environment prior to packaging

The *Listeria* policy does not apply to the following food businesses:

- retail food businesses that sell food directly to consumers and are not required to have a licence under the *Safe Food for Canadians Regulations*
- warehouses or distributors that do not manufacture or import food
- restaurants or similar enterprises (for example, sit-down, buffet, fast food or take-out restaurants, cafeterias, caterers, food stands or wagons, ice cream or coffee shops)
- manufacturers of food that is not intended or sold for human consumption (for example, livestock feed, pet food)
- manufacturers of edible cannabis (Government of Canada, 2023b)
- manufacturers of natural health products (Health Canada, 2017a)
- primary agricultural producers (for example, farms that grow crops, raise animals (including fish), or harvest plants, animals or animal products (CAC, 2020))

Nevertheless, all businesses that sell food in Canada are subject to all relevant provisions of the *Food and Drugs Act*, including sections 4 and 7 (Government of Canada, 2023a).

In addition, the *Listeria* policy does not apply to the following activities:

- pre-process testing (for example, testing of incoming ingredients)
- processing or treating a RTE food known to contain *L. monocytogenes* at levels exceeding those specified in Table 1 in order to bring it into compliance

Moreover, the *Listeria* policy does not provide information on the conduct of food safety investigations or recall activities by regulatory authorities as they are not within the scope of this document.

Nonetheless, in situations for which the *Listeria* policy does not apply, a finding of *L. monocytogenes* should still trigger an assessment by the food business to determine if follow-up actions are needed and if the situation represents a health concern. Risk management actions may be needed.

Note: Health Canada, within its mandate, conducts health risk assessments that can identify risks to human health from foodborne pathogens. Upon request, regulatory authorities can contact the Microbiological Evaluation Division, Bureau of Microbial Hazards, Food Directorate, Health Products and Food Branch for support.

2.1 Application of the policy

For the purpose of the *Listeria* policy, RTE foods are defined as follows:

> RTE foods are any foods that are normally eaten in the same condition as that in which they are purchased. They are not normally further prepared before consumption, except perhaps being washed/rinsed, thawed or warmed (that is, a heat treatment achieving less than a 5-log reduction in numbers of *L. monocytogenes*).
>
> RTE foods subject to the *Listeria* policy often require refrigeration (that is, labelled 'Keep Refrigerated' on the package) or freezing (that is, labelled 'Keep Frozen' on the package) for their preservation until the time of consumption. These RTE foods must have been subjected to a process by the manufacturer in order to render them RTE, or another process to extend their shelf-life, including but not restricted to the use of heat, chemicals, reduction of pH, reduction of water activity (a_w), modified atmosphere packaging and/or storage conditions.
>
> Raw fresh-cut fruits and vegetables that have been peeled, sliced, chopped or shredded prior to being packaged for sale and are intended to be consumed in the same condition as that in which they are purchased are considered to be RTE and are subject to the *Listeria* policy. Examples include shredded bagged lettuce, sliced mushrooms, grated cabbage for coleslaw, fresh-cut melons and fruit salad.

2.1.1 Foods excluded from the policy

Nonetheless, from the RTE foods definition in Section 2.1, the following foods are **excluded** from the *Listeria* policy:

1) foods that have received a processing step achieving a minimum 5-log reduction in numbers of *L. monocytogenes* in a hermetically sealed container by the manufacturer and are not further exposed to the environment prior to consumption (for example, canned foods, refrigerated sous-vide type foods, retort pouches, aseptically processed and packaged foods such as ultra-high temperature (UHT) foods)
2) hot filled/packed foods that have very limited exposure to the environment after filling (for example, maple syrup, jams, jellies, processed cheese)
3) dried goods or low-moisture foods that do not require storage under refrigeration or freezing conditions (for example, cereals, bread, dry pasta, nuts and seeds, dried herbs and spices, dried soup mixes)
4) beverages that do not require storage under refrigeration or freezing conditions (for example, alcoholic beverages, bottled water, carbonated beverages, non-carbonated beverages)
5) raw whole fresh fruits and raw whole fresh vegetables that have only been trimmed, cleaned, brushed, washed, graded or packaged (for example, fresh herbs, whole or trimmed fruits and vegetables, whole leafy vegetables, microgreens, whole mushrooms, berries) as well as sprouts
6) raw meat or raw seafood or raw eggs
    a. except those specifically processed for raw consumption (for example, oysters on the half shell sold as RTE, sushi containing raw fish, tubed seafood for tartare or ceviche, certain beef products such as steak tartar and Carpaccio) which are subject to the *Listeria* policy

Note: Manufacturers of beef products processed for raw consumption should also consult Health Canada's "Guidance Document on *E. coli* O157:H7 and *E. coli* O157:NM in Raw Beef" and take steps to address *E. coli* O157 as a hazard likely to occur (Health Canada, 2014a).

7) oyster shellstock (live) intended for raw consumption
8) refrigerated or frozen processed foods that are solely intended to be cooked before consumption and are clearly labelled on the package as such with a declaration (for example, 'cook thoroughly', 'cook and serve', 'cook and eat') as well as with validated, comprehensive cooking instructions achieving a minimum 5-log reduction in numbers of *L. monocytogenes*
    a. except those defined as being RTE under the *Canadian Standards of Identity* in the *Safe Food for Canadians Regulations* (for example, wieners, frankfurters, hot dogs) (Government of Canada, 2021a; 2023c) which are subject to the *Listeria* policy

Note: In the context of cooking instructions specified on the label of the package, 'cooking' refers to a treatment that achieves a minimum 5-log reduction in numbers of *L. monocytogenes* to be applied by the end-user on a food. Cooking instructions should be validated, comprehensive (that is, time/temperature combinations) and include an internal endpoint temperature (for example, minimum internal temperature of 74°C). Information on a food label must not be false or misleading (including, no deception or erroneous impression regarding its safety) and their labelling must comply with section 5 of the *Food and Drugs Act* (Government of Canada, 2023a). Furthermore, manufacturers should be consistent with how they communicate these cooking instructions in advertising (for example, information on the manufacturer's website).

If there is uncertainty regarding whether a food is subject to the *Listeria* policy, the relevant regulatory authority should be contacted.

2.1.1.1 Requirements and best practices for foods excluded from the policy

While the *Listeria* policy is not applicable to excluded foods, all relevant provisions of federal food legislation, such as sections 4 and 7 of the *Food and Drugs Act*, still apply to these foods (Government of Canada, 2023a). Food businesses should remain vigilant regarding the presence of *L. monocytogenes* if it has been identified as a food safety hazard to be controlled (for example, in a HACCP plan or PCP). In order to mitigate the risk from *L. monocytogenes* (that is, prevent the introduction and/or growth of *L. monocytogenes*) in foods excluded from the *Listeria* policy, manufacturers of such foods are still expected to implement GMPs as well as environmental sampling or end-product testing as appropriate to their operation. Industry-specific best-practice guidelines for the control of *L. monocytogenes* in foods that are not subject to the *Listeria* policy may represent a good resource to help identify and apply control measures that are appropriate to their operation. Factors such as the processing steps, labelling, trend analysis information, well-documented link to illnesses (for example, certain frozen vegetables (EFSA BIOHAZ Panel et al., 2020), enoki mushrooms (WHO, 2020)) could also have an impact on the level of priority for the frequency of verification activities and risk communication strategies. Manufacturers should be able to demonstrate that their food safety system will control *L. monocytogenes* in their foods.

If foods are specifically produced for vulnerable populations, which have an increased susceptibility to infection with *L. monocytogenes*, a greater frequency of verification activities would be expected as compared to foods produced for consumption by the general population. In particular, environmental sampling and end-product testing as per Figures 2 to 4 are recommended for refrigerated or frozen processed foods which are solely intended to be cooked before consumption that are excluded from the *Listeria* policy (see Section 2.1.1 under Foods excluded from the policy), if specifically produced for vulnerable

populations. In addition, strict adherence to and monitoring of GMPs, process controls and other control measures are recommended (CAC, 2020).

A finding of *L. monocytogenes* in a food excluded from the *Listeria* policy should trigger an assessment by the food business to determine what follow-up actions including risk management are needed, particularly if the situation represents a health concern.

3 Roles and responsibilities

The *Listeria* policy was developed by Health Canada, with input from the Canadian Food Inspection Agency (CFIA) and the Public Health Agency of Canada (PHAC). It takes into account the roles and responsibilities of industry, government and consumers.

3.1 Industry

It is the responsibility of food businesses to comply with all applicable Canadian legislative requirements (Government of Canada, 2023a; 2023c; 2023d; 2023e). Food businesses that require a licence under the *Safe Food for Canadians Regulations* should be aware that certain control measures and reporting recommendations described in the *Listeria* policy may be regulatory requirements under the *Safe Food for Canadians Regulations*. For instance, RTE food manufacturers that require a licence under the *Safe Food for Canadians Regulations* must be able to demonstrate that their food safety system will control *L. monocytogenes* in RTE foods.

3.1.1 Ready-to-eat food manufacturers

As *L. monocytogenes* is widespread in nature and may be found in the food processing environment, manufacturers of RTE foods should be able to demonstrate that their food safety system will control *L. monocytogenes*. Manufacturers should carry out environmental sampling, as described in Figures 2 to 4 (see Section 7.2 under Environmental sampling and testing), under the principle that the environment of higher-risk foods should be sampled at an increased frequency. This should be performed to verify the effectiveness of their sanitation program (that is, cleaning and sanitizing) and of their process controls. Findings of *Listeria* spp. may be an indication of the presence of *L. monocytogenes* and should lead to intensified cleaning and sanitizing. A review of the food safety system may also be needed.

Manufacturers must ensure that their labels are in compliance with section 5 of the *Food and Drugs Act* which states: No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety (Government of Canada, 2023a). From a food safety perspective, this is especially important with regards to storage and preparation instructions for consumers.

3.1.2 Ready-to-eat food importers

Imported food must be prepared with at least the same level of food safety controls as food prepared in Canada since they are required to meet the same food safety outcomes. Food importers are required to have a *Safe Food for Canadians Regulations* licence and develop, keep, maintain and implement a written PCP, following Part 4 of the *Safe Food for Canadians Regulations*. They must also have a traceability system in accordance with Part 5 of the *Safe Food for Canadians Regulations*. Importers must have this information readily available to the CFIA. Furthermore, they should always practise safe food storage and handling procedures.

3.1.3 Ready-to-eat food exporters

The term RTE food manufacturers referred to in the *Listeria* policy includes manufacturers of RTE foods for export. Canadian exporters are responsible, at a minimum, for exporting food that meets Canadian food safety requirements (see Section 3.1 under Industry).

3.2 Government

Health Canada develops policies, guidelines and food safety standards with the goal of protecting the health and safety of Canadians. This is done in consultation with stakeholders (for example, federal and provincial/territorial partners, the food industry and its associations). Health Canada publications are intended to help industry comply with applicable Canadian legislative requirements and serve as a resource for regulatory authorities.

It is the role of the CFIA to verify compliance with federal food legislation.

The role of the PHAC is to promote and protect the health of Canadians through leadership, partnership, innovation and action in public health (PHAC, 2020).

In accordance with their mandates, Health Canada, the CFIA and the PHAC work together and contribute to the following:

- providing laboratory services
- conducting food surveillance and food safety investigations
- conducting health risk assessments
- initiating recall actions

Health Canada, the CFIA and the PHAC also work together with other public health officials and provincial/territorial partners to investigate the source of *L. monocytogenes*-related illnesses when an outbreak is suspected, as applicable.

The Government of Canada provides information and science-based educational materials to the medical community, public health officials, the food industry and consumers about foodborne illness, and also provides Canadians with reliable and consistent information about food safety.

3.3 Consumers, caterers and care providers

In addition to the food industry and government authorities, consumers play an important role in reducing foodborne illness. That role calls for Canadians to learn, adopt as well as follow safe food handling, responsible food selection and safe food preparation practices. The Codex Alimentarius Commission's "Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods" provides pertinent information in relation to consumer awareness (CAC, 2009a).

It should be emphasized that caterers and care providers (for example, health care providers, caregivers) to vulnerable individuals (that is, people with weakened immune systems, adults ages 60 and over, as well as pregnant people) have a high level of responsibility in food preparation, as vulnerable individuals have an increased susceptibility to infection with *L. monocytogenes*. Vulnerable individuals should try to avoid the consumption of specific foods or make safer food choices. Furthermore, knowledge about responsible food selection, safe food handling and preparation practices is particularly important to vulnerable populations

and the people who prepare food for them (for example, caterers, care providers) (Government of Canada, 2016; 2021b; 2021c; 2021d; 2023f).

While a lot of information is provided by food manufacturers regarding nutrition, information pertaining to food safety is becoming increasingly common on food packaging. Adherence to the instructions labelled on the package should be followed, as they indicate the manufacturer's specific intentions for proper handling, preparation and usage.

4 Background

L. monocytogenes is a bacterium that is widespread in nature. It has been isolated from feces, sewage, silage, soil, fertilizer, vegetable matter and many foods (Farber and Peterkin, 1991; Farber and Peterkin, 2000; McLauchlin et al., 2004; Soni et al., 2014). A recent meta-analysis estimated the prevalence of *L. monocytogenes* in deli meat to be 2.9%, soft cheese to be 2.4%, and packaged salad at 2.0% (Churchill et al., 2019), suggesting that the prevalence of *L. monocytogenes* in RTE foods may be less than 5%.

It is estimated that approximately 1% of humans carry *L. monocytogenes* in their intestines without developing symptoms (Müller, 1990; Iida et al., 1998; Grif et al., 2001). Depending on the method used for detection, the organism's prevalence has been reported to be as high as 10% in the feces of healthy humans (Hafner et al., 2021). However, *L. monocytogenes* is recognized as the causative agent of the infection known as listeriosis. Listeriosis can be invasive or non-invasive. Invasive listeriosis usually develops in vulnerable individuals while non-invasive listeriosis can develop in people belonging to any population. Several modes of transmission have been identified: mother-to-fetus infection *in utero* or infection during childbirth, infant-to-infant, animal-to-human and transmission through the consumption of food containing *L. monocytogenes* (McLauchlin et al., 2004).

Serious infections of *L. monocytogenes* (that is, invasive listeriosis) in healthy adults are relatively rare. The highest incidence of listeriosis is among people with weakened immune systems, pregnant people and adults ages 60 and over (FAO and WHO, 2004; WHO, 2018; PHAC, 2022). In Canada, invasive listeriosis is a nationally notifiable disease. Invasive listeriosis is characterized by septicemia and meningoencephalitis and may result in death. Symptoms can start as early as 3 days and as late as 3 months after exposure to *L. monocytogenes* (Government of Canada, 2016; WHO, 2018). In pregnant people, symptoms are typically mild. However, the passage of the organism through the placenta may cause miscarriage, stillbirth, or perinatal septicemia and meningitis in the newborn baby. *L. monocytogenes* is the leading cause of death associated with foodborne illness in Canada, for which the cause is known (Thomas et al., 2015a). Invasive infection with *L. monocytogenes* is associated with a high case-fatality rate, that is, 20 to 30% of foodborne listeriosis infections in vulnerable populations are fatal (WHO, 2018). Listeriosis can also lead to serious and long-lasting health problems in infected individuals (Roberts et al., 2009).

In all likelihood, Canadians consume foods that may contain low levels of *L. monocytogenes* on a regular basis. However, the incidence of listeriosis remains relatively low. In 2008, the rate of listeriosis reported in Canada reached its highest point of 7 cases per million population, which was largely attributable to 2 outbreaks involving 57 and 40 confirmed cases each (Gaulin and Ramsay, 2010; Currie et al., 2015; Thomas et al., 2015b). Moreover, from 2011 to 2020, the national reported rate of listeriosis has remained fairly stable, ranging from 5.3 cases per million population in 2016 to 3.3 cases per million population in 2017 (PHAC, 2023). These Canadian rates are comparable to those reported in the United States (for example, 2.8 cases per million population in 2008 to 2016, excluding pregnancy-associated cases) (Pohl et al., 2019) and in the European Union (for example, 4.9 cases per million population in 2021) (EFSA and ECDC, 2022).

5 Scientific basis for the policy

A number of foodborne listeriosis outbreaks have been documented in Canada (see Appendix B) and throughout the world. These have been attributed to a wide variety of foods such as meat spreads, deli meats, sausages, dairy products made from pasteurized and unpasteurized milk, fish, produce and prepackaged foods such as sandwiches and salads (Desai et al., 2019).

The foods implicated in *L. monocytogenes* outbreaks are typically those in which *L. monocytogenes* is present at (or can grow to) levels that could present a health risk to consumers and are not normally further prepared before consumption. The ability of *L. monocytogenes* to grow at temperatures of -0.4 to 45°C, pH values of 4.4 or higher and a_w values of 0.92 or higher are important characteristics that play a role in food safety (ICMSF, 1996). Nevertheless, the potential of acquiring foodborne listeriosis generally increases depending on several factors (FAO and WHO, 2004; CAC, 2009a; Buchanan et al., 2017) such as:

- host susceptibility (for example, underlying health status, immune status, medications)
- strain virulence
- the amount and frequency of consumption of a food containing *L. monocytogenes*
- the frequency, distribution and level of *L. monocytogenes* in the food
- the potential for the growth of *L. monocytogenes* in the food during refrigerated storage
- the refrigerated storage temperature
- the duration of refrigerated storage before consumption

In regard to the latter 3 bullets, quantitative modelling done by the European Food Safety Authority (EFSA) (EFSA BIOHAZ Panel et al., 2018) predicted that the expected number of human invasive listeriosis cases per year could be reduced by 37% if the growth of *L. monocytogenes* is prevented after consumer purchase, thus emphasizing the importance of consumer education.

The *Listeria* policy takes into account the intended consumers of RTE foods (for example, vulnerable populations), the potential for the growth of *L. monocytogenes* to occur in the food, as well as the presence or levels of *L. monocytogenes* in the food. These factors are used to determine the health concern that RTE foods pose to consumers. The potential for the growth of *L. monocytogenes* to occur depends on factors such as pH, a_w, food formulation, the background microorganisms, the use of food additives (see Appendix C), storage conditions and shelf-life.

A definitive dose-response model for *L. monocytogenes* in humans has not been established. However, based on current case data from around the world, the likelihood of any 1 food containing low numbers of *L. monocytogenes* resulting in illness is considered to be very low (FAO and WHO, 2004). Foods that contain low levels of *L. monocytogenes* (for example, less than 100 Colony Forming Units (CFU)/g) pose very little risk (Chen et al., 2003; FAO and WHO, 2004). Furthermore, recent quantitative modelling suggested that the consumption of RTE foods containing more than 2000 CFU/g of *L. monocytogenes* is responsible for more than 90% of invasive listeriosis cases (EFSA BIOHAZ Panel et al., 2018). A U.S. risk assessment, which included a risk categorization of foods, further supports the fact that RTE foods differ in their ability to support the growth of *L. monocytogenes,* and therefore, differ in their risk to cause foodborne listeriosis (FDA and USDA, 2003).

Consequently, the *Listeria* policy separates RTE foods that support the growth of *L. monocytogenes* from those in which its growth is limited to levels not exceeding 100 CFU/g or in which it will not occur throughout the stated shelf-life (see Section 6.1.2 under Category 2 ready-to-eat foods). Internationally, the Codex Alimentarius Commission, the Commission of European Communities and Food Standards Australia New

Zealand (FSANZ) have proposed similar approaches to *L. monocytogenes* in RTE foods, to protect the health of consumers while applying fair practices in food trade (CAC, 2009a; FSANZ, 2014; European Commission, 2020).

Nevertheless, an outbreak in 2015 linked to certain ice cream products consumed by hospital patients emphasized the significance of host susceptibility and underlying health/immune status for listeriosis (Pouillot et al., 2016). All known exposures related to this outbreak were likely due to the consumption of milkshakes rather than to the original ice cream product (Chen et al., 2016a; Farber et al., 2021). Despite widespread exposure, no illnesses were reported among the general population linked to the consumption of the associated ice cream. *L. monocytogenes* was recovered at low levels in 99% (2307/2320) of the ice cream samples tested (Chen et al., 2016b; Pouillot et al., 2016).

This outbreak demonstrated the potential for listeriosis to occur in highly vulnerable individuals if they consume products that do not support the growth of, but do contain low levels of *L. monocytogenes* (Pouillot et al., 2016). Furthermore, a recent study on healthcare-associated foodborne outbreaks between 2001 and 2018 occurring in Organisation for Economic Co-operation and Development (OECD) countries identified *L. monocytogenes* as being responsible for the majority of healthcare-associated foodborne outbreaks in the hospital setting (Boone et al., 2021). These listeriosis outbreaks were associated with high case fatality rates and mainly affected vulnerable individuals.

6 Principles for the control of *Listeria monocytogenes* in ready-to-eat foods

For the purpose of the *Listeria* policy, RTE foods are classified into 2 categories based on their potential to support *L. monocytogenes* growth. The decision tree presented in Figure 1 should be followed to determine the category of a RTE food.

6.1 Demonstrating the ready-to-eat food category (Figure 1) and determining the level of priority for the frequency of process monitoring, environmental sampling and end-product testing

6.1.1 Category 1 ready-to-eat foods

Category 1 RTE foods are those which support the growth of *L. monocytogenes* under reasonably foreseeable conditions of distribution, storage and use throughout the stated shelf-life. As such, process monitoring, environmental sampling and end-product testing should be conducted more frequently for Category 1 RTE foods as compared to Category 2 RTE foods. Furthermore, the detection of *L. monocytogenes* in a Category 1 RTE food, as determined by the applicable sampling and testing methodologies (see Section 7.3 and Table 1 under Sampling and testing of ready-to-eat foods), may trigger a Health Risk 1 concern. Risk management actions may be needed.

6.1.2 Category 2 ready-to-eat foods

Category 2 contains 2 subgroups, for which validation may be necessary to demonstrate that control measures are effective to limit or prevent the growth of *L. monocytogenes*. For more information on validation, please refer to these relevant publications: Validation of Ready-to-Eat Foods for Changing the Classification of a Category 1 into a Category 2A or 2B Food – in relation to Health Canada's Policy on *Listeria monocytogenes* in Ready-to-Eat Foods and *Listeria monocytogenes* Challenge Testing of Refrigerated Ready-to-Eat Foods (Health Canada, 2012a; 2012b). If there is uncertainty regarding the categorization of a RTE food, the relevant regulatory authority should be contacted.

As specified (see Section 7.3 and Table 1 under Sampling and testing of ready-to-eat foods), levels of *L. monocytogenes* exceeding 100 CFU/g in a Category 2 RTE food, as determined by the applicable sampling and testing methodologies, may trigger a Health Risk 2 concern. Risk management actions may be needed.

6.1.2.1 Category 2A ready-to-eat foods

Category 2A: Certain RTE foods in which the growth of *L. monocytogenes* may be limited to levels not exceeding 100 CFU/g under reasonably foreseeable conditions of distribution, storage and use throughout the stated shelf-life. This category includes (Figure 1):

- RTE foods which are known to occasionally contain low levels of *L. monocytogenes* and their processing does not involve a heat treatment (**based on validation**)
    - In other words, a RTE food that may have received a non-thermal processing step by the manufacturer achieving less than a 5-log reduction in numbers of *L. monocytogenes* or no reduction step altogether

  Note: The presence of *L. monocytogenes* in Category 2A RTE foods may be sporadic (for example, the levels could be lower than the method's limit of quantification, but over time may grow to quantifiable levels).

- RTE refrigerated foods with a stated shelf-life of 5 days or less

  Note: Information on a food label must not be false or misleading (including, no deception or erroneous impression regarding its safety) and their labelling must comply with section 5 of the *Food and Drugs Act* (Government of Canada, 2023a). The day of final packaging can be regarded as day 0.

Although these foods can support the growth of *L. monocytogenes*, such growth is generally limited due to factors such as a short refrigerated shelf-life or the presence of a large population of background microorganisms producing compounds such as bacteriocins and organic acids. As such, process monitoring, environmental sampling and end-product testing could be conducted less frequently for Category 2A RTE foods as compared to Category 1 RTE foods and RTE foods specifically produced for consumption by vulnerable populations (Table 1).

As applicable, manufacturers of Category 2A RTE foods should validate and verify their process to demonstrate that levels of *L. monocytogenes* are consistently not exceeding 100 CFU/g throughout the foods' stated shelf-life. In order to confirm that a RTE food remains in Category 2A, manufacturers should regularly monitor the food to demonstrate that it continues to meet the specified criteria that justify its categorization as a Category 2A RTE food. In fact, for those specific RTE foods, testing of the RTE food at the beginning of its shelf-life becomes a key process parameter to confirm that the RTE food meets the criteria that were used in the challenge study (that is, 10 to 30 CFU/g). This is performed to confirm that the concentration of *L. monocytogenes,* at the beginning of the shelf-life (at time 0), never exceeds the 10 to 30 CFU/g level that was used as an inoculum in the challenge study (Health Canada, 2012a; 2012c).

The RTE food manufacturer should be able to demonstrate that the food meets the criteria of Category 2A. In cases where validation was conducted for categorization, the manufacturer should have documentation of adequate validation studies substantiating that the RTE food will only support limited growth of *L. monocytogenes* to levels not exceeding 100 CFU/g throughout the stated shelf-life. If insufficient, inadequate or no information exists regarding the Category 2A categorization of the RTE food, the RTE food will be considered as a Category 1 RTE food (that is, a food in which the growth of *L. monocytogenes* can occur). As such, the sampling and testing methodologies for Category 1 RTE foods should be used (see Section 7.3 and Table 1 under Sampling and testing of ready-to-eat foods).

6.1.2.2 Category 2B ready-to-eat foods

Category 2B: RTE foods in which the growth of *L. monocytogenes* will not occur under reasonably foreseeable conditions of distribution, storage and use throughout the stated shelf-life (CAC, 2009a). This category includes (Figure 1):

- RTE foods for which the pH and a_w values are such that they do not support the growth of *L. monocytogenes*
    - pH < 4.4, regardless of a_w
    - a_w < 0.92, regardless of pH
    - combination of pH < 5.0 and a_w < 0.94

- frozen RTE foods (that is, labelled 'Keep Frozen' on the package)

- other RTE foods in which *L. monocytogenes* does not increase in numbers by more than 0.5 log CFU/g throughout the stated shelf-life **(based on validation)**

  Note: 0.5 log is 2 times the estimated standard deviation (that is, 0.25 log) associated with the experimental enumeration viable counting/plate counts (CAC, 2009a).

Category 2B RTE foods do not support the growth of *L. monocytogenes*. As such, process monitoring, environmental sampling and end-product testing could be conducted less frequently for Category 2B RTE foods as compared to Category 2A RTE foods, Category 1 RTE foods and RTE foods specifically produced for consumption by vulnerable populations (Table 1). As applicable, Category 2B RTE food manufacturers should regularly monitor the physico-chemical parameters of the food (such as pH and a_w), its formulation and so on, to demonstrate that it continues to meet the specified criteria that justify its categorization as a Category 2B RTE food.

The RTE food manufacturer should be able to demonstrate that the food meets the criteria of Category 2B. In cases where validation was conducted for categorization, the manufacturer should have documentation of adequate validation studies substantiating that *L. monocytogenes* cannot grow throughout the stated shelf-life. If insufficient, inadequate or no information exists regarding the Category 2B categorization of the RTE food, the RTE food will be considered as a Category 1 RTE food (that is, a food in which the growth of *L. monocytogenes* can occur). As such, the sampling and testing methodologies for Category 1 RTE foods should be used (see Section 7.3 and Table 1 under Sampling and testing of ready-to-eat foods).

6.1.2.2.1 Frozen ready-to-eat foods

RTE food manufacturers should be able to demonstrate the RTE food category and determine the level of priority for the frequency of process monitoring, environmental sampling and end-product testing. For frozen RTE foods, manufacturers should consider the intended consumers (for example, vulnerable populations); the information specified on the label of the package pertaining to thawing times and temperatures, as well as any refrigerated shelf-life after thawing; and process controls, that is Critical Control Points (CCPs) pertaining to the food's formulation. Information on a food label must not be false or misleading (including, no deception or erroneous impression regarding its safety) and their labelling must comply with section 5 of the *Food and Drugs Act* (Government of Canada, 2023a). If there is uncertainty regarding the categorization of a RTE food, the relevant regulatory authority should be contacted.

Furthermore, frozen Category 2B RTE foods that are not labelled with information pertaining to thawing times and temperatures, or refrigerated shelf-life after thawing, but will be thawed before direct consumption should be monitored and sampled more frequently as compared to frozen Category 2B RTE foods that are consumed directly in the frozen state.

Manufacturers of second-generation RTE foods should consider developing supply-chain controls (for example, a formal agreement with the supplier(s), Certificate of Analysis) in order to have greater confidence that the ingredients to be used in second-generation RTE foods are safe and suitable for use. Examples of such situations involving frozen RTE foods are described below.

1) When initially frozen RTE foods are used as ingredients in other RTE foods, these second-generation RTE end-products, as intended to be sold to consumers, also need to be categorized appropriately, since they could fall into any of the categories described previously, that is Category 1, 2A or 2B.
    a. For example, if a secondary manufacturer uses a frozen Category 2B RTE smoked fish to make a RTE refrigerated smoked fish mousse that supports the growth of *L. monocytogenes* and has a refrigerated shelf-life greater than 5 days, this mousse would be considered a Category 1 RTE food.
2) When an initially frozen RTE food is repackaged and intended by the secondary manufacturer to be stored under refrigeration, these second-generation RTE end-products also need to be categorized appropriately, since they could fall into any of the categories described previously, that is Category 1, 2A or 2B.

There may be situations involving frozen RTE foods where the manufacturer's intended storage condition is not met. The following situations should trigger an assessment to determine if they represent a health concern. Risk management actions may be needed.

3) A frozen RTE food that has been temperature-abused prior to reaching retail. In this situation, the growth of *L. monocytogenes* may have occurred.
4) A finding of *L. monocytogenes* in a frozen RTE food that is labelled 'Keep Frozen' on the package, but is otherwise thawed for sale at retail.
    a. As specified (see Section 2 under Purpose and scope), retail food businesses that sell food directly to consumers are not subject to the *Listeria* policy. Nevertheless, all businesses that sell food in Canada are subject to all relevant provisions of the *Food and Drugs Act*, including sections 4 and 7 (Government of Canada, 2023a).

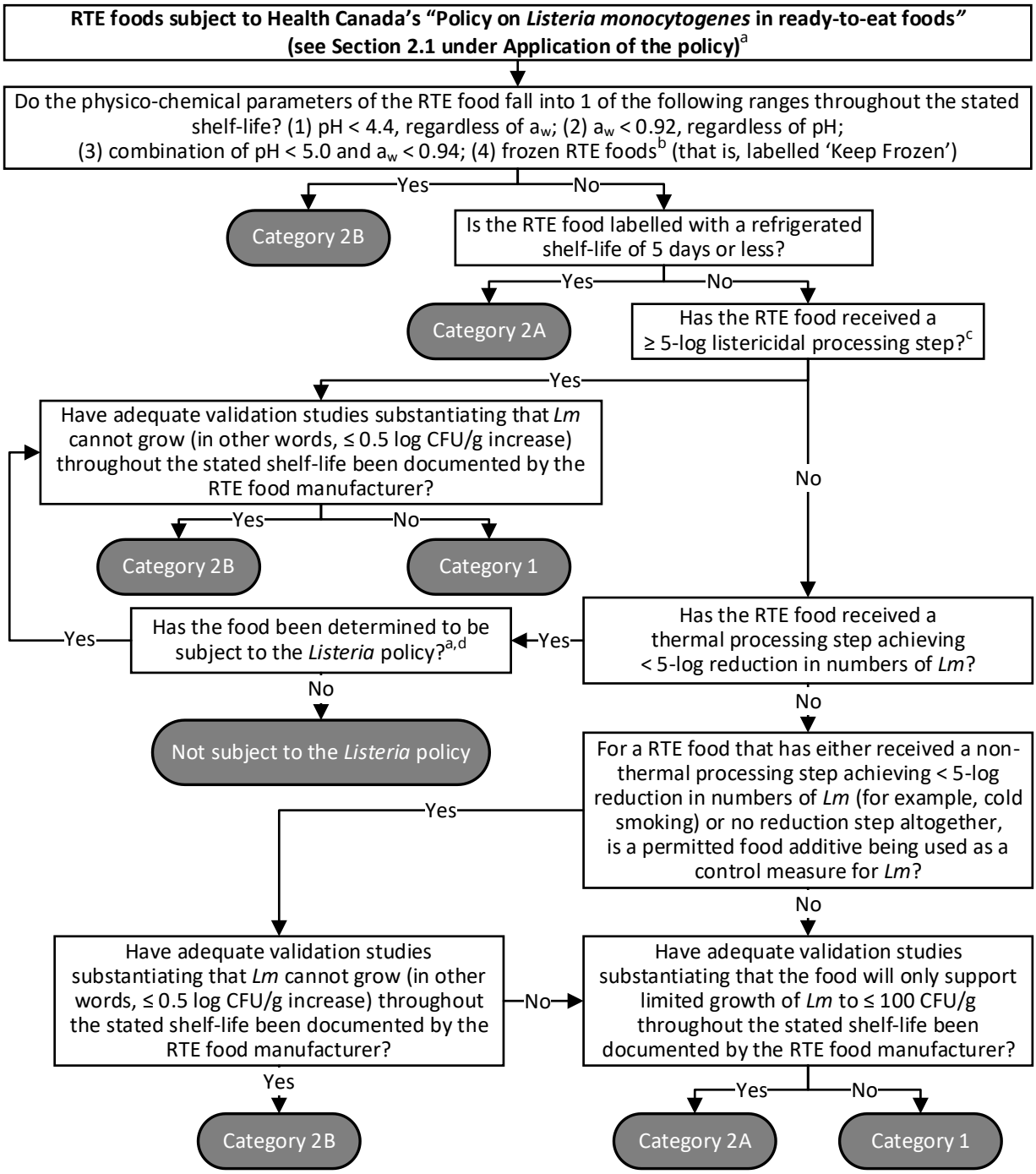
6.1.3 Ready-to-eat foods for vulnerable populations

RTE food businesses should consider their business model and client expectations as they pertain to food for vulnerable populations (for example, food being sold or marketed to such special groups of consumers or institutions). Hence, RTE foods specifically produced for consumption by vulnerable populations are those foods for which food businesses have specified consumption by people with weakened immune systems, pregnant people or adults ages 60 and over (for example, RTE foods that will be consumed in a hospital setting, convalescent care centres, long-term care facilities) in the product description of their HACCP plan or PCP. These RTE foods should be monitored and sampled at a greater frequency as compared to foods produced for consumption by the general population (CAC, 2020) (Table 1). Furthermore, other specific control measures (see Section 7.1.1 under Process control and Appendix C) may be taken for these foods as the presence of *L. monocytogenes* in such foods represents an increased health concern for these populations.

Irrespective of category, the detection of *L. monocytogenes* in RTE foods specifically produced for consumption by vulnerable populations (as specified in Section 7.3 and Table 1 under Sampling and testing of ready-to-eat foods) may trigger a Health Risk 1 concern, and not a Health Risk 2 concern, given the significantly increased susceptibility of vulnerable populations in acquiring foodborne listeriosis (see Section 5 under Scientific basis for the policy). In such situations, risk management actions may be needed.

As per the definition of RTE foods (see Section 2.1 under Application of the policy), certain refrigerated or frozen processed foods labelled on the package with validated cooking instructions would be excluded from the *Listeria* policy. However, as vulnerable individuals have an increased susceptibility to infection with *L. monocytogenes*, additional recommendations as described in Section 2.1.1.1 under Requirements and best practices for foods excluded from the policy should be taken into account.

Figure 1: Categorization of ready-to-eat foods



a) If there is uncertainty regarding whether a food is subject to the *Listeria* policy, the relevant regulatory authority should be contacted.

b) To categorize a frozen RTE food, manufacturers should take into consideration the information specified on the label of the package pertaining to thawing times and temperatures, as well as any refrigerated shelf-life after thawing; and process controls, that is Critical Control Points (CCPs) pertaining to the food's formulation. If there is uncertainty regarding the categorization of a RTE food, the relevant regulatory authority should be contacted.

c) For the purpose of the *Listeria* policy, a '≥ 5-log listericidal processing step' represents a validated treatment by the RTE food manufacturer that achieves a minimum 5-log reduction in numbers of *L. monocytogenes*.

d) For example, this could be processed foods which have a cooked appearance (but are not fully cooked).

7 Control measures to meet the Table 1 microbiological criteria for *L. monocytogenes* in ready-to-eat foods

7.1 Control of ready-to-eat food manufacturing

RTE food manufacturers should have effective GMPs in place and be able to demonstrate that their food safety system controls *L. monocytogenes* in RTE foods in order to meet the microbiological criteria specified in Table 1. As incoming raw ingredients may contain *L. monocytogenes*, RTE food manufacturers should consider developing supply-chain controls on raw ingredients (for example, a formal agreement with the suppliers, Certificate of Analysis, GAP certification) and applying validated processing steps that would eliminate or reduce numbers of *L. monocytogenes*.

RTE food manufacturers should be aware that the following factors influence the potential for the introduction of *L. monocytogenes* in the post-process areas where foods are exposed to the environment prior to packaging (CAC, 2009a):

- infrastructure
- plant layout (for example, traffic control, separation of equipment and utensils between raw and RTE areas)
- equipment design and maintenance (for example, equipment that require disassembly, such as slicing equipment)
- effectiveness of sanitation practices
- employee training and practices

This is managed through the implementation of GMPs, including adequate sanitation practices. Rigorous adherence to GMPs is essential due to the potential presence of *Listeria* spp. in the environment, with their ability to spread and thrive in the processing environment (Farber et al., 2021). As such, a multi-facetted approach should be used to prevent persistence of *Listeria* spp. via the physical disruption of biofilms and application of sanitizers which may need to be rotated, as applicable (Spanu and Jordan, 2020; Mazaheri et al., 2021). In addition, sanitation management can lead to innovations and sanitary design improvement (for example, equipment, facility).

Several scientific publications are available on how to minimize the presence of *Listeria* in RTE food manufacturing environments (Tompkin et al., 1999; Zoellner et al., 2019; Spanu and Jordan, 2020). In addition, workshops and documents developed by food industry trade associations on current best practices for the control of *L. monocytogenes* in RTE foods and the implementation of environmental monitoring programs within specific segments of the industry are also accessible. These resources may represent good supplementary information for RTE food manufacturers.

Furthermore, RTE food manufacturers should conduct on-site observation to assess adherence to GMPs that can influence the presence of *Listeria* spp. in the food processing environment (CAC, 2009a). Keeping in mind that the presence of *Listeria* spp. is an indicator of the potential presence of *L. monocytogenes*, it is not possible to predict, by visual observation alone, the degree to which *Listeria* spp. may occur in areas where RTE foods are exposed both before and during final packaging. An effective environmental monitoring program, supported by investigative sampling to detect sources of *Listeria* spp., should be used to identify additional steps the manufacturer should take to continuously improve its food safety system. Experience indicates that environmental sampling is the most sensitive tool to verify the effectiveness of control

measures to prevent the introduction of *L. monocytogenes* into RTE foods (Tompkin et al., 1992; Tompkin, 2002; Farber et al., 2021).

7.1.1 Process control

Increased knowledge of the ecology of *L. monocytogenes* in RTE foods has clarified the categories of foods in which the growth of *L. monocytogenes* can or will not occur. Some RTE food manufacturers may also use food additives to control *L. monocytogenes* throughout the shelf-life of a food (see Appendix C). Although food additives have a long history of use against foodborne pathogens by limiting their growth or by reducing their numbers, manufacturers should confirm that the specific use of a food additive is permitted in Canada and validate its efficacy in the food under consideration. Furthermore, food processing aids and post-packaging treatments can also be used to eliminate or reduce numbers of *L. monocytogenes* in RTE foods (see Appendix C).

7.2 Environmental sampling (Figures 2, 3 and 4) and testing

Steps should be taken to reduce the potential for the introduction of *L. monocytogenes* into RTE foods by addressing *Listeria* spp. in the food processing environment. It is important that RTE food manufacturers are able to demonstrate that their food safety system will prevent *L. monocytogenes* from establishing itself in their manufacturing facilities by performing environmental sampling and testing. Risk-based frequency details are left to the discretion of the relevant regulatory authority (CFIA, 2023). The presence of *Listeria* spp. in a RTE food plant indicates that GMPs may be inadequate, as it suggests the potential presence of *L. monocytogenes* in the environment or the food. Any observation of the inadequate implementation of GMPs that could lead to the introduction of *L. monocytogenes* into a RTE food should trigger a review of the manufacturer's process and procedures. This review should also take into account environmental and end-product test results.

If *Listeria* spp. are found in the environment, RTE food manufacturers should conduct investigative sampling to determine their origin, following Figures 2 to 4. Investigative sampling differs from the routine environmental sampling used to monitor the control of *Listeria* spp. It involves collecting additional samples from different sites to help identify more clearly the potential sources of *Listeria* spp. Investigative sampling is an indispensable approach for identifying and eliminating harbourage sites (Tompkin, 2002; CAC, 2009a). RTE food manufacturers should identify and eliminate potential sources of *Listeria* spp. (for example, root cause analysis) by performing process review, environmental sampling and end-product testing. Furthermore, if the review indicates that *Listeria* spp. are not being controlled (for example, processing conditions that cannot eliminate *Listeria* spp. in the raw materials, an inadequate food safety system that cannot eliminate *Listeria* spp. from the post-process environment), this should be taken as evidence for the need to improve control measures. RTE food manufacturers should respond, in a timely manner, to all positive environmental test results, with appropriate corrective actions.

The expected steps to be undertaken by RTE food manufacturers when sampling both food contact surfaces (FCSs), that is, any surface or object that comes into contact with RTE foods, and non-FCSs, that is, any surface or object that does not come into contact with RTE foods, and testing for *Listeria* spp., are outlined in this section. The steps indicated in Figures 2 to 4 represent the minimum sampling and testing recommended by Health Canada. Manufacturers can exceed these minimum recommendations. Health Canada's Compendium of Analytical Methods lists methods that have been accepted for use in the administration of the *Food and Drugs Act* and *Regulations* (Health Canada, 2021a). Details on environmental sampling are described in method MFLP-41 (Health Canada, 2010). Methods and laboratory procedures for the analytical

testing of environmental samples for *Listeria* spp. can also be found in the compendium. Industry should confirm that the 'application' section of the method is appropriate for the intended purpose.

It is important to perform environmental sampling in post-process areas where foods are exposed to the environment prior to packaging since positive results could be indicative of the potential presence of *L. monocytogenes*. Verifying that the processing environment is free from *Listeria* spp. (that is, reduced to below detectable levels) is the key to producing safe RTE foods.

A risk-based approach should be used in designing an environmental monitoring program. The environment of the following foods should be monitored and sampled at greater frequencies:

- food that is specifically produced for consumption by vulnerable populations
- food in which the growth of *L. monocytogenes* to levels exceeding 100 CFU/g can occur throughout the stated shelf-life
- food that does not contain *L. monocytogenes* inhibitors
- food that is not subjected to a post-packaging treatment before distribution

The specifics of an environmental sampling plan should be determined based on the probability that finding a *Listeria* spp. positive site could be indicative of the introduction of *L. monocytogenes* into RTE foods. One approach to consider such probability is by dividing the plant into different zones (ICMSF, 2018a; Simmons and Wiedmann, 2018; Spanu and Jordan, 2020). With the zone concept, Zone 1 would represent the highest probability for the introduction of *L. monocytogenes* into RTE foods and Zone 4 would represent the lowest probability for the introduction of *L. monocytogenes* into RTE foods. Zone 1 would include FCSs where RTE foods are exposed to the environment prior to packaging. Zone 2 would include non-FCSs in proximity to Zone 1 (for example, control panels adjacent to FCSs). Zone 3 would be further from the packaging area, but within the processing area (for example, floor drains, walls). Zone 4 would be located outside the processing and packaging areas (for example, outside of the area where RTE foods are exposed, such as loading docks, locker rooms and cafeterias). It would be expected that more environmental samples be taken from Zones 1 and 2, while Zones 3 and 4 may be sampled at a lower frequency.

The environmental monitoring program should be sufficiently robust regarding sampling selection, frequency of sampling, number of samples, method of sampling and so on to enable both RTE food manufacturers and the relevant regulatory authority to conclude, when reviewing data, that the foods being produced are safe (CAC, 2009a; CAC, 2020).

7.2.1 Food contact surfaces

Each RTE food manufacturer should have an environmental monitoring program that has been designed to assess the effectiveness of control measures, including sanitation and other GMPs, as well as the potential for the introduction of *L. monocytogenes* into RTE foods. Environmental monitoring programs should include routine sampling of FCSs that come into contact with exposed RTE foods prior to packaging. Such samples should be collected during production, typically after 3 hours of operation. The use of sponges or swabs to sample the surface areas of equipment is recommended. Examples of FCSs include: chill brines, containers, racks for transportation, conveyor belts, slicers, dicers, shredders, blenders, tables and equipment used to assemble/package foods, packaging equipment, hand tools, gloves, aprons, metal surfaces with gaps (for example, bad welding), food residue sites and other hard to clean areas (Health Canada, 2010).

Furthermore, additional sampling may be conducted immediately before start-up, to verify the effectiveness of sanitation. As part of their verification activities, RTE food manufacturers may find testing for adenosine

triphosphate (ATP) bioluminescence or aerobic colony/plate count (ACC or APC) to be useful for this purpose. However, these methods cannot be used to replace testing for *Listeria* spp.

The number of sites (for example, 1 to 10) tested will vary according to the complexity of the processing system and packaging line. The frequency and points for routine sampling should be plant and line-specific, based on the manufacturing processes and control measures present (Tompkin et al., 1992; Zoellner et al., 2018). Samples should also be collected from non-FCSs as an additional measure of monitoring and verification. An increase in sampling sites (FCSs and non-FCSs), as well as the frequency of sampling, should be considered both during and after special circumstances (for example, construction, the installation or modification of equipment, overhead/ceiling leaks in exposed food areas), since these activities may lead to a loss of *L. monocytogenes* control in the food processing area (Tompkin, 2002; Spanu and Jordan, 2020). RTE food manufacturers should consider seeking expert technical advice to customize the best approach for their environmental sampling.

One of the goals of the *Listeria* policy is to encourage RTE food manufacturers to perform robust environmental sampling on a regular basis and to perform trend analysis on their results to detect problems that need corrective actions. Figures 2 and 3 are reflective of the risk the RTE food may pose to consumers if *L. monocytogenes* is present. RTE food manufacturers should respond as soon as possible to all positive FCS test results, with appropriate follow-up actions, including corrective actions (see Section 7.2.3 under Corrective actions for positive test results of food contact surfaces and non-food contact surfaces) and investigative sampling (as per Figures 2 and 3). These actions should take into account the type and location of the sampling sites, as well as the category of food. At a minimum, the FCSs in the routine monitoring program should be included when re-sampling. In some situations, food in various stages of processing or product build-up can be used as additional FCS samples to further assess the presence of *Listeria* spp. along a production line or system. Furthermore, if FCS samples are found positive at 2 (Figure 2) or more (Figure 3) steps, end-product testing should be performed.

Testing for *Listeria* spp. and reacting to positive results as if they were *L. monocytogenes* provides for a more sensitive and broader environmental monitoring program than would testing for *L. monocytogenes* alone (Farber et al., 2021). Nevertheless, if manufacturers choose to test FCSs for *L. monocytogenes* instead of *Listeria* spp., it is recommended that individual lots of food produced at the time of FCS sampling be held pending results from this testing. End-product testing for *L. monocytogenes* should be performed if *L. monocytogenes* is detected on a FCS (Figures 2 and 3).

7.2.1.1 Persistence of *Listeria* spp. on food contact surfaces

In a situation where 2 or more FCS samples from the same production line (that is, using the same equipment) are found positive for *Listeria* spp. within a short timeframe, such a situation is considered to be potential evidence of persistence and an indication that the food safety system (for example, GMPs, sanitation practices) may be inadequate to prevent the establishment of *Listeria* spp. in the food processing environment. This short timeframe is operation-specific. It will vary based on factors such as production volume, production seasonality and testing frequency.

RTE food manufacturers should respond as soon as possible with appropriate follow-up actions, including corrective actions (see Section 7.2.3 under Corrective actions for positive test results of food contact surfaces and non-food contact surfaces) and investigative sampling. Investigative sampling will assist in finding and eliminating the source of *Listeria* spp., particularly if there is a harbourage site from which *Listeria* spp. or a specific subtype of *L. monocytogenes* is repeatedly isolated (CAC, 2009a). These actions should take into

account the type and location of the sampling sites, as well as the category of food. This information should be communicated as soon as possible to the relevant regulatory authority.

7.2.2 Non-food contact surfaces

Environmental monitoring programs should also include routine sampling of non-FCSs. Examples of non-FCSs include: drains, standing water, cracks in floors and walls, smokehouses, floors in heavily-trafficked areas, tires on fork-lift trucks, foot and wheel baths that are in poor condition, high-pressure hoses, cleaning tools (mops, squeegees, brushes and so on), trash cans, under-side of conveyor belts, hollow rollers, roller guards, bearings, chill tanks, refrigerators, cold rooms, ice makers, overhead pipes, drip pans, wet insulation, maintenance tools, dust from construction and air filtration equipment (Health Canada, 2010).

It is important to perform follow-up actions (including corrective actions, see Section 7.2.3) when non-FCSs test positive for *Listeria* spp. (Figure 4). In general, detection of *Listeria* spp. from non-FCSs, including *L. monocytogenes*, usually precedes their detection from FCSs (Tompkin et al., 1999; D'Amico and Donnelly, 2008). Accordingly, identifying sources of *Listeria* spp. away from the production line and preventing their transfer within the food processing environment is a fundamental principle of *Listeria* control. It should be noted that the sampling sites selected after the completion of corrective actions may differ from those assessed during routine monitoring. Upon re-sampling, the original or nearby sites might be negative, but other sites might reveal a positive, and hence be informative in resolving the problem. Positive test results collected over time can also be used to determine a trend. A review of data from trend analysis would indicate whether the RTE food manufacturer is properly controlling *Listeria* (see Section 7.4 under Importance of trend analysis).

7.2.3 Corrective actions for positive test results of food contact surfaces and non-food contact surfaces

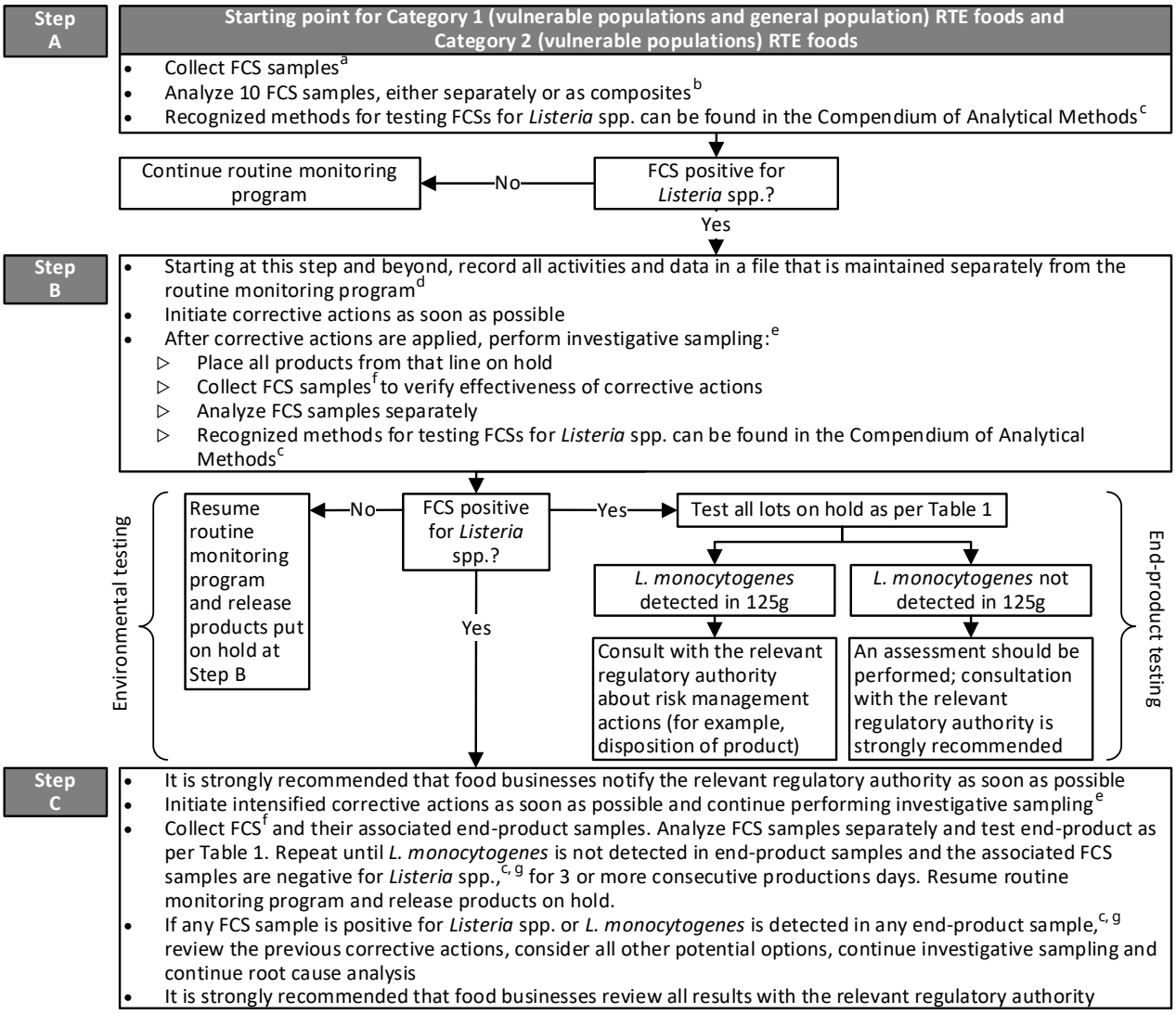
RTE food manufacturers should respond as soon as possible to all positive FCS and non-FCS test results for *Listeria* spp. (Figures 2 to 4) with appropriate corrective actions. These may include the following:

- increasing or correcting sanitation procedures
    - intensified cleaning and sanitizing beyond FCSs, including equipment disassembly
    - verification of cleaning and sanitizing procedures
    - intense cleaning and sanitizing of the surrounding areas
    - modification of equipment for improved cleanability
- performing additional sampling (Figures 2 to 4)
    - timely re-testing of the positive sites
    - testing of RTE foods that were potentially in contact with positive FCSs
- obtaining additional data to confirm hypotheses when conducting root cause analysis
- developing and implementing an investigative sampling plan (for the affected line and possibly the food)
- in-depth review of the RTE food manufacturer's food safety system (for example, HACCP plan) and making necessary changes to reduce the potential for the introduction of *L. monocytogenes* in the post-process areas where foods are exposed to the environment prior to packaging (see Section 7.1 under Control of ready-to-eat food manufacturing)

Corrective actions should be monitored to confirm their effectiveness. All of this information should be documented and integrated into the RTE food manufacturer's trend analysis (see Section 7.4 under Importance of trend analysis).

RTE food manufacturers should attempt to determine the potential sources of *Listeria* spp. by means of process review, environmental sampling (including investigative sampling) and end-product testing.

Figure 2: Sampling guidelines for food contact surfaces, Category 1 ready-to-eat foods and Category 2 ready-to-eat foods specifically produced for consumption by vulnerable populations



a) With the zone concept, Zone 1 includes FCSs where RTE foods are exposed to the environment prior to packaging. The number of meaningful sampling sites (10 recommended) selected on each processing line should depend upon the complexity of the lines. Details on environmental sampling are described in method MFLP-41 (Health Canada, 2010).

b) If analyzing FCS samples as composites, a maximum of 10 FCS samples should be combined.

c) The 'application' section of the method should be appropriate for the intended purpose (for example, MFHPB and MFLP methods; Health Canada, 2021a).

d) The records should include information on corrective actions, investigative sampling, end-product testing and risk management actions (for example, disposition of product).

e) Investigative sampling will assist in finding and eliminating the source of *Listeria* spp., particularly if there is a harbourage site from which *Listeria* spp. or a specific subtype of *L. monocytogenes* is repeatedly isolated.

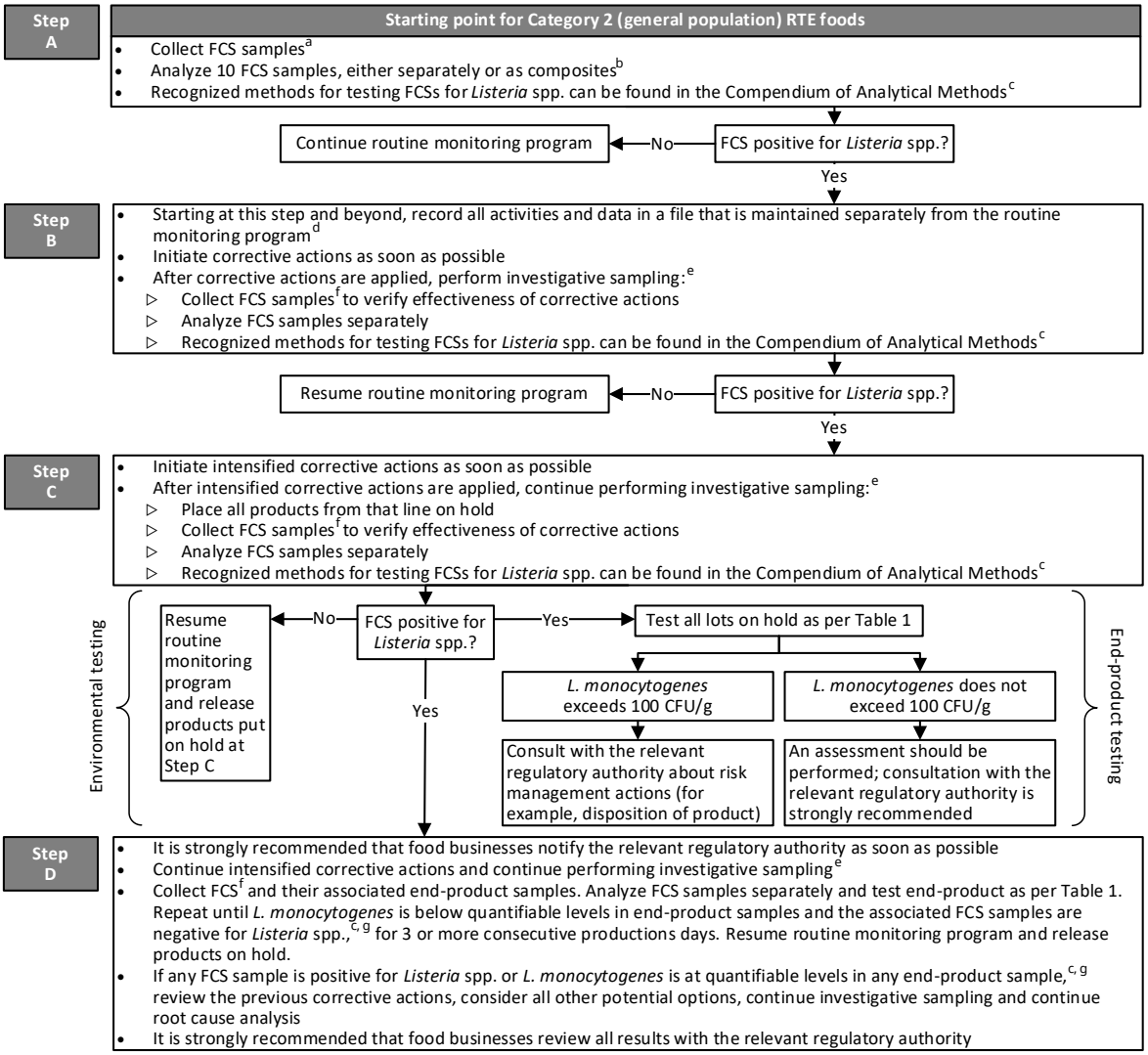
f) At a minimum, the FCS sites in the routine monitoring program should be included. The number and location of samples should be adequate to verify that the entire line is negative and under control.

g) A qualitative method for *L. monocytogenes* (that is, a detection method using enrichment) should be used for end-product testing. Recognized methods for end-product testing can be found in the Compendium of Analytical Methods (Health Canada, 2021a).

Note 1: The steps indicated in this figure represent the minimum sampling and testing recommended by Health Canada. RTE food manufacturers can exceed these minimum recommendations.

Note 2: End-product testing for *L. monocytogenes* should be performed if *L. monocytogenes* is detected on a FCS.

Figure 3: Sampling guidelines for food contact surfaces and Category 2 ready-to-eat foods produced for consumption by the general population



a) With the zone concept, Zone 1 includes FCSs where RTE foods are exposed to the environment prior to packaging. The number of meaningful sampling sites (10 recommended) selected on each processing line should depend upon the complexity of the lines. Details on environmental sampling are described in method MFLP-41 (Health Canada, 2010).

b) If analyzing FCS samples as composites, a maximum of 10 FCS samples should be combined.

c) The 'application' section of the method should be appropriate for the intended purpose (for example, MFHPB and MFLP methods; Health Canada, 2021a).

d) The records should include information on corrective actions, investigative sampling, end-product testing and risk management actions (for example, disposition of product).

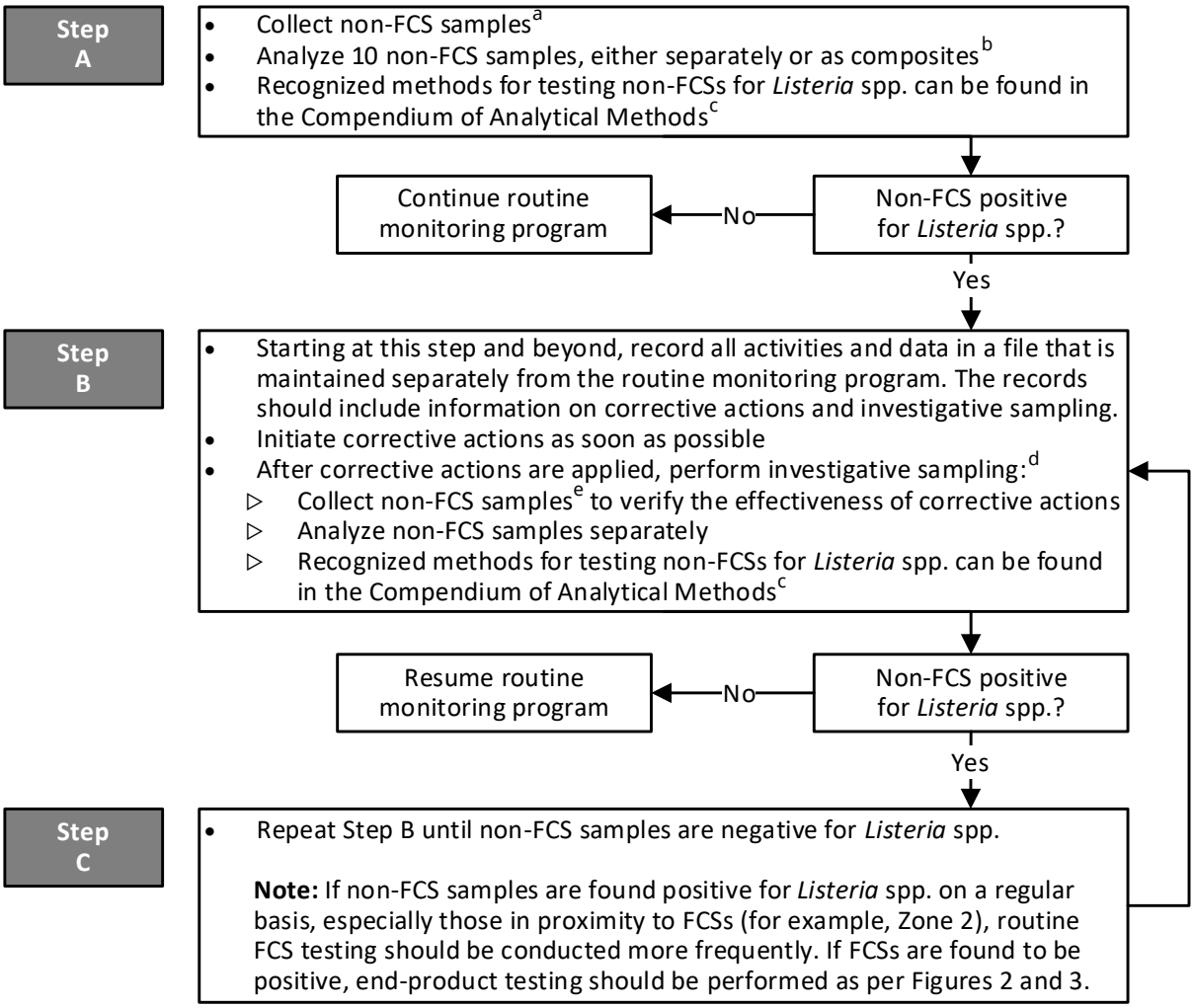
e) Investigative sampling will assist in finding and eliminating the source of *Listeria* spp., particularly if there is a harbourage site from which *Listeria* spp. or a specific subtype of *L. monocytogenes* is repeatedly isolated.

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) A quantitative method for *L. monocytogenes* (that is, an enumerative method done by direct plating onto selective agar) should be used for end-product testing. Recognized methods for end-product testing can be found in the Compendium of Analytical Methods (Health Canada, 2021a).

Note 1: The steps indicated in this figure represent the minimum sampling and testing recommended by Health Canada. RTE food manufacturers can exceed these minimum recommendations.
Note 2: End-product testing for *L. monocytogenes* should be performed if *L. monocytogenes* is detected on a FCS.

Figure 4: Sampling guidelines for non-food contact surfaces, especially those in proximity to food contact surfaces



a) With the zone concept, Zones 2, 3 and 4 include non-FCSs. The number of meaningful sampling sites (10 recommended) selected in the plant should depend upon the complexity of the plant. Details on environmental sampling are described in method MFLP-41 (Health Canada, 2010).

b) If analyzing non-FCS samples as composites, a maximum of 10 non-FCS samples should be combined.

c) The 'application' section of the method should be appropriate for the intended purpose (for example, MFHPB and MFLP methods; Health Canada, 2021a).

d) Investigative sampling will assist in finding and eliminating the source of *Listeria* spp., particularly if there is a harbourage site from which *Listeria* spp. or a specific subtype of *L. monocytogenes* is repeatedly isolated.

e) The sampling sites may differ after completing corrective actions. Upon re-sampling, the original or nearby sites might be negative but sampling other sites might reveal a positive, and hence be informative in resolving the problem.

Note: The steps indicated in this figure represent the minimum sampling and testing recommended by Health Canada. RTE food manufacturers can exceed these minimum recommendations.

7.3 Sampling and testing of ready-to-eat foods (Table 1)

When manufacturing RTE foods, rigorous adherence to GMPs (with a focus on adequate sanitation) coupled with environmental monitoring (that is, implementation of an appropriate environmental sampling plan; Figures 2 to 4) is the most desirable approach to control *Listeria* in the food processing environment. Relying on the results of environmental testing will allow for better decision-making regarding the release of RTE foods, rather than relying solely on end-product testing. Accordingly, microbiological testing of food that results in no detection of *L. monocytogenes* may not portray the true overall microbiological condition of the food, as in general, testing gives only very limited information on the safety status of a food. This is due to, among other things, the non-uniform distribution of bacteria, such as *L. monocytogenes,* within a food (ICMSF, 2018b).

Nonetheless, end-product testing can be informative and is conducted for many different reasons, for example:

- as part of the *Listeria* environmental monitoring program (for example, evaluation of end-product when FCSs test positive for *Listeria* spp., as stipulated in Figures 2 and 3)
- periodic testing to verify the process or the effectiveness of control measures to prevent the introduction of *L. monocytogenes* into RTE foods
- verification of the effectiveness of food additives or food processing aids
- performing trend analysis
- regulatory compliance
- customer requirements
- foreign country requirements
- testing of foods sampled at various points in distribution, including retail, as part of surveillance or food safety investigation activities (for example, testing of previously distributed lots where continued exposure is expected)

Moreover, end-product testing for *L. monocytogenes* should be performed if *L. monocytogenes* is detected on a FCS (see Section 7.2 and Figures 2 and 3 under Environmental sampling and testing).

When testing RTE foods, food businesses should develop and implement:

- written procedures for end-product testing with details on any hold and test procedures
- sampling procedures
- specifics of sampling frequency and size
- methodologies to be used for testing (details regarding methodological approaches are left to the discretion of the relevant regulatory authority (CFIA, 2023))
- follow-up actions

It is recommended that individual lots of food being tested be held pending results from testing, as specified in Table 1. Any test results for *L. monocytogenes* in a RTE food, at levels exceeding those specified in Table 1, should be addressed immediately by the food business. It is strongly recommended that food businesses communicate this information as soon as possible to the relevant regulatory authority having jurisdiction over risk management actions.

Samples of RTE foods submitted for the testing of *L. monocytogenes* should consist of 5 sample units of at least 100 g or mL each (Table 1), taken at random, and should be representative of the lot and the production conditions. In the case where individual lots cannot be differentiated by clear product markings or if the food

business is unable to provide information that would allow for the differentiation of individual lots, then the entire day's production or the whole shipment would be considered as a single lot.

7.3.1 Ready-to-eat foods specifically produced for consumption by vulnerable populations

Irrespective of category, a qualitative method for *L. monocytogenes* (that is, a detection method using enrichment) should be used for end-product testing of RTE foods specifically produced for consumption by vulnerable populations. Recognized methods, such as MFHPB-30 (Pagotto et al., 2011a), can be found in the Compendium of Analytical Methods (Health Canada, 2021a). Industry should confirm that the 'application' section of the method is appropriate for the intended purpose. An analytical sample size of 5 × 25 g for these RTE foods should be used and analyzed separately or as a composite, as specified in Table 1.

When *L. monocytogenes* is detected in RTE foods specifically produced for consumption by vulnerable populations, the food business should start an investigation to determine whether potentially unsafe food has left its control and if so, the extent of distribution (for example, retail level, consumer level). It is also important to try to determine the source of *L. monocytogenes*, where its introduction has occurred and the lots involved. Investigative sampling will assist in finding and eliminating the source of *Listeria* spp., particularly if there is a harbourage site (Figure 2; CAC, 2009a). The food business should take action on identified unsafe lots of food. The investigation may reveal that previous or subsequent lots produced under the same conditions may be impacted and may represent a health concern. In such situations, risk management actions may be needed. More specifically, the detection of *L. monocytogenes* in these RTE foods should trigger immediate follow-up by the food business as described in steps B and C of Figure 2. It is strongly recommended that food businesses communicate this information as soon as possible to the relevant regulatory authority having jurisdiction over risk management actions.

7.3.2 Category 1 ready-to-eat foods

A qualitative method for *L. monocytogenes* (that is, a detection method using enrichment) should be used for end-product testing of Category 1 RTE foods. Recognized methods, such as MFHPB-30 (Pagotto et al., 2011a), can be found in the Compendium of Analytical Methods (Health Canada, 2021a). Industry should confirm that the 'application' section of the method is appropriate for the intended purpose. An analytical sample size of 5 × 25 g for these RTE foods should be used and analyzed separately or as a composite, as specified in Table 1.

When *L. monocytogenes* is detected in a Category 1 RTE food, the food business should start an investigation to determine whether potentially unsafe food has left its control and if so, the extent of distribution (for example, retail level, consumer level). It is also important to determine the source of *L. monocytogenes*, where its introduction has occurred and the lots involved. Investigative sampling will assist in finding and eliminating the source of *Listeria* spp., particularly if there is a harbourage site (Figure 2; CAC, 2009a). The food business should take action on identified unsafe lots of food. The investigation may reveal that previous or subsequent lots produced under the same conditions may be impacted and may represent a health concern. In such situations, risk management actions may be needed. More specifically, the detection of *L. monocytogenes* in these RTE foods should trigger immediate follow-up by the food business as described in steps B and C of Figure 2. It is strongly recommended that food businesses communicate this information as soon as possible to the relevant regulatory authority having jurisdiction over risk management actions.

7.3.3 Category 2 (2A and 2B) ready-to-eat foods

A quantitative method for *L. monocytogenes* (that is, an enumerative method done by direct plating onto selective agar) should be used for end-product testing of Category 2 RTE foods. Recognized methods, such as MFLP-74 (Pagotto et al., 2011b), can be found in the Compendium of Analytical Methods (Health Canada, 2021a). Industry should confirm that the 'application' section of the method is appropriate for the intended purpose. An analytical sample size of 5 × 10 g for this specific category of RTE food should be used and each analytical unit should be analyzed separately, as specified in Table 1.

When levels of *L. monocytogenes* exceed 100 CFU/g in a Category 2 RTE food, the food business should start an investigation to determine whether potentially unsafe food has left its control and if so, the extent of distribution (for example, retail level, consumer level). It is also important to try to determine the source of *L. monocytogenes*, where its introduction has occurred and the lots involved. Investigative sampling will assist in finding and eliminating the source of *Listeria* spp., particularly if there is a harbourage site (Figure 3; CAC, 2009a). The food business should take action on identified unsafe lots of food. The investigation may reveal that previous or subsequent lots produced under the same conditions may be impacted and may represent a health concern. In such situations, risk management actions may be needed.

More specifically, regardless of the *L. monocytogenes* levels in a Category 2 RTE food, immediate follow-up should be triggered by the food business as described in steps C and D of Figure 3, as well as in Section 7.3.4 under Follow-up actions to positive ready-to-eat food test results. It is strongly recommended that food businesses communicate this information as soon as possible to the relevant regulatory authority having jurisdiction over risk management actions. The presence of *L. monocytogenes* at levels between 5 and 100 CFU/g in a Category 2 RTE food, occurring repeatedly at brief intervals, is likely an indication of an inadequate food safety system unable to control *L. monocytogenes*.

7.3.4 Follow-up actions to positive ready-to-eat food test results

Any RTE food that yields a positive test result for *L. monocytogenes* must lead to corrective actions by the food business, such as:

- recalling food (that is, removing implicated foods from further sale or use, at any point in the supply chain)
- initiating investigative sampling
- initiating additional end-product testing
- initiating a review of the food safety system

Table 1: Sampling methodologies and microbiological criteria for *Listeria monocytogenes* in ready-to-eat[a] foods

Ready-to-eat (RTE) food category (intended consumers)	Sampling	Analysis	End-product testing	Action level for *L. monocytogenes*	Level of concern	Level of priority[b]
Any category (vulnerable populations) RTE foods specifically produced for consumption by vulnerable populations, **irrespective** of RTE food category **Category 1 (general population)** RTE foods in which the growth of *L. monocytogenes* **can** occur[c] throughout the stated shelf-life (for example,[d] deli-meats, soft cheeses, hot dogs, meat spreads)	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 × 25 g analytical units,[e] analyzed either separately or composited	Detection	**Detected in 125 g** [f, g]	**Health Risk 1**[h]	High
Category 2A (general population) RTE foods in which a **limited** potential for growth of *L. monocytogenes* to levels not exceeding 100 CFU/g **can** occur[c] throughout the stated shelf-life. A number of factors will be taken into consideration with regards to which foods may fall into this Category, that is, (1) RTE foods which are known to occasionally contain low levels of *L. monocytogenes* and their processing does not involve any heat treatment **(based on validation)**; (2) RTE refrigerated foods with a stated shelf-life of 5 days or less. Such foods could include fresh-cut fruits and vegetables. **Category 2B (general population)** RTE foods in which the growth of *L. monocytogenes* **will not** occur[l] (that is, increase not exceeding 0.5 log CFU/g) throughout the stated shelf-life (**based on validation, as applicable**). Such foods could include ice cream, hard cheese and frozen fruits.	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 × 10 g analytical units,[e] analyzed separately	Enumeration	**> 100 CFU/g**[i, j]	**Health Risk 2**[h, k]	Medium to low

Note: If insufficient, inadequate or no information exists regarding the Category 2A or 2B categorization of the RTE food, it will be considered as a Category 1 RTE food. As such, the sampling and testing methodologies for Category 1 RTE foods, as specified in Table 1, should be used. Should questions arise regarding food categorization, the RTE manufacturer should be able to demonstrate in which category the RTE food falls. In cases where validation was conducted for categorization, the manufacturer should have documentation of adequate validation studies substantiating that *L. monocytogenes* cannot grow or that the RTE food will only support limited growth of *L. monocytogenes* to ≤ 100 CFU/g throughout the stated shelf-life.

a) For a definition of RTE foods, see Section 2.1 under Application of the policy.

b) Other criteria (for example, process, packaging, trend analysis, outbreak data) could also have an impact on the level of priority for the frequency of process monitoring, environmental sampling and end-product testing. Risk-based frequency details are left to the discretion of the relevant regulatory authority (CFIA, 2023).

c) For additional details on determining the RTE food category, see Figure 1 and Section 6.1 under Demonstrating the ready-to-eat food category.

d) These are traditional examples of Category 1 RTE foods.

e) The analytical unit is taken from each sample unit.

f) A qualitative method for *L. monocytogenes* (that is, a detection method using enrichment) should be used for end-product testing of such RTE foods. Recognized methods, such as MFHPB-30 (Pagotto et al., 2011a), can be found in the Compendium of Analytical Methods (Health Canada, 2021a). Industry should confirm that the 'application' section of the method is appropriate for the intended purpose. For additional details, see Section 7.3.1 under Ready-to-eat foods for vulnerable populations and Section 7.3.2 under Category 1 ready-to-eat foods.

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 log CFU/g would be detected and rejected if any of the 5 samples are positive for *L. monocytogenes* (CAC, 2009a).

h) For a definition of health risk levels, see Appendix A.

i) A quantitative method for *L. monocytogenes* (that is, an enumerative method done by direct plating onto selective agar) should be used for end-product testing of such RTE foods. Recognized methods, such as MFLP-74 (Pagotto et al., 2011b), can be found in the Compendium of Analytical Methods (Health Canada, 2021a). This will determine the concentration of *L. monocytogenes* (CFU/g) in the food. Industry should confirm that the 'application' section of the method is appropriate for the intended purpose. For additional details, see Section 7.3.3 under Category 2 (2A and 2B) ready-to-eat foods.

j) 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 5 samples exceeding 100 CFU/g *L. monocytogenes* (CAC, 2009a).

k) Levels of *L. monocytogenes* exceeding 100 CFU/g in a Category 2 RTE food, in any 1 of the analytical units will, at a minimum, trigger a Health Risk 2 concern.

l) For additional details on determining the RTE food category, see Figure 1 and Section 6.1.2.2 under Category 2B ready-to-eat foods.

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

- pH < 4.4, regardless of a_w
- a_w < 0.92, regardless of pH
- combination of factors (for example, pH < 5.0 and a_w < 0.94)
- frozen foods (that is, labelled 'Keep Frozen' on the package)

In the specific context of end-product testing for *L. monocytogenes*, the pH and a_w should be determined for at least 3 out of the 5 analytical units. Recognized methods for measuring pH and a_w, such as MFHPB-03 (pH) and MFLP-66 (a_w), can be found in the Compendium of Analytical Methods (Health Canada, 2021a). Industry should confirm that the 'application' section of the method is appropriate for the intended purpose. The growth of *L. monocytogenes* is presumed to occur if any 1 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).

7.4 Importance of trend analysis

As previously stated, RTE food manufacturers should not rely solely on end-product testing to verify their control measures for *L. monocytogenes*. The manufacturer's food safety system should use modern quality control and statistical methods to monitor the process and the effectiveness of control measures. This will allow for the detection of spatial-temporal patterns suggestive of sources of *L. monocytogenes*, particularly harbourage sites that may then be further investigated and eliminated (Zoellner et al., 2018). Data obtained from trend analysis can be modelled and used to verify control measures, as well as to assess environmental monitoring activities and to better target compliance activities. It is important to note that negative results, if due to an inappropriate sampling methodology, can lead to a false sense of safety. Positive findings should be viewed as the successful identification of an issue that should lead to follow-up actions, including corrective actions (Spanu and Jordan, 2020). Where possible, quality control and statistical methods should include modern graphical techniques (for example, control charts, Pareto diagrams). All data should be made available to individuals responsible for managing and overseeing the implementation and verification of control measures for *L. monocytogenes*. Responsibility for updating and disseminating the data should be assigned to 1 or more individuals within the organization (for example, quality assurance, food safety or HACCP coordinators).

On-going review and analysis of the data for *Listeria* spp. collected during routine monitoring, as well as from investigative sampling, should be performed to detect trends prior to the development of major issues. Such reviews should also provide information on the prevalence of *Listeria* spp. and its fluctuation over time. They also serve to identify issues that should be addressed in a timely manner. Attention should be given to the dates and locations of positive samples to determine whether low-level or sporadic positive samples occur at particular locations that may have gone previously unnoticed (CAC, 2009a). The use of the zone concept for environmental monitoring can be useful for early detection of *Listeria* spp. on non-FCSs to help prevent their transfer to FCSs (see Section 7.2 under Environmental sampling and testing). In situations where there is evidence of persistence (see Section 7.2.1.1 under Persistence of *Listeria* spp. on food contact surfaces), molecular characterization techniques such as whole-genome sequencing may help during root cause analysis to identify harbourage sites (persistence) or transient *Listeria* spp. in the food processing environment. As more information becomes available from trend analysis, it should be used to achieve improved control of *Listeria* as the RTE food manufacturer gains experience and makes necessary adjustments to its food safety system.

Appendix A: Glossary

The following terms have the following meaning for the purpose of the *Listeria* policy.

Control measure: Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level. (CAC, 2020)

Corrective action: Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product if any and prevent or minimize reoccurrence of the deviation. (CAC, 2020)

Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system. (CAC, 2020)

Food: Section 2 of the *Food and Drugs Act* defines 'food' as follows: Food includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever. (*aliment*) (Government of Canada, 2023a)

Food safety system: Managerial and administrative structures and processes to facilitate food safety program's design and delivery, ongoing maintenance, evaluation and continual improvement.

Good Agricultural Practices (GAPs): A generic term that includes all key conditions and practices by primary agricultural producers (for example, farms that grow crops, raise animals (including fish), or harvest plants, animals or animal products (CAC, 2020)) to reduce the risk of product contamination.

Good Manufacturing Practices (GMPs): A generic term that includes all key conditions and control measures during processing that is necessary for manufacturers to produce safe food of suitable quality.

Harbourage site: A harbourage site (also sometimes referred to as a niche) is an area where bacteria thrive (that is, can survive and grow) over a long time period.

Hazard Analysis Critical Control Points (HACCP): A system that identifies, evaluates and controls hazards that are significant for food safety. (CAC, 2009b)

HACCP plan: 'The written document that is based on the principles of HACCP and that delineates the procedures to be followed' by food manufacturers. (NACMCF, 1998)

Health risk assessment: A process which integrates a hazard identification, hazard characterization and exposure assessment determination to obtain a unique risk estimate. (Health Canada, 2011)

Health risk levels:
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, 2011)

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, 2011)

Hermetically sealed container: Section B.27.001 of Division 27, Part B (Foods) of the *Food and Drug Regulations* defines 'hermetically sealed container' as follows: Hermetically sealed container means a container designed and intended to be secure against the entry of microorganisms, including spores. (*récipient hermétiquement fermé*) (Government of Canada, 2023d)

Implicated ready-to-eat foods: At a minimum, all the foods processed on the same line (that is, using the same equipment) as the tested foods may be considered implicated when samples in the tested lot contain *L. monocytogenes* at levels exceeding those specified in Table 1. It should be noted that results from root cause analysis may also trigger the need to include additional foods as part of the implicated foods.

Line: A number of pieces of equipment (for example, slicers, tables, conveyors, packaging or filling machines) used in series in the post-process areas where foods are exposed to the environment prior to packaging.

Lot: A lot consists of all of the same food type processed on a given line, between 2 complete sanitation cycles. It is strongly recommended that the time between 2 cycles be a maximum of 1 day.

Low-moisture foods: Foods that have a water activity (a_w) of 0.85 or below. (CAC, 2018)

Microgreens: Immature seedlings of edible plants harvested above the growth media after 10 to 21 days, between full development of cotyledons and appearance of the first true leaves. (Riggio et al., 2019)

Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control. (CAC, 2020)

Persistence: Repetitive positive food contact surface test results, for example, 2 positive results for *Listeria* spp. from the same production line (that is, using the same equipment) in the ready-to-eat food manufacturing environment within a short timeframe. This timeframe is operation-specific and will vary based on factors such as production volume, production seasonality and testing frequency.

Post-packaging treatment: An additional treatment applied to packaged ready-to-eat foods to reduce the levels of, or to eliminate, *L. monocytogenes* present on the surface of foods due to the introduction of *L. monocytogenes* onto ready-to-eat foods during post-processing, prior to packaging (for example, surface heat pasteurization, high-pressure processing).

Post-process: The exposure of food to the environment after it has been processed to render it ready-to-eat and prior to packaging.

Process review: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether process controls are or have been operating as intended, as part of a ready-to-eat food manufacturer's verification activities (that is, verification of key process parameters used to control *L. monocytogenes*).

Ready-to-eat foods: Defined in Section 2.1 under Application of the policy. As applicable, food businesses should also be aware that the *Safe Food for Canadians Regulations* define 'ready-to-eat', in respect of an edible meat product (Government of Canada, 2023c). It is the responsibility of the food industry to produce safe food and to comply with all applicable Canadian legislative requirements.

Ready-to-eat food manufacturer: Domestic food businesses that manufacture, process, prepare or preserve a packaged ready-to-eat food as well as manufacturers of ready-to-eat foods for export. This includes food businesses that repackage ready-to-eat foods where foods are exposed to the environment prior to repackaging (see Section 3 under Roles and responsibilities, for ready-to-eat food manufacturers and exporters).

Refrigeration: Section B.27.001 of Division 27, Part B (Foods) of the *Food and Drug 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, 2023d)

Relevant regulatory authority: The relevant federal regulatory authority referred to in Health Canada's *Listeria* policy is the Canadian Food Inspection Agency. The *Listeria* policy is applied in the conduct of federal food inspections.

Furthermore, as provincial/territorial food regulatory authorities may be conducting enforcement of their own food legislation, they may apply similar policy considerations in relation to the application of their laws. Hence, Health Canada's *Listeria* policy may serve as a resource for this purpose. In these cases, Health Canada's *Listeria* policy can play a complementary role, but is not intended to provide guidance on legislation that is not within Health Canada's jurisdiction or mandate.

Root cause analysis: Analysis aimed at identifying and correcting the source of the deviation in order to minimize the potential for the deviation to reoccur. It may result in limiting or expanding the amount of product impacted by a deviation. (CAC, 2020)

Sell: Section 2 of the *Food and Drugs Act* defines 'sell' as follows: Sell includes
(a) offer for sale, expose for sale or have in possession for sale — or distribute to one or more persons, whether or not the distribution is made for consideration, and
(b) lease, offer for lease, expose for lease or have in possession for lease.
(*vente*) (Government of Canada, 2023a)

Shelf-life: The period of time during which a food maintains its microbiological safety and sensory qualities at a specific storage temperature. (CAC, 1999)

Trend analysis: Analysis aimed at identifying areas of concerns in relation to the introduction, repeated detection and movement of *Listeria* in the processing environment and food over time. The goal is to drive continuous improvement in process monitoring, root cause analysis and the application of control measures.

Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. (CAC, 2020)

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended. (CAC, 2020)

Vulnerable populations: Vulnerable individuals include members of the following population groups: people with weakened immune systems (for example, people with acquired immunodeficiency syndrome (AIDS), transplant recipients, people with cancer, people on dialysis), pregnant people or adults ages 60 and over. (FAO and WHO, 2004; Government of Canada, 2016; 2021b; 2021c; 2021d)

Water activity (a_w): Section B.27.001 of Division 27, Part B (Foods) of the *Food and Drug Regulations* defines 'water activity' as follows: Water activity means the ratio of the water vapour pressure of a food to the vapour pressure of pure water, at the same temperature and pressure. (*activité de l'eau*) (Government of Canada, 2023d)

Appendix B: Foodborne listeriosis in Canada

Table 2: Foodborne listeriosis associated with foods in Canada

Year(s)	Number of cases (deaths)	Foods	References
1981	41 (17)	Coleslaw mix	Schlech et al., 1983; Pagotto et al., 2006
1996	2 (0)	Imitation crab meat	Farber et al., 2000
2000	7 (0)	Flat whipping cream	Pagotto et al., 2006; Clark et al., 2010
2002	48 (0)	Cheese	McIntyre et al., 2015
2002	17 (0)	Soft and semi-hard raw milk cheese	Gaulin et al., 2003; Pagotto et al., 2006
2002	86 (0)	Cheese made from pasteurized milk	Pagotto et al., 2006; Clark et al., 2010; McIntyre et al., 2015
2008	57 (24)	RTE deli meats	Currie et al., 2015; Thomas et al., 2015b
2008	40 (2)	Cheeses	Gaulin and Ramsay, 2010
2011	1 (0)	Cheese	CFIA, 2011; INSPQ, 2021; MAPAQ, 2021
2014	1 (0)	Caramel apples	PHAC, 2015
2015	3 (1)	Sliced mortadella products	CFIA, 2015a; iPHIS, 2021
2015	1 (0)	Sliced apples and products containing sliced apples	CFIA, 2015b
2015	14 (3)	Packaged salads	PHAC, 2016; Self et al., 2019
2015	34 (4)	Pasteurized chocolate milk	Hanson et al., 2019
2016	1 (0)	Sliced deli meat	CFIA, 2016
2016	6 (1)	Grocery store made RTE foods	VCH, 2016; VCH, 2021
2017 to 2019	6 (0)	Enoki mushrooms	WHO, 2020; CFIA, 2021
2018	7 (0)	Cooked roast beef products	CFIA, 2018; CNPHI, 2021
2019	7 (0)	Cooked diced chicken	CFIA, 2019; PHAC, 2019

Appendix C: Use of food additives, food processing aids and post-packaging treatments for ready-to-eat foods

If present, it is possible for *L. monocytogenes* to transfer from the environment onto RTE foods that are exposed to the environment prior to packaging. RTE food formulations now exist that incorporate food additives or food processing aids to eliminate, or reduce numbers of, *L. monocytogenes*. Post-packaging treatments (also known as post-lethality treatments) can also be applied to reduce or eliminate *L. monocytogenes* in RTE foods. These can be used alone or together for a combined effect. It is important to note that independent of their efficacy, RTE foods should be manufactured under sanitary conditions. Furthermore, the use of such control measures may reduce the relative risk level of the food and could justify a reduced sampling frequency (CFIA, 2023).

i) Food additives

Food additives are regulated under the *Food and Drugs Act* and associated Marketing Authorizations which incorporate by reference their corresponding Lists of Permitted Food Additives (lists) (Health Canada, 2017b). All food additives currently permitted for use in Canada are reported in 1 or more of the lists with conditions about the types of food they are permitted in or upon as well as the maximum level of use. Manufacturers interested in using a food additive that does not appear on 1 or more of the lists or for a purpose, a level or in a food that is not described on the lists are required to file a food additive submission in accordance with Section B.16.002 of the *Food and Drug Regulations* before it can be used in or upon foods sold in Canada (Health Canada, 2021b; Government of Canada, 2023d).

The use of food additives is 1 of various control measures in the overall approach to minimize the risks associated with *L. monocytogenes* in RTE foods. Hence, RTE food manufacturers should validate that the specific use of a food additive is efficacious in the food under consideration, with consistent listericidal or listeriostatic effects (CAC, 2009a).

Research is constantly ongoing to find effective food additives that can provide growth inhibition or reduction of *L. monocytogenes* in RTE foods throughout their shelf-lives. As such, in certain situations, food additives may be used for the purpose of changing the categorization of a Category 1 RTE food into a Category 2A or 2B RTE food (see Sections 6.1.2.1 and 6.1.2.2 respectively) (Health Canada, 2012a; 2012b). Should questions arise regarding food categorization, the RTE food manufacturer should be able to demonstrate in which category the RTE food falls. In cases where validation was conducted for categorization, the manufacturer should have documentation of adequate validation studies substantiating that *L. monocytogenes* cannot grow or that the RTE food will only support limited growth of *L. monocytogenes* to ≤ 100 CFU/g throughout the stated shelf-life.

ii) Food processing aids

Although not defined in the *Food and Drug Regulations*, a food processing aid is considered 'a substance that is used for a technical effect during food processing or manufacture but, unlike food additives, its use does not affect the intrinsic characteristics of the food and it results in no or negligible residues of the substance or its by-products in or on the finished food' (Health Canada, 2014b; 2022a). Their use could be viewed as an additional tool to decrease the levels of *L. monocytogenes*. Nonetheless, the application of food processing aids may not guarantee the complete elimination of *L. monocytogenes,* if present. Therefore, the growth of *L. monocytogenes* may occur afterwards, as food processing aids do not function to inhibit or reduce the growth of *L. monocytogenes* in RTE foods throughout their shelf-lives. Furthermore, the action of certain food

processing aids may be very specific. A multi-faceted evaluation of the safety, suitability and efficacy of such control measures should therefore be considered.

iii) Post-packaging treatments

The use of a post-packaging treatment can also be part of an overall approach to minimize the risks associated with *L. monocytogenes* in RTE foods. That intervention step can reduce the levels or eliminate *L. monocytogenes* present on the surface of foods due to the introduction of *L. monocytogenes* onto RTE foods during post-processing, prior to packaging.

The use of novel technologies for post-packaging 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, 2022b). For 'non-novel' post-packaging treatments, it is highly recommended that the microbiological safety and efficacy of these food processing techniques proposed by the food industry (for example, steam pasteurization, hot water treatment, radiant oven heating, infrared heating, high-pressure processing) be assessed by regulatory authorities.

References

Boone, I., et al, 2021. Healthcare-associated foodborne outbreaks in high-income countries: A literature review and surveillance study, 16 OECD countries, 2001 to 2019. *Eurosurveillance*, vol. 26, no. 41. DOI https://doi.org/10.2807/1560-7917.ES.2021.26.41.2001278.

Buchanan, R.L., et al, 2017. A review of *Listeria monocytogenes*: An update on outbreaks, virulence, dose-response, ecology, and risk assessments. *Food Control*, vol. 75, p. 1–13.

CAC (Codex Alimentarius Commission), 1999. Code of hygienic practice for refrigerated packaged foods with extended shelf life: CAC/RCP 46-(1999) [online]. [accessed 19 December 2022]. Codex texts: Codes of practice. Retrieved from: www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/it/.

CAC (Codex Alimentarius Commission), 2009a. Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods: CAC/GL 61-2007 [online]. [accessed 19 December 2022]. Codex texts: Guidelines. Retrieved from: https://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/.

CAC (Codex Alimentarius Commission), 2009b. Recommended international code of practice general principles of food hygiene: CAC/RCP 1-1969. In: *Food hygiene: Basic texts*. Fourth edition [online]. [accessed 19 December 2022]. ISBN 978-92-5-105913-5. Retrieved from: http://www.fao.org/3/a1552e/a1552e00.pdf.

CAC (Codex Alimentarius Commission), 2018. Code of hygienic practice for low-moisture foods: CXC 75-2015 [online]. [accessed 19 December 2022]. Codex texts: Codes of practice. Retrieved from: https://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/it/.

CAC (Codex Alimentarius Commission), 2020. General principles of food hygiene: CXC 1-1969 [online]. [accessed 19 December 2022]. Codex texts: Codes of practice. Retrieved from: www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/it/.

CFIA (Canadian Food Inspection Agency), 2011. Certain cheese and dairy products produced by EST. 1874 may contain *Listeria monocytogenes* [online]. *Healthy Canadians* [accessed 19 December 2022]. Retrieved from: https://recalls-rappels.canada.ca/en/alert-recall/certain-cheese-and-dairy-products-produced-est-1874-may-contain-listeria-monocytogenes.

CFIA (Canadian Food Inspection Agency), 2015a. Sliced mortadella products sold at Lady York Foods recalled due to *Listeria monocytogenes* [online]. *Healthy Canadians* [accessed 19 December 2022]. Retrieved from: https://recalls-rappels.canada.ca/en/alert-recall/sliced-mortadella-products-sold-lady-york-foods-recalled-due-listeria-monocytogenes.

CFIA (Canadian Food Inspection Agency), 2015b. Sliced apples and products containing sliced apples recalled due to *Listeria monocytogenes* [online]. *Healthy Canadians* [accessed 19 December 2022]. Retrieved from: https://recalls-rappels.canada.ca/en/alert-recall/sliced-apples-and-products-containing-sliced-apples-recalled-due-listeria.

CFIA (Canadian Food Inspection Agency), 2016. Updated food recall warning - Sliced deli meat products sold at Tre Rose Bakery up to and including October 4, 2016 recalled due to *Listeria monocytogenes* [online]. *Inspection Canada* [accessed 17 May 2021].

CFIA (Canadian Food Inspection Agency), 2018. Updated food recall warning - Druxy's Fresh Deli Revolution brand seasoned cooked roast beef recalled due to *Listeria monocytogenes* [online]. *Inspection Canada* [accessed 19 December 2022]. Retrieved from: https://inspection.canada.ca/food-recall-warnings-and-allergy-alerts/2018-03-28/eng/1522267703785/1522267707047.

CFIA (Canadian Food Inspection Agency), 2019. Food recall warning - Glacial Treasure brand frozen chicken products recalled due to *Listeria monocytogenes* [online]. *Inspection Canada* [accessed 19 December 2022]. Retrieved from: https://inspection.canada.ca/food-recall-warnings-and-allergy-alerts/2019-09-30/eng/1569906160390/1569906166724.

CFIA (Canadian Food Inspection Agency), 2021. Sharing bacterial DNA data helps solve international food safety investigations [online]. *Inspection Canada* [accessed 19 December 2022]. Retrieved from: https://inspection.canada.ca/chronicle-360/food-safety/sharing-bacterial-dna-data-helps-solve-internation/eng/1614737830950/1614737831637.

CFIA (Canadian Food Inspection Agency), 2023. Control measures for *Listeria monocytogenes* in ready-to-eat foods [online]. *Inspection Canada* [accessed 3 March 2023]. Retrieved from: https://inspection.canada.ca/preventive-controls/listeria-monocytogenes/eng/1518103693274/1528201904208.

Chen, Y., et al, 2003. *Listeria monocytogenes*: Low levels equal low risk. *Journal of Food Protection*, vol. 66, no. 4, p. 570–577.

Chen, Y., et al, 2016a. Recovery and growth potential of *Listeria monocytogenes* in temperature abused milkshakes prepared from naturally contaminated ice cream linked to a listeriosis outbreak. *Frontiers in Microbiology*, vol. 7, article 764. DOI https://doi.org/10.3389/fmicb.2016.00764.

Chen, Y., et al, 2016b. Prevalence and level of *Listeria monocytogenes* in ice cream linked to a listeriosis outbreak in the United States. *Journal of Food Protection*, vol. 79, no. 11, p. 1828–1832.

Churchill, K.J., et al, 2019. Prevalence of *Listeria monocytogenes* in select ready-to-eat foods — Deli meat, soft cheese, and packaged salad: A systematic review and meta-analysis. *Journal of Food Protection*, vol. 82, no. 2, p. 344–357.

Clark, C.G., et al, 2010. Surveillance for *Listeria monocytogenes* and listeriosis, 1995-2004. *Epidemiology and Infection*, vol. 138, no. 4, p. 559–572.

CNPHI (Canadian Network for Public Health Intelligence, Outbreak summaries), 2021. Personal communication.

Currie, A., et al, 2015. Multi-province listeriosis outbreak linked to contaminated deli meat consumed primarily in institutional settings, Canada, 2008. *Foodborne Pathogens and Disease*, vol. 12, no. 8, p. 645–652.

D'Amico, D.J. and Donnelly, C.W., 2008. Enhanced detection of *Listeria* spp. in farmstead cheese processing environments through dual primary enrichment, PCR, and molecular subtyping. *Journal of Food Protection*, vol. 71, no. 11, p. 2239–2248.

Desai, A.N., et al, 2019. Changing epidemiology of *Listeria monocytogenes* outbreaks, sporadic cases, and recalls globally: A review of ProMED reports from 1996 to 2018. *International Journal of Infectious Diseases*, vol. 84, p. 48–53.

EFSA and ECDC (European Food Safety Authority and European Centre for Disease Prevention and Control), 2022. The European Union one health 2021 zoonoses report. *EFSA Journal*, vol. 20, no. 12, article e07666. DOI https://doi.org/10.2903/j.efsa.2022.7666.

EFSA Panel on Biological Hazards (BIOHAZ), et al, 2018. *Listeria monocytogenes* contamination of ready-to-eat foods and the risk for human health in the EU. *EFSA Journal*, vol. 16, no. 1, article e05134. DOI https://doi.org/10.2903/j.efsa.2018.5134.

EFSA Panel on Biological Hazards (BIOHAZ), et al, 2020. The public health risk posed by *Listeria monocytogenes* in frozen fruit and vegetables including herbs, blanched during processing. *EFSA Journal*, vol. 18, no. 4, article e06092. DOI https://doi.org/10.2903/j.efsa.2020.6092.

European Commission (The Commission of the European Communities), 2020. Current consolidated version: 08/03/2020 of the Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs [online]. [accessed 19 December 2022]. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R2073-20200308&from=EN.

FAO and WHO (Food and Agriculture Organization of the United Nations and the World Health Organization), 2004. Risk assessment of *Listeria monocytogenes* in ready-to-eat foods. *Microbiological risk assessment series* [online], no. 5 [accessed 19 December 2022]. ISSN 1726-5274. Retrieved from: http://www.fao.org/3/y5394e/y5394e.pdf.

Farber, J.M. and Peterkin, P.I., 1991. *Listeria monocytogenes*, a food-borne pathogen. *Microbiological Reviews*, vol. 55, no. 3, p. 476–511.

Farber, J.M. and Peterkin, P.I., 2000. Chapter 44: *Listeria monocytogenes.* In: *The microbiological safety and quality of food*. Gaithersburg, MD: Aspen Publishers Inc., pp. 1178–1232.

Farber, J.M., et al, 2000. A small outbreak of listeriosis potentially linked to the consumption of imitation crab meat. *Letters in Applied Microbiology*, vol. 31, no. 2, p. 100–104.

Farber, J.M., et al, 2021. Alternative approaches to the risk management of *Listeria monocytogenes* in low risk foods. *Food Control*, vol. 123, article 107601. DOI https://doi.org/10.1016/j.foodcont.2020.107601.

FDA and USDA (Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services and Food Safety and Inspection Service, U.S. Department of Agriculture), 2003. Quantitative assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods [online]. *FDA* [accessed 19 December 2022]. Retrieved from: https://www.fda.gov/food/cfsan-risk-safety-assessments/quantitative-assessment-relative-risk-public-health-foodborne-listeria-monocytogenes-among-selected.

FSANZ (Food Standards Australia New Zealand), 2014. Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food [online]. [accessed 19 December 2022]. Retrieved from: https://www.foodstandards.gov.au/publications/Documents/Guidance%20on%20the%20application%20of%20limits%20for%20Listeria%20monocytogenes%20FINAL.pdf.

Gaulin, C., et al, 2003. First documented outbreak of *Listeria monocytogenes* in Quebec, 2002. *Canada Communicable Disease Report*, vol. 29, no. 21, p. 181–186.

Gaulin, C. and Ramsay, D., 2010. Éclosion d'infections à *Listeria monocytogenes* pulsovar 93 liée à la consommation de fromages québécois, 2008. *Province de Québec: Rapport d'investigation et d'intervention* [online]. [accessed 19 December 2022]. Retrieved from: https://www.mapaq.gouv.qc.ca/fr/Publications/Rapporteclosionlisteriose.pdf (French only).

Government of Canada, 2016. Listeriosis (*Listeria*) [online]. *Canada* [accessed 25 January 2023]. Retrieved from: https://www.canada.ca/en/public-health/services/diseases/listeriosis.html.

Government of Canada, 2021a. *Canadian Standards of Identity*: Volume 7 – Meat Products [online]. *Inspection Canada* [accessed 25 January 2023]. Retrieved from: https://inspection.canada.ca/about-cfia/acts-and-regulations/list-of-acts-and-regulations/documents-incorporated-by-reference/canadian-standards-of-identity-volume-7/eng/1521204102134/1521204102836.

Government of Canada, 2021b. Food safety for people with a weakened immune system [online]. *Canada* [accessed 25 January 2023]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-safety-vulnerable-populations/food-safety-people-with-weakened-immune-system.html.

Government of Canada, 2021c. Food safety for adults ages 60 and over [online]. *Canada* [accessed 25 January 2023]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-safety-vulnerable-populations/food-safety-adults-ages-60-over.html.

Government of Canada, 2021d. Food safety for pregnant women [online]. *Canada* [accessed 25 January 2023]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-safety-vulnerable-populations/food-safety-pregnant-women.html.

Government of Canada, 2023a. *Food and Drugs Act* [online]. *Justice Laws* [accessed 25 January 2023]. Retrieved from: https://laws.justice.gc.ca/eng/acts/F-27/index.html.

Government of Canada, 2023b. *Cannabis Exemption* (*Food and Drugs Act*) *Regulations* [online]. *Justice Laws* [accessed 25 January 2023]. Retrieved from: https://laws-lois.justice.gc.ca/eng/regulations/SOR-2016-231/page-1.html.

Government of Canada, 2023c. *Safe Food for Canadians Regulations* [online]. *Justice Laws* [accessed 25 January 2023]. Retrieved from: https://laws.justice.gc.ca/eng/regulations/SOR-2018-108/.

Government of Canada, 2023d. *Food and Drug Regulations* [online]. *Justice Laws* [accessed 25 January 2023]. Retrieved from https://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/.

Government of Canada, 2023e. *Safe Food for Canadians Act* [online]. *Justice Laws* [accessed 25 January 2023]. Retrieved from: https://laws.justice.gc.ca/eng/AnnualStatutes/2012_24/.

Government of Canada, 2023f. General food safety tips [online]. *Canada* [accessed 25 January 2023]. Retrieved from: https://www.canada.ca/en/health-canada/services/general-food-safety-tips.html.

Grif, K., et al, 2001. Prevalence and characterization of *Listeria monocytogenes* in the feces of healthy Austrians. *Wiener klinische Wochenschrift*, vol. 113, no. 19, p. 737–742.

Hafner, L., et al, 2021. *Listeria monocytogenes* faecal carriage is common and depends on the gut microbiota. *Nature Communications*, vol. 12, article 6826. DOI https://doi.org/10.1038/s41467-021-27069-y.

Hanson, H., et al, 2019. *Listeria monocytogenes* associated with pasteurized chocolate milk, Ontario, Canada. *Emerging Infectious Diseases*, vol. 25, no. 3, p. 581–584.

Health Canada, 2010. MFLP-41: Environmental sampling for the detection of microorganisms. In: *Compendium of analytical methods, Vol 3*. [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods/analytical-methods/compendium-methods/laboratory-procedures-microbiological-analysis-foods-compendium-analytical-methods.html.

Health Canada, 2011. Weight of evidence: Factors to consider for appropriate and timely action in a foodborne illness outbreak investigation [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/reports-publications/food-safety/weight-evidence-factors-consider-appropriate-timely-action-foodborne-illness-outbreak-investigation-2011.html.

Health Canada, 2012a. Validation of ready-to-eat foods for changing the classification of a Category 1 into a Category 2A or 2B food in relation to Health Canada's Policy on *Listeria monocytogenes* in ready-to-eat foods (2011) (to be updated) [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/policies/validation-ready-foods-changing-classification-category-1-into-category-food-relation-policy-listeria-monocytogenes-ready-foods-2011.html.

Health Canada, 2012b. *Listeria monocytogenes* challenge testing of refrigerated ready-to-eat foods (to be updated) [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/policies/listeria-monocytogenes-challenge-testing-refrigerated-ready-foods-2012.html.

Health Canada, 2012c. Comments on Health Canada's proposed document Validation of ready-to-eat foods for changing the classification of a Category 1 into a Category 2A or 2B food - In relation to Health Canada's Policy on *Listeria monocytogenes* in ready-to-eat foods, 2011 [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/policies/summary-comments-received-proposed-document-validation-ready-foods-changing-classification-category-1-into-category-food-relation-health.html.

Health Canada, 2014a. Health Canada's guidance document on *E. coli* O157:H7 and *E. coli* O157:NM in raw beef [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidance-document-coli-0157-coli-0157-beef-2014.html.

Health Canada, 2014b. Policy for differentiating food additives and processing aids [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/reports-publications/policy-differentiating-food-additives-processing-aids-2008.html.

Health Canada, 2017a. Guidance document: Classification of products at the food-natural health product interface: Products in food formats [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/classification-products-at-food-natural-health-product-interface.html.

Health Canada, 2017b. Lists of permitted food additives [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted.html.

Health Canada, 2021a. The compendium of analytical methods [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods/analytical-methods/compendium-methods.html.

Health Canada, 2021b. A guide for the preparation of submissions on food additives [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/reports-publications/guide-preparation-submissions-food-additives.html.

Health Canada, 2022a. Food processing aids [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/processing-aids.html.

Health Canada, 2022b. Guidelines for the safety assessment of novel foods [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html.

ICMSF (International Commission on Microbiological Specifications for Foods), 1996. *Listeria monocytogenes*. In: *Microorganisms in foods 5: Characteristics of microbial pathogens.* Blackie Academic & Professional, p. 141–182. ISBN 978-0-412-47350-0.

ICMSF (International Commission on Microbiological Specifications for Foods), 2018a. Sampling to assess control of the environment. In: *Microorganisms in foods 7: Microbiological testing in food safety management*. Second edition. Springer International Publishing, p. 263–292. ISBN 978-3-319-68460-4.

ICMSF (International Commission on Microbiological Specifications for Foods), 2018b. Non-random distribution. In: *Microorganisms in foods 7: Microbiological testing in food safety management*. Second edition. Springer International Publishing, p. 207–209. ISBN 978-3-319-68460-4.

Iida, T., et al, 1998. Detection of *Listeria monocytogenes* in humans, animals and foods. *Journal of Veterinary Medical Science*, vol. 60, no. 12, p. 1341–1343.

INSPQ (Institut National de Santé Publique du Québec), 2021. Personal communication.

iPHIS (Integrated Public Health Information System), 2021. Personal communication.

MAPAQ (Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec), 2021. Personal communication.

Mazaheri, T., et al, 2021. *Listeria monocytogenes* biofilms in the food industry: Is the current hygiene program sufficient to combat the persistence of the pathogen? *Microorganisms*, vol. 9, no. 1, article 181. DOI https://doi.org/10.3390/microorganisms9010181.

McIntyre, L., Wilcott, L. and Naus, M, 2015. Listeriosis outbreaks in British Columbia, Canada, caused by soft ripened cheese contaminated from environmental sources. *BioMed Research International*, vol. 2015, article 131623. DOI http://dx.doi.org/10.1155/2015/131623.

McLauchlin, J., et al, 2004. *Listeria monocytogenes* and listeriosis: A review of hazard characterisation for use in microbiological risk assessment of foods. *International Journal of Food Microbiology*, vol. 92, no. 1, p. 15–33.

Müller, H.E. 1990. *Listeria* isolations from feces of patients with diarrhea and from healthy food handlers. *Infection*, vol. 18, no. 2, p. 97–100.

NACMCF (National Advisory Committee on Microbiological Criteria for Foods), 1998. Hazard analysis and critical control point principles and application guidelines. *Journal of Food Protection,* vol. 61, no. 9, p. 1246–1259.

Pagotto, F., et al, 2006. Canadian listeriosis reference service. *Foodborne Pathogens and Disease*, vol. 3, no. 1, p. 132–137.

Pagotto, F., Hébert, K. and Farber, J., 2011a. MFHPB-30: Isolation of *Listeria monocytogenes* and other *Listeria* spp. from foods and environmental samples. In: *Compendium of analytical methods, vol 2*. [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods/analytical-methods/compendium-methods/methods-microbiological-analysis-foods-compendium-analytical-methods.html.

Pagotto, F., et al, 2011b. MFLP-74: Enumeration of *Listeria monocytogenes* in foods. In: *Compendium of analytical methods, vol. 3*. [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods/analytical-methods/compendium-methods/laboratory-procedures-microbiological-analysis-foods-compendium-analytical-methods.html.

PHAC (Public Health Agency of Canada), 2015. Public health notice update – United States outbreak of *Listeria* infections related to prepackaged caramel apples that may have been distributed in Canada [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/public-health/services/public-health-notices/2014/public-health-notice-update-united-states-outbreak-listeria-infections-related-prepackaged-caramel-apples-that-may-have-been-distributed-canada.html.

PHAC (Public Health Agency of Canada), 2016. Public health notice update – Outbreak of *Listeria* infections linked to packaged salad products produced at the Dole processing facility in Springfield, Ohio [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/public-health/services/public-health-notices/2016/public-health-notice-update-outbreak-listeria-infections-linked-packaged-salad-products-produced-dole-processing-facility-springfield-ohio.html.

PHAC (Public Health Agency of Canada), 2019. Public health notice – Outbreak of *Listeria* infections linked to Rosemount brand cooked diced chicken [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/public-health/services/public-health-notices/2019/outbreak-listeria-infections-cooked-diced-chicken.html.

PHAC (Public Health Agency of Canada), 2020. 2020-21 Departmental plan: Public Health Agency of Canada [online]. *Canada* [accessed 19 December 2022]. Retrieved from: https://www.canada.ca/en/public-health/corporate/transparency/corporate-management-reporting/reports-plans-priorities/2020-2021-departmental-plan.html.

PHAC (Public Health Agency of Canada), 2023. Customize your own chart - Notifiable diseases on-line [online]. *PHAC/ASPC* [accessed 3 March 2023]. Retrieved from: https://diseases.canada.ca/notifiable/charts?c=cc.

Pohl, A.M., et al, 2019. Differences among incidence rates of invasive listeriosis in the U.S. FoodNet population by age, sex, race/ethnicity, and pregnancy status, 2008–2016. *Foodborne Pathogens and Disease*, vol. 16, no. 4, p. 290–297.

Pouillot, R., et al, 2016. Infectious dose of *Listeria monocytogenes* in outbreak linked to ice cream, United States, 2015. *Emerging Infectious Diseases*, vol. 22, no. 12, p. 2113–2119.

Riggio, G.M., et al, 2019. Microgreens – A review of food safety considerations along the farm to fork continuum. *International Journal of Food Microbiology*, vol. 290, p. 76–85.

Roberts, T., et al, 2009. The long-term health outcomes of selected foodborne pathogens [online]. The Center for Foodborne Illness Research & Prevention [accessed 19 December 2022]. Retrieved from: https://foodsafety.osu.edu/sites/cfi/files/imce/DocumentLibrary/Publications/Roberts%20et%20al.%20-%202009%20-%20LTHOs.pdf.

Schlech, W.F., et al, 1983. Epidemic listeriosis – Evidence for transmission by food. *New England Journal of Medicine*, vol. 308, no. 4, p. 203–206.

Self, J.L., et al, 2019. Multistate outbreak of listeriosis associated with packaged leafy green salads, United States and Canada, 2015–2016. *Emerging Infectious Diseases*, vol. 25, no. 8, p. 1461–1468.

Simmons, C.K. and Wiedmann, M., 2018. Identification and classification of sampling sites for pathogen environmental monitoring programs for *Listeria monocytogenes*: Results from an expert elicitation. *Food Microbiology*, vol. 75, p. 2–17.

Soni, D.K., et al, 2014. Virulence and genotypic characterization of *Listeria monocytogenes* isolated from vegetable and soil samples. *BMC Microbiology*, vol. 14, no. 1, article 241. DOI https://doi.org/10.1186/s12866-014-0241-3.

Spanu, C. and Jordan, K., 2020. *Listeria monocytogenes* environmental sampling program in ready-to-eat processing facilities: A practical approach. *Comprehensive Reviews in Food Science and Food Safety*, vol. 19, no. 6, p. 2843–2861.

Thomas, M.K., et al, 2015a. Estimates of foodborne illness – Related hospitalizations and deaths in Canada for 30 specified pathogens and unspecified agents. *Foodborne Pathogens and Disease*, vol. 12, no. 10, p. 820–827.

Thomas, M.K., et al, 2015b. Economic cost of a *Listeria monocytogenes* outbreak in Canada, 2008. *Foodborne Pathogens and Disease*, vol. 12, no. 12, p. 966–971.

Tompkin, R.B., et al, 1992. Control of *Listeria monocytogenes* in processed meats. *Food Australia*, vol. 44, no. 8, p. 370–376.

Tompkin, R.B., et al, 1999. Guidelines to prevent post-processing contamination from *Listeria monocytogenes*. *Dairy, Food and Environmental Sanitation*, vol. 19, no. 8, p. 551–562.

Tompkin, R.B., 2002. Control of *Listeria monocytogenes* in the food-processing environment. *Journal of Food Protection*, vol. 65, no. 4, p. 709–725.

VCH (Vancouver Coastal Health), 2016. Public safety advisory for customers of Foody World [online]. *VCH* [accessed 27 February 2023]. Retrieved from: https://www.vch.ca/en/press-release/public-safety-advisory-customers-foody-world.

VCH (Vancouver Coastal Health), 2021. Personal communication.

WHO (World Health Organization), 2018. Listeriosis [online]. *WHO* [accessed 19 December 2022]. Retrieved from: https://www.who.int/news-room/fact-sheets/detail/listeriosis.

WHO (International Food Safety Authorities Network (INFOSAN), World Health Organization), 2020. INFOSAN quarterly summary, 2020 #2: April-June 2020 [online]. *WHO* [accessed 19 December 2022]. Retrieved from: https://www.who.int/news/item/29-07-2020-infosan-quarterly-summary-2020-2.

Zoellner, C., et al, 2018. Design elements of *Listeria* environmental monitoring programs in food processing facilities: A scoping review of research and guidance materials. *Comprehensive Reviews in Food Science and Food Safety*, vol. 17, no. 5, p. 1156–1171.

Zoellner, C., et al, 2019. EnABLe: An agent-based model to understand *Listeria* dynamics in food processing facilities. *Scientific Reports*, vol. 9, no. 1, article 495. DOI https://doi.org/10.1038/s41598-018-36654-z.