Policy on *Listeria monocytogenes* in Ready-to-Eat Foods: Draft Policy for Consultation

Bureau of Microbial Hazards
Food Directorate
Health Products and Food Branch

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Legislative Context for Health Canada's
"Policy on *Listeria monocytogenes* in Ready-to-Eat Foods" (the *Listeria* policy)

At the federal level of government, the *Food and Drugs Act* and its regulations, the *Food and Drug Regulations*, generally apply to all food sold in Canada, including both imported and domestically produced food, at all levels of trade (i.e., inter-provincial/territorial and intra-provincial/territorial). The *Safe Food for Canadians Act* and its regulations, the *Safe Food for Canadians Regulations*, mainly apply to food that is imported, or prepared for export or inter-provincial/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 sections 4(1)(a), 4(1)(e) and 7 of the *Food and Drugs Act.*

In addition to the administration and enforcement of the *Safe Food for Canadians Act* and its regulations, the Canadian Food Inspection Agency (CFIA) is responsible for the enforcement of the food-related provisions of the *Food and Drugs Act* and its 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 considered regulatory requirements under the *Safe Food for Canadians Regulations* and should refer to the control measures document for these details. Risk-based guidelines on sampling and testing frequency can also be found in that 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 words and phrases used in this policy, including relevant definitions from the *Food and Drugs Act* and its regulations. At the first relevant instance, words and phrases 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 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, *Listeria* infections may result in serious and severe diseases, especially in vulnerable individuals. Foodborne outbreaks of *L. monocytogenes* have mostly been linked to ready-to-eat (RTE) foods that are not normally further prepared before consumption. As such, the implementation and verification of control measures for *L. monocytogenes* in RTE foods are described in this document.

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 (see Section 2.1) that are sold in Canada. These foods have been classified into two categories (see Section 6) based on their potential to support *L. monocytogenes* growth. 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. Furthermore, the intended consumers of RTE foods (e.g., vulnerable populations) are also considered in determining the associated 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[1] and end-product testing. In an effort to manufacture RTE foods that are safe for sale, the *Listeria* policy places an emphasis on environmental sampling in post-process areas where foods are exposed to the environment prior to packaging.

[1] For the purpose of the *Listeria* policy, this includes food contact and non-food contact surfaces.

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:

- The concepts of the *Listeria* policy, including its legislative context, have been presented in a new order for better readability and refined for improved clarity.
- The *Listeria* policy has been adapted to reflect 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 have been presented with more detail (see Section 2).
- The definition of RTE foods has been modified to include more detail (see Section 2).
- A decision tree has been added to facilitate the categorization of RTE foods (see Section 6).
- The *Listeria* policy has been updated to provide more detail on RTE foods specifically produced for consumption by vulnerable populations (see Sections 6 and 7).

2 Purpose and Scope

The *Listeria* policy is intended to assist in the application and verification of activities with respect to *L. monocytogenes* in RTE foods, with the goal of protecting the health and safety of Canadians. In this specific context, it guides industry on how to comply with federal food legislation and it is a resource for the relevant regulatory authority for such enforcement. The application of the *Listeria* policy should permit the early identification of potential persistence of *Listeria* spp.[2] in the food processing environment and demonstrate the effectiveness of the control measures put in place to address *L. monocytogenes* in RTE foods.

In accordance with the *Listeria* policy, RTE foods should be produced under conditions that will minimize or prevent the presence and/or growth of *L. monocytogenes*. This is accomplished, as applicable, 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 the manufacturing of RTE foods
- Preventing the introduction of *L. monocytogenes* during post-processing of RTE foods

The *Listeria* policy does not apply to the following food businesses[3]:

- Retail food businesses that sell food directly to consumers and are not required to have a licence under the *Safe Food for Canadians Regulations* (e.g., supermarkets, grocery stores) (Health Canada, 2013)
- Restaurants or similar enterprises (e.g., sit-down, buffet, fast food or take-out restaurants, cafeterias, caterers, food stands or wagons, ice cream or coffee shops)

[2] For the purpose of the *Listeria* policy, this includes *L. monocytogenes.*
[3] 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, 2022a).

- Manufacturers of food that is not intended or sold for human consumption (e.g., livestock feed, pet food)
- Manufacturers of edible cannabis (Government of Canada, 2022b)
- Manufacturers of natural health products (Health Canada, 2017a)
- Primary agricultural producers (e.g., farms that grow crops, raise animals (including fish), or harvest plants, animals, or animal products (CAC, 2020))

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

- Pre-process testing (e.g., testing of incoming ingredients)
- Reconditioning or reprocessing activities

The conduct of food safety investigations or recall activities by regulatory authorities are not within the scope of the *Listeria* policy.

In situations for which the *Listeria* policy does not apply, a finding of *L. monocytogenes* should 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[4].

[4] 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 *Listeria* 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 (i.e., heat treatment achieving less than a 5-log reduction in numbers of *L. monocytogenes*).
>
> RTE foods subject to the *Listeria* policy often require refrigeration or freezing[5] 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 *Listeria* Policy

Under 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 (e.g., canned foods, refrigerated sous-vide type foods, aseptically processed and packaged foods, retort pouches)
2) Hot filled/packed foods that have very limited exposure to the environment after filling at a minimum of 85°C (e.g., maple syrup, jams, jellies, processed cheese)
3) Dried goods or low-moisture foods that do not require storage under refrigeration or freezing conditions (e.g., cereals, dried herbs, dried spice mixtures, dried soup mixes, dry pasta, bread)
4) Beverages that do not require storage under refrigeration or freezing conditions (e.g., 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 (e.g., fresh herbs, whole or trimmed fruits

[5] i.e., Labelled accordingly as “Keep Refrigerated” or “Keep Frozen” on the package, respectively.

and vegetables, whole leafy vegetables, microgreens[6], whole mushrooms, berries) as well as sprouts

6) Raw meat or raw seafood or raw eggs
    a. Except those specifically processed for raw consumption (e.g., oysters on the half shell sold as RTE, sushi containing raw fish, certain seafood products (e.g., tubed seafood for tartare or ceviche), as well as certain beef products[7] (e.g., steak tartar, Carpaccio)) which are subject to the *Listeria* policy
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 (e.g., *cook thoroughly*, *cook and serve*, *cook and eat*, etc.) as well as with validated, comprehensive cooking[8] 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* (e.g., wieners, frankfurters, hot dogs) (Government of Canada, 2021a; 2022c) which are subject to the *Listeria* policy

If there is uncertainty regarding whether a food is considered RTE, the relevant regulatory authority should be contacted.

2.1.1.1 Requirements and Best Practices for Foods Excluded from the *Listeria* 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, 2022a). Food businesses should remain vigilant regarding the presence of *L. monocytogenes*. In order to mitigate the risk from *L. monocytogenes* (i.e., prevent the presence 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[9]. Factors such as the processing steps, labelling, trend analysis information, well-documented link to illnesses (e.g., certain frozen

[6] For the purpose of the *Listeria* policy, "microgreens" are defined as 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).

[7] 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 also address *E. coli* O157 as a hazard likely to occur (Health Canada, 2014a).

[8] In the context of labelled cooking instructions on 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 (i.e., time/temperature combinations) and include an internal endpoint temperature (e.g., minimum internal temperature of 74°C). Food products must be labelled in a truthful manner (e.g., 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, 2022a).

[9] Industry-specific best-practice guidelines for the control of *L. monocytogenes* in foods that are not considered to be RTE may represent a good resource to help identify and apply control measures that are appropriate to their operation.

vegetables (EFSA BIOHAZ Panel *et al.*, 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, 3 and 4 are recommended for refrigerated or frozen processed foods that are excluded from the *Listeria* policy (see Section 2.1.1), 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 if follow-up actions are needed and if the situation represents a health concern. Risk management actions may be needed.

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, 2022a; 2022c; 2022d; 2022e). Food businesses that require a licence under the *Safe Food for Canadians Regulations* should be aware that certain control measures described in the *Listeria* policy may be considered regulatory requirements under the *Safe Food for Canadians Regulations*[10].

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*. Environmental sampling, as described in Figures 2, 3 and 4 (Section 7.2), should be carried out by manufacturers under the principle that increased sampling frequency should be performed for higher-risk foods. This should be performed to verify the effectiveness of their sanitation program (i.e., cleaning and sanitizing) and of their process controls. Findings of *Listeria* spp. may be an indication of the presence of

[10] 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.

L. monocytogenes and should lead to intensified cleaning and sanitizing. A review of the food safety system may also be needed.

Labels on the package must also be 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, 2022a). From a food safety perspective, this is especially important with regards to storage conditions, best-before dates and preparation instructions for consumers.

3.1.2 Ready-to-Eat Food Importers

Importers are responsible for importing food that is safe and meets all applicable Canadian legislative requirements, including the *Safe Food for Canadians Regulations*. 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. Importers are required to have a *Safe Food for Canadians Regulations* licence and develop, keep, maintain and implement a written PCP, following Part 4, Division 6 of the *Safe Food for Canadians Regulations*. Importers must also have a traceability system. Importers must have this information readily available to the CFIA. Furthermore, importers should always practice 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).

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 (e.g., federal and provincial/territorial partners, the food industry and its associations). These 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 ministries to investigate the source of *L. monocytogenes*-related illnesses when an outbreak is suspected, as applicable.

The Government of Canada continues to provide information and science-based educational materials to the medical community, public health officials, the food industry and consumers about foodborne illness, and 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 (e.g., health care providers, caregivers) to vulnerable individuals (i.e., people with weakened immune systems, adults ages 60 and over, as well as pregnant women) have a high level of responsibility in food preparation, as vulnerable individuals have an increased susceptibility to infection with *L. monocytogenes*. Vulnerable individuals that present a higher risk for foodborne illness should try to avoid the consumption of specific foods, and 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 (e.g., caterers and care providers) (Government of Canada, 2016; 2021b; 2021c; 2021d; 2021e).

While a lot of information is provided by food manufacturers regarding nutrition, more information pertaining to food safety is becoming increasingly common on food packaging. Adherence to the instructions labelled on the package (e.g., storage conditions, best-before dates, cooking instructions, etc.) 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 fecal specimens of healthy animals and humans, as well as from sewage, silage, soil, fertilizer, vegetable matter and many foods (Farber and Peterkin, 1991; Farber and Peterkin, 2000; McLauchlin *et al.*, 2004; 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 up to 10% of humans may carry *L. monocytogenes* in their intestines without ill effects (Mascola *et al.,* 1992; Iida *et al.,* 1998; Grif *et al.,* 2001; Sauders *et al.,* 2005). This organism, however, is recognized as the causative agent of the infection known as listeriosis. Listeriosis can manifest itself as invasive or non-invasive listeriosis. Invasive listeriosis usually develops in people belonging to vulnerable populations while non-invasive listeriosis can develop in 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 consumption of food containing *L. monocytogenes* (McLauchlin *et al.*, 2004).

Serious infections of *L. monocytogenes* (i.e., invasive listeriosis) in healthy adults are relatively rare. The highest incidence of listeriosis is among people with weakened immune systems, pregnant women and adults ages 60 and over. Among adults, the potential for listeriosis increases as individuals age, e.g., as compared to individuals ages 40 to 59 years, Canadian data from 2018 shows that individuals ages 60 and over had nearly a 6-times increased risk of acquiring foodborne listeriosis (PHAC, 2021).

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 women, 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, i.e., 20-30% of foodborne listeriosis infections in vulnerable populations are fatal (Government of Canada, 2016). 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 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 two outbreaks involving 57 and 40 confirmed cases each (Gaulin and Ramsay, 2010; Currie *et al.*, 2015; Thomas *et al*., 2015b). Moreover, from 2011-2019, 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, 2021). These Canadian rates are comparable to those reported in the United States (i.e., 2.8 cases per million population in 2008-2016, excluding pregnant women) (Pohl *et al*., 2019) and in the European Union (4.7 cases per million population in 2016) (ECDC, 2017).

5 Scientific Basis for the *Listeria* 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, in general, the potential of acquiring foodborne listeriosis increases depending on several factors (FAO/WHO, 2004; CAC, 2009a; Buchanan *et al*., 2017) such as:

- Host susceptibility (e.g., 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 growth of *L. monocytogenes* in the food during refrigerated storage
- The refrigerated storage temperature
- The duration of refrigerated storage before consumption

In regards to the latter three 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 (e.g., vulnerable populations), the potential for growth of *L. monocytogenes* to occur in the foods as well as the presence or levels of *L. monocytogenes* in RTE foods. These factors are used to determine the associated health concern that RTE foods pose to consumers. The potential for the growth of *L. monocytogenes* to occur in RTE foods differs depending on factors such as pH, a_w, food formulation, the background microflora, 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 one food

containing low numbers of *L. monocytogenes* resulting in illness is considered to be very low (FAO/WHO, 2004). Foods that contain low levels of *L. monocytogenes* (e.g., less than 100 CFU/g) pose very little risk (Chen *et al.*, 2003; FAO/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/USDA, 2003).

Consequently, the *Listeria* policy separates RTE foods that support the growth of *L. monocytogenes* from those RTE foods in which growth of *L. monocytogenes* will not occur or in which a limited potential for growth to levels not exceeding 100 CFU/g can occur throughout the stated shelf-life (see Section 6.1.2). 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 detected at low levels in 99% (2307/2320) of the ice cream samples tested (Chen *et al.,* 2016b). This outbreak, in products that did not support the growth of, but did contain low levels of *L. monocytogenes*, demonstrated the potential for listeriosis to occur after distribution if highly vulnerable individuals, such as hospital patients, consumed these types of products (Pouillot *et al.,* 2016). Furthermore, a recent study on healthcare-associated foodborne outbreaks (HA-FBO) 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 HA-FBO in the hospital setting (Boone *et al*., 2021). These listeriosis outbreaks were associated with high case fatality 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 two categories based on their potential to support *L. monocytogenes* growth. The decision tree presented in Figure 1 should be followed to determine a RTE food's categorization.

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. As specified in Section 7.3 (Table 1), the presence of *L. monocytogenes* in a Category 1 RTE food, as determined by the applicable sampling and testing methodology, 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 two subgroups, for which validation may be necessary to demonstrate that control measures are effective to limit or prevent the growth of *L. monocytogenes*. For 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. Additional details on Category 2A and 2B RTE foods can be found in Sections 6.1.2.1 and 6.1.2.2, respectively.

As specified in Section 7.3 (Table 1), the presence of *L. monocytogenes* in a Category 2 RTE food at levels exceeding 100 CFU/g, as determined by the applicable sampling and testing methodology, 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 (e.g., durable life date shown as a "best before" date on the label of the package). This category includes (Figure 1):

- RTE foods which are known to occasionally contain low levels of *L. monocytogenes*[11] and their processing does not involve a heat treatment (**with 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
- RTE refrigerated foods with a stated shelf-life of 5 days or less and labelled as such on the package[12,13]

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 background microflora 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.

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 their foods to demonstrate that they continue to meet the specified criteria that justify their 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 (i.e., 10-30 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 10-30 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 its stated shelf-life. If insufficient, inadequate or no information exists regarding the Category 2A

[11] The presence of *L. monocytogenes* in Category 2A RTE foods may be sporadic; the levels could be lower than the method limit of detection, but over time may grow to detectable levels.
[12] The day of final packaging can be regarded as day 0.
[13] Food products must be labelled in a truthful manner (e.g., 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, 2022a).

categorization of the RTE food (e.g., no stated shelf-life on the label of the package), the RTE food will be considered as a Category 1 RTE food (i.e., a food in which the growth of *L. monocytogenes* can occur). As such, the sampling and testing methodology for Category 1 RTE foods, as specified in Section 7.3 (Table 1), should be used.

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 of RTE food 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 (i.e., 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[14] throughout its stated shelf-life **(with validation)**

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. As applicable, category 2B RTE food manufacturers need to monitor the physico-chemical parameters of the food (such as pH and a_w), its formulation, etc., 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 its 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 (i.e., a food in which the growth of *L. monocytogenes* can occur). As such, the sampling and testing methodology for Category 1 RTE foods, as specified in Section 7.3 (Table 1), should be used.

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

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. This should take into consideration the intended consumers (e.g., vulnerable populations); the information specified on the label of the package[15] 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.

Furthermore, frozen Category 2B RTE foods that are not labelled with thawing directions 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 (e.g., 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. 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, it 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, 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. As specified in Section 2, retail food businesses that sell food directly to consumers are not subject to the *Listeria* policy.

[15] Food products must be labelled in a truthful manner (e.g., 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, 2022a).

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, 2022a).

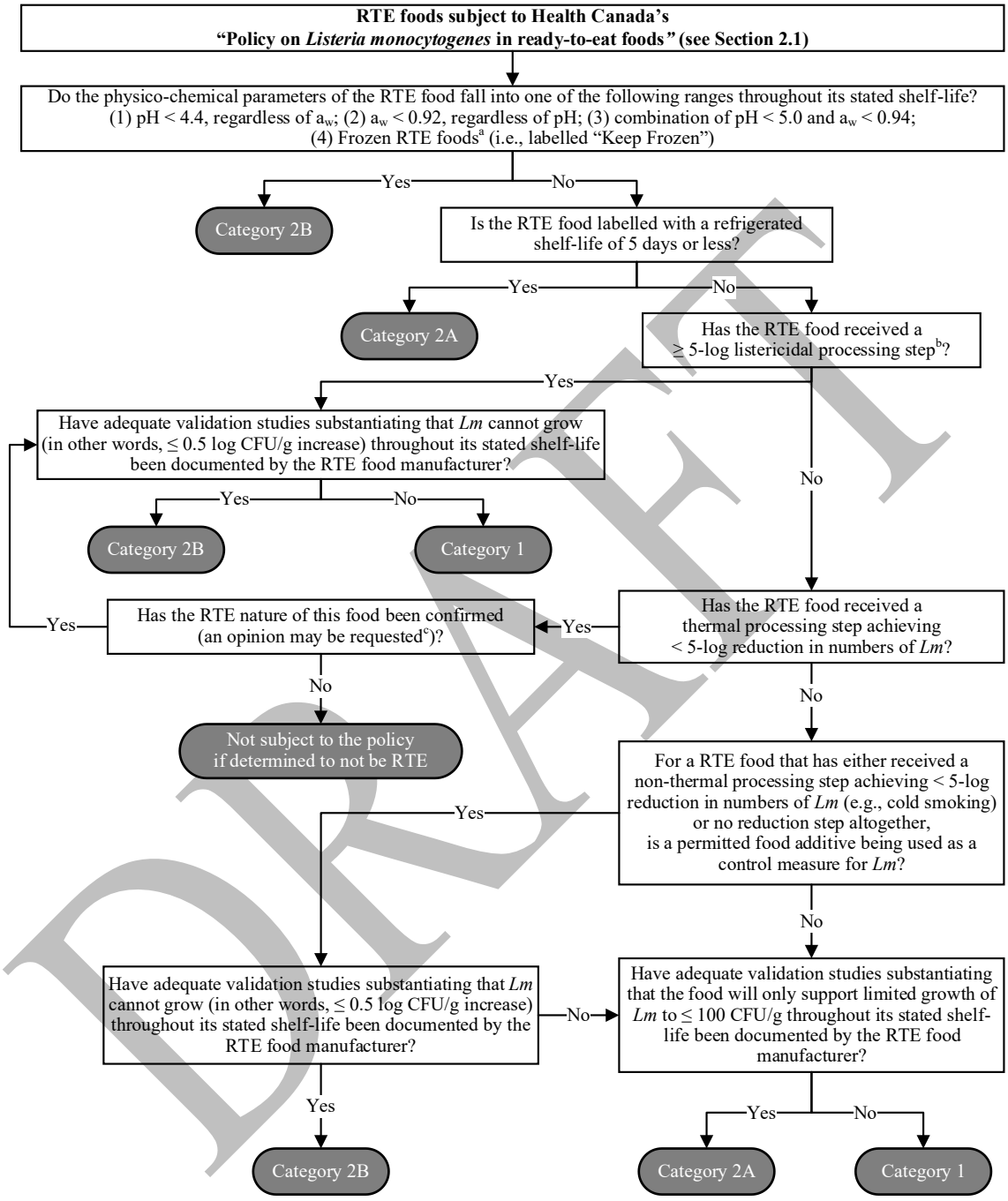
6.1.3 Ready-to-Eat Foods Specifically Produced for Consumption by Vulnerable Populations

RTE foods that are specifically produced for consumption by people with weakened immune systems, pregnant women or adults ages 60 and over (e.g., RTE foods that will be consumed in a hospital setting, convalescent care centers, long-term care facilities) should be monitored and sampled at a greater frequency as compared to foods produced for consumption by the general population (CAC, 2020). Furthermore, other specific control measures may be taken for these foods in order to have greater confidence in their safety as the presence of *L. monocytogenes* in such foods will represent an increased health concern for these populations.

Irrespective of category, RTE foods specifically produced for consumption by vulnerable populations that are found positive for *L. monocytogenes* (as specified in Section 7.3 (Table 1)) 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). In such situations, risk management actions may be needed.

As per the definition of RTE foods (see Section 2.1), 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 are described in Section 2.1.1.1.

Figure 1: Categorization of Ready-to-Eat Foods



a. 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.

b. 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.*

c. 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 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 (e.g., 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 (e.g., traffic control, separation of equipment and utensils between raw and RTE areas)
- Equipment design and maintenance (e.g., equipment that require disassembly, such as slicing equipment)
- Effectiveness of sanitation practices
- Employee training and practices

This is managed through the application 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). Sanitation management can also lead to innovations and sanitary design improvement (e.g., equipment and 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 direct 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 which categories of foods can or cannot support the growth of *L. monocytogenes*. 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. 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 application 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 testing results.

If *Listeria* spp. are found in the environment, RTE food manufacturers should conduct investigative sampling to determine their origin, following Figures 2, 3 and 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 correct potential sources of *Listeria* spp. (e.g., 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 (e.g., due to processing conditions that cannot eliminate *Listeria* spp. in the raw materials, due to 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 unsatisfactory environmental testing results, with appropriate corrective actions.

The expected steps to be undertaken by RTE food manufacturers when sampling both food contact surfaces (FCSs; i.e., any surface or object that comes into contact with RTE foods) and non-FCSs (i.e., any surface or object that does not come into contact with RTE foods), for the presence of *Listeria* spp. in the food processing environment, are outlined in this section. The steps indicated in Figures 2, 3 and 4 represent the minimum sampling and testing recommended by Health Canada. Manufacturers can exceed these minimum recommendations. 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). 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 its 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. (i.e., 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 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 during its 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 lead to 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 the RTE food is exposed to the environment prior to packaging. Zone 2 would include non-FCSs in proximity to zone 1 (e.g., control panels adjacent to FCSs). Zone 3 would be further from the packaging area, but within the processing area (e.g., floor drains, walls). Zone 4 would be located outside the processing and packaging areas (e.g., outside of the area where RTE food is exposed, such as loading docks, locker rooms and cafeterias). It would be expected that more environmental samples be taken from zones 1 and 2, which are closer to the RTE end-products, while zones 3 and 4 may be sampled at a lower frequency.

The environmental monitoring program should be sufficiently robust (e.g., regarding sampling selection, frequency of sampling, number of samples, method of sampling, etc.) to enable both RTE food manufacturers and the relevant regulatory authority to conclude, when reviewing data, that the foods being produced is 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, etc.; table and equipment used to assemble/package foods; packaging equipment; hand tools, gloves, aprons, etc.; metal surfaces with gaps (bad welding, etc.); and food residue sites and other hard to clean areas (Health Canada, 2010).

Furthermore, additional sampling may also 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 (e.g., 1 – 10) tested will vary according to the complexity of the processing system and packaging line. The frequency and points of sampling 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). In some situations, food in various stages of processing or product build-up can be analyzed to further assess the presence of *Listeria* spp. along a production line or system. 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 (e.g., construction, the installation of used or modified 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 respond as soon as possible to all unsatisfactory FCS testing results, with appropriate follow-up actions, including corrective actions (see Section 7.2.3) 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. Figures 2 and 3 are reflective of the risk the RTE food may pose to consumers if *L. monocytogenes* is present. One of the goals of the *Listeria* policy is to encourage RTE food manufacturers to perform aggressive

environmental sampling on a regular basis and to perform trend analysis on their results to detect problems that need corrective actions.

Furthermore, if FCS samples are found positive at one (Figure 2), two (Figure 2) or more (Figure 3) steps, end-product testing should be performed.

RTE food manufacturers should test FCSs for *Listeria* spp., which provides for a more sensitive and broader environmental monitoring program than would testing for *L. monocytogenes* alone. 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 found on a FCS (Figures 2 and 3).

7.2.1.1 Persistence of *Listeria* spp. on Food Contact Surfaces

In a situation where two or more FCS samples from the same production line (i.e., using the same equipment) are found positive for *Listeria* spp. within a short timeframe[16], such a situation is considered to be potential evidence of persistence and an indication that the food safety system (e.g., GMPs, sanitation practices) may be inadequate to prevent the establishment of *Listeria* spp. in the food processing environment. RTE food manufacturers should respond as soon as possible with appropriate follow-up actions, including corrective actions (see Section 7.2.3) and investigative sampling. Investigative sampling will assist in finding and correcting 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 and aerosols; standing water; cracks in floors and walls; smokehouses; floors in heavily-trafficked areas; tires on fork-lift trucks; foot and wheel baths that are not in "good shape"; high-pressure hoses; cleaning tools (mops, squeegees, brushes, etc.); trash cans; under-side of conveyor belts; hollow rollers; roller guards, bearings, etc.; chill tanks; refrigerators, cold rooms; ice makers; overhead pipes; drip pans; wet insulation; maintenance tools; dust from construction; and air filtration (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

[16] In the case of persistence, the determination of a specific timeframe is operation-specific. This will vary based on factors such as production volume, production seasonality and testing frequency.

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 sampling other sites might reveal a positive, and hence be more informative in resolving the problem. Positive testing 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).

7.2.3 Corrective Actions for Unsatisfactory FCS and Non-FCS Testing Results

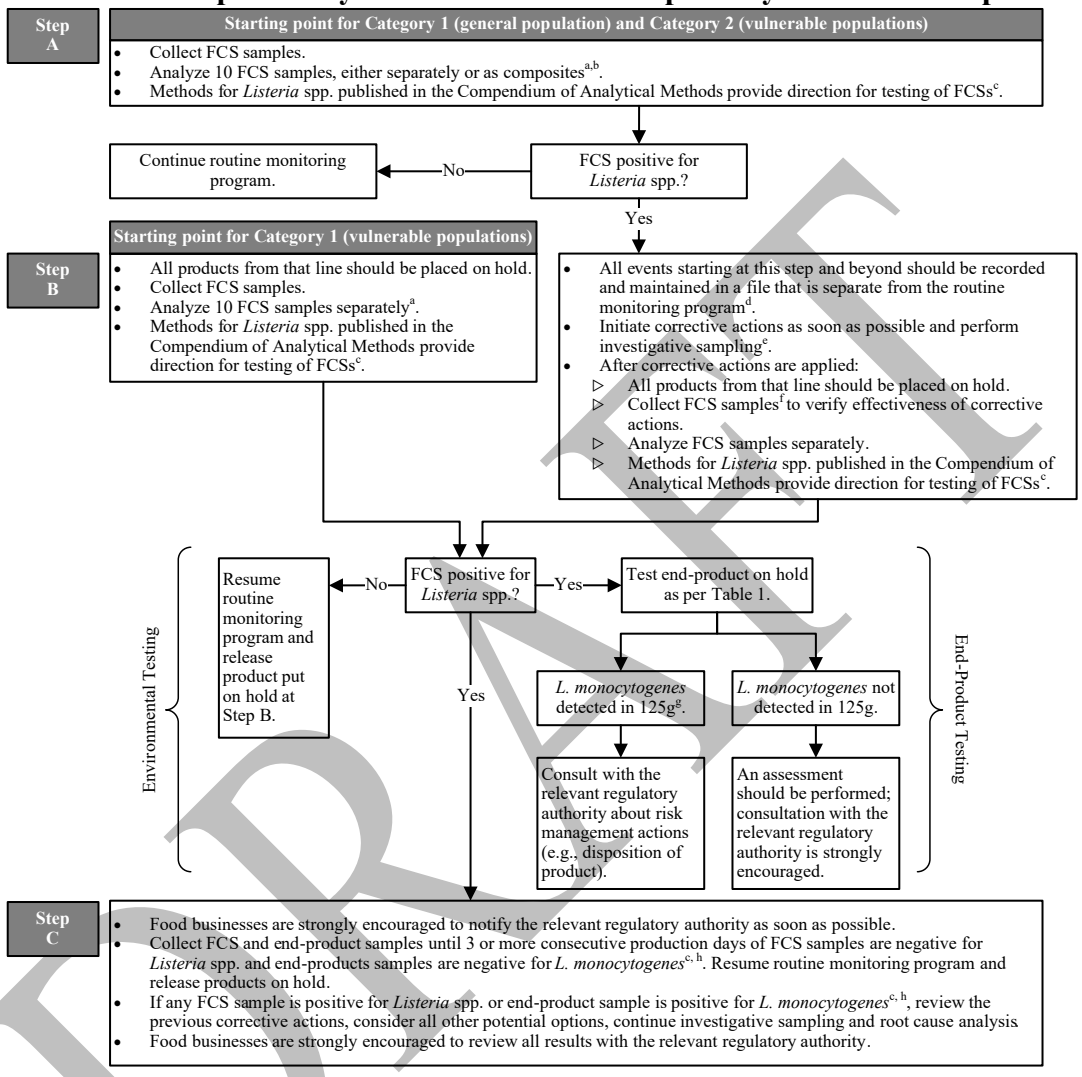
RTE food manufacturers should respond as soon as possible to all unsatisfactory FCS and non-FCS testing results (Figures 2, 3 and 4) with appropriate corrective actions. These may include the following:

- 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, 3 and 4)
    - Timely re-testing of the positive sites
    - Testing of end-products 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 (e.g., HACCP plan) and making necessary improvements

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).

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 and Category 1 Ready-to-Eat Foods Produced for Consumption by the General Population, as well as Category 1 and 2 Ready-to-Eat Foods Specifically Produced for Consumption by Vulnerable Populations

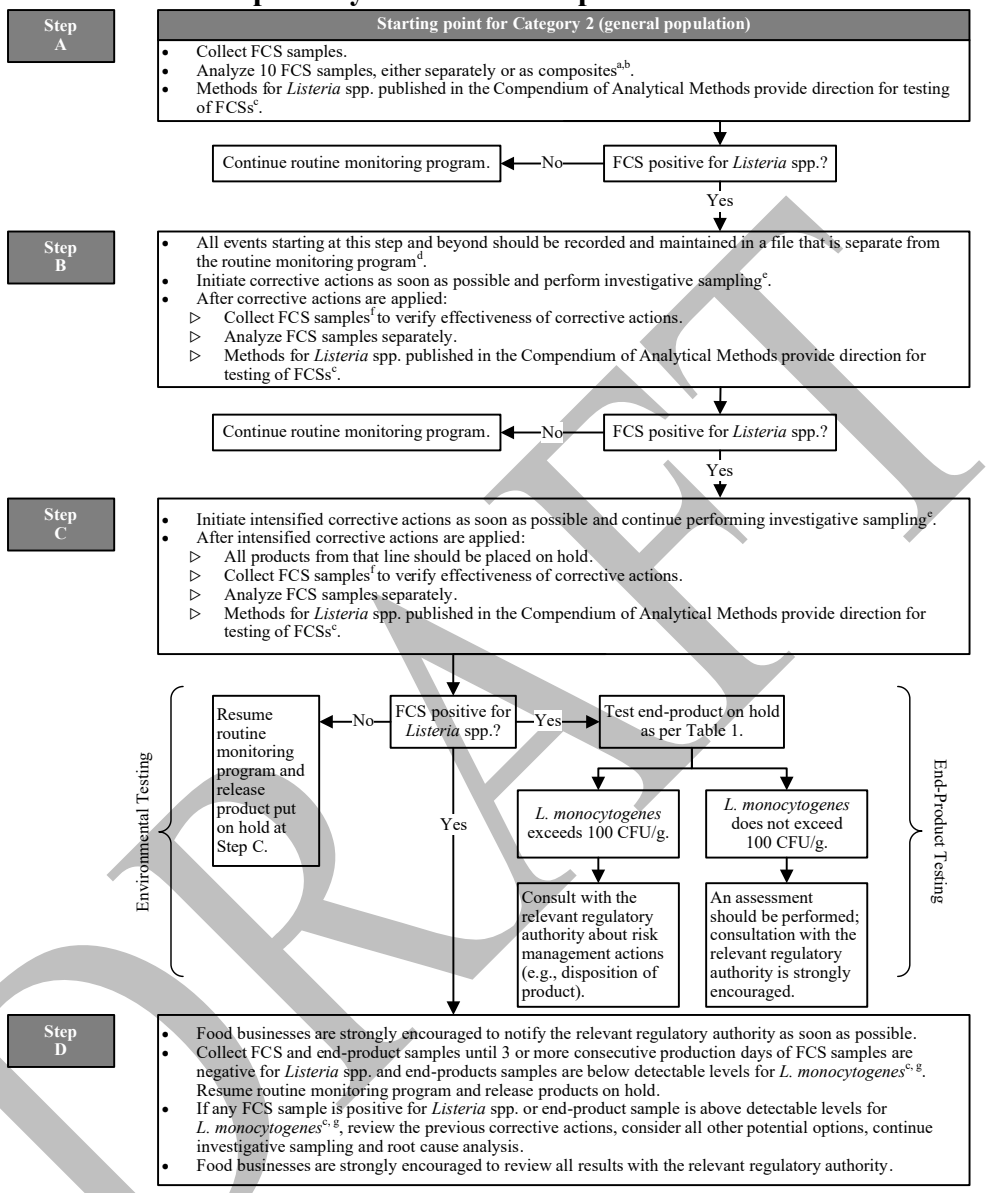


a. The number of meaningful sampling sites (preferably 10) selected on each processing line should depend upon the complexity of the lines.
b. If analyzing FCS samples as composites, a maximum of 10 FCS samples should be composited.
c. The "application" section of the method must be appropriate for the intended purpose (e.g., 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 (e.g., disposition of product).
e. Investigative sampling will assist in finding and correcting 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. If *L. monocytogenes* is detected on end-product at Step B, all subsequent lots of product (i.e., those manufactured after the tested end-product) should be tested.
h. An enrichment method for *L. monocytogenes* (i.e., presence or absence) should be used for end-product testing. The Compendium of Analytical Methods provides direction for end-product testing (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 found 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

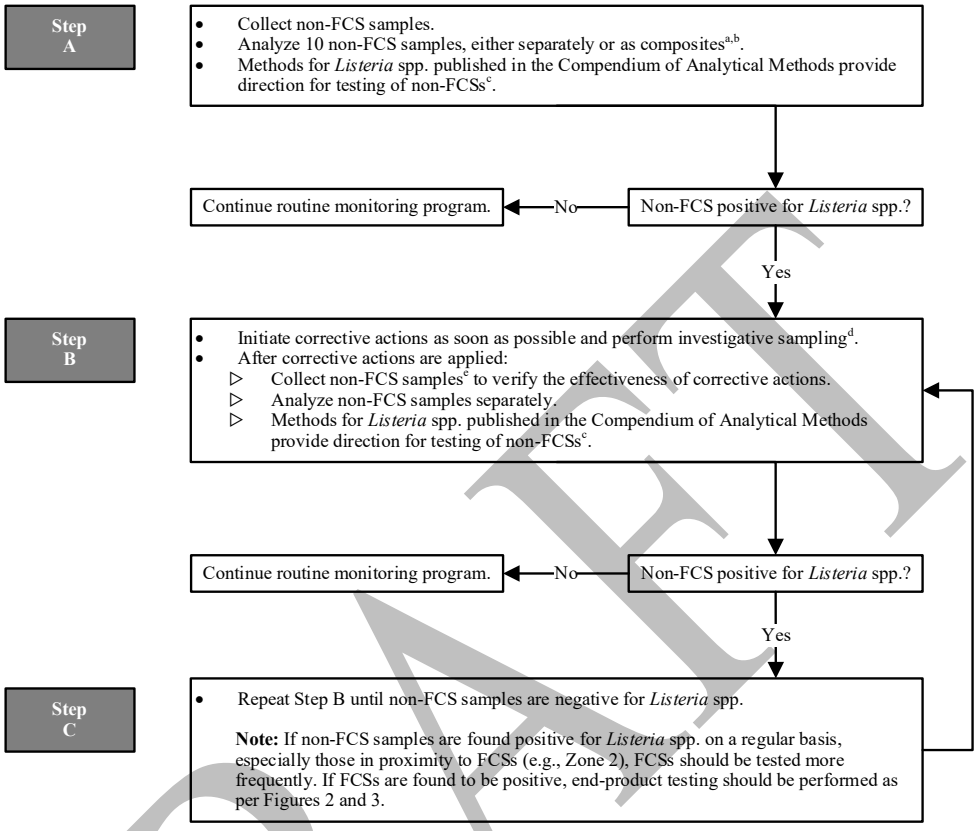


a. The number of meaningful sampling sites (preferably 10) selected on each processing line should depend upon the complexity of the lines.
b. If analyzing FCS samples as composites, a maximum of 10 FCS samples should be composited.
c. The "application" section of the method must be appropriate for the intended purpose (e.g., 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 (e.g., disposition of product).
e. Investigative sampling will assist in finding and correcting 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* (i.e., an enumerative method done by direct plating onto selective agar) should be used for end-product testing. The Compendium of Analytical Methods provides direction for end-product testing (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 found on a FCS.

Figure 4: Sampling Guidelines for Non-Food Contact Surfaces, Especially Those in Proximity to Food Contact Surfaces



a. The number of meaningful sampling sites (preferably 10) selected in the plant should depend upon the complexity of the plant.
b. If analyzing non-FCS samples as composites, a maximum of 10 non-FCS samples should be composited.
c. The "application" section of the method must be appropriate for the intended purpose (e.g., MFHPB and MFLP methods; Health Canada, 2021a).
d. Investigative sampling will assist in finding and correcting 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 more 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 (i.e., implementation of an appropriate environmental sampling plan; Figures 2, 3 and 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 end-products, rather than relying solely on end-product testing. Accordingly, microbiological testing of food that yields an absence of *L. monocytogenes* may not portray the overall true 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 (non-exhaustive list):

- As part of the *Listeria* environmental monitoring program (e.g., 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 end-products
- Verification of the effectiveness of food additives or food processing aids
- Development of 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 (e.g., testing of previously distributed lots where continued exposure is expected)

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

When testing end-products, 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
- 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 unsatisfactory test results for *L. monocytogenes* in a RTE food should be addressed immediately by the food business. It is strongly encouraged to communicate this information to the relevant regulatory authority having jurisdiction over risk management actions.

Samples of RTE end-products 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, as well as 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 their categories, an enrichment method for *L. monocytogenes* (i.e., presence or absence) should be used for end-product testing of RTE foods specifically produced for consumption by vulnerable populations. Methods, such as MFHPB-07, MFHPB-30, MFLP-01 (Pagotto *et al*., 2011a; Warburton *et al.,* 2012; Pagotto and Hébert, 2016), 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 X 25 g for these RTE foods should be used and analyzed separately or composited, as specified in Table 1.

When the presence of *L. monocytogenes* in RTE foods specifically produced for consumption by vulnerable populations is detected, the food business should start an investigation to determine whether potentially unsafe food has left its control and if so, the extent of distribution (e.g., 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 correcting the source of *Listeria* spp., particularly if there is a harbourage site (Figure 2; CAC, 2009a). The food business should take action on an identified unsafe lot 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 end-products should trigger immediate follow-up by the food business as described in steps B and C of Figure 2. It is strongly encouraged to 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

An enrichment method for *L. monocytogenes* (i.e., presence or absence) should be used for end-product testing of Category 1 RTE foods. Methods, such as MFHPB-07, MFHPB-30, MFLP-01 (Pagotto *et al*., 2011a; Warburton *et al.,* 2012; Pagotto and Hébert, 2016), 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 X 25 g for these RTE foods should be used and analyzed separately or composited, as specified in Table 1.

When the presence of *L. monocytogenes* in a Category 1 RTE food is detected, the food business should start an investigation to determine whether potentially unsafe food has left its control and if so, the extent of distribution (e.g., 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 correcting the source of *Listeria* spp., particularly if there is a harbourage site (Figure 2; CAC, 2009a). The food business should take action on an identified unsafe lot 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 end-products should trigger immediate follow-up by the food business as described in steps B and C of Figure 2. It is strongly encouraged to 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* (i.e., an enumerative method done by direct plating onto selective agar) should be used for end-product testing of Category 2 RTE foods. 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 X 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 the presence of *L. monocytogenes* in a Category 2 RTE food exceeds 100 CFU/g, the food business should start an investigation to determine whether potentially unsafe food has left its control and if so, the extent of distribution (e.g., 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 correcting the source of *Listeria* spp., particularly if there is a harbourage site (Figure 3; CAC, 2009a). The food business should take action on an identified unsafe lot 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 a Category 2 RTE food should trigger immediate follow-up by the food business as described in steps C and D of Figure 3. It is strongly encouraged to communicate this information as soon as possible to the relevant regulatory authority having jurisdiction over risk management actions. Furthermore, the presence of *L. monocytogenes* at low levels (not exceeding 100 CFU/g) in a food, occurring repeatedly at brief intervals, is likely an indication of an inadequate food safety system (e.g., HACCP) that cannot reduce *L. monocytogenes* to below detectable levels.

7.3.4 Follow-up Actions to Positive Ready-To-Eat Food Testing Results

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

- Stopping the sale of implicated foods
- Stopping the distribution of implicated foods
- Initiating a review of the food safety system
- Initiating investigative sampling
- Initiating additional end-product testing

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 growth of *L. monocytogenes* **can** occur[c] throughout the stated shelf-life, e.g., "best before" date (e.g.[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 x 25 g analytical units[e], analyzed either separately or com-posited	Presence or absence	**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, e.g., "best before" date. A number of factors will be taken into consideration with regards to which foods may fall into this Category – i.e., (1) RTE foods which are known to occasionally contain low levels of *L. monocytogenes* and their processing does not involve any heat treatment **(with validation)**; (2) RTE refrigerated foods with a stated shelf-life of 5 days or less. Such foods could include: fresh-cut fruits and vegetables, etc. **Category 2B (General Population)** RTE foods in which growth of *L. monocytogenes* **will not** occur[l] (i.e., increase not exceeding 0.5 log CFU/g) throughout the stated shelf-life, e.g., "best before" date (**with validation, as applicable**). Such foods could include: ice cream, hard cheese, frozen fruits, etc.	5 sample units (min 100 g or ml each), which are representative of the lot and the production conditions, taken aseptically at random from each lot	5 x 10 g analytical units[e], analyzed separately	Enumer-ation	**> 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 methodology for Category 1 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 its stated shelf-life.

a- For a definition of RTE foods, see Section 2.1.

b- Other criteria (e.g., process, packaging, outbreak data) could also have an impact on the level of priority for the frequency of process monitoring, environmental sampling and end-product testing.

c- For additional details on determining the RTE food category, see Figure 1 and Section 6.1.

d- These are traditional examples of Category 1 foods.

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

f- An enrichment method for *L. monocytogenes* (i.e., presence or absence) should be used for end-product testing of such RTE foods. Methods, such as MFHPB-07, MFHPB-30, MFLP-01, 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 and 7.3.2.

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 five 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* (i.e., an enumerative method done by direct plating onto selective agar) should be used for end-product testing of such RTE foods. Methods, such as MFLP-74, can be found in the Compendium of Analytical Methods (Health Canada, 2021a). This will determine the Colony Forming Unit (CFU/g) of *L. monocytogenes* 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.

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

k- The presence of *L. monocytogenes* in a Category 2 RTE food at levels exceeding 100 CFU/g 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.

A RTE food in which 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
- Combinations of factors (e.g., pH < 5.0 and a_w < 0.94)
- Frozen foods (i.e., labelled "Keep Frozen" on the package)

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

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 corrected (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 a 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 (e.g., 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 one or more individuals within the organization (e.g., 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). In situations where there is evidence of persistence (see Section 7.2.1.1), 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: Definitions

The following definitions are intended to be used 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).

Durable life:
Section B.01.001 of Division 1, Part B (Foods) of the *Food and Drug Regulations* defines "durable life" as follows: "*Durable life means the period, commencing on the day on which a prepackaged product is packaged for retail sale, during which the product, when it is stored under conditions appropriate to that product, will retain, without any appreciable deterioration, its normal wholesomeness, palatability, nutritional value and any other qualities claimed for it by the manufacturer"* (durée de conservation) (Government of Canada, 2022d).

Durable life date:
Section B.01.001 of Division 1, Part B (Foods) of the *Food and Drug Regulations* defines "durable life date" as follows: "*Durable life date means the date on which the durable life of a prepackaged product ends*" (date limite de conservation) (Government of Canada, 2022d).

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, 2022a).

Food safety system:
"*Managerial and administrative structures and processes to facilitate food safety program's design and delivery, ongoing maintenance, evaluation and continual improvement*" (CFIA, 2013).

Good Agricultural Practices (GAPs):
A generic term that includes all key conditions and practices by primary agricultural producers (e.g., 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 (i.e., 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:
"*Is 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 Canada, 2011):
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 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*".

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, 2022d).

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

Line:
A number of pieces of equipment (e.g., 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 two complete sanitation cycles. It is strongly recommended that the time between two cycles be a maximum of one day.

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

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 unsatisfactory food contact surface testing results, e.g., two positive results for *Listeria* spp. from the same production line (i.e., 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 RTE foods during post-processing, prior to packaging (e.g., 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 (i.e., verification of key process parameters used to control *L. monocytogenes*).

Ready-to-eat foods:
For the purpose of the *Listeria* policy[17], "ready-to-eat foods" are defined in Section 2.1.

Ready-to-eat food manufacturer:
The ready-to-eat food manufacturer referred to in the *Listeria* policy includes domestic food businesses that package ready-to-eat foods, which have been manufactured, processed, prepared or preserved as well as manufacturers of ready-to-eat foods for export that require a licence under the *Safe Food for Canadians Regulations* (see Sections 3.1.1 and 3.1.3) (Government of Canada, 2022c).

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, 2022d).

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: "S*ell 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"

[17] 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, as meaning "*that it has been subjected to a treatment or process that is sufficient to inactivate vegetative pathogenic micro-organisms or their toxins and control spores of food-borne pathogenic bacteria so that the meat product does not require further preparing before consumption except washing or thawing or exposing it to sufficient heat to warm it without cooking it.*" (Government of Canada, 2022c). It is the food industry's responsibility to produce safe food and to comply with all applicable Canadian legislative requirements.

(vente) (Government of Canada, 2022a).

Trend analysis:
Analysis aimed at identifying areas of concerns in relation to the introduction, repeated presence and movement of *Listeria* in the processing environment and food over time. The goal is to reflect 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 such as people with weakened immune systems (e.g., AIDS patients, transplant recipients, cancer patients, dialysis patients, etc.), pregnant women or adults ages 60 and over (FAO/WHO, 2004; Government of Canada, 2016; 2021b; 2021c; 2021e).

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, 2022d).

Appendix B: Foodborne Listeriosis Illnesses in Canada

Table 2: Foodborne Listeriosis Illnesses 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
2017-2019	6 (0)	Enoki mushrooms	CFIA, 2021; WHO, 2020
2018	7 (0)	Cooked roast beef products	CFIA, 2018; CNPHI, 2021
2019	7 (0)	Cooked diced chicken	PHAC, 2019; CFIA, 2019a

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, 2019b).

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 one 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 one 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, 2022d).

The use of food additives is one of the 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 its 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; 2020). 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[18] that can achieve a minimum 3-log reduction in numbers of *L. monocytogenes*, can also be part of an overall approach to minimize the risks associated with *L. monocytogenes* in RTE foods. Such an intervention step can reduce the levels or 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. Examples of post-packaging treatments include surface heat pasteurization (by steam, hot water, radiant oven heating or infrared technology) and high-pressure processing.

[18] 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, 2021c).

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

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