Health Canada – Policy on *Listeria monocytogenes* in ready-to eat foods (2023) Questions & Answers

Canadian Produce Marketing Association (CPMA) members had requested a Question & Answer document be created in response to some of the more common inquiries they had with respect to the Health Canada's - Policy on *Listeria monocytogenes* in ready-to eat foods (2023).

The answers below have been provided by Health Canada (HC), the Canadian Food Inspection Agency (CFIA) or jointly, as applicable.

Members requiring clarification on the answers or with other questions can contact Jeff Hall, jhall@cpma.ca or 1 (647) 409-3570 or Health Canada at Contact Health Canada .

(Note: Links to specific resources can be found in the Endnotes of the document.)

1. **How does the HC policy compare to similar policies used by Canada's largest trading partners?**

Health Canada's *Listeria* policy (2023)[1] is a tool adapted to the Canadian food context. It applies to the manufacturing and importation of ready-to-eat foods sold in Canada. The *Listeria* policy considers the potential for the growth of *Listeria monocytogenes* to occur as well as the presence or levels of *L. monocytogenes* in ready-to-eat foods as factors to determine the health concern these foods represent to consumers.

The categorization of ready-to-eat foods and the action levels in the *Listeria* policy are aligned internationally with:

- the Codex Alimentarius Commission (CXG 61-2007)[2],
- the Commission of European Communities (Commission Regulation (EC) No 2073/2005)[3]
- Food Standards Australia New Zealand[4].

A risk-based approach, like this one, protects the health of consumers while applying fair practices in food trade. That said, Canada's trading partners may choose to apply different food safety measures, such as the USA's "zero-tolerance" approach to *L. monocytogenes* in all ready-to-eat foods (FDA's Draft Guidance for Industry [5]and the USDA FSIS *Listeria* Guideline[6]).

2. What criteria were used to ensure the HC policy protected public health without creating trade disadvantages to Canada's food industry?

Many types of information were considered during the review of Health Canada's *Listeria* policy, including international approaches to *Listeria* in ready-to-eat foods. The *Listeria* policy (2023) incorporates the following principles:

- Imported food must meet the same food safety outcomes as food prepared in Canada and
- Canadian exporters are responsible, at a minimum, for exporting foods that meet Canadian food safety requirements.

The approach described in Health Canada's *Listeria* policy (2023)[1] is like that of the Codex Alimentarius Commission, the joint intergovernmental body established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), in their "Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods" (CXG 61-2007)[2]. It is a risk-based approach that aims to protect the health of consumers while applying fair practices in food trade.

3. Is the 2023 *Listeria* & RTE foods policy a regulation requiring compliance or is it a guidance document to help industry understand and implement a *Listeria* mitigation program?

Health Canada's *Listeria* policy (2023)[1] applies to the manufacturing and importation of ready-to-eat foods that are sold in Canada, as defined in the section "Application of the policy". The *Listeria* policy guides industry on how to comply with federal food legislation and is a resource for the Canadian Food Inspection Agency for such enforcement. Following the application and verification activities described in the *Listeria* policy is a means of exercising due diligence in reducing the risk of *L. monocytogenes* in ready-to-eat foods. Additional information on this topic can be found in the section "Legislative context" of the *Listeria* policy.

Canadian food manufacturers and importers are ultimately responsible for producing safe food and complying with all applicable Canadian legislative requirements. Health Canada's *Listeria* policy is intended to support the interpretation and application of the *Food and Drugs Act*[7]. That said, certain control measures and reporting recommendations described in the *Listeria* policy may be regulatory requirements under the *Safe Food for Canadians Regulations* (SFCR)[8]*.* Food businesses that require a licence under the SFCR should refer to the CFIA's industry guidance entitled "Control measures for *Listeria monocytogenes* in ready-to-eat foods"[9] for further details.

4. What is the relationship between the HC policy and CFIA's "Control measures for *Listeria* monocytogenes in ready-to-eat foods"?

Health Canada's *Listeria* policy (2023)[1] is used by the Canadian Food Inspection Agency in the conduct of federal food inspections. This policy supports the interpretation and application of the *Food and Drugs Act*[7].

The CFIA's industry guidance entitled "Control measures for *Listeria monocytogenes* in ready-to-eat foods"[9] is based on Health Canada's *Listeria* policy. This industry guidance is intended to help food businesses comply with the *Safe Food for Canadians Act*[10] and *Regulations*[8] and the *Food and Drugs Act*[7] and *Regulations*[11]. RTE food manufacturers and importers requiring 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 requirements under this regulation. The CFIA's industry guidance provides these details as well as specific risk-based sampling and testing frequencies for *Listeria*.

5. CFIA's "Control measures…" is a guidance document for industry but how much flexibility do organizations have when developing their own *Listeria* programs?

The "Control measures for *Listeria monocytogenes* in ready-to-eat foods"[9] is intended to help food businesses:

- establish control measures to prevent the introduction of *L. monocytogenes* into RTE foods
- establish procedures to monitor for the presence of *Listeria* in the establishment (environmental sampling program), as well as in RTE foods
- determine follow-up actions when *Listeria* is found on food contact surfaces (FCS), on non-food contact surfaces (non-FCS), in food
- conduct a trend analysis

The implementation of this industry guidance by food businesses helps achieve the control of *L. monocytogenes* and compliance to the related requirements. If they do not follow the industry guidance, they must present evidence of effectiveness of their *Listeria* controls[12].

6. When an inspection takes place, how will the CFIA Inspector determine which commodities are in scope and which are out? (i.e., are baby carrots in, but sprouts / microgreens out)

Health Canada's *Listeria* policy (2023)[1] is the document used by CFIA to determine if the products are in scope of the policy. If there is uncertainty about the inclusion or exclusion of an RTE product from the policy, inspectors can request support via the established process for advice and guidance.

7. Canada and the U.S. negotiated the Food Safety Systems Recognition "Arrangement" which affirms that their national systems ensure equivalent public health outcomes. Given the "Arrangement", if a U.S. company is compliant with FDA regulations would that satisfy the requirements under the SFCR with respect to importer and non-resident importer (NRI) responsibilities as per *Listeria*?

All importers will still need to demonstrate that products meet the Canadian food safety requirements. While US producers do not need to follow Health Canada's *Listeria* policy (2023) in order to export RTE foods to Canada, they need to have effective preventive controls in place that control the hazard of *L. monocytogenes* in RTE foods. It is the importer's responsibility to ensure that the foreign supplier they source from has controls in place that meet the same level of food safety controls as food prepared in Canada.

Refer to Importing food to Canada: a step-by-step guide[13] for how to meet the importer's requirements.

8. Canadian importers, including NRI's, are responsible for ensuring the products they bring into Canada meet the requirements of the SFCR. What systems, documentation, or analytical results are importers expected to have to satisfy CFIA / HC with respect to *Listeria*?

As per the Preventive Control Plans for Importers, importers are required to maintain records to demonstrate that the food they are importing was prepared with at least the same level of food safety controls as food prepared in Canada which includes control measures to prevent the introduction of *L. monocytogenes* in RTE foods. Within their preventive control plan (PCP), importers must identify the relevant hazards in the foods they are importing and provide evidence that their supplier is controlling the hazards. Importers should also have assurances that their foreign supplier has:

- control measures to prevent the introduction of *L. monocytogenes* into RTE foods
- procedures to monitor for the presence of *Listeria* in the establishment (environmental sampling program), as well as in RTE foods
- follow-up actions when *Listeria* is found on FCS, on non-FCS and in food

Importers will need to provide evidence that the control measures are effective through various methods which may include sampling and testing imported food from each supplier at a determined frequency, a Certificate of Analysis with shipments or Supplier Quality Assurances, or through other means.

To demonstrate the foreign supplier from the US is under the Food Safety Systems Recognition Arrangement, the importer must also keep evidence that the food to be imported is part of the arrangement: and that the foreign supplier(s) is subject to the oversight of the foreign government and is in good standing within the recognized system.

9. As per the policies section, 3.1 Industry, "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." can HC provide examples which would satisfy the "demonstrate" requirement of this excerpt?

Under the *Safe Food for Canadians Regulations* (SFCR)[8], food businesses need to:

- Consider *L. monocytogenes* as a hazard that can present a risk of contamination to the food, when conducting a hazard analysis for an RTE food.
- Implement preventive controls and verify their effectiveness to ensure the food they produce, or import is not contaminated with *L. monocytogenes*.
- Respond appropriately to mitigate risk when *Listeria* is detected and notify the CFIA when a food presents a risk of injury to health.
- Document their control measures and the evidence that the control measures are effective in a preventive control plan.

Overall, food businesses must be able to demonstrate that their food safety system will control *L. monocytogenes* in RTE foods. The implementation of the industry guidance by food businesses helps demonstrate the control of *L. monocytogenes* and compliance to the related requirements.

10. Are companies required to test for *Listeria monocytogenes* or will *Listeria* spp. suffice?

Health Canada's *Listeria* policy (2023)[1] encourages ready-to-eat food manufacturers to perform robust environmental sampling and testing for *Listeria* spp. (please refer to Figures 2, 3 and 4). Such testing 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. Nevertheless, if manufacturers choose to test FCSs for *L. monocytogenes* instead of *Listeria* spp., we recommend that individual lots of food produced at the time of FCS sampling be held pending results from this testing. End-product testing for *L. monocytogenes* should be performed if *L. monocytogenes* is detected on a FCS.

In the context of sampling and testing of ready-to-eat foods (for example, evaluation of end-product when FCSs test positive for *Listeria* spp., as stipulated in Figures 2 and 3 of the *Listeria* policy), food businesses must test for *L. monocytogenes* because the microbiological criteria for ready-to-eat foods in Table 1 of the *Listeria* policy is based on *L. monocytogenes*.

11. What laboratory certifications, validations, etc. are required for analytical results to be considered acceptable under the policy?

Section "6.4 Laboratory Procedures"[14] of the "Control measures for *Listeria monocytogenes* in ready-to-eat foods"[9] document provides guidance on acceptable laboratory accreditations and methods to be used for environmental food contact surface and finished product testing.

12. Under what circumstances are qualitative results acceptable versus quantitative results when testing for *Listeria*?

Health Canada's *Listeria* policy (2023)[1] provides guidance for environmental sampling and testing, in addition to microbiological sampling and testing of ready-to-eat foods. More information on these topics can be found in the sections "Environmental sampling (Figures 2, 3 and 4) and testing" and "Sampling and testing of ready-to-eat foods (Table 1)", respectively.
In all circumstances, a qualitative method for *Listeria* spp. should be used for environmental samples.

A qualitative method for *L. monocytogenes* should be used for end-product testing of:

- ready-to-eat foods specifically produced for consumption by vulnerable populations and
- Category 1 ready-to-eat foods.

A quantitative method for *L. monocytogenes* should be used for end-product testing of Category 2 (2A and 2B) ready-to-eat foods.

Section 6.4.1 of the CFIA's industry guidance entitled "Control measures for *Listeria monocytogenes* in ready-to-eat foods"[9] contains additional recommendations for testing of Category 2 ready-to-eat foods with higher risk levels as described in section 6.3 of this document.

Endnotes:

---

[1] Health Canada's Listeria policy (2023)
[2] Codex Alimentarius Commission (CXG 61-2007)
[3] Commission of European Communities (Commission Regulation (EC) No 2073/2005
[4] Food Standards Australia New Zealand
[5] FDA's Draft Guidance for Industry
[6] USDA FSIS Listeria Guideline
[7] Food and Drugs Act
[8] Safe Food for Canadians Regulations (SFCR)
[9] Control measures for Listeria monocytogenes in ready-to-eat foods
[10] Safe Food for Canadian Act
[11] Food and Drugs Regulations
[12] Preventive Control Plan - Evidence showing a control measure is effective
[13] Importing food to Canada: A step-by-step guide
[14] Control measures for Listeria monocytogenes in ready-to-eat foods - 6.4 Laboratory Procedures