Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Canadian Food Inspection Agency

Our vision:
To excel as a science-based regulator, trusted and respected by Canadians and the international community.

Our mission:
Dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

Implementation of the 2011 Health Canada "Policy on *Listeria monocytogenes* in Ready-to-Eat Foods"

Fish, Seafood and Production Division

March, 2012

#2739238

Canada

Objectives

1. To introduce the Health Canada (HC) 2011 *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (hereafter referred to as the *Listeria* policy) to registered establishments and importers
2. To explain the impact of the policy on fish and fish products
3. To provide information on CFIA's role in the implementation, oversight and enforcement of the 2011 HC *Listeria* policy
4. To provide information on industry's roles and responsibilities in relation to the 2011 policy.

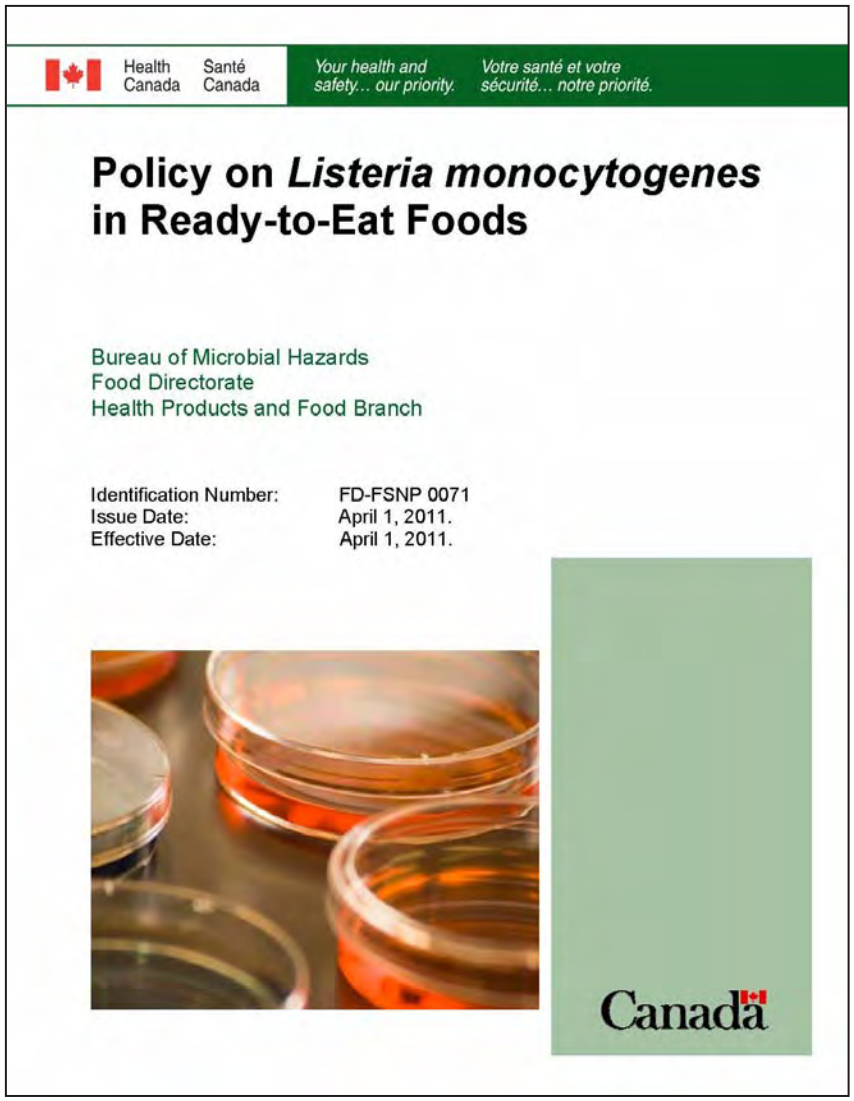
Overview of the presentation

1. Reason for the HC *Listeria* policy revision
2. General characteristics of *Listeria monocytogenes*
3. Roles and responsibilities
4. Foods that are subject to the HC *Listeria* policy
5. HC RTE food categories
6. Fish Inspection Program Guidance Documents
7. Validation Process
8. Next Steps

Key reference documents:

1. Fish Products Standards and Methods Manual, Appendix 2: Bacteriological Guidelines for Fish and Fish Products
2. Fish Products Standards and Methods Manual, Appendix 2, Figure 1: Decision Tree - Determination of the ready-to-eat (RTE) product category
3. Guidelines on the Control Measures for Preventing the Contamination and Growth of *Listeria monocytogenes* (Appendix I)
4. Guidelines for the Development of an Environmental Sampling Program (Appendix J)

Reason for the HC *Listeria* Policy Revision



http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_2011-eng.php

Effective Date

April 1, 2011

- Health Canada is responsible for setting food safety standards
- CFIA is responsible for enforcing these standards

Why was a revision needed?

- Listeriosis outbreak in 2008 resulting in 23 deaths
- Findings of an independent investigator – Weatherill Report, 2009
- Changes in international food safety guidance on *Listeria monocytogenes* (Codex Alimentarius – 2007 & 2009)

Key Revisions

1. Amendment of RTE product categories

Note that, now, fewer products fall under the lower risk category

Lower risk products characteristics:	
Before (under 2004 policy)	**Now (2011 version)**
•pH < 5, or •A_w ≤ 0.92, or •pH < 5.5 & A_w <0.95, or •refrigerated for ≤10days	•**pH < 4.4**, or •**A_w < 0.92,** or •**pH < 5 & A_w < 0.94**, or •**refrigerated for ≤ 5 days**
•Unchanged: frozen until consumption RTE products	

Key Revisions

2. **New end product action levels:**

   Category 1: Detected in 125g (2004 ~ Detected in 25 or 50g)

   Category 2 (2A and 2B): >100 CFU/g

3. **Environmental monitoring program** (i.e. swabbing) should be included in all plants producing RTE foods

4. **"Notify regulator"** included in follow up for industry when industry finds *Listeria monocytogenes* in products or *Listeria* spp. on Food Contact Surfaces (FCS)

5. **Post-lethality treatments** and/or the use of ***Listeria* growth inhibitors** (e.g. sodium diacetate) is encouraged

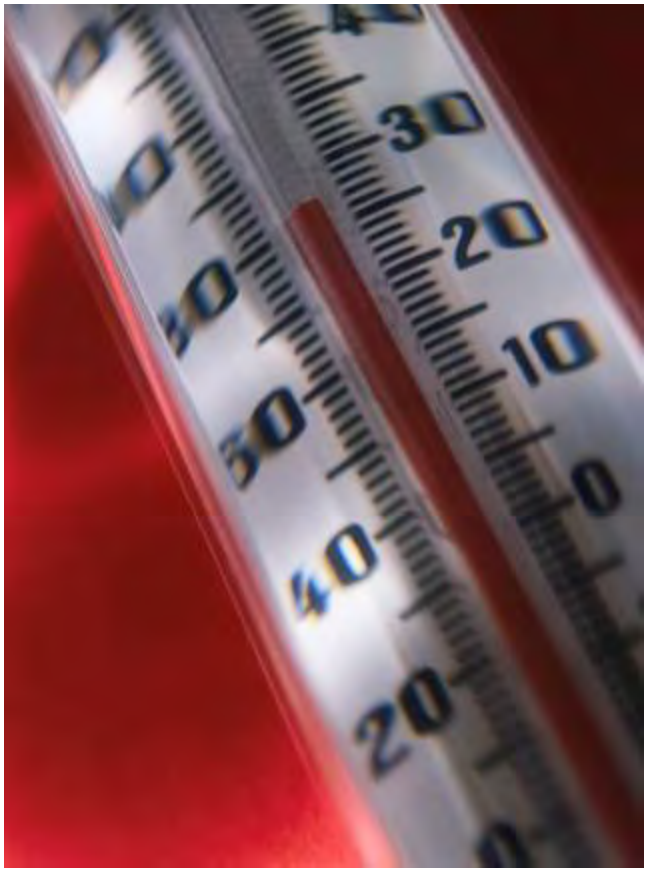
General Characteristics of *Listeria monocytogenes*

Facts about *Listeria monocytogenes*

General characteristics:

1. pathogenic to humans
2. found in soil, water, drains, ventilation systems, cracks, etc.
3. grows between -0.4 and 45°C
4. can live with or without oxygen
5. wide pH range (4.4 or greater)
6. water activity (A_w) ≥ 0.92

Listeria monocytogenes

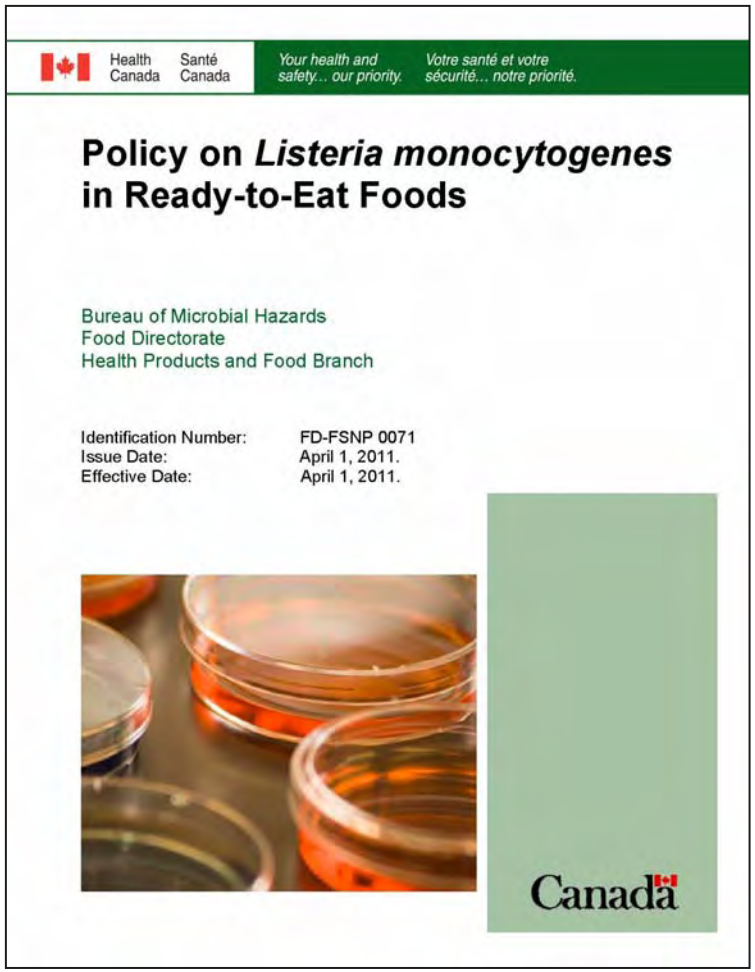


Unique Characteristics

- *Listeria monocytogenes* is widely present in the natural environment
- *Listeria monocytogenes* can grow in foods stored under refrigerated temperatures

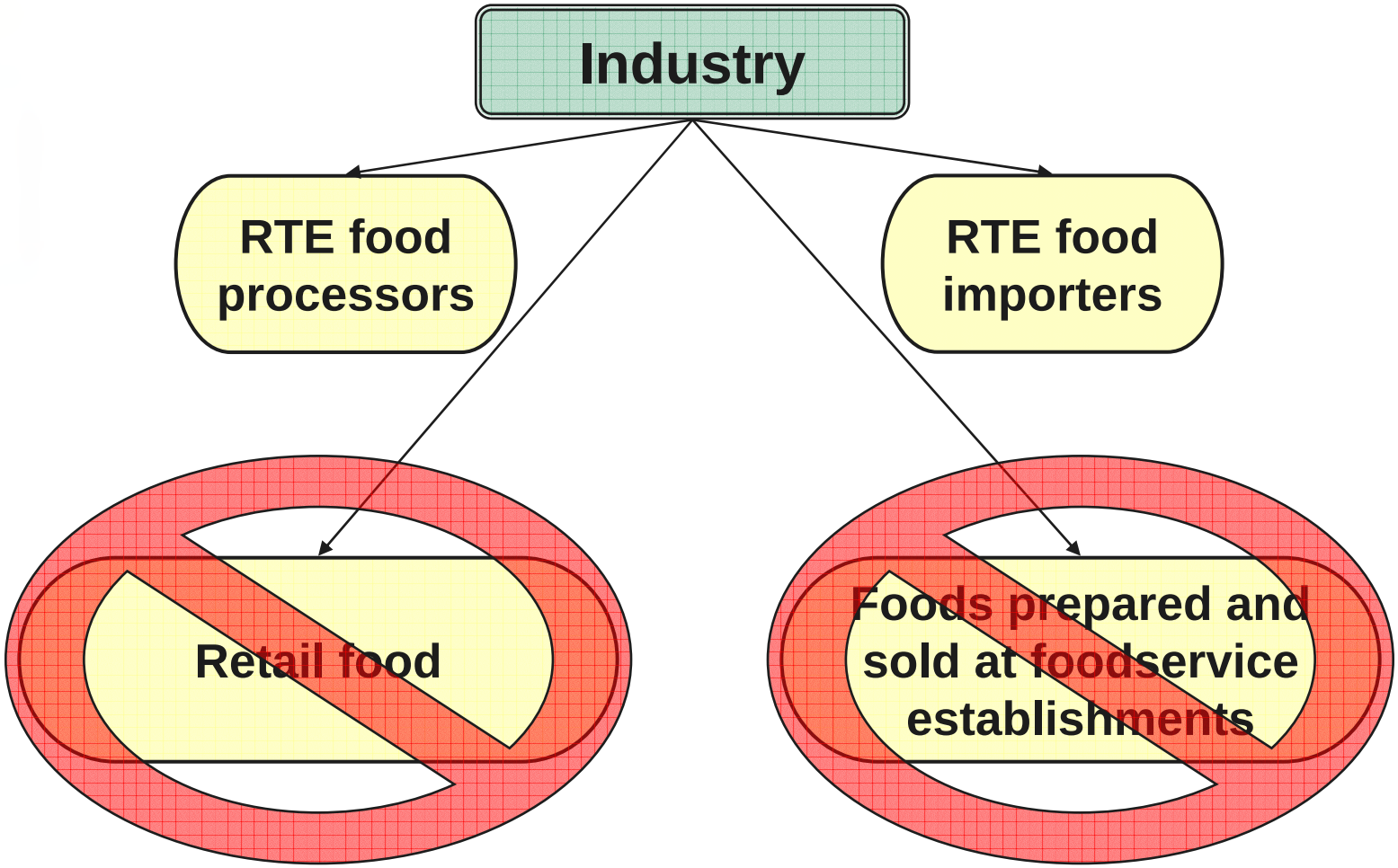
Roles and Responsibilities

Roles and Responsibilities



- Industry
- Government
- Consumers

Roles and Responsibilities



Roles and Responsibilities

RTE food processors

RTE food importers

Must ensure that the foods they sell comply with all applicable legislative and regulatory requirements including Sections 4 & 7 of the *Food and Drugs Act* (FDA) and relevant sections of the *Fish Inspection Act* and *Regulations*

The 2011 HC *Listeria* Policy provides recommendations regarding the verification, monitoring and control of *Listeria* and assist industry in complying with the FDA

Roles and Responsibilities

RTE food processors

RTE food importers

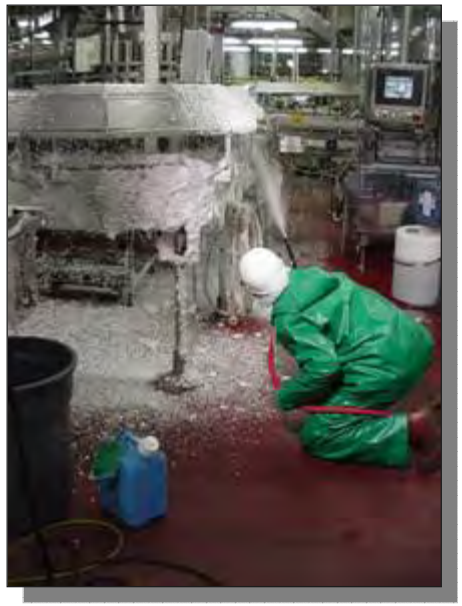
- In order to demonstrate **due diligence**, the recommendations outlined in the HC *Listeria* Policy should be applied by industry
- The HC *Listeria* Policy outlines the **minimum** actions that should be taken to prevent the presence of harmful levels of *L. monocytogenes* in finished RTE foods
- Industry can always go above and beyond these recommendations

Roles and Responsibilities

RTE food processors

The HC *Listeria* Policy advises that RTE food processors minimize the potential for *Listeria* spp. contamination by:

- ✓ Implementing effective **QMP** controls to minimize all potential sources of food contamination
- ✓ Implementing **other controls** when possible (e.g., *Listeria monocytogenes* inhibitors and post-lethality treatments)

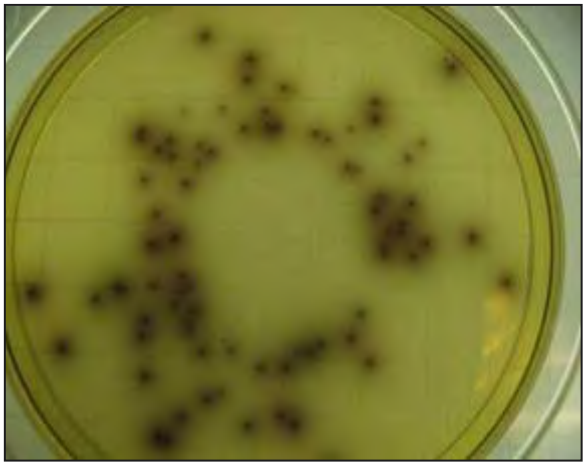


Roles and Responsibilities

RTE food processors

The HC *Listeria* Policy advises that RTE food processors should monitor and verify the effectiveness of their *Listeria* controls by:

1. Implementing an **environmental sampling program**
2. Conducting **end-product testing** when appropriate



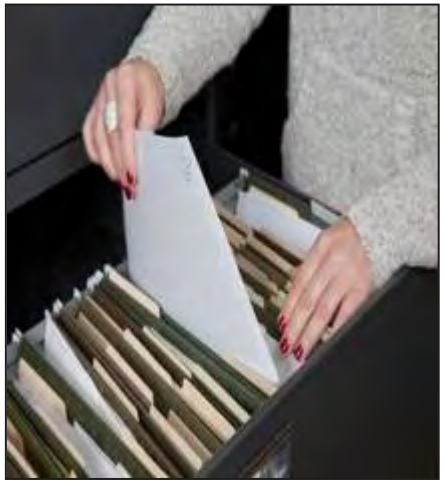
Roles and Responsibilities

RTE food importers

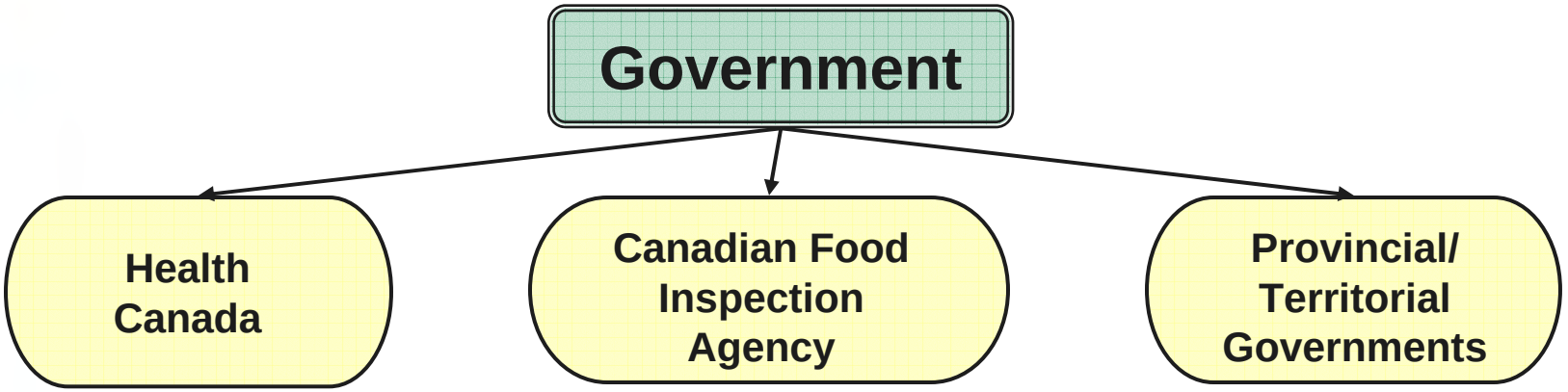
The HC *Listeria* Policy also advises that RTE food importers minimize the potential for *Listeria* contamination by:

Obtaining information on the products they sell:

- Product parameters (e.g., pH and A_w)
- Product shelf life
- Whether or not the product was manufactured using effective GMPs and/or HACCP system for control of *Listeria monocytogenes*



Roles and Responsibilities



Develops food safety standards and policies to help minimize the risk of foodborne illnesses

Consults with CFIA and the provincial/territorial governments on these standards and policies

Helps Canadians maintain and improve their health

Protects Canadians from preventable health risks

Protects consumers through a fair and effective food, animal and plant regulatory regime that supports competitive domestic and international markets

Contributes to the security of Canada's food supply and agricultural resource base

Work together with CFIA to conduct oversight activities of the food industry, such as: providing information to industry, assessing establishments' Listeria controls, taking compliance action, conducting food safety investigation.

CFIA's Responsibilities

1. Works with provincial and territorial governments to ensure food safety requirements are met in the food industry.
2. Inspects establishments and audits their Quality Management Programs (QMPs)
3. Samples and tests product, water, ice and the processing environment
4. Assesses validation data, process controls and verification procedures

Roles and Responsibilities

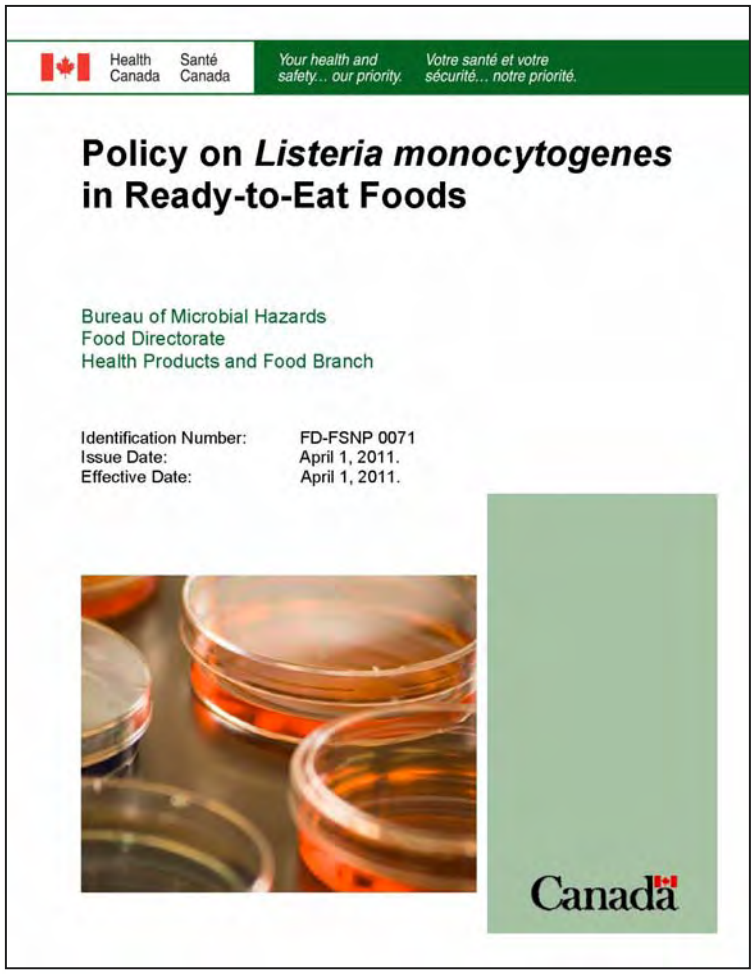
Consumers

Canadian consumers are responsible for learning and adopting the following practices:

- Responsible food selection
- Safe food handling and storage
- Safe food preparation practices

Foods that are subject to the HC *Listeria* Policy

Foods subject to the HC *Listeria* policy



Applies to Ready-To-Eat (RTE) foods sold in Canada, whether domestically produced or imported

Does not apply to RTE foods prepared in retail establishments and food service establishments

*See "RTE food" definition in the 2011 HC *Listeria* policy for more details regarding products covered/not covered.

RTE FOODS

Foods that :
<u>do not</u> require further preparation prior to consumption, other than washing/rinsing, thawing or warming.

Products NOT subject to the HC *Listeria* policy

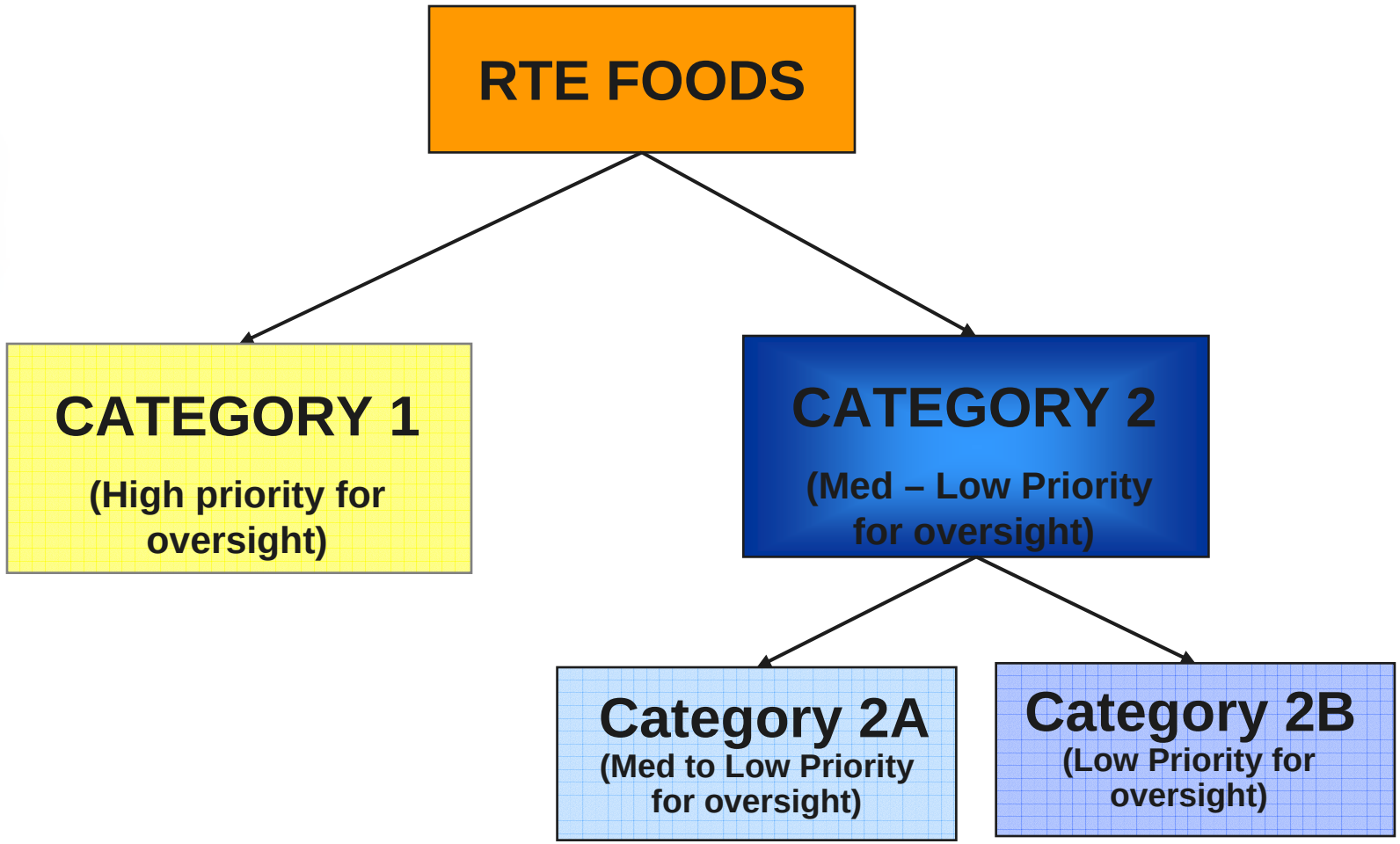
- Products that are fully cooked in a hermetically sealed container and are not exposed to the environment after a validated heat treatment.

- Processed products which require cooking and which are clearly labelled with adequate cooking instructions

- Raw fish or seafood, which includes live molluscan shellfish, are not covered by the policy. **Exception:** sushi which are subject to the provisions of the HC *Listeria* policy.

Health Canada RTE Food Categories

RTE Food Categories Defined in the HC *Listeria* Policy



HC RTE Food Category 1

CATEGORY 1

(High priority for oversight)

- RTE foods in which the growth of *L. monocytogenes* **can** occur.
- RTE products with a shelf life >5 days *with no validated control measures**

Examples:

Refrigerated seafood pâtés or mousses may be classified as Category 1 RTE foods because their pH and water activity generally supports the growth of *L. monocytogenes.*

HC RTE Food Category 1 (cont'd…)

CATEGORY 1

(High priority for oversight)

- Action Level - Detected
- These foods should receive the **highest priority** for industry verification and control, as well as regulatory oversight and compliance activities.
- The presence of *Listeria monocytogenes* in these products would lead to follow-up actions.
- A **Health Risk 1 concern** would likely be triggered and a public alert and recall may be issued if the food has left the control of the processor.

HC RTE Food Category 2

Category 2A

RTE products, which are known to occasionally contain low levels of *L. monocytogenes* and do not have a kill step*

- Refrigerated RTE products with a shelf life of 5 days or less.
- RTE products with shelf life > 5 days and reviewed and confirmed validation studies by regulatory authorities

Example :

HC RTE Food Category 2 (cont'd…)

Category 2A

- Action Level > 100 CFU/g
- These foods should receive a **medium to low priority** with regards to industry verification and control, as well as regulatory oversight and compliance activities
- The presence of *L. monocytogenes* at levels >100 CFU/g in a Category 2A food will lead to follow-up actions and will likely trigger a **Health Risk 2** level of concern
- However, the food becomes a **Health Risk 1** concern if it is intended to be produced for a high-risk population group (e.g., a hospital or a retirement home) or intended for use in a Category 1 food*

HC RTE Food Category 2 (cont'd…)

Category 2B

•Action Level > 100 CFU/g

RTE products in which the growth of *L. monocytogenes* cannot occur throughout the stated shelf life:

- stored under "frozen" conditions until consumption; or
- have a pH < 4.4; or
- have an A_w < 0.92; or
- have a pH < 5.0 AND the A_w < 0.94;
- or products not meeting the physico-chemical parameters above, with a refrigerated shelf life > 5 days, and validated control measures

Food Categories Defined in the *Listeria* Policy

	CATEGORY 1	CATEGORY 2A	CATEGORY 2B
DEFINITION	Includes RTE foods in which Lm **can** grow*	Includes RTE foods in which Lm can grow to levels of **100 CFU/g or less**	Includes RTE foods in which Lm **cannot** grow
NATURE OF CONCERN	**Health Risk 1**	**Health Risk 2** (Health Risk 1 if Lm levels are >100 CFU and food is intended for high risk groups or intended for use in Cat 1 food)	**Health Risk 2** (Health Risk 1 if Lm levels are >100 CFU and food is intended for use in Cat 1 food)
LEVEL OF PRIORITY **(control, monitoring, verification, oversight)**	**High**	**Medium** (unless the food is intended for high risk groups or intended for use in a Cat. 1 food)	**Low** (unless the food is intended for high risk groups or intended for use in a Cat. 1 food)
EXAMPLES			(Frozen)  

POLL

CFIA Decision Tree

Here we will discuss the CFIA Listeria Decision Tree, which is Figure 1 of Appendix 2 of the *Fish Products Standards and Methods Manual*

http://www.inspection.gc.ca/english/fssa/fispoi/man/samnem/app2image.shtml

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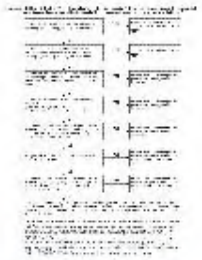
Appendix 2. Figure 1: Decision Tree - Determination of the ready-to-eat (RTE) product category

Appendix 2. Figure 1: Decision Tree - Determination of the ready-to-eat (RTE) product category that a fish product falls under in accordance with the Health Canada "Policy on *Listeria monocytogenes* in Ready-to-Eat Foods"

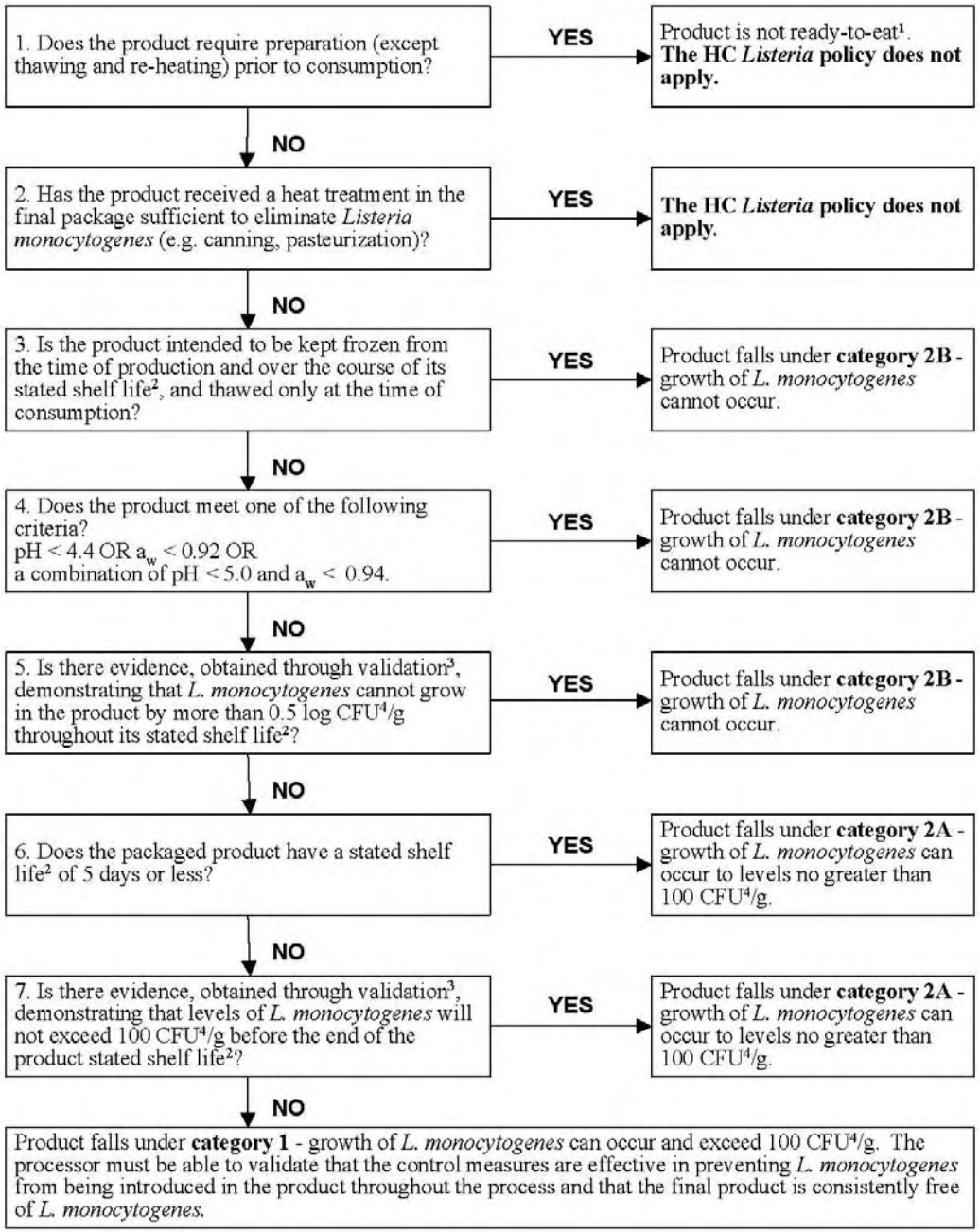
PDF (20 kb)

Click on image for larger view



Schematic - Appendix 2. Figure 1: Decision Tree - Determination of the ready-to-eat product category

Appendix 2. Figure 1: Decision Tree - Determination of the ready-to-eat (RTE)[1] product category that a fish product falls under in accordance with the Health Canada "Policy on *Listeria monocytogenes* in Ready-to-Eat Foods"



Listeria monocytogenes Guidelines

Product Type / Category	Laboratory method	Action Level
Category 1 RTE Fish products (The growth of *L. monocytogenes* CAN occur and could exceed 100 CFU/g before the end of the stated shelf-life.) **• RTE products with a shelf life > 5 days.***	**Presence/absence in 125 g** (MFHPB-30 or equivalent) on 5 sample units of 25 g each	**Detected**
Category 2A RTE Fish products (The growth of *L. monocytogenes* CAN occur but would not exceed levels greater than 100 CFU/g before the end of the stated shelf-life.) **• Refrigerated RTE products with a shelf-life of ≤ 5 days** **• Refrigerated RTE products with a shelf-life of > 5 days validated to not support, to the end of shelf life, the growth of *Lm* to levels exceeding 100CFU/g.**	**Enumeration in 50 g** (MFLP-74 or equivalent) on 5 sample units of 10 g each	**> 100 CFU/g**
Category 2B RTE Fish products (The growth of *L. monocytogenes* CANNOT occur throughout the shelf life.) **• Frozen until consumption RTE products** **• RTE products with a pH <4.4** **• RTE products with an A_w<0.92** **• RTE products with a pH<5.0 AND an A_w <0.94** **• RTE product validated to have Lm growth of < 0.5 log CFU/g**	**Enumeration in 50 g** (MFLP-74 or equivalent) on 5 sample units of 10 g each	**> 100 CFU/g**

Approved Additives:

Additives	Permitted in or upon	Maximum level of use	References
Sodium diacetate	Prepared and preserved fish products, such as smoked fish	Up to 0.25% of final product weight	Interim Market Authorization published in Canada Gazette Part I: February 14, 2009

Processing Aids:

Health Canada has issued a “Letter of No Objection” for the use of Listex P100 (bacteriophage) in cold smoked fish and other food products.

Fish Program Guidance Documents

Fish Program Guidance Documents

NEW
Decision Tree – Determination of RTE Product Category (Figure 1 of Appendix 2 of the Fish Products Standards and Methods Manual, FPSMM)
Guidelines on the Control Measures for Preventing the Contamination and Growth of *Listeria monocytogenes* (Appendix I of the QMP Reference Standard)
Guidelines for the Development of an Environmental Sampling Program (Appendix J of the QMP Reference Standard)
UPDATED
Bacteriological Guidelines , Appendix 2 of the FPSMM
Process Control Document Requirements

Document

Guidelines on the Control Measures for Preventing the Contamination and Growth of *Listeria monocytogenes*

(Appendix I of the QMP Reference Standard)

- Provide guidance on the development and implementation of control measures for *Listeria monocytogenes* by establishments.

- The control measures are meant to prevent, eliminate or reduce *L. monocytogenes* to an acceptable level as well as control and prevent conditions that will enable growth and/or contamination.

Guidelines on the Control Measures for Preventing the Contamination and Growth of *Listeria monocytogenes* (cont'd…)

- The control of *L. monocytogenes* depends on:
  - product characteristics;
  - processing methods;
  - equipment and establishment design.

- Under the Quality Management Program (QMP), the control measures must be identified as part of either the:
  - HACCP plan as a Critical Control Point (CCP);
  - Prerequisite Program; or
  - Regulatory Action Plan (RAP)

Guidelines on the Control Measures for Preventing the Contamination and Growth of *Listeria monocytogenes* (cont'd…)

Product-related Control Measures

- Incoming materials (ingredients)
- Product formulation (A_w, pH)
- Food additives and/or processing aids (inhibitors)
- Storage conditions (inhibits growth) (frozen)
- Shelf life (restricting the shelf life of refrigerated products to 5 days or less)

Guidelines on the Control Measures for Preventing the Contamination and Growth of *Listeria monocytogenes* (cont'd…)

Process-related Control Measures

- Temperature/time controls
- Lethality treatment ("kill step")
- Packaging and filling
- Post-lethality treatments

Guidelines on the Control Measures for Preventing the Contamination and Growth of *Listeria monocytogenes* (cont'd…)

Establishment-related Control Measures (Pre-requisites)

- Prevention of cross-contamination (sanitary zones);
- Enhanced sanitation controls;
- Equipment design & maintenance;
- Personnel hygiene & training programs;
- Instructions for visitors, maintenance and cleaning staff.

Guidelines on the Control Measures for Preventing the Contamination and Growth of *Listeria monocytogenes* (cont'd…)

Verification of Control Measures

The effectiveness and implementation of the control measures used to eliminate, inhibit and prevent the growth of *L. monocytogenes* can be verified through:

- Environmental testing; and
- Product testing.

Document

Guidelines for the Development of an Environmental Sampling Program

(Appendix J of the QMP Reference Standard)

- Developed as a tool to assist processors in establishing an Environmental Sampling Program for *Listeria* spp., including *Listeria monocytogenes,* in the processing environment.

- The 2011 HC *Listeria* Policy states that establishments producing RTE foods should implement an Environmental Sampling Program, which would be integrated to their Quality Management Program (QMP).

Guidelines for the Development of an Environmental Sampling Program

- Environmental sampling assesses the effectiveness of QMP controls in RTE processing environments and the potential for product contamination

- If industry tests for the presence of *L.* spp. in the environment and responds to any positive results in a responsible manner, the risk of producing foods contaminated with potentially harmful levels of *Listeria monocytogenes* can be minimized.

Guidelines for the Development of an Environmental Sampling Program (cont'd...)

The guidelines document includes ….

- **factors** to consider when developing the program;
- **elements** to include in the program;
- the response to follow when *Listeria* spp. is present in the processing environment and;
- the response to follow when there's evidence of persistent contamination in an establishment.

Guidelines for the Development of an Environmental Sampling Program (cont'd...)

Factors to Consider ….

1. The Type of RTE Product
2. Type of Process/Operation
3. Consumer/Target groups
4. Historical Information

Guidelines for the Development of an Environmental Sampling Program (cont'd...)

Elements

1) Sampling Procedures
2) Testing Method
3) Target Organism
4) Sampling Sites
5) Sampling Frequency
6) Review
7) Response when *Listeria* spp. is detected in the processing environment

- Figures 1 and 2 from the 2011 HC *Listeria* Policy will now be discussed:

  http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_2011-eng.php

Policy on Listeria monocytogenes in Ready-to-Eat Foods [Health Canada, 2011] - Microsoft Internet Explorer

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Policy on *Listeria monocytogenes* in Ready-to-Eat Foods (2011)

Health Canada has completed its update of the 2004 policy on *Listeria monocytogenes* in Ready-to-Eat (RTE) foods, in view of enhancing the control of *Listeria* in high-risk foods. The purpose of this policy is to provide guidance to stakeholders regarding verification and control, as well as regulatory oversight and compliance activities of RTE foods with respect to their potential to support the growth of *Listeria monocytogenes*. This policy, developed as a joint effort between Health Canada, the Canadian Food Inspection Agency, and the Public Health Agency of Canada, takes into account the roles and responsibilities of industry, government and consumers.

The updated *Listeria* policy (2011) will come into effect on April 1, 2011.

E-format disclaimer

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Table of Contents

Additional Resources

Summary of Comments Received on Health Canada's proposed policy on *Listeria monocytogenes* in ready-to-eat (RTE) foods - March to May, 2010

Listeria and Listeriosis

Done

Internet

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

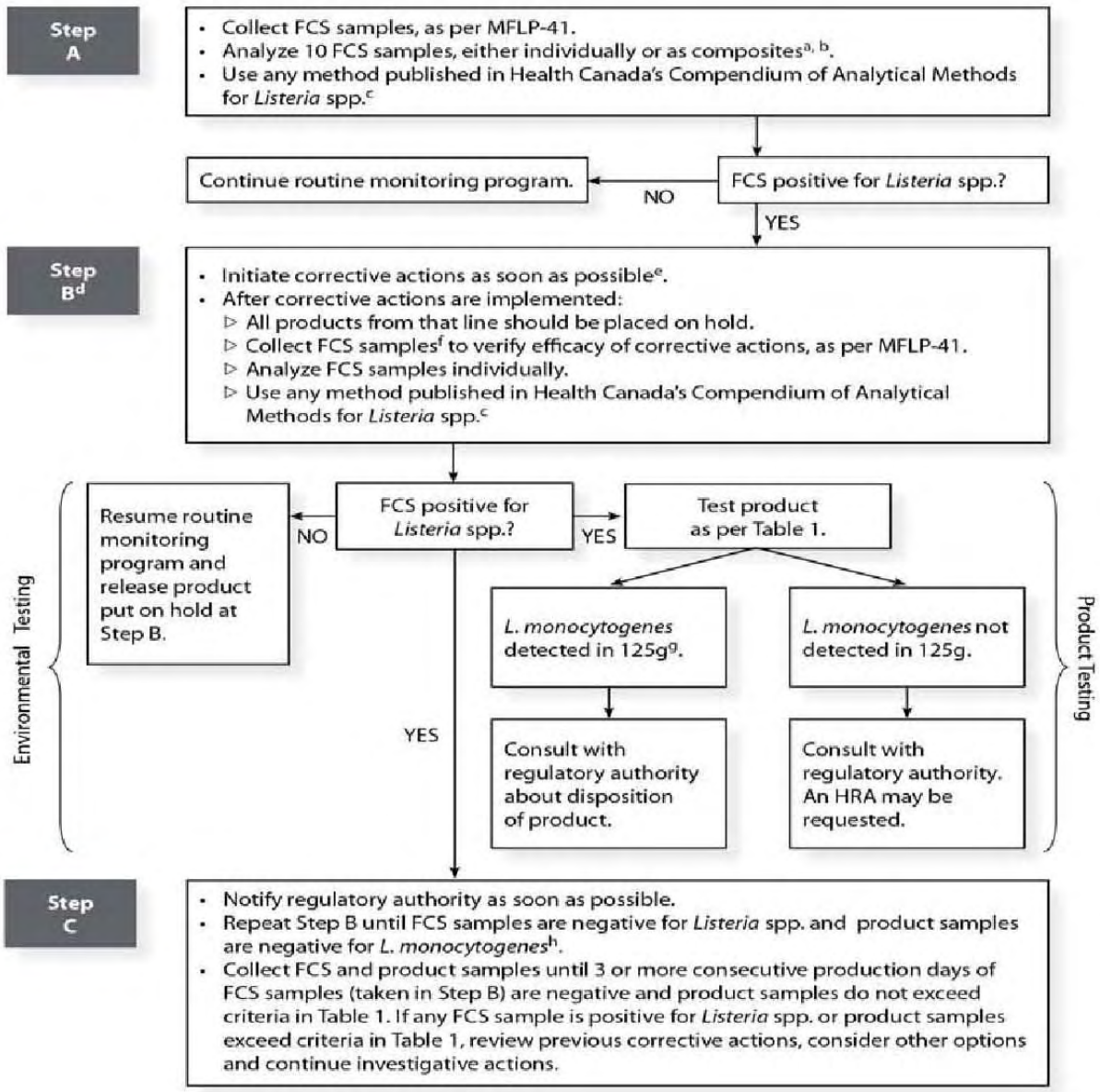
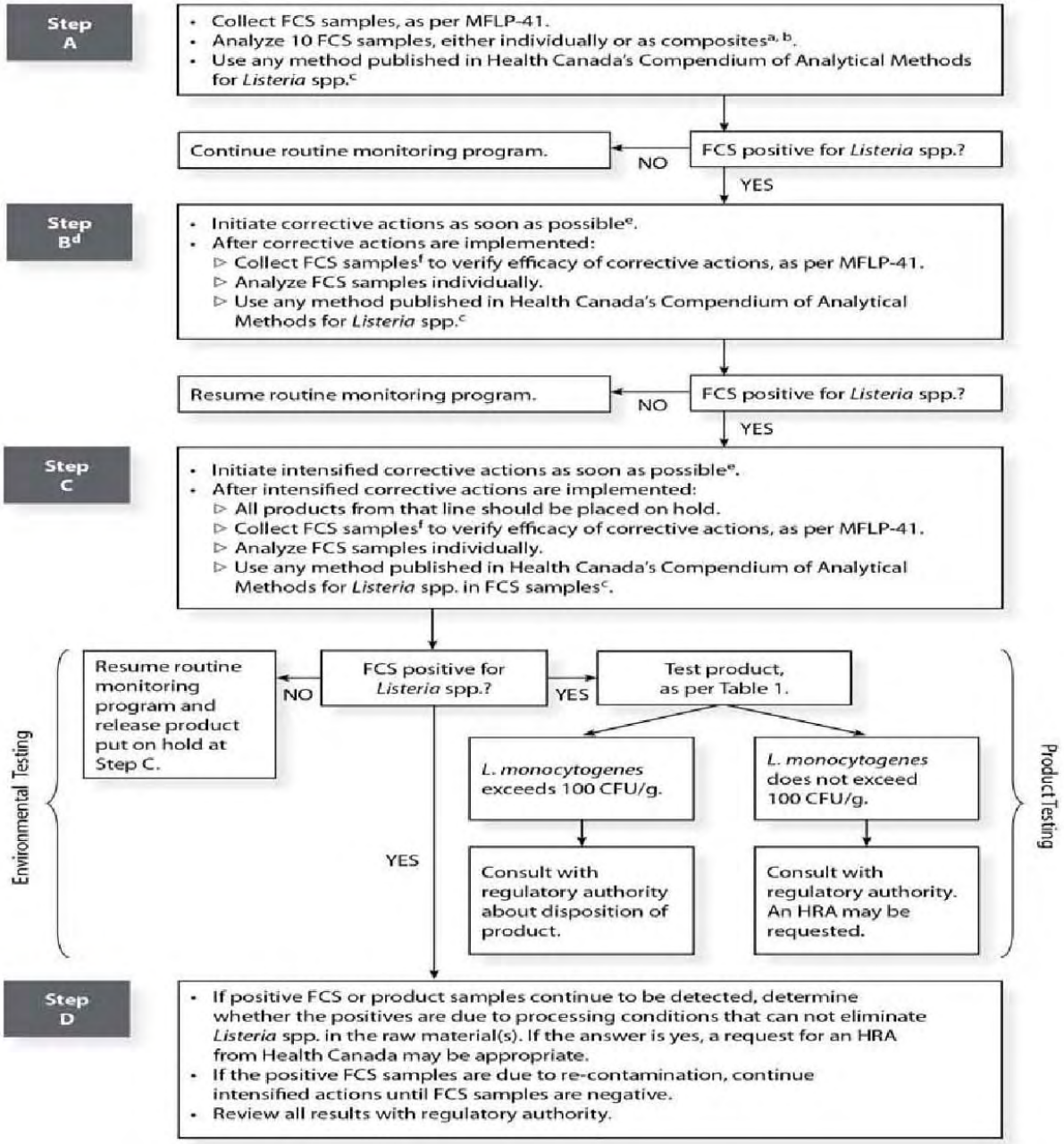


Figure 2: Sampling guidelines for FCS and Category 2 Ready-to-Eat Foods



Trend Analysis & Review

- Should be part of an establishment's verification process
- Can be used to detect trends which may indicate the presence of bacterial niches or biofilms
- Allows the establishment to be more proactive in investigating and mitigating possible sources of *Listeria* spp.
- The results of trend analysis should be used to achieve improved control of *Listeria* over time

Document

Process Control Document Requirements

The document on Process Control Requirements for imported products has been revised and separated into 2 documents:

1) Regulatory Standard on the process control document requirements and

2) Guide to process control technical information

Process Control Requirements (cont'd...)

Regulatory Standard

- Regulatory requirements for process control documents
- Internationally recognized control measures
- Type of processing information required

Guide to Process Control Technical Information

- Technical information, on the control measures, critical limits and critical factors
- Product examples

Important changes…

- **New**: The guide identifies the HC category which applies to each type of RTE product based on the storage conditions, shelf life, use of inhibitors and use of safety parameters (pH, A_w).

- **New**: Information on the sanitation program and other GMPs is now included as a means to demonstrate, in the absence of other processing controls, that a RTE product was processed under sanitary conditions.

Validation Process

Validation

"Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome."

(Codex Alimentarius Commission)

www.codexalimentarius.net/download/standards/11022/cxg_069e.pdf

Validation – Who conducts Validation?

Industry

- It is the responsibility of the processor / importer to demonstrate which category the RTE food belongs to.

- If insufficient, inadequate or no information exists regarding the 2A or 2B categorization of the RTE food product, or if the categorization has not been confirmed by regulatory authorities, it will by default be considered as a Category 1. Hence the method of analysis for Category 1 foods will be applied.

Health Canada "Policy on *Listeria monocytogenes* in RTE Foods", April 2011

Validation – How this fits with QMP?

The QMP (& Hazard Analysis and HACCP Plan) are the tools to manage the implementation of the 2011 HC *Listeria* Policy and control *Listeria* in the product and establishment environment

Compliance to Pre-requisites, RAPs, and associated SOPs is crucial

- control hazards, prevent or eliminate a hazard or reduce the likelihood of occurrence of a hazard to an acceptable level, provide the basic operating conditions and processing environment required to producing safe food

These programs must function as intended, especially at CCPs

Requirements for validation studies:

Health Canada Requirements

- Refer to the Health Canada document "Validation of food safety measures to limit or prevent the growth of *Listeria monocytogenes* in Ready-to-Eat foods" (under review).

Pre-validation tasks:

- Hazard identification
  - Biological hazard: *Listeria monocytogenes*
- Food safety outcome
  - Goal or product criteria to meet: E.g. the growth of *L. monocytogenes* will be less than a 0.5 log CFU/g increase throughout the stated shelf life of the RTE product.
- Identification of the measure(s) that require validation
  - Control measures: product, process, establishment

Requirements for validation studies (cont'd...) :

1) Literature review (relevant and complete)

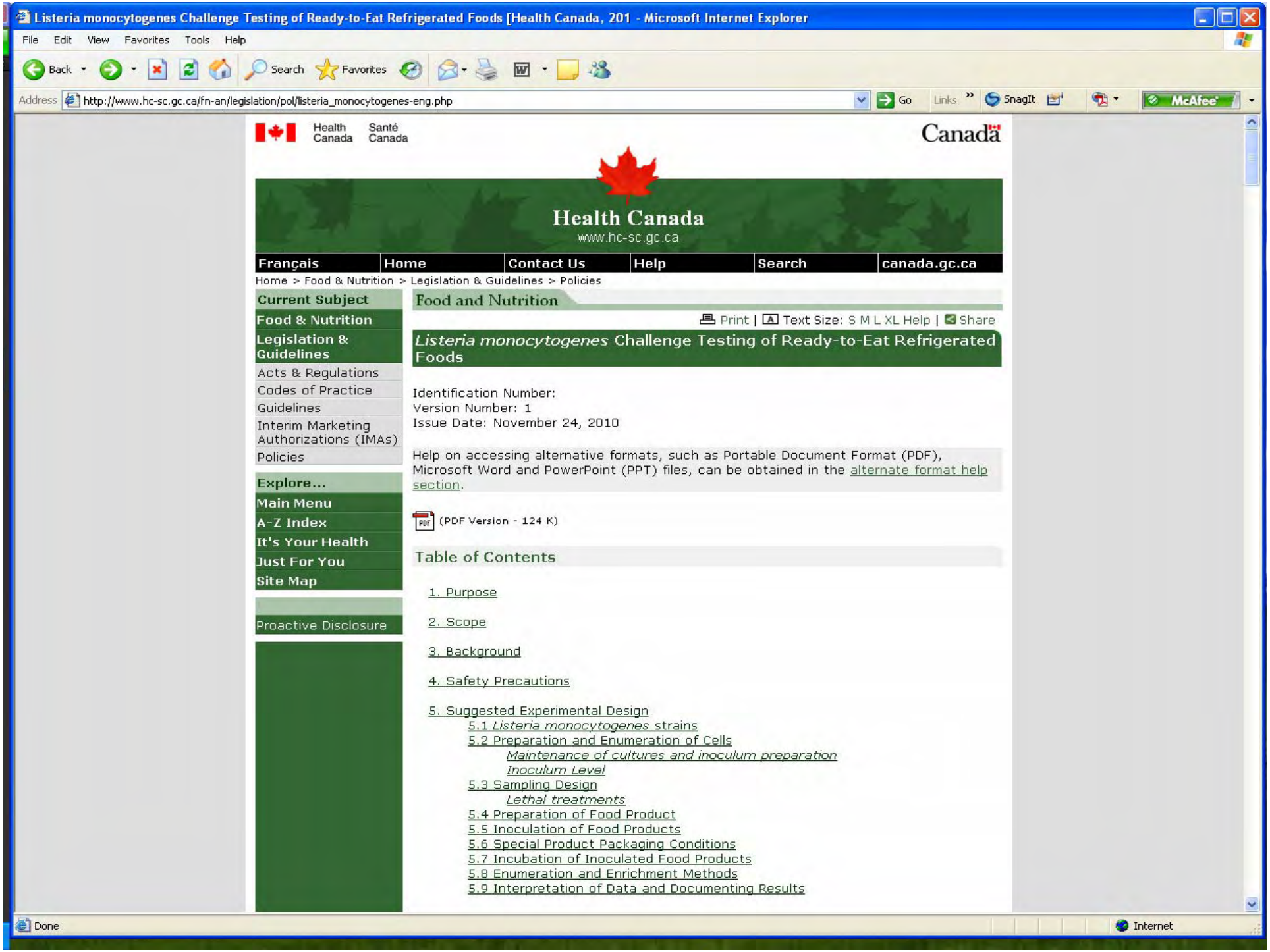
- Review information published in last 10 years

2) Challenge Studies (performed by a qualified laboratory):

- Involves the product being deliberately inoculated with a microorganism of concern (i.e. *Listeria monocytogenes*) to determine the ability of the product to support or inhibit the survival and growth of the microorganism for the duration of the shelf life (under defined storage temperatures).

Note: Challenge studies must meet the requirements of the Health Canada document "*Listeria monocytogenes* Challenge Testing of Ready-to-Eat Refrigerated Foods"

(http://www.hc-sc.gc.ca/fn-an/legislation/pol/listeria_monocytogenes-eng.php**)**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Identification Number:
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Food Directorate

Listeria monocytogenes Challenge Testing of Ready-to-Eat Refrigerated Foods

Food Directorate
Health Products and Food Branch
Health Canada

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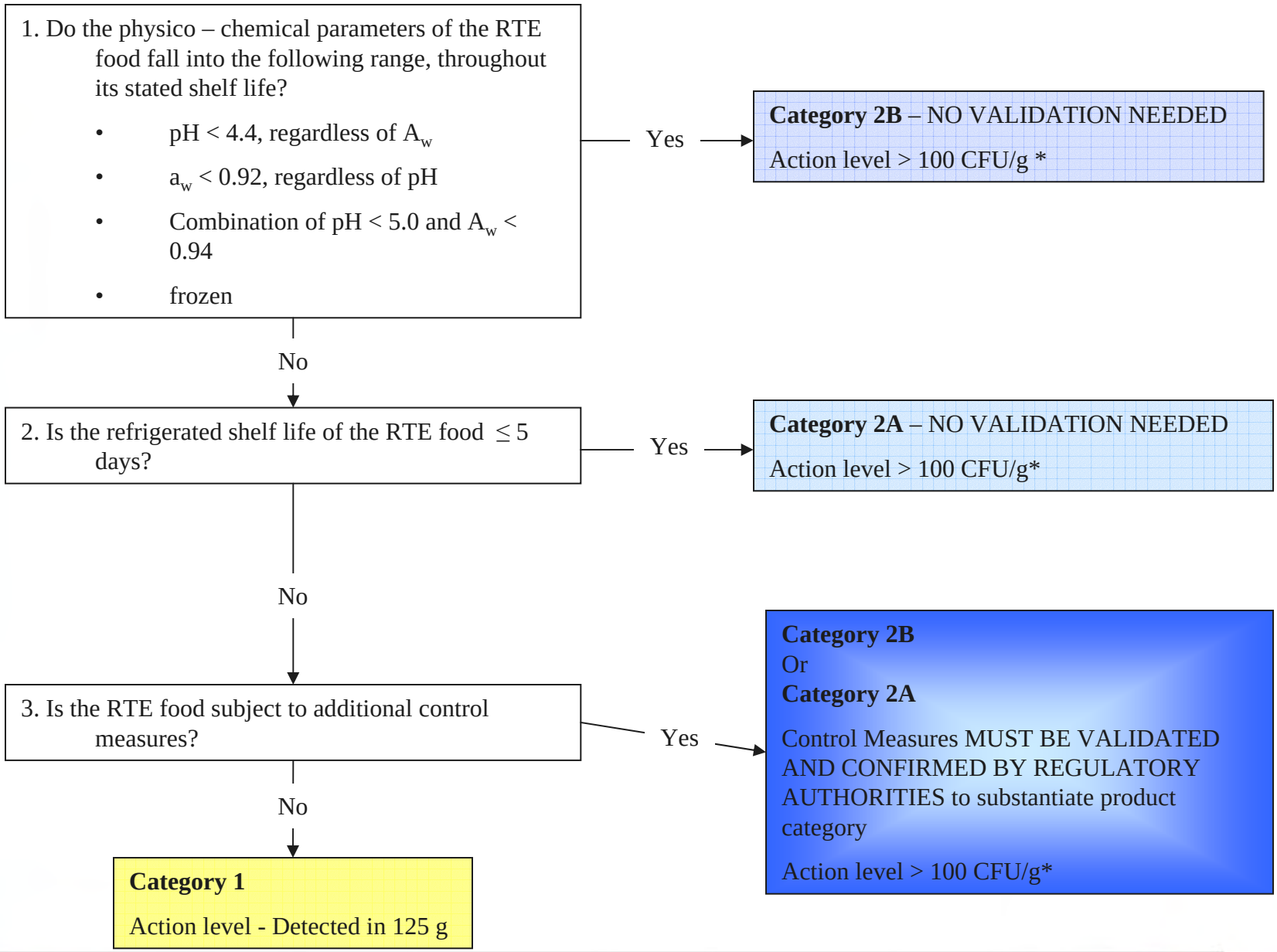
Requirements for validation studies (cont'd...) :

3) Identification and control of key process parameters, meaning:

- Identification of the process parameters applied to reduce, eliminate or inhibit the hazard being addressed.
- Ensuring the controls are in place to ensure these process parameters are respected and the desired safety outcome is obtained (critical control point under the Hazard Analysis Critical Control Plan of the Quality Management Program).

4) Modelling (*optional*)


1. Do the physico – chemical parameters of the RTE food fall into the following range, throughout its stated shelf life?
• 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
Yes
Category 2B – NO VALIDATION NEEDED
Action level > 100 CFU/g *
No
2. Is the refrigerated shelf life of the RTE food ≤ 5 days?
Yes
Category 2A – NO VALIDATION NEEDED
Action level > 100 CFU/g*
No
3. Is the RTE food subject to additional control measures?
Yes
Category 2B
Or
Category 2A
Control Measures MUST BE VALIDATED AND CONFIRMED BY REGULATORY AUTHORITIES to substantiate product category
Action level > 100 CFU/g*
No
Category 1
Action level - Detected in 125 g

When validation studies are/are not required:

1. Do the physio-chemical parameters of the RTE product, fall into the following range, throughout its stated shelf life?

- 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 until consumption

If Yes

- **Category 2B** - NO VALIDATION STUDIES REQUIRED
- Action Level > 100 CFU/g

If No

- What is the refrigerated shelf life?

When validation studies are/are not required (cont'd...) :

2. Is the refrigerated shelf life of the RTE food ≤ 5 days?

If Yes

- **Category 2A** – NO VALIDATION STUDIES REQUIRED
- Action level > 100 CFU/g

The refrigerated shelf life of ≤ 5 days is a time period that would not allow sufficient time, under reasonably foreseeable conditions of distribution, storage and use, for *L. monocytogenes* to grow to levels > 100 CFU/g throughout the stated shelf life.

When validation studies are/are not required (cont'd...) :

If no, i.e. the shelf life is > 5 days,

- The shelf life is >5 days. There could be a time period that could allow sufficient time for *L. monocytogenes* to grow to levels > 100 CFU/g throughout the stated shelf life.
- There are no recognized physico – chemical properties to prevent growth.
- Are there additional control measures?

When validation studies are/are not required (cont'd...) :

3. Is the RTE food subject to other control measures?

If Yes:

- The control measures MUST BE VALIDATED AND CONFIRMED to substantiate the product category:
  - For Category 2A -The RTE food will only support limited growth of *L. monocytogenes* to ≤ 100 CFU/g throughout its stated shelf life.
  - For Category 2B – *L. monocytogenes* will not increase in numbers by 0.5 log CFU/g throughout its stated shelf life, under reasonable foreseeable conditions of distribution, storage and use (i.e. *L. monocytogenes* cannot grow throughout its stated shelf life).

When validation studies are/are not required (cont'd...) :

If no,

- There are no recognized physico-chemical properties to prevent growth
- The shelf life is > 5 days
- There are no control measures – *L. monocytogenes* could potentially grow to levels > 100 CFU/g throughout its stated shelf life.

- **Category 1**
- Action Level: Detected in 125 g

Next Steps

Next Steps for the CFIA

- Product testing will continue as per the Fish Inspection Program Sampling plan for 2011/12
- Inspectors will commence Environmental Sampling in March, 2012
  - Food Contact Surfaces will be tested for all *Listeria* species, including *L. monocytogenes*
- Environmental Sampling will be done as part of a Compliance Verification
- Environmental Sampling will be prioritized based on risk

Next Steps for Importers

- Importers are to determine the product categories for all RTE products they import
- Importers are to provide this information to inspectors for review and confirmation of the product categories
- Importers are to inform suppliers of the recommendations in the 2011 HC *Listeria* Policy, and the implications when a product obtains unsatisfactory test results for *L. monocytogenes* in Canada
- Importers are to verify supplier's process control documentation to ensure *Listeria* controls are in place

Next Steps for Domestic Processors

- Processors are to determine the categories of all RTE products they produce that are subject to the 2011 HC *Listeria* Policy
- This information is to be made available to inspectors for review and confirmation of product categories
- An Environmental Sampling Program should be implemented in their processing facilities.

Questions?


Canada