



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.

Industry Information Session: Implementation of the 2011 Health Canada “Policy on *Listeria monocytogenes* in Ready-to-Eat Foods”

**Canadian Food Inspection Agency, Fresh Fruit and
Vegetable Program and Processed Products
Program - 2013**

Canada



Outline of the Presentation

1. Purpose of the *Listeria* Policy Revision
2. Characteristics of *Listeria monocytogenes*
3. Roles and Responsibilities
4. Fresh and Processed Products Subject to the *Listeria* Policy
5. Ready-to-Eat Food Categories
6. Methods of Analysis
7. Validation of Ready-to-Eat Foods for Re-Categorization
8. Industry Monitoring
9. CFIA Oversight and Verification

Topic

1

Purpose of the *Listeria* Policy Revision

Topic
1

Revised *Listeria* Policy

 Health Canada / Santé Canada

Your health and safety... our priority. / Votre santé et votre sécurité... notre priorité.

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

Bureau of Microbial Hazards
Food Directorate
Health Products and Food Branch

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



Effective Date

April 1, 2011

The *Listeria* Policy was developed and revised by Health Canada (HC), in consultation with the Canadian Food Inspection Agency (CFIA) and the Public Health Agency of Canada (PHAC).

Purpose and Scope of the *Listeria* Policy

- Protect the health of Canadians
- Serve as a tool to assist industry to comply with food safety regulatory requirements
- Provide recommendations to industry on the verification, monitoring and control of *Listeria* in the production of ready-to-eat (RTE) food
- Provide guidance to regulatory authorities on oversight of RTE food production and compliance activities if the food is contaminated with *Listeria monocytogenes* (Lm)

Events Leading Up to the Policy Revision

The *Listeria* Policy was last revised in July of 2004



Events Leading Up to the Policy Revision

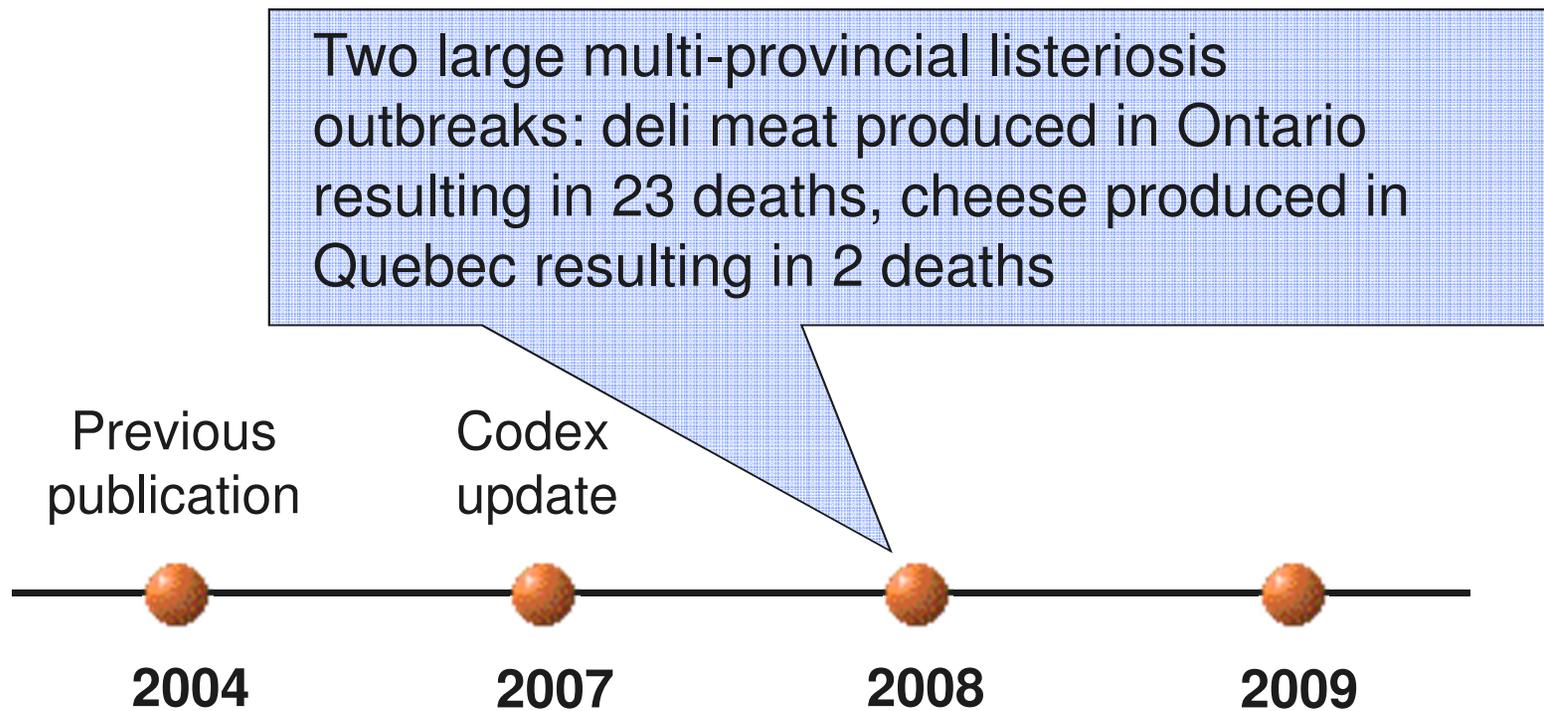
The Codex Alimentarius Commission adopted the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods* (CAC/GL 61 – 2007)

Previous
publication



Topic
1

Events Leading Up to the Policy Revision



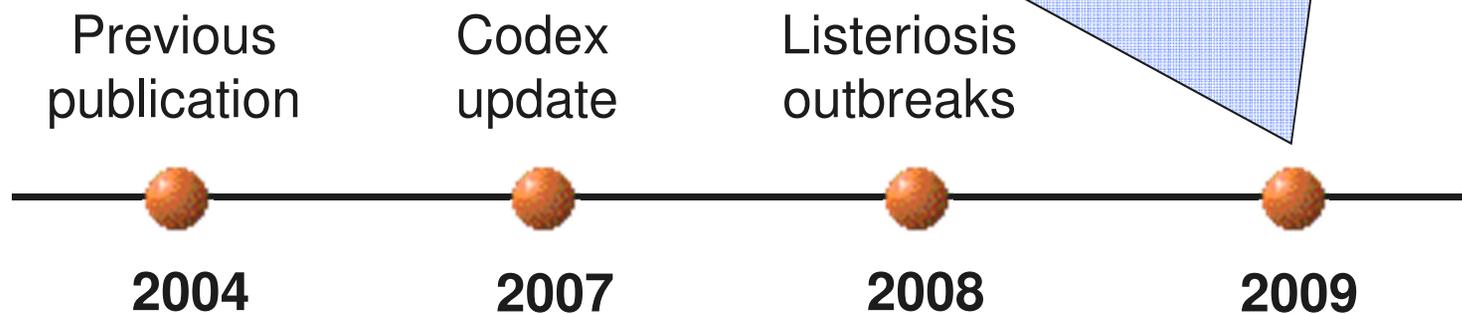
Topic
1

Events Leading Up to the Policy Revision



Prime Minister Harper appoints Ms. Weatherill to conduct an independent investigation

The Weatherill report recommendation #11: "Health Canada should complete the revision of its 2004 *Listeria* Policy, by no later than March 2010."



Goals of the Revised *Listeria* Policy

- Enhance the verification and control of *Listeria spp.* in the food processing environment
- Permit early identification of any potential contamination in the plant environment
- Increase the ability to identify and mitigate the risk of Lm contamination in the finished product

These actions will provide early warning and permit the appropriate interventions to protect consumers

Key Policy Revisions

End-product compliance criteria

RTE food categories

Compliance action decision tree

Environmental monitoring program

Post-lethality treatments/growth inhibitors

Outreach

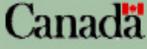
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Policy on *Listeria monocytogenes* in Ready-to-Eat Foods

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Key Policy Revisions

End-product compliance criteria

RTE food categories

Compliance action decision tree

Environmental monitoring program

Post-lethality treatments/growth inhibitors

Outreach

Similar to International Codex Alimentarius Commission standards, the revised *Listeria* Policy contains new compliance criteria for end-products tested for the presence of Lm

Section 1 of the *Listeria* Policy

Key Policy Revisions

End-product compliance criteria

RTE food categories

Compliance action decision tree

Environmental monitoring program

Post-lethality treatments/growth inhibitors

Outreach

Definitions of RTE foods in which growth of Lm can or cannot occur have been modified and/or developed (i.e. new definition of Categories 1, 2A and 2B)

Key Policy Revisions

End-product compliance criteria

RTE food categories

Compliance action decision tree

Environmental monitoring program

Post-lethality treatments/growth inhibitors

Outreach

Decision tree related to compliance action, including environmental testing for *Listeria* spp. and end-product testing for Lm, has been modified to include more details on sampling

Key Policy Revisions

End-product compliance criteria

RTE food categories

Compliance action decision tree

Environmental monitoring program

Post-lethality treatments/growth inhibitors

Outreach

Environmental monitoring program should be included in all plants producing RTE foods, as defined by the *Listeria* Policy

Key Policy Revisions

End-product compliance criteria

RTE food categories

Compliance action decision tree

Environmental monitoring program

Post-lethality treatments/growth inhibitors

Outreach

The use of post-lethality treatments and/or Lm growth inhibitors is encouraged

Key Policy Revisions

End-product compliance criteria

RTE food categories

Compliance action decision tree

Environmental monitoring program

Post-lethality treatments/growth inhibitors

Outreach

Outreach with federal / provincial / territorial community to increase awareness of the risks of listeriosis and to provide guidance on how to reduce the risks

Topic
2

Characteristics of *Listeria monocytogenes*



Listeria

Genus *Listeria* (family *Listeriaceae*)

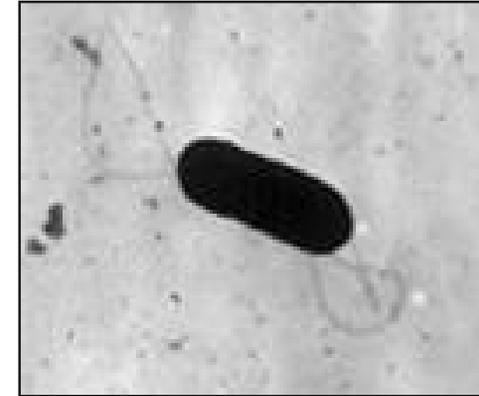


6 most common species:

- *Listeria monocytogenes*
- *Listeria ivanovii*
- *Listeria innocua*
- *Listeria grayi*
- *Listeria welshimeri*
- *Listeria seeligeri*

When the term *Listeria* spp. is used, it refers to any and/or all of the *Listeria* species including Lm

Listeria monocytogenes



General Characteristics:

- Size (1 – 2 μm x 0.5 μm)
- Gram-positive bacterium, rod-shaped, non-spore forming
- Can grow at wide pH range (4.4 or greater), water activity (a_w) \geq 0.92
- Facultative anaerobe
- Measured in colony-forming units (CFU) per gram (g) or per millilitre (ml)

Listeria monocytogenes



Unique Characteristics:

- Widely present in the natural and processing environments (e.g., soil, water, drains, ventilation)
- Grows in food stored under refrigerated temperatures (-0.4 and 45 °C)
- Pathogenic to humans (causes foodborne illness - listeriosis)

What is Listeriosis?

A rare and serious disease

Symptoms may include vomiting, nausea, diarrhea, severe headache, constipation and persistent fever



Serious infections of Lm may cause miscarriages or stillbirths in pregnant women and lead to meningitis, septicaemia and death in high risk populations (e.g., the elderly or immunocompromised)

Risk Factors for Foodborn Listeriosis

- Presence of Lm in the food
- Potential for growth of Lm in the food
- Storage temperature and duration
- Amount and frequency of consumption of a food contaminated with Lm
- Host susceptibility (e.g., high-risk populations)

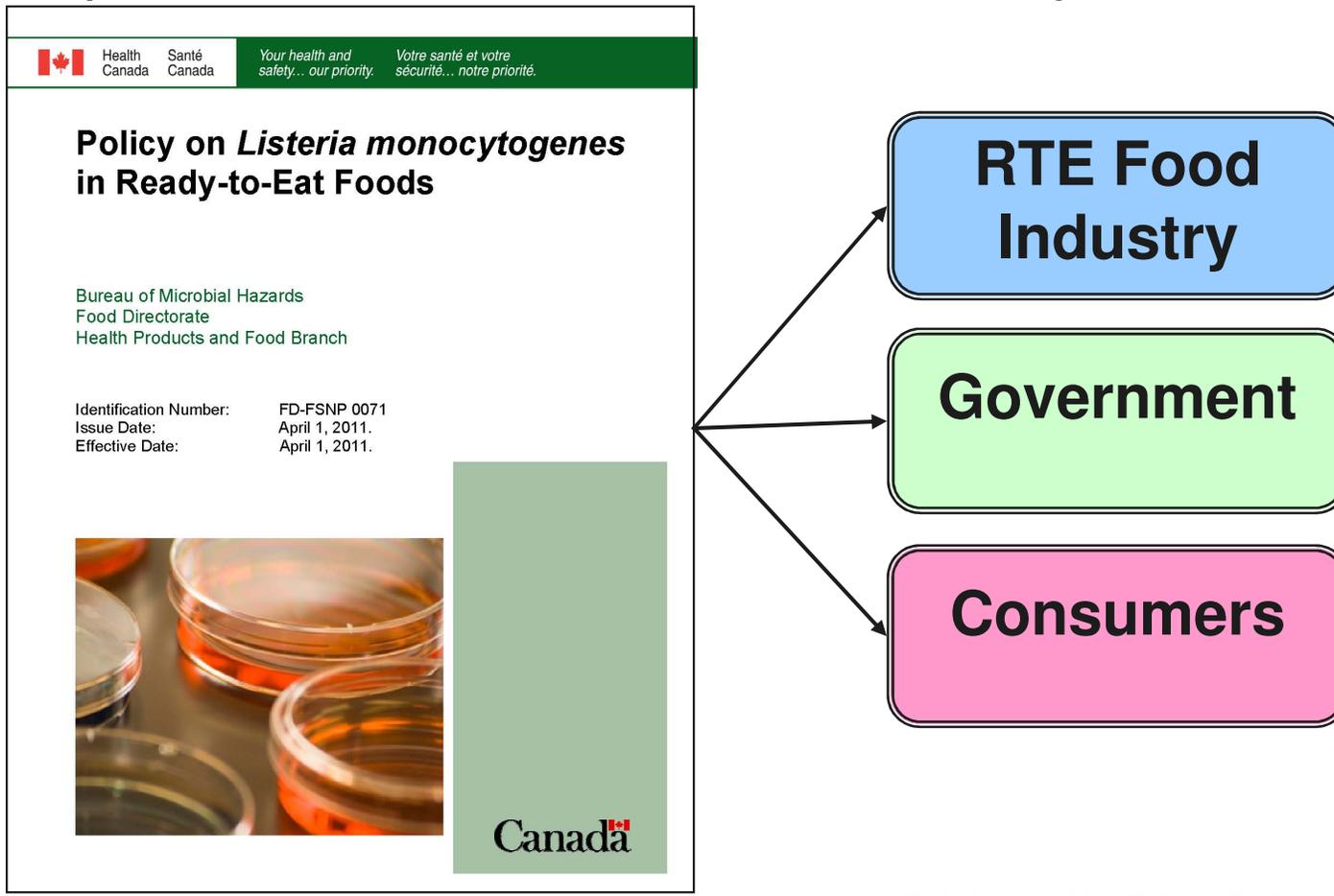


Topic
3

Roles and Responsibilities

Roles and Responsibilities

In relation to the *Listeria* Policy, the following roles and responsibilities are outlined in the Policy:



Roles and Responsibilities



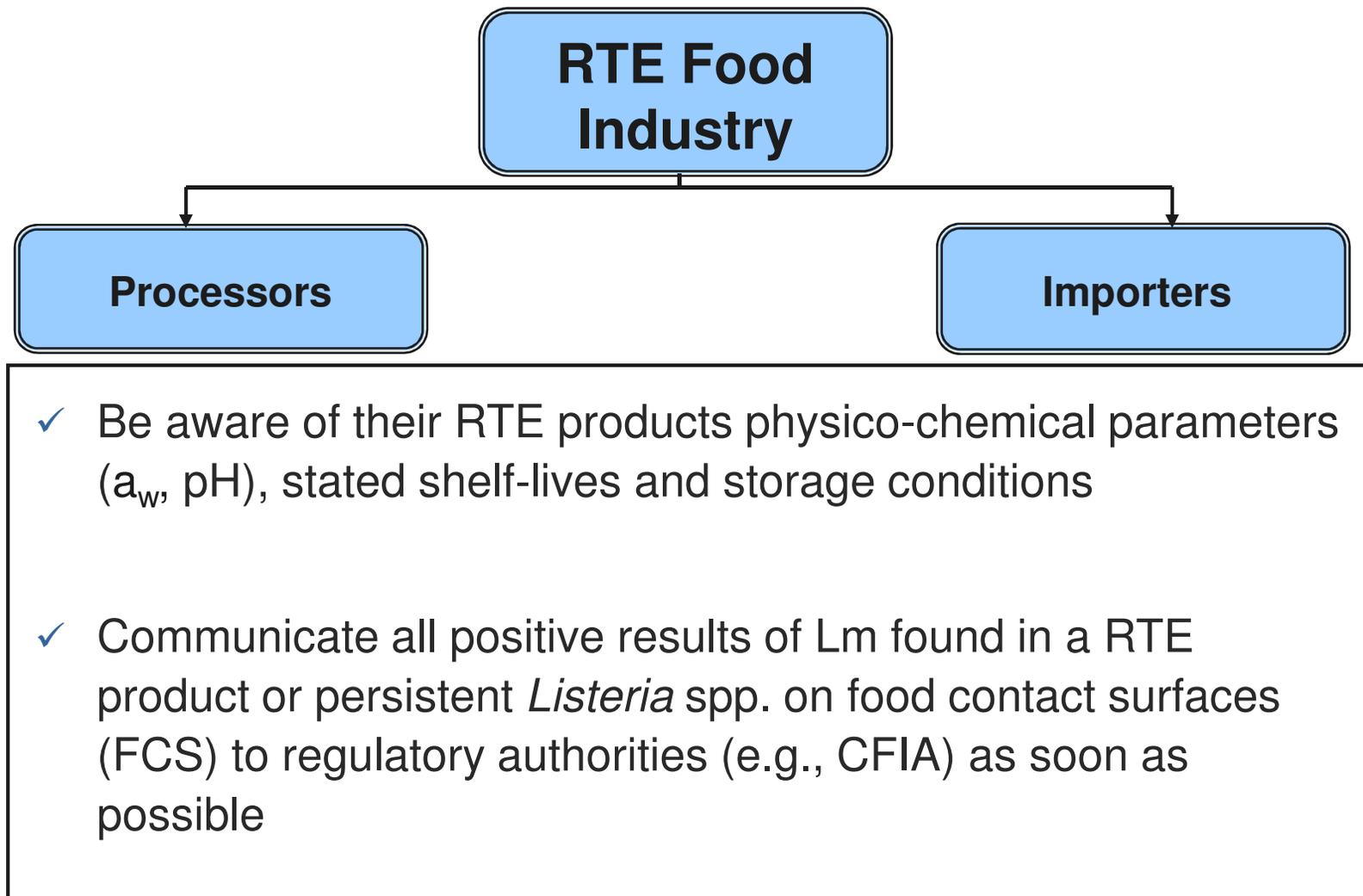
- ✓ Ensure that the food is safe and complies with all applicable legislative and regulatory requirements, such as:
 - Sections 4. (1) and 7 of the *Food and Drugs Act* (FDA)
 - Section 3.1(1) of the *Fresh Fruit and Vegetable Regulations*
 - Section 2.1 (1) of the *Processed Products Regulations*
 - Any applicable provincial regulations

In order to demonstrate due diligence the *Listeria* Policy should be implemented

Section 3 of the *Listeria* Policy



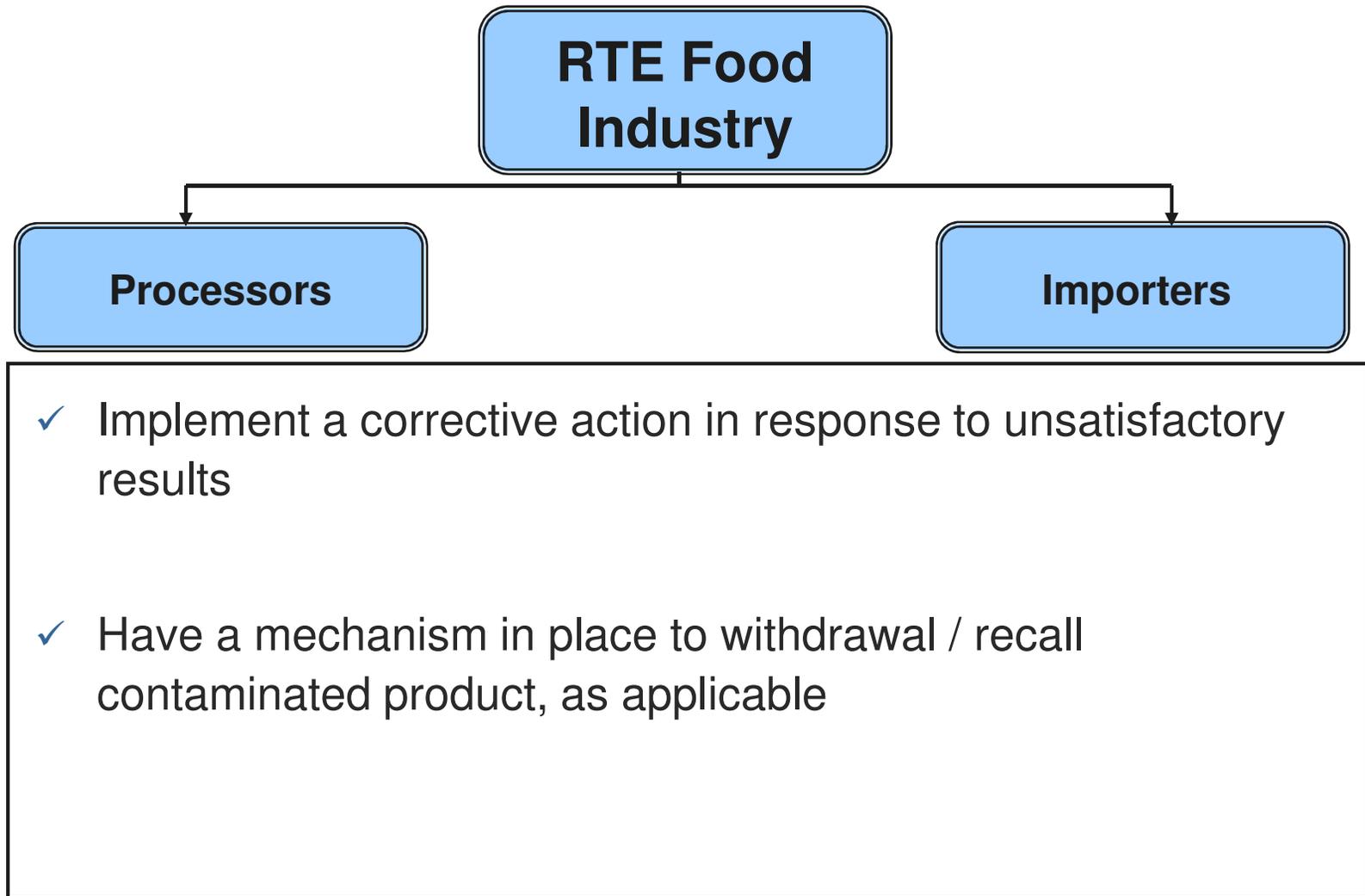
Roles and Responsibilities



Section 3 of the *Listeria* Policy



Roles and Responsibilities



Section 3 of the *Listeria* Policy

Roles and Responsibilities

**RTE Food
Industry**

Processors

- ✓ Implement effective Good Manufacturing Practices (GMP) and/or Hazardous Analysis Critical Control Point (HACCP) system to minimize all potential sources of food contamination
- ✓ Implement routine monitoring sampling (environmental and end-product)

Section 6.2.1 of the *Listeria* Policy



Roles and Responsibilities

**RTE Food
Industry**

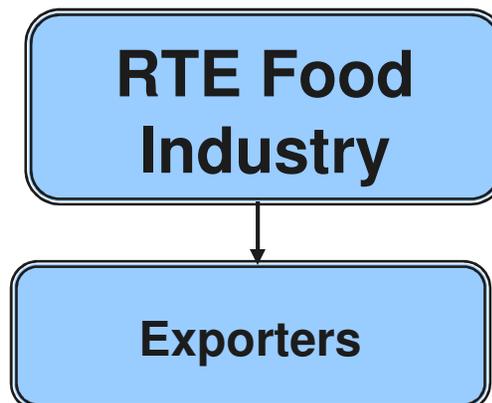
Importers

- ✓ Verify that the foreign processor is supplying safe product that complies with Canadian legislation
- ✓ Provide information on the supplier's food safety programs, including process controls (e.g., Good Agricultural Practices (GAP), GMP's, HACCP)
- ✓ Implement safe food storage / handling procedures

Section 6.2.2 of the *Listeria* Policy



Roles and Responsibilities



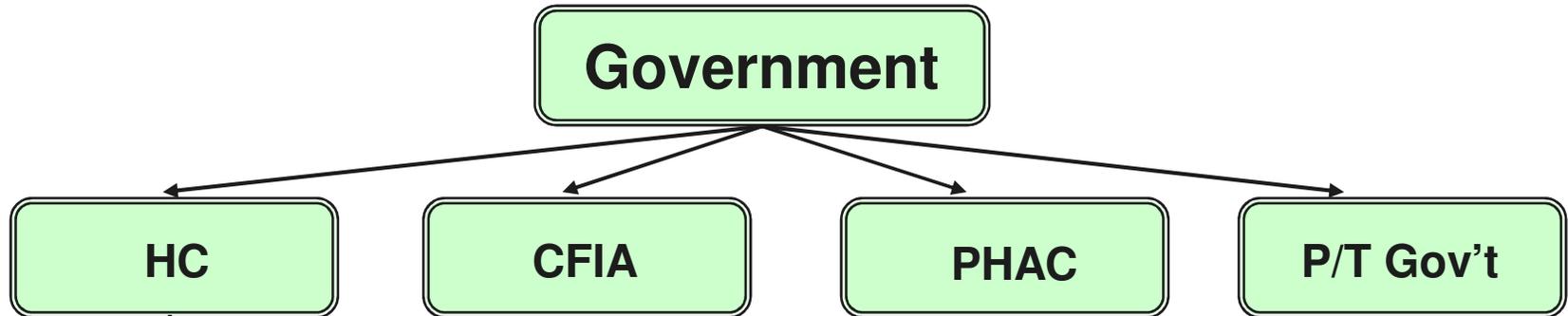
- ✓ Comply with the requirements of the receiving country as well as Section 37 of the *Food and Drugs Act*

“...package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.”

Section 6.2.3 of the *Listeria* Policy



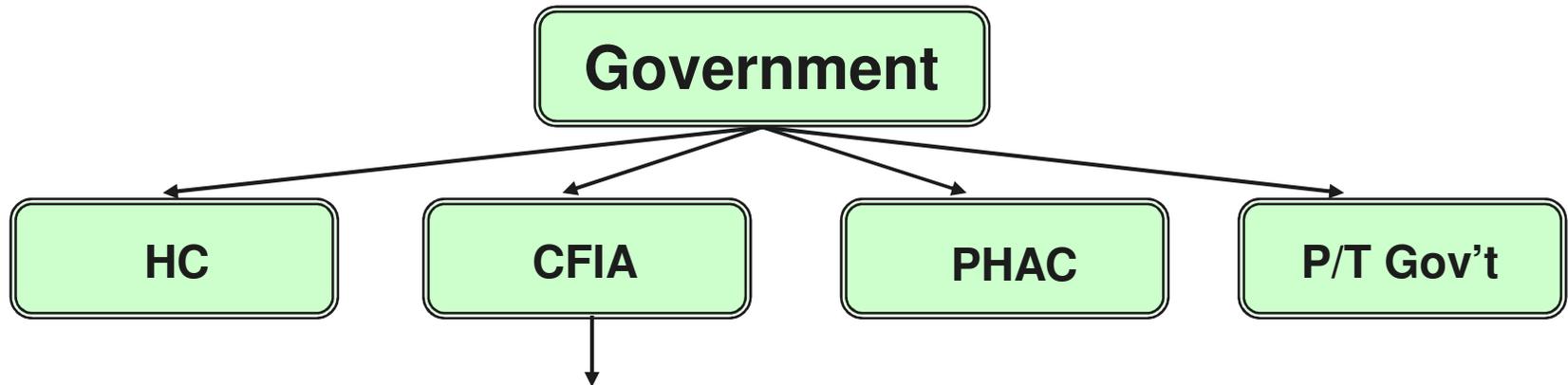
Roles and Responsibilities



- ✓ In consultation with CFIA and provincial/territorial governments, develops food safety standards and policies to minimize the risk of foodborne illnesses
- ✓ Helps Canadians maintain and improve their health

Section 3 of the *Listeria* Policy

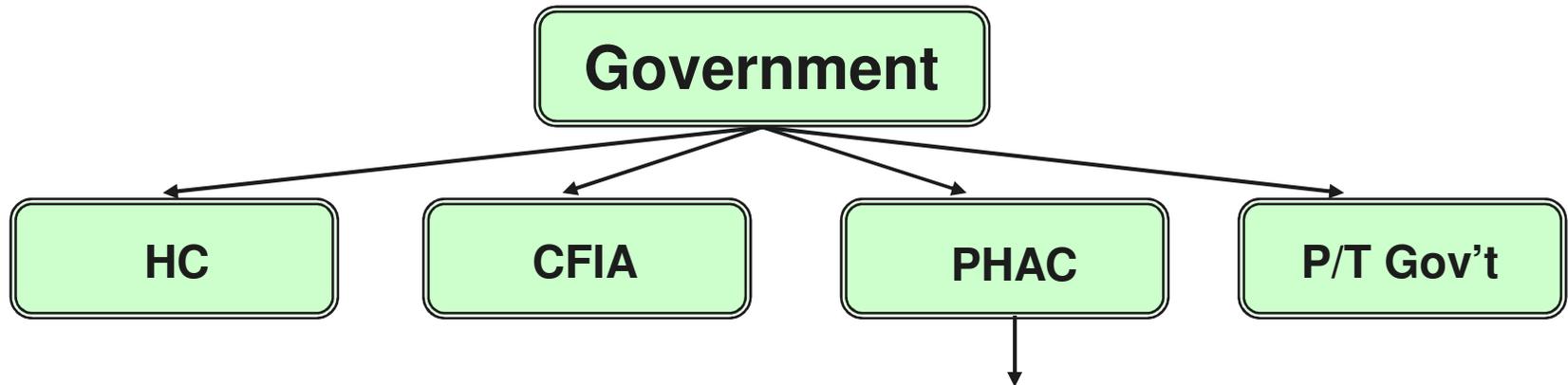
Roles and Responsibilities



- ✓ Protects Canadians from preventable health risks through a fair and effective regulatory regime
- ✓ Oversees the food industry to ensure that it meets its food safety responsibilities
- ✓ Assesses industries validation data for product re-categorization

Section 3 of the *Listeria* Policy

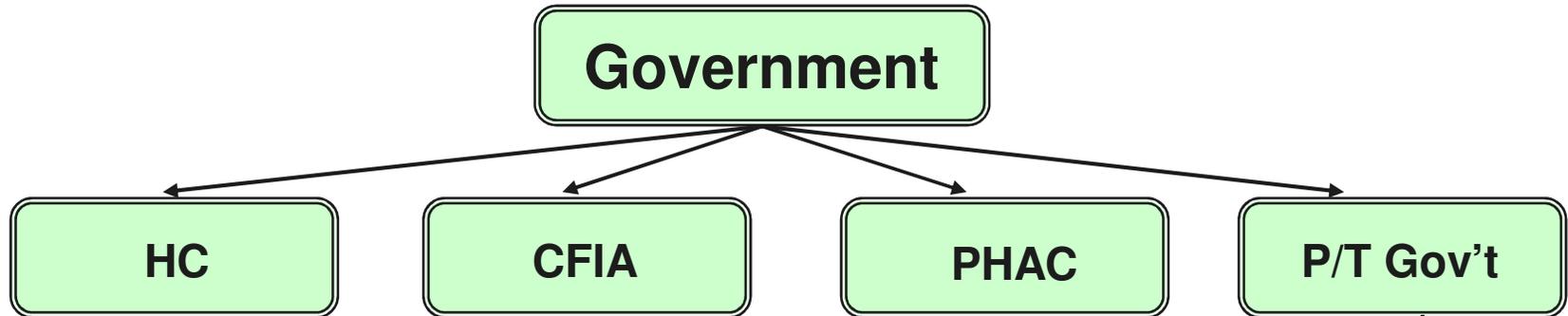
Roles and Responsibilities



- ✓ Promotes and protects the health of Canadians
- ✓ Conducts surveillance of foodborne illness across Canada

Section 3 of the *Listeria* Policy

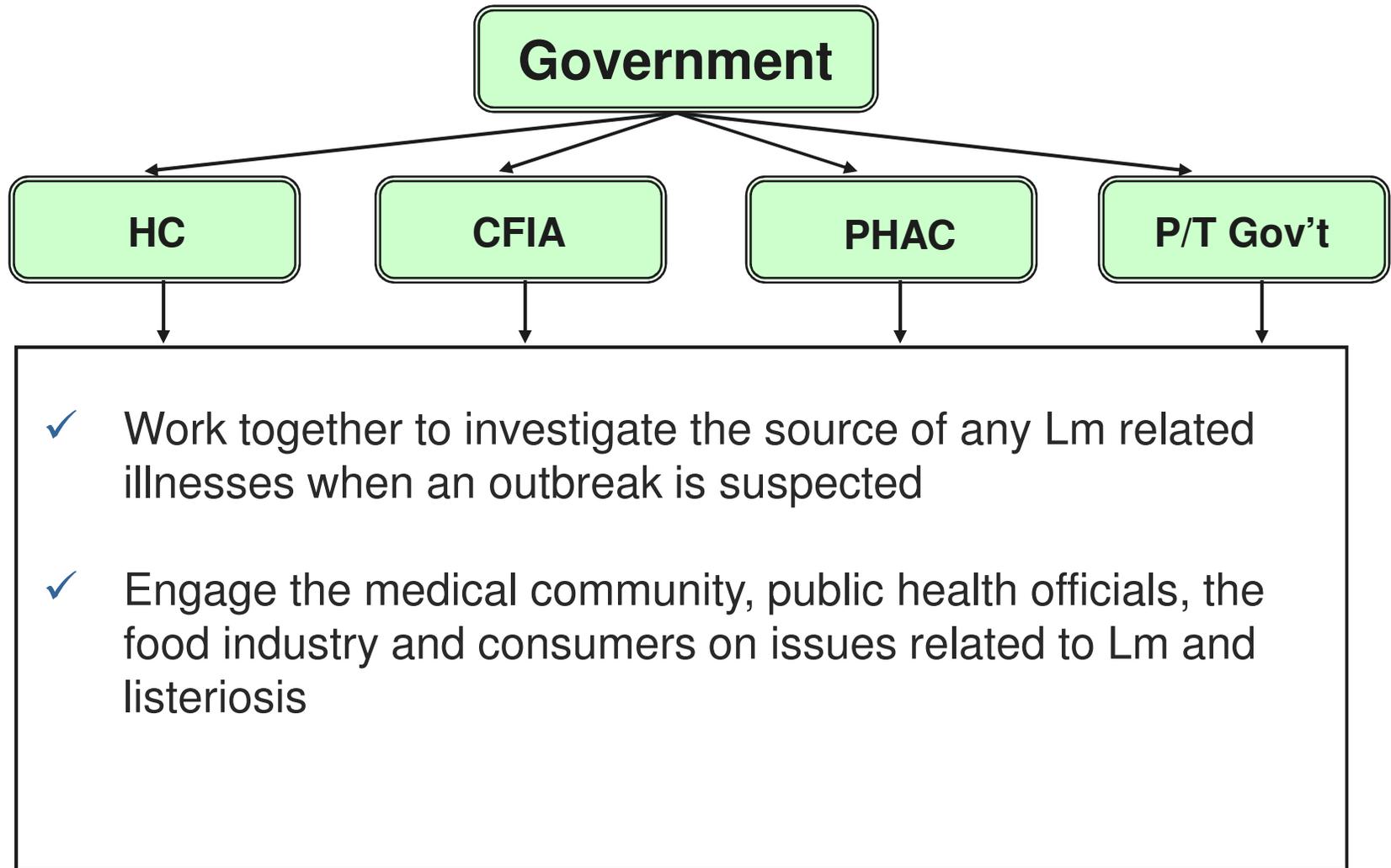
Roles and Responsibilities



- ✓ Oversees the food industry to ensure that it meets its food safety responsibilities
- ✓ Assesses industries validation data for product re-categorization

Section 3 of the *Listeria* Policy

Roles and Responsibilities



Section 3 of the *Listeria* Policy

Roles and Responsibilities

Consumers

- ✓ Learn and implement safe food handling practices
- ✓ Informed food selection
- ✓ Safe food handling, preparation and storage practices

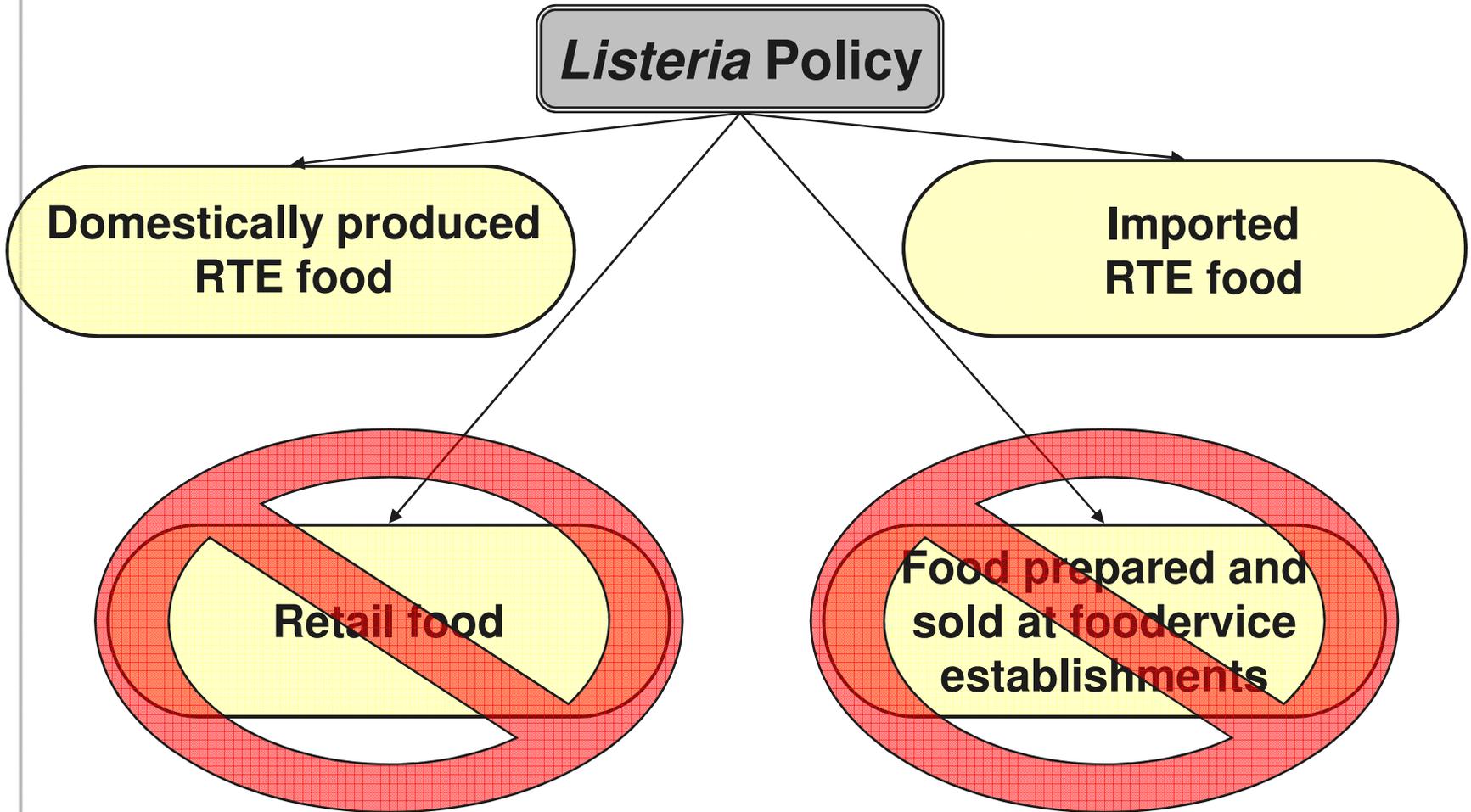


Topic

4

Fresh and Processed Produce Subject to the *Listeria* Policy

Food Subject to the *Listeria* Policy



Section 1 of the *Listeria* Policy

Food Subject to the *Listeria* Policy

The *Listeria* Policy applies to RTE foods (as defined in the Appendix A of HC's *Listeria* Policy):

- That do not require any further preparation before consumption, except washing/rinsing, thawing or warming; and
- That have been subjected to some form of processing in order to render them RTE; and/or
- Which have been subjected to another process to extend their shelf-life

Fresh Produce Subject to the *Listeria* Policy



RTE fresh-cut fruit and vegetables that have been either washed and peeled, either sliced, chopped or shredded prior to being packaged for sale and are intended to be consumed raw and not for further processing or cooking

Fresh Produce Not Subject to the *Listeria* Policy



Whole fresh fruit and vegetables that have only been trimmed, cleaned, brushed, washed, graded, packaged or otherwise prepared for human consumption



Non-RTE fresh-cut produce that have been either washed, peeled, sliced, chopped or shredded prior to being packaged for sale with cooking instructions on the package

RTE Processed Fruits and Vegetables Subject to the *Listeria* Policy

RTE fruits and vegetables subjected to a process that does not achieve a 5 log reduction and packaged in **non-hermetically sealed** containers



Frozen fruits



Certain frozen
vegetables



Refrigerated
pickles, olives
and sauerkraut

RTE Processed Fruits and Vegetables Not Subject to the *Listeria* Policy

RTE fruits and vegetables processed to a minimum of **5 log reduction** using a validated thermal process, retorting, aseptic process and are packed in **hermetically sealed** containers



Canned Fruits



Canned Vegetables



Jams and Jellies



Shelf stable fruit juices



Shelf stable pickles



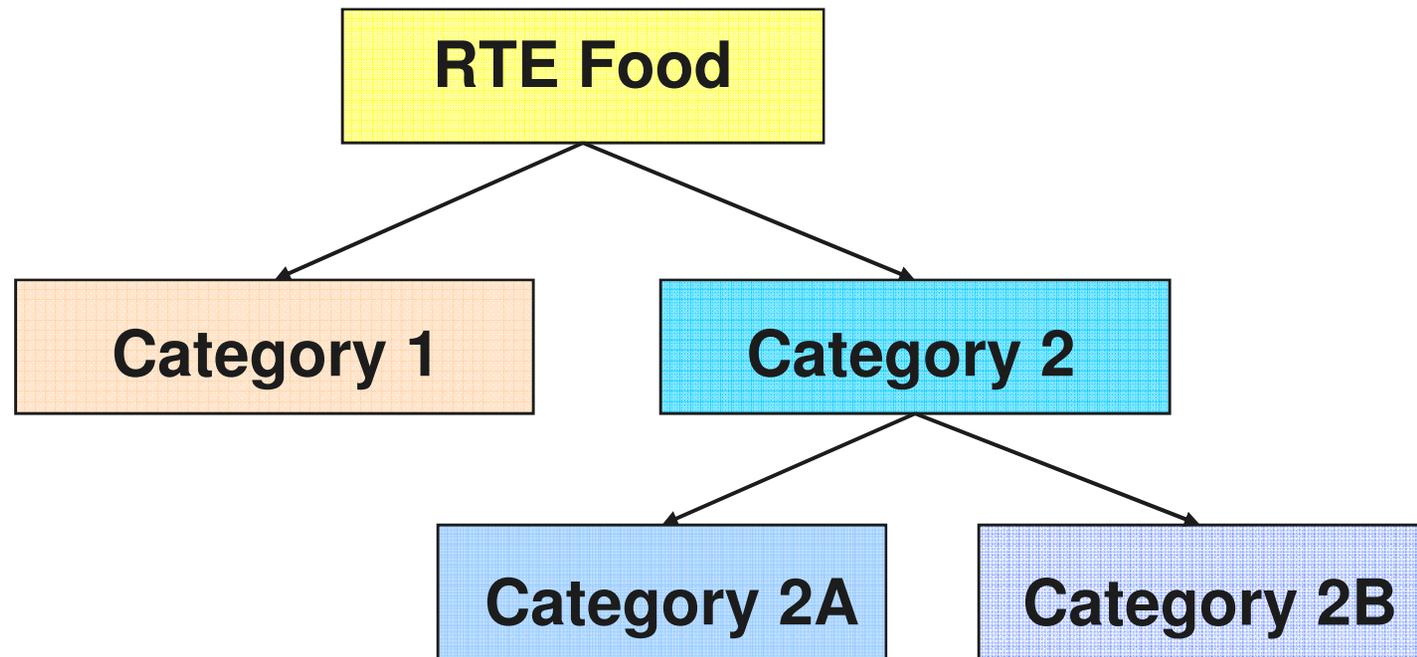
Shelf stable olives

Topic
5

RTE Food Categories

RTE Food Categories

In the *Listeria* Policy, RTE food have been classified into two categories, based upon health risk



Regardless of the RTE food categorization, industry must produce safe foods as per the *Food and Drugs Act and Regulations*

Category 1

- **Definition:** RTE fresh-cut produce, which can support the growth of *Lm* throughout the stated shelf-life to levels >100 CFU/g and which have a refrigerated shelf-life of >5 days

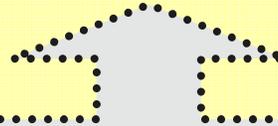
By default a food is considered Category 1 if validated data is unavailable, insufficient, or inadequate to demonstrate it is either a Category 2A or 2B or its categorization has not been confirmed by the regulatory authorities (e.g., CFIA)

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



Category 1

- **Definition:** RTE fresh-cut produce, which can support the growth of *Lm* throughout the stated shelf-life to levels >100 CFU/g and which have a refrigerated shelf-life of >5 days
- **Sample Size:** 5 units of minimum 100 g each



Samples should be representative of the lot and the production conditions, taken aseptically at random from each lot

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



Category 1

Topic 5

- **Definition:** RTE fresh-cut produce, which can support the growth of Lm throughout the stated shelf-life to levels >100 CFU/g and which have a refrigerated shelf-life of >5 days
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enrichment (presence / absence) method for Lm published in HC's Compendium of Analytical Methods

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 1

- **Definition:** RTE fresh-cut produce, which can support the growth of Lm throughout the stated shelf-life to levels >100 CFU/g and which have a refrigerated shelf-life of >5 days
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enrichment (presence / absence) method for Lm published in HC's Compendium of Analytical Methods
- **Action Level:** Detection in 125 g (5 x 25 g analytical units analysed either separately or composited)

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



Category 1

- **Definition:** RTE fresh-cut produce, which can support the growth of Lm throughout the stated shelf-life to levels >100 CFU/g and which have a refrigerated shelf-life of >5 days
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enrichment (presence / absence) method for Lm published in HC's Compendium of Analytical Methods
- **Action Level:** Detection in 125 g (5 x 25 g analytical units analysed either separately or composited)
- **Nature of Concern:** Health Risk 1

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

Category 1

- **Definition:** RTE fresh-cut produce, which can support the growth of *Lm* throughout the stated shelf-life to levels >100 CFU/g and which have a refrigerated shelf-life of >5 days
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enrichment (presence / absence) method for *Lm* published in HC's Compendium of Analytical Methods
- **Action Level:** Detection in 125 g (5 x 25 g analytical units analysed either separately or composited)
- **Nature of Concern:** Health Risk 1
- **Level of Priority:** High; for industry control, monitoring, verification and regulatory oversight / compliance activities

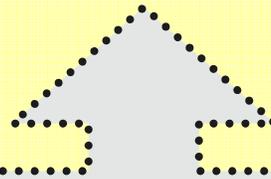
Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



Category 2A

Topic 5

- **Definition:** RTE fresh-cut produce, in which a limited potential for growth of Lm to levels ≤ 100 CFU/g can occur throughout the stated shelf-life



- RTE food with a refrigerated shelf-life of ≤ 5 days; **validation not required**
- RTE foods which are known to occasionally contain low levels of Lm and do not have a kill step that achieves a ≥ 5 -log reduction in numbers of Lm; **validation required**
- If information is insufficient, inadequate or no information exists to demonstrate that there is limited growth of Lm throughout the shelf-life, as determined by validated data, the food will be considered as a Category 1 RTE food

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2A

Topic 5

- **Definition:** RTE fresh-cut produce, in which a limited potential for growth of Lm to levels ≤ 100 CFU/g can occur throughout the stated shelf-life
- **Sample Size:** 5 units of minimum 100 g each

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2A

Topic 5

- **Definition:** RTE fresh-cut produce, in which a limited potential for growth of Lm to levels ≤ 100 CFU/g can occur throughout the stated shelf-life
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enumeration method for Lm published in HC's Compendium of Analytical Methods

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2A

Topic 5

- **Definition:** RTE fresh-cut produce, in which a limited potential for growth of Lm to levels ≤ 100 CFU/g can occur throughout the stated shelf-life
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enumeration method for Lm published in HC's Compendium of Analytical Methods
- **Action Level:** >100 CFU/g in any one sub-unit (5 x 10 g analytical units)

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2A

Topic 5

- **Definition:** RTE fresh-cut produce, in which a limited potential for growth of Lm to levels ≤ 100 CFU/g can occur throughout the stated shelf-life
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enumeration method for Lm published in HC's Compendium of Analytical Methods
- **Action Level:** >100 CFU/g in any one sub-unit (5 x 10 g analytical units)
- **Nature of Concern:** 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

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



Category 2A

Topic 5

- **Definition:** RTE fresh-cut produce, in which a limited potential for growth of Lm to levels ≤ 100 CFU/g can occur throughout the stated shelf-life
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enumeration method for Lm published in HC's Compendium of Analytical Methods
- **Action Level:** >100 CFU/g in any one sub-unit (5 x 10 g analytical units)
- **Nature of Concern:** Health Risk 2
- **Level of Priority:** Medium to low; for industry control, monitoring, verification and regulatory oversight / compliance activities

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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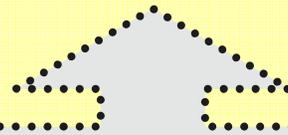
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Category 2B

Topic 5

- **Definition:** RTE food, in which Lm cannot grow (i.e., <0.5 log CFU/g throughout the stated shelf-life)



RTE food that meet the following criteria will not support the growth of Lm:

- Stored under “frozen” conditions (until consumption), or
- pH <4.4 , regardless of a_w , or
- $a_w <0.92$, regardless of pH, or
- Combination of pH <5.0 and $a_w <0.94$

Validation not required

Note: Products not meeting these physico-chemical parameters **require scientific validated data** to demonstrate that the food does not support the growth of Lm. This validation information must be reviewed and confirmed by the relevant regulatory authority.

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2B

Topic

5

- **Definition:** RTE food, in which Lm cannot grow (i.e., <0.5 log CFU/g throughout the stated shelf-life)
- **Sample Size:** 5 units of minimum 100 g each

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2B

Topic

5

- **Definition:** RTE food, in which Lm cannot grow (i.e., <0.5 log CFU/g throughout the stated shelf-life)
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enumeration method for Lm published in HC's Compendium of Analytical Methods

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2B

Topic

5

- **Definition:** RTE food, in which Lm cannot grow (i.e., <0.5 log CFU/g throughout the stated shelf-life)
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enumeration method for Lm published in HC's Compendium of Analytical Methods
- **Action Level:** >100 CFU/g in any one sub-unit (5 x 10 g analytical units)

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2B

Topic 5

- **Definition:** RTE food, in which Lm cannot grow (i.e., <0.5 log CFU/g throughout the stated shelf-life)
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enumeration method for Lm published in HC's Compendium of Analytical Methods
- **Action Level:** >100 CFU/g in any one sub-unit (5 x 10 g analytical units)
- **Nature of Concern:** Health Risk 2

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

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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Category 2B

Topic

5

- **Definition:** RTE food, in which Lm cannot grow (i.e., <0.5 log CFU/g throughout the stated shelf-life)
- **Sample Size:** 5 units of minimum 100 g each
- **Laboratory Method:** Any enumeration method for Lm published in HC's Compendium of Analytical Methods
- **Action Level:** >100 CFU/g in any one sub-unit (5 x 10 g analytical units)
- **Nature of Concern:** Health Risk 2
- **Level of Priority:** Low; for industry control, monitoring, verification and regulatory oversight / compliance activities

Section 6.1, 7.3, Table 1 and App. A of the *Listeria* Policy



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RTE Food Categories

RTE Foods Intended for High-Risk Population

- Should receive the highest priority for industry control, monitoring and verification, as well as regulatory oversight and compliance activities
- May be considered to represent a Health Risk 1 concern, irrespective of product type and associated category rating



Section 6.1 of the *Listeria* Policy

	CATEGORY 1	CATEGORY 2A	CATEGORY 2B
DEFINITION	RTE fresh-cut produce, which can support the growth of Lm throughout the stated shelf-life to levels >100 CFU/g and which have a refrigerated shelf-life of >5 days	RTE foods, in which a limited potential for growth of Lm to levels no greater than 100 CFU/g can occur throughout the stated shelf-life	RTE foods, in which Lm cannot grow
SAMPLE SIZE	5 units of minimum 100 g each	5 units of minimum 100 g each	5 units of minimum 100 g each
LABORATORY METHOD	Any enrichment (presence/absence) method for Lm published in HC's Compendium of Analytical Methods	Any enumeration method for Lm published in HC's Compendium of Analytical Methods	Any enumeration method for Lm published in HC's Compendium of Analytical Methods
ACTION LEVEL	Detection in 125 g	>100 CFU/g in any one sub-unit	>100 CFU/g in any one sub-unit
NATURE OF CONCERN	Health Risk 1	Health Risk 2 (Health Risk 1 if food is intended for high risk groups or intended for use in Cat 1 food)	Health Risk 2 (Health Risk 1 if food is intended for high risk groups or intended for use in Cat 1 food)
LEVEL OF PRIORITY	High	Medium - Low (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)

Topic
6

Methods of Analysis

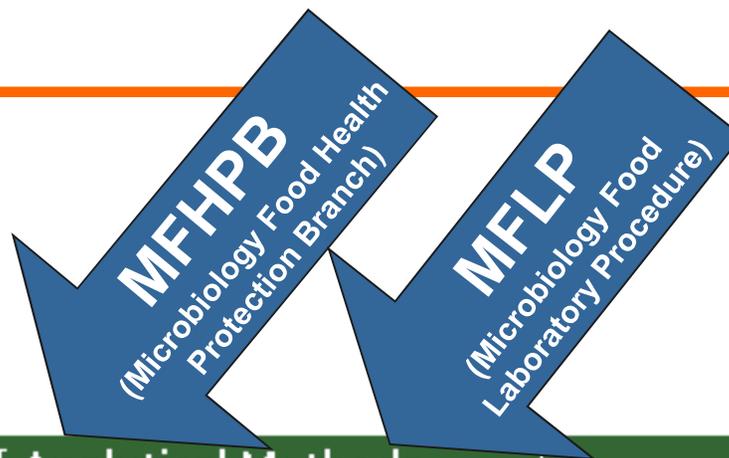
Methods of Analysis

- Environmental sampling should be conducted according to **MFLP-41**
- Testing for environmental and product samples should be conducted according to any method published in HC's *Compendium of Analytical Methods* in which the “**Application**” section is **appropriate for the intended purpose**

Sections 7.2 and 7.3 of the *Listeria* Policy

To find the appropriate laboratory method, go to HC's *The Compendium of Analytical Methods*;

<http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php>



The Compendium of Analytical Methods



Topic 6

	Environmental Samples Using i-Check™	
MFLP-39	Detection of <i>Listeria</i> spp. From Environmental Surfaces Using iQ-Check™ <i>Listeria</i> spp. Real-Time PCR Test Kit	April 2011
MFLP-41 ←	Environmental Sampling for the Detection of Microorganisms	July 2010
MFLP-42	Isolation and Enumeration of the <i>Bacillus Cereus</i> Group in Foods	May 2011

Environmental Sampling for the Detection of Microorganisms

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the [alternate format help section](#).



(PDF Version - 244 K)

1. Application

This procedure is applicable to the sampling of the environment for microorganisms in food establishments in support of compliance activities relative to Section 7 of the Food and Drugs Act, and Health Canada policies such as the Policy on *Listeria monocytogenes* in ready-to-eat (RTE) Food and the Canadian Food Inspection Agency Directives (CFIA) and guidelines. This environmental sampling procedure applies to both food contact surfaces (FCS) and non-food contact surfaces (NFCS) in a food manufacturing plant. It describes the procedures to be used for the collection and handling of environmental samples for microbiological assessment. This revised procedure replaces MFLP-41A and MFLP-41B dated September 1992 and July 2006, respectively.

To find an accredited lab, go to;

Standards Council of Canada (SCC) webpage;



Standards Council of Canada
Conseil canadien des normes

<http://www.scc.ca/en/search/palcan/food>

**Canadian Association for Laboratory Accreditation
Inc (CALA) webpage;**



CALA

<http://www.cala.ca/index.html>

Validation of RTE Foods for Re-categorization

For more information, refer to HC's document, *Validation of Ready-to-Eat Foods for Changing the Classification of a Category 1 into a Category 2A or 2B Food*

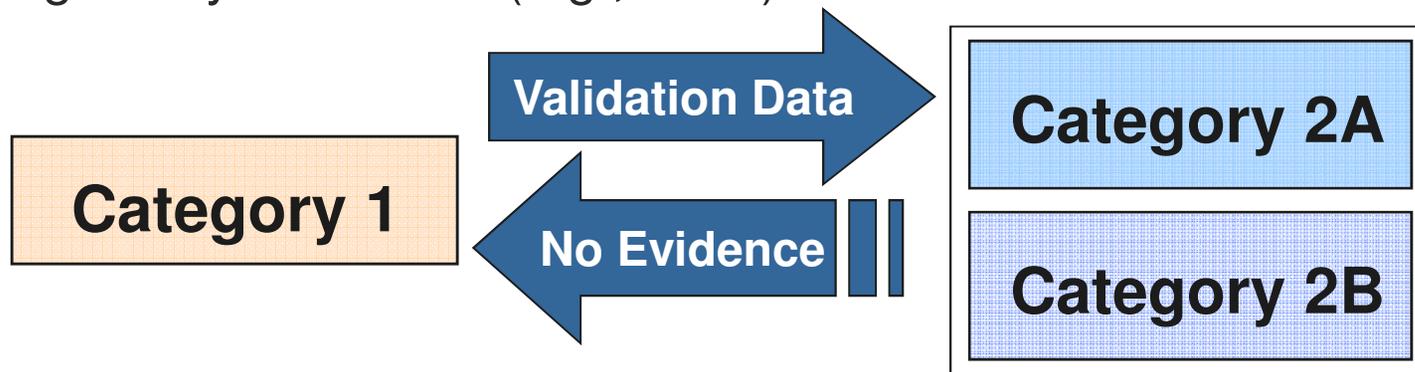
Validation – Definition

Codex Alimentarius Commission (2008) defines validation as:

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

Validation of RTE Foods for Re-Categorization – Purpose

- Demonstrate using scientific evidence that a RTE food product, covered by HC's *Listeria* Policy, is Category 2 (2A or 2B)
- The product is considered to be Category 1, if insufficient, inadequate or no information exists to demonstrate a 2A or 2B categorization or if the categorization has not been confirmed by regulatory authorities (e.g., CFIA)



Pre Validation

a) Hazard identification:

- Presence of unacceptable levels of Lm in RTE foods as per HC's *Listeria* Policy (i.e., >100 CFU/g of Lm at any time throughout the stated shelf-life)

b) Identification of food safety outcome:

- Category 2A RTE Food: Lm, when present, should be limited to a maximum of 100 CFU/g throughout the stated shelf-life
- Category 2B RTE Food: Growth of Lm will be less than a 0.5 log CFU/g increase throughout the stated shelf-life of the RTE product

c) Identification of the measure(s) that need to be validated:

- Challenge studies need to demonstrate when RTE foods are processed according to specified parameters, the desired food safety outcome is achieved

Validation of RTE Foods for Re-Categorization

- **Challenge Studies – Mandatory**
- **Identification of Key Process Parameters, and Provisions of Evidence of their Control – Mandatory**
- **Literature Review – Recommended**
- **Modelling – Optional**

Section 2 of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Mandatory

- To determine the ability of the product to support limited or inhibit the survival and growth of *Lm* throughout the duration of the stated shelf-life
- Results must demonstrate that the food safety outcome is met

Challenge studies should be conducted as per HC's, *Lm* Challenge Testing of Ready-to-Eat Refrigerated Foods

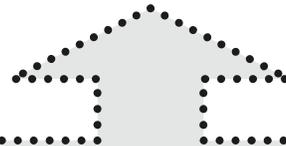
Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains



- Use a pool of at least 3-5 strains (can be up to 10)
- Certain serotypes should be included (1/2a, 1/2b and 4b)
- Include strains isolated from the same, or similar types of food
- If available, use an outbreak strain, or sporadic cases
- Cultures are available from international culture collections (e.g., “American Type Culture Collection” (ATCC) and International Life Sciences Institute” (ILSI))

Section 3.2 and 4.2 (b) of HC’s Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells



- Consult with an expert food microbiologist
- Storage of cells should minimize the number of transfers to minimize mutations
- HC's Challenge Study document provides guidance to:
 - Avoid multiple passages
 - Incubate cells at refrigeration temperatures since the RTE foods will be refrigerated
 - Enumerate cells of a working inoculum

Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level



- Inoculation level used should be 10-30 CFU/g to attempt Category 2A classification
- Inoculation level to demonstrate Category 2B classification has not been pre-set by regulatory authorities. The initial level of inoculum can vary, so long as, for example, it does not overload the preservative system/natural hurdles associated with the product and that the concentrations can be easily enumerated. Examples of level of inoculation are presented in Table 1 of HC's, Lm Challenge Testing of RTE Foods

Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level
- Sampling design



- Minimum of 3 lots of products must be tested for Lm in triplicate at each sampling time (i.e., a minimum of 5* time points throughout the stated shelf-life, including time zero and at the end of the shelf-life)

*If the product has an extended refrigerated shelf-life, additional time points throughout the stated shelf-life of the product should be considered, in order to account for possible variations in the growth of Lm

Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level
- Sampling design
- Preparation of food product

- 
- Need to know the critical parameter and process variability of the product
 - Use “worse-case” conditions (i.e., most permissive for growth of Lm)
 - Consider competing background microorganisms

Section 3.2 and 4.2 (b) of HC’s Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level
- Sampling design
- Preparation of food product
- Inoculation of food product



- Inoculation method should reflect the way contamination is likely to occur and the condition of the product at that point
- Examples of inoculation methods are available in HC's, Lm Challenge Testing of RTE Foods

Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level
- Sampling design
- Preparation of food product
- Inoculation of food product
- Special product packaging conditions

- 
- Inoculated product should be packaged as intended for sale
 - Special care is needed to maintain Modified Atmosphere Packaging (MAP) conditions following inoculation (e.g., must be monitored during challenge study)

Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level
- Sampling design
- Preparation of food product
- Inoculation of food product
- Special product packaging conditions
- Incubation of inoculated food products

- 
- Validation studies for changing the classification of a Category 1 into a Category 2A or 2B food must be performed at a temperature of 7 °C or above

Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level
- Sampling design
- Preparation of food product
- Inoculation of food product
- Special product packaging conditions
- Incubation of inoculated food products
- Enumeration and enrichment methods

- 
- Samples should be diluted 1:5 (can use up to 1:10 for difficult to spread matrices)
 - Should use quantitative determination for Lm (e.g., MLFP-74 available in HC's Compendium)

Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level
- Sampling design
- Preparation of food product
- Inoculation of food product
- Special product packaging conditions
- Incubation of inoculated food products
- Enumeration and enrichment methods
- Documentation of results

- 
- Document all results of the challenge study in a report
 - Include information on all required components of the challenge study
 - Raw data and any graphical representations/interpretations should be included

Validation of RTE Foods for Re-Categorization

Challenge Studies – Recommended Experimental Design

- Lm strains
- Preparation and enumeration of cells
- Inoculum level
- Sampling design
- Preparation of food product
- Inoculation of food product
- Special product packaging conditions
- Incubation of inoculated food products
- Enumeration and enrichment methods
- Documentation of results

The experimental design must be detailed and rationale for each parameter should be included in the validation data

Section 3.2 and 4.2 (b) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Identification of Key Process Parameters, and Provision of Evidence of their Control – **Mandatory**

- Key process parameters (e.g., a_w , pH) need to be clearly identified and documented
- Adequate controls of key process parameters must be implemented and documented to provide evidence that the food safety outcome is not compromised
- The same controls must be applied to the process parameters used in the challenge study

Section 3.2 and 4.2 (c) of HC's Validation Document



Validation of RTE Foods for Re-Categorization

Literature Review – Recommended

- Pertinent publications should include possible level of Lm contamination and growth profile in the RTE product(s) and/or similar products

Modeling – Optional

- Mathematical modeling could be conducted for a group of similar RTE products
- A challenge study must be performed on the RTE product which represents the highest risk for Lm within the grouping
- A rationale supported by scientific evidence and the modeling documentation should be provided for evaluation

Section 3.2 and 4.2 (a) (d) of HC's Validation Document



Validation – Additional Information

- After validation, if a change is made to a control measure or product, the appropriateness of the validation studies supporting the categorization of the RTE food may need to be confirmed
- If the change is determined by regulatory authority to be substantial, the need for re-validation / re-categorization may be triggered

Other approaches to validation may be considered by the regulatory authority, on a case by case basis

Section 5 of HC's Validation Document



Validation – Summary

- It is the responsibility of the processor / importer to demonstrate in which category their RTE food belongs
- When industry wants to re-categorize a RTE product, validation studies should be completed according to HC's procedures
- Validation data should be submitted to the relevant regulatory authority (i.e., CFIA) for evaluation and confirmation

Section 1 and 5 of HC's Validation Document



Topic
8

Industry Monitoring

Industry Monitoring

- **Monitoring sampling** is conducted to verify the effectiveness of the control measures which are used to eliminate, inhibit and prevent the growth of Lm
- Sampling should include both:



and



Section 7 and Figures 1, 2 and 3 of the *Listeria* Policy



Industry Monitoring – Routine Environmental Sampling

- Test for the presence of *Listeria* spp. on both food contact surface (FCS) and non-food contact surface (Non-FCS)
- The number of meaningful sample sites (preferably 10) depends upon the complexity of the processing system



Section 7.2 of the *Listeria* Policy

Industry Monitoring – Routine Environmental Sampling

- Environmental sampling for *Listeria* spp. helps verify the effectiveness of the GMPs / HACCP
- Presence of *Listeria* spp. on FCS could indicate that the controls (i.e., sanitation) are inadequate
- If Non-FCS samples (near to FCSs) are found positive for *Listeria* spp. on a regular basis, FCS should be tested more frequently

Persistent contamination could be an indication of inadequate GMPs

Section 7.2 of the *Listeria* Policy

Industry Monitoring – End Product Testing

- End-product sampling may be conducted for various reasons, including when FCS test positive for *Listeria* spp.
- Testing may be required to verify RTE foods meet compliance criteria for Lm
- Samples submitted for Lm analysis should consist of 5 sample units of at least 100 g each



Sections 6.2, 7.3 and Table 1 of the *Listeria* Policy



Listeria Policy: Figures 1, 2 and 3



Health Canada / Santé Canada

Your health and safety... our priority. / Votre santé et votre sécurité... notre priorité.

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

Bureau of Microbial Hazards
Food Directorate
Health Products and Food Branch

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



Canada

Figure 1: Sampling Guidelines for FCS and Category 1 RTE food

Figure 2: Sampling Guidelines for FCS and Category 2 RTE food

Figure 3: Sampling Guidelines for Non-FCS

Section 7.2 of the *Listeria* Policy



Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

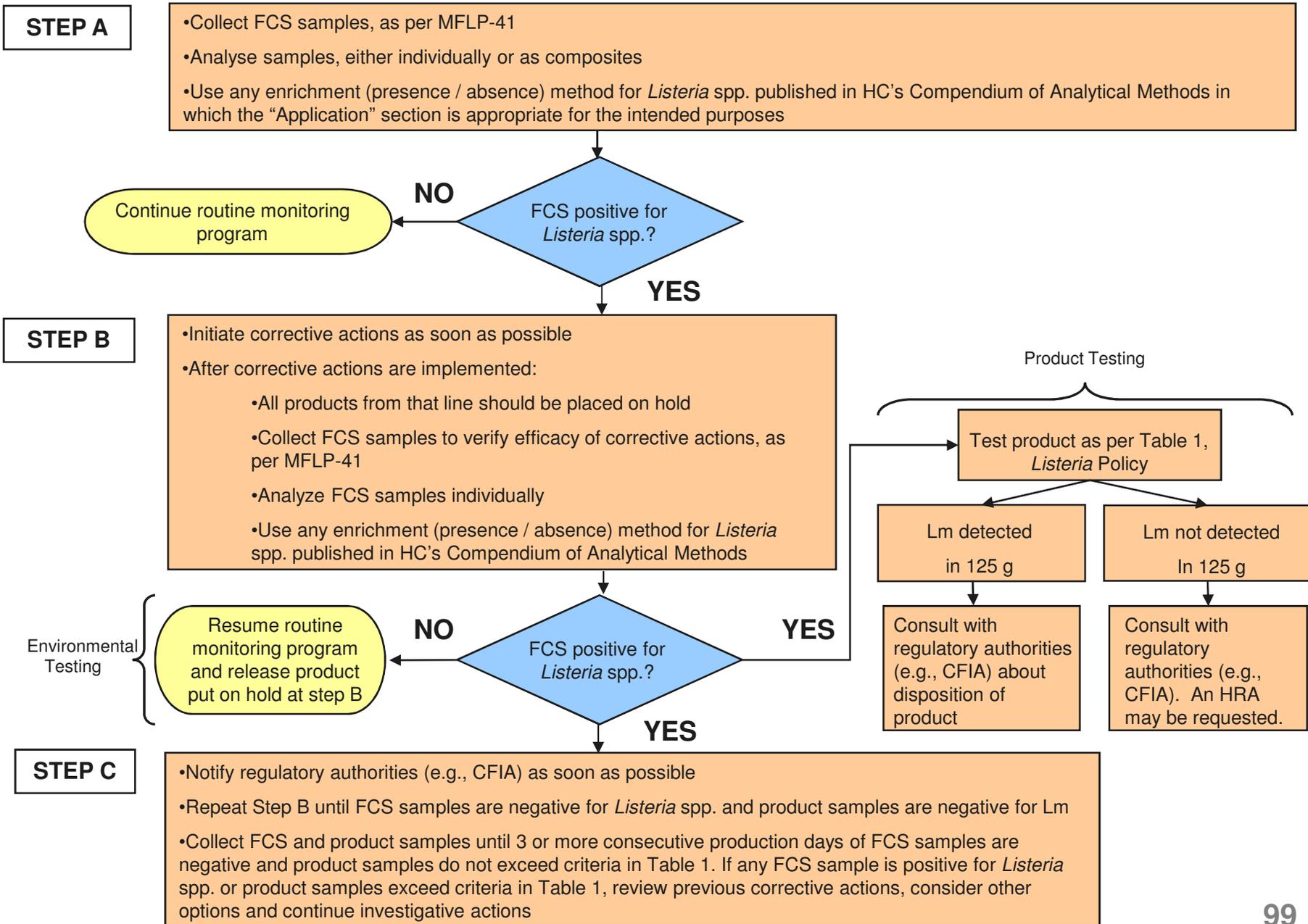
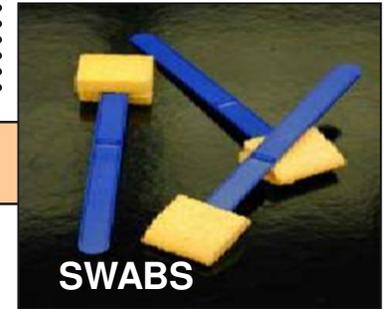


Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP A

Purpose is to determine if *Listeria* spp. is present

- Collect FCS samples, as per MFLP-41



- Collect preferably 10 FCS samples
- Samples should be collected during production, typically 3 hours into production
- Frequency and the number of sampling sites should reflect the manufacturing processes and controls
- Special circumstances may warrant an increase in the frequency of sampling and/or the number of sample sites

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP A

- Collect FCS samples, as per MFLP-41
- Analyze samples either individually, or as composites

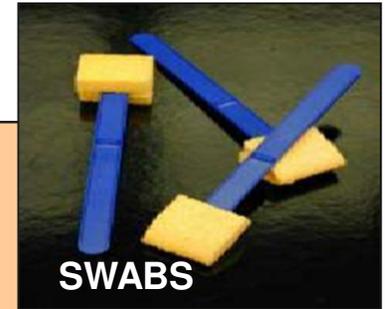


Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP A

- Collect FCS samples, as per MFLP-41
- Analyze samples either individually, or as composites
- Use any enrichment (presence / absence) method for *Listeria* spp. published in HC's Compendium of Analytical Methods in which the "Application" section is appropriate for the intended purpose

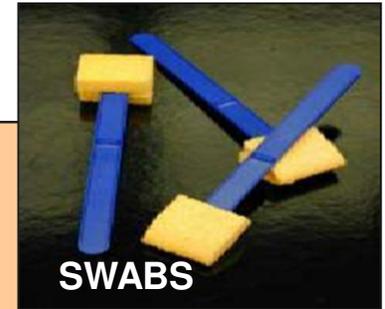


Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

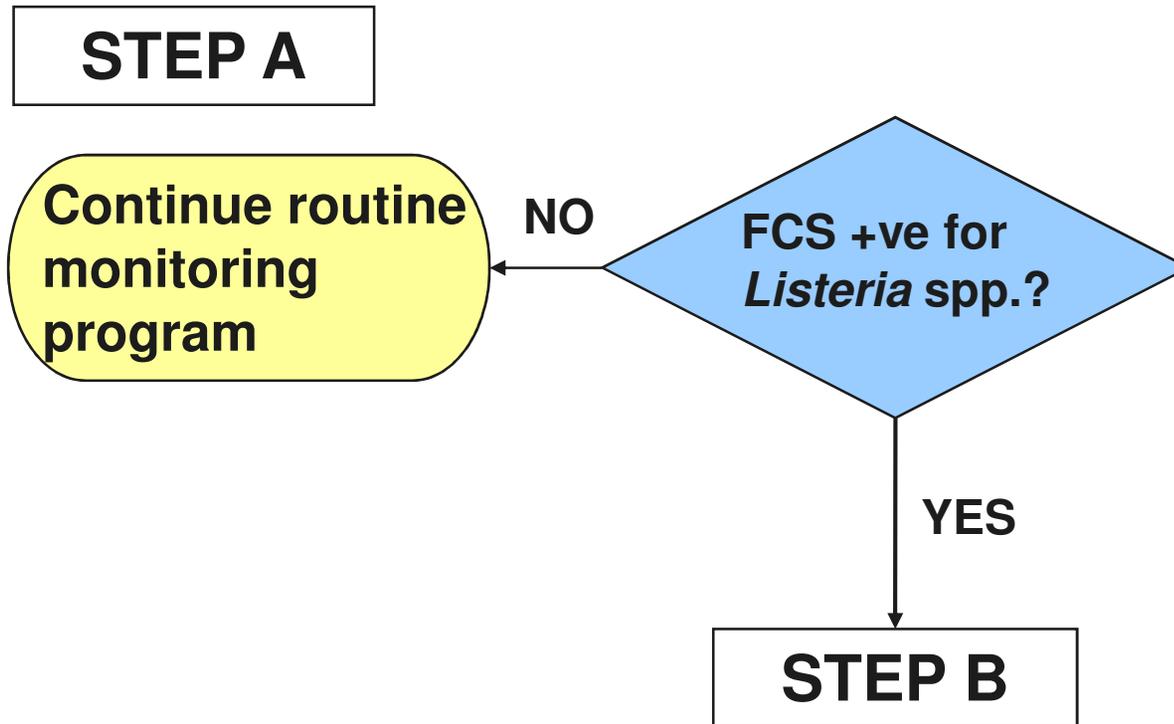


Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP B

• Initiate corrective actions ASAP



- Step B and onward should be recorded to include information on corrective actions, investigational sampling, product testing and/or disposition
- Corrective actions:
 - Prevent or eliminate Lm
 - Control conditions that will enable growth
 - Be monitored to confirm effectiveness

Section 6 and 7 of the *Listeria* Policy

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP B

- **Initiate corrective actions ASAP**



- Corrective actions should include:
 - In-depth review of the food safety system (GMPs / HACCP) to ensure compliance and adjusting it, if necessary
 - Improvement in sanitation procedures
 - Identification of the source of the contamination through investigational sampling

Section 6.2.1.2 of the *Listeria* Policy

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP B

- **Initiate corrective actions ASAP**
- **After corrective actions are implemented:**
 - **All products from that line should be placed on hold**

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP B

- **Initiate corrective actions ASAP**
- **After corrective actions are implemented:**
 - **All products from that line should be placed on hold**
 - **Collect FCS samples to verify efficacy of corrective actions, as per MFLP-41**

- 
- At a minimum, the FCS sites in the routine monitoring program should be included
 - The number and location of samples sites should be adequate to verify that the entire line is negative for *Listeria* spp.

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP B

- **Initiate corrective actions ASAP**
- **After corrective actions are implemented:**
 - **All products from that line should be placed on hold**
 - **Collect FCS samples to verify efficacy of corrective actions, as per MFLP-41**
 - **Analyze FCS samples individually**

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP B

- **Initiate corrective actions ASAP**
- **After corrective actions are implemented:**
 - **All products from that line should be placed on hold**
 - **Collect FCS samples to verify efficacy of corrective actions, as per MFLP-41**
 - **Analyze FCS samples individually**
 - **Use any enrichment (presence / absence) method for *Listeria* spp. published in HC's Compendium of Analytical Methods in which the "Application" section is appropriate for the intended purpose**

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

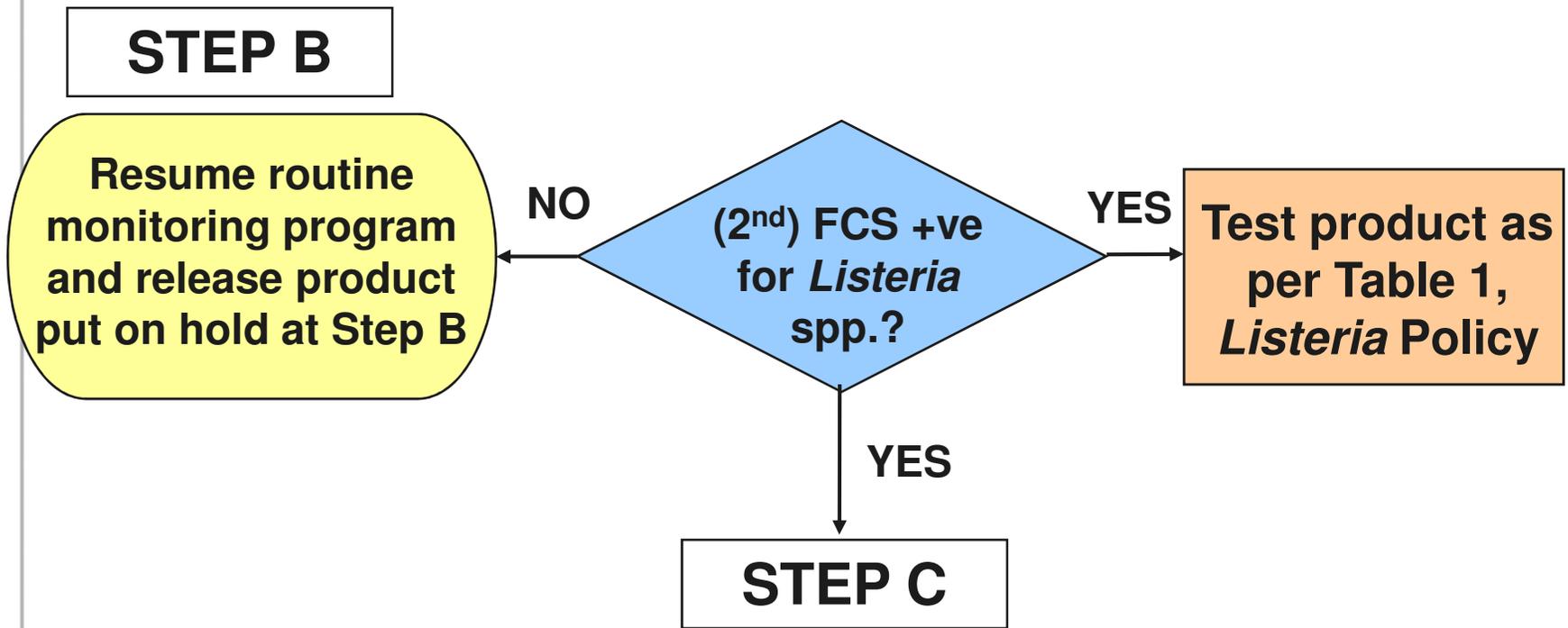


Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP B

Test product as
per Table 1,
Listeria Policy

- End-product sampling should be linked to the environmental sampling
- 5 sample units should be collected aseptically at random from the implicated lot
- Each sample unit should consist of at least 100 g

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

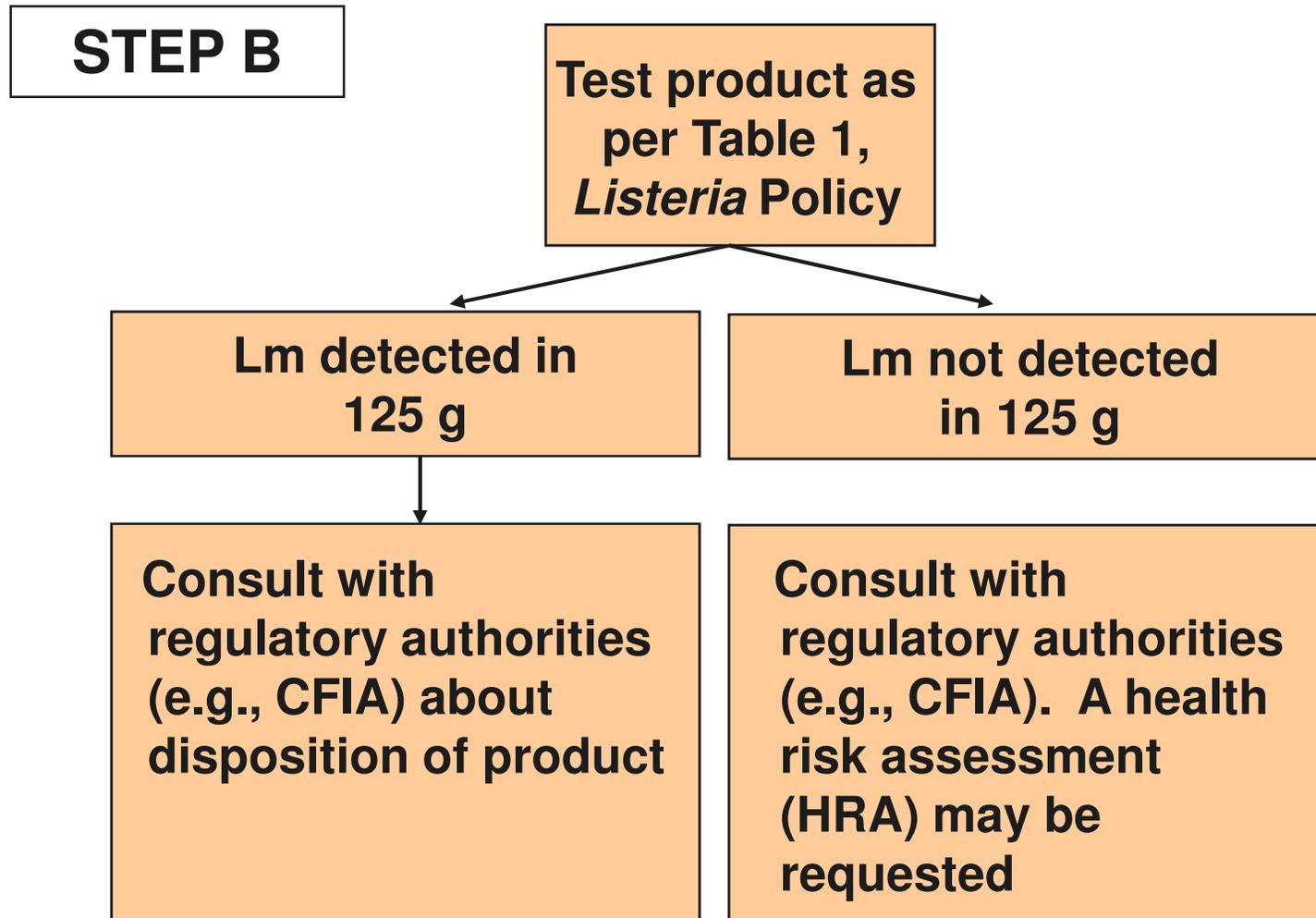


Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

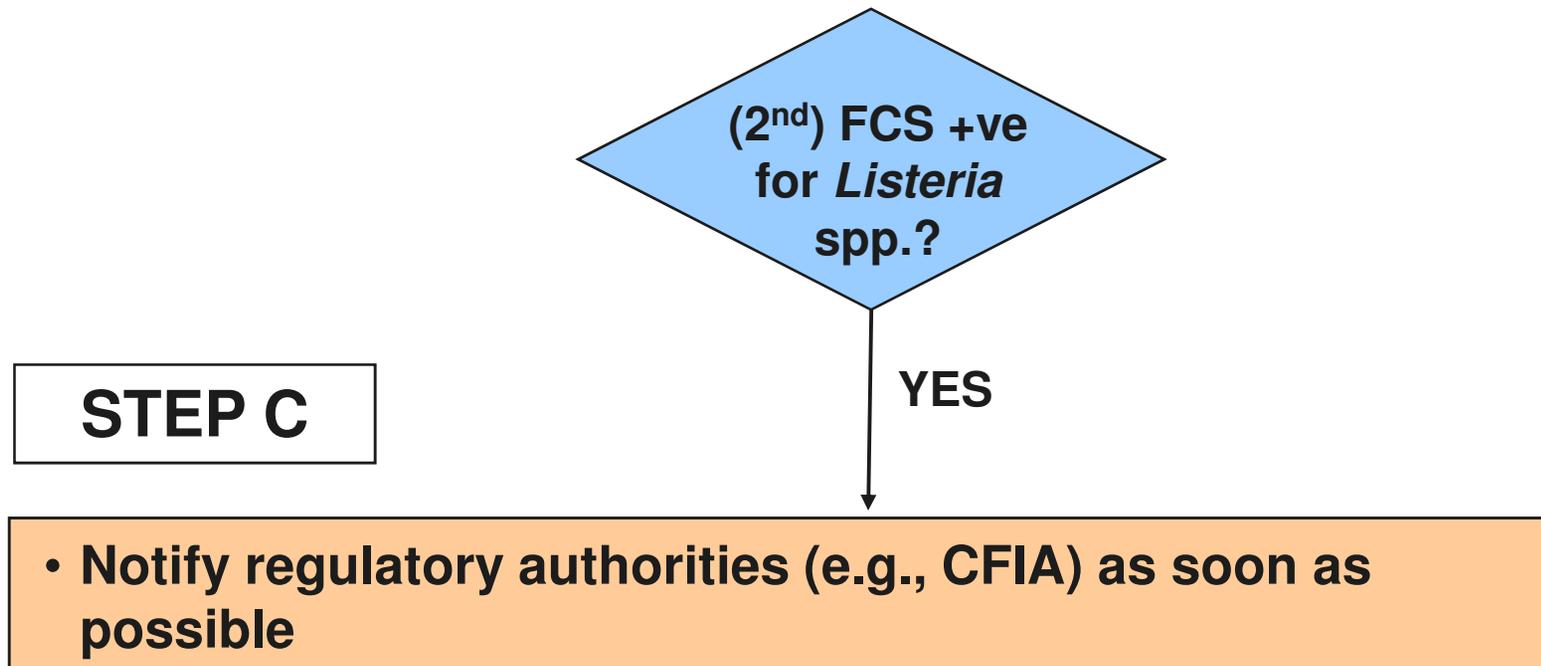


Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP C

- Notify regulatory authorities (e.g., CFIA) as soon as possible
- Repeat Step B until FCS samples are negative for *Listeria* spp. and product samples are negative for Lm



Hold and test each lot of product until the results demonstrate that control of *Listeria* has been achieved

Figure 1: Sampling Guidelines for FCSs (Category 1 RTE Food)

STEP C

- Notify regulatory authorities (e.g., CFIA) as soon as possible
- Repeat Step B until FCS samples are negative for *Listeria* spp. and product samples are negative for Lm
- Sample FCS and end-product until results are negative for 3 or more consecutive production days and product samples do not exceed criteria for Lm

Fig. 1: FCSs (Category 1 RTE Foods)

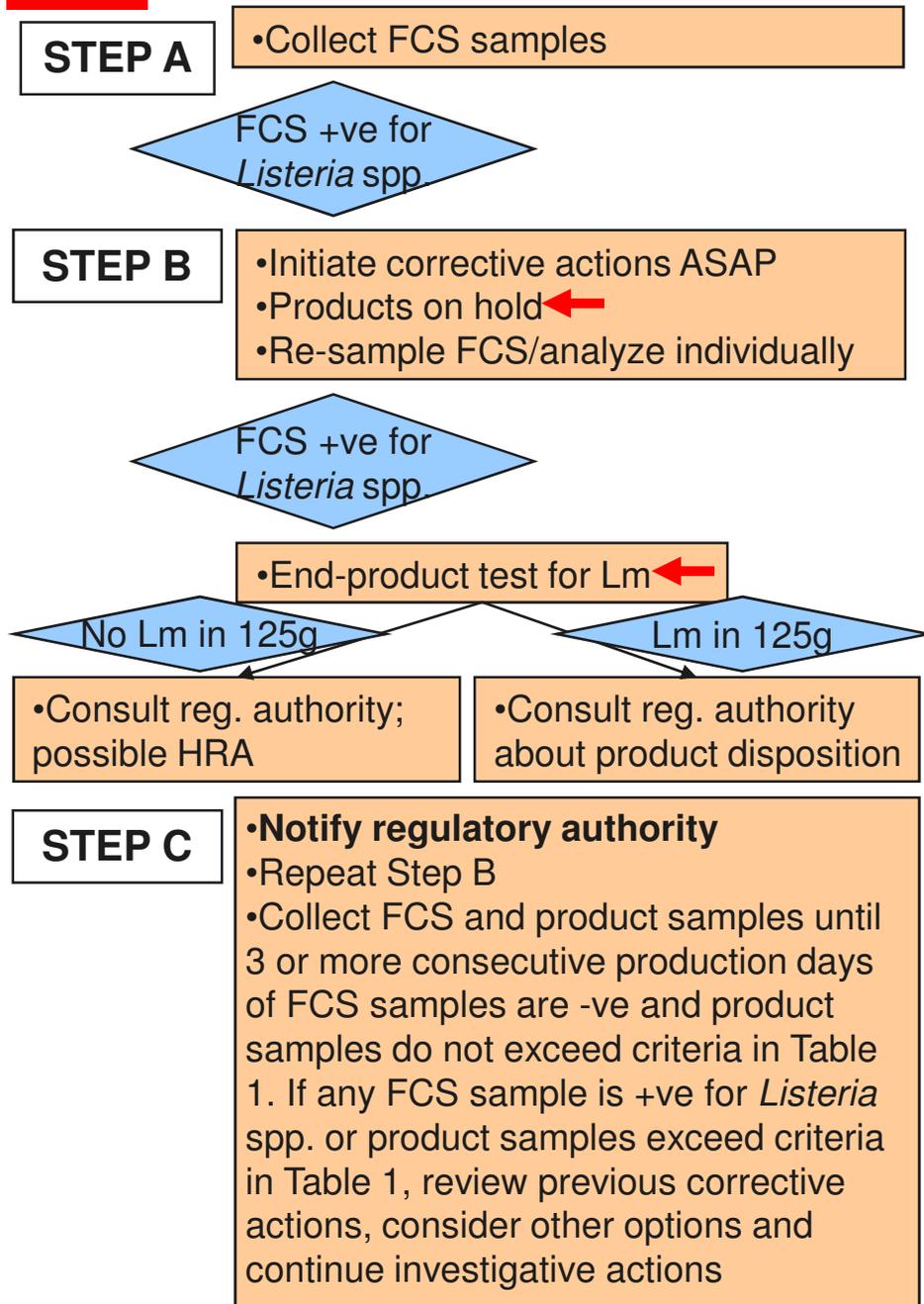


Fig. 2: FCSs (Category 2 RTE Foods)

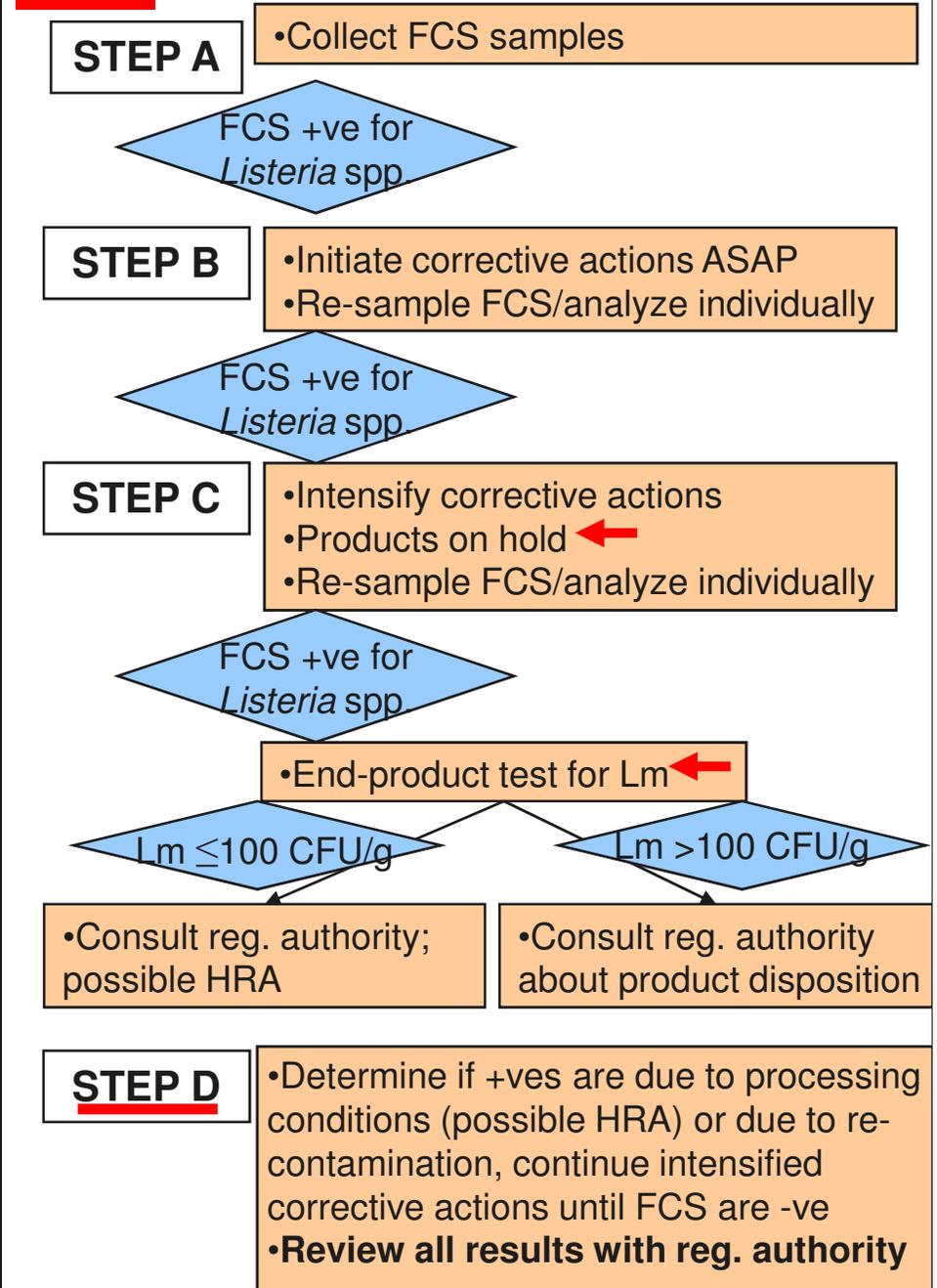
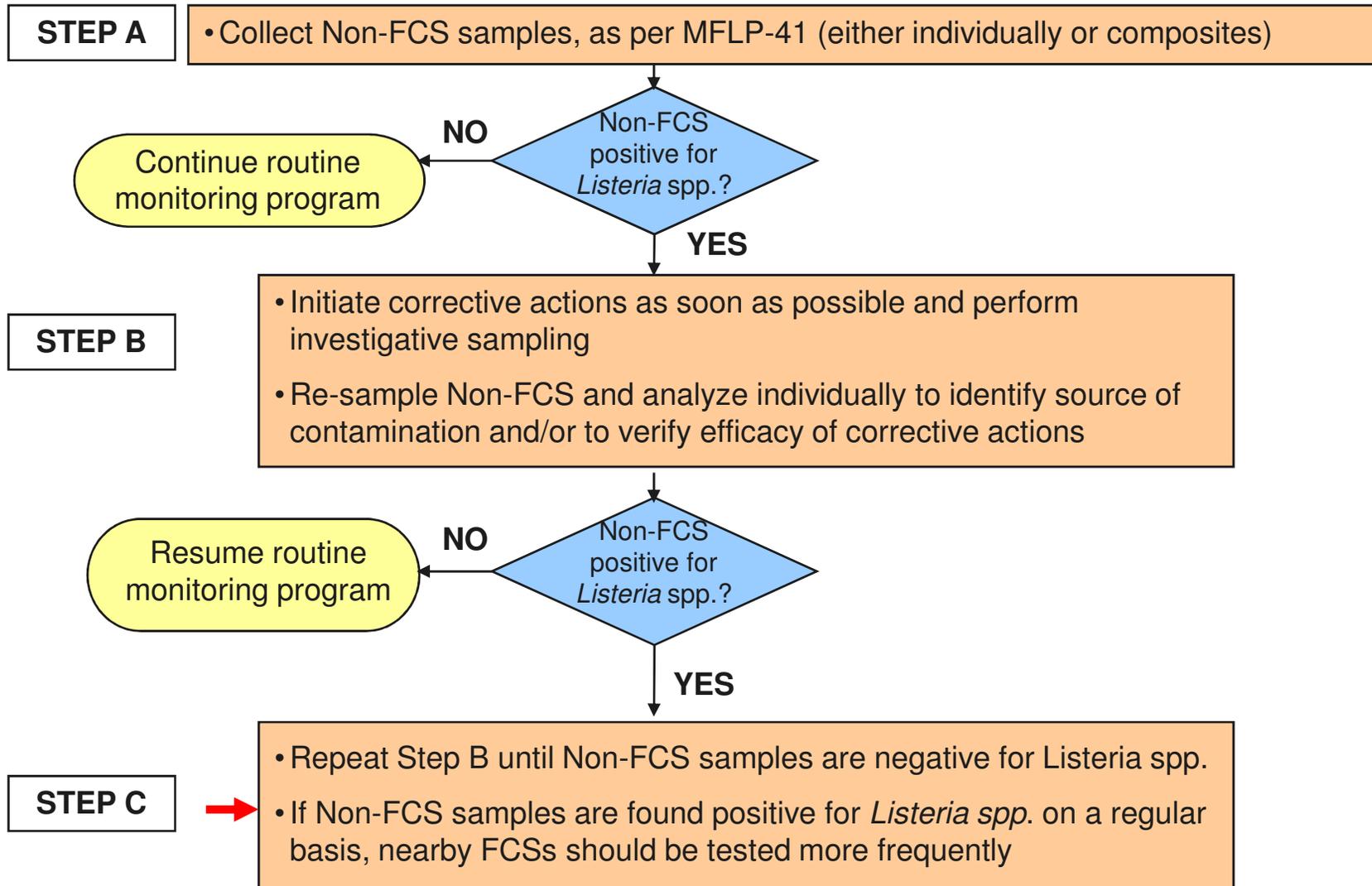


Figure 3: Sampling Guidelines for Non-FCSs, In Proximity to FCS (Category 1 and 2 RTE Food)



Industry Monitoring



- Trend analysis should be part of a company's verification process
- Data can be used to model and predict risk
- The results should be used to achieve improved control of *Listeria* over time

Topic
9

CFIA Oversight and Verification

CFIA Oversight

- Verification of industry's compliance with applicable *Acts and Regulations*
- Assessment of GMPs at RTE fresh-cut and processed fruit and vegetable establishments
- Product testing of domestic and imported RTE fresh-cut and processed fruit and vegetables for the detection of Lm

CFIA Verification

- Conduct on-site inspections in order to verify *Listeria* controls and corrective actions
- Assess *Listeria* controls of foreign suppliers at the importer
- Collect end-product and/or environmental samples
- Detain and/or recall of affected product, as applicable

Sections 6.2.1 and 6.2.2 of the *Listeria* Policy

CFIA Verification

Focus of CFIA's On-Site Inspection

- Production procedures (e.g., GMPs/HACCP Program)
- Process controls
- Deviation and corrective action procedures
- Equipment design, ventilation and packaging material
- Sanitation practices
- Employee hygiene practices
- Process flow (product / personnel)
- Post-process handling, storage and distribution
- Product traceability

Sections 6.2.1.1 of the *Listeria* Policy





Question's and Answer's

Additional Questions?

Contact FFV.CFIA@inspection.gc.ca



Reference Documents

Reference Documents – Health Canada

1. *Policy on Listeria monocytogenes in Ready-To-Eat Foods.*
(2011)
2. *Summary of Comments Received on Health Canada's Proposed Policy on Listeria monocytogenes in Ready-to-Eat (RTE) Food* - March to May, 2010
3. *The Compendium of Analytical Methods*, Vol 2 and 3.
4. *Summary of Methods in the Compendium of Analytical Methods for Listeria spp. and Listeria monocytogenes.*

Reference Documents – Health Canada

5. *Validation of Ready-to-eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B Food.* – in relation to HC's Policy on *Listeria monocytogenes* in Ready-to-Eat Foods (2011)
6. *Summary of Comments Received on Health Canada's Proposed Document Validation of Ready-to-Eat Foods for Changing 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 - October to November, 2011*
7. *Listeria monocytogenes Challenge Testing of Ready-to-Eat Refrigerated Food.*



Reference Documents – CFIA

1. *General Principles of Food Hygiene, Composition and Labelling*
2. *Good Importing Practices for Food, Code of Practice*
3. *Code of Practice for Minimally Processed Ready-to-Eat Vegetables*
4. *Food Safety Enhancement Program Manual*
5. *Guidelines for the Use of Food Additives and/or Processing Aids Intended for Fresh Fruit and Vegetable*
6. *Canada's 10 Least Wanted Foodborne Pathogens - Listeria monocytogenes*

Reference Documents – Codex

1. Codex Alimentarius Commission, CAC/GL 69-2008. *Guidelines for the Validation of Food Safety Control Measures*
2. Codex Alimentarius Commission, CAC/GL 61-2007. *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods*
3. Codex Alimentarius Commission, CAC – 2009a. *Proposed Draft Microbiological Criteria for Listeria monocytogenes in Ready-to-Eat Foods*
4. Codex Alimentarius Commission, CAC – 2009b. *Recommended International Code of Practice General Principles of Food Hygiene*



Reference Documents – Codex

5. Codex Alimentarius Commission, CAC/RCP 53-2003. *Code of Hygienic Practice for Fresh Fruits and Vegetables*
6. Codex Alimentarius Commission, CAC/RCP 46-1999. *Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life*
7. Codex Alimentarius Commission, CAC/RCP 8-1976. *Code of Practice for the Processing and Handling of Quick Frozen Foods*

Reference Documents – Other

1. Ministry of Agriculture, Food and Rural Affairs. *Food of Plant Origin Cleaning and Sanitation Guidebook*. (2006)
2. *On-Farm Food Safety Manual from Canada-GAP/CHC*. Chlorination of Water for Fluming and Cleaning Fresh Fruits and Vegetables and Cleaning Equipment. (2013)
3. Standards Council of Canada – Directory of Accredited Clients
4. Canadian Association for Laboratory Accreditation Inc – Directory of Accredited Laboratories

Reference Documents – Other

5. Food and Drug Administration. *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce.* (2001)

Canada