Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

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MEAT HYGIENE DIRECTIVE

2011-28

SUBJECT: Chapter 4 - Annex H and Annex I

Revised policy on the control of *Listeria monocytogenes* in Ready-to-Eat meat and poultry products.

Annex H:
Policy on the Control of *Listeria monocytogenes* in Ready-to-Eat (RTE) Meat and Poultry Products.

Annex I:
Risk-based Verification Sampling of Ready-to-Eat (RTE) Meat and Poultry Products.

ENGLISH VERSION

Please add Annex H and Annex I to Chapter 4 of your Manual of Procedures.

FRENCH VERSION

Please add Annex H and Annex I to Chapter 4 of your Manual of Procedures.

Le 1 avril 2011

DIRECTIVE DE L'HYGIENE DES VIANDES

2011-28

OBJET : Chapitre 4 – annexe H et annexe I

Politique revisée sur le contrôle de *Listeria monocytogenes* dans les produits de viande et de volaille prêts-à-manger.

Annex H :
Politique sur le contrôle de *Listeria monocytogenes* dans les produits de viande et de volaille prêts-à-manger (PAM).

Annexe I :
Un plan de vérification de l'échantillonage fondé sur les risques pour les produits de viande et de vollaile prêts-à-manger (PAM)

VERSION ANGLAISE

Veuillez ajouter l'annexe H et l'annexe I au Chapitre 4 de votre Manuel des Méthodes.

VERSION FRANÇAISE

Veuillez ajouter l'annexe H et l'annexe I au Chapitre 4 de votre Manuel des Méthodes.

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Policy on the Control of *Listeria monocytogenes* in Ready-to-Eat (RTE) Meat and Poultry Products

1.0 *Listeria*

1.1 Description

Listeria monocytogenes is a Gram-positive, non-spore forming, rod-shaped bacterium. It is very hardy, resistant to drying, freezing, and high salt concentrations. It can grow readily at refrigeration temperatures and in vacuum-packaged meat and poultry products. *Listeria* can be destroyed by thoroughly cooking meat and poultry products.

1.2 Occurrence

L. monocytogenes is widely distributed in nature, occurring in soil, sewage, vegetation, water, silage, livestock, and humans. It is well adapted to survival in cold, moist environments commonly found in meat and poultry processing establishments. Meat products most commonly associated with outbreaks of listeriosis include hot dogs, deli-meats, jellied pork tongue and pâté. Cooked meat and poultry products can be contaminated from equipment, from the handling of raw products by personnel, or from reservoirs of *Listeria* in the post-lethality ready-to-eat environment.

1.3 Concern

Immunocompromised individuals, pregnant women, neonates, and the elderly are most susceptible to infection. *L. monocytogenes* most often causes symptoms such as vomiting, nausea, cramps, diarrhoea, severe headache, constipation and persistent fever. In some instances, these symptoms may be followed by septicaemia, miscarriages, meningitis and encephalitis. Death is rare in immunocompetent persons affected with listeriosis, but is approximately 30% in the high-risk group. The infective dose for *L. monocytogenes* in humans is not exactly known, but may be less than 1,000 organisms/g of food consumed by some susceptible people.

2.0 Ready-to-eat meat and poultry products

Processed meat and poultry products that do not require any further preparation before consumption, except washing/ rinsing, thawing or warming, are considered Ready-to-Eat (RTE) foods.

The following definition applies to RTE meat and poultry products according to the *Meat Inspection Regulations* (*MIR*), *1990*:

“Ready-to-eat means, in respect of a meat product, a meat product that has been subjected to a process sufficient to inactivate vegetative pathogenic microorganisms or their toxins and control spores of food borne pathogenic bacteria so that the meat product does not require further preparation before consumption except washing, thawing or exposing the product to sufficient heat to warm the product without cooking it.”

It is the responsibility of the operator to determine whether the meat product produced in the establishment is RTE or Non-RTE (NRTE). Product labelling does not determine the classification of a meat product. For example, labelling a meat product (that meets the definition of RTE) with full cooking instructions (required for NRTE) does not change the fact that it is indeed a RTE meat product. Regardless of the label, a meat product that meets the definition of RTE will be classified as such and will be subjected to all applicable sampling and testing requirements as per this policy. A careful evaluation of an operator’s Hazard Analysis Critical Control Points (HACCP) plan and validation results, as well as on-site process and product labelling verification by the Inspector-in-Charge (IIC) and/or the Food Safety Enhancement Program (FSEP) or the Area Program Specialist, may be required to confirm classification of products into RTE or NRTE categories. In general, if a meat or a poultry product has received a heat treatment to achieve 6.5D or 7.0D lethality of *Salmonella* spp., respectively, according to time and temperature parameters listed in MOP

Chapter 4 (Section 4.3 and Annex D) or has received a processing intervention step (e.g., fermentation, dry curing, etc.) according to MOP Chapter 4, then the product is classified as RTE. If further preparation of a meat and poultry product is required (e.g., cooking) before consumption, then the product is considered as NRTE.

The assembled convenience food is a product containing meat and non-meat components. Such products are classified into RTE and non-RTE categories according to the following criteria:

Ready-to-Eat (RTE) meat products:

i) The assembled food undergoes a full lethality step post-assembly at the establishment, e.g., fully cooked pizza, meat spaghetti sauce.

ii) The meat and non-meat components of the assembled food are in a RTE stage prior to their assembly at the establishment and none of them will receive further lethality treatment for pathogens before consumption, e.g., sandwiches, chicken salad.

Non Ready-to-Eat (NRTE) meat products:

i) The meat components of the assembled food have not received a full lethality treatment for pathogens of concern at the establishment, e.g., par-fried breaded chicken nuggets.

ii) The meat component in the assembled food is in the RTE stage while at least one other ingredient is in the NRTE stage and will require further cooking before consumption, e.g., pizza with raw dough, frozen entrees with NRTE vegetables.

For heat-treated products which are NRTE but may be mistaken as RTE products, section 94 (6.1) of the MIR will apply, i.e.,

“If any meat product is not a ready-to-eat meat product but has the appearance of or could be mistaken for a ready-to-eat meat product, the meat product shall bear the following information on its label:

(*a*) the words “must be cooked”, “raw product”, “uncooked” or any equivalent words or word as part of the common name of the product to indicate that the product requires cooking before consumption; and

(*b*) comprehensive cooking instructions such as an internal temperature-time relationship that, if followed, will result in a ready-to-eat meat product.”

Such heat-treated meat and poultry products do not fall under this policy, and should not be tested for *L. monocytogenes*.

3.0 Categories of RTE meat and poultry products and classification of RTE establishments

Based on the health risk and the potential for the growth of *L. monocytogenes*, the RTE meat and poultry products are divided into the following two risk categories as per the Health Canada’s “Policy on *Listeria monocytogenes* in Ready-to-Eat Foods - 2010”.

Category 1: Includes RTE meat and poultry products that support the growth of *L. monocytogenes*. These products receive highest priority for industry verification and control, and for CFIA oversight and compliance activities.

Category 2: Category 2 RTE products are further divided into two sub-categories:

Category 2A: Includes RTE products in which limited growth of *L. monocytogenes* to levels ≤ 100 CFU/g can occur throughout the stated shelf-life. Initially, this category includes RTE products which are known to occasionally contain low levels *L. monocytogenes* and do not

have a kill step and/or RTE refrigerated foods with a shelf-life of ≤ 5 days. For RTE products not subjected to a kill step, operators must validate and regularly verify that the levels of *L. monocytogenes* in the product(s) are consistently ≤ 100 CFU/g throughout the stated shelf-life of the product(s). If the validation and verification information is not available or inadequate, the RTE product(s) will be considered as Category 1 product(s) for all sampling, verification and compliance purposes.

Category 2B: Represents RTE products in which the growth of *L. monocytogenes* cannot occur throughout the stated shelf-life of the product(s). A RTE food in which *L. monocytogenes* numbers do not increase by 0.5 log CFU/g, throughout the stated shelf-life, is considered not to support growth of the organism. Growth of *L. monocytogenes* is assumed not to occur in RTE foods, if the physico-chemical parameters fall within the following range:

a) pH < 4.4, regardless of aw
b) aw < 0.92, regardless of pH
c) Combination of factors (e.g. pH < 5.0 and a_w < 0.94)
d) Frozen foods

Validation studies are not required when Category 2B products meet the above-mentioned criteria.

3.1 Antimicrobial agents and post-lethality procedures

Operators can employ antimicrobial agents/processes and/or post-lethality procedure(s) to suppress or limit growth of *L. monocytogenes* in RTE products. Such procedures must be validated by the operators and accepted by the CFIA. The operator must validate any change in the procedure to ensure the effectiveness and consistency.

Antimicrobial agents

Antimicrobial agents are food additives that are approved by Health Canada and can be used to potentially control the growth of *L.. monocytogenes* in RTE foods. Examples of currently approved antimicrobial agents are: potassium lactate, sodium acetate, sodium diacetate and sodium lactate.

An antimicrobial agent is considered acceptable if it allows no more than 2 log CFU/g increase in *L. monocytogenes* throughout the stated shelf-life of the product. RTE products produced using this criterion may qualify to a lower Relative Risk Level (RRL) for sampling purposes within their respective food risk category, but cannot be moved to a lower food risk category.

Category 1 RTE products can be moved to Category 2B when permitted antimicrobial agents are used to limit the growth of *L. monocytogenes* to < 0.5 log CFU/g throughout the stated shelf life of the product. Operators must validate and present data according to section 3.2 to demonstrate that the growth of *L. monocytogenes* will not occur in the product throughout the stated shelf life.

Post-lethality procedures

Post-lethality procedures refer to procedures implemented by operators in the post-lethality processing environment to control or eliminate *L. monocytogenes* in RTE meat and poultry products. For example, operators can employ validated post-lethality treatment(s) to reduce the levels or inactivate any *L. monocytogenes* found on the surface of RTE products due to post-lethality contamination or can simply rely on sanitation measures alone (no post-lethality treatment).

A post-lethality treatment is considered satisfactory when it achieves at least 3-log reduction in number of *L. monocytogenes* in RTE products, e.g., High-Pressure Processing (HPP) at 87000 psi for 3 minutes.

3.2 Validation and monitoring of processing parameters for Category 2 products

The growth of *L. monocytogenes* in RTE products can also be controlled by using permitted antimicrobial agents. Operators must validate the processing parameters to demonstrate that there is limited or no growth of *L. monocytogenes* throughout the stated shelf life of the product(s) in order to confirm the classification of products in either Category 2A or 2B. Otherwise the product(s) will be treated as Category 1 for all sampling, verification and compliance purposes.

Demonstration to prove that Category 2 products support limited growth/no growth of *L. monocytogenes* throughout the stated shelf-life can be provided by conducting experiments in naturally-contaminated foods, challenge studies, information from the scientific literature, validated predictive microbiological modeling supplemented with other data sources or a combination of these. The following Health Canada guideline documents can be consulted for more details:

"Validation of Food Safety Measures to Limit or Prevent the Growth of *Listeria monocytogenes* in Ready-to-Eat Foods"

"Listeria monocytogenes Challenge Testing of Ready-to-Eat Refrigerated Foods." Available at: http://www.hc-sc.gc.ca/fn-an/legislation/pol/listeria_monocytogenes-eng.php

For Category 2A and 2B products, the growth limiting physico-chemical characteristics (e.g., pH and a_w) and other product parameters (e.g., validated use of antimicrobial agents) shall be monitored and verified regularly according to the establishment's HACCP plans. Any change in the process that could affect the growth limiting parameter(s) must be verified to ensure the effectiveness and consistency of the process. Such controls are important to confirm and justify the classification of RTE meat and poultry products into Category 2A or 2B, otherwise, products will be treated as Category 1 RTE product.

The frequent presence of *L. monocytogenes* at low levels (≤ 100 CFU/g) in Category 2A or 2B products could be an indication of inadequate good manufacturing practices (GMPs) and process control; therefore, appropriate corrective actions must be implemented by the operators.

A finding of *L. monocytogenes* in the following situations may require a Health Risk Assessment (HRA) on a case-by-case basis:

1. Frozen products (Category 2B) are temperature abused leading to thawing of the product(s), or
2. Category 2 products used as ingredients in Category 1 products, or
3. Category 2A or 2B products intended for high-risk population groups such as immunocompromised individuals, pregnant women, neonates, and elderly people.

3.3 Classification of establishments

Establishments producing RTE meat and poultry products are classified according to the risk category of products produced (1, 2A or 2B) and the RRL under which these products are produced. The RRL is the overall *L. monocytogenes* associated risk as determined according to the following factors:

A. Risk category of the RTE meat and poultry product
B. Antimicrobial agents/ processes, and
C. Post-lethality procedures

Based on these factors, the following RRLs are assigned to different categories of RTE meat and poultry products produced in RTE establishments:

Risk Category of RTE product(s)	Relative Risk Level (RRL)		
	Antimicrobial agent *	Post-lethality treatment	
		None	Yes
Category 1	None	High	Medium High
	Yes	Medium High	Medium
Category 2A	None	Medium	Medium Low
	Yes	Medium Low	Low
Category 2B	NA	Low	Very Low

*Antimicrobial agent allows no more than 2 log CFU/g increase in *L. monocytogenes* throughout the stated shelf-life of the product; NA: Not applicable

The testing frequency of an establishment is based on the risk category of RTE products (1, 2A or 2B) and the RRL under which these products are produced (Very low to High). For an establishment producing more than one category of RTE products under different RRLs, the establishment's sampling frequency will default to the RRL under which the highest risk category product(s) is produced.

The following classification may be used for establishments producing RTE meat and poultry products:

Category 1 : Category 1 High; Category 1 Medium High; or Category 1 Medium
Category 2A : Category 2A Medium; Category 2A Medium Low; or Category 2A Low
Category 2B : Category 2B Low or Category 2B Very Low

4.0 CFIA Testing Program

There are six programs for *Listeria* monitoring/verification in federally registered establishments producing RTE meat and poultry products:

1) M205: This is a RTE environmental (Food Contact Surface- FCS) monitoring plan for *L. monocytogenes* and other *Listeria* species, and is linked to the random RTE product sampling plan M200.

2) M200: This is a random RTE meat and poultry product sampling plan for domestic products for monitoring of *L. monocytogenes* and *Salmonella* spp. in RTE products, as well as for *E. coli* O157:H7 in uncooked dry or semi-dry fermented products containing beef. The plan is linked to M205 FCS monitoring plan.

3) M205RB: This is a RTE environmental (FCS) monitoring plan for *L. monocytogenes* and other *Listeria* species, and is linked to the risk based RTE meat and poultry product sampling plan M200RB for domestic products.

4) M200RB: This is a targeted risk-based RTE meat and poultry product sampling plan for *L. monocytogenes* in domestic products. This sampling plan is linked to M205RB FCS sampling plan.

5) The Risk-based Verification Sampling of RTE meat and poultry products: This is a CFIA sampling plan implemented by operators under CFIA supervision (Section 5.3) to monitor *L. monocytogenes* and *Salmonella* spp. in RTE products, as well as for *E. coli* O157:H7 in uncooked dry or semi-dry fermented products containing beef.

6) M203: This is a RTE product sampling plan for imported products to monitor *L. monocytogenes* and *Salmonella* spp. in RTE products, as well as for *E. coli* O157:H7 in uncooked dry or semi-dry fermented products containing beef. Refer to instructions in the Guidelines for the Microbiology Sampling Plans in Red Meat and Poultry Products

distributed annually for red meat and poultry products and to the Meat Hygiene Manual of Procedures (MOP) Chapter 10 for additional information.

The sampling of Food Contact Surfaces (FCS) and/or RTE product(s) under respective sampling plans should be evenly distributed throughout the production year. Establishments engaged in seasonal manufacturing of RTE products shall be tested during the production period.

In establishments operating with multi-commodity production lines, sampling of FCS or product under CFIA or operator's sampling plans must be performed when RTE meat and poultry products are being produced. Any unsatisfactory test result originating from non-meat product(s) may have an impact on RTE meat and poultry product(s), as per the CFIA's "lot" definition, if full sanitation is not performed in-between.

4.1 Tracking *Listeria* test results by the CFIA

All *Listeria* test results from operator and CFIA testing (FCS and RTE Product), including result(s) from follow-up testing, are tracked by the IIC. Appropriate Compliance and Verification System (CVS) tasks are rated as "satisfactory" or "unsatisfactory" based on the laboratory results. The IIC shall verify and track results of *Listeria* testing until the establishment has corrected the problem. The processing establishment complex supervisor, Area Program Specialist and the Inspection Manager are to be informed of all unsatisfactory results.

4.2 M205: Listeria environmental monitoring of FCS

All federally registered meat and poultry establishments producing RTE meat or poultry products that are exposed in the post-lethality environment shall be tested by the CFIA under this sampling plan. The purpose is to monitor the effectiveness of sanitation and GMPs in preventing contamination of RTE processing environment and products by *L. monocytogenes.*

The M205 sampling is conducted at the same time as the random RTE domestic product sampling under the M200 sampling plan. Operators must be informed 24 hours in advance of sampling so that they can hold the product affected by the sampling. In multi-line operations, a production line is selected randomly on the day of sampling.

4.2.1 Sampling Frequency

Sampling frequency is stated in the Guidelines for the Microbiology Sampling Plans in Red Meat and Poultry Products under sampling plan M205.

4.2.2 Sampling procedures

The operational centre in each area supplies *Listeria* environmental sampling kits to the IIC. Instructions on sanitary sampling techniques are available in the training material "Sampling for M205". Any problems with the sampling kits should be immediately reported to the Area Program Specialist for processing/microbiology.

Samples shall be collected and submitted to the CFIA lab in accordance with instructions pertaining to sampling plan M205. Pre-moistened swabs will be used to sample FCS (any surface or object that comes into contact with the RTE meat or poultry product) in the post-lethality treatment areas of the establishment. For fermented or dry-cured products, FCS should be swabbed after the point in the process where the product has achieved RTE status as per the operator's written program. Ten swabs are provided in each kit to swab 10 different FCS sites. If 10 sites are not available, a minimum of five sites must be swabbed. A 900 cm^2 surface should be swabbed whenever possible. Surfaces should be swabbed three hours (T3) or more after the start of the operations. If the time of production is less than three hours, the samples should be taken in the second half of the production period. The sampling sites should be documented on CFIA/ACIA 5165 (LSTS User Service, "Meat" Form)

Food Environmental Sampling Submission Form which accompanies the shipment to the CFIA lab. The CFIA labs will test the composite samples for the presence of *L. monocytogenes* and other *Listeria* species.

4.2.3 CFIA Follow-up on unsatisfactory results

The IIC must inform the operator (or representative) as soon as possible, either in person and/or electronically, if there is an unsatisfactory test result due to the presence of *L. monocytogenes* and also if any other *Listeria* species has been detected (Appendix 1). An establishment that has an unsatisfactory result for *L. monocytogenes* under M205 is not considered to be operating according to GMPs. The IIC will examine the test results of the product that was sampled simultaneously under the M200 random product sampling plan from the same production lot and line that revealed unsatisfactory M205 results. The appropriate CVS sampling task(s) will be rated as "Unsatisfactory" and a Corrective Action Request (CAR) will be issued to the operator.

The IIC will receive a corrective action plan from the operator within 5 working days of the notification of an unsatisfactory test result. The IIC and/or the complex supervisor will review the action plan, verify the on-site activities proposed in the action plan, and oversee the operator's follow-up actions. The IIC may consult the Area Program Specialist when required for program clarification and advice and/or may submit the action plan to the Area Program Specialist for review and comments. The IIC will collect FCS and product samples towards the end of the operator's follow-up testing to verify compliance (Table 1).

The Area Program Specialist will provide additional information on a case-by-case basis when the results of these additional tests are available.

4.2.4 Operator's follow-up on unsatisfactory results

Operators receiving a CAR because of an unsatisfactory result under sampling plan M205 are required to take immediate corrective actions. The operator must also submit an action plan to the IIC within 5 working days of the notification of the unsatisfactory result. The action plan must indicate all the corrective measures that will be implemented to eliminate *L. monocytogenes* from the RTE environment. This includes the requirement to test the same FCS free of *Listeria* spp. for three consecutive times (Appendix 2 or 3, as applicable according to the risk category of the product and type of the production line). The first FCS follow-up sample must be taken as soon as possible within the 5 production days after the notification of an unsatisfactory test result. The three follow-up FCS samples must be collected within 10 production days after the notification of an unsatisfactory test result.

When *Listeria* species other than *L. monocytogenes* are detected, the operator must take corrective actions and perform follow-up testing of the same FCS for *Listeria* spp. as soon as possible within 5 production days after the notification of the test result (Appendix 1).

4.3 M200: Random RTE product testing for *L. monocytogenes*

This is a random sampling plan for domestic RTE meat and poultry products. This plan applies to all risk Categories (1, 2A or 2B) of RTE meat and poultry products, whether or not they are exposed to the environment after being processed. Only one type of RTE product is randomly selected on a given production day. The RTE product is tested for *L. monocytogenes*, *Salmonella* spp., as well as for *E. coli* O157:H7 if it is an uncooked dry or semi-dry fermented product containing beef.

The M200 sampling plan is linked to the M205 sampling plan. In multi-line operations, a production line is randomly selected on the day of sampling. The IIC must inform operators 24 hours in advance of sampling so that they can hold the product affected by the sampling.

Table 1: Follow-up samples collected by the CFIA in response to unsatisfactory test results obtained under CFIA FCS and product sampling plans

RTE product testing	**FCS testing**	**Verification sampling is performed by the CFIA towards the end of the operator's follow-up testing under plan*:**	
A. Random sampling plans			
M200	**M205**		
Unsatisfactory	Unsatisfactory	M200**D**	M205**D**
Satisfactory	Unsatisfactory	M200**I**	M205**D**
Unsatisfactory	Satisfactory	M200**D**	M205**I**
RTE product testing	**FCS testing**	**Verification sampling is performed by the CFIA towards the end of the operator's follow-up testing under plan*:**	
B. Risk-based sampling plans			
M200RB	**M205RB**		
Unsatisfactory	Unsatisfactory	M200RB**D**	M205RB**D**
Satisfactory	Unsatisfactory	M200RB**I**	M205RB**D**
Unsatisfactory	Satisfactory	M200RB**D**	M205RB**I**

Note: **D** is "Directed sampling", and **I** is "Investigative sampling."
*The IIC must obtain a sample submission number from the Area Program Specialist.

4.3.1 Sampling frequency

The sampling frequency is stated in the Guidelines for the Microbiology Sampling Plans in Red Meat and Poultry Products under sampling plan M200.

4.3.2 Sampling procedures

The RTE product samples must be collected aseptically by the IIC as per the guidance provided in the Guidelines for the Microbiology Sampling Plans. Five intact sample units of 250 g each are collected and submitted to the CFIA laboratory. Please refer to the training module "Control measures for *Listeria* in RTE meat products" for information on sample collection.

It is strongly recommended to hold the product affected by the sampling pending the receipt of the laboratory Report of Analysis (ROA). As a minimum, all products produced under the same conditions as the tested lot are considered implicated (e.g., products processed on that day on the same processing line, or using the same equipment, between two full sanitation cycles) in the event of unsatisfactory test result. Distributed product may be subjected to a recall.

4.3.3 CFIA Follow-up on unsatisfactory results

The IIC must inform the operator (or representative) of the unsatisfactory test result as soon as possible, either in person and/or electronically. An establishment receiving an unsatisfactory M200 test result is not considered to be operating according to GMPs. The IIC will examine the results of M205 sampling associated with the unsatisfactory M200 product test result. The IIC will rate the appropriate CVS task as "Unsatisfactory", and will issue a CAR to the operator.

The following assessment criteria are used to interpret laboratory test results for RTE meat and poultry products:

Category 1 products:

Unsatisfactory : *L. monocytogenes* is detected.

Satisfactory : *L. monocytogenes* is not detected.

Category 2 products:

Unsatisfactory : If any of the 5 subunits reveal *L. monocytogenes* >100 CFU/g.
Investigative : If ≥ 2 subunits reveal *L. monocytogenes* > 50 to ≤ 100 CFU/g.
Satisfactory : If *L. monocytogenes* is not detected; or if < 2 subunits reveal *L. monocytogenes* > 50 to ≤100 CFU/g and all other subunits have < 50 CFU/g.

A "hold-and-test" procedure for end product testing will be initiated immediately on the affected production line by the operator under CFIA supervision based on the RTE product category (Appendix 7). The IIC and/or the complex supervisor will review the action plan submitted by the operator and verify on-site activities proposed in the action plan. The IIC may consult the Area Program Specialist for program clarification and advice and/or may submit the action plan to the Area Program Specialist for review and comments. The IIC must keep track of all follow-up samples associated with an unsatisfactory result. The IIC will also collect follow-up product (Five intact sample units of 100 g each) and FCS samples towards the end of the "hold-and-test" period to verify compliance (Table 1).

4.3.4 Operator's follow-up on unsatisfactory results

Operators receiving a CAR because of an unsatisfactory result under sampling plan M200 are required to take immediate corrective actions and to submit an action plan to the IIC within 5 working days of the unacceptable test result. The action plan must indicate all the corrective measures that will be implemented to prevent product contamination by *L. monocytogenes*. This includes the "hold-and-test" procedure for end product testing that must start immediately on all new production lots produced on the affected line after the notification of the unsatisfactory test result (Appendix 7).

4.4 M205RB: *Listeria* environmental monitoring of FCS associated with risk-based product testing under M200RB plan

This environmental sampling plan is linked to the domestic risk based M200RB RTE product sampling plan. All federally registered establishments producing RTE meat or poultry products that are exposed in the post-lethality environment are sampled under this plan to monitor the effectiveness of sanitation and GMPs in the RTE processing environment. The FCS are tested for *L. monocytogenes* and other *Listeria* species.

Under M200RB, the highest risk product produced on the sampling day is selected and FCS are swabbed from the same production line under the M205RB plan. Where the highest risk category product is produced on multiple lines, a production line is selected at random. Operators must be informed 24 hours in advance of sampling so that they can hold the product affected by the sampling.

4.4.1 Sampling Frequency

The frequency of FCS sampling is based on the risk category of RTE products and the RRL under which these products are produced. Refer to section 4.5.2.

4.4.2 Sampling and follow-up procedures

The FCS sampling procedures, CFIA follow-up on unsatisfactory results and operator's follow-up on unsatisfactory results are similar to those described under M205 sampling plan (Section 4.2 and Appendix 1).

CFIA follow-up verification sampling is performed towards the end of an operator's follow-up testing under the appropriate sampling plan, i.e., M205RBD, M205RBI (Table 1).

4.5 M200RB: Risk-based RTE meat and poultry product sampling for domestic products

This is a targeted risk-based monitoring plan for domestic RTE meat and poultry products. The highest risk product produced in the establishment on the sampling day is selected for testing under M200RB. The product is tested only for the presence of *L. monocytogenes*.

This sampling plan is linked to the M205RB environmental sampling plan. The highest risk product produced on the sampling day is selected under M200RB plan according to section 4.5.1 and the same production line is sampled under M205RB. Where the highest risk category product is produced on multiple lines, a production line is selected at random for sampling. The operator must be informed 24 hours in advance of sampling so that they can hold the product affected by sampling.

4.5.1 Risk prioritization of RTE products

In establishments producing more than one RTE product on the day of sampling, the highest risk post-lethality exposed RTE product must be sampled according to these guidelines. The products are listed in decreasing order of risk (sliced deli-meats being the highest risk):

1. Deli-meats that are sliced in a federally registered establishment
2. Deli-meats shipped whole from the federal establishment. (This does not include cook-in-bag products; only those exposed post-lethality.)
3. Hotdog products
4. Deli-salads, pâtés, and meat spreads
5. Fully cooked type products (other than cooked products in 1-4 above)
6. Fermented products
7. Dried products
8. Salt-cured products
9. Products labelled as “Keep Frozen”

Note: All these products will be considered as Category 1 products if they do not meet the physico-chemical and other relevant processing parameters of Categories 2A or 2B products as per section 3.0. Any deviation in the key processing parameter must be corrected and verified to confirm compliance and classification of product(s) into Category 2A or 2B.

4.5.2 Sampling frequency

The sampling frequency is determined according to the risk category of RTE products produced and the RRL under which these products are produced as per section 3.3. The following guidelines are used to determine the sampling frequency of an establishment under M200RB and M205RB plans:

Risk Category of RTE product(s)	M200RB and M205RB Sampling frequencies based on RRL		
	Antimicrobial Agent*	Post-lethality treatment	
		None	Yes
Category 1	None	4 samples per year	3 samples per year
	Yes	3 samples per year	2 samples per year
Category 2A	None	2 samples per year	1 sample per year
	Yes	1 sample per year	1 sample per year
Category 2B	NA	1 sample per year	0 samples per year

*Antimicrobial agent allows no more than 2 log CFU/g increase in *L.. monocytogenes* throughout the stated shelf-life of the product; NA: Not applicable

4.5.3 Sampling procedures

The RTE product samples must be collected aseptically by the IIC as per the guidance provided in the Guidelines for the Microbiology Sampling Plan. Five intact sample units of 100 g each are collected and submitted to a CFIA laboratory.

It is strongly recommended to hold the product affected by the sampling pending laboratory result. In the event of an unsatisfactory test result, all products produced under the same conditions as the tested lot may be considered implicated.

4.5.4 Follow-up procedures

CFIA and operator's follow-up procedures on unsatisfactory results are similar to those described under M200 sampling plan (Section 4.3 and Appendix 4 and 5).

CFIA follow-up verification sampling is performed towards the end of an operator's follow-up testing under the appropriate sampling plan, i.e., M200RBD, M200RBI (Table 1).

4.6 CFIA's action during extended non-compliance

Operators producing RTE meat and poultry products must implement control measures when there are ongoing findings of *L. monocytogenes* or *Listeria* spp. on FCS or *L. monocytogenes* in the product. CFIA inspection staff will take appropriate actions, such as intensified inspection, in-depth review, etc., when the continuous presence of *Listeria* on FCS or in the product is encountered. The situations that warrant immediate action are:

a) **Repetitive:** Two consecutive unsatisfactory sampling events from samples taken from the same production line for either the product or FCS, regardless of the sampling plan, i.e., operator's sampling (mandatory or not), CFIA sampling or follow-up sampling, etc.

b) **Recurrent:** Two unsatisfactory sampling events from samples taken from the same production line for either the product or FCS in a moving window of the five latest sampling events on that line, regardless of the sampling plan.

c) **Systemic:** Multiple unsatisfactory sampling events from samples taken from different production lines for either the product or FCS. For example:

   - Three or more production lines have unsatisfactory results from samples taken during the same week;
   - Two or more production lines have recurrent problems.

Note: Only one sampling event can take place on a production line between two complete sanitation cycles, i.e., one sampling event/production line/day.

4.6.1 Intensified CFIA inspection

Intensified CFIA inspection can be described as the extra oversight/ follow-up measures CFIA inspectors will perform during a situation of extended non-compliance by an operator. Intensified CFIA inspection is required whenever a repetitive, recurrent or systemic problem is identified. The inspector must closely monitor the implementation of an operator's action plan and take additional action(s) where necessary. Such actions may include, additional verification sampling for FCS or product(s); intensified follow-up to verify implementation and effectiveness of the corrective actions and preventative measures; a reassessment of operator's action plan; and/or additional CVS tasks related to Critical Control Points (CCPs), equipment design, process validation, maintenance and calibration, sanitation, GMPs, employee/product traffic pattern, ventilation, etc., beyond the prescribed frequency.

4.6.2 CFIA's in-depth review

The in-depth review is triggered when intensified inspections do not resolve the situation. The goal of an in-depth review is to identify deficiencies that may be responsible for the unsatisfactory conditions and continuing presence of *Listeria* in either the post-processing environment or the product. An in-depth review will also assess if the operator's HACCP system:

- Is designed to effectively control *Listeria* hazards;
- Meets the FSEP and program requirements; and
- Is reassessed to ensure *Listeria* hazards remain under control.

Please refer to MOP Chapter 18 for further information concerning in-depth review.

5.0 Operators program

Operators producing RTE meat and poultry products must implement adequate controls in their establishments to mitigate the risk posed by *L. monocytogenes*. Their HACCP system must therefore include, without being limited to, the following information as it pertains to controlling *L. monocytogenes*:

1. Procedures and validation of a post-lethality treatment and/or an antimicrobial agent or a process, when used.

2. Sanitation guidelines:

    - General cleaning
    - Determining the effectiveness of Sanitation Standard Operating Procedures (Visual examination and testing)
    - Procedures (Sanitation Standard Operating Procedures (SSOP))
    - Employee/product traffic control (Including prevention of cross-contamination)
    - Employee hygiene
    - Sanitizers

    Note: Cleaning and repairing of equipment(s) during operation should be avoided unless the work can be done without creating a hazard from cross-contamination.

3. Equipment design and maintenance: Particular attention must be paid to the equipment used in the RTE processing area. More precisely, the equipment must be fit for the proposed use, and be well designed for easy cleaning and evaluation after sanitation. Operators must provide a detailed description of procedures that will ensure proper disassembly, maintenance and sanitation of the inner gear-housings for all equipment

used for slicing and/or cutting RTE products.

4. Extra precautions are necessary to control employee traffic, product flow and environment during construction and maintenance activities.

5. Take into consideration the end-user of the RTE products.

6. For processes which do not include a kill step (such as the production of prosciuttos or uncooked fermented products), control of the microbiological quality of the incoming raw ingredients, including microbiological specifications for the raw meat.

7. All establishments using the same facility or common equipment to produce Category 1 and 2 (2A or 2B) RTE products must review their HACCP plans, GMPs, control documents, product segregation and sanitation steps. This is important because Category 2 RTE products, with occasional low levels of organisms (≤ 100 CFU/g), may be released into commerce provided GMPs are in place. However, Category 2 products can contaminate Category 1 products when common production line/equipments are used. The cross-contamination can be prevented by using dedicated production line/equipments or by processing Category 1 products at the beginning of the operation or after full clean-up and sanitation.

8. Validate and regularly monitor the appropriate product parameters to confirm and justify the classification of RTE products into Category 2A or 2B according to section 3.0.

In order to demonstrate product compliance, operators have to verify the effectiveness of their HACCP controls by implementing the following mandatory sampling procedures:

1. Mandated environmental sampling of FCS as per section 5.2.

2. The Risk-based Verification Sampling of RTE Meat and Poultry Products according to Annex I.

In addition, operators should implement environmental sampling of non-food contact surfaces (NFCS) as per section 5.4.

5.1 Laboratory procedures

The following requirements are applicable to both the mandated environmental FCS testing as well as any product testing performed by operators as part of the *Listeria* verification:

1. All samples have to be analyzed in an accredited laboratory, except non-mandated FCS and all NFCS samples.

2. The methods of analysis to be used by the laboratories have to be within the scope of their accreditation **or** evidence must be available to demonstrate that the process is underway for adding the method to the scope of accreditation with the accrediting body (e.g., Standards Council of Canada). However, this does not apply to operator's non-mandated FCS and all NFCS samples.

3. The operator shall indicate, for each sample submitted, the method of analysis that is to be used by the laboratory. Approved methods can be found in the Health Canada Compendium of Analytical Methods at the following site. The "application" section of the method chosen must be appropriate for the intended purpose.

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

   Other methods of analysis (e.g., AOAC, ISO, NMKL, FSIS, BAM etc.), for both *L. monocytogenes* in food product and environmental samples and *Listeria* spp. in environmental samples, will be considered with the provision of validation data acceptable to the CFIA to support the requested method.

Positive results from any rapid screening methods are considered presumptive. *Listeria* spp. confirmation and speciation of *L. monocytogenes* can be accomplished by using motility agar, hemolysis and carbohydrate testing as a minimum, as described in MFHPB-30.

4. The operator must inform the CFIA of all unsatisfactory test results by a written or electronic notification as soon as they are aware of them.

5. The CFIA will audit compliance to these criteria.

Notes:

1. Any follow-up testing required by the operator in response to an unsatisfactory test result is considered mandatory testing.

2. Category 2 products submitted for testing must meet specific criteria (e.g., pH, a_w, freezing, antimicrobials, etc.) which must be verified by operators, as applicable, to confirm and justify the classification of RTE meat and poultry products into Category 2A or 2B according to section 3.0.

5.2 Operator's mandated sampling of Food Contact Surfaces

Operators must design, implement and maintain an environmental sampling program for testing FCS for the presence of *Listeria* spp. Testing of FCS for *Listeria* spp. and reacting to positive results as if they were *L. monocytogenes* provides a more sensitive and broader *Listeria* control program in RTE meat processing establishments than would testing for *L. monocytogenes* alone (Health Canada's Policy on *Listeria monocytogenes* in Ready-to-Eat Products, 2010; Industry Best Practices - Draft, 2009). The testing frequencies specified below (Section 5.2.3) for FCS must be met or exceeded.

5.2.1 Target organism for operator's mandated sampling of FCS

Operators must test FCS for *Listeria* spp. as per Appendix 2 or 3. The first detection of *Listeria* spp. on a FCS will trigger corrective actions, but 2 or 3 consecutive findings of *Listeria* spp. on the same FCS for Category 1 or Category 2 products, respectively, will be considered "unsatisfactory" and the product must be tested for *L. monocytogenes*. Operators can indicate whether or not they will confirm a *Listeria* spp. (presumptive positive) result to species level at any stage. If they confirm *L. monocytogenes* on FCS, the result will be considered as "unsatisfactory" and the product must also be tested for *L. monocytogenes*.

5.2.2 Sample collection for operator's mandated sampling of FCS

Operators must follow industry best practices when implementing their environmental sampling of FCS. Operators should collect samples from ten (10) different FCS sites from each production line. This will be considered as one sampling event for the selected production line. If 10 FCS sites are not available, a minimum of 5 sites must be sampled. Operators must also provide a rationale to the IIC for testing less than ten (10) sites. No more than ten (10) samples should be composited, as this process makes it more difficult to trace the source of the contamination. Operators should not mix FCS samples with NFCS samples. Should the operator decide to mix different surfaces, the result will be considered as affecting a FCS, but will not count toward the minimum number of tests required for FCS. The individual locations for the composite sample should be noted to assist in determining the site of contamination when an unsatisfactory result is obtained.

The surfaces must be swabbed three hours (T3) or more after the start of the operation. This will provide a reliable assessment of the working conditions as the elapsed time will have allowed surfaces to be inoculated. If the time of production is less than three hours, the samples must be taken in the second half of the production shift. Should operators wish to specifically verify the sanitation of a specific structure or equipment, additional samples may

be taken prior to start-up (T0). The CFIA strongly encourages this practice. A 900 cm^2 surface should be swabbed whenever possible.

When testing for *Listeria* spp.on a FCS (Appendix 2 or 3, as applicable) and when the next sampling is scheduled before the results of the previous FCS test are received, it is strongly recommended to hold the product, pending the laboratory report, since an unsatisfactory result may trigger the need to test this product.

Please refer to section 5.1 for sampling methodology requirements.

5.2.3 Testing frequency for operator's mandated sampling of FCS

Food contact surfaces on each production line must be tested at the following minimum frequencies. The sampling frequency is determined according to the risk category of RTE product and the RRL under which these products are produced as per section 3.3. For an establishment producing more than one category of RTE products under different RRLs, the establishment's sampling frequency will default to the RRL under which the highest risk category product(s) is produced. A dedicated production line used exclusively for the production of a lower risk category product may be sampled at a lower frequency; however, a written proposal must be submitted to the IIC for approval. Sampling of FCS must be evenly distributed throughout the prescribed period.

Risk Category of RTE product(s)		**FCS testing frequency according to the RRL**		
		Antimicrobial agent**	**Post-lethality treatment**	
			None	**Yes**
Category 2B		**NA**	2/year/line	1/year/line
Category 2A		**None**	4/year/line	2/year/line
		Yes	2/year/line	1/year/line
Category 1: See below				
Non-deli, non-hot-dogs		**None**	1/month/line	1/2months/line
		Yes	1/2months/line	1/3months/line
Deli and hot-dogs	Very Small volume est.*	**None**	1/month/line	1/2months/line
		Yes	1/2months/line	1/3months/line
Deli and hot-dogs	Small volume est.*	**None**	2/month/line	1/month/line
		Yes	1/month/line	1/2months/line
Deli and hot-dogs	Medium volume est.*	**None**	3/month/line	3/2months/line
		Yes	3/2months/line	1/month/line
Deli and hot-dogs	Large volume est.*	**None**	4/month/line	2/month/line
		Yes	2/month/line	1/month/line

* Very small: up to 100,000 kg of RTE meat products produced per year
Small: from more than 100,000 kg to up to 2,000,000 kg of RTE meat products produced per year
Medium: from more than 2,000,000 kg to up to 6,000,000 kg or RTE meat products produced per year
Large: more than 6,000,000 kg of RTE meat products produced per year

** Antimicrobial agent allows no more than 2 log CFU/g increase in *L. monocytogenes* throughout the stated shelf-life of the product; NA: Not applicable

5.2.4 Results and follow-up for operator's sampling of FCS

The first detection of *Listeria* spp. on a FCS must trigger corrective actions by the operator. For a line producing Category 1 products, two consecutive tests, including the follow-up tests, confirming *Listeria* spp. on the same FCS will be considered equivalent to *L. monocytogenes* (Appendix 2) and will trigger the same follow-up actions as a *L. monocytogenes* result. For a dedicated line producing only Category 2 products, three consecutive tests, including follow-up tests, confirming *Listeria* spp. on the same FCS will be considered equivalent to *L. monocytogenes* (Appendix 3) and will require the same follow-up actions as for *L. monocytogenes*.

The same food contact surfaces that were included in the original sample must be tested during the follow-up testing, either individually or as a composite sample, and must be negative for *Listeria* spp. for three consecutive tests. The first FCS follow-up sample must be taken as soon as possible within the 5 production days after the notification of an unsatisfactory test result. The three follow-up FCS samples must be completed within 10 production days after the notification of an unsatisfactory test result. It is strongly recommended to hold the product as an unsatisfactory result will trigger the need to analyse the product.

As indicated under section 5.1, operators must inform the IIC as soon as they are aware of any *Listeria* spp. results. The IIC must inform the processing establishment complex supervisor and the Area Program Specialist of any of the following unsatisfactory test results:

1. *L. monocytogenes* is detected on a FCS
2. Two consecutive *Listeria* spp. detected on a line producing Category 1 product
3. Three consecutive *Listeria* spp. detected on a dedicated line producing Category 2 product

Any of the above situations will trigger the following actions:

- The IIC will issue a CAR to the operator. The operator must present an action plan to the IIC within 5 working days.

- Product testing for *L. monocytogenes*; this must cover the product produced at the time of sampling of FCS but may also include potentially implicated products which came in contact with the tested FCS that generated the unsatisfactory result. The product is tested by the operator according to Appendix 4 or 5, as applicable.

- Three consecutive follow-up negative tests for *Listeria* spp on the same FCS as described previously.

The IIC and the complex supervisor shall ensure that results of *Listeria* testing are tracked until the establishment has corrected the problem. The IIC will collect FCS samples towards the end of an operator's follow-up testing to verify compliance (Table 2). An evaluation may be done to determine whether or not intensified CFIA inspection or an in-depth review should be conducted.

Table 2: Follow-up samples collected by the CFIA for unsatisfactory test results obtained under an operator's FCS and product sampling plans

RTE product testing	FCS testing	Verification sampling is performed by the CFIA towards the end of the operator's follow-up testing under plan:	
		RTE product	FCS
Unsatisfactory	Unsatisfactory	MX200	MX200
Unsatisfactory	Satisfactory	MX200	MX200
Satisfactory	Unsatisfactory	None	If needed*

* FCS samples are collected under MX200 based on previous history or trend analysis.

5.3 Operator's Implementation of the CFIA's Risk-based Verification Sampling of RTE Meat and Poultry Products

All operators producing RTE meat or poultry products that are exposed to the environment after processing must implement the CFIA's "Risk-based Verification Sampling of Ready-to-Eat (RTE) Meat and Poultry Products". This sampling plan targets all RTE meat and poultry products that are exposed to the processing environment after the lethality step or after achieving the RTE status. Further details regarding this sampling plan, including follow-up measures, can be found in Annex I.

It takes into consideration the level of risk inherent to the product (with reference to its composition, pH, a_w, salt content, antimicrobials, etc.), as well as the post-lethality procedures implemented by the operator in the processing environment.

All product sampling must be done for the detection of *L. monocytogenes* and *Salmonella* spp. If the product is an uncooked dry or semi-dry fermented sausage and contains beef, it will also be analysed for *E. coli* O157:H7. Unsatisfactory results are handled in a similar manner as those from the CFIA's M200 and M200RB sampling plans, but follow-up FCS and product testing is conducted under sampling plan MX200, Special Request Microbiological Testing- Red Meat and Poultry Products (Table 2).

If at any time unsatisfactory results are obtained, the CFIA must be informed of the results as soon as the operator is aware of them. When *L. monocytogenes* is detected in RTE products, the operator will perform follow-up procedures according to Appendix 4 or 5 (as applicable), and will implement the "hold-and-test" policy for end product testing as per Appendix 7. When other pathogens are detected, the follow-up procedures will be determined on a case-by-case basis in consultation with the Area Program Specialist.

The IIC and the complex supervisor must keep track of all follow-up samples associated with an unsatisfactory result. The IIC will also collect RTE product samples towards the end of "hold-and-test" follow-up sampling to verify compliance (Table 2).

5.4 Operator's sampling of Non-Food Contact Surfaces (NFCS)

The primary purpose of environmental sampling in RTE establishments is to verify the effectiveness of the sanitation procedures and GMPs. All establishments producing RTE meat and poultry products should implement sampling programs to monitor NFCS for *Listeria* spp. If *Listeria* spp. is present, this should be taken as an evidence of the need to improve the control of *Listeria* spp. in the processing environment.

The sampling frequency should be evenly distributed throughout the year and can be determined according to Industry Best Practices. The recommended procedure and follow-up actions when testing NFCS for *Listeria* spp. are described in Appendix 6.

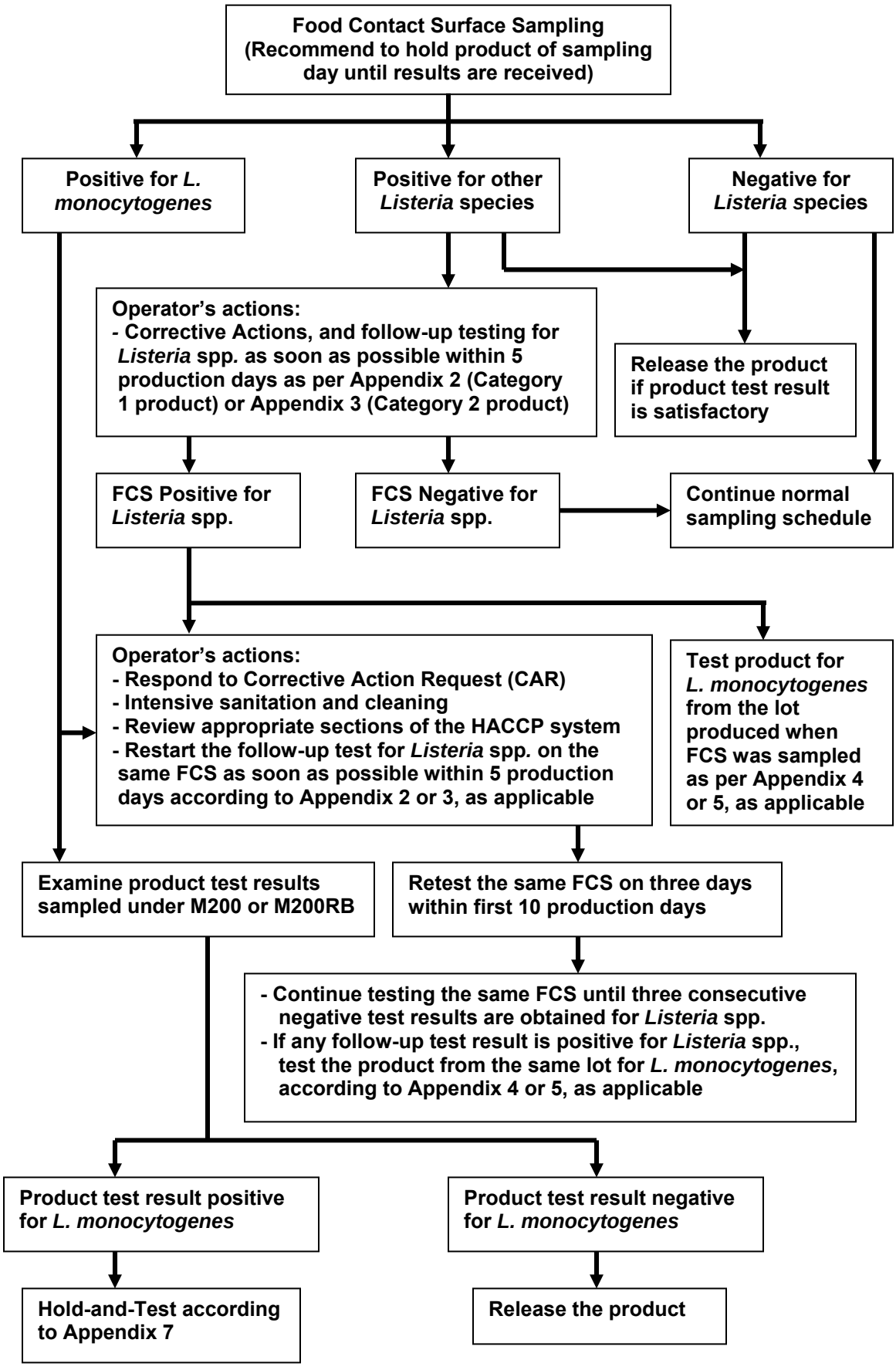
NFCS samples can be analysed by using methods deemed appropriate for the purpose by the industry. It is not mandatory to use an accredited laboratory for analysis of NFCS samples. All sampling results must become part of the operator's *Listeria* trend analysis and must be available to the CFIA upon request.

5.5 Operator's trend analysis of results

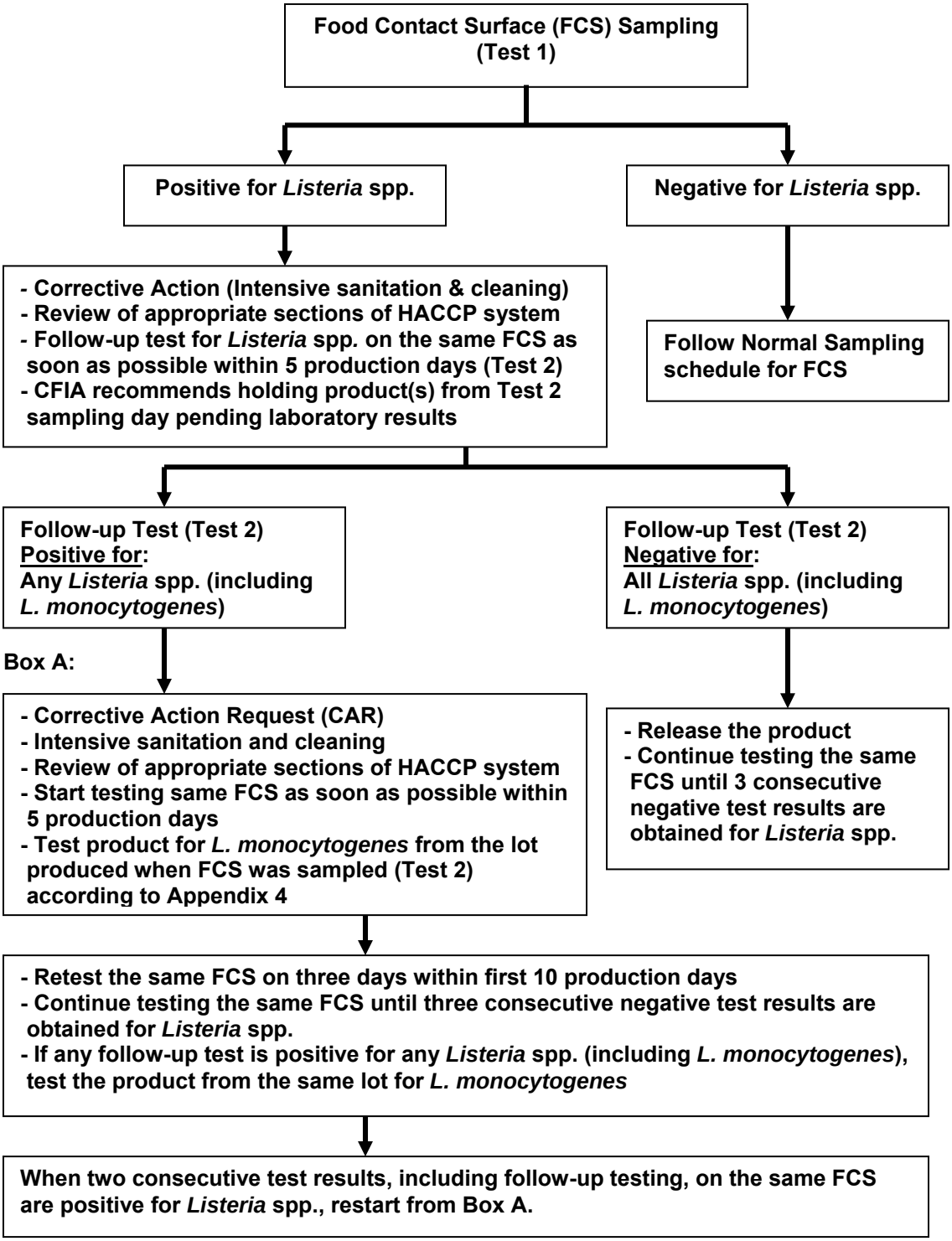
Performing trend analysis on test results is an essential component of any sampling program designed to monitor a microbiological risk. Operators are therefore required to include this procedure in their HACCP system. They must also indicate the parameters that they will use to assess whether or not the risk is controlled. When the risk is not controlled, corrective actions must be implemented.

All unsatisfactory test results (e.g., NFCS, FCS or product) must be included in the trend analysis. Particular attention must be paid to the follow-up actions taken when the number of unsatisfactory results obtained is either high or on the increase, as well as, when the *Listeria* detection is moving from a NFCS to a FCS. The operator must react to these situations in a rapid and efficient way. In addition, if the establishment often finds itself in such a situation, it would indicate that the provisions of the HACCP system are not stringent enough to control the risk posed by *Listeria*. All pertinent aspects of the HACCP system must then be re-evaluated and the required adjustments implemented.

Appendix 1. CFIA's Procedure (M205 and M205RB) when Food Contact Surfaces are tested for *L. monocytogenes* on production lines used for Category 1 and 2 products.

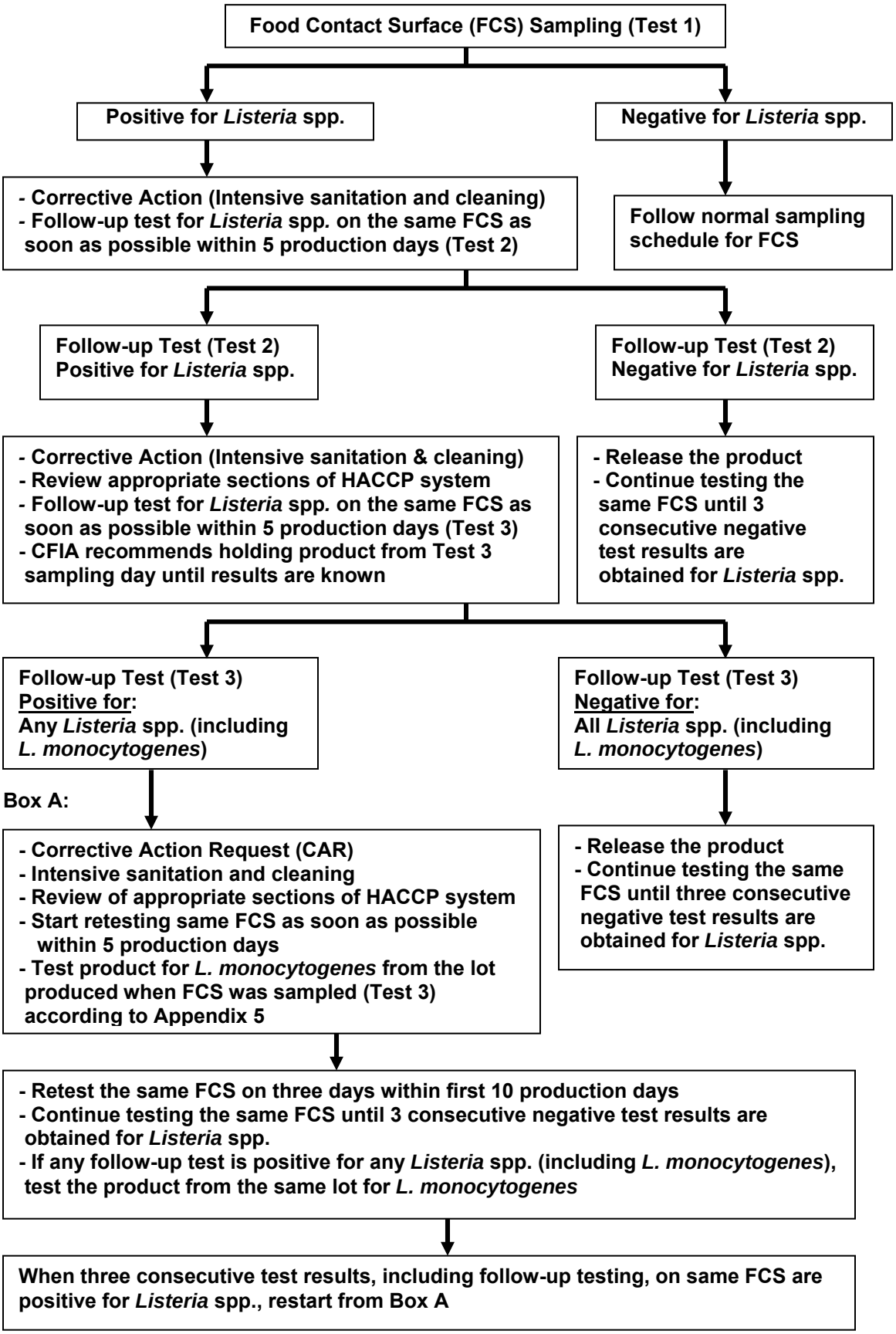


Appendix 2. Operator's procedure when Food Contact Surfaces are tested for *Listeria* spp. on production line(s) used for Category 1 products (dedicated or non-dedicated lines).



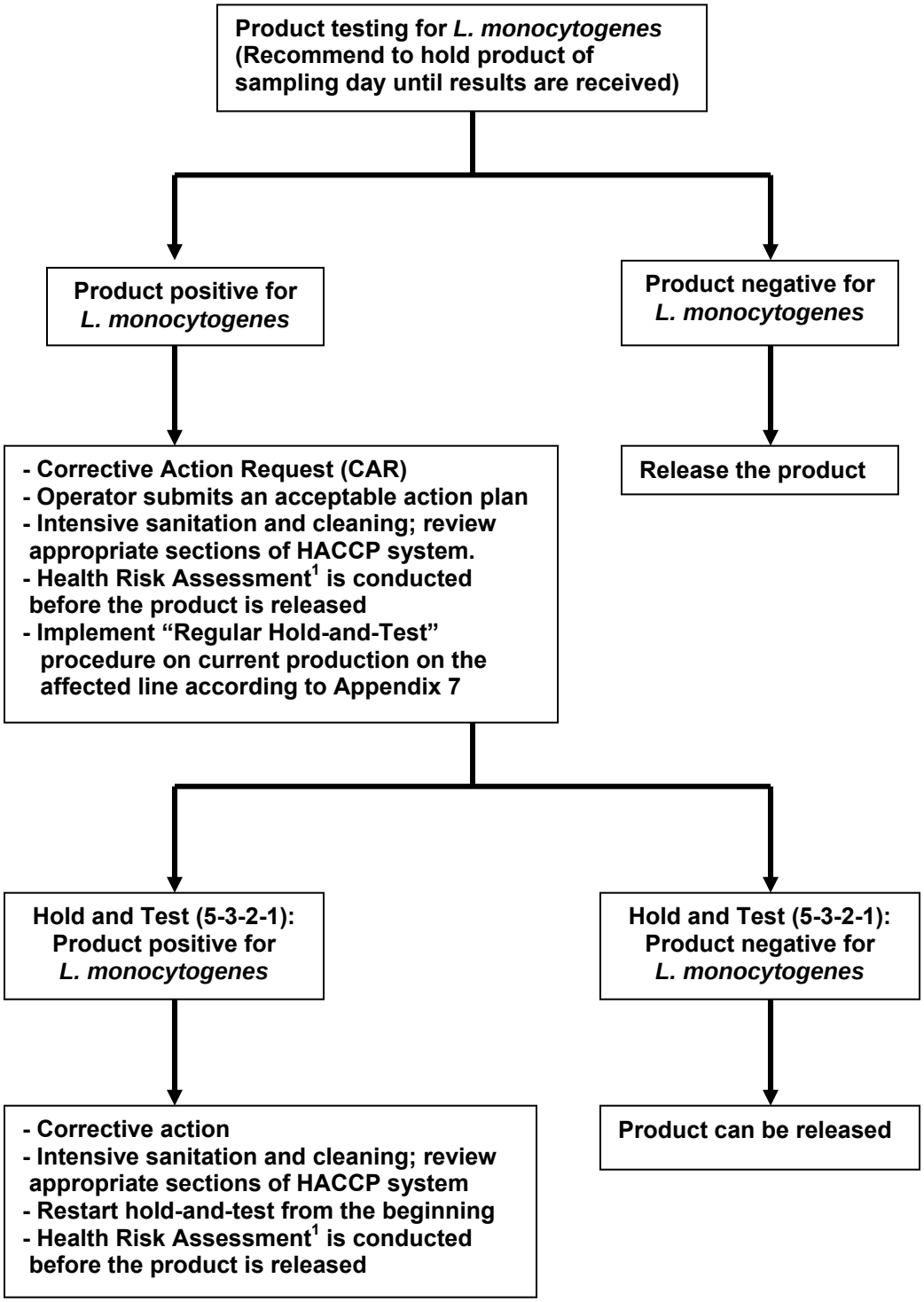
Note: When any FCS tests positive for *L. monocytogenes*, the product from the same lot must be tested for *L. monocytogenes.*

Appendix 3. Operator's procedure when Food Contact Surfaces are tested for *Listeria* spp. on production line(s) dedicated to Category 2A or 2B products.



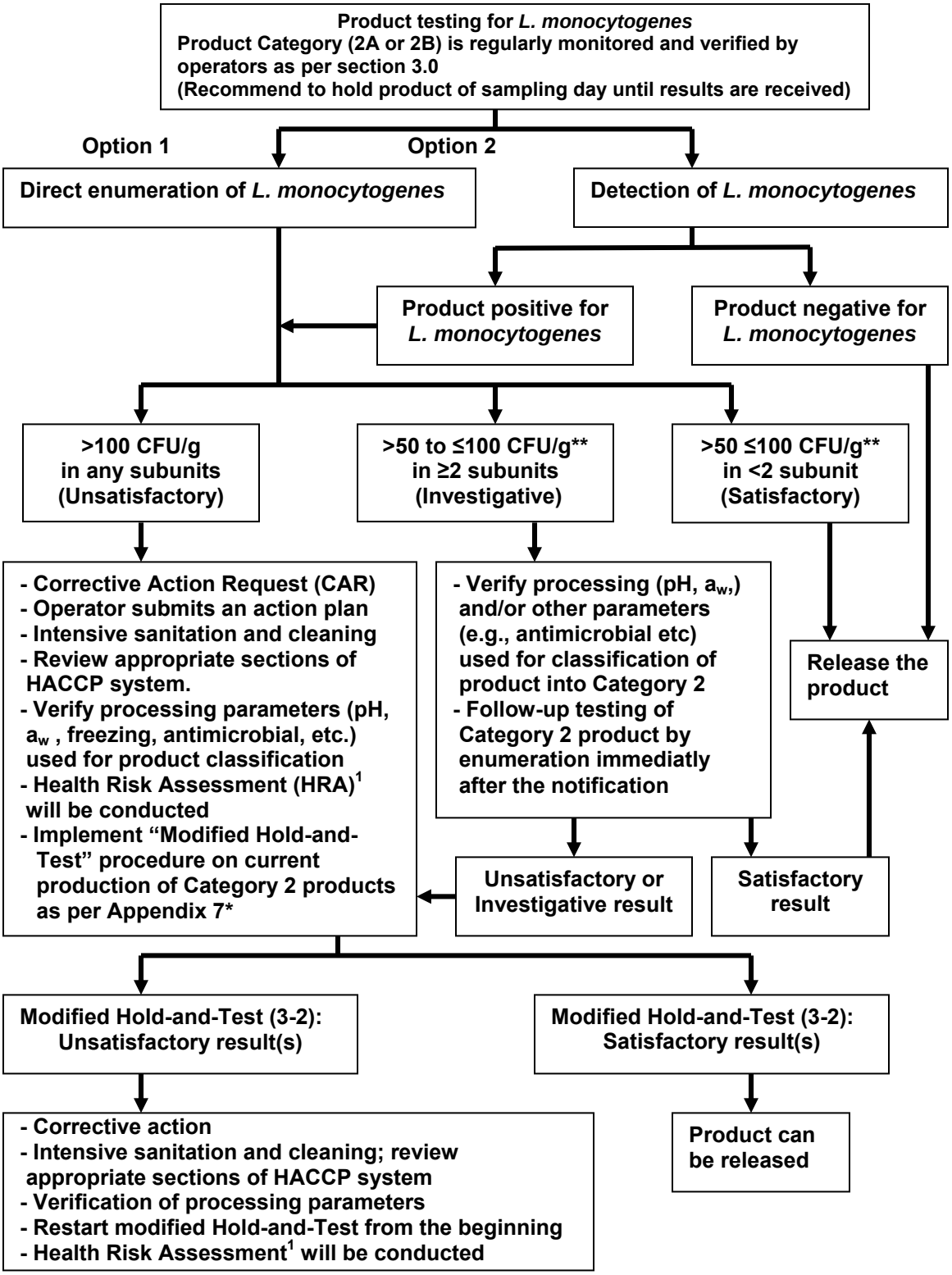
Note: When FCS tests unsatisfactory, the product must also be tested for *L. monocytogenes.*

Appendix 4. Operator's or CFIA's procedure when Category 1 product(s) is tested for *L. monocytogenes*



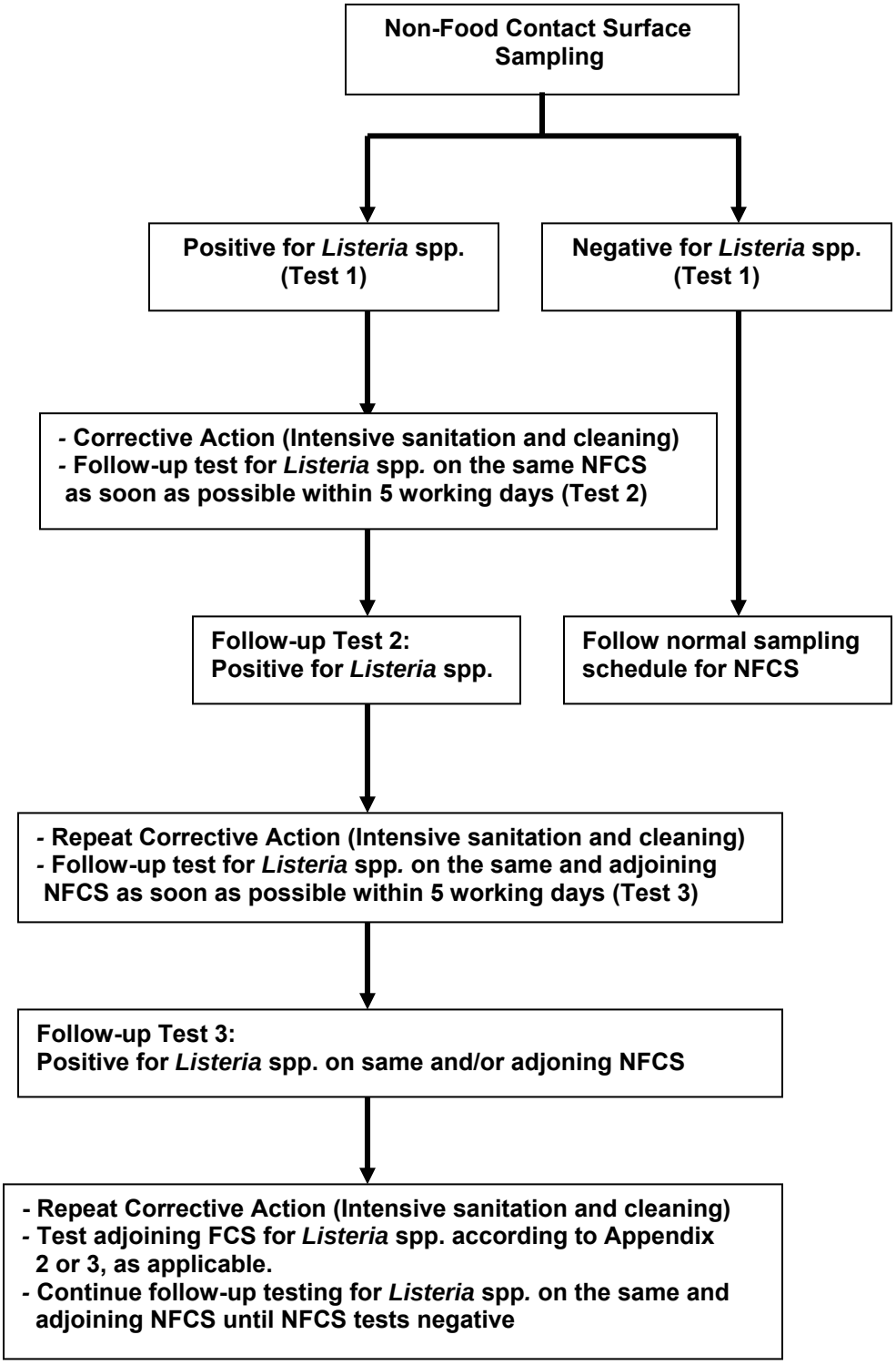
[1] Contact the Area Program Specialist for Health Risk Assessment

Appendix 5. Operator's or CFIA's procedure when Category 2 product(s) are tested for *Listeria monocytogenes*.



[1] Contact the Area Program Specialist for HRA before the product is released.
* Modified Hold-and-Test (3-2) is also required for Category 1 products when the production line is non-dedicated and Category 1 product are still being produced on the line. If Category 1 products test positive, regular hold-and-test (5-3-2-1) will follow on Category 1 products as per Appendix 7.
** Product must meet importing country's requirements for export, and HRA is required if the intended use is for high-risk population groups.

Appendix 6. Recommended procedure for testing Non-FCS (NFCS) for *Listeria* spp.



Appendix 7: Follow-up end product testing under "Hold-and-Test" procedure

(A) Regular Hold-and-Test procedure:

Operators must implement regular hold-and-test (5-3-2-1) end product testing whenever a Category 1 RTE meat and poultry product tests unsatisfactory for *L. monocytogenes* for any reason (e.g. CFIA sampling, Operator's testing, process control, client initiated testing, etc.). This is to ensure that the new product lots produced on the affected line are safe prior to their distribution. The same product that was assessed unsatisfactory under original sampling plan should be sampled under hold-and-test. If not available, a similar product or another high-risk product can be selected from the affected line in consultation with the IIC. Five sample units, each weighing a minimum of 100 g, should be sampled by the operator and submitted to an accredited laboratory for *L. monocytogenes* analysis.

The sampling frequency during a hold-and-test procedure must be:

- one sample every day in the first weeks (total 5 samples);
- one sample on alternate days in the second week (total 3 samples);
- one sample after two days interval in the third week (total 2 samples); and
- one sample in the fourth week.

A "week" refers to 5 consecutive production days on the affected line. If a sample tests unsatisfactory during the follow-up testing, the "hold-and-test" procedure starts from the beginning.

(B) Modified Hold-and-Test procedure:

Operators must implement modified hold-and-test (3-2) end product testing when:

1. Category 2 product produced on a dedicated production line tests unsatisfactory for *L. monocytogenes*.

2. Category 2 product produced on a non-dedicated production line tests unsatisfactory for *L. monocytogenes*. The modified hold-and-test is implemented for both Category 2 and 1 products, if the Category 1 products are still being produced on the affected line. Category 1 and 2 products must be tested separately under modified hold-and-test.

The modified hold-and-test procedure is implemented when a Category 2 product tests unsatisfactory for any reason (e.g. CFIA sampling, Operator's testing, process control, client initiated testing, etc.). This is to ensure that the new product lots produced on the affected line are safe prior to their distribution. The same product that was assessed unsatisfactory under the original sampling plan should be sampled under hold-and-test. If not available, a similar product or another high-risk product can be selected from the affected line in consultation with the IIC. Five sample units, each weighing a minimum of 100 g, should be sampled by the operator and submitted to an accredited laboratory for *L. monocytogenes* analysis.

The sampling frequency under a modified hold-and test must be:

- one sample every day during the first three production days (total 3 samples);
- one sample on alternate days after the fourth production day (total 2 samples);

If a sample tests unsatisfactory during the follow-up testing, the modified "hold-and-test" procedure starts from the beginning for Category 2 products. However, when Category 1 product tests unsatisfactory during modified hold-and-test, the regular hold-and-test procedure follows on Category 1 products produced on non-dedicated lines.

Glossary

Antimicrobial agent
A substance in or added to a RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents that can be added to RTE products: Sodium diacetate, sodium lactate and potassium lactate either alone or in combination.

Antimicrobial process
An operation, such as freezing, applied to a RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product
A ready-to-eat meat or poultry product that is typically sliced, either in an official establishment or after distribution from an official establishment, and is typically assembled in a sandwich for consumption.

Food Contact Surface (FCS)
Any surface or object that comes into contact with the RTE meat or poultry product.

Hotdog product
A ready-to-eat meat or poultry frank, frankfurter, or wiener.

Lethality treatment
A process, including the application of an antimicrobial agent, which eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Lot
For the sampling purpose, a lot is defined as all products produced under the same conditions using the same equipment, which are produced between two satisfactory complete sanitation operations. A sanitation operation is considered satisfactory if it cuts off the transfer of microbial contamination from one lot to another. The lot size should be the same as the one used by the operator in normal circumstances for commercial purposes. The operator cannot reduce the size of the lot in anticipation of testing requirements.

Post-lethality exposed product
A ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment. (This excludes cook-in-bag products.)

Post-lethality processing environment
The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment
A lethality treatment that is applied or is effective after post-lethality exposure e.g. HPP. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

ANNEX I

Risk-based Verification Sampling of Ready-to-Eat (RTE) Meat and Poultry Products

1. Introduction and scope

The following sampling plan must be implemented by operators who produce ready-to-eat (RTE) meat and poultry products that are exposed to the environment after processing.

The implementation date for this sampling plan was April 1, 2009.

2. Classification of establishments

Establishments producing RTE meat and poultry products are classified according to the risk category of products produced (1, 2A or 2B) and the Relative Risk Level (RRL) under which these products are produced (Annex H, section 3.3). The RRL of *L. monocytogenes* is determined according to the following factors, as applicable:

a. Risk Category of the RTE meat and poultry product
b. Antimicrobial agents/processes, and
c. Post-lethality procedures

3. Frequency of testing

The testing frequency increases as the level of associated food safety risk increases. The testing frequency of an establishment is based on the risk category of RTE products (1, 2A or 2B) and the RRL under which these products are produced (Very low to High). For an establishment producing more than one category of RTE products under different RRLs, the establishment's sampling frequency will default to the RRL under which the highest risk category product(s) is produced. The following product sampling frequencies should be followed:

Risk Category of RTE product(s)	**Product sampling frequency based on RRL**		
	Antimicrobial agent*	**Post-lethality treatment**	
		None	**Yes**
Category 1	**None**	12 samples per year	9 samples per year
	Yes	9 samples per year	6 samples per year
Category 2A	**None**	6 samples per year	4 samples per year
	Yes	4 samples per year	3 samples per year
Category 2B	**NA**	3 samples per year	1 sample per year

*Antimicrobial agent allows no more than 2 log CFU/g increase in *L. monocytogenes* throughout the stated shelf-life of the product; NA: Not applicable

4. Sample collection

The operator is responsible for the sample collection process that includes the following steps:

4.1. Training of the designated employee(s) who will work with the sampling plan in order to meet the sampling plan's objectives and specifications.

4.2. Collecting samples in the post-processing RTE area of the establishment according to Appendix B. This must be done under direct CFIA supervision.

4.3. Operators shall prepare and have a written sampling program for risk-based testing of RTE products that covers sample collection, preparation and shipping procedures. It shall also cover means to ensure tamper-evidence, to protect the integrity of samples and to maintain the chain of custody (e.g., how samples are handled, packaged and shipped).

Samples must be appropriately sealed under CFIA supervision (tamper evident).

The shipping procedures shall specify:

- who packages the samples and where the packaging is done;
- where samples are kept pending shipment;
- who ships the samples; and
- where samples are shipped (laboratory) and how samples are shipped (shipping agent).

The general guideline for the sample collection, shipping and integrity protection is provided in Appendix B.

4.4 The VIC/IIC (Veterinarian/Inspector-in-Charge) will review and approve the establishment's written program. The VIC/IIC will verify the sampling activities and will complete the appropriate inspection tasks as per the Compliance Verification System (CVS).

It is recommended to hold the sampled "lot" pending laboratory result.

5. Target Pathogens

The samples will be analysed for *L. monocytogenes* and *Salmonella* spp. If the product is an uncooked dry or semi-dry fermented sausage and contains beef, it will also be analysed for *E. coli* O157:H7.

6. Methods of analysis

For each sample, five 25 g test portions/samples for a total of 125 g sample size for Category 1 product, and five 10 g test portions/samples for a total of 50 g sample size for Category 2 product, as defined by Health Canada's "Policy on *L. monocytogenes* in Ready-to-Eat Foods" (2010), will be analysed for *L. monocytogenes*; and five 65 g test portions/samples for a total of 325 g sample size will be analysed for *Salmonella* spp. The analysis for *E. coli* O157:H7, when required, will be conducted on five 65 g test portions/samples for a total of 325 g sample size.

The following analytical methods are to be used:

- *Listeria monocytogenes*

  The Compendium methods MFHPB-30 and MFLP-28. Alternate methods*: the FSIS MLG 8.07 and 8A.04.

- *Salmonella spp.*

  The Compendium methods MFHPB-20 and MFLP-29. Alternate methods*: the FSIS MLG 4.05 and 4C.03.

- *E. coli* O157:H7 and O157:NM (Nonmotile)
  The Compendium methods MFLP-80 and MFLP-30. Alternate methods*: the FSIS MLG 5.05 and 5A.02.

*Note: Alternate methods will be considered exclusively for products to be exported to the United States

The samples must be analysed in a laboratory accredited by the Standards Council of Canada (SCC) and the required methods must be included in the laboratory scope of accreditation. The operator must therefore ensure that the methods used, which are not yet in the scope of accreditation, are included in the scope for the next SCC audit.

Approved methods can be found in the Health Canada Compendium of Analytical Methods at the following site, but the "application" section must be appropriate for the intended purpose.

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

7. Laboratory reports

- The laboratory report must clearly indicate the common name of the product tested as well as the date on which the sample was collected by the operator.

- The laboratory report must be sent simultaneously to both the operator and the CFIA's National Micro Sampling Plans Unit in Ottawa at the following address:

  National Micro Sampling Plans
  Floor 4, Room 250
  1400 Merivale Road, Tower 2
  Ottawa, (ON), K1A 0Y9
  or fax: (613) 773-5957
  or email: RTE-PAM@inspection.gc.ca

- The operator must also advise the IIC upon reception of the laboratory analysis.

Please note that if, for whatever reason, the laboratory is unable to analyse and make an evaluation of the sample submitted for analysis, a replacement sample must be sent as soon as possible.

8. Follow-up on positive results

When pathogens are detected in a sample, the sampled lot is considered contaminated (adulterated) and following measures must be taken:

8.1. The contaminated lot must remain under the operator's control.

8.2. The IIC will issue a Corrective Action Request (CAR) that requires the operator to submit an action plan to the IIC within five working days of the notification of an unsatisfactory test result. The action plan must meet all requirements of an acceptable action plan as stated in Chapter 18 of the Meat Hygiene Manual of Procedures. The action plan must clearly state which subsequent production lots will be tested for the pathogen to verify the effectiveness of the corrective actions and preventative measures.

Please refer to the Meat Hygiene Manual of Procedures (MOP Chapter 18) for additional information on specific follow-ups.

8.3. The CFIA notification procedures must be clearly outlined in the written sampling program (e.g., who in the company will notify the VIC/IIC when the analysis is completed and the result is unsatisfactory, e.g., *Listeria monocytogenes* was detected in a sample).

8.4. In the unlikely event that the sampled lot was distributed before the positive result was received or if it is determined that there are other products in distribution that are implicated by the positive result, the CFIA will immediately notify the OFSR (Office of Food Safety and Recall). If any of the

involved product was exported, the regulatory authority of concerned countries would also be immediately notified (e.g.: FSIS {Food Safety and Inspection Service} would be informed and provided with the distribution details if the products had been exported to the United States).

8.5. For RTE meat and poultry products, zero tolerance applies for tested pathogens, including *Listeria monocytogenes*, in products that support its growth (Category 1). Importing countries may have different requirements; refer to MOP Chapter 11 for country specific requirements.

9. Record keeping

All laboratory reports should be kept for at least one year after the end of the sampled product's shelf life.

Other records should be kept as per the operator's HACCP plan.

Appendix A

The following list must be used when two or more products are produced on the day of testing.

The highest risk post-lethality exposed RTE product produced at the time of collection must be sampled. The products are listed in decreasing order of risk (sliced deli meats being the highest risk):

1. Deli meats that are sliced in the federal registered establishment
2. Deli meats shipped whole from the federal establishment. (This does not include cook-in-bag products; only those exposed post-lethality.)
3. Hotdog products
4. Deli salads, pâtés, and meat spreads
5. Fully cooked type products (other than cooked products in 1-4 above)
6. Fermented products
7. Dried products
8. Salt-cured products
9. Products labelled as “Keep Frozen”

Note: All these products will be considered as Category 1 products if they don’t meet the physico-chemical and other relevant processing parameters of Categories 2A or 2B products as per section 3.0 of Annex H. Any deviation in the key processing parameter must be corrected and verified to confirm compliance and classification of product(s) into Category 2A or 2B.

Appendix B

The following general guidelines should be followed for sample collection and shipping procedure, and for the maintenance of the integrity of samples:

1. Sample collection must be carried out on the RTE finished products that were post-lethality exposed.

2. Sample collection will be carried out by the individual who is designated in the establishment's written protocol and has received the required training. Sampling supplies, such as sterile gloves, sterile sampling solutions, hand soap, sanitizing solution, etc., as well as specific materials needed for sampling, will need to be assembled prior to beginning sample collection.

3. A sample consisting of five sample units shall be drawn at random from each lot selected for sampling. Each sample unit shall consist of 250 g or five intact units weighing at least a total of 1250 g. Do not sample the same lot for M200 or M200RB (managed by the CFIA) and Risk-based (managed by industry) programs.

4. Unopened, original containers shall be sampled, when possible.

5. If the product is in bulk, several sample units can be collected from one container, while ensuring that the total number of sample units is not collected from one container. More than one sample unit may also be collected from large institutional or bulk containers when the total number of sample units required exceeds the number of containers in the lot. The collected sample units shall be placed in sterile containers. A sample unit will consist of more than one container when the lot consists of containers smaller than 150 g (e.g., six - 25 g containers in each sample unit).

6. Aseptic techniques shall be employed in collecting the sample units.

7. The sample must be properly identified. This includes the name of the product, the production date or code, and the lot of production it represents (in the event that the laboratory result should be unsatisfactory). The production lot must be identified and approved according to CFIA policy (Please refer to the glossary for lot definition).

8. Depending on the nature of the product, the sample units must either be kept refrigerated (0-4°C) or frozen at all times. The temperature of refrigerated samples must not exceed 7°C upon its arrival at the laboratory.

9. The operators must have a written procedure explaining how they ensure that samples are protected from temperature abuse during sampling, storage and transportation to the laboratory, as well as from potential tampering.

10. Samples must be sent to a laboratory accredited to perform the analysis by the methods considered acceptable.