

Meat Industry Best Practices For Control of *Listeria monocytogenes*

Developed by the
Canadian Meat Industry
Listeria monocytogenes Working Group

Edited by Dr. Merv Baker

October 2012

Version 1.0



Foreword

The purpose of this document is to provide Canadian ready-to-eat meat establishments with guidance designed to enhance their ability to control *Listeria monocytogenes* (*Lm*) and prevent contamination of finished products. *Lm* is the most challenging foodborne pathogen to control in the RTE processing environment – and yet it must be controlled because *Lm* is also the deadliest RTE foodborne pathogen when susceptible consumers are exposed.

Best Practices are defined as the collective processes, procedures and steps that, when implemented systematically and consistently will achieve the intended objective, which in this case is the effective control of *Lm*. In this document, the best practices are built around the following three pillars:

1. **Good Manufacturing Practices (GMPs)** – Diligent and consistent adherence to GMPs prevents *Listeria* species from entering and becoming established in the RTE processing areas. The GMPs may include the use of specific product-oriented antimicrobial interventions.
2. **Sanitation** - Meticulous implementation of a comprehensive and systematic sanitation program that includes regular teardown and sanitizing of the processing equipment destroys contaminants and prevents the establishment of harbourage sites (areas where *Listeria* species could persist and flourish).
3. **Environmental Sampling and Testing** - The use of a robust environmental sampling and testing program verifies the effectiveness of the GMPs and sanitation program and provides for a rapid and vigorous reaction when contamination is detected, to identify and eliminate the source(s) and to correct the root cause(s).

Owners and operators of all RTE meat establishments are expected to support and ensure adoption and implementation of the best practices. In federally registered establishments the principal mechanism for implementation is expected to be by integrating them into each establishment's HACCP system. The implementation process could be used as an opportunity to create or reinforce a food safety culture in the establishment.

While this document has been developed by representatives of the federally registered sector of the Canadian meat industry, it is anticipated that operators of non-registered establishments will find it equally useful.

Implementation of all the best practices described in the document is not meant to be obligatory. There are too many variables in the meat industry to presume that all practices will be applicable in all circumstances. However, it is expected that the choice of alternative measures or procedures will be documented and justified by a credible scientific rationale explaining why the alternative was chosen and why it should be expected to achieve the same (or better) outcome as the best practice it is replacing.

The Best Practices in this document are designed to be complementary to the Listeria control policies administered by Health Canada (Health Canada, 2011) and the Canadian Food Inspection Agency (CFIA, 2011; CFIA, 2011a). Therefore, applying the best practices will assist establishments in complying with Canadian regulatory requirements. The document is expected to serve a useful purpose for regulators as well. Inspection staff in the CFIA and counterparts in provincial ministries or departments will be able to use it as an additional reference in assessing the control measures implemented by individual establishments. However, in doing so, it will be essential that inspectors respect the nonbinding nature of best practices and the acceptability of justified alternative measures or procedures.

This Best Practices document was conceived and developed as an expression of the Canadian meat industry's collective commitment to achieving the highest practicable standard of Listeria control and food safety in the manufacturing of ready-to-eat (RTE) meat products. Following the occurrence of a serious listeriosis outbreak caused by contaminated RTE products from a single processing establishment in 2008, the Canadian Meat Council, along with the Canadian Poultry and Egg Processors Council and the Further Poultry Processors Association of Canada, formed an Industry Technical Working Group to provide advice to regulators to support the development of effective Lm control policies and to identify measures or "best practices" that could be implemented to prevent further occurrences of foodborne listeriosis.

A subset of dedicated Working Group members volunteered to participate in a drafting group to compile and document best practices for control of Listeria in a form that would serve as a reference guide for operators of RTE meat processing establishments. This document is the result of their efforts. The Canadian meat industry acknowledges the hard work of the drafting group members, especially Nyla Dubiel, Peter Stein, Claudette Pshebniski, Ron Judge, Blaise Ouattara and Merv Baker, as well as the latter's role in the onerous task of editing the many draft iterations of the document.

The contents have been drawn from a wide range of sources, including scientific literature, advice from academic and industry experts, training materials compiled by the American Meat Institute, industry protocols, and the experience and expertise of the members of the Working Group. In addition, the document has benefited from the advice of academic experts, as well as CFIA and Health Canada officials who reviewed and commented on it prior to publication. This document has had a long and arduous gestation period, due in large part to the evolving regulatory requirements and the constant growth in knowledge about Lm and how it can best be controlled. No doubt these factors will continue to evolve and grow. Therefore, the document has been deemed "evergreen", and the participating industry associations are planning to establish a process to perform regular updates.

Editor's Biography

Dr. Merv Baker is a graduate of the Ontario Veterinary College, University of Guelph. His career experience includes the management of laboratory services supporting the national animal health, plant health and food safety programs of Agriculture and Agri-Food Canada. Dr. Baker developed a career with the Canadian Food Inspection Agency following its inception in 1997, where he served in a variety of executive positions, with responsibilities ranging from food inspection policy development and program design to Bovine Spongiform Encephalopathy (BSE) control and negotiation of conditions for resumption of trade in Canadian beef products following the occurrence of BSE in 2003.

Since retiring from the Canadian Food Inspection Agency in 2007, Dr. Baker has worked as a private consultant in the fields of food safety, traceability of animals and food products, and international trade in food products. Dr. Baker is currently chairing the Industry *Listeria monocytogenes* Working Group that was formed by the Canadian Meat Council in partnership with other national industry associations to develop Best Practices for the meat processing industry that will raise the standard for *Listeria monocytogenes* control in Canada.



Table of Contents

Foreword	2
Editor’s Biography	4
Table of Contents	5
Glossary.....	9
Section 1: Introduction and Regulatory Context.....	11
1.1. Introduction	11
1.1.1. Scope	11
1.1.2. What is <i>Listeria monocytogenes</i>	11
1.1.3. Factors affecting the survival and growth of <i>Listeria</i> <i>monocytogenes</i>	13
1.1.4. Foods at risk of <i>Listeria monocytogenes</i> contamination	13
1.1.5. Hazard analysis critical control point (HACCP) systems.....	14
1.2. Overview of the current regulatory policies and sampling requirements	15
1.2.1. Division of regulatory authorities.....	15
1.2.2. Health Canada policy on <i>Listeria monocytogenes</i> in ready-to-eat foods	15
1.2.3. CFIA policy on the control of <i>Listeria monocytogenes</i> in ready-to-eat meat and poultry products.....	17
1.2.3.1. Descriptions of ready-to-eat products, risk categories and relative risk levels.....	17
1.2.3.2. CFIA testing programs	18
1.2.3.2.1. CFIA testing programs implemented by CFIA.....	18
1.2.3.2.2. CFIA testing programs implemented by operators.....	20
1.2.3.3. Follow-up on unsatisfactory test results	20
1.2.3.4. CFIA actions during extended noncompliance	22
1.2.3.5. Operator sampling of non- food contact surface	22
1.2.3.6. Operator trend analysis	23
Section 2: Good Manufacturing Practices	24
2.1. Introduction	24
2.2. Physical plant design.....	25
2.3. Personnel training.....	26
2.4. Hygienic practices.....	27

2.4.1. Cleanliness	28
2.4.1.1. Hand washing and/or sanitizing and drying.....	28
2.4.1.2. Protective clothing: smock or uniform.....	28
2.4.1.3. Protective clothing: footwear	29
2.4.1.4. Protective clothing: gloves.....	29
2.4.2. Employee health.....	30
2.4.3. Traffic flow	30
2.4.3.1. Personnel flow.....	30
2.4.3.2. Product flow	31
2.4.3.3. Tools and equipment flow	31
2.4.4. Maintenance activities	32
2.4.5. Equipment specifications and design	32
2.4.6. Sanitation activities.....	33
2.5. Incoming material receiving and storage.....	34
2.6. Processing control measures	36
2.6.1. Intrinsic factors	36
2.6.1.1. Moisture content.....	36
2.6.1.2. pH and acidity	36
2.6.1.3. Antimicrobial agents.....	37
2.6.2. Extrinsic factors	38
2.6.2.1. Time and temperature conditions.....	38
2.6.2.2. Processing steps.....	38
2.6.2.2.1. Lethality processes.....	38
2.6.2.2.2. Post-lethality processes	39
2.6.3. The “hurdle” approach	39
2.6.4. Validation and challenge studies	41
Section 3: Sanitation Practices.....	43
3.1. Introduction	43
3.2. General cleaning and sanitation procedures.....	44
3.2.1. Area preparation.....	44
3.2.2. Scrapping	45
3.2.3. Pre-rinse.....	45
3.2.3.1. Some rinsing best practices	45
3.2.4. Inspection after the pre-rinse by the sanitation crew	46
3.2.5. Detergent application / Manual cleaning / Scrubbing.....	46
3.2.6. Final rinsing	47
3.2.7. Final sanitation inspection by supervisor or quality assurance personnel	47
3.2.8. Flood sanitizing.....	48

3.2.9. Drying	49
3.3. Special sanitation procedures and cleaning methods.....	49
3.3.1. Operational sanitation.....	49
3.3.2. Double sanitizing or shock sanitizing	50
3.3.3. Clean-in-place.....	50
3.3.4. Clean-out-of-place	51
3.3.5. Steam cleaning.....	51
3.3.6. Heat treatment.....	52
3.4. Cleaning frequencies	52
3.5. Verification of sanitation effectiveness.....	53
3.6. Bacteria harbourage and biofilm formation	53
3.6.1. Harbourage.....	53
3.6.2. Biofilm.....	54
Section 4: Environment and Product Testing.....	56
4.1. Introduction	56
4.2. Lot definition.....	56
4.3. Environmental sampling plan for food contact surface and non- food contact surface.....	57
4.3.1. Environmental sampling procedure	58
4.3.1.1. Tools required	58
4.3.1.2. Sponge/Swab types	58
4.3.1.3. Sponge/Swab area.....	59
4.3.1.4. Sponging/Swabbing procedure	59
4.3.2. Frequency and numbers of environmental samplings	60
4.3.2.1. Scheduling of sampling	60
4.3.2.2. Frequency of sampling.....	60
4.3.2.3. Distribution of sampling across zones.....	60
4.3.2.4. Factors to consider with respect to sampling frequency.....	61
4.3.2.5. Sample size.....	62
4.3.2.6. Individual versus composite samples.....	62
4.4. Food product sampling plan	62
4.5. Sampling and sample handling.....	63
4.5.1. Operator training.....	63
4.5.2. Representative product sample	63
4.5.3. Aseptic product sampling.....	64
4.5.4. Product and environmental sample documentation.....	64
4.5.5. Shipping samples	64

4.5.5.1. Refrigerated foods, environmental samples and dry-cured meats	64
4.5.5.2. Frozen foods	65
4.5.5.3. Sponges/swabs	65
4.5.5.4. Transportation	65
4.6. Mandated operator sampling of ready-to-eat products	65
4.7. Mandated operator sampling of food contact surfaces	66
4.8. Holding product until test results have been received	66
4.9. Follow-up on food contact surface positive results.....	66
4.9.1. Communication of results	66
4.9.2. Quarantine of implicated production	67
4.9.3. Collection of finished product samples for testing (n ≥ 5)	67
4.9.4. Environmental swabs for investigational purposes	67
4.9.5. Risk assessment and action plan	67
4.9.6. Investigational environmental sample results	67
4.9.6.1. Negative	67
4.9.6.2. Positive.....	67
4.9.7. Follow-up	68
4.10. Data/Trend analysis guidelines.....	68
Appendix 1 - Potential sources of <i>listeria monocytogenes</i> in a food processing facility.....	70
Appendix 2 - Effective ways to find and remove bacterial harbourage Sites.....	71
Appendix 3 - Examples of food contact surface and non- food contact surface for environmental sampling.....	74
Appendix 4 - Guidelines for environmental sampling plans	75
Appendix 5 - Example scenario for positive <i>Listeria</i> species result from food contact surface.....	76
Appendix 6 - Example of an approach to investigate positive test results to determine and eliminate the source(s) of contamination.....	79
Appendix 7 - Data analysis tools	81
References	85

Glossary

Best practices - the collective processes, procedures, and steps that, when implemented systematically and consistently will achieve the intended objective, such as the effective control of *Listeria* in ready-to-eat meat establishments.

Biofilm - a community of bacterial cells that a) adhere to each other and to surfaces, and b) are surrounded, held together and protected by glue-like materials (polysaccharides) that they produce.

Harbourage site - a specific area on or near food contact surfaces where *Lm* can survive, multiply and potentially contaminate food because the site provides conditions necessary for microbial growth (nutrients in the form of food residues, humidity, and suitable temperature). These are often located in difficult to clean areas, allowing them to develop in spite of the routine sanitation practices being carried out.

Food contact surface - any surface or object that comes into direct contact with the ready-to-eat meat product, including both routine food contact surface (i.e. belts, conveyors, slicing blades, etc.) and incidental food contact surface (i.e. employee gloves, aprons, etc.).

***Listeria monocytogenes* (Lm)** - a species of bacteria that is known to cause a potentially serious disease, listeriosis, in humans and animals.

***Listeria* species (Lspp)** – a group of bacterial species that includes one human disease-causing species (*Listeria monocytogenes*) and seven other species that do not cause disease in humans and most animals.

Listericidal – describes a process or substance that is capable of killing *Lspp*.

Niche – see harbourage site, above.

Ready-to-eat (RTE) 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” (Government of Canada, 2012).

Ready-to-eat (RTE) product lot - all RTE products packaged between two complete sanitation procedures.

Reservoir – a harbourage site or niche that serves as a continuing source of *Lm* and results in continuous or sporadic contamination of materials in proximity to or passing by the location of the reservoir.

Shelf life (durable life) - the period determined by the manufacturer during which a packaged food product will retain its normal wholesomeness, palatability, nutritional value and compliance with regulatory limits for *Lm* contamination when stored under appropriate conditions.

Transfer point – a location in a processing operation where there is a higher probability of contamination being transferred to another location because of crossing or continuing movement of people or materials.

Ubiquitous – widespread to the extent of seeming to be everywhere.

Section 1: Introduction and Regulatory Context

1.1. Introduction

1.1.1. Scope

This document is intended for use by all businesses that manufacture ready-to-eat (RTE) meat¹ products for sale, or that purchase RTE meat products for further processing such as slicing or packaging.

A RTE meat product is defined as:

“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” (Government of Canada, 2012)

In general, if a meat product has received a heat treatment to achieve lethality of *Salmonella* spp according to time and temperature parameters listed in the Meat Hygiene Manual of Procedures (CFIA, 2010) or has received a processing intervention step (e.g.: fermentation, dry curing, etc.) then the product is classified as RTE. If further preparation is required (e.g.: cooking) before consumption, then the product is considered as non-RTE. 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 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 (CFIA, 2011).

1.1.2. What is *Listeria monocytogenes*?

Listeria species (*Lspp*) are considered to be ubiquitously distributed in the natural environment. *Lspp* and *Listeria monocytogenes* (*Lm*) specifically have been isolated from many different environments, including soil, water, vegetation, sewage, animal feeds, farm environments and food processing environments, and from the feces of healthy animals and humans (Sauders and Wiedmann, 2007; Health Canada, 2011).

The genus *Listeria* has eight recognized species (den Bakker, 2010): *L. monocytogenes*, *L. innocua*, *L. seeligeri*, *L. ivanovii*, *L. marthi*, *L. welshimeri*, *L. rocourtiae* and *L. grayi*.

¹ All references to “meat” in this document are intended to encompass meat from all species, including poultry meat.

Only *Lm* is widely recognized as pathogenic (able to cause disease) in humans and animals, while the other species are generally regarded as nonpathogenic. Most strains of *Lm* are pathogenic, with some strains having greater potential to cause disease than other strains. As well, several studies have shown that there is considerable variation in virulence (severity of disease caused) within the species (Tompkin, 2002). The vast majority of human cases of listeriosis throughout the world are caused by three serotypes of *Lm* (4b, 1/2a and 1/2b) (Farber and Peterkin, 2000).

Lm is a foodborne pathogen that can cause listeriosis, a usually mild but potentially severe disease with symptoms that may include nausea, cramps, diarrhea, severe headache, constipation or persistent fever and more serious manifestations such as septicemia, meningoencephalitis², spontaneous abortion, stillbirth and even death (CFIA, 2008; ILSI, 2005). Although listeriosis is a relatively rare disease in Canada, it has a high mortality rate amongst susceptible populations, which include pregnant women and their unborn, newborn children, the elderly, and individuals with weakened immune systems (CFIA, 2008). The likelihood of *Lm* establishing a serious systemic infection depends on a number of factors, including the number of microorganisms ingested, host susceptibility, and virulence of the specific strain ingested. Listeriosis most often affects individuals with chronic disease (e.g.: cancer, diabetes, malnutrition, AIDS), fetuses, neonates (the newborn, assumed to be infected before birth), the elderly, and individuals being treated with immunosuppressive drugs (e.g.: organ transplant patients). The incubation period of listeriosis can range from a few days up to three months (Codex Alimentarius, 2009).

Lm has been isolated from a wide variety of foods, including raw vegetables, raw and pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, butter, fermented raw-meat sausages, raw and cooked poultry, raw and processed meats (all types) and raw, preserved and smoked fish (Codex Alimentarius, 2009) .

Unlike most other foodborne pathogens, *Lm* can survive and multiply at refrigeration temperatures. This is not of major concern with food products that will be cooked prior to consumption as *Lm* is relatively sensitive to heat treatment. While RTE meat products are treated to reduce or eliminate *Lm*, on rare occasions, these environmental bacteria can recontaminate the product as it is being handled, further processed and packaged (AMI, 2008). Therefore, it is important to understand the factors that affect the survival and growth of *Lm*, the risks associated with various food products and the means to control them.

² Inflammation of the brain and surrounding membranes.

1.1.3. Factors affecting the survival and growth of *Listeria monocytogenes*

Understanding the factors that positively or negatively impact the survival and growth of *Lm* in food processing environments and food products is essential to the development and management of effective control measures. In food, the growth of *Lm* is dependent on the intrinsic characteristics of the product (e.g.: pH, water activity, background microflora, etc.), the extrinsic characteristics of the products (e.g.: temperature, packaging, relative humidity) and processing techniques (e.g.: cooking, non-thermal processing, post-lethality treatment, antimicrobial agents or processes). Temperature, pH and water activity (a_w) at appropriate levels can effectively control *Lm* in RTE meat products. *Lm* growth and survival limits are outlined in table 1.

Table 1: Factors influencing growth and survival limits for *Listeria monocytogenes*

Parameter	Minimum	Optimum	Maximum	Can survive (but no growth)
Temperature °C	-0.4	25 - 37	45	-18
°F	31.3	77 - 99	113	0
pH	4.4	7.0	9.4	3.3 - 4.3
Water activity (a_w)	0.92	---	---	< 0.92

(IFT, 2003; Health Canada, 2011; ICMSF, 1996)

As shown in table 1, *Lm* has the ability to survive and grow over wide temperature and pH ranges. This is critical in the processing environment, and knowledge of such factors permits the identification of the foods that are at higher risk of *Lm* contamination and the degree of risk.

1.1.4. Foods at risk of *Listeria monocytogenes* contamination

Due to the ubiquitous nature of *Listeria spp*, several categories of food may become contaminated with *Lm* and linked with cases of listeriosis. However, the associated risk is dependent on the number and impact of control measures applied to minimize the growth and survival of *Lm*. High risk foods are those having the following properties (ILSI, 2005):

- Have the potential for contamination with *Lm*;
- Support the growth of *Lm* to high numbers;
- Are RTE;

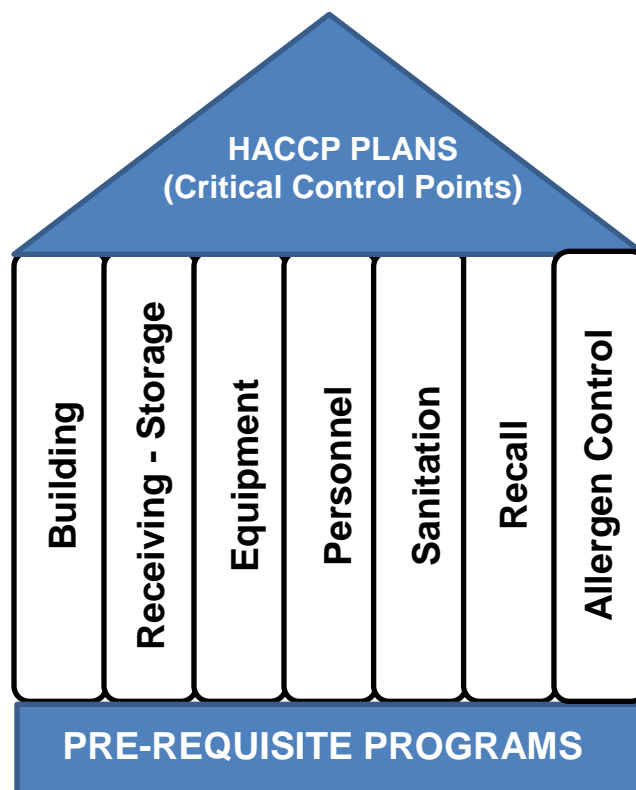
- Require refrigeration; and
- Are stored for an extended period.

Foods most commonly associated with outbreaks of listeriosis include hot dogs, deli meats, pâté, milk, cheese (mainly soft and semisoft) and RTE fish products (Health Canada, 2011). Cooked meat products can be contaminated by equipment, personnel handling raw products, or from reservoirs or niches of *Listeria* spp in the ready-to-eat processing environment (CFIA, 2011). Meat products, including but not limited to non-dried delicatessen meats, frankfurters (without reheating), raw/undercooked products and pâté and other meat spreads appear to be of much greater risk (CFIA, 2008; US FDA/FSIS, 2003).

1.1.5. Hazard analysis critical control point (HACCP) systems

While recognizing that the details of application may vary depending on the circumstances of the RTE meat processing operation, all the sections developed in this Best Practices document (Good Manufacturing Practices, Sanitation, Environmental and Product Testing) should be part of each operator’s Hazard Analysis Critical Control Point (HACCP) system (Figure 1).

Figure 1. Constituents of the federal HACCP system in Canada



HACCP is “a system which identifies, evaluates, and controls hazards which are significant for food safety” (Codex Alimentarius, 2003). HACCP system provides a science based and systematic means to assess hazards and to establish control systems that focus on prevention of hazards to enhance the safety of foods.

In Canada, the Food Safety Enhancement Program (FSEP) is the CFIA's approach to encourage and support the development, implementation and maintenance of HACCP systems in all federally registered food establishments. Implementation of FSEP and HACCP systems is mandatory in federally registered meat establishments. In addition, operators are required to reassess their HACCP systems and make appropriate adjustments to adapt to changes in their operations or to respond to new information regarding hazards and control measures.

1.2. Overview of the current regulatory policies and sampling requirements

1.2.1. Division of regulatory authorities

At the federal level, responsibilities for food safety are shared between Health Canada and the CFIA. Health Canada develops food safety policies and standards and conducts risk assessments while the CFIA is responsible for developing inspection policies and compliance and enforcement activities.

1.2.2. Health Canada policy on *Listeria monocytogenes* in ready-to-eat foods

On April 1, 2011, Health Canada's new policy on *Lm* in RTE foods came into effect (Health Canada, 2011). The policy is based on GMPs and the principles of HACCP. It was developed using a health risk assessment approach and uses as its foundation a combination of inspection, environmental sampling and end-product testing to verify control of *Lm* in RTE foods. Focus is given to environmental verification and control, especially in post-lethality areas. The policy applies to RTE foods sold in Canada, whether produced domestically or imported.

The standards and compliance guidelines in the new Health Canada policy have been incorporated into the CFIA policy (see Section 1.2.3., below) and therefore have important implications for all federally registered RTE meat establishments.

Salient features of the Health Canada policy that are reflected in the CFIA policy include the following:

- Definitions of RTE foods in which growth of *Lm* can or cannot occur and end-product compliance criteria have been aligned with the international standards of Codex Alimentarius.

- The differentiation of foods in which growth of *Lm* can occur from foods in which growth cannot occur can be determined by measuring the increase of *Lm* over the expected shelf life of a food product. An increase of no more than 0.5 log CFU/g would define the product as a food in which growth of *Lm* cannot occur, while an increase of more than 0.5 log CFU/g would denote a product in which growth can occur.
- The presence of factors known to control growth of *Lm* in food products, such as certain levels of pH and/or water activity freezing or approved antimicrobial additives, can also qualify products for recognition as foods in which growth of *Lm* cannot occur, subject to validation in certain cases (Health Canada, 2012).
- The end-product compliance criteria include a regulatory action level of >100 CFU/g in food products that do not support the growth of *Lm* and in other products that have limited potential for growth over a specified shelf life. The application of this criterion is contingent upon the products having been produced under conditions that could be reasonably expected to effectively control *Lm*.
- There is no change in the requirement for absence of *Lm* throughout the expected shelf life of RTE foods in which growth of *Lm* can occur, although absence is now based on a negative test of a 125 g sample (previously 25 g).
- RTE foods have been classified into two risk categories based principally on the ability of the foods to support growth of *Lm* during their stated shelf life. Category 1 contains products in which the growth of *Lm* can occur. Category 2 contains two subgroups: 2A) RTE food products in which limited growth of *Lm* to levels no greater than 100 CFU/g can occur throughout the stated shelf life; and 2B) RTE food products in which the growth of *Lm* cannot occur throughout the expected shelf life of that food.
- Category 1 food products should receive the highest priority for industry verification and control, as well as regulatory oversight and compliance activities, while Category 2 products should receive a lower priority.
- Where a change in classification from a Category 1 into a Category 2A or 2B food is sought, validation data must be provided to regulatory authorities for evaluation and confirmation of the final classification of the RTE product (Health Canada, 2012).
- The compliance action decision tree, including environmental testing for *Lspp* and end-product testing for *Lm*, has been modified to include more details related to sampling.
- All RTE food-producing plants should have an environmental monitoring program encompassing both food contact surfaces and non-food contact surfaces.
- The use of post-lethality treatments and/or *Lm* growth inhibitors is encouraged.
- The list of food products implicated in listeriosis outbreaks has been updated.

1.2.3. CFIA policy on the control of *Listeria monocytogenes* in ready-to-eat meat and poultry products

On April 1, 2011, CFIA issued their revised *Listeria* policy (CFIA, 2011) to align their regulatory requirements with the provisions of Health Canada's new *Listeria* policy, which also came into effect on that date. The CFIA policy prescribes the regulatory requirements for operators of RTE meat processing establishments and serves as the primary reference document for CFIA inspection staff whose role is to verify compliance with the requirements.

Note: The following text provides an overview of the CFIA policy and is provided solely for the purpose of illustrating the regulatory environment within which the industry best practices for control of *Lm* need to be applied in federally registered RTE establishments. For compliance purposes, establishment operators are directed to the CFIA Website for access to the complete policy documents.

1.2.3.1. Descriptions of ready-to-eat products, risk categories and relative risk levels

The CFIA policy clarifies the distinction between RTE and non-RTE meat products and the basis for dividing RTE meat products into Risk Categories 1, 2A and 2B, in accordance with the Health Canada policy. The assigned risk categories are combined with information on whether antimicrobial agents or processes and/or post-lethality interventions are used to determine the relative risk levels of meat products produced in RTE establishments. The relative risk levels are used in turn to determine certain testing frequencies for RTE establishments.

Risk Category 1

Risk Category 1 includes RTE meat products that support the growth of *Lm*. Establishments making these products are expected to give them the highest priority for control and verification procedures and are subject to the highest priority for CFIA oversight and compliance activities.

Risk Categories 2A and 2B

Establishments producing Risk Category 2A or 2B products are eligible for reduced *Listeria* testing frequencies and CFIA oversight. To have products recognized in these categories operators are required to demonstrate that the products meet the following criteria:

- For Category 2A, limited growth of *Lm* to levels no greater than 100 CFU/g can occur throughout the stated shelf life of products with no kill step and/or RTE refrigerated products with a shelf life of no more than 5 days. The operator must validate and regularly verify that the levels of *Lm* in products with no kill step are consistently no greater than 100 CFU/g throughout the stated shelf life. Otherwise, the products will default into Category 1.
- For Category 2B, growth of *Lm* cannot occur throughout the stated shelf life of the product. The operator must validate that *Lm* numbers do not increase by 0.5 log CFU/g throughout the shelf life of the product to demonstrate that the product does not support growth of *Lm*. Products with the following physico-chemical characteristics are presumed not to support growth of *Lm* and are exempt from the validation requirement:
 - pH <4.4, regardless of a_w
 - a_w <0.92, regardless of pH
 - Combination of factors, such as pH <5.0 and a_w <0.94
 - Frozen foods

Operators are required to regularly monitor and verify the growth-limiting characteristics (e.g.: pH, a_w , antimicrobial agents, etc.) in accordance with their HACCP plans in order to maintain CFIA recognition of Category 2A and 2B products.

1.2.3.2. CFIA testing programs

The CFIA policy also describes the testing programs carried out by CFIA inspection staff for *Lm* and *Lspp* on food contact surfaces and *Lm* in finished products in RTE meat establishments, as well as the program for testing of imported RTE meat products. Sampling procedures and the requisite follow-up to unsatisfactory test results by CFIA and the operator are prescribed.

1.2.3.2.1. CFIA testing programs implemented by CFIA

CFIA testing programs M200 and M205

Under CFIA's M200 and M205 sampling plans, inspectors randomly select the day of sampling and the production line to be sampled. A sample of finished product (M200) is collected from the selected line and food contact surface samples (M205) are collected from the same line. CFIA laboratories test the product samples for *Lm* and *Salmonella* spp, as well as *E. coli* O157:H7 in the case of uncooked dry or semi-dry fermented sausage containing beef. The food contact surface samples are tested for *Lspp* and *Lm*. The sampling frequency is set at the beginning of each fiscal year (two times per RTE meat establishment in 2012-2013).

CFIA testing programs M200RB and M205RB

CFIA's M200RB and M205RB sampling plans are more focused, with the highest risk product produced in the establishment on the sampling day being selected for testing (M200RB). The food contact surface of the line on which that product was produced are sampled at the same time (M205RB). Product samples are tested for *Lm* in a CFIA laboratory and the food contact surface samples are tested for *Lspp* and *Lm*. The frequency of sampling for each establishment is determined by the relative risk level of the products produced in the establishment. The range of frequencies set for fiscal year 2012-2013 is displayed in table 2.

Table 2: CFIA sampling frequencies for the M200RB and M205RB sampling plans

M200RB and M205RB sampling frequencies based on relative risk levels			
Ready-to-eat product category	Antimicrobial agent ³	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	N/A ⁴	1 sample per year	0 samples per year

(CFIA, 2011)

In establishments producing more than one RTE product, decisions by inspectors on which product to sample on a given day under the M200RB sampling plan are guided by the list of product types reproduced below. The product types are listed in order of decreasing risk and the highest risk post-lethality exposed product being produced on the sampling day would be selected for testing.

- Deli-meats sliced in the establishment
- Deli-meats shipped whole from the establishment, excluding cook-in-the-bag-type products
- Hotdogs
- Deli-salads, pâtés and meat spreads
- Fully cooked products other than the above

³ Use of a permitted antimicrobial agent that allows no more than a 2 log cfu/g increase in *Lm* throughout the shelf life of the product.

⁴ Not applicable

- Fermented products
- Dried products
- Salt-cured products
- Frozen products

1.2.3.2.2. CFIA testing programs implemented by operators

In addition, the CFIA policy requires all operators of RTE meat establishments to implement a testing program to verify the effectiveness of their control measures and to demonstrate product compliance. The tests must be carried out in an accredited laboratory using a method listed in the Health Canada Compendium of Analytical Methods (Health Canada, 2011a) and appropriate to the purpose.

- Testing of food contact surface for *Lspp* at the appropriate minimum frequency listed in table 3. For Category 1 production lines, if two or more consecutive samples from the same food contact surface are found to be positive, the operator is required to conduct tests for *Lm* in finished products exposed to the food contact surface and to take corrective actions to eliminate and prevent further contamination. For Category 2 production lines, the follow-up actions are triggered by three or more consecutive positive results for *Lspp* on food contact surface.
- Sampling of finished RTE products at the appropriate minimum frequency listed in table 4. These samples must be tested for *Lm* and *Salmonella* spp, as well as *E. coli* O157:H7 if the product is an uncooked dry or semi-dry sausage containing beef (CFIA, 2011a).

Notes:

- 1) Regardless of the reason for testing, operators need to keep in mind the importance of maintaining control of all products that could be implicated by a positive test result until the test results are available, to preclude the possibility of product recalls.
- 2) Operators are required to inform CFIA of all unsatisfactory test results, including detections of *Lspp* on food contact surface and *Lm* either on food contact surface or in finished product.

1.2.3.3. Follow-up on unsatisfactory test results

The detection of *Lm* on a food contact surface or a second positive finding of *Lspp* (third in the case of Category 2 products) would require the development of an action plan and the implementation of corrective measures to eliminate the organism from the RTE environment. In addition, finished product from the lot produced when the food contact surface was sampled would be subjected to testing for *Lm*. The effectiveness of the corrective measures would have to be verified by retesting the food contact surface until three consecutive negative results have been obtained.

Table 3: Frequency for mandated operator testing of food contact surface

Food contact surface testing frequency based on relative risk level				
Ready-to-eat product category		Antimicrobial agent ⁵	Post-lethality treatment	
			None	Yes
Category 2B		N/A ⁶	2/year/line	1/year/line
Category 2A		None	4/year/line	2/year/line
		Yes	2/year/line	1/year/line
Category 1:				
Non-deli, non-hot dogs		None	1/month/line	1/2 months/line
		Yes	1/2 months/line	1/3 months/line
Deli & hot dogs	Very small volume est. ⁷	None	1/month/line	1/2 months/line
		Yes	1/2 months/line	1/3 months/line
Deli & hot dogs	Small volume est. ⁷	None	2/month/line	1/month/line
		Yes	1/month/line	1/2 months/line
Deli & hot dogs	Medium volume est. ⁷	None	3/month/line	3/2 months/line
		Yes	3/2 months/line	1/month/line
Deli & hot dogs	Large volume est. ⁷	None	4/month/line	2/month/line
		Yes	2/month/line	1/month/line

(CFIA, 2011)

Table 4: Frequency for mandated operator testing of finished ready-to-eat products

Product sampling frequency based on relative risk level			
Ready-to-eat product category	Antimicrobial Agent ⁵	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	N/A ⁶	3 samples per year	1 sample per year

(CFIA, 2011a)

⁵ Use of a permitted antimicrobial agent that allows no more than a 2 log CFU/g increase in *Lm* throughout the shelf life of the product.

⁶ Not applicable

⁷ The size of establishments is based on their annual production of RTE meat products, i.e.:

- Very small – up to 100.000 kg
- Small –100.000 up to 2.000.000 kg
- Medium – 2.000.000 up to 6.000.000 kg
- Large – more than 6.000.000 kg

When *Lm* is detected in a finished Category 1 RTE meat product, the operator is required to implement a “hold and test” procedure immediately on finished product from the implicated production line. Development and implementation of an action plan to guide the operator’s response is also required. The hold and test procedure for Category 1 products comprises a series of tests on finished products over a four week period with the weekly product sample numbers set at five, three, two and one, respectively. A modified hold and test procedure can be applied when a Category 2 product has given an unsatisfactory test result for *Lm*, i.e. >100 CFU/g. Under the modified procedure the testing period is reduced to two weeks and the weekly sample numbers would be three and two, respectively. In either case, CFIA will also collect samples toward the end of the testing period to verify compliance.

When test results reveal that one or more sample units (sub-samples) from a Category 2 product contain between 10 and 100 CFU/g of *Lm*, CFIA will undertake investigative sampling of the product. If the investigative tests reveal that one or more sample units remain within that range or if any sample units are found to contain more than 100 CFU/g of *Lm*, the results will be considered to be unsatisfactory and the operator will be required to respond with an action plan laying out the intended corrective measures and with implementation of the modified “hold and test” procedure.

1.2.3.4. CFIA actions during extended noncompliance

CFIA will implement intensified inspection measures and/or an in-depth review of an establishment when the following situations are encountered:

- Two consecutive unsatisfactory test results on either food contact surface or finished product samples from the same production line, whether arising from CFIA or operator sampling;
- Two unsatisfactory test results on either food contact surface or finished product samples from the same production line within a moving window of the last five sample collections, regardless of the sampling plan; or
- Multiple unsatisfactory test results on either food contact surface or finished product samples from different production lines, such as three or more production lines having unsatisfactory test results during the same week or multiple production lines having recurrent unsatisfactory test results within a defined period.

1.2.3.5. Operator sampling of non-food contact surface

The CFIA policy recommends that all RTE meat establishments implement testing programs to monitor non-food contact surface for the presence of *Lspp* as a means to

verify the effectiveness of their sanitation programs and GMPs. While the design and implementation these programs are left to the operators` discretion, CFIA does stipulate that the results must become part of the operator`s trend analysis and be available to CFIA on request.

1.2.3.6. Operator trend analysis

Operators are required to develop a procedure for trend analysis to enable detection of, and reaction to increases in unsatisfactory results or the movement of contamination from non-food contact surface to food contact surface. The procedure must include the parameters that the operator would use to determine whether the risk of *Listeria* contamination is under control and to trigger corrective actions when loss or lack of control is indicated. All test results from non-food contact surface, food contact surface and finished product testing must be included in the trend analysis.

Section 2: Good Manufacturing Practices

2.1. Introduction

Good manufacturing practices (GMPs) are guidelines that outline the aspects of production that can impact the safety or quality of products. The GMPs described in this section are the minimum sanitary and processing requirements for production of safe and wholesome food and control of *Listeria*.

For effective control of *Lspp*, processors must adopt good manufacturing practices that take both a systematic and a preventive approach to control food safety hazards throughout the manufacturing process. In federally registered establishments, this is achieved through the incorporation of GMPs for *Lm* control into the establishment's HACCP system, in order to affect control during manufacturing, while also ensuring compliance with applicable regulations and policies (CFIA, 2012). HACCP systems comprise prerequisite programs and HACCP plans. Most of the GMPs would be incorporated into the establishment's prerequisite programs while interventions would be incorporated into the product/process-specific HACCP plans. Nonregistered establishments that do not have HACCP systems in place should develop Standard Operating Procedures (SOPs) to guide the implementation of GMPs in their operations (e.g.: product flow and handling, storage, facility maintenance and construction, etc.).

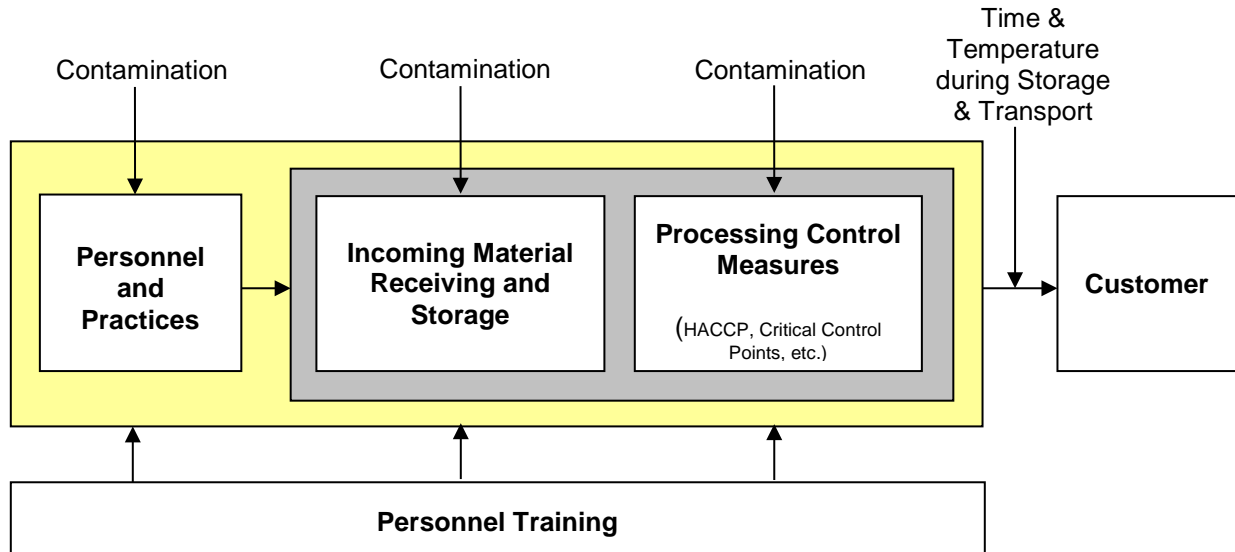
The incidence of *Lm* in RTE foods ranges from 0 - 10 % (Farber and Peterkin, 2000; Gombas *et al.*, 2003; Ryser and Marth, 2007; Little *et al.*, 2009). Therefore, it is important to recognize that *Lm* contamination of RTE meat products is a hazard likely to occur and must be addressed as a biological hazard in the establishment's HACCP plan (Farber and Peterkin, 1991; Henning and Cutter, 2001). Figure 2 identifies potential pathways for introduction of *Lm* contamination into RTE processing facilities and potential control measures that may be implemented through GMPs. Each is discussed in more detail in subsequent parts of this section. In addition, more specific information on potential sources of *Lm* contamination is provided in Appendix 1.

All federally registered meat processing facilities are required to maintain a recognized HACCP system to ensure the production of safe food (CFIA, 2012). At each step in the manufacturing of a RTE meat product, the potential for *Lm* contamination is variable and is influenced by the following factors:

- the introduction of *Lm* from the environment or personnel;
- the initial number of *Lm* present in incoming raw materials;

- the increase or reduction of *Lm* due to the modification of growth conditions or specific control measures, respectively (ILSI, 2005); and
- the controls in place in the post-lethality area of the facility where RTE meat products are exposed to the environment.

Figure 2. Factors influencing contamination and control of *Listeria monocytogenes* in ready-to-eat products (Adapted from ILSI, 2005)



An important means to limit the risk of *Lm* contamination is ensuring that employees are trained and knowledgeable about the sources of contamination and practices that can minimize or prevent *Lm* contamination of food. In addition to training and other GMPs for *Lm* control, this section also describes the specific process controls plant operators can incorporate into their HACCP systems to control or prevent *Lm* contamination throughout the RTE manufacturing process.

For the most part, the GMPs for *Lm* control are quite basic and applicable to the control of other pathogens as well. They are practices that every food establishment should have in place. Effective control of *Lm* demands diligent and consistent adherence to GMPs because of its prevalence in the environment, ease of spread, and ability to flourish in the RTE processing environment.

2.2. Physical plant design

When undertaking a construction project, whether building a new plant or renovating an existing facility, the design should incorporate features that will facilitate control of *Lm* and

other foodborne pathogens. Examples of features that should be considered include the following:

- Designing the layout to facilitate control of traffic flow for both personnel and employees.
- Providing sufficient space around processing equipment to help prevent cross-contamination by passing people and materials, splashing or aerosol transfer.
- Compartmentalizing the RTE processing area to help prevent cross-contamination.
- Avoiding niches where *Lspp* could grow and persist.
- Ensuring that all surfaces are easy to clean.
- Providing facilities for hand washing and footwear decontamination at entrances to the processing area(s) and clean-out-of-place tanks for removable pieces of equipment and tools.

2.3. Personnel training

The establishment trains employees in appropriate personal hygiene and hygienic handling of food. Training in food hygiene is provided at the beginning of employment and is reinforced and updated at appropriate intervals. The establishment provides technical training appropriate for the complexity of the manufacturing process and the tasks assigned (CFIA, 2012).

In any food processing facility, food safety knowledge and training are critical. All personnel, whether permanent, temporary or seasonal, who enter an RTE area, including management, maintenance, sanitation, inspectors, contractors and visitors, should be trained or instructed on what to do and what not to do while in the RTE area (US FDA, 2008; US Industry Associations, 1999), and why their actions are so important. The curriculum and level of training should be appropriate to the reason for them entering the RTE area. Training provides personnel with both the knowledge and skills required to follow company policies and procedures designed to control critical food safety risk factors (Conference for Food Protection *Listeria monocytogenes* Intervention Committee, 2006).

It is essential for RTE food processing facilities to design and implement a food safety training program appropriate for their operation. The training program should be tailored to the needs of the different categories of trainees, whether production oriented, maintenance, management or visitors, for example, and may include all or appropriate parts of the following:

- The nature of pathogens including *Lm* and potential harbourage sites (Codex Alimentarius, 2009)

- Pathogens, including *Listeria*, and their impact on food processing and food safety (Henning and Cutter, 2001), as well as the consequences of contamination for the company
- Personal hygiene requirements, including hand washing and drying, and their importance in protecting the integrity of RTE products (US Industry Associations, 1999; Henning and Cutter, 2001; Snelling *et al.*, 2010)
- Basic sanitation and food handling principles and procedures (Henning and Cutter, 2001)
- Effective control measures for pathogens, including *Lm*, during processing, distribution, marketing, use and storage and how to ensure that the measures consistently operate as intended (US FDA, 2008; Codex Alimentarius, 2009).
- The means to verify the effectiveness of control programs, including sampling and testing of food contact surface, non-food contact surface and RTE finished products (US FDA, 2008; Codex Alimentarius, 2009).
- Control of product that could be affected by positive test results.
- Planned response to positive test results and corrective actions (US FDA, 2008).

With regard to employees, it is recommended that training be conducted before they perform job activities in an RTE area, including sanitation and maintenance activities, with refresher training provided on a regular and ongoing basis (Codex Alimentarius, 2009). Only properly trained personnel, with a strong understanding and working knowledge of the impact of personnel hygiene and hygienic practices, should work in operations that are most susceptible to post-processing contamination.

In addition to the above, supervisory personnel should also receive training in coaching techniques that will enable them to guide and encourage employees to properly and consistently apply the knowledge gained during their training sessions. Coaching, which may entail reiterating and reinforcing the substance and importance of the training provided will generally be more effective than threats or disciplinary measures in achieving sustained behavioural change among the trained employees.

2.4. Hygienic practices

Microbiological cross-contamination is a major concern with respect to *Lm* contamination of RTE meat products, and it may occur at any step in which the products are exposed to the environment, during processing and transportation, at retail and in the home (Codex Alimentarius, 2009). This section describes several routes via which cross-contamination of RTE products may occur during processing, and practices that facilities can employ within their programs to mitigate the risk.

2.4.1. Cleanliness

The establishment has and enforces a policy to ensure good personal hygiene and hygienic behaviour and habits that prevent the contamination of food products. The policy includes procedures for hand washing and/or sanitizing, protective clothing and personal hygiene (CFIA, 2012).

2.4.1.1. Hand washing and/or sanitizing and drying

- At a minimum, hand washing and/or sanitizing locations must be available at all entrances to RTE production areas.
- All employees should thoroughly wash their hands:
 - before entering an RTE production area
 - before putting gloves on
 - before resuming duties after a break
 - after touching an unclean surface
 - before handling RTE product (Henning and Cutter, 2001; US FDA, 2008).
- Thorough drying of washed hands is also very important. Washing should reduce the numbers of bacteria on the skin surface of the hands but will not eliminate them. Residual wetness increases the likelihood that the remaining bacteria will be transferred to surfaces and items touched. Furthermore, when the hands remain damp after frequent washings the skin is more likely to become irritated, which can create conditions that lead to an increase in the variety and numbers of bacteria colonizing the skin. Immediate drying of the hands with disposable paper towels or an ultra-rapid forced-air dryer effectively reduce the bacterial population on the skin and prevent the transfer of bacteria from the surface of the hands to the surfaces subsequently touched. Conventional warm air dryers have been shown to be less effective, particularly when the hands are rubbed together during drying (Snelling *et al.*, 2010).

2.4.1.2. Protective clothing: smock or uniform

- All employees and visitors should wear a smock or uniform that protects against the contamination of RTE products (Henning and Cutter, 2001). It is also recommended that smocks or uniforms worn in RTE processing areas be distinguished from those of employees handling raw materials (e.g.: color coded) (US Industry Associations, 1999; Henning and Cutter, 2001). Smocks or uniforms may also be further coded by department, zone or functionality of personnel within the RTE area (e.g.: to distinguish food product handlers from non-food product handlers, such as employees handling inedible material within the RTE area).

- Employees should change into a clean smock or uniform prior to entering areas of RTE processing (Henning and Cutter, 2001). An establishment may choose to designate an area prior to entering the RTE processing area for employees to change into clean clothing (Codex Alimentarius, 2009).
- Clothing designated for the RTE area is to be worn only in RTE production areas, and should be removed when leaving the RTE production area for any reason.
- Employee smocks or uniforms should be changed at least daily, or more often if needed. All protective clothing should be either laundered or disposed of daily (Henning and Cutter, 2001).
- Additional disposable garments (e.g.: disposable plastic aprons and sleeves) may be worn over other clothing in RTE areas. If used, they must be changed and discarded when soiled.

2.4.1.3. Protective clothing: footwear

- All employees should wear footwear that is made of impermeable material and is in good repair and either easily cleanable or disposable.
- It is recommended that footbaths or equivalent boot sanitizing methods (e.g.: boot spray, dry powdered sanitizer, etc.) be used when entering RTE processing areas. Proper control measures should be implemented to ensure any boot sanitizer used is maintained at the proper concentration (Henning and Cutter, 2001).

2.4.1.4. Protective clothing: gloves

Note: Gloves can provide added protection against contamination but they are never a substitute for proper hand washing. In fact, if they are not used properly, they can become a source of contamination.

- Disposable (single use) plastic gloves should be used in RTE areas and changed and discarded when soiled or systematically at specified intervals. Cotton gloves must not be used for direct handling of RTE products.
- Disposable gloves should be discarded and replaced after an employee touches any unclean surface. If multi-use gloves are worn, they should be washed and sanitized after an employee touches any unclean surface.
- Gloves worn outside of areas where RTE foods are processed should be discarded before entering the RTE production area (Henning and Cutter, 2001).
- Gloves can be a physical hazard and must be considered as such in the development or review of the HACCP system.

2.4.2. Employee health

No person is permitted to work in a food handling area when he or she is known to be suffering from or known to be a carrier of a disease likely to be transmitted through food (CFIA, 2012).

All RTE meat processing facilities must maintain a policy whereby employees who exhibit signs or symptoms of communicable diseases (e.g.: gastroenteritis, jaundice, etc.) are prohibited from working in food production areas.

2.4.3. Traffic flow

Hygienic operations are promoted throughout the facilities by means of a regulated flow in the process, from the arrival of raw material to the final product. Physical or operational separations occur to prevent contamination of food via employee traffic patterns, product flow and equipment. The traffic pattern of personnel and visitors prevents cross-contamination of food products (CFIA, 2012).

It is recommended that all RTE meat processing facilities establish traffic patterns to control movement of personnel, incoming material, product, and tools and equipment between raw and finished product areas to minimize the transfer of pathogens, including *Lm*, and risk of *Lm* cross-contamination (Codex Alimentarius, 2009).

Access to the post-lethality processing area should be limited to entryways with readily available hand washing and footwear sanitizing facilities. There should be no direct access from the outdoors.

2.4.3.1. Personnel flow

- Foot traffic into RTE food preparation areas should be controlled to the extent that only individuals with proper training and compliance to preventive procedures are permitted entry (Conference for Food Protection *Listeria monocytogenes* Intervention Committee, 2006).
- Employees should not work in both raw and RTE areas, if possible. If they must work in both areas, they should change protective clothing and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear before entering the RTE area (US Industry Associations, 1999; Codex Alimentarius, 2009; Henning and Cutter, 2001).
- There should be separate designated areas for raw and RTE personnel to avoid cross-contamination via personnel (e.g.: separate lunch rooms, employee facilities, etc.). Where this is not possible, there should be a program to mitigate risk of contamination from raw to RTE product handlers, such as staggering breaks and lunch and the

inclusion of effective sanitizing methods for movement both into and out of common areas (Henning and Cutter, 2001). Where areas of poor employee flow are recognized, there should be increased attention to sanitation measures and testing/monitoring in these areas to prevent cross-contamination.

- Employees handling multiple products or moving from one line to another should change gloves and outer clothing, as necessary (Henning and Cutter, 2001).
- If possible, only designated employees should handle “dirty” items, such as trash, pallets, product waste, scrap product, etc. Any employee who handles such “dirty” items must follow the established RTE program requirements prior to coming into contact with RTE products or food contact surfaces (Henning and Cutter, 2001).
- All plant tours should flow from the finished product area to the raw product area. It is recommended that visitors not be brought directly into the RTE area to avoid potential cross-contamination.

2.4.3.2. Product flow

Ideally, a processing facility should ensure complete separation of raw and RTE foods throughout all areas of receiving, storage and preparation. If space is limited and raw and RTE foods have to be kept in the same area, separation should be achieved by using sufficient physical space, physical dividers, different production times for raw and RTE food items with a complete cleaning and sanitizing in between, or storing raw foods below RTE foods (Conference for Food Protection *Listeria monocytogenes* Intervention Committee, 2006).

2.4.3.3. Tools and equipment flow

- All plants should designate tools and equipment to be used only for RTE processing (e.g.: maintenance tools, employee utensils, carts, forklifts, pallet jacks, racks, tubs/containers, etc.). It is recommended that all designated equipment be clearly and easily distinguishable. Signs should be posted around the plant to reinforce the designation.
- Pallets, boxes, shipping containers or other items from outside the food establishment should not be brought directly into RTE food preparation areas, since they may be a source of pathogen and *Lm* contamination (Conference for Food Protection *Listeria monocytogenes* Intervention Committee, 2006). Where this is not practical, it is recommended that they be cleaned and disinfected before entry into the RTE production area (Codex Alimentarius, 2009).
- Ensure that the outer surfaces of tool boxes and other containers are cleaned and sanitized before entering the RTE area. Use of canvas tool bags and the like should be prohibited.

- Color-coding of equipment, handles on knives or tongs, and other utensils can be a useful visual means to distinguish items that are used only in the raw area or only in the RTE processing area and are not interchangeable.

2.4.4. Maintenance activities

Equipment and containers used in the establishment are designed and constructed so as to ensure that they can be adequately cleaned, disinfected and maintained to avoid the contamination of food (CFIA, 2012).

- Establishments should implement an effective, scheduled preventive maintenance program to prevent the development of harbourage sites and equipment failures during operation. Equipment failures during production increase the risk of *Lm* contamination as equipment is being repaired. The preventive maintenance program should be written and include a defined maintenance schedule (Codex Alimentarius, 2009).
- Maintenance personnel in the RTE area should comply with the same hygiene requirements as production employees (Codex Alimentarius, 2009). This includes changing protective clothing and other soiled clothing, washing and sanitizing hands, and cleaning and sanitizing footwear before entering the RTE area.
- RTE product and packaging materials must be removed or otherwise protected during any necessary maintenance activities.
- Maintenance tools should be washed and disinfected prior to use (Codex Alimentarius, 2009). All processing equipment that may have been contaminated during any maintenance activities must be cleaned and sanitized prior to use.
- Tools should be carried in containers made from impermeable, easy-to-clean nonporous materials (e.g.: no canvas bags) and the containers should not be placed on or near food contact surfaces.
- Whenever possible, defective equipment should not be repaired in a food preparation area during operation (US Industry Associations, 1999). When repairs during operations are necessary, the repairs and subsequent cleaning and sanitizing of the equipment must be done in a manner that prevents cross-contamination.

2.4.5. Equipment specifications and design

- Equipment sanitary design and operation are critical elements in reducing the risk of *Lspp* contamination in RTE meat establishments. When preparing purchase specifications for new processing equipment, operators should be guided by the 10 Principles of Sanitary Design developed by an American Meat Institute task force in consultation with equipment manufacturers, certifying organizations and government officials (AMI, 2001). Applying the principles will help to ensure that the new equipment

will be cleanable and will reduce the probability of growth niches or harbourage sites developing on or in the equipment.

- The purchase specifications could also include a visit by a technician to go over preventive maintenance, disassembly and proper cleaning procedures. This information should be incorporated into the establishment's maintenance and sanitation protocols.
- Existing equipment that has proven to be difficult to clean should be modified to improve cleanability or replaced at the earliest opportunity.

2.4.6. Sanitation activities

The sanitation program is carried out in a timely manner. Food or packaging materials are not contaminated during or subsequent to cleaning and sanitizing of equipment (CFIA, 2012).

- It is recommended that sanitation employees be designated for cleaning by zone/area of the production area and do not cross from raw to RTE. Where this is not possible, sanitation employees should clean RTE areas first, and then move to other areas.
- Employees who clean utensils and equipment for raw materials should avoid cleaning RTE utensils and equipment. If this is not possible, RTE utensils and equipment must be cleaned before those used for other purposes (Codex Alimentarius, 2009).
- Central foam and sanitation stations should be located in each area along with colour designated hoses, such that they are not moved from one room/area to another.
- Standing water should be removed, and if it occurs repeatedly, steps should be taken to improve drainage.
- Any employee tools should remain in the RTE area at all times and should be cleaned and sanitized before storage and again before use.
- Employee tools and other items of personal equipment should be subject to routine cleaning and disinfection by sanitation employees using prescribed procedures. Disinfection should preferably be by immersion in water of $> 80^{\circ}\text{C}$ for ≥ 1 min. or by immersion in a listericidal disinfectant solution for the prescribed period.
- Pallets used in an RTE area should be easily cleaned and sanitized.
- All wheels of transport equipment (e.g.: carts, forklifts, pallet jacks, racks, etc.) used in an RTE area should be cleaned and sanitized.
- Eliminate brooms from wet RTE areas and replace with easily cleanable tools (ILSI, 2005).
- Boots must be washed and sanitized at least once a day and clothing must be laundered daily.

- In registered establishments all sanitation activities must be described in detail in its Sanitation Prerequisite Program, including all steps, responsible parties, schedules, and products used, as well verification and deviation procedures.
- Further guidance is provided in the next section of this document, Section 3 Sanitation.

2.5. Incoming material receiving and storage

Incoming materials are handled and stored in a manner to prevent damage and/or contamination (CFIA, 2010a).

Within an RTE processing environment, it is important to recognize that incoming materials (e.g.: raw materials, ingredients, packaging material, etc.) are potential sources of pathogens, including *Lm*. Control of contamination on incoming materials can play a role in ensuring that finished RTE product does not pose a food safety risk.

All elements destined for use in the post-lethality processing area, including packaging materials, should be protected from cross-contamination while in storage and when being moved. This should include protection from personnel and other materials.

The extent of control deemed necessary for raw material should be commensurate with the potential for the incoming material, as well as the finished product, to contain and support the growth of pathogens, including *Lm*. For example, in the event that a process does not include a validated listericidal step it becomes even more critical to consider the hazard associated with the incoming raw material, especially if the end product is capable of supporting the growth of *Lm*, and to implement control measures to reduce the incidence and levels of *Lm* in the raw material.

During the hazard analysis process, the following questions should be asked for each incoming material in relation to *Lm* in RTE processing facilities:

- Could *Lm* be present on or in this material?
- Are any returned or reworked products used as ingredients?
- Could any incoming ingredients result in a hazard due to the presence, survival and/or growth of *Lm*?
- Does the amount and type of ingredients/additives and the resulting pH of the final product, affect the growth or survival of *Lm*?
- Does the amount and type of humectants and the resulting water activity have an effect on *Lm* growth or survival in the final product?
- Has adequate refrigeration been maintained for products during transit or in holding? (CFIA, 2012)

All incoming materials, including ingredients and processing aids, that come into contact with the product or are used in the product preparation, must be recorded (listed on HACCP Form 2 in the case of federally registered establishments) and be approved or permitted for use by applicable regulatory agencies (CFIA, 2012). The CFIA “Reference Database for Hazard Identification”, reference texts, scientific publications and industry association guides may be helpful in describing the hazards associated with both incoming materials and process steps (CFIA, 2012).

Potential control measures for incoming raw materials may include, but are not limited to:

- Establishing purchase specifications on acceptable limits of *Lm* in raw material that suppliers would be required to meet.
- Requiring the supplier to provide a letter of guarantee or certificate of analysis for each lot delivered that confirms compliance with the purchase specifications for *Lm*. To be confident in the information provided by the supplier, an establishment may choose to test ingredients on a periodic basis to ensure purchase specifications are being met (US FDA, 2008).
- Adopting an in-house raw material *Lm* testing program for randomly selected lots and suppliers, whereby either the raw material or final product is kept on hold and tested for the presence of *Lm* and is not released until results are received and proven acceptable according to specifications.
- Adopting an in-house raw material testing program that focuses on suppliers with a history of supplying *Lm* contaminated material.
- Limiting the purchase of raw materials and ingredients to suppliers with the proven ability to deliver materials with minimal levels of *Lspp* contamination.

The emphasis of a raw material testing program should be on understanding the ability of a supplier to provide a safe and wholesome product and its suitability for the manufacture of RTE products. A high frequency or high load of *Lm* on a raw material may be a reflection of faulty practices at the supplier’s manufacturing facility that need to be investigated and addressed.

Ultimately, it is the responsibility of the RTE food processor to maintain a program whereby any hazard that may be present in incoming materials cannot be carried through to the final product. Contaminated materials may be received only if the processor has the ability to reduce any contaminant to acceptable levels, which in the case of *Lm*, are absence in Category 1 finished products and no more than 100 CFU/g in Category 2 finished products when they are not intended for susceptible populations or for export to the US.

2.6. Processing control measures

Each establishment must conduct a complete hazard analysis for all of its processes and products in order to identify and control all hazards effectively (CFIA, 2012).

To effectively control *Lm* in a RTE environment, establishments can adopt process control strategies at various stages throughout the production process to minimize *Lm* contamination and to prevent *Lm* growth (ILSI, 2005; Codex Alimentarius, 2009). As a first step, development and regular reassessment of a HACCP system should be conducted to understand and identify the potential risks involved in the production of specific RTE products and to ensure proper process control measures are implemented and monitored.

There are many factors that influence the survival and/or growth of *Lm* in RTE meat products. The microbiological safety and stability of many foods can be controlled, either in whole or in part, by both intrinsic factors (characteristics of the final product) and extrinsic factors (characteristics of the product environment) (IFT, 2003). This section describes both intrinsic and extrinsic factors, or a combination thereof, that influence the potential for *Lm* contamination and subsequent growth, and the critical nature of process validation.

2.6.1. Intrinsic factors

2.6.1.1. Moisture content

Microorganisms, including *Lm*, need water to grow in RTE food products, and therefore, the control of moisture content is a common means of microbial control and food preservation (IFT, 2003). The water available for microbial growth in food is measured in terms of the water activity (a_w) of the food product. The closer the a_w value is to 1, the more moisture is available for microbial growth.

Depending on the food matrix, *Lm* growth may be controlled in foods that have $a_w \leq 0.92$ (IFT, 2003; Health Canada, 2011). If using a_w as the primary control mechanism to prevent growth of *Lm*, challenge testing is recommended to verify the effectiveness when the target a_w is near the growth limit of *Lm* (≤ 0.92) (IFT, 2003). Monitoring to confirm consistent a_w throughout production batches and throughout the product itself is also important.

2.6.1.2. pH and acidity

Microorganisms have a pH optimum, minimum and maximum for growth in RTE food products. As such, pH can be used as a control measure, either through fermentation or addition of acids to control *Lm* or for food preservation (IFT, 2003).

Depending on the matrix, *Lm* growth may be controlled in foods that have a pH below 4.4 (IFT, 2003). As with other factors, pH usually acts along with other parameters in the food to inhibit microbial growth, such as a_w , temperature and preservatives (IFT, 2003). Simultaneous application of growth inhibition factors, such as osmotic stress and acidity produces a synergistic effect by avoiding the opportunity for organisms to adapt to one inhibitor before exposure to the other (Lemay *et al.*, 2000). For example, *Lm* is considered not to grow in foods that have a pH < 5.0 and a_w < 0.94 (Health Canada, 2011).

2.6.1.3. Antimicrobial agents

Antimicrobial compounds may be present in an RTE meat product as the result of naturally occurring compounds, formation of compounds as a result of processing methods or the addition of biological or chemical preservatives/additives to inhibit pathogens and/or extend the product shelf life (IFT, 2003).

Formulating products with antimicrobial agents, such as potassium lactate, sodium acetate, sodium diacetate, sodium lactate or combinations thereof, may be done to reduce or inhibit the growth of *Lm* (ILSI, 2005). In addition, biologically based preservation methods include the use of lactic acid bacteria, bacteriocins, bacteriophages and other natural substances that have antimicrobial properties. Lactic acid bacteria can control other microorganisms by producing lactic acid in situ, which reduces the pH of the product. The lactic acid bacteria may also produce other antimicrobial substances such as bacteriocins and propionic acid which contribute to the control of *Lm* (ILSI, 2005; Maragkoudakis *et al.*, 2009). “Natural” inhibitors that can be added to product formulations include celery powder (as a source of nitrite) and vinegar (acetic acid, as an acidifier).

In deciding on which antimicrobial agent to use, it is important to consider the spectrum and duration of antimicrobial activity, as well as the impact on sensory characteristics of the product (IFT, 2003). The selection and use of added antimicrobial agents is governed by regulations. General information on additives that are approved for use in Canada, including the terms of use, can be found in Division 16 of the *Food and Drug Regulations* (Government of Canada, 2012a). Information on additives that have been approved but are not yet incorporated into the *Regulations* can be found in the list of Interim Marketing Authorizations (Health Canada, 2011b). Antimicrobial additive suppliers may have more up-to-date information on products that were recently approved for use or are in the latter stages of approval.

2.6.2. Extrinsic factors

2.6.2.1. Time and temperature conditions

Time and temperature control are critical in RTE food processing because of the ability of *Lm* to grow at refrigeration temperatures. The rate of microbial growth is a function of temperature and time - as either the storage temperature or duration increases, the number of cells in a food product will also increase (Codex Alimentarius, 2009). Therefore, prevention of the growth of *Lm* can be greatly enhanced by establishing time and temperature controls throughout the production process. This may include the use of thermal processing (pasteurization, cooking, steam injection, etc.), as well as temperature controls during the distribution and storage phases (ILSI, 2005).

Establishing control as per the CFIA Meat Hygiene Manual of Procedures will ensure the maintenance of temperatures of raw materials, work-in-process (WIP) and finished meat products. As a general guideline, all materials and finished products should be held in an environment that allows no opportunity to alter the properties of the products in an unfavourable way throughout the shelf-life of the products (IFT, 2003).

2.6.2.2. Processing steps

Processing steps that are intended to reduce or destroy pathogens, including *Lm* during the manufacture of a product must be validated to confirm their effectiveness in achieving the expected reduction or elimination of the pathogen (see Section 2.6.4., below, for guidance on validation procedures).

2.6.2.2.1. Lethality processes

The most common lethality process used in the manufacture of RTE meat products is cooking. In this case, the lethality of the thermal process is dependent both on the temperature used and the time required at this temperature to accomplish the desired rate and level of destruction. *Lm* is relatively heat sensitive and therefore is easily destroyed by cooking to the internal temperatures listed in the CFIA Meat Hygiene Manual of procedures, Chapter 4, Annex D (CFIA, 2010). As with any cooking procedure, uniform exposure of the products to the required temperature is a critical factor, meaning that the absence of “cool spots” in the cooking chamber needs to be verified.

Non-thermal processes that may achieve lethality include dry fermentation or dry curing. For example, a bactericidal process can be achieved through a combination of appropriate pH

and a_w levels, complemented in some cases by the use of a bacteriocin-producing starter culture in the manufacture of certain dry-fermented products.

2.6.2.2.2. Post-lethality processes

Post-lethality processes are designed to destroy any pathogens, including *Lm* that may have contaminated finished products following the lethality treatment, e.g. while being sliced and/or packaged.

Examples of thermal post-lethality processes include steam pasteurization, hot water treatment, radiant oven heating and infrared heating of packaged products. In the case of cook-in-the-bag products, the post-lethality thermal process may be applied in the home or in a food service setting.

The most common non-thermal post-lethality method is high pressure processing (HPP). In HPP, product is loaded into a sealed chamber and the pressure within the chamber is then raised, by compressing water to a predetermined level, and held for a period specific to the product and purpose. The effect of pressurization is to inactivate vegetative microorganisms, including *Lm*, without affecting the organoleptic and sensorial characteristics of the products. The hydrostatic pressure is applied uniformly and therefore generally has no deleterious effect on the integrity of the product or package.

Meat products subjected to HPP could be regarded by Health Canada as novel foods under Division 28 of the *Food and Drug Regulations* and could be subject to a comprehensive assessment by the Food Directorate of Health Canada. Health Canada has issued a letter of no objection to the use of HPP for the control of *Lm* in RTE meat products, based on adherence to specific operating criteria (Health Canada, 2007). A subsequent submission resulted in Health Canada approving a broader range of criteria that allow RTE meat products to be subjected to multiple cycles for longer periods (Health Canada, 2011c). Approvals of such submissions are publicly notified on the Health Canada Website (Health Canada, 2011d). Further information on novel foods, recent approvals and the applicable regulations and guidelines for the safety assessment of novel foods can be found on the Health Canada Website (Health Canada, 2010).

2.6.3. The “hurdle” approach

Considering the fact that *Lm* has the ability to grow over a wide range of conditions, this pathogen is best controlled using the “hurdle” or multiple barrier approach (Jay *et al.*, 2005). That is, an establishment will need to choose different, and possibly several control measures to reduce the risk of *Lm* contamination in RTE products. While individual control

measures alone may not be effective in eliminating *Lm*, they may be effective in combination with other control measures.

Multiple strategies should be employed throughout processing by building in measures to prevent *Lm* from entering the facility, establishing harbourage and growing if it becomes established. All potential measures should be considered when establishing and implementing a *Lm* control program.

Effective control of *Lm* in food plants is dependent on a number of elements, including the following:

- Scrupulous adherence to good manufacturing practices (GMPs);
- Stringent traffic pattern control of people and materials;
- Optimal sanitary equipment and facility design;
- Thorough and consistent sanitation procedures;
- Maintaining a low-moisture environment; and
- Diligent environmental testing to verify the overall effectiveness of these measures.

If any of the above elements are compromised, effective control of *Lm* in the plant environment on a consistent basis cannot be achieved (ILSI, 2005). Therefore, the development of additional product-based hurdles is strongly recommended to provide an added measure of safety. To be effective, these hurdles must either inhibit growth of *Lm* or inactivate it and be designed specifically for each different product type.

For certain products, e.g. cooked deli meats, a single additional hurdle may be sufficient, such as the use of an antimicrobial additive or a post-lethality treatment like HPP.

However, for uncooked RTE products, e.g. dry fermented or dry cured, application and control of multiple additional hurdles are necessary. These typically are designed to inhibit bacterial growth by their effects on pH, a_w and, in some cases, production of natural inhibitory substances, i.e. bacteriocins. For example, incorporation of appropriate lactic acid-producing bacteria (i.e. a starter culture) into the formulation and process can prevent or reduce the growth of other bacteria by competitive inhibition and by producing acids that will lower the pH of the product to levels that will prevent growth of *Lm*. Some lactic acid bacteria also produce bacteriocins that are effective against *Lm*. In addition or alternatively, the product formulation and process can be adjusted to lower the a_w of the product to levels that will inhibit the growth of *Lm*. These hurdles need to be applied simultaneously or in a sequence that will produce a synergistic effect on *Lm*, as well as other pathogens and spoilage organisms, and prevent them from adapting to, and overcoming the effects of any individual hurdle. When employing multiple hurdles the intensity of each can be adjusted to

achieve effective control over *Lm* growth without adversely affecting the quality and flavor the product (Leister, 2004).

Operators are encouraged to review the formulations and manufacturing processes for all of their products and to identify additional hurdles that could be used to enhance growth inhibition or elimination of *Lm* from finished products. It is recommended that processors seek expert advice to customize the best approach for their processing methods and products to gain full advantage of the “hurdle” approach. In addition, the effectiveness of the chosen process must be validated, as outlined in Section 2.6.4., below.

To summarize, the following are some examples of hurdle approaches:

- GMPs + sanitation + thermal processing
- GMPs + sanitation+ thermal processing + antimicrobial additive(s)
- GMPs + sanitation + thermal processing + post-packaging treatment
- GMPs + sanitation + thermal processing + antimicrobial additive(s) + post-packaging treatment
- GMPs + sanitation + raw material controls + dry fermentation or dry cure processing
- GMPs + sanitation + dry fermentation or dry cure processing + post-packaging treatment

2.6.4. Validation and challenge studies

When establishing and implementing a process control measure, it is important to validate the measure and to verify its effect on a regular basis to ensure continued efficacy. There are several approaches available for demonstrating that a process consistently limits the growth of, or destroys viable cells of *Lm*, including:

- Reference to scientific literature or previous validation studies;
- Scientifically valid experimental trials;
- Statistically designed surveys and/or mathematical modeling; and
- Challenge studies (ILSI, 2005).

Establishments wishing to have products recognized in Category 2 under the Health Canada and CFIA *Listeria* policies should refer to the guidance provided by Health Canada on the requirements for Validation of Ready-to-Eat Foods for Changing the Classification of a Category 1 into a Category 2A or 2B Food (Health Canada, 2012).

Establishments must document in detail their procedures for producing RTE products. All processing control measures must be validated and verified. Documentation may include: operational parameters (e.g.: pH, a_w , concentration of antimicrobial agents, etc.), cook temperatures, oven/equipment settings, operational sanitation information, employee product handling procedures, and maintenance records on RTE lines and equipment. This

information should enable early detection of developing problems and help identify products that could be involved if there is a process control failure.

It is recommended that all establishments implement a monitoring program to ensure that processes and procedures for the control of *Lm* are consistently applied and are effective. This may include: visual inspections, observations, tracking chemical use, monitoring records and reviewing cleaning charts, and food safety audits.

The processing control measures and post-processing interventions could be designated as CCPs in HACCP plans, complete with critical limits, monitoring and verification steps and deviation procedures.

It may also be necessary to perform a challenge study to determine the adequacy of control measures in a process. This involves inoculating the target organism (e.g.: *Lm*) into a product to determine the effect of control measures such as a post-lethality treatment or antimicrobial agent or process, on the survival and growth of the organism. Challenge studies are performed in an offsite laboratory setting and can provide valuable information regarding the growth or survival of *Lm* under reasonably foreseeable conditions. Health Canada has published a document to provide advice on the design of challenge test studies for *Lm* (Health Canada, 2010a).

In addition to verifying that the process controls within the food safety control system are effective and operating as designed, process control or verification testing of Sanitation Standard Operating Procedures (SSOPs), the processing environment and finished product is also important. Analysis of this information can help RTE food processors:

- identify critical sanitation points,
- detect changing patterns of contamination,
- assess the continuing performance of a food safety control system, and
- ensure corrective actions are implemented before microbiological criteria are exceeded (Codex Alimentarius, 2009).

Section 3: Sanitation Practices

3.1. Introduction

Control of *Lm* is a challenge to a processing plant's sanitation program. The pathogen can grow in a damp environment, attach to surfaces that come in contact with foods, establish a niche or harbourage site and form biofilms. Any *Lm* in the RTE processing environment must be destroyed to prevent build-up and exposure of finished meat products.

An effective sanitation program requires:

- a structured approach;
- well-trained personnel, time and patience;
- meticulous attention to sequence and thoroughness of procedures; and
- regular teardown and deep cleaning of processing equipment.

Proper and effective sanitation involves both cleaning and sanitizing, and verifying that the cleaning and sanitizing are effective. This involves the following:

- Development of sanitation standard operating procedures (SSOPs) — Each establishment must develop a written SSOP that describes all sanitation procedures that will be performed each day, before, during and after operations with specific frequencies, cleaning processes and responsible persons.
- Implementation of SSOPs — All preoperational procedures identified in the SSOP must be done daily, before processing operations start. Each procedure must be performed at the specified frequency and must be monitored daily.
- Maintenance of SSOPs — Each establishment must routinely determine if the written SSOP is still effective in preventing product contamination.

This section on the sanitation best practices includes general cleaning and sanitation procedures, special sanitation procedures and cleaning methods, frequency of cleaning, and verification of the effectiveness of the sanitation program. The risk of listeriosis appears to be at its highest when virulent strains of *Lm* become established in the RTE products processing environments. Bacterial harbourage and biofilm formation are two important factors that directly impact the success of any sanitation process and are addressed at the end of this section.

3.2. General cleaning and sanitation procedures

To achieve an effective sanitation program, detailed SSOPs should be developed to describe specific methods, types of cleaning/sanitizing solutions to be used and the timeline for performing the tasks on different pieces of equipment and areas. Records should be kept to show that each step has been performed at the correct time. The basic steps required for routine cleaning of equipment and surfaces are outlined below:

- Area preparation
- Scrapping
- Pre-rinse
- Inspection by sanitation crew
- Detergent application and manual scrubbing
- Final rinse
- Final inspection by supervisor or quality assurance personnel
- Flood sanitizing
- Drying

3.2.1. Area preparation

All the products, films and packaging materials, pallets, and inedible bins should be removed from the area to be cleaned. Where there are large amounts of solid waste, it should be removed before water is used in the area. Waste can be collected by a squeegee and then shoveled into waste containers.

- Squeegee scraps on the floor (easier on a dry floor) into piles or into inedible bins
- Empty garbage bins
- Dry clean equipment, conveyor belts, tables, floors to remove meat particles and other debris. Some equipment such as slicers and dicers need to be disassembled so that parts can be cleaned thoroughly.
- Remove and lock up code daters, latex gloves, etc., in their cabinets (don't forget that the cabinets must be emptied and cleaned themselves at least once a week) or in a separate room. Ensure all items are in a sanitary state before storing them away.
- Cover all the water sensitive pieces of equipment with stretch wrap or plastic. These sensitive pieces should be manually cleaned after the final rinse using an alcohol-based cleaner/sanitizer or dry-steam cleaning unit.

3.2.2. Scrapping

If production has left piles of scrap, use a shovel to move the scrap into containers for inedible waste. Manually remove product soils from equipment and place into rework or inedible containers.

3.2.3. Pre-rinse

The purpose of pre-rinsing is to prevent drying of the soil on the surfaces and to loosen and collect small amounts of solid waste. Pre-rinsing should be carried out with potable water supplied from a water hose (water tap) or from a low pressure cleaner.

Water temperature should be adjusted to the types of soil on the specific areas. Cold water or warm water up to 55°C (130°F) for pre-rinsing will be sufficient on most surfaces. Hot water may coagulate proteins and can only be recommended when the dirt types mainly consist of fat. If large amounts of solid waste have been collected by pre-rinsing, it must be removed before application of detergent.

Water pressure is also important in performing pre-rinsing. A high pressure will generally require less water volume to achieve the rinsing operation while reducing the water pressure would require more water. For example, rinsing with 69 bars (1,000 psi) water pressure uses 19 litres per minute (5 US gallons per minute or gpm), compared to up to 45 litres per minute (12 US gpm) with a rinsing water pressure set at 20.7 bars (300 psi). Depending on the nature of the environment to be cleaned and the cleaning equipment available, a balanced combination of pressure and water flow should be chosen. Since hot water is very expensive and effluent charges are based on volume of water to be treated, most plants use a moderate rinse water pressure, typically 40 to 55 bars (600 to 800 psi). Furthermore, a high pressure rinse may produce aerosols that will mobilize bacteria and recontaminate food contact surfaces.

3.2.3.1. Some rinsing best practices

- Use a high pressure trigger gun with 41cm (16") extension and stainless steel nozzle rather than a hand held ball valve and bullet nozzle for rinsing. The nozzle should provide a 5-15 degree spray angle. A gun assembly allows the higher water pressures (rinsing closer to the nozzle where the pressure and mechanical action is the highest) to contact soils and provide a faster more complete rinsing of the soils. An angled nozzle also allows the operator to better direct the soils than a zero degree nozzle. Also an angled nozzle has a wider cutting edge of higher pressure that cleans large areas faster and better than a bullet nozzle which has a much narrower cutting edge and can spread soils in all directions.

- In both cases, use a swivel at the hose end to reduce hand fatigue from turning the hose every time you re-position the gun.
- Rinsing should be from the top down. Start with overhead conveyors or the top of equipment when rinsing. This reduces the need for repetitive rinsing of the same surfaces and saves time and hot water.
- Rinse from one end of the room or line to the other. Ensure you do the floor as you go. If you rinse the equipment first and then go back to do the floor, you may recontaminate the bottom half of the equipment again with soils mobilized by the floor rinsing.
- Work together with your sanitation co-workers. Do not rinse your soils onto the already rinsed floors or equipment.
- Rinse to visual cleanness.
- Clean everything, not just what got visibly dirty from production. The pre-rinse should include:
 - Equipment in the area that was not used by production.
 - Walls, as high as you can reach.
 - Behind and underneath cabinets and equipment that are low to the floor.
 - Drain covers and the drains down to the water in the trap.

3.2.4. Inspection after the pre-rinse by the sanitation crew

To prevent having to go back to do several re-cleans because of pre-operational (pre-op) observations, every sanitation employee should do their own inspection of the equipment they have just pre-rinsed. Look inside, underneath and on top of equipment, etc., before moving to the next step.

3.2.5. Detergent application / manual cleaning / scrubbing

After the pre-rinse, the processing room and equipment should look visibly clean, inside and out. The purpose of applying detergent is to break down and loosen the soil from surfaces and prevent the soil already loosened from re-depositing. This principle will be the same for all detergents but the systems for application of detergents may differ.

A good detergent should include the following characteristics:

- Work with hard water (up to 10 grains of hardness per gallon).
- Clean properly at a concentration of 5 % or less.
- Have enough alkalinity to convert fats and oils into soap (saponify).

- Produce and maintain stable foam for at least 15 min. at a concentration of 2% or less.
- Have at least 600 ppm of available chlorine at a concentration of 2 % total detergent for protein removal.
- Contain surfactants and wetting agents to allow soil penetration and streak-free rinsing.

Application of detergent as foam may be recommended if the rinsing which follows is carried out by a low pressure system. The low pressure system will add less energy to the cleaning system than high pressure cleaning or manual cleaning. It will therefore be necessary to utilize chemical energy as far as possible. Good foam must contain moisture to provide the chemical–soil interface which allows cleaning to occur. Examples of best foam application techniques follow:

- Apply thinly using a 40 degree wide angle foam nozzle to cover up to a meter wide.
- Ensure total coverage inside and outside, on top and underneath.
- Apply foam from the bottom to the top in order to know where it was applied already.
- After foam has been applied and is acting, use a brush to scrub heavily soiled areas.

Detergent may also be applied as gels. Gels are cleaners that get thick at a concentration of 3 %. Their advantage is that they extend contact time with soils without drying and therefore can clean more effectively. They also typically rinse better without streaking. Generally, if gels are allowed to dry, they can be rehydrated and will continue to work and still rinse freely.

3.2.6. Final rinsing

The purpose of final rinsing is to remove the broken down and suspended soil and detergent residues with water. Rinsing can be carried out with potable water under pressure (low or high) or with water and manual force. If pressure systems are used for rinsing, a pressure of 30 bars (425 PSI) and 20 L of water per minute (5 gpm) will give adequate cleaning results, from both hygienic and economic perspectives. The optimal water temperature for rinsing will depend on several criteria, including types of detergent and soil to be removed, as well as the types of surfaces to be cleaned. In nearly all cases, a temperature of 40°C (105°F) will be sufficient. Rinsing operations should be done from one end of the room to the other, doing equipment in the same direction as product flow.

3.2.7. Final sanitation inspection by supervisor or quality assurance personnel

At this step, the establishment should determine whether the cleaning and sanitizing procedures it used were effective. A visual inspection is done to ensure that no visible meat or product residue remains on any of the surfaces, including equipment, walls, floors, and

especially those food contact surfaces and areas that may serve as niches for bacteria. If any residue is noted during final sanitation inspection, the affected areas should be re-cleaned, including pre-rinsing, detergent application, final rinse, and another final inspection step. If done properly, the final sanitation inspection will reduce the need for re-cleaning, and therefore less potential for cross- contamination during the re-cleaning.

During the final inspection, the establishment should also verify that condensation has not built up on ceilings and overheads as a consequence of using large volumes of water in the sanitation process. Condensation that could drip onto food contact surfaces or product should be removed before the final sanitation step and operations start-up. As well, consideration should be given to increasing the air flow through the room(s) to prevent formation of condensation.

3.2.8. Flood sanitizing

Generally, the purpose of the sanitizing step is to destroy microorganisms or reduce their number to a level that will not lead to contamination of food. It is important to use solutions that are compatible with the equipment materials, such as stainless steel or heavy plastic, and to use solutions that are effective in destroying a broad spectrum of microorganisms. Oxidizing sanitizers (e.g.: chlorine, iodine, peracetic acid) or a quaternary ammonium product (quat) are generally more effective in sanitizing meat processing environments. However, oxidizing sanitizers may have corrosive effects over time. It is recommended to spray vulnerable metal with food grade mineral oil after sanitizing.

A rotation of sanitizers should be considered to ensure an effective sanitizing step. When using sanitizers other than oxidizing types, rotating sanitizers will help prevent the development of microorganisms resistant to a particular sanitizer.

The CFIA maintains a list of all the sanitizers that are approved for use in registered meat plants in Canada. This includes sanitizers approved for no-rinse applications, and for incidental contact (CFIA, 2011b).

Application of the sanitizing solution has to be carried out using low pressure and cold water at 10 - 20 °C (50 - 70 °F). This can be achieved with typical tap water with a flow rate of 3 to 5 US gpm and a pressure of 3 - 4 bars (45 to 60 psi). Spraying devices consisting of manual sprayers, sprayers carried on the back, or mobile pressure containers are generally used and set to provide a wide stream that covers all the surfaces.

3.2.9. Drying

Bacteria cannot grow in dry conditions, while bacteria in pooled water that remains within cleaned equipment can be spread to all parts of the equipment when it is turned on. Therefore, all equipment in, and RTE processing facilities themselves should be thoroughly dried after sanitizing. Drying can be accomplished by mopping all standing water from equipment, fixtures, floors and walls, then operating the air conditioning system of the facility to evaporate and remove water remaining as films or droplets and to dry the insides of equipment. Maintaining dry conditions during processing is also effective for inhibiting growth and spread of bacteria, including *Lm*.

3.3. Special sanitation procedures and cleaning methods

3.3.1. Operational sanitation

These are established procedures that describe the daily, routine sanitary procedures that will be conducted during operations to prevent product contamination. Established procedures for operational sanitation must result in a sanitary environment for preparing, storing, or handling any meat product. Established procedures during operations might include, where applicable:

- Equipment and utensil cleaning/sanitizing/disinfecting during production, as appropriate, at breaks, between shifts, and at mid-shift cleanup, in a manner that will prevent cross-contamination.
- Procedures for employee hygiene, such as cleanliness of outer garments and gloves, hair restraints, hand washing, health, etc.
- Product handling in raw and in cooked product areas.

It is generally recommended to use alcohol-based non-aqueous sanitizers, usually with quaternary ammoniums and organic acids with the following specific applications:

- Before production starts, during breaks, lunch times and shift changes, on all food contact surfaces.
- During production for production workers' gloves and bare hands.
- Where a wet clean and sanitizing is not possible or desirable.
- By quality assurance personnel for hands and food contact surface during online sampling.
- On water-sensitive equipment like scales, touch pads, control buttons, knobs and switches.
- Outside and inside (not directly on electronics) electrical panels.

Sometimes equipment is finished being used before the production shift ends. If possible, the equipment should be removed from the RTE area or sprayed with an alcohol-based product to help prevent soils from drying on the equipment and making it harder to clean the equipment hours later.

3.3.2. Double sanitizing or shock sanitizing

It is sometimes recommended to double sanitize. This means using a higher than normal concentration of sanitizer to flood-sanitize an area and/or piece of equipment, and then follow up immediately or just before production starts with a re-sanitizing of the same surfaces with the normal no-rinse sanitizer concentration. This procedure is most often used in the following situations:

- When there is construction in the building and dust in the air.
- After weekends when there has been intensive maintenance work done.
- When equipment has been deep cleaned for the first time.
- In the warmer months when room temperatures are difficult to maintain below 10°C (50°F) and the humidity is high.
- If production is stopped for a period that may favour biofilm build up, e.g. after a long weekend.

3.3.3. Clean-in-place (CIP)

CIP cleaning is a method of cleaning the interior surfaces of pipes, vessels, tanks, spiral freezers, processing equipment and associated fittings without disassembly. The benefit to industries that use CIP is that the cleaning is faster, less labour intensive and more repeatable, and poses less chemical exposure risk to employees.

CIP cleaning uses a chemical/water reservoir that is heated and then pumped through the equipment or apparatus, often in a continuous loop, to clean the inner surfaces. Depending on soil load and process geometry, the CIP design principle delivers one of the following:

- highly turbulent, high flow-rate solution to effect good cleaning (applies to pipe circuits and some filling equipment);
- solution as a low-energy spray to fully wet the surface (applies to lightly soiled vessels where a static spray ball may be used); or
- a high energy impinging spray (applies to highly soiled or large diameter vessels where a dynamic spray device may be used).

3.3.4. Clean-out-of-place

Clean-out-of-place cleaning uses a tank containing a hot chemical solution that is recirculated at high volume and low pressure to clean parts, etc., placed in the tank. This method of cleaning is very efficient and fast if set up properly. Significant savings in water, energy, labour, and chemical are realized by using this system. The heavy flow of water and its weight moving over soiled parts scrubs off the most stubborn soils and penetrates even the deepest hidden crevasses inside parts. It is a very efficient and effective way to clean the following:

- Pipes
- Buggies
- Mats and stands
- Garbage bins and pails
- Utensils and shovels
- Cutting boards
- Belts of all materials
- Internal equipment parts, rollers, etc.

When using a clean-out-of-place tank, be careful when cleaning soft metals. The chemical most often used is a caustic based product. Therefore, add the soft metals to the Clean-out-of-place tank for a few minutes only. Then remove and rinse immediately.

Note: More specific instructions for cleaning different types of materials may be available from the chemical suppliers or manufacturers.

3.3.5. Steam cleaning

The use of steam cleaning units is expanding in RTE plants. The benefit of this method is the ability to clean, loosen soils and kill bacteria with heat treatment. This is a slow process and areas cleaned at one time are small. Therefore, it is a specialized tool best suited for the following cleaning tasks:

- Electrical panels (Caution: Consult maintenance and the manufacturer);
- Heavy dried on soils found deep inside equipment;
- Killing bacteria suspected to be inside or underneath equipment parts that do not come apart; and
- Gaskets glued onto equipment.

The steam cleaner can also be used together with chemicals (mostly foam cleaners or caustics) for very tough-to-clean soils. Consult your chemical supplier(s) for recommendations on which chemicals to use.

3.3.6. Heat treatment

Note: warning: talk to your equipment manufacturer first!

This method has sometimes been used for cleaning and sanitizing as well. On difficult to access equipment, parts can be placed inside an oven or smoke house and heated to temperatures approved by the equipment supplier using wet bulb (steam). The idea is to raise the temperature of the equipment and all internal parts to a temperature high enough to kill all bacteria that are hidden inside the equipment. This is not a normal practice and typically is used only if bacterial counts do not decrease or if the harbourage area cannot be accessed by disassembly. Heat treatment is typically used primarily on equipment similar to wiener peelers and slicer parts among others.

The drawbacks of this method include:

- Using smokehouse capacity;
- Can be hard on metals and plastics; and
- Electronic components may be damaged.

3.4. Cleaning frequencies

Listed below are recommended frequencies for cleaning and sanitizing of processing equipment and the plant environment. The frequencies should be adjusted according to the specific operating conditions in the establishment and the results of ongoing microbiological monitoring of sanitation effectiveness.

- a. Daily:** All processing equipment, floors and drains, waste containers and storage areas
- b. Weekly:** Walls
- c. Weekly/monthly, as appropriate:** Condensate drip, coolers, loading docks, inside equipment harbourage areas
- d. Quarterly:** Cooling units and overheads
- e. Annually:** Freezers

3.5. Verification of sanitation effectiveness

Establishments should verify the effectiveness of their sanitation program by testing food contact surfaces and other relevant environmental surfaces, as described in the next section of this document, Section 4 Environmental and Product Testing.

3.6. Bacteria harbourage and biofilm formation

These are two different but very important sources of bacterial contamination commonly found in food plants. Both take time to develop and are often difficult to find and difficult to remove. They may take months or even years to build to a level where bacteria start to seep out and contaminate food contact surfaces or products during production, although under ideal conditions they can develop in a matter of a few days.

3.6.1. Harbourage

Harbourage sites are specific areas where *Lm* can survive, multiply and potentially contaminate food. They are most dangerous when they develop on or near food contact surface or deep within processing equipment. Harbourage sites provide conditions necessary for microbial growth (nutrients in the form of food residues, humidity, and suitable temperature). They usually develop in difficult to clean and sanitize places, and may be easily overlooked during day-to-day sanitation operations. Steps for identifying potential harbourage of *Lspp* include reviewing literature, physically inspecting processing equipment, and conducting microbiological surveys within the food plant environment. Trend analysis of microbiological testing results can also help identify potential harbourage sites (see Section 4.10 Data/Trend analysis guidelines). Past in-plant surveys have found *Lspp* in the following locations (Ahamad and Marth, 1990; Bernard and Sveum, 1994), many of which could become harbourage sites if not properly cleaned and sanitized:

- Floor drain systems and soil around drains;
- Cleaning aids such as brushes, sponges, etc.;
- Product and/or equipment wash areas;
- Walls and ceilings that may be wet or have absorbed enough water to support bacterial growth;
- Damaged equipment, cracks and crevices, hollow conveyor rollers;
- On/off control switches;
- Open bearings within equipment, such as slicers; and
- Standing water in production areas.

The most serious harbourage sites are located deep within processing equipment. They can develop there, unseen, over extended periods and go undetected until downstream test results provide a clue to their existence or an investigation into a human listeriosis case or outbreak is traced to RTE meat products that were manufactured with the contaminated equipment.

Some effective ways to find and correct harbourage sites in processing equipment are presented in Appendix 2.

3.6.2. Biofilm

Biofilms may be defined as communities of bacterial cells that a) adhere to each other and to surfaces, and b) are surrounded, held together and protected by glue-like materials (polysaccharides) that they produce. Biofilms can develop on a variety of wet or moist food processing surfaces, including metals, glass, plastics and rubber that are not completely cleaned or not cleaned often enough (Fatimi and Frank, 1999; Pitchiah *et al.*, 2008). They can be formed by a single species or multiple species of bacteria, other microorganisms, debris and corrosion products. Biofilms can be extremely difficult to remove by normal cleaning and sanitizing procedures and reduce the effectiveness of many conventional sanitizers.

Biofilms are a concern in the meat processing environment because they may act as reservoirs for *Lm* and other microbes and result in product contamination. Prevention of biofilm formation may be accomplished through the following strategies (Sofos, 2009):

- Appropriate cleaning and sanitation programs;
- Combination of proper cleaning and sanitation agents, adequate exposure/contact time and proper temperature; and
- Extensive scrubbing to achieve a complete removal of biofilms.
- It is important to note that drying of surfaces will also help to prevent biofilm formation.

To confirm the presence of a biofilm, locate a suspect site and swab the site after conventional cleaning. Slightly scratch or scrape the surface that has been swabbed using a hard plastic or stainless steel pointed utensil like a knife tip. Swab the surface again and the knife tip and compare the bacteriology results. If the first swab has a low bacterial count and the second ones are higher, then the presence of a biofilm at that location is likely.

The following are some of the common biofilm locations in meat processing establishments: Slicers, packaging equipment, conveyors, dicers, blenders, hand tools, gloves, aprons, spiral freezers, containers, bins, baskets, equipment framework, floors, sinks, inside hoses, sponges, brushes, floor scrubbers, trolleys, fork lifts, condensate, carts,

gaskets, walls, roller guards, ice makers, motor housings, mops, tow motors, rubber seals around doors, on/off switches, inside air lines, standing water, scrapers, inside hollow implements, trash cans, condensate drip pans, lube tracks, HVAC (heating, ventilating and air conditioning) systems and of course drains!

The composition and design of surface materials can influence the ease and speed with which biofilms can form. In experiments conducted by Pitchiah *et al.* (2008), *Lm* accumulated more quickly on surfaces made from acetal, polyurethane and polypropylene than those made from stainless steel. Higher numbers were found within two days, demonstrating the potential for biofilms to develop over a weekend on the more vulnerable materials. However, given sufficient time, only 3-4 days in these experiments, the results showed that biofilms could develop on any of the surfaces evaluated, including the different forms of stainless steel. Generally surfaces with greater amounts of interconnecting material (e.g.: interlocking parts) and lower mesh counts can be more prone to bacterial attachment and biofilm formation. However, they could develop on any type of surface that has not been properly cleaned and sanitized (Pitchiah *et al.*, 2008).

Since biofilms can be difficult to detect and challenging to remove, the best approach is to focus on prevention. The steps listed below should be helpful in that regard.

- When purchasing new or replacement equipment, especially equipment with food contact surfaces, design specifications should include:
 - Smooth, easy to clean surface materials;
 - Minimal interconnecting or interlocking parts; and
 - In the case of conveyor belts, a relatively high percent open mesh to reduce the surface area available for bacterial attachment or the use of string- or spaghetti-type belts, which can be cleaned while running or when removed.
- Daily sanitation procedures should be designed around the following critical steps:
 - dry cleaning;
 - pre-rinsing;
 - application of a detergent with vigorous scrubbing;
 - rinsing;
 - sanitizing; and
 - air drying.
- Use careful visual examination under strong lighting, including oblique views, and microbiological testing to detect biofilms in the earliest stages of formation.
- Culture suspect surfaces with the scratch and swab method described above.
- Perform additional cleaning and sanitizing procedures before resuming operations after weekends, especially long weekends and other significant periods of downtime.
- Trend analysis of microbiological testing results can also help identify potential biofilm sites (see Section 4.10. Data/Trend analysis guidelines).

Section 4: Environment and Product Testing

4.1. Introduction

The primary purpose of environmental and product testing is to verify the effectiveness of measures in place to control the pathogen, including corrective actions, and to verify the absence of detectable levels of *Lm* in Category 1 finished products or the presence of no more than 100 CFU/g in Category 2 products.

For environmental testing, sampling both food contact surface and non-food contact surface enables a more complete understanding of the effectiveness of the *Listeria* control program within the plant and the potential for contamination of finished product, as opposed to testing food contact surface only. Testing for *Lspp* and reacting to positive results as if they reflected the presence of *Lm* provides a more sensitive and more cost-effective control program than would testing for *Lm* alone. If *Lspp* are present, there is a higher probability that *Lm* could be present (Tompkin, 2002). An important advantage of environmental testing is that it is nondestructive and can be repeated over and over to observe trends that may provide an early indication of potential problems. Sampling of non-food contact surface provides the opportunity to detect and eliminate contamination from the processing environment before it reaches food contact surfaces and finished products.

It is particularly important to look for trends in the frequency and/or locations of the positive results. While each positive finding must be addressed, the greatest value comes from observing the trends and detecting patterns that will facilitate the identification and elimination of sources and root causes of contamination.

4.2. Lot definition

The definition of a product lot is relevant to both environmental and product testing. When testing either food contact surface or products, all finished products manufactured on the line being sampled should be held until the results are known. Having a precise lot definition facilitates the identification and control of the products being held and their ensuing disposition. It also facilitates the tracking and recovery of product in the event of a subsequent need to recall or withdraw certain products from the marketplace.

A product lot may be defined as all RTE product packaged between two complete sanitation procedures.

- a. It is highly recommended to perform a complete sanitation on a daily basis. Lots would then correspond to specific days of production with a maximum of 2 shifts and a 3rd shift for sanitation.

- b. Therefore, lots placed on hold for *Lm* testing would all bear the same best before date, allowing easier lot traceability.
- c. Within a day's production, product lots can be subdivided by production line, providing all equipment used to handle, process (e.g.: slice) and package the product is dedicated to the line.

4.3. Environmental sampling plan for food contact surface and non-food contact surface

The testing program must be designed to detect any *Lspp* that may be present, i.e. to test-to-find, to enable appropriate corrective actions to be taken before the contamination can develop into a more serious problem. This can be accomplished by dividing the plant into the zones, which start with food contact surface and fan out in decreasing proximity to the food contact surface (Kornacki, 2007). The terms "zone" and "level" can be used interchangeably and the choice is up to the company. For the sake of simplicity, within this document only the term "zone" is used.

Zone 1

Food contact surfaces: any surface or object that comes into direct contact with the RTE meat product, such as slicer blades, conveyors, peelers, tables, utensils, trucks, brine chill, gloves, aprons, etc.

Zone 2

Non-food contact surfaces near food contact surface, including exterior surfaces of equipment, control panels, switches, framework/housings, guides, shields, guards, rollers, etc., and non-food contact surface that could spread bacteria to food contact surface, such as refrigeration units, blowers, etc.

Zone 3

More distant non-food contact surface within the RTE processing room between the point of thermal processing (or other lethality processing) and the packaging area, such as phones, jiggers, forklifts, floors, drains, walls, overheads (lights, ceiling, drip pans, piping), etc.

Zone 4

Non-food contact surface outside the RTE production room(s), such as employee change rooms, cafeteria, hallways, drains, etc.

More comprehensive lists of examples of food contact surface and non-food contact surface where *Lspp* may be present are provided in Appendix 3.

In designing the sampling plan, emphasis should be placed on verifying absence of contamination on food contact surface, i.e. Zone 1 sampling, followed by decreasing numbers of samples from Zones 2, 3 and 4, respectively. See Section 4.3.2., below, for guidance on sample numbers and their distribution across the zones.

4.3.1. Environmental sampling procedure

Note: Additional guidance on environmental sampling can be found in the Health Canada Compendium of Analytical Methods – MFLP-41 (Health Canada, 2010b).

4.3.1.1. Tools required

- Carrying tub (dedicated for RTE areas)
- Spray bottle with sanitizing solution
- Sterile sponges or swabs
- Sterile sample bags
- Sterile gloves
- D/E Neutralizing broth (or other buffer solution – must be appropriate to the testing method to be used – check with lab)
- Report/swab sheets
- Clean hook (to lift the drain grate)

4.3.1.2. Sponge/Swab types

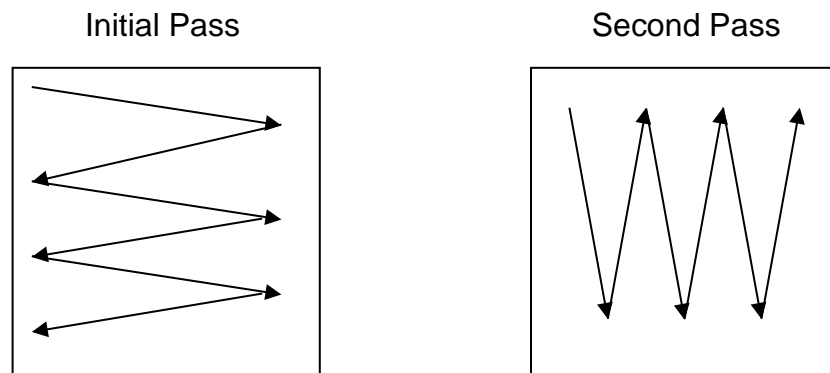
Sponges can range from SpongeSicles™ to pre-moistened (hydrated) sponges to dehydrated sponges to which a buffer solution is added prior to sampling. Further, the buffer solution used with the sponge should be specific to the methodology chosen for the analysis and able to neutralize the detergent and sanitizer used in the facility (Health Canada, 2010b). Sponges may be mounted on a stick to reduce the likelihood of contamination; otherwise, sterile gloves must be worn to handle and manipulate them.

Swabs can range from pre-moistened swabs to dehydrated swabs to which a buffer solution is added prior to sampling.

Sponges are preferred for most surfaces to maximize the surface area sampled and the efficiency of *Lspp* recovery. Commercially available ready-to-use sponges may be more cost-effective than other types because of lower labour costs and reduced risk of pre-sampling contamination (Kovacevic *et al.*, 2009). Swabs are more appropriate for sampling smaller surfaces and difficult to reach areas (e.g.: crevices, screws, slots, cracks, etc.).

4.3.1.3. Sponge/Swab area

The target sample area should dictate whether sponges or swabs are used (see Section 4.3.1.2., above). This information should be reviewed prior to proceeding with sampling. Generally, a sponge sample should cover 900 cm² (e.g.: 30 cm x 30 cm) whenever possible, and a swab sample should represent a 10 cm x 10 cm (100 cm²) area, or the entire area for smaller surfaces and for crevices, slots, etc. Ensure good coverage by slightly overlapping each successive pass of the sponge/swab. Once the first pass is complete, rotate the direction of swiping 90° and repeat, as illustrated below.



4.3.1.4. Sponging/Swabbing procedure

Prior to starting the sampling procedure, review all test sites and determine the sampling order to ensure that Zone 1 sites for all lines are all sampled first (generally at $T \geq 3$ hours, i.e. 3 hours or more after start of production), followed by all Zone 2 sites. All Zone 3 and Zone 4 sites are to be sampled after Zone 1 and Zone 2 sites are sampled on all lines.

Drains are sampled last. The drains in production areas should be sampled before drains in coolers or other areas. Zone 3 drain samples should be taken in the following manner:

- Using a brisk scrubbing motion, wipe the outer grate of the drain with the sponge.
- Lift the grate and wipe the outer edges and underside of the grate (some drains may require a clean/sterile hook to lift the grate).
- Place the grate down on a disposable plastic liner and remove the drain basket.
- Wipe the top lip and underside lip of the basket. If a sanitizing puck or ring is present, be very careful to avoid contact with the sanitizing puck or ring. Do NOT sample the bottom or sides of the basket if a sanitizer is present.
- Put the basket aside on a disposable plastic liner.
- Wipe the inside edges of the drain itself as far as feasible.

4.3.2. Frequency and numbers of environmental samplings

Previous results from environmental monitoring at each processing plant, as well as the other factors listed below in Section 4.3.2.4., should influence the frequency and number of samples collected. The following distribution across zones can be used as a guide to determine appropriate sample numbers. The percentages can be adjusted as results and circumstances warrant.

- Zone 1 – 40-60% of sponge/swab samples
- Zone 2 – 20-40% of sponge/swab samples
- Zone 3 – 10-20% of sponge/swab samples
- Zone 4 – 0 -10% of sponge/swab samples

4.3.2.1. Scheduling of sampling

The day of the week on which samples are collected should be randomized but all days must be tested alternatively over time. The interval between sampling days should be long enough to allow the results of the previous collection to be reviewed and acted upon, if necessary, before collecting the next set of samples. This will allow the company to adjust procedures in the event of a positive test result.

4.3.2.2. Frequency of sampling

Many establishments should sample each production line at least weekly, with emphasis on food contact surface (Tompkin, 2002). Lower frequencies can be contemplated when sufficient data have been generated to demonstrate that *Lspp* is being well controlled in the RTE processing environment.

The minimum frequencies for food contact surface sampling established by CFIA for fiscal year 2012-2013 (see Section 1.2.3.2.2., Table 3) may be sufficient for RTE meat establishments in which food contact surface contamination is a rare event and only sporadic short-lived contamination is found in Zones 2 and 3. Otherwise, higher frequencies should be implemented until control is verified.

4.3.2.3. Distribution of sampling across zones

Using Zone 1 food contact surface sample numbers as a base and the percentages recommended in Section 4.3.2., above, the numbers of samples that should be collected from Zones 2, 3 and 4 can be calculated. To illustrate, a large volume establishment with five production lines producing Risk Category 1 products with no antimicrobial agent or

post-lethality treatment would be collecting around 50 food contact surface sponge or swab samples per week (assuming 10 per line). This establishment could plan to collect a total of 125 environmental sponge/swab samples from all zones (e.g.: 40% = 50, 100% = 125) with the following distribution:

Zone 1	50 sponge/swab samples per week
Zone 2	38 sponge/swab samples per week (≈30% of 125)
Zone 3	25 sponge/swab samples per week (≈20% of 125)
Zone 4	12 sponge/swab samples per week (≈10% of 125)

The sample numbers may be adjusted within or between Zones 2 - 4 as appropriate to an establishment's previous results and trend analysis and the other circumstances listed in Section 4.3.2.4., upward when contamination is detected and downward when results show that *Lspp* is being well controlled.

Additional guidance on the design of sampling plans and selection of sampling sites is provided in Appendix 4 of this document.

4.3.2.4. Factors to consider with respect to sampling frequency

The following factors should influence the frequency of food contact surface and non-food contact surface sampling and the numbers of sponge or swab samples being collected:

- The age and condition of the processing facility and their effects on the ease of cleaning and sanitizing of all surfaces. Older facilities and operations with maintenance challenges may tend to have more cracks and crevices and difficult-to-clean surfaces, which increase the likelihood of *Lspp* persisting in the environment, often in harbourage sites and/or biofilms. More testing may be needed under such circumstances to detect and eliminate contamination as it occurs.
- When implementing a new operation or during and following new construction or maintenance projects. While *Lspp* is not noted for airborne transmission it can be carried around an establishment on dust particles. Special attention to cleaning and sanitation and verification of effectiveness by frequent sampling are warranted to prevent contamination.
- Previous results from the environmental sampling program. Any positive results on food contact surface or multiple positive findings in Zones 2-3, especially if found in consecutive samplings, should trigger more frequent and intensive sampling to identify the sources and root causes of the contamination.
- The categories of products being produced. Establishments producing only Category 2 products may choose to sample at minimal frequencies and intensity. However, it would be dangerous to develop a tolerance for environmental contamination because repeated

positive results would still leave the establishment vulnerable to regulatory compliance and enforcement actions. In addition, exporting establishments would still have to guard against shipping product contaminated with any level of *Lm* to markets with zero tolerance policies.

- The target consumer population. Establishments manufacturing products intended for consumption by vulnerable populations, such as the residents of health care and senior citizen facilities, must meet the highest standard possible for *Listeria* control. Frequent verification of control by environmental testing would be warranted.

4.3.2.5. Sample size

The number of food contact surface sponges or swabs to be collected from each production line is commonly set at ten, where there is sufficient surface area to warrant that number. Data have shown that when *Listeria* contamination was detected on food contact surface, the distribution was limited and either the level was low or the organism was not widespread across the surfaces being sampled. The data suggested that the higher the numbers of sponges collected, the greater the probability of detecting contaminated surfaces (Tompkin, 2002). Therefore, production lines with more food contact surface area should require a proportionally larger number of sponges per sampling to provide reasonable assurance that contamination will be detected if present.

4.3.2.6. Individual versus composite samples

If affordable, food contact surface (Zone 1) sponge/swab samples should be tested individually in order to expedite the follow-up investigation and the application of corrective measures when one or more samples test positive. Samples from the other zones can generally be tested in composites of up to five sponges/swabs. Decisions on whether or when to test samples in composite or individually can be guided by the likelihood of positive test results, based on previous test results from each zone and the facility's overall record of control. In investigational testing to determine the root cause and eliminate the source of positive findings, all samples should be tested individually.

4.4. Food product sampling plan

It should be noted that finished product testing is not a reliable food safety control measure. It is useful in verifying the absence of significant levels of *Lm* contamination, but may fail to detect unevenly distributed or very low numbers of *Lm*, which, in certain products, could multiply to infective levels under the right conditions of time and temperature.

Nevertheless, sampling of finished products at some frequency should be done to supplement the environmental sampling and verify that the environmental testing program

is sufficiently sensitive and functioning as expected. Experience indicates that sampling RTE food occasionally can detect contamination that is missed by the routine environmental sampling (Tompkin, 2003).

The minimum sampling frequencies established by CFIA for process verification purposes by the operator in fiscal year 2012-13 are displayed in Section 1.2.3.2.2., Table 4. Ordinarily, each sample would comprise a minimum of five sample units, i.e. $n = 5$.

A company may choose to set a higher standard for management of both food safety and business risk by:

- increasing the number of product lots tested at the CFIA frequencies (e.g. at least one product from each production line);
- increasing the frequency of product testing; and/or
- increasing the number of sample units to be collected on each occasion to $n = 10, 20$ or more.

The latter enhancement would offer the considerable advantage of enabling detection of lower numbers of the organism with higher levels of confidence, thereby increasing the probability that contaminated lots could be detected and contained. To illustrate, at sampling rates of $n = 5, 10, 20$ and 60 , there would be a 95% probability of detecting and containing lots with product contamination rates of approximately 45%, 25%, 15% and 5% , respectively (Dahms, 2003).

The International Commission on Microbiological Specifications for Foods (ICMSF) is a useful source of information on the design of risk-based sampling plans for foods (ICMSF, 2011). A concise overview on the design of sampling plans, including statistical aspects can be found on the ICMSF Website (Dahms, 2003).

4.5. Sampling and sample handling

4.5.1. Operator training

Quality assurance personnel designated to collect product and environmental samples must receive regular training and refresher training on sampling procedures.

4.5.2. Representative product sample

The intention is to collect samples that are representative of the lot. Given the uneven distribution of bacteria, specifically pathogens, in meat products, at least five sample units of the same lot should be collected for analysis. For each sample, aseptically collect five

sample units, or the number specified in the establishment's sampling plan, at random from each lot selected for sampling. In the case of five sample units, each one should consist of 150 g of product or one intact unit weighing at least 150 g. The size of each sample unit may vary depending on how many are being collected.

4.5.3. Aseptic product sampling

Every effort should be made to avoid contamination of samples during collection. Use aseptic sampling techniques that include, but are not limited to sanitized sample collection areas, sterilized sampling equipment and sterile gloves. Whenever possible, consumer-ready food should be sampled from the original unopened packages, taking care not to contaminate the food sample.

4.5.4. Product and environmental sample documentation

Sample units must be clearly labelled and identified to permit good traceability. This can be achieved by writing descriptive terms or numbering each sample unit directly on the container or a firmly attached label, making sure that the ink cannot be washed off. Consider taking a digital image of the product.

A lab sample submission form or sampling report should be prepared with relevant details such as time of sampling, sample site, particular observations on packaging, parameters required for testing (e.g.: *Lm* or *Lspp*) and methodology requested. For environmental samples, instructions should be provided on whether the sponges or swabs are to be tested individually or as composites.

4.5.5. Shipping samples

4.5.5.1. Refrigerated foods, environmental samples and dry-cured meats

Refrigerated foods, environmental samples and dry cured meats should be cooled and transported in a cooler with ice packs. The objective is to maintain a temperature between 0°C and 7°C until arrival to the laboratory.

Freezing of these samples (refrigerated or dry cured products and environmental samples) may compromise the analyses and measures should be taken to ensure this does not occur. The samples should be insulated from direct contact with ice packs to avoid freezing.

4.5.5.2. Frozen foods

Frozen foods should arrive at the laboratory frozen and not be allowed to thaw during shipping. Transport samples in a cooler using ice packs or dry ice where necessary.

Note: Air shipments containing dry ice may require special packaging and labelling to comply with Transport Canada's Transportation of Dangerous Goods Regulations. The intended courier or carrier should be consulted in advance to avoid shipping delays.

4.5.5.3. Sponges/Swabs

Place the sponge/swab samples in a cooler with several cold packs and transfer to the lab within 24 hrs. Make sure it is properly closed to avoid leakage during transport. The samples should be insulated from direct contact with ice packs to avoid freezing.

4.5.5.4. Transportation

Collected sample units should be transported to the laboratory as promptly as possible. Most methodologies indicate that the analysis should commence within 24 hours from the time of sampling (Always check the specific method for clarification).

For transportation, all samples must be packed to avoid breakage, spillage or cross-contamination. Where necessary, containers should be protected by additional packaging material. Finished products, raw materials, and environmental samples should be packaged separately or shipped separately to avoid possible cross-contamination.

4.6. Mandated operator sampling of ready-to-eat products

The samples must be submitted to a laboratory accredited by the Standards Council of Canada where they will be tested for *Lm* by an approved method. The methods of analysis used must fall within the laboratory's scope of accreditation, or be scheduled for inclusion in the scope of the next Standards Council of Canada audit.

Methods approved for testing of RTE meat products in registered establishments are listed in Health Canada's Compendium of Analytical Methods (Health Canada, 2011a). The application section of the chosen method must include testing of RTE meat products.

4.7. Mandated operator sampling of food contact surfaces

Routine food contact surface samples should be tested for *Lspp* in accredited laboratories using approved methods.

Follow-up samples must be submitted to an accredited laboratory where they will be tested for *Lspp* by an approved method. The methods of analysis used must fall within the accredited laboratory's scope of accreditation, or be scheduled for inclusion in the scope of the next Standards Council of Canada audit.

Methods approved for testing of food contact surface samples in registered establishments are listed in Health Canada's Compendium of Analytical Methods (Health Canada, 2011a). The application section of the chosen method must include testing of environmental samples.

4.8. Holding product until test results have been received

As a general rule, when food contact surface or finished product samples are collected for testing, all products that could be implicated by a positive test result should be placed on hold until negative results have been received. Decisions on the degree of control required can take into account the likelihood of the test results being positive. Should products be released and subsequently found to have been exposed to or contaminated with *Lm*, the products could be subject to recall. Furthermore, products for which test results are pending are not eligible for export to the US.

4.9. Follow-up on food contact surface positive results (an example of steps to follow)

4.9.1. Communication of results

When positive results are obtained for *Lspp*, by prior arrangement, the microbiology laboratory must immediately notify quality assurance personnel at the establishment, who in turn will notify the production department manager and sanitation supervisor, and the local CFIA Inspector for Zone 1 positives.

If a Zone 1 positive result is obtained, the quality assurance manager will also notify appropriate management personnel and corrective actions will be taken immediately. The affected line will resume production under finished product quarantine for a minimum of 3 consecutive production days.

4.9.2. Quarantine of implicated production

The quality assurance manager will work with the Production Manager to physically identify the finished product quarantined, by use of designated visual signage (i.e., caution tape around the pallet, HOLD tags or other).

4.9.3. Collection of finished product samples for testing (n ≥ 5)

Implicated finished products should be sampled in case product testing will be required.

4.9.4. Environmental swabs for investigational purposes

Investigative swabs should be taken on Zone 1 surfaces as follows: Minimum of 10 T = 0 swabs (after sanitizing, before start of production) and minimum of 10 T ≥ 3 swabs (≥ 3 hours after start of production). Swabs should be collected upstream, downstream, and on the positive site and tested for *Lspp*.

4.9.5. Risk Assessment and action plan

Quality assurance, production and sanitation managers will meet to discuss risk assessment and action plan for corrective action.

4.9.6. Investigational environmental sample results

4.9.6.1. Negative

If all of the investigational test results are negative:

- The finished product placed under quarantine can be released for shipping.
- Follow up on the action plan created during the investigation.

4.9.6.2. Positive

If any of the Zone 1 swabs collected from the previously positive site on 3 consecutive days are positive, the quality assurance manager will immediately:

- Notify the management team and CFIA Inspector. Further investigation will be started (a “Broader and Deeper Seek and Destroy” must be implemented). “Broader and Deeper” refers to:
 - Investigating areas that have not yet been investigated, including Zones 2 and 3.
 - Investigating equipment in a deeper level of disassembly.
 - Challenging cleaning and sanitizing procedures, chemicals, etc.
- Finished product samples collected at Step 4.9.3. will be sent to be tested for *Lm* at an accredited laboratory.
- In order to resume regular production/shipping, the affected line must achieve three consecutive days of negative food contact surface sponge/swab results to verify the effectiveness of the corrective actions.
- Any positive swab result during the three consecutive days of quarantine production will trigger the re-start of the investigational cycle.
- After regular production resumes, enhanced environmental monitoring and attention to GMPs will be implemented.

4.9.7. Follow-up

Within one week after regular production resumes, it is recommended that management conduct a “debrief” to capture lessons learned and update all SOPs as necessary. The lessons learned will be sent to the company’s senior management group.

More detailed guidance on test and hold procedures that could be applied during the course of an investigation into a food contact surface positive result is provided in Appendix 5. Follow-up “Seek and destroy” procedures are described in Appendix 6 of this document.

4.10. Data/Trend analysis guidelines

To gain full value from a *Listeria* sampling program establishments need to organize and review all test results as they become available and, most importantly, examine them in the context of previous test results. Reviewing the results for the previous four to eight samplings would provide a moving window that could help detect patterns and trends over that period, e.g. the past one to two months where sampling is being done weekly. Annual and/or quarterly reviews are also highly recommended because they provide a longer term perspective that could identify previously inapparent problems (Tompkin, 2002). Senior managers should choose to be involved in these reviews, given the importance of effective *Listeria* control to a company’s brand(s) and bottom line.

Establishments sampling at optimal frequencies and levels will quickly generate very large amounts of data. The use of spreadsheets or software written or adapted for this purpose can be used, along with modern quality control and statistical methods, to make the data manageable and to facilitate analysis of the data. Raw and statistical data can be displayed on control charts and other graphical or diagrammatic tools to further facilitate the analysis and interpretation of the data. The objectives are: (1) to verify the effectiveness of the establishment's *Listeria* control program; and (2) to look for patterns or trends in the data, particularly with respect to frequency (timing) and locations of positive food contact surface and non-food contact surface test results. This approach can enable detection and resolution of problems before they can lead to serious consequences (Health Canada, 2011). For example, noting the occurrence of sporadic positives at certain locations may help to identify a contamination transfer point or signal the presence of a nearby harbourage site. As well, the findings can help to redirect sampling efforts to make the sampling and control programs more effective and enable resolution of problems before they become more serious. For examples of data analysis tools, please refer to Appendix 7 of this document.

Appendix 1. Potential sources of *Listeria monocytogenes* in a food processing facility

<p>Potential in-plant product sources of <i>Listeria monocytogenes</i></p>	<ul style="list-style-type: none"> • Raw product and ingredients • Solutions to chill foods (e.g.: brine solutions) • Unclean equipment, exterior of equipment, and unused equipment • Door handles and handles of equipment • Pallets, pallet jacks • Push carts, especially the wheels • Rework • Returned product • Personnel (e.g.: clothing, gloves, boots or direct product contact, flow) • New employees, visitors and contractors
<p>Possible post-lethality food contact surface <i>Listeria monocytogenes</i> contamination</p>	<ul style="list-style-type: none"> • Slicers, dicers, cutting boards, saws, casing peelers, etc • Knives, knife racks, tubs, bowls, platters and utensils • Packaging equipment and materials • Sponges and brushes for cleaning • Tables, shelves and racks, conveyors, belts • Lugs, tubs and containers • Hand tools, gloves, and aprons
<p>Potential reservoirs of <i>Listeria monocytogenes</i></p>	<ul style="list-style-type: none"> • Floors and drains • Standing water (e.g.: condensation drip pans) • Ceilings and overhead pipes • Refrigeration condensation units • Wet insulation (exposed to processing area) • Cleaning tools (sponges, brushes, squeegees) • Overhead rails and trolleys • Maintenance tools/storage (wrenches, screwdrivers, tool box, etc) • Wooden pallets • Forklifts/pallet jacks, motor housings on food processing equipment • Unsealed joints in food preparation areas, such as riveted information tags or plates on equipment • Scales • Food wrapping machines • <input type="checkbox"/>Hoses and nozzles
<p>Other areas where <i>Listeria monocytogenes</i> may be present</p>	<ul style="list-style-type: none"> • Any recess or hollow material: rollers, switch boxes, box cutters, motor housings • Rusted materials: equipment frames, pipes, shelving • Cracked or pitted rubber hoses, door seals • Walls that are cracked, pitted, or covered with inadequately sealed surface panels • Wet floors and standing water • Vacuum/air pressure pumps, lines, and hoses • Ice machines and drain areas under and behind ice machines • Hollow table and/or equipment legs/supports • Trash containers • Air filters • Conveyor drive components • Open bearings • Airborne bacteria or aerosol moisture droplets • Disruptive construction projects • Seams and seals around cooler, freezer and refrigerator doors • Air filters, blowers, vents and fans

(Henning and Cutter, 2001; Codex Alimentarius, 2009).

Appendix 2. Effective ways to find and remove bacterial harbourage sites

Each establishment should have a comprehensive cleaning program in place that assures the cleaning and sanitizing of all processing equipment with the aim of removing all soils and inactivating all bacteria that are on and, most importantly, inside the equipment. The success of finding and eliminating bacterial harbourage within equipment requires a commitment by the company of its maintenance and cleaning resources to complete the intensive equipment disassembly and cleaning programs listed below.

Equipment disassembly and cleaning program:

- **Basic - daily:** This basic equipment disassembly includes removing parts and components that are designed to be removed easily and daily to allow proper sanitation. This includes belts, blades, product grippers, scales, some rollers, shear bars, etc. This may be done by trained production or sanitation employees or maintenance personnel. The procedure is done with the equipment in place on the production floor.
- **Level 1 – Weekly to monthly:** This equipment disassembly is more intensive, is definitely done by maintenance, and can take up to 2 days to complete. It is typically done on weekends and may be carried out in conjunction with preventive maintenance programs, like lubrication, bearing changes, etc. The equipment is dismantled to a great extent with most major components either removed or opened, including inter-liefers, slicing heads, check weighers, rollers, transfer lines, vacuum packaging machines, etc. The equipment is taken apart mainly to allow better exterior cleaning of the parts and access to remote points in the equipment, including electrical boxes, panels, etc. Proper lock-out procedures must be observed for safety.
- **Level 2 – Semi-annually:** This level of equipment disassembly is very extensive and when done the first time is done almost to the frame with all components taken apart. Sequential swabs are done before cleaning and in the same places after cleaning to verify effectiveness. This procedure is done together with major preventive maintenance and should be done with the equipment removed from production. This can take from 3 - 5 days to complete. Basically, after this procedure is done the equipment should look and run like new.
- **Notes and comments on equipment cleaning:** Maintenance staff should be trained to perform the re-assembly of the equipment in a hygienic manner to avoid recontamination. As well, all internal areas of the equipment should be treated with a gel-sanitizer or an alcohol-based sanitizer. This will help maintain sanitary conditions inside the equipment for days and weeks to come.
 - **Swab results:** During disassembly, take sequential total plate count (TPC) and *Lspp* swabs to determine the extent and depth of the contamination, especially during the Level 2 program. When the swab results are received, you will know how deep the contamination was and the potential risk. If a number of sequential swabs from the

latter, deeper phase of the disassembly had no detectable counts, then that part of the disassembly will not need to be done during the next semi-annual disassembly. If *Lspp* was not found during the first cleaning, it may not be necessary to test for *Lspp* during all subsequent cleanings. TPC could be enough to detect contamination and validate sanitation, as well as to provide guidance on the depth to which the next disassembly should be done. However, it would be prudent to include *Lspp* on occasion.

General guidance on equipment disassembly and cleaning

- First, look at the manual that came with the equipment for guidance on how to break down the equipment in the easiest way.
- Contact the equipment manufacturer or distributor and have them come into the plant and demonstrate how to take it apart and where the water sensitive areas are. Take notes and pictures during the demonstration to incorporate into the establishment's maintenance manuals and training materials.
- When there is time and the piece of equipment has already been cleaned normally, work with a mechanic and start disassembly of the equipment. Remember to first lock out the equipment for safety.
- As parts, including guards, conveyor belts, rollers, assemblies, panels, etc., are removed, they expose more of the internal workings of the equipment.
- Take rollers apart; remove belt runners, drive sprockets, TEFC (Totally Enclosed Fan Cooled) fan covers, etc.
- Expose bearings, drive shafts, seals and pistons, etc., as well as slicer heads, check weighers, gripper towers, shear bars, modified atmosphere packaging valve assemblies, etc.
- Look for hollow tubing that has cracked welds, or holes, and find bolted-together parts and their overlaps, spot welding, etc.
- Do not overlook the insides of electrical panels and transformer / control boxes, which are usually located under the mechanical working parts of processing equipment.
- Document the details of the equipment breakdown, recording how and what was disassembled.
- As these parts are removed they will start to reveal soils and potential *Lspp* harbourage areas. For all these areas take micro swabs of the soiled areas. Establish a baseline and review results over time to monitor trends and enable early detection of impending problems, such as declining effectiveness of the cleaning and sanitizing procedures.

- Start to clean the areas and parts of the equipment using a clean-out-of-place tank or manually clean with hoses or with towels and alcohol-based products, depending on the sensitivity of the equipment to water.
- For cleaning sensitive equipment it may be possible to use a dry-steam cleaning unit to clean and sanitize water sensitive parts. This is a time consuming process but can be very effective. This process can also be used to loosen stubborn soils that are hard to access.
- Once the parts are cleaned, re-swab the parts in the same areas that were swabbed when soiled. This will establish the effectiveness of the cleaning and sanitizing step.
- Start the reassembly, taking time to record how long it took to complete the teardown–cleaning–reassembly process for scheduling the next time and for similar pieces of equipment.
- As parts and equipment are reassembled, apply neutral gel cleaner and sanitizer products to the areas for extended sanitizing effect. This will help prevent the re-deposition of soils and harbourage area formation. If this type of product is not available, use the alcohol-based product instead.
- Remember to add this process to the master sanitation schedule. A monthly frequency is recommended until you are confident that soils will not re-deposit within a month. Then move the frequency to two months, etc., until you are comfortable that harbourage does not occur between tear downs and cleanings.
- When the equipment is subsequently subjected to normal cleaning under the daily program, it is recommended to double sanitize for the first two weeks to reduce the risk of loosened harbourage contaminating food contact surface.
- During the normal pre-op swabbing procedure, test at T=0 and T=3 for the first week after the initial deep teardown was done. If *Lspp* is found or total plate count results are higher than expected, there may still be harbourage inside the equipment that was missed and the procedure should be repeated as soon as possible to find and eliminate the residual harbourage.
- Continue the process on all RTE food contact equipment, including slicers, scales, accumulation assemblies, conveyor belt assemblies, check weighers, vacuum pack or MAP pack equipment, peelers, dicers, etc.
- Equipment that is constructed to hygienic design specifications will not harbour detritus, and should be amenable to cleaning treatments that remove all hazardous bacteria, unless parts of the equipment fail or deteriorate. When equipment persistently harbours detritus, consideration should be given to modifying the equipment to enhance its cleanability, or to replacing it with equipment that meets hygienic design specifications.

Appendix 3. Examples of food contact surface and non- food contact surface for environmental sampling

<p>Food contact surfaces where <i>Listeria monocytogenes</i> may be present</p>	<ul style="list-style-type: none"> • Containers (bins, tubs, baskets) • Racks for transporting exposed product • Conveyor scrapers • Peeler apparatus • Spiral freezers/blast freezers • Disassembled slicers, dicers, blenders • Packaging equipment • Sites soiled by food residue • Conveyors • Peelers • Collators • Belts • Gloves, sleeves, aprons (where applicable to direct food contact) • Weighing equipment • Tables • Hoppers • Solutions to chill foods (e.g.: brine solutions)
<p>Non-food contact surfaces where <i>Listeria monocytogenes</i> may be present</p>	<ul style="list-style-type: none"> • Exterior of equipment • Motor housings on food processing equipment • Unsealed joints in food preparation areas, such as riveted information tags or plates on equipment • Bolted metal-to-metal surfaces • Improperly welded metal surfaces with gaps • Door handles, plastic door curtains and handles of equipment • Pallets, pallet jacks, forklifts • Push carts, especially the wheels • Personnel (e.g.: clothing, gloves, boots not contacting product) • Floors and drains • Standing water (e.g.: condensation drip pans) • Walls, ceilings and overhead pipes, rails and trolleys • Refrigeration condensation units • Insulation (exposed to processing area) • Cleaning tools (sponges, brushes, squeegees) • Maintenance tools/storage (wrenches, screwdrivers, tool box, etc) • Scales • Food wrapping machines • Hoses and nozzles • Vacuum/air pressure pumps, lines, and hoses • Any recess or hollow material: rollers, switch boxes, box cutters, motor housings • Equipment frames, pipes, shelving • Rubber hoses, door seals • Ice machines and drain areas under and behind ice machines • Hollow table and/or equipment legs/supports • Trash containers • Air filters • Open bearings • Seams and seals around cooler, freezer and refrigerator doors • Air filters, blowers, vents and fans

(Henning and Cutter, 2001; Codex Alimentarius, 2009; Health Canada, 2010b)

Appendix 4. Guidelines for environmental sampling plans⁸

Biased, not random:

- Focused on finding the problem.
- The location of positives may be more important than their number. Focus first on areas that are repeatedly positive and those where traffic could transfer contamination to other sites, i.e. transfer points. Caution: Sporadic positive sites should not be taken lightly either. Detachment of *Lm* from biofilms or harbourage sites may occur sporadically, particularly during formative stages.
- Use indicator sites that are more likely to be positive than an average site.
- Sample higher risk areas (e.g.: Zone 1) at a higher rate than lower risk areas.
- Frequently include nonspecific sites which are open for the investigator to try to find problems (take 5 samples every other week of potential problem areas).

Dynamic, not static:

- As process control procedures and practices evolve sites may change. If this happens the plan may be changed. Sites that are consistently negative can be replaced by sites that have been tested less frequently in order to broaden coverage of the processing environment.
- Corrective actions taken, particularly when process redesign is involved, should lead to changes to the sampling plan.
- Seasonality may prompt changes in the sampling plans.
- Production load or volume may cause plan change.
- An approach that could be considered is to create lists of all potential sampling sites in each zone. Select a set of sites to be tested on one occasion based on previous results or randomly. At each subsequent sampling, replace a percentage of the sites so that all potential sites will be tested within a reasonable period. Continue to cycle consistently negative sites and persistently test positive sites and their immediate surroundings until they too are consistently negative.

⁸ Drawn from a *Listeria* Control Workshop sponsored by the American Meat Institute and the Canadian Meat Council

Appendix 5. Example scenario for positive *listeria* species result from food contact surface of a category 1 production line

Notes:

- (1) Assumes utilizing a screening method with the first notification of a presumptive positive result for *Lspp* coming 3 days from the time the swab was taken.
- (2) Decisions on when to hold product pending receipt of test results should take previous experience into account and the likelihood of the test results being positive. During the early stages of a testing program and in establishments that have found evidence of *Lspp* contamination in the recent past or that have construction or renovation projects in progress, the default position should be to hold products that would be implicated by a positive test result until negative results have been received. Establishments with a well-founded high degree of confidence that the results will be negative may contemplate shipping product before the test results are known.

Day 0 - Sampling Event #1:

- Environmental swab taken on a Zone 1 – direct food contact surface
- Sampling areas and production lot recorded
- Holding product is recommended if feasible in light of shelf-life and capacity to retain product.

Day 1:

- Holding product from Day 1 production on the same line is recommended if feasible in light of shelf-life and capacity to retain product.

Day 2:

- Holding product from Day 2 production on the same line is recommended if feasible in light of shelf-life and capacity to retain product.

Day 3 - Upon receipt of results:

NEGATIVE

- All product that may have been on hold can be shipped under normal protocol;
- Continue with routine sampling.

PRESUMPTIVE POSITIVE

- Place product under investigation and hold until confirmed results are received from the laboratory (could be 2-3 days from the initial presumptive positive results);
- Communicate with the “scheduler” (production personnel) and other levels of staff if needed, that the affected line will resume production under investigation;
- Commence investigation by gathering information as it relates to the potentially affected area;
- Verify ability to locate product from Day 0 - 3 and collect product samples from each respective day’s production on that line (n ≥ 5) and place samples on hold;
- Deep clean the equipment where the presumptive positive result was found, aggressively clean the affected line and area, and conduct regular sanitation in all other areas of the plant. Intensify sampling on lines and area adjacent to the positive location.

Day 4 - First day of production under investigation:

- Start-up the line as per normal procedures with enhanced monitoring of sanitation effectiveness, GMP compliance, and operational practices;
- Pack off all production on that line and place product under investigation until confirmed results are received from the laboratory. Hold product pending satisfactory results.

Day 5 - Second day of production under investigation:

NEGATIVE

- All products under investigation are shipped under normal protocol.

RESULTS PENDING

- If result is still PENDING further confirmation, start-up the line as per normal procedures with enhanced monitoring of sanitation effectiveness, GMP compliance, and operational practices;
- Pack off all production on that line and place product under investigation until confirmed results are received from the lab. Hold product pending satisfactory results from the laboratory.

Day 6 - Third day of production under investigation:

NEGATIVE

- All products under investigation are shipped under normal protocol.

CONFIRMED POSITIVE for *Listeria* species

- Pack off all production on that line and shut down the affected line at the end of the production day. Notify CFIA Inspection staff of the positive result;
- Deep clean the equipment where the positive result was found, aggressively clean the affected line and area, and conduct regular sanitation in all other areas of the plant;
- Take investigative swabs and product samples during “Seek and Destroy” (investigation) activities to support root cause analysis;
- Inform the “scheduler” (production personnel) and other key personnel if needed, that the affected line will resume production under quarantine.

Day 7 Start of Sampling Event #2 (First day of quarantine production):

- Start-up the line as per normal procedures with enhanced monitoring of sanitation effectiveness, GMP compliance, and operational practices
- Take 10 T = 0 and 10 T ≥ 3 hours swabs upstream, downstream, and on the positive site (All Zone 1 sites).
- Collect finished product samples from the line - sample size is dependent on the company’s risk assessment of the situation (minimum n = 5, maximum n = 60).
- Place signage to identify quarantined product (yellow caution tape, HOLD tags, etc.).
- Clean and sanitize the line at the end of production as per daily SSOPs.
- Test the affected food contact surface swabs/sponges for *Lspp* and analyze individually (no composites).

Day 8 and beyond

- On subsequent days continue to gather finished product samples but do not perform testing until the food contact surface swab results (Day 7) are known and confirmed positive for *Lspp*.
- Test product samples from the day of the second sampling event (Day 7) for *Lm*.
- Repeat hold and test protocol until three consecutive days of negative results are achieved.

Appendix 6. Example of an approach to investigate positive test results to identify and eliminate the source(s) of contamination

1) Seek and Destroy is executed; however, only the applicable sections of the Seek and Destroy Audit are completed based on the location of the positive finding.

- For Zones 2 and 3: The plant management team members will execute the “Seek and Destroy” investigation as a group.
- For Zone 4: The quality assurance team will execute the “Seek and Destroy” focusing on General Cleaning Practices and Traffic Flow.
- In both scenarios, the investigating team should include an experienced microbiologist who has practical knowledge of the plant operations.
- The positive site must be tested for three consecutive days in order to verify that the corrective actions were effective. This is to be done regardless of the zone designation of the positive site.

2) Planning and Information gathering using:

- The history of positives and history of adjacent areas.
- Production and maintenance logs.
- Non-routine activity such as: excessive downtime, maintenance activity, or any other non-routine activity.
- Interview employees.
- From the point when production is finished, isolate the affected line and area much like a “crime scene”. Observe the line and equipment looking for material buildup on and near the positive site. Take pictures and samples of “points of interest” before dry pickup is started.
- During sanitation, observe the dismantling process and again look for buildup that was not apparent when the line was assembled. Again, take pictures and gather samples. Take investigative environmental samples. In this situation, swabs may be used to sample cracks, crevices, seams, and joints, etc., where a sponge may not be effective. There is no preset number of investigative swabs/sponges to take. Take as many as there are “points of interest”. Look at ways to clean potential growth niches by: a) using clean-out-of-place methods; b) dismantling to a deeper level of teardown; or c) steam cleaning or cooking the particular piece of equipment (Refer to Section 3 Sanitation for additional guidance).
- If material buildup is observed, inform the sanitation crew who will remediate the positive site and the adjacent areas.

3) Seek (Root Cause Analysis)

- Review the data and records available from the point of exiting thermal processing to the application of primary packaging. Drains should not be considered sources but rather, collection points, i.e. what is contaminating the drain? The drain could be source if a backup is observed and the drain is located in an area where traffic could come in contact with the contents of the drain and transfer the contamination elsewhere.
- Develop hypotheses (what is the root cause or source of the contamination) keeping in mind the following scenarios:
 - Sporadic – random incidental contamination.
 - Event Driven – construction, downtime maintenance, non-daily cleaning.
 - Systemic – harbourage and niche points, process step (e.g.: contaminated brine).
- Determine what additional data must be obtained to eliminate or confirm each hypothesis.
- Develop a sampling plan. Since the line is in quarantine, there should be no restrictions in the number of swabs and the zones from which swabs are taken. The sampling plan should address the possibility of a growth niche or a transfer points.
- Develop an action plan, i.e. immediate changes to mitigate further potential for contamination during quarantine production.

4) Destroy (Corrective Action)

- Implement corrective actions (immediate changes) with the intent to continue to make significant changes to the situation in order to mitigate further risk while the line is in quarantine.
- Monitor sanitation daily to ensure SSOP's are being followed.
- Observe pre-op with a view to determine whether there are obvious deviations in the sanitation process, i.e. possible growth niches.
- Maintain a GMP monitor on the affected line where the positive was found. (Mandatory for a Level 1, best practice for Levels 2 and 3). Observe people behavior and traffic to identify potential transfer points.

5) After the “Seek and Destroy” procedure is complete

- Quality assurance personnel must document the Seek and Destroy Event: Background, Items completed during the Seek and Destroy, Outcome – lessons learned and follow-up items.
- Debrief on the changes made and potential longer term hazards/risks.
- If multiple changes are made, develop an action plan to assess which changes are most effective and should be sustained.
- Reassess and adjust HACCP system accordingly.

Appendix 7. Data analysis tools

From an American Meat Institute/Canadian Meat Council *Listeria* workshop:

- Must recognize the biased, non-random, variable and dynamic nature of the sampling plan generating the data.
- Traditional tools for statistical analysis (mean, standard deviation, correlation coefficient, etc.) can often mislead as opposed to appropriately directing the investigation team.
- The best statistical tool is often a Pareto analysis, which ranks grouped data.

1. Preparation for data analysis

Record and summarize all test results in a spreadsheet or similar tool, like the one illustrated in Figure 3.

Figure 3. Spreadsheet display of data

Provide management reports				
Summary Contact Surfaces				
Operation	Line	n	nL+	%L+
Slicing	1	520	9	1.7 %
	2	520	5	1.0 %
Franks	Brine	104	0	0.0 %
	1	520	0	0.0 %
	2	520	0	0.0 %
IQF		624	6	1.0 %
	Total	2808	20	0.7 %

2. Use plant floor map to display positive environmental results

On the drawing of the floor map of your processing facility, like the one illustrated below in Figure 4, identify positive and negative results of environmental sample analysis, along with the dates of sampling.

A modified version of the above entails the addition of labelled grids to facilitate the communication and analysis of test results based on spatial and temporal characteristics. The grid pattern is illustrated in Figure 5.

Figure 4: Floor map

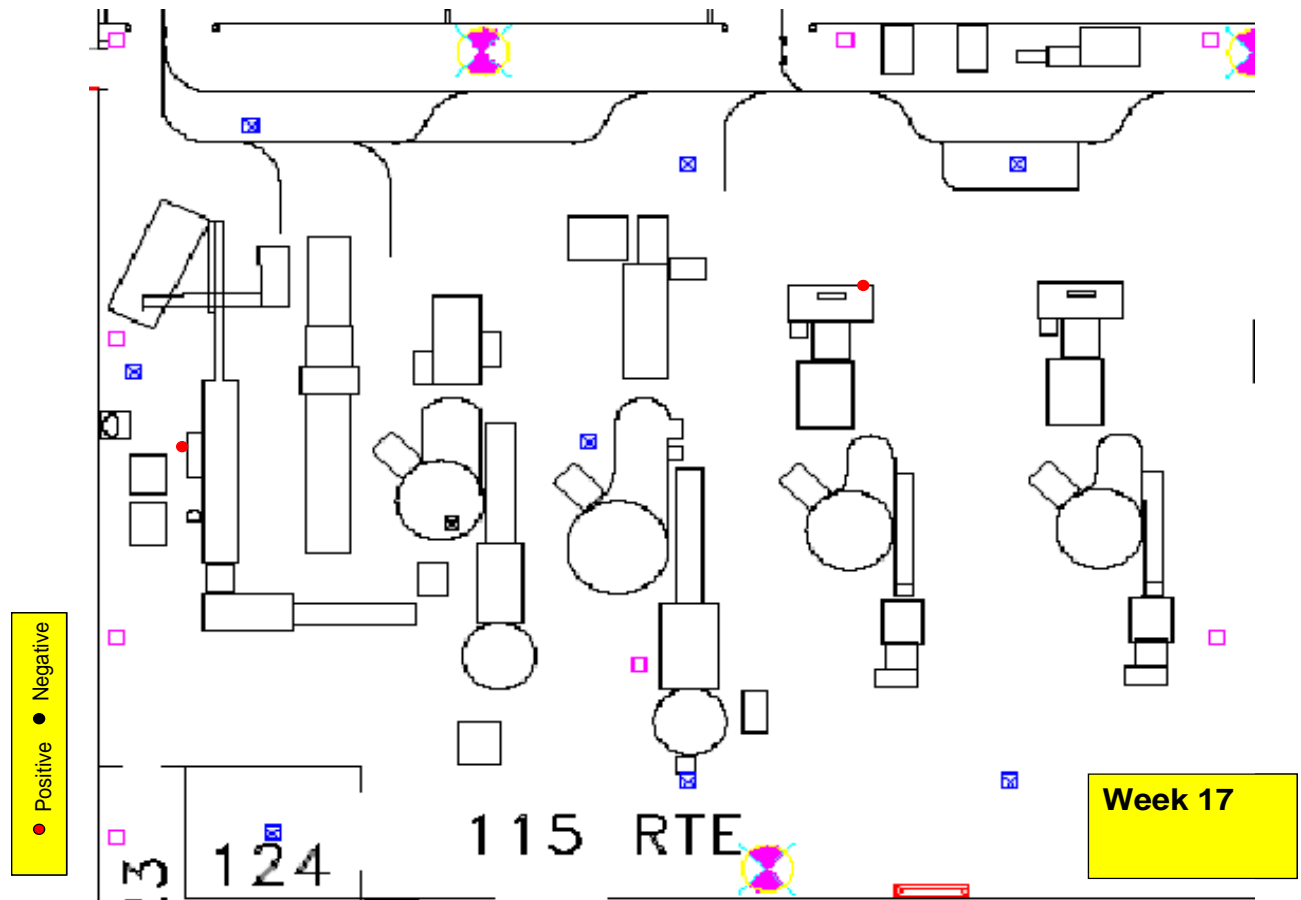


Figure 5. Floor map grid

Location Tracking

- Divide plant area into grids
- Enable location tracking and analysis

	A	B	ZZ
1				
2				
....				
N				

3. Pareto analysis

Pareto analysis is a statistical technique in decision making that is used for selection of a limited number of tasks that produce significant overall effect. It uses the Pareto principle - the idea that by doing 20 % of work you can generate 80 % of the advantage of doing the entire job. Or, in terms of quality improvement, a large majority of problems (80 %) are produced by a few key causes (20 %).

Pareto analysis is useful where many possible courses of action are competing for attention, as may be the case when analyzing *Lspp* test data and investigating the occurrence of certain patterns of positive test results. Estimating the benefit expected from each action can guide the selection of the most effective actions that could deliver a total benefit reasonably close to the maximum possible. When the main causes of problems are identified, other tools like the Ishikawa diagram can be used to identify the root causes of the problems.

Pareto analysis provides a creative way of looking at causes of problems because it helps stimulate thinking in an organized manner. However, one potential downside is that it could exclude important problems that are small initially but grow over time.

A Pareto chart contains both bars and a line graph, as illustrated in Figure 6, below. The bars display individual values in descending order, e.g. frequency of occurrence or other important measure, and the line graph shows the cumulative percentage of the values represented by the bars. The purpose is to highlight the most important among a (typically large) set of factors. In quality control or food safety, the Pareto chart often represents the most common sources of defects, the highest occurring type, or the most frequent reasons for results being out of specification. These charts can be generated by simple spreadsheet programs, such as Microsoft Excel.

4. Bar chart

A bar chart or bar graph is a chart with rectangular bars with lengths proportional to the values that they represent, as illustrated in Figure 7, below. Bar charts are used to compare two or more values that were taken over time or under different conditions, usually on small data sets. It is a visual display used to compare the amount or frequency of occurrence of different characteristics of data and it is used to compare groups of data.

Figure 6. Pareto chart

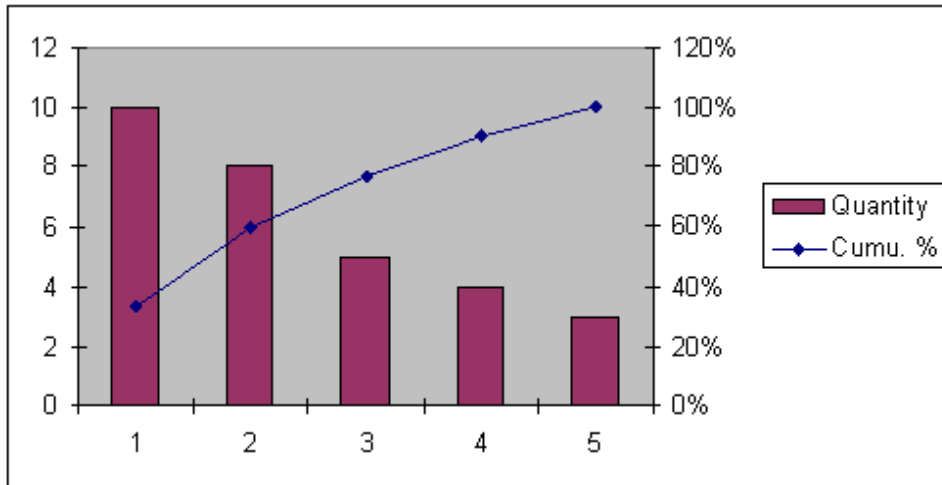
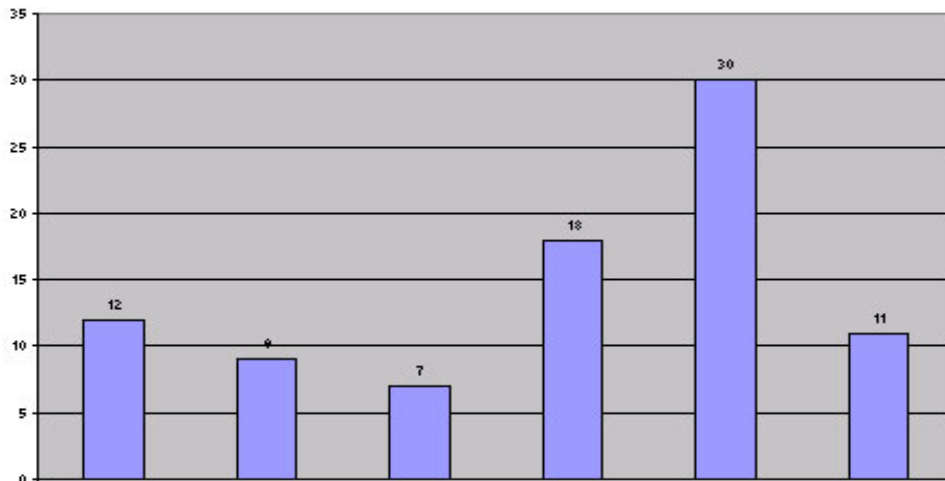


Figure 7. Bar chart



References

Ahamad, N. and Marth, E. 1990. Acid Injury of *Listeria monocytogenes*. *J. of Food Prot.*, 53: pp 26-29.

AMI (American Meat Institute). 2001. Equipment Design Task Force. AMI Fact Sheet: Sanitary Equipment Design. Available at: <http://www.meatami.com/ht/a/GetDocumentAction/i/11006> (Accessed on October 1, 2012).

AMI (American Meat Institute). 2008. AMI Fact Sheet on *Listeria monocytogenes*. Available at: <http://www.meatami.com/ht/a/GetDocumentAction/i/11478> (Accessed on October 1, 2012).

Bernard, D. and Sveum, W. 1994. Industry perspectives on *Listeria monocytogenes* in foods: manufacturing and processing. *Dairy Food Environ. Sanit.*, pp 140-143.

CFIA (Canadian Food Inspection Agency). 2008. Food Safety Facts on *Listeria*. Available at: <http://www.inspection.gc.ca/english/fssa/concen/cause/listeriae.shtml> (Accessed on October 1, 2012).

CFIA (Canadian Food Inspection Agency). 2010. Meat Hygiene Manual of Procedures, Chapter 4 - Annex D, Cooking Time/Temperature Tables. Available at: <http://inspection.gc.ca/english/fssa/meavia/man/ch4/annexde.shtml> (Accessed on October 1, 2012).

CFIA (Canadian Food Inspection Agency). 2011. Meat Hygiene Manual of Procedures, Chapter 4, Annex H, Policy on Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products. Available at: <http://www.inspection.gc.ca/english/fssa/meavia/man/ch4/annexhe.shtml> (Accessed on October 1, 2012).

CFIA (Canadian Food Inspection Agency). 2011a. Meat Hygiene Manual of Procedures, Chapter 4 - Annex I: Risk-based Verification Sampling of Ready-to-Eat Meat and Poultry Products. Available at: <http://www.inspection.gc.ca/english/fssa/meavia/man/ch4/annexie.shtml> (Accessed on October 1, 2012).

CFIA (Canadian Food Inspection Agency). 2011b. Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products. Available at: <http://active.inspection.gc.ca/scripts/fssa/reference/reference.asp?lang=e&cmd=1&cat=2&subcat=0> (Accessed on October 1, 2012).

CFIA (Canadian Food Inspection Agency). 2012. Food Safety Enhancement Program Manual. Available at: <http://www.inspection.gc.ca/english/fssa/polstrat/haccp/manue/tablee.shtml> (Accessed on October 1, 2012).

Codex Alimentarius. 2003. Recommended International Code of Practice General Principles of Food Hygiene. In: *Basic Texts of Food Hygiene - Fourth Edition*, pp 1 - 33. Available at: ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene_2009e.pdf (Accessed on October 1, 2012).

Codex Alimentarius. 2009. Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods. In: *Basic Texts of Food Hygiene - Fourth Edition*, pp 89 - 125. Available at: ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene_2009e.pdf (Accessed on October 1, 2012).

Conference for Food Protection *Listeria monocytogenes* Intervention Committee. 2006. Voluntary Guidelines of Sanitation Practices, Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* Within Food Establishments. Available at: <http://www.foodprotect.org/media/guide/2006CFPLmInterventionvoluntaryguidelines.pdf> (Accessed on October 1, 2012).

Dahms, S. 2003. Microbiological sampling plans - Statistical aspects. Available at: http://www.icmsf.org/main/articles_papers.html (Accessed on October 1, 2012).

den Bakker, H.C., Bundrant, B.N., Fortes, E.D., Orsi, R.H., Wiedmann, M. 2010. A population genetics-based and phylogenetic approach to understanding the evolution of virulence in the genus *Listeria*. *Appl. Environ. Microbiol.* 76 pp 6085 – 6100.

Farber, J. and Peterkin, P. 1991. *Listeria monocytogenes*, a food-borne pathogen. *Microbiol. Rev.* pp 476 - 511.

Farber, J. and Peterkin, P. 2000. *Listeria monocytogenes*. Chapter 4. In: *The Microbiology of Food*. B. Lund, A. Baird-Parker, & G. Gould (Eds.), Chapman and Hall, London, UK. pp 1178 - 1232.

Fatimi, P. and Frank, F. 1999. Inactivation of *Listeria monocytogenes*/*Pseudomonas* biofilms by peracid sanitizers. *J. of Food Prot.* pp 761 - 765.

Gombas, D.E., Chen, Y., Clavero, R.S. and Scott, V.N. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. *J. Food Prot.* 66 pp 559 - 569.

Government of Canada. 2012. Meat Inspection Regulations, 1990. Available at: <http://laws.justice.gc.ca/en/M-3.2/SOR-90-288> (Accessed on October 1, 2012).

Government of Canada. 2012a. Food and Drug Regulations, Division 16 - Food Additives. Available at: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870 (Accessed on October 1, 2012).

Health Canada. 2007. Use of High Hydrostatic Pressure for the Control of *Listeria monocytogenes* in Ready to Eat (RTE) Meats and Poultry. Available at: <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/nf-an138decdoc-eng.php> (Accessed on October 1, 2012).

Health Canada. 2010. Genetically Modified (GM) Foods and Other Novel Foods. Available from: <http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php> (Accessed on October 1, 2012).

Health Canada. 2010a. *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 (Accessed on October 1, 2012).

Health Canada. 2010b. *MFLP-41 Environmental Sampling for the Detection of Microorganisms*. Available at: <http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/volume3/mflp41-eng.php> (Accessed on October 1, 2012).

Health Canada. 2011. Policy on *Listeria monocytogenes* in Ready-to-Eat Foods (2011). Available at: http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_2011-eng.php (Accessed on October 1, 2012).

Health Canada. 2011a. The Compendium of Analytical Methods. Available at: <http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php> (Accessed on October 1, 2012).

Health Canada. 2011b. Interim Marketing Authorization. Available at: <http://www.hc-sc.gc.ca/fn-an/legislation/ima-amp/index-eng.php> (Accessed on October 1, 2012).

Health Canada. 2011c. Use of Multiple-cycle High Pressure Processing (HPP) Treatment of Ready to Eat (RTE) Meat and Poultry Products. Available at: <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/pressure-pression-eng.php> (Accessed on October 1, 2012).

Health Canada. 2011d. Novel Food Decisions. Available at: <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php> (Accessed on October 1, 2012)

Health Canada. 2012. Validation of Ready-to-Eat Foods for Changing the Classification of a Category 1 into a Category 2A or 2B Food. (Accessed on November 29, 2012)

Henning, W. and Cutter, C. 2001. Controlling *Listeria monocytogenes* in Small and Very Small Meat Plants. Available at: <http://www.fsis.usda.gov/OPPDE/Nis/Outreach/Listeria.htm> (Accessed on October 1, 2012).

ICMSF (International Commission on Microbiological Specifications for Foods). 1996. *Listeria monocytogenes*. In: *Microorganisms in Foods 5. Characteristics of Microbial Pathogens*, Blackie Academic & Professional, London (ISBN 0412 47350 X), pp 141-182.

ICMSF (International Commission on Microbiological Specifications for Foods). 2011. *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*. Springer (ISBN 978-1-4419-9373-1).

ILSI (International Life Sciences Institute). 2005. Research Foundation/Risk Science Institute, Expert Panel on *Listeria monocytogenes* in Foods. Achieving Continuous Improvement in Reductions in Foodborne Listeriosis - A Risk-Based Approach. *J. of Food Prot.*, 68: pp 1932 - 1994.

IFT (Institute of Food Technologists). 2003. Factors that Influence Microbial Growth. In *Comprehensive Reviews in Food Science and Food Safety*. Vol. 2 Supplement, pp. 21 - 32.

Jay, J.M., Loessner, M.J and Golden, D.A. 2005. *Modern Food Microbiology - Seventh Edition*. Springer.

Kornacki, J. L. 2007. Detecting Sources of *Listeria monocytogenes* in the Ready-To-Eat Food Processing Environment. Available at: http://www.fsis.usda.gov/PDF/Seminar_Detecting_Sources_of_LM.pdf (Accessed October 1, 2012).

Kovacevic, J., Bohaychuk, V. M., Barrios, P. R., Gensler, G. E., Rolheiser, D. L., and McMullen, L. M. 2009. Evaluation of Environmental Sampling Methods and Rapid Detection Assays for Recovery and Identification of *Listeria* spp. from Meat Processing Facilities. *J. of Food Prot.*, pp 696 - 701.

Leister, L. 2004. Hurdle Technology. In: *Encyclopedia of Meat Sciences*. W. K. Jensen, M. Dikeman, & C. Devine (Eds.). Elsevier Ltd. pp 640 - 647.

Lemay, M.J., Rodrigue, N., Gariépy, C. and Saucier, L. 2000. Adaptation of *Lactobacillus alimentarius* to environmental stresses. *Internat. J. of Food Micro.*, 55: pp 249 - 253.

Little, C.L., Sagoo, S.K., Gillespie, I. A., Grant, K. and McLauchlin, J. 2009. Prevalence and level of *Listeria monocytogenes* and other *Listeria* species in selected retail ready-to-eat foods in the United Kingdom. *J. Food Prot.*, 72 pp 1869 - 1877.

Maragkoudakis, P., Mountzouris, K., Psyrras, D., Cremonese, S., Fischer, J. and Cantor, M. 2009. Functional Properties of novel protective lactic acid bacteria and application in raw chicken meat against *Listeria monocytogenes* and *Salmonella enteritidis*. *Int. J. Food Micro.* pp 219-226.

Pitchiah, S., Alvarado, C. Z. and Brashears, M. M. 2008. Biofilm Formation of *Listeria monocytogenes* on Various Conveyor Belt Surfaces. *Food Prot. Trends*, 28 (11), pp 760 - 764.

Ryser, E. and Marth, E. (Eds). 2007. *Listeria*, Listeriosis, and Food Safety (3rd Ed). New York: Marcel Dekker.

Sauders, B. D. and Wiedmann, M. 2007. Ecology of *Listeria* Species and *L. monocytogenes* in the Natural Environment. In: *Listeria*, listeriosis and food safety – Third Edition. E. T. Ryser, & E. H. Marth (Eds.) CRC Press Taylor and Francis Group. pp 21 - 53.

Snelling, A. M., Saville, T., Stevens, D. and Beggs, C.B. 2010. Comparative evaluation of the hygienic efficacy of an ultra-rapid hand dryer vs conventional warm air hand dryers. Available at: <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2672.2010.04838.x/pdf> (Accessed on October 1, 2012).

Sofos, J. 2009. Sanitation. Biofilms: our constant enemies. *Food Safety Magazine*, February/March.

Tompkin, R. 2002. Control of *Listeria monocytogenes* in the Food-Processing Environment. *J. of Food Prot.* pp 709 - 725.

Tompkin, R. B. 2003. Environmental sampling - A tool to verify the effectiveness of preventive hygiene measures. Accessible at: http://www.icmsf.org/main/articles_papers.html (Accessed on October 1, 2012).

US FDA/FSIS (Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services and Food Safety and Inspection Service, U.S. Department of Agriculture). 2003. Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. Accessible at: <http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm> (Accessed on October 1, 2012).

US FDA (Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Human Health and Services). 2008. Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance - Contains Nonbinding Recommendations. Available at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm> (Accessed on October 1, 2012).

US Industry Associations. 1999. Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs) for Ready-to-Eat (RTE) Products. HACCP Alliance, North American Meat Processors, Central States Meat Association, South Eastern Meat Association Southwest Meat Association, Food Marketing Institute, National Meat Association, and American Association of Meat Processors. Available at: <http://www.haccpalliance.org/sub/food-safety/quifinal2.pdf> (2012).