FACILITIES INSPECTION MANUAL - APPENDIX I

GUIDELINES ON THE CONTROL MEASURES FOR PREVENTING THE CONTAMINATION AND GROWTH OF LISTERIA MONOCYTOGENES
GUIDELINES ON THE CONTROL MEASURES FOR PREVENTING THE
CONTAMINATION AND GROWTH OF LISTERIA MONOCYTOGENES ..........3

1. Purpose .............................................................................................................3

2. Scope ..................................................................................................................3

3. References ..........................................................................................................3

4. Guidelines ...........................................................................................................4

4.1 The biological hazard “Listeria monocytogenes” ......................... 4

4.2 Control Measures for L. monocytogenes ........................................ 5

4.2.1 Knowledge and identification of factors required for
establishment specific control measures ...................................................... 5

4.2.2 General Control Measures - Linkages between HACCP,
Supporting Programs [Prerequisites, Regulatory Action Points
(RAP) and SOPs], and Control Measures .................................................. 6

4.2.3 Product Related Control Measures ...................................................... 6

4.2.4 Process-Related Control Measures ....................................................... 8

4.2.5 Establishment-Related Control Measures ................................. 10

4.3 Verifying Control Measures ................................................................. 12
GUIDELINES ON THE CONTROL MEASURES FOR PREVENTING THE CONTAMINATION AND GROWTH OF *LISTERIA MONOCYTOGENES*

1. Purpose

This document provides guidelines for federally registered establishments with respect to the requirements set out by the Quality Management Program (QMP) Reference Standard and their application to prevent the contamination and growth of *Listeria monocytogenes* in RTE fish products.

2. Scope

These guidelines are to be considered by operators of federally registered fish processing establishments who produce RTE fish products subject to the Health Canada “Policy on *Listeria monocytogenes* in Ready-to-Eat Foods” as part of their requirement to design, implement and maintain a QMP Plan that meets the requirements of the QMP Reference Standard.

3. References

Canadian Food Inspection Agency (2005) Fish Products Standards and Methods Manual (Hereafter referred to as FPSMM)


Codex Alimentarius (CAC/GL 61-2007) Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in food.

Health Canada (2011) Policy on *Listeria monocytogenes* in Ready-to-Eat Foods. (Hereafter referred to as the “HC *Listeria* Policy”.)


4. Guidelines

4.1 The biological hazard “Listeria monocytogenes”

*Listeria monocytogenes* (*L. monocytogenes*) is a pathogenic bacteria commonly found in the environment that can cause Listeriosis, an illness that can lead to death. Healthy adults and children can develop Listeriosis, but it is more likely to develop amongst pregnant women, the elderly (>60 years old) and immuno-compromised individuals (e.g., cancer patients, people affected with the Acquired Immune Deficiency Syndrome (AIDS), people with liver problems, etc.). Food products contaminated with *L. monocytogenes* at levels exceeding 100 CFU/g (colony-forming units of bacteria per gram of product) have been implicated in outbreaks of Listeriosis. *L. monocytogenes* is normally destroyed by cooking therefore, only ready-to-eat (RTE) products are considered a risk for contamination with *L. monocytogenes* since these products are intended for consumption without additional cooking.

*L. monocytogenes* is a unique food pathogen that can grow at refrigeration temperatures, is found everywhere in the environment and has a high tolerance to salt. Contamination of the incoming materials, growth of the pathogen during processing and/or during storage of the final product, as well as cross-contamination during processing must all be considered as potential hazards when conducting the hazard analysis of a RTE product as part of the Hazard Analysis Critical Control Point (HACCP) component of the Quality Management Program (QMP).

These hazards must be addressed through the application of Critical Control Points (CCPs) or enhanced control measures in the prerequisite programs and associated Standard Operating Procedures (SOPs). An establishment is required to document all CCPs and control measures in their HACCP plan and other relevant sections of the QMP plan.

When a final product supports the growth of *L. monocytogenes*, the use of a regular prerequisite program is not sufficient to prevent cross-contamination and
pathogen growth in the final product. CCPs and/or enhanced control measures must be included to address the risks associated specifically with \textit{L. monocytogenes}.

\textbf{4.2 Control Measures for \textit{L. monocytogenes}}

Control measures for \textit{L. monocytogenes} are implemented to prevent, eliminate or reduce \textit{L. monocytogenes} to an acceptable level as well as control and prevent conditions that will enable growth and/or contamination. Prerequisite programs, sanitation and employee training are essential in controlling \textit{L. monocytogenes} and preventing recontamination. Controlling the presence of \textit{L. monocytogenes} in the environment will reduce the risk of contamination.

Establishments producing RTE foods must implement controls to ensure that their products are in compliance with the \textit{L. monocytogenes} guidelines for fish and fish products (Appendix 2, FPSMM). Control measures should be developed using regulatory requirements and relevant scientific information from current literature. Assistance from recognized authorities (e.g., processing experts) is recommended to obtain and evaluate this information given that, ultimately, it is the responsibility of the processor to demonstrate that such control measures will reduce the risk to an acceptable level.

The control of \textit{L. monocytogenes} is product, process and establishment specific (National Fisheries Institute, 2002). The history of known contamination in an establishment should be considered when designing control measures.

The following control measures are recommendations. Processors may use other control measures, provided they validate and verify the effectiveness of the control measures and critical limits.

\textbf{4.2.1 Knowledge and identification of factors required for establishment specific control measures}

Knowledge specific to the process flow of the establishment, product characteristics, method of product manufacturing, processes such as lethality treatments, equipment and the establishment structure should be acquired to:

- Determine the applicable RTE product category as per the HC \textit{Listeria} Policy; (see Appendix 2 of Fish Products Standards and Methods Manual: http://www.inspection.gc.ca/english/fssa/fispoi/man/samnem/app2e.shtml);
- Identify the impact of each location and step in the process on the pathogen content of the food (includes areas in the product flow that pose the greatest risk of product contamination, areas that are difficult to clean); and
Establish effective control measures for *L. monocytogenes*.

The identification of establishment specific factors that pose potential risk of contamination is important for these factors to be managed by the control measures. Problems with respect to *L. monocytogenes* (e.g. potential signs of a control measure not working resulting in a loss of control) and the appropriate response should be identified.

### 4.2.2 General Control Measures - Linkages between HACCP, Supporting Programs [Prerequisites, Regulatory Action Points (RAP) and SOPs], and Control Measures

QMP supporting programs (i.e. Background Product and Process Information, Prerequisite Program, RAPs and associated SOPs) provide ongoing support for the HACCP system and the production of safe food. Compliance to supporting programs provides the basic operating conditions and processing environment required to ensure the HACCP plan is effective.

The intent of HACCP is to focus control at Critical Control Points (CCPs). Therefore programs to support the HACCP systems must be effective in achieving their intended purpose related to food safety. These programs support the HACCP system in practice by:

- Functioning as intended, especially at CCPs;
- Preventing contamination (pest control, construction & equipment maintenance, employee hygiene, etc.);
- Achieving their food safety objectives; and
- Ensuring effective treatments (e.g. equipment functions as intended).

The Prerequisite Program and associated SOPs provide protection from hazards from the surrounding environment and keep low-risk potential hazards from becoming serious problems that could adversely impact on food safety. The RAP plan identifies processing steps where control measures are applied to ensure that the product complies with the *Fish Inspection Regulations* (FIR).

### 4.2.3 Product Related Control Measures

- **Incoming Materials**

Control of incoming material is essential to ensure a final product is safe for human consumption. Incoming materials must be separated from the semi-finished and finished products. RTE food processors should implement procedures that are validated and verified to eliminate or reduce *L. monocytogenes* in incoming materials.

Recommended procedures include, but are not limited to:
- Separating incoming materials from semi-finished and finished products;
- Sourcing from reputable supplier(s);
- Monitoring the temperature of incoming materials;
- Handling and washing of incoming materials; and
- Testing and verifying initial load of bacteria.

**Product Formulation**

Control of product formulation is essential to ensure that the enhanced control measures, CCPs and associated critical limits address the risk of *L. monocytogenes*.

In accordance with the HC *Listeria* Policy, safety parameters such as pH, salt content or water activity ($a_w$) can be used to control microbial growth in a variety of RTE foods. Establishments may consider adjusting these product characteristics based on scientific information or expert advice to reduce or eliminate growth of *L. monocytogenes*. A RTE product will not support growth of *L. monocytogenes* when:

a) pH < 4.4, regardless of $a_w$;
b) $a_w$ < 0.92, regardless of pH or;
c) Factors are combined appropriately (e.g., pH < 5.0 and $a_w$ < 0.94).

**Food Additives and/or Processing Aids**

Certain food additives and processing aids may be used as a control measure to limit or inhibit the growth of *L. monocytogenes* in specific foods.


Processing aids are not subject to mandatory pre-market approval however their use must be consistent with that of a processing aid and not that of a food additive. The Health Canada Policy for Differentiating Food Additives and Processing Aids (http://www.hc-sc.gc.ca/fn-an/pubs/policy_fa-pa-eng.php) provides guidance for determining whether a substance is a food additive or a processing aid in a given context of use.
• **Freezing of Finished Product**

The growth of *L. monocytogenes* is inhibited at freezing temperatures; therefore, freezing can be used as a control measure to prevent pathogen growth. In this case, the product label must have the statement “Keep Frozen” on the principal display panel. The temperature of the freezer storage area in the establishment must also be monitored to prevent temperature abuse which could result in the partial or complete thawing of the product which could allow *L. monocytogenes* to grow.

• **Restricting the Refrigerated Shelf Life of the Finished Product**

The processor is responsible for establishing a product shelf life and must validate that the product will remain safe for consumption for the duration of the stated shelf life. To establish a safe shelf life, scientific evidence can be obtained from a recognized authority in the form of a product-specific reference or challenge study on the probable survival and growth of *L. monocytogenes*.

The duration of a product’s shelf life is affected by many factors including product characteristics (aw, pH, intrinsic microbiology), use of additives, temperature exposure during processing, packaging, post-lethality treatments and final product storage conditions (refrigeration, freezing).

*L. monocytogenes* can grow at refrigeration temperatures. Depending on the combination of factors for a particular product, establishments may need to restrict the refrigerated shelf life to ensure product safety. Reducing the refrigerated shelf life of RTE products ensures there is insufficient time for pathogen growth to exceed the *L. monocytogenes* guidelines (Appendix 2, Fish Products Standards and Methods Manual).

4.2.4 **Process-Related Control Measures**

• **Temperature/Time Controls during Processing**

The proliferation of *L. monocytogenes* can be reduced by controlling the amount of time (from successive processing steps) that the product is exposed to temperatures which are optimal for the growth of this pathogen. Processors should focus on managing the time and temperature conditions for the actual product rather than the room temperature controls.

• **Lethality Treatment (“kill step”)**

In general terms, thermal lethality refers to the ability of a heating process to kill bacteria and is typically expressed as the amount of time at a certain internal temperature necessary to achieve a given logarithm (log) reduction of a
pathogen. Cooking, retort procedures and pasteurization are examples of lethality treatments or "kill steps".

A lethality treatment such as cooking is an effective control measure for \textit{L. monocytogenes}. To be a valid lethality treatment, the cooking must result in a 5 log reduction or more of \textit{L. monocytogenes}. The length of time at the designated internal product temperature needed to accomplish the 5 log reduction will vary depending on the product.

Because of the prevalence of \textit{L. monocytogenes}, the potential for re-contamination following a kill step is quite high. Lethality treatments that do not occur in the final container must have additional control measures after cooking to prevent re-contamination. Lethality treatments in the final container must have control measures to address potential recontamination during cooling; water used for cooling can be a source of microbial contamination.

A lethality treatment in a process would constitute a critical control point (CCP) which requires validation to demonstrate effectiveness against the target organism, in this case \textit{L. monocytogenes}, and to show that the treatment results in the required amount of pathogen reduction. The kill step must be delivered consistently within critical limits and have monitoring procedures in place. It is recommended that establishments hire a competent authority to conduct validation studies and establish critical limits for lethality treatments. Establishments may also use reliable information obtained through literature searches, regulatory standards and guidelines to gain knowledge about the hazards of \textit{L. monocytogenes} and effective critical control limits.

- **Containers, Packaging and Filling**

Control measures must be in place to avoid possible contamination of the product during filling. Use of unsanitary equipment (e.g., spouts, dispensers), utensils or containers could re-introduce pathogens, particularly in RTE foods which receive no further heat processing (see Enhanced Sanitation Controls in 4.2.5).

Establishments may choose to use sterile containers or aseptic filling techniques as control measures to prevent the contamination or re-contamination of the final product. Aseptic processing and packaging involves putting a commercially sterile product in to sterile containers which are then hermetically sealed with a sterilized closure in a manner which prevents recontamination of the product. While effective for \textit{L. monocytogenes}, aseptic techniques are highly complicated and slight modifications or deviations from the prescribed process may have a significant impact on product safety. Aseptic processing and packaging techniques must be developed and validated by a competent authority.

- **Post-Process Lethality Treatments**
Post-process lethality treatments are used to reduce or inactivate any *L. monocytogenes* which may be present on the final product as a result of post-process contamination.

Post-process lethality treatments are discussed in the HC *Listeria* Policy (Appendix C, Part ii). The effectiveness of different post-process lethality treatments (e.g., surface heat pasteurization, high pressure processing) varies depending on the product type. In most cases, proposed post-process treatments must undergo a comprehensive assessment and be approved by Health Canada prior to use.

**4.2.5 Establishment-Related Control Measures**

- **Prevention of Cross–Contamination**

Cross-contamination can occur as a result of traffic flow (e.g. movement of people, equipment etc. in processing / packaging areas) or unscheduled maintenance. To prevent the reintroduction of *L. monocytogenes* into the processing environment, the control of cross-contamination is essential. Areas where the exposed food is most likely to be contaminated during the process flow should be assessed.

Identification of sanitary and/or restricted access zones will facilitate control of traffic flow patterns between the incoming ingredients and the processed product sides of the operation. Failure to establish and/or observe established traffic flow patterns, especially between processing and packaging areas, can transport *L. monocytogenes* back into a clean environment. The risk of contamination is highest between product cooking/pasteurizing and packaging.

Enhanced control measures and possibly CCPs are necessary to prevent cross-contamination given the prevalence of *L. monocytogenes* in the environment. Hand washing frequency, footwear cleaning protocols, outer clothing protocols and movement of carts and/or equipment between different processing areas are examples of measures that should be enhanced to ensure *L. monocytogenes*-specific control measures.

- **Enhanced Sanitation Controls**

*L. monocytogenes* is known to form biofilms, which are colonies of the bacterium attached to a surface and surrounded by a protective sheath of proteins and sugars. Biofilms are commonly found in niches such as closed systems, areas where moisture accumulates and between close fitting materials. As biofilms are more difficult to eliminate using basic cleaning and sanitization procedures, enhanced sanitation controls should be implemented specifically for *L. monocytogenes* and biofilms.
Enhancements to the sanitation controls include the use of different types of sanitizers on a rotational basis to prevent resistance. The periodic use of sophisticated detergents such as quaternary ammonium compounds or peracetic acids combined with mechanical action (i.e. scrubbing) will improve the removal of proteins, fats, and oils from equipment and other surfaces. The concentrations of sanitizers used and the length of time the sanitizer is left in contact with each surface type (food contact and non-food contact surfaces, floors, boots) should be in accordance to the manufacturer’s instructions to achieving proper sanitation.

Sanitizing with high temperatures may be particularly useful for biofilms when manufacturers’ instructions permit such application. Hot water and/or steam sanitation is an effective alternative to chemical sanitation and should be used as much as possible as a final step when equipment is difficult to clean.

Sanitation controls can be further enhanced by designating cleaning equipment (e.g., brushes, scrubbers and carts) for use only in specific areas where the risk of L. monocytogenes contamination and/or transport is the highest and ensuring that the equipment does not become a source of contamination by maintaining it in proper condition between uses and replacing it often.

Support equipment such as floor scrubbers, fork lifts, pallet jackets, wheeled trash bins etc. should be included in the cleaning and sanitization process. Equipment, such as slicers, brining equipment, and any equipment with removable parts, should receive special attention.

The frequency of cleaning and sanitizing of the equipment and environment should be based on the history and microbiological data of each establishment. The use of an environmental sampling program allows an establishment to acquire sufficient information to develop a baseline, make comparisons over time, observe trends, and possibly identify the source of emerging sanitation problems.

- Equipment Design & Maintenance

Due to the nature and prevalence of L. monocytogenes, equipment design and maintenance will require extra consideration for establishments processing RTE foods. Quality Control and sanitation personnel should be included in equipment design and purchase decisions.

Equipment should be designed to facilitate cleaning and minimize the potential for breakdowns. Processors should consider the ease of cleaning as well as compatibility with the cleaners and sanitizers that will be necessary to combat L. monocytogenes. They should also strive to prevent “harbourage sites”, small
niches where *L. monocytogenes* can persist and multiply, such as cracks, seams, drain covers or other sites where water and debris can collect.

**• Personnel Hygiene & Training Programs**

While employee hygiene and training are covered in the Quality Management Program prerequisite programs, establishments need to identify the prevention and elimination of *L. monocytogenes* as an objective of their training program.

Control measures are more effective when personnel are trained to understand the necessity of the measures. Incorporating *L. monocytogenes* specific training and assessing the effectiveness of personnel training are ways to enhance the basic prerequisite programs.

**• Visitors, Maintenance and Cleaning Staff**

Processors should ensure that visitors, maintenance staff and cleaners are made aware of the necessary hygiene requirements and consider the increased risk of contamination when unscheduled maintenance involves outside contractors.

**4.3 Verifying Control Measures**

Environmental sampling programs and product testing can be used to verify the effectiveness of the control measures.

Data obtained from an environmental sampling program helps identify the source of contamination when results are positive, which will enable timely corrective actions and trend analysis. The CFIA has produced “Guidelines for the Development of an Environmental Sampling Program”, which are available at: [http://www.inspection.gc.ca/english/fssa/fispoi/man/fimmii/fiiialle.pdf](http://www.inspection.gc.ca/english/fssa/fispoi/man/fimmii/fiiialle.pdf)

Product testing is a second option. While it may determine whether or not a product is contaminated, it will not provide any indication on the cause of contamination, which control measure should be improved, if a new measure should be added nor how to prevent future occurrences. In addition, when present, pathogens will not be distributed evenly within a product or a lot, therefore end-product testing alone cannot ensure product safety. Product testing will be most useful if restricted to verification of product-related control measures such as shelf life determination or assessing the effectiveness of additives.