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2. The *Intent Statement* - indicates the primary objective of the Reference Standard Requirement. It is the stated intent of the Reference Standard Requirement which is key for CFIA personnel using this document in an assessment of a QMP Plan.
3. *Compliance Guidelines* - provide acceptable options to meet the intent of the Reference Standard Requirements.
4. For some elements, or parts thereof, *Compliance Notes* provide guidance on specific points.
5. The *Appendices* provide detailed guidance and options for the development of QMP controls to meet the requirements of the Reference Standard and the Fish Inspection Regulations. Additional appendices may be developed as needed.

The controls and methods described in this document are not necessarily the only valid means of achieving the desired results. Alternative strategies to those described in the Compliance section and/or the Appendices, that address the Reference Standard Requirement such that the Intent is satisfied, should be considered when assessing compliance.

A food production facility may be subject to a wide range of applicable legislation at the municipal, provincial and federal level. Quality system controls respecting acts, regulations and/or standards, other than those identified within this document, are not required to be addressed in the QMP Plan. Notwithstanding, processors should ensure that all processing operations and products meet other applicable legislation and market requirements.



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**1. MANAGEMENT ROLES AND RESPONSIBILITIES**

**Reference Standard Requirement:**

- 1.1 The position responsible for the QMP Plan must be identified.
- 1.2 It is recommended that the processor describe how the QMP was developed and how it will be implemented.

**Intent:**

Management commitment is critical to the successful development, implementation, and maintenance of the QMP Plan.

**Compliance Guidelines:**

- 1. The name, business address, business telephone number and the title of the person responsible for the QMP at the establishment must be identified.
- 2. It is not mandatory but it is strongly recommended that senior management of the establishment demonstrate their commitment to the QMP in writing.

Managers can demonstrate commitment by taking on responsibilities under the QMP, supporting training knowledge, and encouraging and motivating establishment personnel in the development, implementation and maintenance of the QMP. Management participation will set a good example, promote quality management, and foster cooperation in the establishment.

Managers can perform tasks such as explaining the QMP to personnel; allocating equipment, materials, staff and space to QMP activities; and assigning quality management duties.

The following are some options for demonstrating management roles and responsibilities:

- a) an organisation chart;
- b) a written description of each manager's accountability;
- c) a written description of company dispute-resolution processes, e.g., between production staff and

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quality management staff;

- d) a vision statement or mission statement that emphasizes quality management;
- e) a QMP Plan internal audit schedule, with management roles indicated;
- f) documentation of management's role in corrective and preventive actions;
- g) a written statement of commitment signed by all management staff;
- h) Prerequisite Plan, RAP Plan and HACCP Plan procedure manuals; and/or
- i) a signed statement of management commitment to quality management training, accompanied by a list of training opportunities for personnel, broken down by job requirements.

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**2. BACKGROUND PRODUCT AND PROCESS INFORMATION**

**Reference Standard Requirements:**

- 2.1 Processors are required to identify product and process information in the form of a Product Description, Process Flow Diagram and where applicable, an Establishment Floor Plan.
  - 2.1.1 The Product Description must identify those product attributes and characteristics that are important in ensuring a safe and acceptable fish product.
  - 2.1.2 The Process Flow Diagram must outline all of the production steps and assists in identifying those steps that are important in processing a safe fish product meeting all regulatory requirements.
  - 2.1.3 The Establishment Floor Plan identifies cases where hazards are controlled through the application of sanitary or restricted access zones.

**Intent:**

In order to develop the Prerequisite and RAP Plans and to conduct the hazard analysis and determination of critical control points, the establishment's QMP development team will need to identify and assess product/process information and the establishment layout.

The purpose of a product description is to identify and document all product attributes including those process and packaging characteristics which influence the safety and acceptability of the fish product.

The purpose of a process flow diagram is to verify and document the process steps to aid in determining when and where control measures and monitoring procedures should be established.

The purpose of an establishment floor plan is to document where sanitary zones or restricted access areas are being used as control measures for identified hazards.

**Compliance Guidelines:**

1. Product Description

For each product or groups of products processed in the

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establishment, a product description should include:

- a) a descriptive product name;
- b) the source of raw material used in producing the product;
- c) important characteristics of the final product which may affect product safety;
- d) all ingredients;
- e) product packaging;
- f) end product use;
- g) product shelf life;
- h) market destination;
- i) labelling instructions for safe product storage (where applicable);
- j) special distribution controls or instructions (where applicable);

Information contained in the product description must be supportable. In particular, physical characteristics, composition, packaging, and/or shelf-life attributes which impact on the risk of a hazard or its likelihood of occurrence must be substantiated. This data is usually found in association with the HACCP Plan.

The development of an accurate and complete product description is essential to the further development of the QMP Plan including the HACCP and RAP Plans. More detailed guidelines and references for the development of an accurate product description can be found in Appendix A of this document.

## 2. Process Flow Diagram

A process flow diagram must be included in the QMP Plan for each of the products or groups of products that are produced in the establishment. The process flow diagram must outline all the production steps and must be complete and accurate.

Dependant on the nature of the product, product-specific

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regulations (e.g., for molluscan shellfish), and the product holding conditions and time before shipping, the final step of "shipping" may or may not be an important process step. Normally this final step would be included, and if this step is excluded, justification should be provided in the hazard analysis documentation.

**Note:** When the RAP and HACCP Plans are completed, the RAP and Critical Control Points (CCP) should be indicated on the process flow diagram.

### 3. Establishment Floor Plan

If the application of sanitary zones or restricted access areas has been identified as a control measure during the development of a HACCP Plan, then an establishment floor plan must be included in the QMP Plan. The plan must clearly show the flow of materials, personnel and product within the establishment and outline all sanitary zones and restricted access areas.

The term "sanitary zone" refers to that part of a processing area with sensitive processing steps or high risk products, for which a set of controls meeting specified criteria have been established to control all vectors of potential contamination or cross contamination, including air movement, personnel hygiene and sanitation procedures.

The term "restricted access zone" refers to that part of a processing area where personnel movements are restricted and personnel hygiene and sanitation procedures are in place to control potential contamination or cross contamination, but that does not meet the specific requirements of a sanitary zone.

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**3. THE PREREQUISITE PLAN**

**Reference Standard Requirements:**

3.1 Establishment Environment Program

Processors are required to identify:

- 3.1.1 the establishment environment standard that is applied in the facility; as a minimum the standard must meet the requirements of the Fish Inspection Regulations;
- 3.1.2 the actions that are taken by the processor to ensure the standard is met;
- 3.1.3 the record keeping system to record corrective actions when problems are identified;
- 3.1.4 the corrective action system in place to address deficiencies when they are identified.

3.2 Lot Accountability and Notification Program

- 3.2.1 For the purposes of carrying out a product recall, processors are required to have a product identification and distribution system that allows for the rapid identification of the first shipping destination.
- 3.2.2. As part of the Lot Accountability and Notification Program the processor is also required to have procedures to notify the CFIA of any valid health and safety complaints.

**Intent:**

Processors are required to identify controls on establishment design, construction and maintenance in order to provide assurance, that the food will be produced under sanitary conditions, of control of all potential sources of significant contamination, and that will allow the rapid recall of product from first shipping destinations.

**Compliance Guidelines:**

The Prerequisite Plan has two components: the Establishment Environment Program; and the Lot Accountability and Notification Program

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The Establishment Environment Program includes *Construction and Equipment* and *Sanitation and Personnel Hygiene*.

1. The Construction and Equipment section describes the controls to ensure that the establishment facilities and equipment are suitably designed and built and maintained in a state appropriate for safe food processing.
2. The Sanitation and Personnel Hygiene section describes the cleaning and sanitizing procedures, the hygiene procedures for personnel and visitors, as well as pest control measures and procedures.

Each section must include:

- a) the standard that is applied in the facility. At a minimum, the standard must meet the requirements of Schedules I and II of the Fish Inspection Regulations as described in the Facilities Manual. A copy of the standard must be included or, where the standard is a part of the laws, regulations or other documents published by the Government of Canada, it may simply be referenced. In either case, the standard must be in the establishment and readily available for review in printed or electronic format.

Where fresh fish is unloaded, handled, held or transported at a registered establishment, conveyances and equipment must comply with Schedule V of the Fish Inspection Regulations, "Requirements For Conveyances And Equipment Used For Unloading, Handling, Holding And Transporting Fresh Fish".

- b) the control measures that are employed to ensure the processing facility is in compliance with the standard.

For the Construction and Equipment section, the control measures ensure that the processing facility is suitably designed, built, and maintained. Control measures can include: training production personnel on the standard so that they can identify deficiencies; routine inspection of the facility; maintenance schedules; procedures for scheduled equipment maintenance and calibration; controls for a safe water supply.

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For the Sanitation and Personnel Hygiene section, the control measures ensure the facility is operated and maintained in compliance with the standard. Control measures must include written sanitation, personnel hygiene, and pest control programs. Guidelines for developing these written programs can be found in the Appendices of this document.

- c) The monitoring procedures that are used to ensure that the control measures are being correctly and consistently carried out. The monitoring procedures must clearly specify what is being monitored, how it is being monitored, at what frequency, and by whom. The frequency of each monitoring action must be sufficient to ensure that the standard is being met.

In the Prerequisite Plan, processors are not required to record the results of monitoring unless a problem is identified. In these cases, the processor must record the problem and the corrective action information.

- d) The corrective actions to be taken when monitoring identifies a deviation from the standard. The corrective action should include actions to fix the immediate problem and to prevent a recurrence of the problem.
- e) The record-keeping system for recording the results of monitoring and corrective actions when problems are identified. The corrective action record should allow for the recording of a description of the deviation, the part of the standard not complied with, the corrective action taken, the person(s) responsible for the action, the date the action was taken, the date it was verified as effective, the person responsible for verifying and, if applicable, any interim preventative measures for long-term corrective actions. A copy of the corrective action record must be included.

3. Lot Accountability and Notification Program

- a) Processors must provide a written description of the system used to trace fish to their first shipping destination. For each shipment of fish this must include:

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- the name and address of the person to whom each shipment was sent;
  - the type of fish;
  - the quantity of fish;
  - the method of transportation, including manifest and container numbers or other information that is sufficient to identify or trace the location of the fish;
  - the date on which the fish was shipped; and
  - the date on which the fish was processed.
- b) Processors should establish specific procedures to address the requirement for notification of CFIA, within 24 hours, in the event of any valid health and safety complaints. A "valid" complaint means where the initial investigation indicates the health of consumers is at risk.
- c) For health and safety complaints the following records must be kept:
- the date and time when the processor received information questioning the safety of fish processed or exported by the registered establishment, and a description of the information;
  - in cases where the complaint is confirmed: the date and time it was confirmed; the name, address and telephone number of the informant; the method of investigation and the results obtained; the corrective actions taken; and the date and time when the CFIA was notified.

**Compliance Notes**

1. Construction Materials

Where the suitability of construction materials is in question, the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products* (also called the *Reference Listing*) should be consulted. The Reference Listing may be accessed at:

<http://www.inspection.gc.ca/english/ppc/reference/cone.shtml>

Construction materials used for construction, renovation, and maintenance should be selected on the basis of chemical and physical suitability of the materials in relation to their intended use.

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## 2. Chemicals

All non-food chemicals are controlled under the Establishment Environment Program. Non-food chemicals include, bleaches, cleaners, deodorizers, desiccants, disinfectants, denaturing agents, floor-drying compounds, industrial antifreeze, inks, lubricants, pesticides, protective oils, refrigerating brine additives, refrigerants (immersion freezing), sanitizers, and water-treatment compounds. These compounds include chemicals which may be acceptable for food contact and those that are not.

Processors must ensure that these chemicals are approved for their intended use and must have controls to ensure that these chemicals are applied according to their intended use and stored to prevent unintentional contact with food products. The acceptability of chemicals for their intended use must be documented in the QMP Plan. Chemical acceptability is substantiated by inclusion in the *Reference Listing*.

Non-food chemicals used outside of the fish processing and support areas need not be substantiated in the *Reference Listing*; however, the processor must have controls in place to ensure these products do not enter into, or contaminate, areas where fish and/or input materials are handled or stored.

Examples of chemicals exempt from the requirement for inclusion on the *Reference Listing* include, pesticide products for outdoor use only, products used in offices or similar non-regulated areas, products used in cafeterias or lunch rooms, products used in heating systems, products used outdoors only for sewage or waste water systems, products used in cooling towers or evaporator condensers, products used for the cleaning or maintenance of the exterior of vehicles, and products for use in the maintenance shop on non-food contact equipment.

## 3. Ice

When ice is used for processing, as a processing aid or as an ingredient, and that ice is manufactured in the registered facility, the processor will set out control measures under the Establishment Environment Program. Control measures to address requirements for the ice manufacturing equipment, holding, storage, and the

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quality of the water source and supply should be considered.

When ice is used for processing, as a processing aid or as an ingredient, and that ice is manufactured outside of the registered processing establishment, the controls under the QMP are two-fold. The processor will set out controls under the Establishment Environment Program for requirements relating to the holding and storage of the ice. Secondly, the processor will establish controls for the transport and the quality of ice under the RAP Plan.

4. Standard Operating Procedure (SOP)

A Standard Operating Procedure (SOP) is an effective means for establishing, documenting, and communicating a control measure associated with the Prerequisite Plan, RAP Plan, or HACCP Plan. A SOP is a detailed set of instructions which describes how to carry out a repetitive task. Trained personnel can use a SOP for a specific task to carry out that task with little further direction.

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**4. THE REGULATORY ACTION POINTS (RAP) PLAN**

**Reference Standard Requirements:**

4.1 The RAP Plan must describe the controls to ensure that:

fish is handled properly during processing and results in a final product that is not tainted, decomposed or unwholesome and meets all applicable sections of the *Fish Inspection Regulations*;

any ingredients added to the fish product or packaging material used are acceptable for food and meet all regulatory requirements as specified in the *Fish Inspection Regulations* and the *Food and Drugs Act and Regulations*; and

labelling and coding of all fish products meet the requirements of the *Fish Inspection Regulations* and is not false, misleading or deceptive.

As part of the RAP Plan the processor must identify:

- 4.1.1 The fish product standard(s) and the ingredient and packaging requirements to which they must comply;
- 4.1.2 The controls that are implemented in production to ensure the standards and requirements are met;
- 4.1.3 The record keeping system to record corrective actions when problems are identified;
- 4.1.4 The corrective action system in place to address deficiencies when they are identified.

**Intent:**

Within the RAP Plan, processors are required to document and apply controls that ensure the fish is handled properly while under the control of the registered establishment and result in a final product that meets all requirements of the applicable sections of the *Fish Inspection Regulations*. The three areas that must be addressed are minimum acceptable product quality, input materials, and labelling.

**Compliance Guidelines:**

1. Minimum acceptable product quality

This section of the RAP Plan describes the controls to

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ensure that fish will be handled properly while under the control of the registered establishment and will result in final products that meet all applicable sections of the *Fish Inspection Regulations*.

2. Input materials (Ingredients and Packaging Material)

This section of the RAP Plan describes the controls to ensure that any ingredients added to the fish product and any packaging material used are acceptable for food and meet all regulatory requirements.

3. Labelling and Code Markings

This section of the RAP Plan describes the controls to ensure that the labelling and code markings of fish products is accurate, legible, and not misleading.

Each section must include:

- a) The standard that is applied at the facility. The standard may be the CFIA standard as set out in the Fish Products Standards and Methods Manual, applicable sections of the Regulations, or another standard equivalent or superior to these. The standard must outline the accept/reject criteria which identifies compliance.

A copy of the standard must be included or, where the standard is a part of the laws, regulations or other documents published by the Government of Canada, it may simply be referenced. In either case, the standard must be in the establishment and readily available for review in printed or electronic format.

For minimum acceptable product quality, the standard identifies minimum compliance parameters for product safety (tainted, decomposed and unwholesome) and quality, if applicable.

For input materials (ingredients and packaging material), the standard identifies the minimum compliance parameters for input material acceptability for use in food processing or production and compliance to all applicable regulatory requirements specified in the *Fish Inspection Regulations* and the *Food and Drugs Act and Regulations*.

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For packaging material, primary considerations include that all packaging materials must be new, clean and sound and approved for food use. Packaging material must not impart any undesirable substance to the food product, either chemically or physically and should protect food sufficiently to avoid contamination. The acceptability of packaging materials for their intended use must be documented in the QMP Plan. For packaging materials which contact (or may contact) food<sup>1</sup>, the acceptability is substantiated by inclusion in the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products*.

Ingredients must be identified and acceptable for food use. Ingredient acceptability can be substantiated by several methods: a manufacturer's attestation; documentation from a recognised government or non-governmental authority; results of analysis from an accredited laboratory; and ingredients commercially prepared and labelled for food preparation use. Where product additives are used, their identity and concentration is in compliance with the Food and Drug Regulations. Guidance on additives for fish and fish products for sale in Canada can be found on the CFIA Internet site, in the *Guide to Additives Permitted in Fish and Fish Products*.

For labelling and code markings, the standard identifies the minimum compliance parameters to ensure that the labelling and coding of all fish products is accurate, legible, not misleading and meets the requirements of the *Fish Inspection Regulations*. These requirements include any specific species requirements found in the body of the regulations, as well as those set out in Part II - Labelling.

- b) The control measures applied to ensure that final product will meet the standard(s) and that any

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<sup>1</sup> As an example: Fresh fish fillets wrapped in polyvinyl bags, inside insulated Styrofoam containers, inside waxed cardboard boxes. The polyvinyl bags have direct food contact, the Styrofoam containers may contact the fish through minor breakage of the Styrofoam material, the waxed cardboard does not contact the fish. The polyvinyl bags and Styrofoam boxes should be made of material substantiated as approved for food contact; the waxed cardboard boxes need not be substantiated.

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product not meeting the standard will be removed from production.

Control measures can include inspections, evaluations, sampling, pre-printing label evaluations, pre-use review and final product label and coding inspections. For information on supplier quality assurance (SQA) as a control measure, refer to the Appendices of this document. Sampling plans must be at least equivalent to those used by the CFIA.

- c) The monitoring procedures used to ensure that the control measures are being correctly and consistently carried out. The monitoring procedures must clearly specify what is being monitored, how it is being monitored, at what frequency, and by whom. The frequency identified for each monitoring activity must be sufficient to ensure that the standard is being met.

Under the RAP Plan processors are not required to record the results of monitoring unless a problem is identified. In these cases, the processor must record the problem and the corrective action information.

- d) The corrective actions to be taken when monitoring identifies a deviation from the standard. These actions must include both fixing the immediate problem and preventing the problem from happening again. This section must describe how all product not meeting the standard is identified and segregated, culled, and reworked or disposed of in an appropriate manner.
- e) The record-keeping system for recording the result of monitoring and corrective actions when problems are identified. The corrective action record should allow for the recording of a description of the deviation, the part of the standard not complied with, the corrective action taken, the person(s) responsible for the action, the date the action was taken and the long-term preventative steps (if applicable). A copy of the corrective action record must be included.

**Compliance Notes**

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**Note 1.** Receipt of incoming fish and other input materials from suppliers

Where the processor receives fish from suppliers, the processor must establish control measures to ensure, protect, and preserve the quality of that fish. An effective type of control measure is the use of a Supplier Quality Assurance (SQA) agreement. A SQA can be an effective control measure to address many types of situations where an understanding between business parties is required. For example, for transport requirements (i.e., transport vehicles are clean, proper care has been taken, and the vehicles have not been used to transport hazardous materials), temperature control requirements, withdrawal from medicated feeds (i.e., for cultured species) as well as many other requirements.

Guidelines for developing a SQA as a control measure are outlined in the Appendices of this document.

**Note 2.** Standard Operating Procedures

A standard operating procedure (SOP) is an effective means for establishing, documenting and communicating a control measure associated with the Prerequisite Plan, RAP Plan, or HACCP Plan. A SOP is a detailed set of instructions which describes how to carry out a repetitive task. Trained personnel can use a SOP for a specific task to carry out that task with little further direction.

**Note 3.** Identification of Input Materials (ingredient and packaging materials)

Processors should consider all processing steps to identify ingredients. Some components to the final product may not be immediately recognisable as "an ingredient" because they are added to the product indirectly (i.e., as a processing aid) rather than by formulation. For example, when wood chips or sawdust is used in smoking fish product, the processor must identify and consider the input material (sawdust) which is the precursor to the ingredient, natural wood smoke. Also, when ice used for processing is received from facilities outside of the registered establishment (i.e., the ice is not under the Establishment Environment Program), the processor must identify and consider the input material (ice) which is the precursor to the ingredient, added water or ice.

Packaging material includes cartons, wrapping materials,



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films, synthetic casings, netting, trays, pouches, bags and any other material used in the shipping of food products which may come into contact with the food product shipped.

**Note 4.** Regulatory requirements other than the FIR

Processors are not required to establish controls within the QMP Plan to ensure that regulatory requirements outside of the FIR are met. Nonetheless, processors must ensure all final products are in compliance with all applicable regulations including, *Food and Drug, Consumer Packaging and Labelling*, and *Weights and Measures*, and foreign country legislation for exported products

**Note 5.** Documentation associated with the RAP Plan

Documents must be included in the QMP Plan which substantiate the acceptability of the packaging materials. (e.g., their listing in the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products*).

Processors must document any specialised packaging requirements, such as oxygen permeable packaging for ready-to-eat chilled products, set out in the Food and Drug Regulations.

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**5. THE HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) PLAN**

**Reference Standard Requirement:**

5.1 Processors must develop, document and implement a HACCP Plan to control any health and safety hazards related to the product or process. The processor must apply the seven principles of HACCP to identify any significant hazards and for those significant hazards identified, develop a HACCP Plan to prevent, eliminate or reduce the hazard to an acceptable level.

The HACCP system consists of the following seven principles:

- 5.1.1 Principle 1 - Conduct a hazard analysis.
- 5.1.2 Principle 2 - Determine the Critical Control Points (CCPs).
- 5.1.3 Principle 3 - Establish critical limit(s).
- 5.1.4 Principle 4 - Establish a system to monitor control of the CCP.
- 5.1.5 Principle 5 - Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
- 5.1.6 Principle 6 - Establish procedures for verification to confirm that the HACCP system is working effectively.
- 5.1.7 Principle 7 - Establish documentation concerning all procedures and records appropriate to these principles and their application.

**Intent:**

Every processor must analyse their products and processes to determine if any health and safety hazards are present and, where significant hazards are identified, appropriate controls are put in place. The application of the HACCP principles must be consistent with the Recommended International Code of Practice - General Principles of Food Hygiene, CAC/RCP 1-1969, Rev.3 (1997), Amd. (1999).

**Compliance Guidelines:**

1. Conduct a Hazard Analysis

- a) The hazard analysis and the development of the HACCP Plan is conducted by a HACCP team, including at least one member who has knowledge of HACCP from either formal training or experience.

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- b) The hazard analysis is conducted at each process step for every product type. Process steps where a significant hazard may be introduced or where a hazard may increase to an unacceptable level must be identified.
- c) The hazard analysis includes the identification of all potential hazards (biological, chemical, physical), the determination of the significance of the hazard identified, i.e., consideration of its severity and the likelihood of occurrence and, if applicable, justification for a determination of non-significance of a hazard.
- d) The processor demonstrates that they have considered all process steps in conducting their hazard analysis. A Hazard Analysis Worksheet, or equivalent, is used to organise and document the hazard analysis.
- e) The processor considers all activities and materials in the establishment, including incoming fish, ingredients, packaging materials, establishment personnel, the establishment itself, product descriptions, the process flow diagram documented in the Background Product and Process Information section, as well as consumer complaint information, and epidemiological and technical literature available when conducting the hazard analysis.
- f) For some establishments, the hazard analysis will not identify any significant hazards. The HACCP component of the QMP Plan would therefore only include the hazard analysis and other applicable documentation (examples are given in number 7 below *Establish a Documentation and Record-Keeping System.*) The determination of CCPs and associated controls would not be applicable.

2. Determine Critical Control Points (CCPs)

- a) For each significant hazard identified in the first step, there is an appropriate preventive measure in place to prevent or eliminate the hazard or reduce it to an acceptable level.
- b) The method and results of the CCP determination are documented and CCPs are indicated on the process flow diagram.

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3. Establish Critical Limits

- a) Critical limits are established for each CCP identified. A critical limit means the maximum or minimum value to which a hazard must be controlled at a critical control point. For example, a temperature or time which must be achieved to ensure destruction of a pathogenic bacteria, a specific pH to prevent the growth of bacteria, a level of a preservative, a size of detectable shell pieces, or the presence of acceptable product analysis documentation from a SQA supplier of raw materials.
- b) The critical limits are validated to demonstrate that they are effective and the validation is documented.

4. Establish Monitoring Procedures

- a) At each CCP, the processor has established monitoring procedures to determine that the system is operating within the critical limits identified. It is important to have monitoring procedures which produce immediate measurable results to which action can be initiated since there may be potential food safety implications.
- b) The monitoring procedures include what will be monitored, if applicable how the critical limits and preventive measures will be monitored, how frequently monitoring will be performed, and who will perform the monitoring.
- c) For each monitoring activity, the processor has established that personnel performing the monitoring have the knowledge and ability to conduct the procedure. Where specialised skills are required in order to adequately monitor a process or perform an activity which is critical to ensure product safety, appropriate training requirements, experience, and/or skills are identified. For example, the following positions are recognised as requiring specialised skills: retort operator, can closing machine operator, can screening machine operator, and container integrity inspector. Personnel in these positions require special knowledge and experience.

## 5. Establish a Corrective Action System

- a) Corrective action procedures are established to be initiated when monitoring indicates that the process is operating outside the defined critical limits. The corrective action procedures are established in advance so the personnel conducting the monitoring will have direction on the steps to take when a deviation is identified.
- b) The corrective action procedures address: the correction of the deficiency that gave rise to the problem; the identification and segregation of all affected product; the culling, re-working, and/or disposition of affected product in an appropriate manner.
- c) The corrective action procedures address: the prevention or reduction in likelihood of reoccurrence of the problem (e.g., by investigating how the problem developed); if a review of the QMP Plan (e.g., to determine where changes of procedures, control measures, standards, etc., are needed) is needed; the implementation of necessary changes; identification of changes in the QMP amendment log.
- d) The corrective action procedures include a record system to document at least the details of the problem, including the date the problem was identified, the corrective action taken, the person(s) responsible for the action, the date the action was taken and the changes needed to eliminate or prevent re-occurrence of the problem.

## 6. Establish Verification Procedures

- a) Verification activities are an additional level of control and monitoring to ensure the HACCP Plan is operating as it was designed. The verification activities are conducted in addition to the CCP monitoring, but on a less frequent basis, in order to review the implementation of the plan through the records or through additional tests or analysis. For each monitoring activity, the processor must establish and document verification procedures to ensure that the CCP is working as designed.
- b) The verification procedures include what will be

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verified, how it will be verified, how frequently verification will be performed, and who will perform the verification.

- c) Verification activities are performed by qualified personnel and usually by personnel not associated with monitoring of the CCP.

7. Establish Documentation and Record Keeping

- a) Processors keep two types of records associated with HACCP, "documentation" and "records". Documentation refers to those records which are created as a result of the development of the HACCP Plan, and records, which are created as a result of the implementation of the HACCP Plan.
- b) Documentation is maintained as a record of HACCP Plan development, recognising the support and input from many individuals and usually over a considerable period of time. During this phase there are numerous decisions taken and authorities referenced. This information is essential to justify, if necessary, to regulatory agencies or customers why certain actions or activities are taken and also to assist in future development and evolution of the plan. Documentation includes the QMP and HACCP Plans as well as component parts such as SOPs. It also includes the hazard analysis, product attribute data, CCP determination, critical limit validation data, personnel training records, and manufacturer specifications for operation and maintenance of specialised equipment.
- c) Records are generated by the procedures or activities performed and any corrective actions taken. The processor establishes a record-keeping system that ensures that CCP monitoring records, corrective action records and verification records are complete, accurate, legible, and available for review. These records include all information required in the QMP Plan and are initialled or signed and dated by the person responsible for monitoring and by the person responsible for reviewing to verify the monitoring or corrective actions where this review is identified in the QMP Plan as a verification activity. A copy of each record is included in the HACCP Plan.



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Additional guidance on electronic records system can be found in the Appendices of this document.



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**6. VERIFICATION & MAINTENANCE OF THE QMP PLAN**

**Reference Standard Requirements:**

- 6.1 Processors are required to perform the following verification activities to ensure that their QMP Plan is functioning correctly.
  - 6.1.1 Before implementation the processor is required to validate the critical limits of CCPs.
  - 6.1.2 Before implementation the processor is required to review the QMP Plan to ensure that all of the necessary controls are in place and that it meets the requirements of the Reference Standard.
  - 6.1.3 Once the QMP Plan is implemented the processor is required to perform routine verification of the HACCP Plan to ensure it is functioning effectively.
  - 6.1.4 Once the QMP Plan is implemented the processor is required to verify or validate any changes to the QMP Plan or to critical limits that may occur in the ongoing development of the QMP Plan.
  - 6.1.5 Once the QMP Plan is implemented the processor is required to review the QMP Plan at least once per year.
  - 6.1.6 To ensure that the QMP Plan is accurately documented, processors are required to maintain a list of amendments of any changes to their QMP Plan.

**Intent:**

The QMP Plan is a dynamic document and verification is a systematic and comprehensive approach to ensure continuous maintenance and improvement to the QMP Plan in order to confirm that the QMP meets the needs of the fish processor in producing a safe, wholesome, fairly traded product.

**Compliance Guidelines:**

There are five main activities that a processor is required to perform to verify the QMP Plan.

Before implementation of the QMP Plan, the processor is required to:

1. Validate the critical limits for all identified Critical

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Control Points. The processor must obtain supportive evidence or documentation to confirm that the parameters of the critical limit for each CCP are sufficient to prevent, eliminate or reduce to an acceptable level, food safety hazards in the final product. There are two components to this supportive evidence or documentation:

- sound and reliable scientific evidence, standards from an accepted authority, advice from an accepted authority, or a regulatory standard to demonstrate that the process, if operated within the established critical limits, will result in a safe product, and
  - sufficient technical data, gathered through testing and measurement of the process in a processing establishment, to demonstrate that the process can operate within the chosen critical limits.
2. Review the QMP Plan to ensure that it complies with the requirements of the Reference Standard. This includes:
- reviewing the Prerequisite and RAP Plans to confirm that all the necessary controls and documentation are in place. This includes the strategy for monitoring, the taking of records when required, and the implementation of appropriate corrective actions, as outlined in the QMP Plan; and
  - reviewing the HACCP Plan to confirm that all the necessary controls and documentation are in place. This includes the strategy for monitoring and recording at CCP, the implementation of appropriate corrective actions, and the verification of the HACCP Plan to ensure the system is working effectively.

Once the QMP Plan is implemented, the processor is required to:

3. Perform routine verification procedures to confirm that the HACCP system is working effectively (HACCP principle 6). For CCP verification, the processor must complete independent tests, measurements, sampling, review of monitoring procedures and records etc., as necessary and at an appropriate frequency, to verify that the control measures implemented at each CCP are effective and being implemented as described in the plan.
4. Re-validate QMP controls or CCP critical limits as

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changes are made to raw materials, products, processes, equipment, or in response to adverse review findings, recurring deviations, new information on hazards or control measures, on-line observations, and/or new distribution or consumer handling practices where potential hazards may be encountered.

5. Review the QMP Plan, at least once per year, including:

- verifying the HACCP Plan, to confirm that it is complete, accurately reflects current products and processes (product descriptions, process flow, and establishment layout), has effective controls over the significant hazards, and the monitoring of the critical limits is at a frequency sufficient to ensure that products remain in compliance. This verification should include, as appropriate, product sampling and testing, a review of process deviations, corrective actions, audit findings, and consumer complaints. The HACCP Plan is also verified following a system failure or, when there is a significant change in the product or process.
  
- conducting a review of the QMP Plan, including Prerequisite and RAP Plans, to confirm that these programs are complete and functioning effectively. Verification activities for the Establishment Environment Program can use a combination of visual observation, record review, surface swabs or other methods of microbiological analysis of surfaces such as contact plates, or ATP (adenosine triphosphate) bioluminescence. Mock recall exercises are effective verification of the traceability system. Verification of the RAP Programs can include product and incoming material testing and label inspection at atypical inspection points or using more stringent sampling regimes.

This review would confirm that all corrective actions, problems and consumer complaints have been evaluated to ensure the results were effective and that all amendments and other required written changes have been made to the QMP Plan.

The processor should consider the yearly operating schedule in order to best schedule the annual review of the QMP Plan. Some verification activities require the establishment to be in typical production mode in order to assess (for example,

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swab samples for microbiological analysis), whereas some verification activities, such as equipment calibrations may better be scheduled during shutdown periods. All elements of the QMP Plan should be reviewed in the course of each year, however, each element need not be reviewed simultaneously. The QMP Plan should describe the schedule and method by which each element will be reviewed.



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**7. RECORD KEEPING**

**Reference Standard Requirements:**

- 7.1 Records must be kept for the QMP Plan as follows:
  - 7.1.1 For all Prerequisite and RAP Plans, record keeping may be "by exception".
  - 7.1.2 For the HACCP Plan, record keeping is mandatory for all testing, measurements, and monitoring at CCPs and for corrective actions when the critical limits are exceeded.
  - 7.1.3 For all verification activities and results, record keeping is mandatory.
  - 7.1.4 For amendments or changes to the QMP Plan, a record must be maintained.

**Intent:**

Two types of records are components of the QMP Plan, the record of the development and the components of the quality management program, referred to as "documents" or "documentation" and those records taken as a result of the implementation of the quality management program, simply termed "records".

It is important to balance the volume of record keeping with the true needs of the organisation and the resources available to deliver the system. The development, usage and maintenance of documentation and records should be sufficient to provide evidence that the system was developed properly, is being implemented as written, and can demonstrate trends to identify a problem.

**Compliance Guidelines:**

1. Copies of all of the records (e.g., blank examples) described in the QMP Plan, including monitoring, verification, corrective action and personnel training records, are part of the QMP Plan documentation.
2. When records by exception are permitted, records are only required when a deficiency is identified during the monitoring procedures. In these cases the processor is required to record the deficiency and document it using a Corrective Action Record.

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3. When a QMP Plan or any part of its documentation is amended, the date and the changes and the date they are made must be recorded. An accepted practice is to include an amendment log in the QMP Plan. This will ensure that the written QMP Plan continues to reflect the controls that are being applied in the processing operation.
4. The effectiveness of record keeping is improved by ensuring that personnel understand why they are taking records, when, and how to complete the record accurately. The processor should review records periodically to ensure they are current and relevant. Records may contain information outside of the scope of the QMP Plan and processors may combine records to reduce paper load.
5. Records remain current, legible, readily identifiable and retrievable. The location of all files and records in respect of the QMP Plan must be identified. The retention time for records is a very important issue. Records must be retained for at least 36 months and should be retained for a period of time which is relevant to the product shelf life. Records should be stored in a manner which is secure, easily accessible, and which protects the integrity of the record.
6. Consideration can also be given to technology to allow for continuous monitoring or automatic capture of data through computers or remote sensors. When microprocessor technology is used, specific controls must be developed to control the creation and maintenance of electronic records and electronic signatures. Further guidance on this subject is provided in the Appendices of this document.



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**APPENDICES**

- Appendix A - Guidelines for the development of a product description
- Appendix B - Guidelines for the development of a sanitation program
- Appendix C - Guidelines for the development of a pest control program
- Appendix D - Guidelines for the development of a personnel hygiene program
- Appendix E - Criteria for an acceptable supplier quality assurance agreement
- Appendix F - Guidelines for the use of electronic records and signatures
- Appendix G - Guidelines for Verification and Maintenance of the QMP

## APPENDIX A GUIDELINES FOR THE DEVELOPMENT OF A PRODUCT DESCRIPTION

The importance of the product description, including the intended use, distribution, and consumer information should not be underestimated.

The product description has two major roles:

- a) it contains sufficient information regarding the product which is essential to the hazard analysis and the development of safety and regulatory controls in the QMP Plan;
- b) to describe the scope of the QMP Plan, i.e., all of the documentation, controls, reports, corrective actions, etc., in the QMP Plan that pertain specifically to the product described in this section.

Information contained in the product description must be supportable. In particular, physical characteristics, composition, packaging, and/or shelf-life attributes which impact on the risk of a hazard or its likelihood of occurrence must be substantiated. This data is usually found in association with the HACCP Plan.

The product description can be developed using the following 3-step approach:

### Step 1 - Describing the product in consumer terms

The product should be described in consumer terms, including:

- a) the product name

This should use the acceptable common name associated with the species, and the manner of processing or intended preparation.

For example, fresh aquaculture raised Atlantic salmon, canned chinook salmon, salt cod, etc.

The *List of Canadian Acceptable Common Names for Fish and Seafood*, also referred to as the "Fish List", identifies the English and French common names for fish and seafood which are acceptable for use in Canada.

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The 'List of Canadian Acceptable Common Names for Fish and Seafood' is available on the CFIA Internet.

b) the type of product packaging

This should describe the packaging of the final product and may include multiple types of packaging.

Key issues associated with food safety are selective barrier films, vacuum packaging, recycled packaging materials, the acceptability of food contact materials, and identification of potential sources of physical contamination (i.e., product packed in glass represents a potential source of contamination from broken glass).

Any characteristics of the packaging which may affect the multiplication of microbial pathogens and/or the formation of toxins should be identified. For example, the potential for growth and toxin production of *Clostridium botulinum* in products packaged in selective barrier (i.e., oxygen permeable) films, and vacuum or modified atmospheric packaging and the potential growth of *Listeria monocytogenes* in products packaged for extended shelf-life.

Step 2 - Describe any factors which may result in the addition of ingredients or other compounds to the product

Consider and identify any sources of intentional and/or unintentional additions to the product which may affect product safety, including:

a) the source of incoming fish where it could affect product safety

Fish, whether migratory or non-migratory may be disposed to naturally occurring or man-made contaminants or other compounds in the environment.

In general, Canadian products should be identified by the waters where the fish was harvested or the location closest to it. However, where a known risk exists, it is important to identify any source(s) that is not acceptable. For example, a fisheries exclusion zone or area closed to harvesting as a food safety precautionary measure.

Bivalve molluscs must be identified by specific harvest

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area or areas.

Imported fish must be identified by the country of origin, and where geographic risks apply, by more specific localities.

- b) processing steps or processing aids which could affect product safety or regulatory compliance

Any compounds that are added to the product, either directly or indirectly, such that they are part of the product whether or not the component is listed on the label, must be identified.

Fish culture, harvesting, processing, and/or transport operations should be considered. For example, consider the following ingredients, processing aids, or residual compounds that may be added to the product:

- aquaculture therapeutants
- sawdust used to naturally smoke fish
- ice used to pack fresh fish during transport, processing or in the final product
- boiler compounds in steam used to pre-cook fish
- water used to flume or wash fish
- traditional ingredients (salt, sugar, spices, vinegar, etc.) must also be listed.

- c) the important characteristics of the final product which are intended to affect product safety or influence the growth of disease-causing pathogens, such as additives, salt concentration, water activity ( $a_w$ ), or pH.

Step 3 - Describe the conditions of distribution, intended use, and consumers of the food

Consider and identify the factors which impact on product safety and regulatory compliance, including:

- a) the product market, i.e., within Canada or outside Canada;
- b) special distribution controls or instructions for safe product distribution, e.g., "Keep Refrigerated" or "Keep Frozen";
- c) labelling instructions that may be applicable for safe product storage and preparation, e.g., "Keep

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Refrigerated";

- d) the intended end product use which may effect the product safety.

For example, consider: Will the food be heated by the consumer? Will there likely be leftovers? Is the food intended for the general public? Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirm, immuno-compromised individuals)? Is the food for institutional use or for the home?

- e) the product's shelf life.

For example, consider: the potential growth of *Listeria monocytogenes* in extended shelf-life products; the potential effect of shelf life on the integrity of sensitive packaging materials.

**APPENDIX B  
GUIDELINES FOR THE DEVELOPMENT OF A SANITATION PROGRAM**

An effective sanitation program is an essential support for any food safety program. While it is not an integral part of the HACCP Plan, which is restricted to process steps, the sanitation program must be in place before a HACCP Plan can be properly introduced.

Cleaning is the removal of dirt or debris by physical and/or chemical means.

Sanitizing is the process used to rid or reduce the number of microbes (microorganisms) on the surface. Sanitizing cannot be accomplished until surfaces are clean. Sanitizing cannot be effective without a good pest control program as described in Appendix C.

The food processing establishment is a distinctive environment and a sanitation program should be designed to meet the specific needs of that environment to ensure that fish and fish products are prepared under sanitary conditions.

Cleaners and sanitizers should be selected to be effective in the processing conditions found at the establishment. These products are known to have differences in activity relative to ambient temperature, cleaning water characteristics, and the level and type of processing debris present. The method of product use, i.e., the application method, concentration and contact time will affect the performance of cleaning and sanitizing products.

An effective written sanitation program includes the following:

1. Procedures for equipment sanitation which specify step-by-step instructions for equipment to be cleaned and sanitized, including:
  - person(s) or positions responsible;
  - identification of equipment and utensils;
  - disassemble/reassemble instructions when required for cleaning, disinfecting, lubrication, and inspection;
  - methods of cleaning, disinfecting, and rinsing;
  - chemicals and concentrations used;
  - time and temperature requirements for cleaning and disinfecting;
  - lubricants used where applicable; and
  - frequencies for cleaning and sanitizing.



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2. Procedures for establishment sanitation which specify step-by-step instructions for premises, processing, and storage areas to be cleaned and sanitized, including:
  - person(s) or position(s) responsible;
  - identification of premises, processing, and storage areas;
  - methods of cleaning, disinfecting, and rinsing;
  - chemicals and concentrations used;
  - time and temperature requirements for cleaning and disinfecting;
  - frequencies for cleaning and sanitizing; and
  - methods to prevent the contamination of food or packaging materials during, or subsequent to, cleaning and sanitizing.
3. The identification of acceptable cleaning and sanitizing equipment and its intended use.
4. The identification of acceptable cleaning chemicals and/or compounds, their intended use, and instructions for proper application.

**APPENDIX C  
GUIDELINES FOR THE DEVELOPMENT OF A PEST<sup>1</sup> CONTROL PROGRAM**

Sanitizing cannot be effective without a good pest control program. Pest Control is the reduction or eradication of pests (macro organisms). These include flies, cockroaches, mice and rats, as well as weevils and other animals and insects that can target food products. Pest control cannot be effectively accomplished unless and until proper cleaning and establishment maintenance has occurred. If no pests are present, cleaning followed by sanitizing is sufficient. If, however, pests are present, they must be controlled before the sanitizing step. This is because the pests will re-contaminate any surface that may have been sanitized.

Establishment management is responsible for identifying a competent person to develop a pest prevention and control program and to give them the necessary support to carry out the program and ensure that pesticides are used in accordance with label instructions. Persons who apply pesticides in industrial and institutional settings have a responsibility to use the needed pesticide, to apply it correctly (according to label instructions), and to be certain there is no hazard to man or the environment.

An effective written pest control program includes the following:

1. Controls to prevent the entrance of pests to the facility, including:
  - measures to prevent the entry of pests and animals, through proper construction and layout of facilities
  - measures to control the opening and closure of doors and windows
  - measures to exclude animals such as dogs, cats and birds.
  
2. Controls to eliminate or prevent the harbourage of pests in and around the facility, including:
  - measures to maintain an outside establishment environment that does not provide a habitat for pests (i.e., establishment surroundings must be free of debris, stagnant water or improperly disposed of offal),

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<sup>1</sup> In Canada, "pest" refers to the following four major groupings: insects (e.g., flies, cockroaches, weevils); rodents (e.g., mice, rats); birds (e.g., gulls, crows, pigeons, small building-nesting birds); and other animals (e.g., cats, dogs, wild mammals).

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- where applicable, a list of chemicals and devices used for pest control, the concentration applied, the locations where applied, and the method and frequency of application,
  - where applicable, a plan of bait and trap locations,
  - where applicable, a system to record the date of chemical or device applications, chemicals or devices used, results of the application, corrective actions taken, and
  - the name of the responsible person.
3. Identification of properly maintained pest control equipment and its intended use.
  4. The identification of acceptable chemicals and/or compounds, their intended use, and procedures for proper application.
  5. Procedures to ensure that the pest control program is carried out in a manner that does not contaminate food or packaging materials during, or subsequent to, pest control applications.
  6. The name or position of persons responsible for pest control, including, where applicable, the name of the pest control company or the name of the person contracted for the pest control program.



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**APPENDIX D  
GUIDELINES FOR THE DEVELOPMENT OF A PERSONNEL HYGIENE PROGRAM**

Anyone who works in a food handling area must maintain a high degree of personal cleanliness, and the way in which they work must also be clean and hygienic.

In developing the QMP Plan, management must:

- decide what training or supervision their food handlers need by identifying the areas of their work most likely to affect food hygiene. Food handlers must receive adequate supervision, instruction, and/or training in food hygiene.
- take care to ensure that no persons, while known or suspected to be suffering from, or to be a carrier of, a disease likely to be transmitted through food or while afflicted with infected wounds, skin infections, sores, or with diarrhoea, is permitted in any food handling areas in any capacity in which there is a likelihood of that person directly or indirectly contaminating the food with pathogenic micro-organisms.

The Codex Alimentarius General Principles of Food Hygiene lists the following illnesses and injuries which should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered: jaundice; diarrhoea; vomiting; fever; sore throat with fever; visibly infected skin lesions (boils, cuts, etc.); and discharges from the ear, eye, or nose.

The Prerequisite Plan should contain an effective written personnel hygiene program, which addresses the following:

1. Communication of the company policy on personnel hygienic practices, including communicable diseases, to employees, visitors and guests.
2. Cleanliness and conduct of personnel, including hand washing, use of hand and/or foot dips, clothing or jewellery which could contaminate food, unsanitary behaviour or practices
3. The health of personnel, including prevention of personnel suffering from a communicable disease or with open cuts or wounds from being employed in a processing area of an



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establishment.

4. Prevention of contamination and cross-contamination of the food product by control over the storage of employee personal belongings, and the control of personnel and visitor traffic.



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**APPENDIX E  
CRITERIA FOR AN ACCEPTABLE SUPPLIER QUALITY  
ASSURANCE AGREEMENT**

See "Criteria for an Acceptable Supplier Quality Assurance Agreement"  
at:  
<http://www.inspection.gc.ca/english/fssa/fispoi/qual/sqaaqfe.shtml>

**APPENDIX F  
GUIDELINES FOR THE USE OF ELECTRONIC RECORDS AND SIGNATURES**

**Electronic Records**

When QMP records are created and/or stored using microprocessor technology, these electronic systems can be classified as "open" or "closed" systems. A closed system is an environment where the system access is controlled by the persons who are responsible for the content of the electronic records on the system. An open system is an environment in which the system access is not controlled by the persons who are responsible for the content of the electronic record on the system. For example, a processor has purchased off-the-shelf HACCP software to record and store data, and generate reports of CCP monitoring. If the processor does not have access to the data storage files generated by the software, this system is considered closed. If the processor has access to the content of those data files generated by the software the system is considered open. The distinction between open and closed governs who is responsible for implementing controls to ensure the authenticity and integrity of electronic records. If the system is closed then the software manufacturer is responsible, otherwise the food processor is responsible.

When fish processors use electronic records in place of paper records required for QMP, they must develop and implement additional controls to demonstrate the reliability of the electronic records.

Processors should be able to demonstrate compliance with the following requirements:

1. Documentation of the computer system operation, maintenance, and modifications is part of the QMP Plan.
2. Computer systems are validated to ensure their accuracy, reliability, consistency and ability to discern invalid or altered records.
3. Computer systems are able to generate accurate and complete copies of records in a readable text format for inspection purposes.
4. Computer systems contain an adequate means to protect records for accurate and timely retrieval throughout the record retention period. This may include systems to maintain appropriate backup records.



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5. Computer systems limit record access to authorised individuals.
6. Computer systems have a rigorous security protocol to ensure that only authorised individuals can use the system, electronically sign a record, access the operation or computer system, alter a record, or perform operations.
7. Management establishes and implements policy that holds individuals responsible and accountable for data recorded and/or actions taken under their electronic signatures.

**Electronic Signatures**

When a QMP record is made it should be signed or initialled by the responsible party. Similarly, when an electronic record is created, the computer systems will require identification of the person who created the record, this identification is called the "electronic signature".

When electronic signatures are used in association with QMP records, the following characteristics should be associated with the electronic signature:

1. The electronic signature contains a unique identifier for the signer, the date and time of signing.
2. The electronic signature is clearly linked with one (or more) electronic record(s).
3. Controls are in place to ensure that electronic signatures and their links to records cannot be removed, copied, or otherwise manipulated.
4. Each electronic signature is unique to only one individual and is not re-used or re-assigned at any time.
5. Identity of persons authorised to use electronic signatures are documented in the QMP Plan.

## **APPENDIX G GUIDELINES FOR VERIFICATION AND MAINTENANCE OF THE QMP**

### **Purpose**

This document provides guidelines about the requirements set out by Element 6 of the QMP Reference Standard - Verification and Maintenance of the QMP Plan; and specific requirements set out by Element 5 of the QMP Reference Standard - the HACCP plan.

### **Key Criteria**

The objective in developing a verification and maintenance program is to use all available information to confirm that the QMP meets the needs of the fish processor in producing a safe, wholesome and fairly traded product. The key criteria for such a program are:

1. *Written outline* - The plan must have enough detail to clearly outline the "what" and "how" actions that will be completed when assessing each Verification and Maintenance element component. The plan should also outline "who" is responsible for carrying out the plan.
2. *Appropriate timing* - Verification and Maintenance activities should be timed so that changes can be made and implemented to ensure the QMP functions correctly and remains effective during production. The frequency of each Verification and Maintenance activities should be linked to the amount of change occurring in the operation (i.e., more often for rapidly changing products vs more stable production).
3. *Records* - Records must be kept for all verification and maintenance activities to demonstrate what took place, the extent of these activities, and the results.
4. *Amendments* - the processor must keep a list of all amendments made to the QMP (i.e., amendment log).

### **Compliance Guidelines**

There are 4 main requirements to be met:

- 1) Complete review of QMP prior to implementation
- 2) Validation - before starting a process and when changes are made to the process
- 3) HACCP Verification while operating (Codex HACCP Principle 6)
- 4) Verification/maintenance activities for the entire QMP plan with specific requirements for the HACCP plan.

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**1) Complete Review**

When submitting a QMP Plan for System Verification, the processor must provide evidence that the QMP Plan has been reviewed to confirm that it is *complete* and all the necessary controls and documentation for all elements of the Reference Standard are in place. One way to ensure this is accomplished is by using a checklist completed in sufficient detail to demonstrate that an assessment was carried out and the plan met the criteria (an example is available in Chapter 2, Subject 1, Appendix C of this manual).

**2) Validation**

**Before** implementation of the QMP, validation of HACCP controls and CCP critical limits must be completed and submitted as part of the initial QMP submission for System Verification. There are two parts to this validation:

- a) **scientific evidence** - must be collected to establish that the parameters for the critical limits for each CCP are sufficient to prevent, eliminate or reduce to an acceptable level, the food safety hazards in the final product (examples of scientific evidence include a process authority (NFPA), published research data, Health Canada regulatory standard).
- b) **in-plant testing** - sufficient tests and measurements must be conducted during test trials of the process to *clearly demonstrate* that the process is able to consistently meet the chosen critical limits.

Once production has started, **revalidation of HACCP controls or CCP critical limits** is required where changes are made to raw materials, products, or processes, or in response to adverse audit findings, recurring deviations, new information on hazards or new distribution and consumer-handling practices where potential hazards may be encountered:

For each Critical Control Point on the production line, the critical limits are *based on stable conditions*, i.e., the raw materials, the equipment and all the process steps remain the same. If any of these change, control measures must be evaluated to confirm they are still effective, and critical limits must be re-validated to ensure safe food is still being produced.

Other events such as, but not limited to, the following may point to a need to re-validate QMP controls or CCP critical

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limits:

- ▶ adverse findings from a CV or other external audit which found problems with the process or controls.
- ▶ deviations from critical limits which keep occurring and cannot be eliminated.
- ▶ a new hazard is identified or a new time/temperature process is published by a process authority.
- ▶ changes to distribution/marketing, e.g., extended shelf life or consumer packaging (oxygen permeable packaging).

**3) Codex HACCP Principle 6 - verification during production  
(Reference Standard 5.1.6)**

Once production is underway the processor is required to perform two ongoing verification procedures to confirm that the HACCP system is working effectively (Principle 6 - Codex HACCP model). These activities would normally be completed by someone not directly involved in the production process, such as a supervisor, manager or some other person (e.g., Quality Control) with the authority to review the production.

- a) **Records Review** of the monitoring actions for CCP critical limits and corrective actions taken must be verified frequently to confirm they are occurring as described in the plan. This includes calibration records of instruments used in the measurement of Critical Control Point parameters (e.g., temperatures, pH, weight, flow rate).

The Records Review is intended to verify that:

- monitoring activities were performed at the frequency required by the HACCP plan and all results were within the Critical Limits;
- no monitoring activities were missed and all records were completed accurately and correctly;
- all deviations were followed up immediately with Corrective Actions.

HACCP plans rely on accurate measurements (e.g., temperatures, pH, weight, flow rate) to ensure the CCPs are operating within critical limits. The instruments or equipment that require calibration for accurate CCP monitoring should be described in the HACCP plan. The recommended frequency of calibration is dependant on the likelihood that the instrument will go out of calibration and, if it does, the likelihood that a Critical Limit will not be met.

- b) **Independent checks** must be completed to verify that the



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control measures implemented at each CCP are adequate and effective. This verification step must be done on a routine basis, at an appropriate frequency so that corrective action could be successfully initiated and final product controlled if a problem were to be discovered.

Independent Checks are observations, measurements, analytical tests, samples, etc. These are completed separately from the monitoring activities and are intended to be an additional level of control to demonstrate that the identified hazard is being controlled adequately. Observations might involve a second individual watching the monitoring activity being performed. Measurements might involve a second individual performing the monitoring activity separately from the production monitoring.

The verification plan must include a description of the independent checks, the timing of the activity, the individual performing the checks, and the corrective action to be taken if the results indicate a problem with the monitoring.

**4) Specific requirements for the HACCP plan and verification/  
maintenance activities for the rest of the QMP**

**a) Specific requirements for the HACCP plan**

The purpose of a HACCP is to prevent food safety hazards from occurring and to accomplish this, the entire HACCP plan must be evaluated at least once each year to confirm that it:

- is complete;
- accurately reflects current products and processes;
- has effective controls over all significant hazards;
- has monitoring of the critical limits at frequencies sufficient to ensure that products remain in compliance; and
- has corrective action procedures that work efficiently and effectively.

For processes that do not currently have significant hazards, it is crucial that the Hazard Analysis is reviewed to confirm that there have been no changes in the product formulation or process steps that might require a re-evaluation of hazards for significance.

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**b) Verification/maintenance activities for the rest of the QMP**

The processor must review **all** other elements of the QMP Plan, (i.e., Management Roles and Responsibilities, Product Descriptions, Process Flow Diagram, Prerequisite Programs, RAP Controls) at least once every year. This review must verify that the QMP Plan is *current, complete and accurate*, such that the written document matches what is actually occurring during production.

This review would confirm that all corrective actions and any problems or consumer complaints that occurred over the year have been analysed with written amendments or other appropriate changes made to the QMP Plan. The processor should consider their yearly operating schedule in order to best schedule the annual review of the QMP Plan. Some review activities require the establishment to be in full production mode in order to assess (for example, swab samples for microbiological analysis), while other review activities, such as equipment or instrument calibrations may better be scheduled during shutdown periods. All elements must be reviewed in the course of each year, but they need not all be reviewed at the same time.

The types of Annual Review activities can be found in Table 1.

**Table 1 - Types of Review Activities**

Examples of verification and maintenance activities include, but are not limited to, the examples provided in the following table.

QMP Element	What	How (Activities)
1. Management Roles and Responsibilities	<b>Changes:</b> Organization New Staff	Review responsibility for QMP and decision-making process.
2. Background Product and Process Information	<b>Changes:</b> Existing products (suppliers, formula, etc.) New products. <b>Problems:</b> Corrective actions to resolve problems	- Compare and review product descriptions with processed products in plant.  - Examine records



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	<p>and/or non-conformities.</p> <p><b>Review</b> One or more products with attention to those with significant hazards.</p>	<ul style="list-style-type: none"> <li>- Compare diagram and/or floor plan with actual layout of the production floor.</li> </ul>
3. Pre-Requisite Plan	<p><b>Changes:</b> New equipment New sanitation products New procedures New work shift New employees New requirements</p> <p><b>Problems</b> Deficiencies Corrective actions Non-conformities</p> <p><b>Review</b> Sub-elements such as construction, sanitation program, pest control, product accountability and notification.</p>	<ul style="list-style-type: none"> <li>- Examine records</li> <li>- Recall simulation</li> <li>- Inspect facilities and equipment</li> <li>- Observe procedures</li> <li>- Verify effectiveness of cleaning (e.g., swabs, ATP testing)</li> <li>- Check effectiveness of training</li> <li>- Check for updates (e.g., FIR, standards)</li> </ul>
4. Regulatory Action Point (RAP) Plan	<p><b>Changes</b> New supplier New label Coding New standard/requirement New employees New procedures Production volume</p> <p><b>Problems</b> Deficiencies Corrective actions Non-conformities Complaints</p> <p><b>Review</b> Sub-elements (e.g., minimum acceptable product quality, ingredients, packaging, labelling and coding)</p>	<ul style="list-style-type: none"> <li>- Examine records</li> <li>- Confirm training</li> <li>- Check for updates</li> <li>- Observe procedures</li> <li>- Inspect product and labels</li> <li>- Check calibration records for completeness</li> </ul>



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5. HACCP Plan	<p><b>Changes</b> New hazard New employee Critical limit change New procedure SQA changes Change in production volume</p> <p><b>Problems</b> Deficiencies Corrective actions Non-conformities Complaints</p> <p><b>Review</b> Hazard analysis and HACCP Plan for a selected product</p>	<ul style="list-style-type: none"><li>- Examine records</li><li>- Confirm training</li><li>- Literature search, check for updates</li><li>- Review data to validate critical limits</li><li>- Sampling to test for specific hazards (biological, chemical and/or physical)</li><li>- Observations (ensure all hazards have been considered)</li></ul>
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**FACILITIES INSPECTION MANUAL - APPENDIX I**

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



## FACILITIES INSPECTION MANUAL – APPENDIX I

### 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)

Canadian Food Inspection Agency (2010) Food Safety Facts on *Listeria*.  
<http://www.inspection.gc.ca/english/fssa/concen/cause/listeriae.shtml>

Canadian Food Inspection Agency (2011) Process Control Document Requirements  
<http://www.inspection.gc.ca/english/fssa/fispoi/import/pol/contc.shtml#no4341b>

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”.)

Huss, H. H. et al. (2000) Control Options for *Listeria monocytogenes* in Seafoods. International Journal of Food Microbiology 62:267-274

National Fisheries Institute & National Food Processors Association Smoked Seafood Working Group (2002). *Listeria monocytogenes* Control Manual, Draft 9.



Tompkin, R.B. et. al. (1999) Guidelines to Prevent Post-Processing Contamination from *Listeria monocytogenes*. Dairy, Food and Environmental Sanitation 19(8):551-562

Tompkin, R.B. (2002) Control of *Listeria monocytogenes* in the Food Processing Environment. Journal of Food Protection 65(4):709-725

US Food and Drug Administration, Center for Food Safety and Applied Nutrition (2008). Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance.

#### **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 immunocompromised 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 *L. monocytogenes*.

#### **4.2 Control Measures for *L. monocytogenes***

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

##### **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 *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**

The use of food additives or processing aids may be considered a control measure to limit or inhibit the growth of *L. monocytogenes* in specific foods.

Additives for use in fish and fish products must be chosen in accordance with the relevant sections of the *Food and Drug Regulations* (FDR). The use of antimicrobial additives or processing aids specifically to control *L. monocytogenes* is discussed in Appendix C of the HC *Listeria* Policy.

Consultation with Health Canada is required for the use of an approved processing aid. In the event that the use of a new processing aid is proposed, a submission must be sent to Health Canada for review and approval.

References that may assist establishments in the selection and use of additives are available on the CFIA website. Refer to "Guide to Additives Permitted in Fish and Fish Products" at:

<http://www.inspection.gc.ca/english/fssa/fispoi/product/additi/guidee.shtml>

- **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 ( $a_w$ , 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 *L. monocytogenes*. To be a valid lethality treatment, the cooking must result in a 5 log reduction or more of *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 *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 *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 *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 *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/fiiiiale.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.



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## **Appendix J - Guidelines for the Development of an Environmental Sampling Program**



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## 1. Purpose

The purpose of this document is to provide guidelines with respect to the design and implementation of an environmental sampling program for *Listeria monocytogenes* (*L. monocytogenes*) that meets the requirements of the Quality Management Program Reference Standard.

## 2. Scope

These guidelines are intended for federally registered fish processing establishments that produce Ready-to-Eat (RTE) fish products subject to the Health Canada [Policy on \*Listeria monocytogenes\* in Ready-To-Eat Foods](#).

## 3. Definitions

**Environmental sampling:** activity that consists of collecting environmental samples, i.e. samples of Food Contact Surfaces and non-Food Contact Surfaces, using swabs (e.g. sterile sponges or cotton swabs).

**Food Contact Surfaces (FCS):** any surface or object that comes into contact with the Ready-To-Eat product (i.e. after the food has been subjected to some form of processing to render it RTE - e.g. cooking, smoking, etc.).

***Listeria* spp:** The abbreviation “spp” means “species” and refers to any of the seven species in the genus *Listeria*.

**Non-Food Contact Surface (non-FCS):** Any surface or object that does not normally come into contact with the RTE product (e.g. floors, ceilings, walls, drains, etc.)

**Production Line:** A number of pieces of equipment (e.g., slicers, tables, conveyors, packaging or filling machines) used in series in the post-lethality environment, as applicable, to prepare RTE foods for final packaging.

## 4. References

Appendix 1: Sample *Listeria* Environmental Sampling Program Checklist



Health Canada's Policy on *Listeria monocytogenes* in Ready-to-Eat Foods (The "*Listeria* policy")

Health Canada's Compendium of Analytical Methods (Volume 3 and 2).

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

Appendix 2 of the Fish Products Standards and Methods Manual - Bacteriological Guidelines for Fish and Fish Products.

## 5. Guidelines

An environmental sampling program is a verification tool by which the processing environment and equipment are tested for the presence of microorganisms to verify the effectiveness of the control measures used to eliminate sources of contamination.

The inclusion of an environmental sampling program as a monitoring procedure under the Sanitation and Personnel Hygiene sections of the Quality Management Program is strongly recommended in order to be able to adequately verify the effectiveness of the control measures in controlling *Listeria* spp. and potential sources of product contamination.

The test results from environmental sampling provide valuable information for establishing a frequency of cleaning and sanitizing which is adequate and determining which cleaning and sanitizing materials and methods are effective. Testing of the environment also provides information on the prevalence of *Listeria* spp. in the establishment which can be used as a baseline to identify trends over time and help identify the source of an emerging sanitation problem(s) which would require an increase, review or amendment in the sanitation control measures.

### 5.1. Factors to consider when developing an environmental sampling program

It is important for the personnel who develop and implement the environmental sampling program to have a strong knowledge of microbiology, as well as hygienic practices, aseptic techniques and food processes used in the establishment.

The environmental sampling program needs to be reflective of the risk to consumers if the RTE product becomes contaminated. The following factors need to be considered and the thought process documented when developing each element of an



environmental sampling program:

**5.1.1 Type of RTE product:**

The characteristics of the RTE foods produced and whether or not it supports the growth of *L. monocytogenes* – category 1, 2a or 2b<sup>1</sup>;

**5.1.2 Type of process/operation:**

The processing steps (e.g. *L. monocytogenes* lethality step, addition of growth inhibitors, pH adjustments, freezing, etc.) and the likelihood of cross-contamination with *L. monocytogenes*, based on the layout of the facility, the design of the equipment, the product flow, the employees flow, the use of restricted movement of workers or sanitary zones, etc.

**5.1.3 Consumer/Target groups:**

The likely consumers of the RTE product. Some groups of the population such as the elderly, pregnant women and immunocompromised individuals are much more at risk if exposed to *L. monocytogenes*.

**5.1.4 Historical information:**

Test results collected over time constitute an important source of knowledge on the history of the presence of *Listeria* in the processing environment. This data will facilitate the analysis of trends (in terms of potential sources of contamination, fluctuations over time, etc.) and can be used to improve *Listeria* controls.

**5.2 Elements of an environmental sampling program**

**5.2.1 The sampling procedures:**

A description of the sampling materials (sterile swabs or sponges) used and how they are handled, the procedures used to collect samples from the environment, the personnel training, and a description of how the collected samples are handled, labeled, stored and shipped for testing. The method recognized by the Canadian Food Inspection Agency (CFIA) for conducting environmental sampling, MFLP-41, can be found in Health Canada's *Compendium of Analytical Methods*.

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<sup>1</sup>Information on the categories can be found in Appendix 2 of the Fish Products Standards and Methods Manual: [Bacteriological Guidelines for Fish and Fish Products](#)



### 5.2.2 The testing method:

A description of the method used to test for *Listeria* spp.. The methods recognized by the CFIA to test for the presence of *Listeria* spp. can be found in Health Canada's *Compendium of Analytical Methods*. Note that the methods to be used must fit the intended purpose. The CFIA recognizes the results of testing conducted by laboratories accredited under ISO/IEC 17025.

The testing method may use composite sampling, when validated, by which up to 10 environmental samples of the same type (FCS or non-FCS) may be combined and tested as one composite sample.

### 5.2.3 Target organism:

A description of the microorganisms the samples are tested for. In the case of an Environmental Sampling Program for *Listeria* spp., including *L.*

*monocytogenes*, the samples would be tested for all *Listeria* spp.. Monitoring the processing environment for the presence of all *Listeria* spp. may provide a better indication of the effectiveness of the control measures in place than would testing for *L. monocytogenes* alone.

### 5.2.4 The sampling sites:

A description of the sites which are to be sampled per production line based on the process flow chart, traffic flow and critical control points.

The sampling sites consist of Food Contact Surfaces (FCS) and non-Food Contact Surfaces (non-FCS). These sites need to be identified on a schematic of the process flow for each RTE production line. Examples of FCS and non-FCS are provided in MFLP-41. Testing non-FCS is a valuable tool to detect potential sources of contamination in the plant before it expands to FCS and becomes a risk to consumers.

Sponge or swab samples should be collected, per production line, from at least 10 surfaces that come into contact with the exposed foods before final packaging. A reduced number of sites could be used if there is a rationale for it (e.g. RTE food exposed to the environment only in a very limited number of steps and/or areas). Follow the instructions included in MFLP-41.

### 5.2.5 The sampling frequency:

A description of when and how often environmental samples are taken.

Samples from the surface areas of equipment should be collected during production, typically after 3 hours of start up operation. Samples can also be collected before operation, to focus more specifically on the effectiveness of the



cleaning and sanitation procedures applied at the end of a shift. The sampling frequency recommended, per production line, based on 5 production days per week is:

- Once per week for category 1 products
- Every other week for category 2A products
- Once per month for category 2B products

When sufficient data has been compiled, a trend analysis, along with a review of the sampling frequency and the number and location of sites should be conducted to identify any gaps in the program, as well as areas that need improvement.

Special circumstances such as construction in the facility, or the installation of previously used or modified equipment, can compromise *Listeria* control. In circumstances like these, an increase in the frequency of sampling or in the number of sample sites may be warranted.

#### **5.2.6 Review:**

A description of the process followed to review the suitability of the sampling sites selected and the sampling frequency. The sites selected are subject to review, on a regular basis, to ensure that they are adequate in verifying the effectiveness of the Sanitation Program in eliminating *L. monocytogenes* from the processing environment. This includes provisions for when major changes or disruptions take place (e.g. construction, installation of new or modified equipment, major maintenance, unusual weather events, etc.), which could result in the loss of control for *Listeria*.

An example of an Environmental Sampling Program Checklist is provided in Appendix I.

#### **5.3. Response to FCS samples testing positive for *Listeria* spp.**

A description of the process followed in response to the presence of *Listeria* spp. on a FCS sample.

##### **5.3.1 Corrective actions:**

A description of the corrective actions to be taken to eliminate the source of contamination depending on:

- 1) whether this is a first or persistent finding;
- 2) the type of sample in which *Listeria* spp. was detected (i.e. FCS or non-FCS);
- 3) the category of the food processed by the establishment; and
- 4) whether *L. monocytogenes* or *Listeria* spp. has been detected.



Examples of appropriate corrective actions which would be expected, after the initial finding of *Listeria* spp. on a FCS sample, include but are not limited to:

- increased, intensified cleaning and sanitizing;
  - equipment disassembly (beyond FCS if applicable);
  - correction of sanitation design, address any required corrective measures;
  - consultation with chemical supplier to determine if chemicals used are appropriate (concentration, contact time, water temperature) and which alternate sanitisers can be applied;
  - determining through observations and/or employee interviews whether sanitation and operations procedures are being adhered to, and if not, correcting the situation;
- review of process flow and plant floor diagram to ensure that the potential for cross-contamination is controlled;
- review of the sanitary control measures to prevent cross-contamination (e.g. restrict employees flow, establish sanitary zones, etc.). ;

### 5.3.2 Verification of the Corrective Actions

A description of the process for verifying the effectiveness of the corrective actions taken, which includes taking new FCS samples from the same FCS as soon as possible within 5 production days after *Listeria* spp. were detected. The following should also be implemented:

#### **A) Line producing Category 1 RTE products**

- The holding of Category 1 RTE products produced during this sanitation shift.

##### Negative FCS results:

-The release of Category 1 RTE products held.

##### Positive FCS results:

- Determining the cause and source of persistent contamination in order to take new corrective actions.

- Refer to section 5.4.

#### **B) Line producing Category 2 RTE products**

##### Positive FCS results:

- Taking additional corrective actions.

- Taking new FCS samples after the new corrective actions have been completed.

- Holding Category 2 RTE products produced during this sanitation.

- If the FCS are found positive again for *Listeria* spp.:

- Determining the cause and source of persistent contamination in order to determine the new corrective actions to be taken.

- Refer to section 5.4.



## 5.4 Persistent Contamination

A description of the process followed when *Listeria* spp. is detected on the follow-up FCS samples taken after the corrective actions.

### 5.4.1 Determining the Cause and Source

Determining the cause and source of persistent contamination by conducting an in-depth review of the control measures in place for eliminating and preventing the growth of *Listeria* in the processing environment which may include but is not limited to:

- additional FCS sampling to identify the exact sources of contamination;
- review of the written Sanitation program - has anything changed (i.e. new staff, different cleaning chemicals, new equipment, etc.)?
- on-site observation of cleaning and sanitizing procedures, with particular attention to areas identified as positive for *Listeria* spp. What tools/equipment are being used? Are they used appropriately? Are written procedures being followed - if yes, are they effective? Are the chemicals identified in the written plan being used and are they mixed properly and applied according to manufacture's instructions?
- discussion with sanitation crew - do they have any ideas on what may be resulting in the contamination; have they noticed anything different; has there been a change in shift or members of the crew?
- review of previous weekly and monthly test results (trend) in relation to the product and environmental swabs - are there any trends that could identify a possible source or reason for positive result(s)? Does the sampling frequency need to be increased? Are the sampling sites adequate?
- historical perspective - has this happened before? Where? When?
- what product may be affected - scope (how many days production since last negative result; status of inventory and shipments for period in question; shipping data, etc.);
- review of the HACCP plan including the process and product flow (sources of cross-contamination);
- review of the controls for incoming material and ingredients;
- review of the equipment design.

The CFIA should be contacted for assistance with determining the potential causes for the contamination and the additional corrective actions needed to address the situation.

### 5.4.2 Additional Corrective Actions

- The testing of products, which were held when the follow up FCS samples were taken, for *L. monocytogenes* using appropriate procedures and methods. Approved methods can be found in the Health Canada [Compendium of Analytical Methods](#) at the following site:



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

The “application” section of the method chosen must be appropriate for the intended purpose.

- Notifying the CFIA when *L. monocytogenes* is detected in a Category 1 RTE product or exceeds 100 CFU/g in a Category 2 RTE product.
- For plants producing Category 1 products, the hold and testing of products for *L. monocytogenes* and FCS for *Listeria* spp.(including *L. monocytogenes*) until they are found to be compliant for at least three consecutive production days.
- Taking additional corrective actions each time *Listeria* spp. are detected in follow-up FCS samples.
- Notifying the CFIA when *L. monocytogenes* is detected in a Category 1 RTE product or exceeds 100 CFU/g in a Category 2 RTE product.

## Appendix 1

### **LISTERIA ENVIRONMENTAL SAMPLING PROGRAM CHECKLIST**

<b>1. Sampling procedure:</b>	Yes/No	Comments
- a description of the materials used to collect samples		
- a description of the procedures used to collect samples		
- an environmental sampling method recognized by the CFIA and prescribed in Health Canada’s <i>Compendium of Analytical Methods</i> (MFLP-41).		
<b>2. Testing method:</b>	Yes/No	Comments
- a description of the method used to test for <i>Listeria</i> spp. or <i>Listeria monocytogenes</i> .		
- information on the lab performing the analysis (e.g. testing is conducted in and results are obtained from ISO/IEC 17025 accredited labs)		
<b>3. Target organism:</b>	Yes/No	Comments
- a description of the micro organism(s) the samples are tested for ( <i>Listeria</i> spp. or <i>L. monocytogenes</i> )		
<b>4. Sampling sites:</b>	Yes/No	Comments



- a description of sites to be sampled per production line		
- sites consist of Food Contact Surfaces and Non-Food Contact Surfaces		
- a schematic of the process flow for each RTE production line (Potential sites of biological cross contamination between raw and ready-to-eat products or employee flow are identified)		
- a requirement for collection of at least 5 sponge/swab samples from Food Contact Surfaces before final packaging		

<b>5. Sampling frequency:</b>	Yes/No	Comments
- a description of when and how often environmental samples are taken (recommended frequency: category 1 = 1/week, category 2A = every other week, category 2B = 1/month)		
- a schedule of when to start sampling (e.g. 3 hours or more after start up of operation)		
- a plan for when to increase the number of sample sites (ie. under special circumstances, construction, use of previously used or modified equipment).		

<b>6. Sampling Site Review:</b>	Yes/No	Comments
- a description of the process followed to regularly review the suitability of the sampling sites and the sampling frequency.		
- provisions for instances where construction, new equipment, change in process flow, etc. could result in a loss of control for <i>Listeria</i> .		
- a description of what is to be done with data collected (i.e. trend analysis, QMP revisions, etc.)		

<b>7. Response to Presence of <i>Listeria</i> spp.</b>	Yes/No	Comments
- a description of the corrective actions to be taken when a sample is positive for <i>Listeria</i> .		
- a description of the follow-up to verify the corrective actions		
- a description of the response to finding <i>Listeria</i> spp. again		
- a description of the response to persistent contamination		