Appendix J - Guidelines for the Development of an Environmental Sampling Program
Table of Contents

1 Purpose ................................................................. 3
2 Scope .................................................................. 3
3 Definitions .................................................................. 3
4 References .................................................................. 3
5 Guidelines ............................................................... 4

5.1 Factors to consider when developing an environmental sampling program ........................................... 4
5.1.1 Type of RTE product ............................................. 5
5.1.2 Type of process/operation ....................................... 5
5.1.3 Consumer/Target groups ....................................... 5
5.1.4 Historical information ........................................... 5

5.2 Elements of an environmental sampling program ................................................................................. 5
5.2.1 The sampling procedures ....................................... 5
5.2.2 The testing method ................................................. 6
5.2.3 Target organism ................................................... 6
5.2.4 The sampling sites ................................................ 6
5.2.5 The sampling frequency ....................................... 6
5.2.6 Review ................................................................. 7

5.3 Response to FCS samples testing positive for Listeria ................................................................. 7
5.3.1 Corrective actions ............................................... 7
5.3.2 Verification of the Corrective Actions ....................... 8

5.4 Persistent Contamination ........................................ 9
5.4.1 Determining the Cause and Source ....................... 9
5.4.2 Additional Corrective Actions ............................... 10

6 Listeria Environmental Sampling Program Checklist ............................................................... 11
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

*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 2b¹;

### 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*.

¹Information on the categories can be found in Appendix 2 of the Fish Products Standards and Methods Manual: [Bacteriological Guidelines for Fish and Fish Products](http://example.com/bacteriological-guidelines)
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 is provided in Listeria Environmental Sampling Program Checklist

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:
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.
**LISTERIA ENVIRONMENTAL SAMPLING PROGRAM CHECKLIST**

<table>
<thead>
<tr>
<th>Establishment Name:</th>
<th>Registration #:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mailing Address:</th>
<th>Telephone #:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fax #:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Establishment Manager:</th>
<th>Quality Management Coordinator:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CFIA Reviewer:</th>
<th>Date of Review:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Background Product and Process Information

<table>
<thead>
<tr>
<th>List all ready-to-eat products produced</th>
<th>Category (1, 2A, 2B)</th>
<th>Identify critical processing steps (i.e. lethality step, use of growth inhibitors, pH adjustment, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

|                                        |                       |                                                                                                  |

List the most likely consumers of the RTE products. Are any of them members of high-risk population groups (the elderly, pregnant women or immunocompromised individuals)?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

**Review comments:**

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

CFIA Reviewer Signature: ________________________ Date: ________________________
### LISTERIA ENVIRONMENTAL SAMPLING PROGRAM CHECKLIST

<table>
<thead>
<tr>
<th>1. Sampling procedure:</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>- a description of the materials used to collect samples</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- a description of the procedures used to collect samples</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- an environmental sampling method recognized by the CFIA and prescribed in Health Canada’s <em>Compendium of Analytical Methods</em> (MFLP-41).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Testing method:</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>- a description of the method used to test for <em>Listeria</em> spp. or <em>Listeria monocytogenes</em>.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- information on the lab performing the analysis (e.g. testing is conducted in and results are obtained from ISO/IEC 17025 accredited labs)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Target organism:</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>- a description of the micro organism(s) the samples are tested for (<em>Listeria</em> spp. or <em>L. monocytogenes</em>)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Sampling sites:</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>- a description of sites to be sampled per production line</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- sites consist of Food Contact Surfaces and Non-Food Contact Surfaces</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 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)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- a requirement for collection of at least 5 sponge/swab samples from Food Contact Surfaces before final packaging</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Sampling frequency:</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 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)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- a schedule of when to start sampling (e.g. 3 hours or more after start up of operation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- a plan for when to increase the number of sample sites (i.e. under special circumstances, construction, use of previously used or modified equipment)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>a description of the corrective actions to be taken when a sample is positive for <em>Listeria</em>.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a description of the follow-up to verify the corrective actions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a description of the response to finding <em>Listeria</em> spp. again</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a description of the response to persistent contamination</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>