Export of Live Lobsters and Lobster Products Containing Tomalley - Guidance Document

Purpose

This document provides a reference standard for the controls to export lobsters to countries with requirements for levels of Paralytic Shellfish Poison (PSP) toxin in the hepatopancreas.

Scope

This document applies to exporters who ship live lobsters and lobster products containing tomalley to countries with a standard for PSP toxin in lobster. For example, Japan has a standard for PSP in the hepatopancreas of lobsters of 80 µg/100 g and tests imported lobsters to verify compliance with Japanese Food Sanitation Law. The following sets out the requirements for a plan to manage shipments of lobsters to markets requiring enhanced controls for PSP in lobster hepatopancreas.

Standard

1. Element/Section - Management Roles and Responsibilities

Intent - Management clearly identifies and supports the person, or position, that is responsible for the design, implementation and maintenance of the export certification plan.

Requirements

1.1 The plan must clearly identify the name(s) and/or position(s) of the person(s) responsible for its development along with any service providers that were involved in its design.

1.2 The plan must identify the name or title of the person who will be responsible for managing it and the location in Canada where the plan will be managed.

Exporters are required to identify the person or position responsible for the implementation and maintenance of the plan. This information must include as a minimum the name, business address, and business telephone number of the responsible person at a location in Canada.
1.3 Management must ensure that capable personnel are responsible for the design, implementation and maintenance of the plan.

The completed plan must be signed by a senior level manager or the owner of the business as applicable. A second signature will be needed if a different person employed by the exporter is identified as being responsible for the overall implementation and maintenance of the plan.

By signing the plan, the person(s) must include a statement that acknowledges responsibility to ensure that it has been designed and will be implemented and maintained in accordance with this reference standard. In making this statement, management must indicate that there will be sufficient resources available to implement and maintain the plan. The statement must also acknowledge that the exporter understands that failure to implement and maintain the plan in accordance with this reference standard will result in the CFIA advising the importing country that the exporter no longer has appropriate control of exported lobsters.

2.0 Element - PSP Control Measures

2.1 Section - Product Controls

**Intent** - Exporters ship lobsters that will satisfy the importing country's requirements.

**Requirements**

2.1.1 The plan must provide a full description of the type of lobsters that are being exported:

- the primary method of preservation (e.g., fresh/live, frozen, canned), the form (e.g., live, whole, meat, tomalley) and any other secondary processing (cooked);
- the origin of lobsters that specifies as a minimum, the date of harvest and the Lobster Fishing Area (LFA) designated by the Department of Fisheries and Oceans; and
- the identity of the establishment(s) where the lobsters were stored, processed, and packaged with confirmation that the establishment(s) operated with a Quality Management Program Plan or equivalent in compliance with the *Fish Inspection Regulations*.

2.1.2 The plan must provide a full description of the controls for incoming live lobsters to ensure that they were harvested, handled and transported to the establishment under sanitary conditions (i.e. Schedules III and V of the Fish Inspection Regulations as applicable).

2.1.3 The plan must describe the process to control each lot before shipping to verify that it will meet the importing country’s standard for PSP.

**This control must include testing to check lobsters for the presence or absence of PSP. Testing may be performed by the exporter or by a third party.** The testing procedures must clearly specify what is being tested, how it is being tested, at what frequency, and by whom. The frequency must be sufficient to control shipments to satisfy the importing country’s PSP standard.
The procedures to test lobsters should consider factors, such as, but not limited to:

- the size of the LFA and variations in the occurrence of PSP throughout the LFA;
- historical knowledge and other sources of information about the occurrence of PSP in lobsters from the LFA;
- migration patterns;
- changing conditions that would indicate an increased probability in the occurrence of PSP in a LFA or portion of the LFA; and
- the capacity to segregate lobsters from different parts of the LFA.

Exporters may wish to consider arrangements with other parties to enhance their knowledge about PSP and lobsters as part of their efforts for continuous improvement of their testing procedures.

Exporters may supplement product testing with additional controls. Examples may include, but are not limited to, checking:

- documents regarding the origin of incoming lobsters to verify that they are complete and accurate; or
- quantities and description of incoming lobsters to verify that they correspond to accompanying documents.

The objective of this control is to provide exporters with the means to continuously gather and review information about the levels of PSP in lobsters in order to prevent the shipment of lobsters with unacceptable levels of PSP.

2.2 Corrective Actions

**Intent** - Exporters have a written plan to take corrective actions in the event that monitoring shows that exported products did not satisfy the import country's requirements.

**Requirements**

2.2.1 Exporters have prepared and documented, in advance, the corrective actions that will be taken when monitoring shows that the lobsters will not satisfy an importing country’s PSP requirements.

This process must set out the:

- procedures to segregate lobsters that do not meet an importing country’s requirement; and
- record keeping system to record corrective actions when problems are identified and to document changes to the plan.

Corrective actions must include steps to notify CFIA of any consignments of lobsters that are refused entry into the importing country because they exceeded the PSP standard.
3.0 Element - Consignment Storage and Transportation

3.1 Section - Storage and Transportation Sanitary Requirements

**Intent** - While under the control of the exporter, lobsters are transported and stored under sanitary conditions.

**Requirements**

3.1.1 Exporters are required to ensure that all facilities used to store and transport lobsters meet the applicable requirements set out by the *Fish Inspection Regulations*.

Controls for storage and transportation protect lobsters from contamination and keep appropriate storage temperatures in compliance with Canadian requirements.

3.2 Section - Secure Storage and Transportation

**Intent** - While under the control of the exporter, consignments are transported and stored under secure conditions to prevent product loss or substitution.

**Requirements**

3.2.1 While under their control, exporters must take reasonable measures to deliver the lobsters in terms of the quantities and description in accordance with the terms of delivery set between the exporter and the buyer.

These measures are followed during shipping and storage while the exporter is responsible for the consignment.

3.3 Section - Storage and Transportation Monitoring and Corrective Actions

**Intent** - Control measures include procedures to monitor storage and transportation conditions and to take and document corrective actions when monitoring shows that fish were stored or transported under unacceptable conditions.

**Requirements**

3.3.1 As part of the controls for consignment storage and transportation, the exporter must have a system of monitoring and documenting corrective actions that set out the:

- procedures to monitor controls to ensure that they are followed and are effective;
- corrective action system used to resolve deficiencies when they are identified and to prevent them from recurring; and
- record keeping system to record corrective actions when problems are identified and to document changes to the plan.
When exporters use third party service providers for the storage and transportation of consignments, the exporter must take measures to monitor and verify the service provider’s compliance with the Fish Inspection Regulations.

4.0 Element - Verification & Maintenance of the Plan

4.1 Section - Ongoing Maintenance

**Intent** - The design of the plan is reviewed to confirm that it accurately represents the process to control the shipment of lobsters in response to any changes to the operation of the business.

**Requirements**

4.1.1 Exporters must perform regular verification and maintenance activities to ensure that the plan is kept up to date as a result of:

- changes to business operations, such as new suppliers, or the introduction of new procedures;
- information related to the occurrence of PSP in a harvest location;
- corrective actions that are taken as a result of planned monitoring activities as part the process of continuous improvement;
- corrective actions that are the result of CFIA regulatory review activities; or
- corrective actions that are the result of notifications of lobsters exceeding a foreign country’s PSP standard.

4.2 Section - Annual Review

**Intent** - The plan must be designed, implemented and maintained to control lobsters to satisfy foreign country PSP standards. The plan is a dynamic document. Exporters must perform a systematic and comprehensive annual review of the plan.

**Requirements**

4.2.1 The annual review must describe how the exporter assesses all aspects of the plan to verify that the plan is being implemented as designed and that it controls lobsters to satisfy an importing country’s PSP tolerance. To conduct an effective annual review, the exporter must perform the following types of verification activities:

1. conduct a review of the written plan to confirm that it complete and reflects the controls necessary to satisfy the importing country’s PSP standard;
2. verify that all in-house controls are being implemented as designed and are functioning effectively; and
3. verify that service providers are delivering the assigned service(s) and implementing assigned controls as described in the plan.
The annual review must result in a verification of all controls identified in the plan. Suitable activities to achieve compliance with this requirement include, but are not limited to: visual observation, mock recalls to track product to point of harvest, a review of monitoring records, a review of corrective actions, a review of audit findings and complaints.

5.0 Element - Record and Document Control

5.1 Section - Documents and Records are Complete and Available

**Intent - Records and documents are legible, stored in a secure manner, and available for inspection.**

**Requirements**

5.1.1 Exporters must identify the address in Canada where all records and documents relevant to the plan are maintained. All records must be maintained at one location.

5.1.2 Records and documents are complete and include all the records, including blank examples, described in the plan including monitoring, verification, corrective action and personnel training records.

5.1.3 Records must be maintained at a secure location for at least three years.

Records are legible, readily identifiable and retrievable. Records must be maintained in a manner which is secure, easily accessible and protects the integrity of the record.

When electronic records are used, specific controls must be developed to control the creation and maintenance of electronic records and electronic signatures.

5.2 Section - Amendment Log

**Intent** - The plan is up to date with a record of any changes made over the past three years.

**Requirements**

5.2.1 Processors maintain a list of amendments to their plan to ensure that documents are up to date and accurate.

5.2.2 The amendment log must identify historical documents for the last three years.

Date modified: 2011-05-03