

Canadian Shellfish Sanitation Program - Manual of Operations

CHAPTER 1

ADMINISTRATION

1.1 Administrative Responsibilities and Procedures

The Canadian Food Inspection Agency (CFIA), Fisheries and Oceans Canada (DFO) and Environment Canada (EC) are directly involved in the sanitary control of the shellfish industry. The respective responsibilities were established with the formation of these departments in 1979 and the CFIA in 1997, and have been affirmed in a Memorandum of Understanding (Appendix V). These responsibilities are as follows:

a) Canadian Food Inspection Agency

The CFIA is the lead agency for the overall CSSP coordination and is also responsible for the control of handling, storage, transportation, processing and labelling of shellfish including imports (*Fish Inspection Act and Regulations*); the Marine Biotoxins Control Program (*Fisheries Act and Regulations*); and liaise with foreign governments on matters relevant to shellfish sanitation.

b) Environment Canada

Environment Canada is responsible for the monitoring of water quality in shellfish areas and the classification of shellfish harvesting areas on the basis of growing water surveys under authority of the Fisheries Act and Regulations, and as per the Canada/U.S. Memorandum of Agreement (see Appendix IV).

c) Fisheries and Oceans Canada

DFO is responsible for the enforcement of closure regulations and enacting the opening and closing of shellfish areas under the authority of the *Fisheries Act and Regulations*.

Program coordination is achieved through periodic CSSP Executive Steering Committee and Interdepartmental Shellfish Committee meetings at National Headquarters and Regional Interdepartmental Shellfish Committees in the

Canadian Shellfish Sanitation Program - Manual of Operations

Atlantic, Quebec and Pacific regions. These regional committees are chaired by the Canadian Food Inspection Agency and are composed of representatives from the CFIA, DFO, Environment Canada and appropriate provincial government departments. The mandate of the regional committees is as follows:

- a) to review growing area surveys and classify all shellfish areas;
- b) to review the policies, procedures, criteria and regulations affecting the implementation and the regional application of the Canadian shellfish Sanitation Program including making recommendations to the National Interdepartmental Shellfish Committee;
- c) to recommend in writing to the Regional Directors General of DFO changes pertaining to the classification of shellfish growing areas;
- d) to make recommendations to the Regional Head, Marine Water Quality Monitoring Unit, Environment Canada, regarding regional growing area survey needs and priorities;
- e) to review and discuss any changes to biotoxin survey requirements, location and/or closures;
- f) to develop procedures to address specific regional issues;
- g) to review submission from interested parties for potential referral and/or presentation to the ISC;
- h) to provide input and advice to the ISC on program changes needed to accommodate specific regional issues and priorities;
- i) to make recommendations to the senior managers of CFIA, DFO, and EC regarding regional shellfish growing area survey needs and priorities;
- j) to recognise provincial shellfish working groups to identify survey requirements for bacterial and biotoxins on a provincial basis, and to identify policy issues related to delivery of the CSSP in consultation with industry and other stakeholders;

Canadian Shellfish Sanitation Program - Manual of Operations

- k) to establish working groups as required; and
- l) to prepare a CSSP interdepartmental regional report.

The regulatory requirements and administrative arrangements are such that:

- a) Shellfish Program requirements apply to all actual and potential shellfish areas.
- b) Shellfish Program requirements apply to all shellfish harvesters.
- c) Shellfish Program requirements apply to all persons handling the shellfish prior to its delivery to the certified shipper.
- d) The following records of shellfish sanitation activities are maintained:
 - i) laboratory quality assurance records and other related data;
 - ii) individual growing area reports (see Chapter 2);
 - iii) relay activities permitted and a record of supervision provided (see Chapter 10); and
 - iv) patrol activity reports, including numbers of arrests, prosecutions, and the results of prosecutions (see Chapter 3).
- e) Records and reports are made available on request for authorised audits including those that may be conducted by U.S. officials in connection with the 1948 Shellfish Agreement.

A Memorandum of Understanding has been established between the Canadian Food Inspection Agency, Fisheries and Oceans Canada and Environment Canada concerning the respective responsibilities of the departments within the Canadian Shellfish Sanitation Program.

NOTE:

Effective implementation of the regional shellfish program requires good liaison among the various federal and provincial agencies overseeing the shellfish industry. As a

Canadian Shellfish Sanitation Program - Manual of Operations

result, a provincial committee on shellfish has been established in each province of the Atlantic Region. The mandate of the provincial committee is as follows:

- a) promotion of the exchange of information and liaison between agencies and groups involved in the shellfish fishery;
- b) development of education and information programs on shellfish growing area problems and recommending implementation to the appropriate agency;
- c) reviewing existing data on shellfish and recommending resource development projects and sanitary and water quality survey priorities;
- d) monitoring progress in the development of plans and programs to eliminate or prevent pollution of shellfish areas and encouraging corrective action for specific problem areas; and
- e) acting as an advisory group to Environment Canada and the provinces.

1.2 Legislation

The legal authority for the Canadian Shellfish Sanitation Program is provided by the *Fisheries Act*, the *Management of Contaminated Fisheries Regulations*, the *Fish Inspection Act* and the *Fish Inspection Regulations*. The Acts and Regulations enable CFIA, DFO and Environment Canada to:

- a) classify all actual and potential shellfish areas as to their suitability for shellfish harvesting on the basis of sanitary quality and safety of the public health. This authority allows the responsible department to designate as closed any actual and potential shellfish areas where classifications are based upon outdated information and are not representative of existing sanitary conditions;
- b) control the harvesting of shellfish from areas which are classified as contaminated or otherwise closed. This authority allows the responsible department to:
 - i) issue harvest licences;

Canadian Shellfish Sanitation Program - Manual of Operations

- ii) patrol shellfish areas;
- iii) apprehend persons harvesting illegally; and
- iv) effectively prosecute persons apprehended harvesting shellfish from closed areas;
- c) regulate and supervise relaying, transplanting, cleansing and replanting of shellfish. This authority allows the responsible Departments to obtain copies of monitoring data and to require that the industry collect and maintain certain harvesting and processing records;
- d) restrict harvesting of shellfish from actual and potentially affected shellfish areas in a public health emergency. Administrative procedures required in connection with such emergency actions are rapid and in general require no more than one day to complete;
- e) prevent the sale, shipment or possession of shellfish which cannot be identified as having been produced in accordance with the regulatory requirements or which are otherwise unfit for human consumption, and to detain or seize such shellfish;
- f) register, certify, inspect and audit each shellfish facility to determine the level of conformity with the *Fish Inspection Regulations* including verification and effectiveness of the QMP Plan and applicable provisions of this Manual. Inspection includes the authority to review and copy necessary records to determine whether compliance with the applicable requirements is being maintained;
- g) regulate the shipping conditions and labelling requirements for shellstock to protect against contamination and to provide for accurate source identity. These controls apply to every person that handles shellfish from the point of harvest through each certified shipper and up to the retail point of sale;
- h) regulate the export, import, processing, packaging, shipping, storage and repacking of shellfish to protect against contamination and product quality degradation, to maintain source and lot identity and

Canadian Shellfish Sanitation Program - Manual of Operations

maintained by the Canadian Food Inspection Agency.

- c) Compliance Verifications of registered facilities shall be conducted following the procedures described in Chapter 3, Subject 3 of the Facilities Inspection Manual.
- d) Enforcement actions are taken as per the policies and procedures outlined in the Fish Inspection Program Compliance Management Process.

When a Certificate of Registration is removed for cause, the Canadian Food Inspection Agency shall notify the United States Food and Drug Administration (FDA).

- e) A shellfish facility which has had its Certificate of Registration removed for cause may not export. A Certificate of Registration may be reinstated once the CFIA has verified that all instances of non-compliance have been corrected and the requirements of the *Fish Inspection Regulations* have been met. The policy is set out in Chapter 2 of the Facilities Inspection Manual. Upon reinstatement of a Certificate of Registration, the Canadian Food Inspection Agency in Ottawa shall notify the FDA immediately.
- f) Adequate records documenting the degree of compliance with the registration requirements shall be maintained in a district office central file for at least three years and made available to the FDA upon request during an official program audit. These records will include:
 - i) inspection, systems verification and compliance verification reports of certified processors;
 - ii) notification letters and actions taken regarding compliance verifications and certification withdrawals;
 - iii) records of shellfish sample results and follow-up actions taken (see Appendix III - Enforcement Policy for Molluscs Exceeding Established Bacteriological Levels);
 - iv) records of complaints or inquiries and follow-up actions taken; and

Canadian Shellfish Sanitation Program - Manual of Operations

- v) records of prosecutions.

Certification for the Interstate Certified Shellfish Shippers List (ICSSL)

- a) Each registered establishment that wants to be certified for the Interstate Certified Shellfish Shippers List (ICSSL) must apply to the CFIA in writing by using the "Application for Registration of Fish Processing Establishments" form.
- b) The shellfish processing establishment must be listed on the ICSSL as a Reshipper, Repacker, Shellstock Shipper, Shucker Packer, or Depuration Processor, as described in the Definitions section of this manual.

When the same establishment performs depuration and another type of shellfish processing operation (e.g., depuration and shucking), each operation must be listed separately on the ICSSL, using a unique registration number with different suffixes that correspond with each shellfish processing operation (e.g., XYZ Shellfish Co., Town, Province, 1234 DP, 1235 SP). An establishment that performs more than one shellfish processing operation will only be responsible to pay registration fees as a single establishment (see Chapter 2, Subject 4 of the Facilities Inspection Manual).

- c) Shellfish brokers and licensed fish importers involved in reshipping shellfish to and within the United States must meet the requirements of Appendix XI of this manual before being certified for the ICSSL.
- d) An ICSSL listing for a registered molluscan shellfish processing establishment must be renewed annually. The expiration date of Canadian registered shellfish processors on the ICSSL is November 30th of each year.
- e) A compliance verification for establishments which require ICSSL certification inspection should be scheduled to be conducted within 180 days of the ICSSL expiry date.
- f) The Fish, Seafood and Production Division of the CFIA is responsible for completing the US FDA form "FDA 3038 - Interstate Shellfish Dealer's Certificate" on line and posting on the Interstate Certified Shellfish

Canadian Shellfish Sanitation Program - Manual of Operations

Shippers List web site. The shellfish certificates forwarded to the FDA for posting should provide the following information:

- i) the usual business name and alternative names that should appear on the Interstate Certified Shellfish Shippers List (hereinafter referred to as the "List");
- ii) a business address and telephone number where inspections are conducted;
- iii) a unique certificate number for each business unit consisting of a one to five digit arabic number preceded by the two letter provincial abbreviation and followed by the two letter abbreviations for the type of operation the dealer is qualified to perform: shucker packer (SP), repacker (RP), shellstock shipper (SS), reshipper (RS), or controlled purification [depuration] (DP);
- iv) an expiration date of November 30th.
- v) date of inspection/compliance verification;
- vi) inspector's name; and
- vii) date certified.