

CHAPTER 1

ADMINISTRATION

1.1 Administrative Responsibilities and Procedures

The Canadian Food Inspection Agency (CFIA), the Department of Fisheries and Oceans (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 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 is the designated contact point for exchanges of information with the Division of Shellfish Sanitation, Bureau of Foods, Food and Drug Administration, Department of Health, Education and Welfare, Washington, DC, on matters covered by the Memorandum of Agreement of April 30, 1948.

b) Environment Canada

Environment Canada is responsible for the monitoring of water quality in shellfish growing 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) Department of Fisheries and Oceans

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

Program coordination is achieved through periodic

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Interdepartmental meetings at National Headquarters and Shellfish Growing Area Survey and Classification Committees in the Atlantic, Quebec and Pacific regions. These regional committees are chaired by Environment Canada 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 growing areas;
- b) to review the policies, procedures, criteria and regulations affecting the implementation and application of shellfish growing area classifications;
- c) to recommend to DFO changes in regulations pertaining to the classification of shellfish growing areas; and
- d) to make recommendations to the Regional Director, Environmental Protection, Environment Canada, regarding regional growing area survey needs and priorities.

The regulatory requirements and administrative arrangements are such that:

- a) Shellfish Program requirements apply to all actual and potential shellfish growing 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 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 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 growing 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*, the Fish Inspection Regulations and the Canada - United States Bilateral Agreement on Shellfish (Appendix IV). The Acts, Regulations and the Memorandum of Understanding between the CFIA, DFO and Environment Canada enable the Departments to:

- a) classify all actual and potential shellfish growing 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;
 - ii) patrol growing areas;
 - iii) apprehend persons violating restrictions; 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 growing 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 integrity and to provide for proper labelling and packaging;
- i) regulate the controlled purification of shellstock to prevent illegal diversions, ensure cleansing, protect against recontamination, verify product quality and purification effectiveness, maintain production and product quality records and provide for proper labelling and packaging;
- j) suspend, revoke, void, or refuse to issue or renew a Certificate of Registration in accordance with the policies set out in the Facilities Inspection Manual;
- k) evaluate laboratories performing shellfish analyses in accordance with the requirements of this Manual;
- l) collect samples and conduct appropriate bacteriological, chemical and physical tests necessary to determine product quality and monitor the effectiveness and performance of process operations;
- m) prohibit the export - or possession of - shellfish from: unidentified sources; uncertified dealers or unapproved growing areas; sources which did not harvest, transport, process or pack the shellfish in accordance with requirements of the Fish Inspection

Regulations; or sources which might otherwise cause the shellfish to be unfit for human consumption (that is tainted, decomposed or unwholesome). Shellfish exhibiting the above defects shall be detained or seized.

1.3 Certification and Registration Procedures

Shellfish establishments shall be registered and certified in accordance with the following criteria and procedures:

- a) The Shellfish Program requirements shall be applied to all commercial shellfish harvesters; all persons handling the shellfish prior to its delivery to the processor; all persons engaged in controlled purification, wet storage, shucking, packing and repacking; or other forms of processing for export.
- b) Each facility shall be registered according to the procedures described in Chapter 2, Subject 1 of the Facilities Inspection Manual and, if applicable, certified to the Interstate Certified Shellfish Shippers List (ICSSL) according to Chapter 2, Subject 2 of the Facilities Inspection Manual, published and 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 Chapter 7 of the Facilities Inspection Manual.

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 whose Certificate of Registration has been 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

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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
 - v) records of prosecutions.
- g) The CFIA is responsible for completing Form FDA 3038, Interstate Shellfish Dealer's Certificate, and forwarding the completed form to the FDA Division of Cooperative Programs for posting on the Interstate Certified Shellfish 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 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

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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); and

- iv) an expiration date that is preferably the same for all firms, and preferably the last day of a month.
- h) The following guidelines are followed in managing the issuance of shellfish certificates:
 - i) when a change is made to an existing, unexpired certificate or a withdrawn certificate, a new corrected certificate is issued;
 - ii) shippers are informed by the certifying officer of the probable date their names will appear on the List and should be advised against making shipments prior to the date. If shipments must be made before the appearance of the shipper's name on the List, the certifying officer will notify the FDA headquarters' office;
 - iii) if CFIA officials cancel a shellfish shipper's Certificate of Registration, the FDA is notified immediately and a completed Form FDA 3038, is forwarded to the FDA Division of Cooperative Programs informing them that the shipper should no longer be listed on the ICSSL;
 - iv) ICSSL renewal certificates should be sent to the FDA so they are received by the FDA's Division of Cooperative Programs prior to the date of posting of the List (usually the 15th of the month) for the month that the original certificates expire. Certificates will be withdrawn automatically from the List on the date of expiration unless renewal forms have been received by the FDA; and
 - v) inspectors are provided with appropriate equipment and supplies to conduct inspections and compliance verifications of certified shippers.