Canadian Shellfish Sanitation Program - Manual of Operations

18/06/2012

Foreword

The Canadian Shellfish Sanitation Program (CSSP) Manual of Operations is an essential reference document for government staff involved with duties related to the classification and patrolling of shellfish harvesting areas and the harvesting, processing and distribution of shellfish. The manual has been compiled through input from regional staff of the Canadian Food Inspection Agency (CFIA), Fisheries and Oceans Canada (DFO) and Environment Canada (EC). To facilitate the application of the Canada/United States Shellfish Agreement of 1948, the manual incorporates some material from the United States' National Shellfish Sanitation Program (NSSP) Manual of Operations, which is applicable to the Canadian program. Although some administrative and technical differences exist between the CSSPand the NSSP manuals, the Programs are equivalent in providing reasonable assurance that bivalve molluscs are safe for consumption.

The manual outlines the authorities (acts and regulations), policies and procedures which apply to the Canadian program and which will be used to evaluate regional activities associated with the Shellfish Sanitation Program including governing the control of shellfish growing areas, and the harvesting, processing and distribution of shellfish. The manual will be reviewed on a regular basis and amended when necessary to ensure that the policies and procedures remain up-to-date.

This manual is also integrally linked to the Facilities Inspection Manual, published and maintained by the Canadian Food Inspection Agency. The Facilities Inspection Manual sets forth the requirements for registration, inspection, audit and enforcement of seafood processing facilities, including shellfish facilities, that come under the jurisdiction of the Fish Inspection Regulations. The Facilities Inspection Manual also describes how each facility must design and implement their own Quality Management Program (which includes Hazard Analysis Critical Control Point (HACCP) principles) and how the CFIA assesses compliance through regulatory verification.

This manual is not intended to be all inclusive. It is to be used in conjunction with other appropriate source materials and is meant to be a reference source and not a training manual.

Enquiries concerning processing and distribution should be directed to:

Senior Policy Analyst - CSSP
Canadian Food Inspection Agency
1400 Merivale Road
Tower 2, 5th Floor
Ottawa, Ontario
K1A 0Y9

Enquiries concerning the classification of growing areas should be directed to:

Director, Water Quality Monitoring and Surveillance
Science and Technology Branch
Environment Canada
200 Sacré-Cœur Blvd., 12th Floor
Gatineau, Quebec
K1A 0H3

Enquiries concerning patrolling and harvesting should be directed to:

Enforcement Branch
Conservation and Protection Directorate
Fisheries and Oceans Canada
200 Kent Street
Ottawa, ON
K1A 0E6

Amendment Register

PDF (194 kb)

No.	Date	Chapter/Subject Amended
4	January 2018	• Chapter 13 - Outbreaks of shellfish-related illness (New) New guidance for responding to illnesses linked to bivalve shellfish consumption.
3	July 2016	• **Chapter 4** - Clarify the requirements for human waste containment on vessels and its application to all vessels during harvesting or aquaculture maintenance activities within 3 nautical miles of shore. Appendix H of the Facilities Inspection Manual on guidelines for "Effective HACCPControls for Molluscan Shellfish Processing Establishments" has also been revised to include guidance on the HACCP controls for human waste containment.
2	July 2013	• **Definitions** - A new definition for "marginally contaminated areas" has been added. The definition of "closed status" has been updated to reflect the potential for harvesting in closed areas, provided specific requirements are met. The various definitions for "Relay" and "depuration" have been updated as a result of these changes. The definition for "Scheduled purification process" has been removed as it is no longer used in the manual. (Version 2) • **Chapter 2** - Information has been added regarding harvesting in conditional areas while in the closed status (section 2.3.3 and 2.3.5). Details have been included about re-classification of conditionally classified areas when a conditional management plan (CMP) cannot be implemented (sections 2.3.3 and 2.3.5). Sections 2.3.6, prohibited classification, has been revised to reflect guidance from Health Canada on managing the risk of viruses associated with waste water treatment plants. (Version 2) • **Chapter 10** - The chapter has been updated to consistently use the term "validation" with respect to depuration and relay processes. The minimum depuration time has been changed to 44 hours (from 48), provided that the process has been validated. Information in Section 10.2.4 has been removed pending an update to the requirements for

No.	Date	Chapter/Subject Amended
		laboratories housed within registered establishments. In section 10.2.5, text has been added to allow for approved area shellfish and shellfish destined for depuration to be transported together, provided QMP controls are in place. Text has been revised in Section 10.4.1 to reflect the potential for harvesting in areas in the closed status, as per the definition. (Version 3) • **Appendix 9** - The protocol for the Management of a Conditional Area has been updated to reflect the new wording in Chapter 2 regarding the classification of conditional areas when a conditional management plan (CMP) cannot be implemented. (Version 2)
1	18 June 2012	• **Definitions** - Revision to the definition of wet storage to provide clarification on the use of the word temporary. A time frame of less than 60 days has been added. (Version 3) • **Chapter 11** - Provides additional guidance for making any significant changes to area/regional/district marine biotoxin control plans (11.4) (Version 2) • **Appendix 3** - Changes to come in line with CFIA's move of focus from sampling in harvest areas to sampling at registered molluscan shellfish processing establishments. Text in Appendix III and flow chart have been updated to incorporate testing for Salmonella into the procedures. (Version 2)

Definitions

Approved Area

The classification of a shellfish growing area which has been approved by the shellfish control authority for growing or harvesting shellfish for direct marketing. The classification of an approved area is determined through a sanitary survey conducted by the shellfish control authority in accordance with Chapter 2 of this Manual. An approved shellfish growing area may be temporarily placed in the closed status when a public health emergency, resulting from for instance, a hurricane or flooding, is declared.

Blower

A container for washing shucked shellfish which uses forced air as a means of agitation.

Canadian Association for Laboratory Accreditation Inc. (CALA)

A recognized ISO accrediting body.

Canadian Shellfish Sanitation Program

A program to classify harvesting areas and control the commercial and recreational harvesting of molluscs and processing of product for the consumer market.

Certification Number

The number assigned by the Canadian Food Inspection Agency (CFIA) to each certified shellfish dealer. It consists of a one to five digit number preceded by the two letter province abbreviation and followed by the two letter symbol designating the type of operation certified.

Coliform Group

The coliform group includes all of the aerobic and facultative anaerobic, Gram-negative, non spore-forming bacilli which ferment lactose with gas formation within 48 hours at 35°C.

Commingling

The act of combining different lots of shellfish or shucked shellfish.

Conditional Management Plan (CMP)

An agreement signed by relevant parties for the management of shellfish in conditionally classified areas.

Conditionally Restricted Area

The classification of a shellfish growing area which has been determined by the shellfish control authority to meet, at a minimum, the restricted classification criteria for a predictable period. The period is conditional upon established performance standards specified in a conditional management plan.

Conditionally Approved Area

The classification of a shellfish growing area which has been determined by the shellfish control authority to meet approved area criteria for a predictable period. The period is conditional upon established performance standards specified in a conditional management plan.

Container

Any bag, sack, tote, conveyance or other receptacle used for containing shellfish for holding or transporting.

Container Relaying

The transfer of shellfish from marginally contaminated areas to approved areas for natural biological cleansing in a container using the ambient environment as a treatment system.

Controlled Purification or Depuration

The process of using a controlled, aquatic environment to reduce the level of bacteria and viruses in live shellfish.

CSSP Laboratory

A laboratory performing CSSP testing for regulatory purposes that has been accredited to the international standard ISO/IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories by a recognized accrediting body. The laboratory must be listed in the accrediting body's directory of accredited laboratories and have a valid scope of accreditation which includes methods specified by the CSSP.

Dealer

A commercial shellfish shipper, reshipper, shucker-packer, repacker, or depuration processor or operation.

Depuration Plant

A depuration plant is a facility of one or more depuration units. A depuration unit is a tank or series of tanks supplied by a single process water system.

Depuration Processor (DP)

A person who receives shellstock from approved areas or marginally contaminated areas and submits such shellstock to an approved controlled purification process.

Detection

The point in time at which a waste water treatment or collection system release / discharge incident (as defined in the relevant CMP) is first detected by a waste water treatment plant or collection system operator (or delegate).

Dry Storage

The storage of shellstock out of water.

Emergency Closure

A shellfish harvesting area in the open status my be placed in the closed status when it is suspected that shellfish may be contaminated as a result of an emergency situation. These emergency situations may include natural or operational events such as hurricanes, flooding, and emergency oil, toxic chemical and major sewage spills.

Extended Container Relaying

The transfer of shellfish from marginally contaminated areas to approved areas for natural biological cleansing in a container, using the ambient environment as a treatment system, for a period of 14 days or greater.

Faecal Coliform Group

The faecal coliform group includes bacteria of the coliform group which will produce gas from lactose in a suitable multiple tube procedure liquid medium (EC or A-1) within 24 ± 2 hours at 44.5 ± 0.2°C in a water bath.

Growing Area

An area which supports or could support live shellfish.

Harvest Lot

A collection of bulk shellstock or containers of shellstock from a defined growing area taken by one or more harvesters and removed from the water for delivery to the processing plant on the same day. Where the amplitude of the tide does not allow harvesting except during a low-running (spring) tide, the product can be wet stored on the beach for a maximum of two weeks and taken to the processing plant as a lot.

Harvester

A person who takes shellfish, by any means, from a growing area.

Harvesting record

Is an official record identifying where, when, and the quantity of shellfish that was harvested by a harvester.

Heat Shock

The process of subjecting shellstock to any form of heat treatment, such as steam, hot water or dry heat for a short period of time prior to shucking to facilitate removal of the meat from the shell without substantially altering the physical or organoleptic characteristics of the shellfish.

Integrated Multi-trophic Aquaculture (IMTA)

The raising of shellfish and finfish within a 125 metre radius of one another in the marine environment.

ISO/IEC 17025:2005

An internationally recognized standard describing the General Requirements for the Competence of testing and Calibration Laboratories jointly developed by the International Organization of Standardization (ISO) and the International Electrotechnical Commission (IEC). (See also definitions for SCC and CALA)

Lease

A defined geographic area in a marine environment described by a federal or provincial agency and approved by the Competent Authority (Shellfish Control Agency or provincial equivalent) for the purposes of culturing, harvesting and/or relaying (exploratory or commercial) of bivalve molluscs. This definition includes all tenures, licenses of occupation or license issued under MCFR to an individual, group or company by the Competent Authority.

Lot of Shellstock

A collection of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area by one or more harvesters.

Lot of Shellstock for Depuration

Shellstock harvested from an area at a particular time and delivered to one depuration plant.

Lot of Shucked Shellfish

A collection of containers of no more than one day's shucked shellfish product produced under conditions as nearly uniform as possible and designated by a common container code or marking.

Marginally Contaminated Area

A classified area from which shellfish may be harvested for controlled purification and /or relay. Some examples include conditionally approved (in closed status), restricted and conditionally restricted.

Marine Biotoxins

Poisonous compounds accumulated by shellfish feeding upon toxin containing dinoflagellates, such as Alexandrium(formerly Gonyaulax and Protogonyaulax) cantenella, A. fundyense, A. tamarensis, and Ptychodiscus brevis, or marine diatoms such as Pseudo-Nitzchia species (formerly Nitzschia pungens).

Master Harvester

A person employed, or assigned, by a federally registered shellfish establishment, to carry out specific monitoring duties at approved or conditionally approved shellfish areas in the open status and maintain records for the establishment, as described in the Quality Management Program.

Most Probable Number (MPN)

The MPN is a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.

National Shellfish Sanitation Program (NSSP)

The cooperative United States, State-Food and Drug Administration (FDA)-Industry program, for certification of interstate shellfish shippers as described in the NSSP Manual of Operations, Parts I and II. Foreign governments may be members by having a current Memorandum of Understanding (MOU) or agreement with the FDA.

Natural Relaying

The transfer of shellfish from marginally contaminated areas to approved areas for natural biological cleansing, using the ambient environment as a treatment system for periods of 14 days or greater.

Notification

The point in time at which one of the federal CSSP partners receives notice from a waste water treatment or collection system operator (or delegate) of a release / discharge incident (as defined in the relevant CMP).

Poisonous or Deleterious Substance

A toxic compound occurring naturally or added to the environment that may be found in shellfish for which a regulatory tolerance limit or action level has been established or may be established to protect public health. Examples of naturally occurring substances would be paralytic shellfish toxins and trace elements, such as mercury, geologically leached from the environment. Examples of added substances would be agricultural pesticides and polynuclear aromatics from oil spills.

Process Batch

A quantity of shellstock used to fill each separate tank, or series of tanks, supplied by a single process water system for a specified depuration cycle in a depuration activity.

Prohibited Area

The classification of a shellfish growing area determined by the shellfish control authority where shellfish harvesting for food purposes is not permitted.

Quality Management Program (QMP)

A fish inspection and control system, that includes procedures, inspections and records, for the purpose of verifying and documenting the processing of fish and the safety and quality of fish processed in, exported from or imported into Canada.

Recognized Non-GoC Sampler

An individual or company employee who is not a Government of Canada CSSP employee (e.g. contractor, volunteer, employee from other government departments, indigenous peoples, individual grower, etc.), who has been deemed competent by the CSSP shellfish control authority to collect marine water and/or shellstock samples according to prescribed CSSP sampling procedures.

Regional Interdepartmental Shellfish Committee (RISC)

The committee established under the Canadian Shellfish Sanitation Program (CSSP), composed of area/regional Fisheries and Oceans Canada (DFO), Environment Canada (EC), the Canadian Food Inspection Agency (CFIA) staff to, manage, prioritize, and coordinate CSSP activities. RISCs provide input, advice and financial decisions on the classification of shellfish growing areas and on the management of microbiological, chemical and/or biotoxin contamination.

Relaying

The transfer of shellfish from marginally contaminated areas to approved areas for natural biological cleansing using the ambient environment as a treatment system.

Remote Shellfish Area

A shellfish growing area that has no human habitation and is not impacted by any actual or potential pollution sources.

Repacker (RP)

A person other than the original certified shucker-packer who repacks shucked shellfish into other containers. A repacker may also repack and ship shellstock. A repacker shall not shuck shellfish.

Reshipper (RS)

A person who purchases shucked shellfish or shellstock from other certified shippers and sells the product without repacking or relabelling to other shippers, wholesalers or retailers.

Response

A series of actions taken by the federal shellfish control authorities as defined in the relevant CMP based on the classification of the area which will serve to ensure that product does not reach market and that the implicated area is placed in closed status.

Response Line

The boundary at which the sewage effluent plume is predicted to lie during a waste water treatment plant or collection system release/ discharge incident when the competent shellfish control authority will respond.

Restricted Area

The classification of a shellfish growing area determined by the shellfish control authority where shellfish shall not be harvested for direct consumption.

Sanitary Survey

The evaluation of all actual and potential pollution sources and environmental factors having a bearing on shellfish growing area water quality.

Sanitize

The treatment to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing the number of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Standards Council of Canada (SCC)

A recognized ISO accrediting body.

Scheduled Heat Shock Process

The process selected by the processor and approved by the shellfish control agency to heat shock a shellfish species in order to facilitate shucking without adversely affecting the microbial quality or altering the organoleptic characteristics of the species.

Seed

A submarket size bivalve shellfish requiring a minimum of 6 months to reach market size under normal growing conditions, that has been gathered from a lease site or directly from the wild, or grown in a hatchery, and transplanted or relayed to a private lease site or public shellfish bed for grow-out.

Shellfish

All edible species of oysters, clams, mussels and scallops (except for the adductor muscle) either shucked, in the shell, fresh or fresh frozen or whole or in part. For the purposes of marine biotoxin control predatory gastropod molluscs shall also be included.

Shellfish-related illness cluster

Laboratory confirmed or clinical illness Footnote 1 in one or more individuals all exposed together to the same shellfish at the same time in the same location. Footnote 2 Footnote 3

Shellstock

Shellfish in the shell.

Shellfish Control Agency / Authority

The department or agencies of the Government of Canada that are signatories to the Interdepartmental Memorandum of Understanding which is found in Appendix V of this manual.

Shellstock Shipper (SS)

A person who grows, harvests, buys, or repacks and sells shellstock. They are not authorised to shuck shellfish nor to repack shucked shellfish. A shellstock shipper may also ship shucked shellfish.

Short-term Container Relaying

The transfer of shellfish from marginally contaminated areas to approved areas for natural biological cleansing in a container using the ambient environment as a treatment system for periods of less than 14 days.

Shucked Shellfish

Shellfish, whole or in part, from which one or both shells have been removed.

Shucker Packer (SP)

A person who shucks and packs shellfish. A shucker packer may act as a shellstock shipper or may repack shellfish originating from other certified dealers.

Spat

Newly settled spawn of bivalve shellfish that has been cultivated in a laboratory or hatchery or collected from the wild using a variety of techniques (e.g., monofilament lines, cement-coated collectors, etc.).

Spring Tide

A tide of increased range that occurs twice monthly at the new and full phases of the moon.

Status

Describes whether shellfish harvest is permitted and is independent of the classification of the area Footnote 4

- **Open** - Any classified area where shellfish harvest is authorized.
- **Closed** - Any classified area where shellfish harvest is not authorized.
  There may be circumstances under which areas in closed status can be harvested for depuration or relay provided they meet the requirements for such.

Transaction Record

A form(s) used to document each purchase or sale of shellfish at the wholesale level.

Turbidity

Reduced water clarity resulting from the presence of suspended matter.

Wet Storage

The temporary storage (less than 60 days) of "live" shellfish from approved sources, intended for marketing, in containers or floats in natural bodies of "seawater" or in tanks containing natural or synthetic seawater.

Footnotes

Footnote 1

Illness compatible with a pathogen or toxin known to be associated with fish or shellfish.

Return to footnote 1 referrer

Footnote 2

Secondary illness in the same household would be excluded.

Return to footnote 2 referrer

Footnote 3

During an outbreak, multiple clusters can occur if individuals are exposed in different places or at different times.

Return to footnote 3 referrer

Footnote 4

Open and closed status differs from openings and closures made pursuant to a prohibition order issued under the Management of Contaminated Fisheries Regulations (MCFR). For example, a restricted area in the Open Status or a conditionally classified area in closed status is limited to the harvest of shellfish by a MCFR licence for depuration or relay.

Return to footnote 4 referrer

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, for the identification and evaluation of pollution sources and for the recommendations of the classification of shellfish harvesting areas on the basis of growing water surveys.

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 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, EC 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 areas;
d. to make recommendations to the Regional Head, Marine Water Quality Monitoring Unit, EC, 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;
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 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 EC 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 the CFIA, DFO and EC 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;
    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 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. collect samples and conduct appropriate bacteriological, chemical and physical tests necessary to determine product quality and monitor the effectiveness and performance of process operations;
l. prohibit the export - or possession of - shellfish from: unidentified sources; uncertified dealers or unapproved shellfish 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 Registration and Certification Procedures

Registration

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 in accordance with the procedures identified in Chapter 2, Subject 1 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 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 - Procedures for Molluscs Exceeding CFIA Bacteriological Guidelines);
    iv. records of complaints or inquiries and follow-up actions taken; and
    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 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.

Chapter 2 - Shellfish Area Survey and Classification

2.1 Introduction

In order to minimize the potential health risks associated with consuming bivalve molluscan shellfish and to protect public health, it is necessary that the water quality in shellfish areas be surveyed and that actual and potential sources of pollution be identified. Following such surveys, the shellfish areas are classified as to their suitability for the harvesting of shellfish according to accepted water quality standards and general sanitary conditions in the shellfish area. The following sections describe the various types of surveys used to assess shellfish areas, and the principles used in assigning specific classifications to these areas.

Environment Canada's Marine Water Quality Monitoring Program is the first line of defence in the sanitary control of shellfish. The program is designed to identify and evaluate all sources of pollution to shellfish growing and harvesting waters. Since these waters are a pathway by which pathogenic micro-organisms and other contaminants are introduced into shellfish, the classification of shellfish areas with respect to their pollutant levels (actual and potential) is of paramount importance in determining the suitability of shellfish for human consumption.

There is extensive evidence of illness in humans associated with the consumption of contaminated shellfish (Rippey, 1991; Hackney and Pierson, 1994). The more common of these illnesses include: typhoid, salmonellosis, gastroenteritis, infectious hepatitis, Vibrio parahaemolyticus and Vibrio vulnificus infections, paralytic shellfish poisoning (PSP), and amnesic shellfish poisoning (ASP) (Rippey, 1991). The positive relationship between sewage pollution of shellfish areas and enteric disease has been discussed by Hackney and Pierson, (1994) and Burkhardt and Calci, (2000).

Pollution of shellfish areas can occur from a variety of sources and under many different conditions. Generally, pollution sources are divided into two broad categories: point and non-point. A point source of pollution enters the receiving water at discrete, measurable locations such as in releases/discharges from wastewater treatment and collection systems, pulp mills, food processing establishments, etc. Non-point source pollution refers to contamination from sources related to the activities of man and to natural processes in the watershed which are diffuse or dispersed. Such sources do not enter at discrete, identifiable locations and are difficult to measure or define. The United States Food and Drug Administration (USFDA, 1995) has described eight types of non-point source pollution which may affect shellfish areas. These include urban runoff, agricultural runoff, animal faecal pollution, sewage discharges from boats, wildlife faecal matter, dredging operations, mining (e.g., leaching), and silviculture practices. Both point and non-point pollution sources can release chemical and/or microbiological contaminants of public health concern.

Any requests for new area classification must be submitted in writing to the chairperson of the Regional Interdepartmental Shellfish Committee (RISC). Each CSSP department/agency will assess the impact of the request on departmental/agency responsibilities and will report back to the RISC before any work commences on classifying a new area. (Refer to Appendix XIII for procedures)

The following sections of this Chapter outline the requirements for shellfish area surveys and classification.

2.2 Shellfish Growing Water Surveys

Under the Canadian Shellfish Sanitation Program (CSSP), shellfish growing water surveys form the basis for assigning and maintaining the classification of an area as suitable for shellfish harvest. The type of survey required for a given area depends on prior knowledge of both water quality and pollution source types. Surveys are categorized as:

- comprehensive;
- annual review; and
- re-evaluation.

The requirements for each of these surveys are outlined in the following text.

2.2.1 Comprehensive Surveys

The comprehensive survey is a detailed evaluation and assessment of all environmental factors including actual and potential pollution sources which affect the water quality in a shellfish area.

A comprehensive survey is conducted in areas where previous data are non-existent or obsolete, or where significant changes have occurred in the pollution status of the area which may affect its classification.

The requirements for conducting a comprehensive survey are:

a. a shoreline sanitary investigation designed to identify and evaluate all actual and (potential) sources of pollution affecting the shellfish area;
b. an evaluation of the meteorological and hydrographic factors that may affect the distribution of pollutants throughout the area; and
c. a bacteriological examination of the growing waters which is designed to determine the extent of faecal contamination, and provide quantitative data for the classification of growing waters. Where available, other bacteriological data/studies (e.g., sediment, shellfish analysis, pollution inputs) should also be considered for classification purposes.

Specific Requirements for Comprehensive Surveys

a. Bacteriological monitoring should be conducted under varied environmental conditions. The number and location of sampling stations selected should be adequate to produce the data necessary to effectively evaluate all point and non-point sources of pollution.
b. A minimum of fifteen (15) samples shall be collected at each station. In remote shellfish areas this requirement may be modified if warranted by the sanitary conditions in the area.
c. In certain circumstances, an alternative sampling strategy, systematic random sampling, may be used. All sampling requirements, i.e. standards, sampling frequency, and data analysis are as outlined in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2007.

2.2.2 Annual Review Survey

Annual review surveys update the classification of the area. They are conducted to confirm that sanitary conditions have not changed and that the classification is still valid.

The requirements for conducting annual review surveys are:

a. a file review to evaluate the changes in existing and new pollution sources; and
b. a shoreline sanitary investigation if deemed necessary; and

c. a minimum of five (5) samples collected at each station for non-remote areas and two (2) samples for remote areas.

2.2.3 Re-evaluation Survey

A re-evaluation survey updates the classification of the area, requiring an in depth assessment of the elements of the comprehensive survey. The complexity and extent of a re-evaluation survey will be specific for each area.

The requirements for conducting a re-evaluation survey are:

a. a complete re-evaluation of the classification of each shellfish area once every three years (this requirement may be modified in remote shellfish areas if warranted by the sanitary conditions in the area); and
b. when the annual review shows that the sanitary quality of an area is likely to be significantly altered by changes in the pollution sources. In this case a re-evaluation of a shellfish area will be performed within one year.

Specific Requirements for Re-evaluation Surveys

a. Bacteriological monitoring should be conducted under varied environmental conditions. The number and location of sampling stations selected should be adequate to produce the data necessary to effectively evaluate all point and non-point sources of pollution Footnote 3.
b. A minimum of 5 samples shall be collected at each station for non-remote areas and two (2) samples for remote areas.
c. The analysis of at least the last fifteen (15) water samples from each representative station and other field works will be undertaken as deemed necessary to determine the appropriate classification for the area.

2.2.4 Documentation

a. A report shall be prepared for each survey containing data and assessments for components of the surveys described in the previous sections.
b. A file containing all pertinent sanitary survey information, including the dates and results of preceding surveys and reports is maintained by the shellfish control authority for each classified shellfish area.

2.3 Classification of Shellfish Areas

2.3.1 Classification versus status of a shellfish area

The CSSP recognizes five major classification categories:

- Approved;
- Conditionally Approved;
- Restricted;
- Conditionaly Restricted; and
- Prohibited.

Specific area classifications, and their boundaries, are assigned to shellfish areas based on sanitary and water quality survey results. Recommendations for classification are reviewed by Regional Interdepartmental Shellfish Committees before adoption.

The status of a shellfish area is separate and distinct from its classification and may be open or closed for the harvesting of shellstock. Refer to Status in Definitions section of this Manual.

2.3.2 Approved Classification

Shellfish areas may be classified as Approved if the area is not contaminated with faecal material, pathogenic micro-organisms, poisonous or deleterious substances, to the extent that consumption of the shellfish might be hazardous. The following conditions must also be met:

a. the median or geometric mean faecal coliform Most Probable Number (MPN) of the water does not exceed 14/100 mL, and not more than 10% of the samples exceed a faecal coliform MPN of 43/100 mL, for a five-tube decimal dilution test; Footnote 4 or
b. The chemical levels meet the standards/tolerances outlined in Appendix II of this Manual and in the Fish Products Standards and Methods Manual, Appendix III Canadian Guidelines for Chemical Contaminants and Toxins in Fish and Fish Products.

Evidence of potential pollution sources such as sewage lift station overflows, direct sewage discharges, septic tank seepage, etc., is sufficient to exclude the growing waters from the approved classification.

2.3.3 Conditionally Approved Classification

Conditionally Approved is the classification of a shellfish area which has been determined by the shellfish control authority to meet the Approved criteria for a predictable period. These shellfish areas are subject to intermittent pollution caused by releases/discharges from wastewater and collection systems, seasonal populations, non-point source pollution, or boating activity. The period meeting the Approved criteria (for other than seasonal boating activity) is conditional upon established performance standards specified in a Conditional Management Plan. A conditionally approved shellfish area which does not meet the Approved shellfish area criteria is placed in closed status by the shellfish control authority.

An area may be classified as "Conditionally Approved" if the following conditions are met:

a. when placed in open status, the area meets all of the requirements of an Approved area;
b. conditions which will result in the area reverting to closed status are:
    i. easily identified by routine measurement and reporting; and
    ii. predictable and/or controllable.

Specific Requirements

a. Shellfish can be harvested in conditionally approved areas only when:
    i. procedures have been followed as outlined in Appendix IX to develop and implement a Conditional Management Plan outlining the responsibilities and duties of all parties;
    ii. all necessary measures have been taken to ensure that performance standards will be met; and
    iii. precautions have been taken to assure that shellfish will not be marketed from the areas during any period when the area fails to meet the performance standards or before the shellfish can purify themselves of polluting micro-organisms.

b. The conditionally approved area shall be immediately placed in the closed status when the criteria established in the Conditional Management Plan are not met. A conditionally approved area which has placed in the closed status shall not be re-opened to shellfish harvesting until:
    i. the criteria established in the Conditional management plan are fully met;
    ii. a time has elapsed which is sufficient, under environmental conditions, to permit natural biological cleansing of the shellfish; (Note: With respect to conditionally approved areas based on performance of wastewater treatment and collection systems, under no circumstances will the affected area be opened sooner than seven (7) days after the release/ discharge event ceased); and
    iii. verification indicates that the bacteriological quality of the water and shellfish has again met the Approved area standards. For water quality, the median of the samples collected for the area in one survey cannot exceed 14 MPN/100 ml and no more than 10% of the samples can exceed 43 MPN/100ml. In five (5) shellstock samples, only one (1) fecal coliform result may exceed 230 MPN/100g, and no result may exceed 330 MPN. (Note: With respect to conditionally approved areas based on performance of wastewater treatment and collection systems, the area may return to the open status without verification sampling if a minimum of 21 days has elapsed since the release/discharge event ceased.)
c. A conditionally-approved area in closed status may be harvested provided the area meets the requirements outlined in section 2.3.4 - Specific Requirements b) and 2.3.6 and the harvester is licensed under the Management of Contaminated Fisheries Regulations.
d. The conditionally approved classification shall be re-evaluated by the regional interdepartmental shellfish committee if/when a conditional management plan cannot be implemented. In the case of conditionally classified areas based on the operation of a wastewater system, the classification must take into account the assumed failure conditions of the system.
e. In addition to the verification monitoring previously outlined, monitoring is required to confirm that the Approved classification criteria are being met when the area is in the open status. When the Conditional Management Plan is based on the operation and performance of a wastewater treatment and collection system, combined sewer overflows, or other point sources of pollution, monthly samples minimum five (5) are required during the period(s) when the area is in the open status. Alternatively, the minimum number of water quality samples may be supplemented with effluent samples provided that minimum frequency requirements are maintained. When the Conditional Management Plan is based on the effects of non-point pollution, such as rainfall events, stormwater run-off, and seasonal variations, a minimum of five (5) water samples shall be collected during the period when the area is in the open status.
f. Seasonal closures based on the presence of boats may not require analysis of water and shellfish before reopening; however, there must be verification to ensure that the boats are no longer present.
g. The Conditionally Approved area shall be evaluated at least once each year by the Regional Interdepartmental Shellfish Committee. The evaluation shall include the review of the annual report provided by DFO (or other agency by agreement with DFO), with input from CFIA and EC, documenting all data relating to the operation of the Conditionally Approved area.
h. There should be a complete understanding of the purpose of the conditionally approved classification by all parties concerned, including the shellfish industry. If the cooperation of all interested parties is not assured, the federal partners will not approve the area for direct harvesting.
i. Any failure to meet the conditions of the Conditional Management Plan must be immediately reported to and acknowledged by the federal partners.
j. If at any time any party to the Conditional Management Plan fails to fulfill the requirements as set forth in the Plan, the Regional Interdepartmental Shellfish Committee (RISC) will determine whether the area classification or status will be changed.
k. All data relating to the operation of a Conditionally Approved area, will be maintained in a file by the shellfish control authority or authorities.

2.3.4 Restricted Classification

Restricted is the classification of shellfish area where the harvesting of shellfish is not permitted, except by license issued under the Management of Contaminated Fisheries Regulations (DFO, 1990) due to contamination by faecal material, pathogenic micro-organisms, poisonous or deleterious substances, to the extent that consumption of the shellfish might be hazardous.

Shellfish areas are classified as Restricted under any of the following conditions:

a. the shoreline sanitary survey, other monitoring program data or other events, indicates that the area is contaminated, or has the potential to become contaminated, provided that the area is not contaminated to the extent where it would be classified as Prohibited;
b. the median or geometric mean faecal coliform Most Probable Number (MPN) of the water exceeds 14/100 mL, and/or more than 10% of the samples exceed a faecal coliform MPN of 43/100 mL, for a five-tube decimal dilution test Footnote 5 or
c. the chemical levels exceed the standards/tolerances outlined in Appendix II and the Fish Products Standards and Methods Manual, Appendix III Canadian Guidelines for Chemical Contaminants and Toxins in Fish and Fish Products.

Specific Requirements

a. No shellfish shall be taken from these areas except by licence under the Management of Contaminated Fisheries Regulations (DFO, 1990) whereby the shellfish must be subject to a decontamination plan (e.g., for depuration, natural relaying, container relaying or canning), which has been accepted by the shellfish control authority. Such areas must meet the criteria outlined below (see also Chapter 10, Policy and Procedures for Controlled Relaying and Depuration). Harvesting from areas classified as Restricted may be allowed on a limited basis by licence issued under the Management of Contaminated Fisheries Regulations noted above the for the purpose of scientific investigation, food and bait purposes.
b. If an area within a Restricted classification is to be used for depuration, the following criteria must be met:

   The median or geometric mean faecal coliform (MPN) of water shall not exceed 88/100 mL and not more than 10% of the samples shall exceed a faecal coliform MPN of 260/100 mL, for a five-tube decimal dilution test Footnote 6.

c. The Restricted classification will not be revised upward without at least a re-evaluation survey report indicating improvements in sanitary conditions and water quality and upon meeting the appropriate classification standards.
d. Depending on the degree of contamination in the growing waters, it may not be possible to adequately depurate or naturally purify the shellfish. In these cases, no harvesting is permitted under any circumstances. These areas are classified as Prohibited Areas (see Section 2.3.6).

2.3.5 Conditionally Restricted Classification

Conditionally Restricted is the classification of a shellfish area which has been determined by the shellfish control authority to meet, at a minimum, the Restricted classification criteria for a predictable period. These shellfish areas are subject to intermittent pollution caused by releases/discharges from wastewater treatment and collection systems, seasonal populations, non-point source pollution, or boating activity. The period meeting the Restricted criteria (for other than seasonal boating activity) is conditional upon established

performance standards specified in a Conditional Management Plan. Harvesting is prohibited when a Conditionally Restricted shellfish area is in the closed status.

An area may be classified as Conditionally Restricted, if the following are met:

a. during those times when harvesting is permitted (i.e., in the open status of its classification), the area meets all of the requirements of a Restricted area;
b. conditions which will result in the area reverting to closed status are:
    i. easily identified by routine measurement and reporting; and
    ii. predictable and/or controllable.

Specific Requirements

a. Shellfish can be harvested in conditionally restricted areas only when:
    i. procedures have been followed as outlined in Appendix IX to develop and implement a documented conditional Management Plan outlining the responsibilities and duties of all parties;
    ii. all necessary measures have been taken to ensure that performance standards will be met, and;
    iii. precautions have been taken to assure that shellfish will not be depurated or relayed from the areas during any period when the area fails to meet the performance standards or before the shellfish can purify themselves of polluting micro-organisms.
b. Harvesting will immediately cease in a Conditionally Restricted area in the closed status. A conditionally restricted area in the closed status shall not be re-opened to shellfish harvesting (for depuration or relaying purposes) until:
    i. the criteria established in the Conditional Management Plan are fully met;
    ii. a time has elapsed which is sufficient, under environmental conditions, to permit natural biological cleansing of the shellfish; (Note: With respect to wastewater treatment and collection systems, under no circumstances will the affected area be opened for restricted harvesting sooner than seven (7) days after the release/discharge event ceased. The area may return to the open status without verification sampling if a minimum of 21 days has elapsed since the release/discharge event ceased);
    iii. specific to harvest for depuration, verification that the bacteriological quality of the water and shellfish has again met standards. For water quality, the median of the samples collected for the area in one survey cannot exceed 88 MPN/100 mL and no more than 10% of the samples can exceed 260 MPN/100 mL. Shellstock samples shall not exceed 2300 MPN/100g.
    iv. specific to harvest for long term relay, seven (7) days after the release/discharge event has ceased (without verification sampling).
c. A conditionally-restricted area in closed status may be harvested provided that the area meets the requirements outlined in section 2.3.4 - Specific Requirements b) and 2.3.6 and the harvester is licensed under the Management of Contaminated Fisheries Regulations.
d. The conditionally restricted classification shall be re-evaluated by regional interdepartmental shellfish committee if/when a conditional management plan cannot be implemented. In the case of conditionally classified areas based on the operation of a wastewater system, the classification must take into account the assumed failure conditions of the system.
e. In addition to the verification monitoring previously outlined, monitoring is required to confirm that the Restricted classification criteria are being met when the area is in the open status. When the Conditional Management Plan is based on the operation and performance of a wastewater treatment or collection system, combined sewer overflows, or other point sources of pollution, monthly

samples minimum five (5) are required during the period(s) when the area is in the open status. Alternatively, the minimum number of water quality samples collected from the conditional area may be supplemented with effluent samples provided that the minimum frequency requirements are maintained. When the Conditional Management Plan is based on the effects of non-point pollution, such as rainfall events, stormwater run-off, and seasonal variations, a minimum of five (5) water samples shall be collected during the period when the area is in the open status.

f. The Conditionally Restricted area shall be evaluated at least once each year by the Regional Interdepartmental Shellfish Committee. The evaluation shall include the review of the annual report provided by DFO (or other agency by agreement with DFO), with input from CFIA and EC, documenting all data relating to the operation of the Conditionally Restricted area.
g. There should be a complete understanding of the purpose of the Conditionally Restricted classification by all parties concerned, including the shellfish industry. If the cooperation of all interested parties is not assured, federal partners will not permit harvesting of shellfish.
h. Any failure to meet the conditions of the Conditional Management Plan must be immediately reported to and acknowledged by the federal partners.
i. If at any time any party to the Conditional Management Plan fails to fulfill the requirements as set forth in the Plan, the Regional Interdepartmental Shellfish Committee will determine whether the area classification or status will be changed.
j. All data relating to the operation of a conditionally restricted area will be maintained in a file by the shellfish control authority or authorities who are signatories to the Management Plan.

2.3.6 Prohibited Classification

Shellfish shall not be harvested from prohibited areas for any purpose, with the exception of harvesting for seed, spat, bait and for scientific purposes, all of which shall be fished under the Management of Contaminated Fisheries Regulations.

1. The following areas shall be defined as prohibited areas:

a. the area within a minimum 300-metre radius around points of continuous or intermittent discharge from a sanitary sewage system;
b. the area around points of continuous sanitary discharge which does not achieve adequate viral reduction through a combination of wastewater treatment and dilution in the shellfish growing area;
c. the area within a minimum 300-metre radius around industrial outfalls;
d. the area within a minimum 125-metre radius around marinas or wharves;
e. areas where, due to the degree of contamination in the growing waters (i.e., waters having excessive concentrations of fecal material or other poisonous or deleterious substances), it may not be possible to adequately depurate or naturally purify the shellfish.

2. The following areas are prohibited unless defined otherwise by the Regional Interdepartmental Shellfish Committee:

a. subject to b), the area within a minimum 125-metre radius from wharves, finfish net pens, floathomes or other floating living accommodation facilities; or
b. the area within a minimum 25-metre radius from a floathome or floating living accommodation facility located within a shellfish tenure/lease where a zero effluent discharge and appropriate waste management are a condition of the aquaculture license/lease and where verification, compliance and enforcement by the licensing agency is reported annually to Environment Canada.

Specific Requirements

a. Shellstock spat and seed may be collected for grow-out from contaminated areas, including prohibited areas, by a licence issued under the Management of Contaminated Fisheries Regulations (DFO, 1990) providing that they are moved to approved growing areas for an acceptable period of time prior to their final harvest and sale for human consumption. The intent is that shellstock referred to as spat or seed is well under the minimum normal marketable size for that species and would require a grow-out period of at least 6 months to reach the market size. In recognition that the accumulation and elimination of microbiological and chemical contaminants in shellfish differs, the following requirements shall apply:
    - The grow-out period for spat or seed collected within a microbiologically contaminated prohibited area by a licence issued under the Management of Contaminated Fisheries Regulations (DFO, 1990) must be a minimum of six months.
    - The grow-out period for spat or seed collected within a chemically contaminated prohibited area by a licence issued under the Management of Contaminated Fisheries Regulations (DFO, 1990) must be a minimum of twelve months unless a chemical contaminant reduction study demonstrates elimination in a shorter time period.
b. Harvesting shellstock for bait from a prohibited area requires a license under the Management of Contaminated Fisheries Regulations (DFO, 1990).
c. Harvesting shellstock for scientific purposes from a prohibited area requires a license issued under Section 52 of the Fishery (General) Regulations (DFO 1993) and a license under the Management of Contaminated Fisheries Regulations (DFO, 1990).

2.3.7 Process for Classification - Role of Regional Interdepartmental Shellfish Committees

Environment Canada will present survey results and recommendations for classification to the appropriate Regional Interdepartmental Shellfish Committee as soon as practical after the surveys are completed. The Committee will consider the information and classify the area.

2.3.8 Documenting the Classification

All classifications will be documented in the survey reports (comprehensive, annual review, and re-evaluation). Final decisions by the Regional Interdepartmental Shellfish Committee will be reflected in file reports and minutes of the regional meetings.

2.4 Sub-tidal and Offshore Areas

Sub-tidal shellfish areas within five (5) km of land and which are located well removed from pollution sources and other sanitary concerns are at a very low risk of becoming contaminated with fecal coliform bacteria. The sanitary quality of such areas used for direct shellfish harvesting may be more appropriately assessed by evaluating actual and potential pollution sources in the area, coupled with occasional bacteriological testing of the shellfish at the establishment level.

When the Regional Interdepartmental Shellfish Committee is satisfied on the basis of information submitted to it by DFO, EC and CFIA that the waters from which such shellfish are taken are of such a nature as will ensure that the shellfish are wholesome, the said committee will recognise the area acceptable for sub-tidal harvesting and its boundaries.

Offshore areas beyond five (5) km from land are considered acceptable for sub-tidal harvesting unless otherwise closed.

Footnotes

Footnote 3

Requirements a), b), and c) will be different if systematic random sampling is used. Refer to the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2003..

Return to footnote 3 referrer

Footnote 4

If systematic random sampling is used, the standard is based on the use of the calculated 90th percentile. Refer to the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2007.

Return to footnote 4 referrer

Footnote 5

If systematic random sampling is used, the standard is based on the use of the calculated 90th percentile. Refer to the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2007.

Return to footnote 5 referrer

Footnote 6

If systematic random sampling is used, the standard is based on the use of the calculated 90th percentile. Refer to the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2007.

Return to footnote 6 referrer

Chapter 3 - Control of Harvesting

The control of harvesting from shellfish areas is a vital part of the control procedures for a comprehensive shellfish sanitation program. There must be assurances that shellfish are only harvested from areas in the open status with the appropriate licences where required. Potentially hazardous shellfish must be prevented from reaching the consumer. It is the responsibility of the Conservation and Protection Directorate in each Fisheries and Oceans Canada (DFO) Region to provide sufficient personnel and equipment for surveillance activities that will act as a deterrent to illegal harvesting.

3.1 Patrol Policy Document

Specific patrol requirements that may be applied to technical and administrative situations vary among Regions. Consequently, a patrol policy document shall be developed by each Region and kept current. The policy document shall describe patrol organization and activities necessary to deter illegal harvesting, and will meet the following requirement:

a. A patrol policy document shall contain the following provisions:
    i. method of identifying shellfish areas;
    ii. description of area-specific patrol problems;
    iii. listing of areas to be patrolled;
    iv. frequency and nature of patrol;
    v. type and frequency of reporting; and
    vi. educational measures.
b. The patrol policy document shall be reviewed annually, revised when necessary and communicated to other regional shellfish control agencies.
c. The patrol policy document shall be placed in a central file and made available on request for authorized audits including those that may be conducted by U.S. Food and Drug Administration officials in connection with the 1948 Canada-US Bilateral Agreement on Shellfish Sanitation.

3.2 Licensing of Harvesters

Specific regulations under the Fisheries Act may require licensing of harvesters.

Licences may be issued pursuant to the Management of Contaminated Fisheries Regulations to harvesters or processors for the taking of shellfish from restricted and conditionally restricted areas.

DFO shall maintain a record in a central file of all the licenses issued. This file should contain a copy of notices published for the information of harvesters concerning changes in area classification or status and changes in applicable laws and regulations.

3.3 Identification of Restricted or Prohibited Areas (including areas in the closed status)

The measures necessary to accomplish boundary delineation and notification may vary among regions provided that the following criteria are met:

a. the boundaries of areas as well as any areas in the closed status shall be marked by fixed objects or landmarks or otherwise described in a manner which permits easy recognition of the boundaries; and
b. Information with respect to harvest activities permitted in shellfish areas shall be conveyed to harvesters through a number of methods, including publication or broadcast in local media, electronic fishery notices, or by the posting of notices in affected areas and at shellfish processing plants, if applicable.

3.4 Prevention of Illegal Harvesting

In planning, executing and reporting on patrols for illegal harvest prevention, regions shall ensure that:

a. when there is evidence that shellfish are being illegally harvested, educational programs and other compliance promotion measures shall be developed to deter harvesting;
b. shellfish areas shall be patrolled with due consideration given to surveillance conducted at night time, during weekends and holidays and other harvesting conditions; and,
c. complete records of patrol activities, including violations and court actions, shall be maintained in a central office of the Regional patrol agency.

Chapter 4 - Harvesting and Handling Shellstock

Each registered facility must consider, and where applicable, incorporate the following components in the development and implementation of their Quality Management Program.

4.1 Vessels and Conveyances

All vessels used for harvesting or transporting shellfish and all vehicles used for hauling bulk, bagged, containerized, or otherwise packaged shellstock shall be constructed, operated, and maintained in accordance with Schedule III, Requirements for Vessels used for Fishing or Transporting Fish, and/or Schedule V, Requirements for Conveyances and Equipment used for Unloading, Handling, Holding and Transporting Fresh Fish, of the Fish Inspection Regulations. Specific requirements applying to shellstock to be depurated or relayed are outlined in Chapter 10 of this manual.

4.2 Washing of Shellstock

4.2.1 Shellstock shall be washed reasonably free of sediments and detritus as soon after harvesting as is feasible. Shellstock shall be washed at the time of harvest at the harvest site. Where this is not practical because of harvesting methods or climatic considerations, the shellstock shall be washed only in a registered facility.

4.2.2 Water used for washing shellstock shall be obtained from an approved shellfish area, or from other safe sources approved by the CFIA.

4.3 Human Wastes

Measures must be in place to prevent contamination of shellfish by human wastes during shellfish harvesting and aquaculture maintenance activities.

Vessels are expected to comply with the following requirements and any other relevant federal, provincial, or territorial legislation or requirements. It is the vessel operator's responsibility to inquire about any additional requirements.

4.3.1 Vessels are prohibited from discharging raw sewage or human waste within 3 nautical miles of the shore unless the discharge is passed through a marine sanitation device that reduces the fecal coliform count to an acceptable level. Footnote 7

4.3.2 Vessels conducting shellfish activities within 3 nautical miles of the shore are expected to have a designated human waste receptacle or holding tank unless it is feasible and normal practice to return to shore to use washroom facilities. A designated human waste receptacle or holding tank means a portable toilet, a secured toilet Footnote 7 or other containment device.

4.3.3 Human waste holding tanks must meet all of the following requirements:

a. They must be made of impervious, cleanable materials, designed to prevent spillage.
b. They must have a tight-fitting lid.

c. They must be used only for the purpose intended.
d. They must be secured and in an appropriate location to prevent contamination of the shellfish area or any onboard shellfish due to spillage or leakage.
e. They must be emptied into an approved sewage disposal system in a manner that will not cause contamination of shellfish or shellfish harvest area.
f. They must be cleaned after they are emptied.

4.3.4 Every person onboard a shellfish harvest vessel must wash and sanitize their hands after using or cleaning a waste receptacle, or after using an onshore washroom facility.

4.4 Shellstock Identification

4.4.1 Shellfish harvesters shall be licensed as required by DFO or provincial regulations.

4.4.2 Sacks, boxes, and other shellstock harvesting containers shall be clean and fabricated from approved material.

4.4.3 The harvester shall identify shellstock, when required as a condition of licence or provincial regulation, with a durable, waterproof tag or label on each container of shellstock. When shellfish are sold in bulk, the harvester shall provide a transaction record prior to shipment.

4.4.4 The harvester tags, labels, or the transaction record shall contain the following information:

a. the harvester's name;
b. the most precise identification of the harvest location as is practical (e.g., Long Bay, Smith's Bay, or a lease number); and should include Area number (and sub-area if applicable);
c. the date of harvesting; and
d. the common name and quantity of shellfish.

4.4.5 When harvesters are not required to tag or label shellstock as a condition of a DFO licence or provincial regulation then the registered facility is required to identify the shellstock upon receipt so that the identity of the shellstock lot can be maintained throughout processing. The procedure for maintaining identity must be described in the registered facility's Quality Management Program.

4.5 Use of Master Harvesters

A Master Harvester should have a valid license to harvest shellfish, must be familiar with the local shellfish areas and must be willing to meet the conditions described in the Quality Management Program (QMP) of the registered establishment he/she works for.

The registered establishment is responsible for reviewing the background(s) of all Master Harvesters prior to the Master Harvester being assigned monitoring duties under the Quality Management Program. The Master Harvester must be able to demonstrate a willingness to work with the establishment, under the Fish Inspection Regulations, to ensure that the hazards associated with shellfish are controlled through accurate, reliable and consistent monitoring and reporting.

The QMP control measures for Master Harvesters must also include details on duties to be assigned to the Master Harvester, training (if required), specific monitoring activities at the harvest site(s), verification activities (by the establishment), corrective action procedures for non-compliance and record keeping (accurate, legible and auditable).

4.6 Temperature Control of Shellfish From Shellfish Areas to Registered Facilities

Temperature of shellstock shall be controlled during transport when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.

Footnote

Footnote 7

Refer to Transport Canada's Vessel Pollution and Dangerous Chemicals Regulations (sections 88, 89, 96), entered into force on March 30, 2012 under the Canada Shipping Act.

Return to footnote 7 referrer

Chapter 5 - Wet Storage

Wet storage is the temporary storage (less than 60 days) of live shellfish from approved sources, intended for marketing, in containers or floats in natural bodies of seawater (nearshore sites) or in tanks containing natural or synthetic seawater (onshore systems). The following requirements apply to wet storage in both nearshore sites and onshore systems. These requirements do not apply to relay operations or to the movement of shellfish to new shellfish areas for 60 days or more. For pre-depuration wet storage see chapter 10, section 10.2.

Wet storage of live shellstock is subject to the requirements of the Fish Inspection Act and Regulations (FIR).

5.1 Source of Shellfish

Shellfish for wet storage shall be harvested from approved or conditionally approved harvest areas in the open status.

5.2 Wet Storage Requirements

Each registered establishment conducting wet storage must consider and incorporate the requirements of this chapter, as applicable, in the development and implementation of their Quality Management Program (QMP). Any hazards that are associated with nearshore wet storage sites that are not operated by a registered establishment must be controlled under the QMP of a registered establishment. Further guidance on the application of HACCP critical control points in shellfish processing establishments can be found in Chapter 3, Subject 4, Appendix H of the CFIA Fish, Seafood and Production Division Facilities Inspection Manual. Wet storage shall only be practised in compliance with the provisions described in each establishment's QMP.

5.2.1 Onshore Indoor Wet Storage Systems

For new establishments, the CFIA will evaluate onshore wet storage systems during the registration process. This will involve an assessment of the establishment's QMP plan and inspection of the onshore wet storage system. Registered establishments that add onshore wet storage systems or change an existing wet storage system will be evaluated by the CFIA during ongoing regulatory verification activities.

Water Quality

a. Natural seawater used for wet storage systems shall meet the requirements of section 14(3) of Schedule I of the FIR when the storage tanks are set up and operated as a flow-through system. Areas that are classified as approved by Environment Canada are considered to meet this requirement. In the case of unclassified areas, the proponent must demonstrate upon start up, and on a regular basis that the water will meet section 14(3) of schedule I of the FIR.

Seawater that is recirculated or does not meet section 14(3) of schedule I of the FIR shall be treated. The quality of the water prior to disinfection shall not exceed a median or geometric mean of 88 faecal coliform/100 mL (less than or equal to 10% do not exceed 260 MPN/100 mL).

b. Synthetic seawater used for wet storage must be made from water meeting requirements of section 14(1) of Schedule I of the FIR. Salt added to increase salinity or produce synthetic seawater shall be food grade.

c. Water must not be used for onshore wet storage if the source area is in the closed status unless a validated/approved system is in place to control all potential hazards. The source area shall not exceed a median or geometric mean of 88 faecal coliform/100 mL (less than or equal to 10% do not exceed 260 MPN/100 mL) and be free of viral contamination while in closed status.

Water Treatment Systems

a. Water treatment systems shall provide an adequate quantity and quality of water to maintain the quality of the shellfish in wet storage, and the treatment shall not affect the safety of the shellfish. Each water treatment system must be validated to ensure it can eliminate or reduce the potential microbiological or biotoxin hazards to an acceptable level.

b. Ongoing monitoring and verification of each water treatment system is required:

   i. For systems using UV treatment, UV intensity and water flow rate must meet manufacturer's specifications for effective treatment.

   ii. The turbidity must meet the manufacturer's specifications for water receiving UV disinfection. In the absence of manufacturer specifications, turbidity must not exceed 20 Nephelometric Turbidity Units.

   iii. Post treated water shall meet a standard of ≤ 2 coliforms/100mL. This shall be verified on a regular basis.

   Note: Special consideration must be given if chlorine or ozone is used in the treatment process. It is recommended that proponents contact CFIA prior to installing treatment systems that use chlorine or ozone. The use of such may produce toxic by-products and may not be suitable in wet storage systems.

   iv. Water filtration systems designed to control biotoxin hazards must eliminate toxic phytoplankton from the source water prior to reaching wet storage tanks. Further guidance on how shellfish in wet storage systems affected by biotoxin closures is assessed is found in chapter 11, section 11.6.

c. Disinfection units shall be cleaned, serviced, and tested as per Manufacturer's specifications to ensure effective disinfection.

Tanks and Plumbing

In addition to meeting the applicable requirements of schedule I and II of the FIR shellfish processing establishments shall meet the following requirements:

a. Tanks are constructed so as to be easily accessible for cleaning and inspection, to be self-draining or equivalent (e.g. an alarm installed or a back up system), and to meet food-contact surface requirements. Plumbing is designed and installed so that cleaning and sanitizing will be effective;

b. Construction of shellstock containers and loading depth must ensure the free flow of water to all shellstock. The wet storage of shellstock in standing water is not permitted;

c. Tanks and plumbing shall be cleaned and sanitized as necessary to prevent contamination of the tanks and water.

Shellfish Handling Requirements

a. Shellfish shall be washed and culled to remove dead, broken, or cracked shellfish prior to wet storage in tanks. Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage.

b. Shellfish from different harvest lots shall not be commingled during wet storage in tanks. Lot identity must be maintained.

c. Bivalve molluscs shall not be stored with other non bivalve mollusc species in the same tank. Where multiple tank systems use a common water supply system for bivalve molluscs and other non bivalve mollusc species, water shall be effectively disinfected prior to being put into tanks containing the bivalve molluscs or, the water is supplied to the tanks containing the bivalve molluscs first.

5.2.2 Onshore Outdoor Wet Storage Systems

a. All requirements from section 5.2.1 must be met.

b. The wet storage system must be located on the same property as the federally registered establishment.

c. The wet storage tanks must be covered. Tank covers shall:

   i. Prevent entry and contamination by birds, animals or vermin; and

   ii. Remain closed while the system is in operation except for periods of tank loading and unloading, cleaning or monitoring/verification activities.

5.2.3 Nearshore Wet Storage

a. Nearshore wet storage sites operated by registered establishments will be evaluated as part of the QMPregulatory verification or registration process. Nearshore wet storage sites not operated by registered establishments must be evaluated for compliance to requirements before commencing operation. If approved, the CFIA will provide notice in writing of the approval which will remain valid until there are changes made to the wet storage system or otherwise determined by the CFIA.

b. The requirements for nearshore wet storage include:

   i. The location of the storage site must be in an area classified as approved or conditionally approved*.

ii. Shellstock containers must be constructed to ensure the free flow of water to all shellstock;

*Classification of the nearshore storage site must be confirmed with Environment Canada.

c. Shellfish may only be removed from a nearshore wet storage site when in the open status.

5.3 Labelling and Identification of Shellstock

a. The identity of the shellfish must be maintained as per chapter 4 section 4.4.

b. Labeling requirements can be found in chapter 7.

5.4 Record Keeping

In all cases, records shall be maintained by the processor that clearly indicates the harvest and wet storage history of the product.

Chapter 6 - Shucking and Packing Shellfish

Each registered facility must consider, and where applicable, incorporate the following components in the development and implementation of their Quality Management Program (QMP).

6.1 Facility Requirements

Facilities in which shellfish are shucked and packed or repacked shall be registered in accordance with the appropriate requirements of Sections 14 and 15 of the Fish Inspection Regulations (FIR). Detailed registration compliance requirements are contained in the CFIA's Facilities Inspection Manual, Chapter 5, Subject 1 - Facility Compliance Requirements.

6.2 Heat Shock

The heat shock method of preparing shellfish for shucking is not intended to open, kill, blanch or cook the shellfish but rather to cause the shellfish to relax its adductor muscles and contract its body so it can more easily be shucked. A variety of heat shock processes are currently in use and a large number of techniques are possible. Consequently, the Manual requirements are general in nature and emphasise the use of process schedules developed by or in cooperation with competent individuals. Other aspects of the process that require controls include washing of shellstock, cooling of heat shocked shellfish, refrigeration of heat shocked shucked shellfish, and cleaning of equipment.

6.2.1 Washing of Shellstock

a. Immediately prior to the heat shock operation all shellstock to be subjected to the heat shock process shall be washed with running water from an approved source of adequate supply and pressure and culled of dead animals and those with broken shells. Washing by immersion is prohibited.

b. Shellstock shall be handled in a manner which prevents their contamination during the wash cycle.

6.2.2 Heat Shock Process

a. A scheduled process shall be used in each processing facility utilising heat shocking. Scheduled processes should be developed by qualified or experienced persons. The facility shall incorporate the approved scheduled process into their Quality Management Program (QMP).

b. Factors which may affect the process shall have been adequately studied and provided for in establishing the process. Factors to be considered include but are not limited to: type and size of shellfish; time and temperature of exposure; type of process (e.g., hot water immersion, steam tunnel, steam retort); size of the tank, tunnel or retort; water-to-shellfish ratios in tanks; and temperature and pressure recording devices.

c. The physical and sensory properties of the species shall not be changed by the scheduled process and the shellfish must remain alive until shucked.

d. The process shall not result in increased microbial deterioration of the shucked shellfish.

e. Data collected to validate the heat shock process must be incorporated into the facility's QMP.

f. The scheduled process shall be posted at a conspicuous location in the plant and all responsible persons shall be familiar with the requirements.

6.2.3 Cooling of Heat Shocked Shellstock

a. All hot dipped shellstock shall be cooled with flowing water from an approved source immediately after the heat shock process.

b. All heat shocked shellstock shall be handled in such a manner as to preclude contamination during the cooling process.

6.2.4 Cooling of Shucked Shellfish

All shellstock which have been subjected to the heat shock process shall be shucked and the meat cooled to at least 7°C within two hours after the heat shock process and placed in storage at a temperature between -1°C and 4°C.

6.2.5 Changing of Heat Shock Tank Water

If a heat shock water tank is used, it is to be completely drained and flushed at three-hour intervals or less in such a manner that all mud and detritus remaining in the dip tank from previous dippings are eliminated.

6.3 Labelling of Shucked Shellfish

a. Each individual package of fresh or frozen shellfish meats shall have permanently recorded on the container of the product:

   i. the common name of the shellfish;
   ii. net contents as net weight unless, in the case of oyster and clam meats that are not frozen, the container or label is marked with a statement of net contents in terms of fluid measure or by count; and
   iii. the registration number of the processor and the name and address of the person by whom or for whom the fish is processed or by whom it is distributed; and
   iv. if the shucked shellfish originate from depurated shellstock then the label must indicate that they have been depurated.
   v. The principal display panel on each package of fresh or frozen shucked shellfish shall contain a legible **best before** date except for those packages with a capacity of 64 fluid ounces or more which will show **date shucked**. The date will consist of either the number of the day of the year or the abbreviation for the month and number of the day of the month. For frozen shellfish, the year will be added to the date.

b. The Date shucked shall appear on the lid and also the side wall or bottom of durable containers with a capacity of 64 fluid ounces or more. The side wall is considered the principal display panel.

c. Frozen shellfish shall be labelled as frozen in type of equal prominence immediately adjacent to the name of the shellfish.

d. All labelling information on shucked shellfish destined for retail sale in Canada must be in English and French and, if sold fresh must include a "best before" date and the statement "keep refrigerated". The dates must be indicated in a manner demonstrated in section B.01.007(4) (d) and (5) of the Food and Drug Regulations: "the day of the month shall be shown after the month and shall be expressed in numbers". **The use of the Julian calendar is unacceptable**.

e. All required information shall be provided in a legible and indelible form.

6.4 Commingling policy

a. Shipping containers should be filled with product which represents the same harvest lot (same harvest location/day removed from water); however, if desired in order to fill the last container of a lot, it is permissible to mix 2 lots if the product is identified as such and appropriate records kept.

b. In the event of product recall, all commingled containers shall be recalled.

6.5 Records

a. Complete, accurate and legible records must be maintained in accordance with section 15(10)(d) of the Fish Inspection Regulations. These records shall be sufficient to document that shellfish are from an approved source and to permit a container of shellfish to be traced back to the specific harvest lot from which it was taken. Purchases and sales shall be recorded in a permanently bound ledger book or by other means acceptable to the CFIA.

b. Records covering purchases and sales of fresh and frozen shellfish shall be retained for a period of at least three years.

Chapter 7 - Shellstock Shipping and Labelling

PDF (294 kb)

A shellstock shipper may buy and sell shellstock from a harvester or other certified dealer, may reship shellstock or shucked shellfish, and may relabel and repackage shellstock. A shellstock shipper may not shuck, relabel, or repack shucked shellfish. Facilities certified as shucker-packers and repackers may also ship shellfish under their shucker-packer (SP) or repacker (RP) certification number.

Each registered facility must consider, and where applicable, incorporate the following components in the development and implementation of their Quality Management Program.

7.1 Shellstock Identification, Harvesting and Handling

All shellstock shall originate from an approved source. It shall be harvested, handled and identified in accordance with the requirements of Chapter 4 of this manual.

7.2 Shellstock Storage, Shipping, and Record Keeping

a) Conveyances used to transport shellstock shall be constructed, maintained and cleaned in accordance with the requirements of Schedule V of the Fish Inspection Regulations (FIR). Shellstock shall be transported in adequately refrigerated vehicles when the shellstock have been previously refrigerated or when ambient temperatures are such that unacceptable bacterial growth or deterioration may occur.

All shellstock shipments destined for the United States (with shipping times exceeding 4 hours duration) must be made in mechanically refrigerated vehicles maintained at or below 7.2°C. A suitable time-temperature recording device shall accompany each shipment. When shipments to the U.S. are 4 hours or less in duration, shellstock and shucked shellfish products may be shipped in well-iced containers and no thermal recorder is needed.

b) Buildings in which shellstock are held or repacked shall comply with the appropriate requirements of Schedules I and II of the FIR and shall be federally registered.

c) Shellstock in storage shall be protected from contamination and maintained at temperatures between -1°C and 4°C.

d) All equipment and conveyances which come into contact with shellstock shall be maintained and cleaned in accordance with the requirements of each registered facility's documented sanitation program.

e) Ice used for shellstock refrigeration shall be manufactured, stored and handled in accordance with Section 14(7) and (8) of Schedule I of the FIR.

f) Shellstock shall be identified in accordance with the requirements of Chapter 4 (section 4.4) of this manual, and delivery/shipping records must be maintained in accordance with the requirements of Section 15(10)(d) of the FIR.

g) Sacks, boxes, and other shellstock packing containers shall be new, clean and fabricated from approved materials. Packaging materials used for direct contact with shellstock shall be those contained in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products published by the Canadian Food Inspection Agency. Materials such as seaweed and newspaper are not permitted.

7.3 Labelling Shellstock

1) Non Retail Packages for Sale in Canada

a) A durable, waterproof tag or label shall be securely affixed to each container. The tag or label shall contain the following information in English or French and in a legible and indelible form:

i. the date of processing;
ii. the most precise description of the location the shellfish were harvested from as is practical (e.g., NB16 Bar Road, BC18-4 Swanson Channel, QC Baie Laval N-4.1.2, etc.);
iii. the registration number of the processor and the name and address of the person by whom or for whom the fish is processed or by whom it is distributed;
iv. the type and quantity of shellfish. If this information is preprinted on the bag or box and is accurate, this information does not have to be repeated on the tag;
v. if the shellstock are depurated then the tag or label shall include the depuration cycle code; and
vi. shellstock that has been relayed or wet stored shall be labelled:
    a. if wet stored for less than 14 days, the harvest area is the original harvest area prior to wet storage;
    b. if wet stored nearshore or onshore in an untreated flow thorough system for 14 days or greater, the harvest area is the wet storage site;
    c. if relayed the harvest area is the relay site.

2) Retail Packages for Sale in Canada

a) A durable, waterproof tag or label shall be securely affixed to each container. The tag or label shall contain the following information in English and French and in a legible and indelible form:

i. the date of processing
ii. a "best before" date or date of harvest and the statement "Keep refrigerated". The best before date must be indicated in the manner demonstrated in section B.01.007(4)(d) and (5) of the Food and Drug Regulations: "the day of the month shall be shown after the month and shall be expressed in numbers". **The use of the Julian calendar is unacceptable**;
iii. the most precise description of the location the shellfish were harvested from as is practical (e.g., NB16 Bar Road, BC18-4 Swanson Channel QC Baie Laval N-4.1.2 etc.);
iv. the registration number of the processor and the name and address of the person by whom or for whom the fish is processed or by whom it is distributed;
v. the type and quantity of shellfish;
vi. if the shellstock are depurated then the tag or label shall include the depuration cycle code; and
vii. shellstock that has been relayed or wet stored shall be labelled:
    a. if wet stored for less than 14 days, the harvest area is the original harvest area prior to wet storage;
    b. if wet stored nearshore or onshore in an untreated flow thorough system for 14 days or greater, the harvest area is the wet storage site;
    c. if relayed the harvest area is the relay site.

3) Export to the United States

Consult the United States Food and Drug Administration's National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

4) Export to other countries

Consult the labelling requirements for the importing country.

7.4 Commingling policy

a) Shipping containers should be filled with product which represents the same harvest lot (same harvest location/day removed from water); however, if desired to fill the last container of a lot, it is permissible to mix 2 lots if the product is identified as such and appropriate records kept.

b) In the event of product recall, all product from a commingled lot will be recalled.

Chapter 8 - Repacking and Reshipping

Each registered facility must consider, and where applicable, incorporate the following components in the development and implementation of their Quality Management Program.

8.1 Repacking

A repacker is a shipper, other than the original certified shucker-packer who repacks shucked shellfish into other containers. A repacker may also repack and ship shellstock. A repacker shall not shuck shellfish.

A repacking establishment shall be registered in accordance with the appropriate requirements of the Fish Inspection Regulations. The establishment shall meet the additional criteria specified in Chapter 6 (section 6.3) of this manual when repacking shellfish meats for the U.S. market and those set out in Chapter 7 when shipping shellstock.

8.2 Reshipping

A reshipper is one who transhipps shucked shellfish in original containers, or shellstock from certified shippers to other dealers or to final consumers. Reshippers are not authorized to shuck or repack shellfish.

Reshippers shall comply with all applicable requirements of Chapter 6 and Chapter 7 of this manual.

8.3 Repacking and Relabelling Shellstock

a) Only clean and wholesome shellfish shall be repacked or reshipped.

b) Shellstock repacking facilities shall meet the requirements of Section 7.2 b) of Chapter 7.

c) Shellstock from different lots shall not be commingled during repacking or reshipping.

d) Sacks, boxes, and other shellstock packing containers shall be new, clean and fabricated from approved materials. Packaging materials used for direct contact with shellstock shall be those contained in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products published by the Canadian Food Inspection Agency. Materials such as seaweed and newspaper are not permitted.

e) Repackaged shellstock shall be labelled in a manner as described in section 7.3 of chapter 7.

Chapter 10 - Policy and Procedures for Controlled Relaying and Depuration

PDF (109 kb)

Relay systems (natural or in containers) and land-based depuration establishments are efficient methods of achieving microbiologically safe bivalve molluscs. This chapter outlines the requirements for the operation of these types of activities in Canada.

Section 4(2) of the Management of Contaminated Fisheries Regulations allows for a license to fish for food purposes in an area that is contaminated, following approval of a decontamination plan. Under the Canadian Shellfish Sanitation Program (CSSP) Memorandum of Understanding (MOU) between the Canadian Food Inspection Agency (CFIA), Fisheries and Oceans Canada (DFO) and Environment Canada (EC), the CFIA advises on these decontamination plans. This is done under the authority of the Fish Inspection Regulations (FIR) which also contain the requirements for the processing (i.e., depuration), transportation and holding of shellfish.

Anyone proposing to relay or develop a depuration facility must be able to meet these requirements before a license for harvesting can be issued. This is in addition to any commercial shellfish license required regionally.

Additionally, each registered facility must consider, and where applicable, incorporate the following components in the development and implementation of their Quality Management Program.

10.1 Procedures for Approval of a Depuration Facility or Relay Operation

When an interest is expressed by someone wishing to set up a depuration facility or relay operation, the following procedures apply:

a. The applicant is to submit a proposal to the local CFIA office. The proposal must include the following:
    i. a description of where any facility is to be located and the proposed timetable for construction;
    ii. if applicable, in consultation with DFO, the planned harvesting areas, and expected harvest quantity;
    iii. the proposed shellfish area;
    iv. the process water source for any depuration facility, or when applicable, the relay site;
    v. the depuration facility and equipment design (section 10.2.2) including provisions for laboratory facilities;

vi. the planned utilisation of any product during the evaluation period; and
vii. a detailed description of the controls that will ensure that labelling, harvesting, transport, operational and pre- and post-depuration storage requirements are met.

b. The proposal is to be forwarded by CFIA to the applicable DFO and EC offices for evaluation. The responsibilities for evaluating the proposals are as follows:
   i. EC: responsible for the classification of the shellfish area and the relay site;
   ii. DFO: responsible for the control of harvest in contaminated areas and the issuance of harvest licenses pursuant to the Management of Contaminated Fisheries Regulations.
   iii. CFIA: responsible for evaluating the proposal against the criteria defined in the depuration or relay protocols described in sub-sections 10.2, 10.3, and 10.4

   A maximum of four weeks is recommended for the return of comments.

c. After the proposal has been reviewed, CFIA will advise the applicant that:
   i. the proposal is accepted as a basis for continuation of the project; or
   ii. changes to the proposal are necessary.

   A meeting may be arranged with the applicant to explain the process and to clarify specific requirements.

d. Project Approval

   Once the project proposal is accepted, and the applicant is prepared to commence operations, the following steps must be completed:

   i. any building and storage facility must be inspected and the processing water approved;
   ii. any facility design and operation must conform to protocol and must meet Fish Inspection Regulation (FIR) requirements; and
   iii. as applicable, a Memorandum of Agreement (Annex 10D), an approved operational protocol, and/or the License (Annex 10C) are signed.

Each registered facility that depurates or relays shellfish must consider, and where applicable, incorporate the following components (10.2 - 10.4) in the development and implementation of their Quality Management Program.

10.2 Depuration Facility Protocol

All companies planning to develop a depuration system or presently engaged in depuration must conform to the requirements of the QMP and the criteria contained in the following sections.

10.2.1 Harvest Areas

Overlay waters must have median or geometric mean faecal coliform counts not exceeding 88 MPN/100 mL, not more than 10% of samples exceeding 260 MPN/100 mL, based on Environment Canada surveys and recommendations (see Chapter 2).

10.2.2 Processing Water and Facility Requirements

The following are intended as guidelines. Any deviations from the following may be made only after discussion with the CFIA and when their efficacy has been proven through validation.

a. Water

Processing water is required to meet or exceed the following minimum requirements:

i. the water must be from a source approved by the CFIA;
ii. water from sources vulnerable to contamination must undergo bactericidal treatment resulting in an absence of total coliforms/100 mL (defined as <2 total coliforms/100 mL). Protected sources, i.e., drilled wells, that consistently meet the standard need not be treated;
iii. the oxygen* content shall be at least 5 ppm or 50% saturation;
iv. the salinity* shall be ± 20% of the median salinity regime of the area where the bivalve molluscs are harvested, unless salinities outside this range are established as a result of the scheduled depuration process evaluation;
v. the turbidity* shall be less than 20 Jackson Turbidity Units (or equivalent Nepholometric turbidity units);
vi. the temperature* shall be adequate to permit normal metabolic activity of bivalve molluscs, the limits to be determined by process evaluation;
vii. for closed or recirculating systems, the ammonia level of process water must remain below 0.9 ppm;
viii. there shall be no undesirable chemicals or other substances which may affect pumping of bivalve molluscs; and
ix. Shellfish depuration facilities will be required to:
    a. cease using a water supply that is sourced from an area affected by a biotoxin closure or
    b. filter the water supply to remove any toxic phytoplankton (using a validated system).

    Shellfish in depuration systems affected by biotoxin closures will be assessed using the same criteria found in Chapter 11, section 11.6.

Note: The criteria marked * may be naturally variable at different locations.

b. Facility

All facilities must meet the following minimum requirements:

i. all buildings (including storage) must conform to sections of the Fish Inspection Regulations (FIR) including, but not limited to, sections 6(1), 14(1), 15(1), 16, 20 - 23 and Schedules I and II;
ii. storage facilities must be designed to maintain physical separation between shellstock to be depurated and other shellstock (depurated and approved area harvests); and
iii. adequate washing and culling facilities must be present.

c. Off-site Storage

Note: Prior to depuration, pre-process shellstock may be held in wet storage (in near-shore intertidal/subtidal areas). Such wet storage helps provide sufficient inventory for the depuration facility and also allows the shellfish to acclimate to the local sea water conditions in which they will be depurated.

If wet storage of pre-process shellstock is carried out off site (separate location from the main registered establishment), the operators must ensure that:

i. control and oversight is maintained over such storage locations, that all potential hazards associated with storage are considered, and that these are incorporated into the QMP of a registered establishment;
ii. vehicles and equipment used to transport shellfish from the storage facility to the main establishment meet the requirements of Schedule III and Schedule V of the FIR;
iii. restricted access to stored shellfish is maintained; and
iv. records are maintained at the registered establishment which permit CFIA officials to identify lots at the storage area.

Refer to sections 10.2.5 (c) and (d) for further storage considerations.

d. Tanks

Tanks shall be:

i. constructed of corrosion resistant, non-toxic, non-absorbent, and easily cleaned material;
ii. self-draining to facilitate cleaning;
iii. easily accessible for cleaning and inspection;
iv. maintained in good repair;
v. able to maintain a minimum flow rate of 107 litres per minute per cubic metre of shellstock. The above criteria are equivalent to 1 U.S. gallon per minute per U.S. bushel (1.24 cubic feet);
vi. constructed so as to provide adequate water flow throughout the tank (so that shellstock has adequate access to incoming clean water);
vii. constructed to ensure they contain water and shellstock at a minimum volume ratio of 4:1 (equivalent to 142 litres of water per 35.24 litres shellstock, or 5 cubic feet of water per U.S. bushel) for soft clam, and water and shellstock at a minimum volume ratio of 6.4:1 (equivalent to 227 litres of water per 35.24 litres shellstock, or 8 cubic feet per U.S. bushel) for hard clams (Manila and littleneck) and oysters. Limits for other species would be determined with CFIA during scheduled process evaluation); and
viii. constructed such that there is sufficient volume to permit a minimum of 7.6 centimetres (3 inches) of water clearance around each container. This spacing is necessary to provide for uniform water flow through and around processing containers.

e. Processing containers

Processing containers shall be:

a. constructed of corrosion resistant, non-toxic, non-absorbent, easily cleanable material; and
b. of a suitable size and shape to permit:
    i. a mid-cycle washing of shellfish;
    ii. an adequate flow of water to all shellfish;
    iii. a maximum depth of Manila and littleneck clams of 10 cm (4 inches);
    iv. a maximum depth of soft-shelled clams in containers of 20 cm (8 inches); and
    v. a maximum depth of 30 cm (12 inches) in Pacific oysters, 10 cm (4 inches) in Atlantic oysters and hard-shelled clams.

The loading criteria for other species would have to be determined by experimentation.

Note: Deviations from these criteria may be allowed only if process validation studies (see 10.2.7) show that the depuration process consistently yields bacteriologically acceptable product.

f. Water treatment

A water system is installed to provide an adequate quantity and quality of water for the controlled purification process. Any treatment must not leave residues that may interfere with the process. The quality of the incoming water prior to any disinfection shall meet or exceed the requirements specified in section 10.2.1 above. In North America an ultraviolet light (UV) system is the most common method of marine water treatment. Other methods may include chlorination/dechlorination or ozonation/deozonation.

Ultraviolet tubes must be regularly checked for intensity and must be replaced as prescribed by the manufacturer.

If, prior to UV treatment, water turbidity exceeds limits [see 10.2.2 a)v)], sand filters or the equivalent may be used as a pre-treatment. The requirements of the UV system for pre-treatment must be checked at the time of installation. The manufacturer of sand filters should be consulted for proper maintenance and the turbidity checked regularly (validation data are required).

An automatic shut off is required (which may be connected to a UV sensor to ensure light efficiency) before or after the ultraviolet system or other means to ensure that untreated water does not enter the tanks in the event of power or ultraviolet system failure. If the shut down was significant and/or the water level drops below the level of any shellstock in the tank, in a self-draining system, then the cycle must restart at the beginning of that 24-hour cycle. The time for a shut down to be significant is determined on a system-by-system basis and must be documented in an establishment's QMP.

(**Warning: It is dangerous to look directly at ultraviolet bulbs without eye protection.** Signs stating this danger should be prominently displayed.)

Biological filters are also common equipment in recirculating systems. They are needed to reduce ammonia to acceptable levels and to remove waste metabolites. The manufacturer of biofilters should be consulted for proper maintenance.

10.2.3 Shellstock Separation Requirements

The handling and wet storage of approved area bivalve molluscs is permitted at a depuration facility if the control for separation in time and space of depurated and approved area bivalve molluscs is documented and controlled so that there is no chance of mixing.

10.2.4 Laboratory

under development

10.2.5 Operational Controls

a. Harvesting Controls

i. Harvesting areas will be designated and/or assigned by the appropriate DFO office.
ii. A harvesting plan must be submitted to the appropriate DFO office and approved prior to the harvest. It shall contain:
    a. the names of all harvesters;
    b. the exact location in which they will be digging; and
    c. the exact date of each harvest.
iii. Each lot of shellfish must be identified and maintained physically separate.

iv. At the time of harvesting, all containers of shellfish in a lot must be properly identified and the records shall show:
    a. the date of harvest;
    b. the area of harvest;
    c. the harvester's name;
    d. the quantity harvested by each harvester; and
    e. the harvest license number
v. A designated "Master Harvester" will be responsible for supervising the harvesting and maintaining the identity of the lot to the storage facility or depurator.

These records must be maintained and available for review.

b. Transport

The shellfish must be transported from the harvest area to the storage area and/or to the depuration facility in a manner approved by the CFIA that meets the requirements of Schedule V of the Fish Inspection Regulations (FIR). The transportation of approved area shellfish and shellfish destined for depuration is permitted if the facility can demonstrate adequate QMP controls for identification and separation during transport.

c. Dry Storage at a Registered Facility

i. It is recommended that as short a time as possible elapse between the time of harvesting and the onset of depuration. In no case shall pre-process dry storage of shellfish exceed three days from the date and time of harvest to the date and time of the start of the depuration process. Water spray or mist over shellstock in dry storage is permitted. The system must be designed to prevent contamination to the shellstock.
ii. Storage temperature of bivalve molluscs prior to depuration shall not be:
    a. greater than the temperature of the process water; and/or
    b. more than 3°C below the process water temperature.
iii. Post-process storage temperature shall not exceed 4°C.

d. Wet Storage Off-Site

Bivalve molluscs may be held for up to 21 days in wet storage prior to depuration, providing:

i. the storage area meets the growing area classification for depuration (10.2.1)
ii. the location is designated in the harvest license and is under constant supervision to prevent theft; and
iii. the system is not in the validation phase.

e. Handling

i. Shellfish shall be washed and culled prior to depuration. During this procedure, shellfish shall not be mishandled or subjected to thermal shock. The quantity of culled shellfish and the method of disposal shall be recorded.
ii. A tank shall not contain more than one harvest lot of bivalve molluscs.

f. Container Sanitation

i. Between depuration cycles, containers and depuration tanks shall be scrubbed clean, disinfected (with approved disinfectant), and rinsed to ensure no residue remains.
ii. Tanks of bivalve molluscs shall be thoroughly hosed down at the end of each 18-24 hour period in the depuration cycle, in a manner which will not contaminate the shellstock.

10.2.6 Records

Up-to-date QMP records must be maintained at all times and must be available for QMP Compliance Verification. A listing of record types may be found in Annex 10A.

All forms used to record data must be included in the depuration protocol for approval before being used (examples of some forms are included in Annex 10B).

10.2.7 Process Validation

The facility must prove with a minimum of 20 lots that the depuration process is consistently cleansing the shellfish. In this assessment, each lot used must have 0 hr. results greater than or equal to a geometric mean of 230 faecal coliform/100 g, with no sample < 100. The number and location of samples to be drawn at zero, twenty-four, and forty-four hours[Footnote 8] will be approved by the CFIA. These samples may be taken over a number of tanks if these tanks are identical in all characteristics such as flow and dimensions. The services of an independent statistician may be used. The intent of these samples is to determine that all locations in the tank facilitate depuration.
The maximum zero hour limit for depuration of not less than 44 hours[Footnote 8] will be 2,300 faecal coliforms/100 g. If the system can consistently cleanse shellfish with higher zero hour faecal coliform counts, an approved Modified Schedule of not less than 72 hours may be used. The CFIA will establish a depuration cycle time and maximum faecal coliform level for each individual system, based on facility performance. Sampling plans to adjust these parameters post-process validation must be approved by the CFIA.
The depuration system will be considered to be working satisfactorily under defined processing parameters when faecal coliform analyses of samples of depurated bivalve molluscs meet the criteria as listed in Table 10.1. All sample locations in the tank must be shown to be equally effective in depurating shellstock.

Table 10.1 End Product Standards For Overall Depuration Facility Performance Evaluation (Faecal coliforms/100 g)

Shellfish Species	Geometric Mean	Upper 10 [Note 9]
Soft clam (Mya arenaria)	50	130
Hard clam (Mercenaria mercenaria, Protothaca staminea, Venerupis philippinarum)	20	70
Blue Mussel (Mytilus edulis)	20	70

Shellfish Species	Geometric Mean	Upper 10 Note 9
Oyster (Crassostrea virginica, Crassostrea gigas)	20	70

Table Notes

Table Note 9

Upper 10 percent level is where no more than 10 percent of the samples' results used in the evaluation may exceed the value established as the upper 10 percent level for each species

Return to table note 9 referrer

During the evaluation period the product may be released, by the CFIA, to the market upon receipt of acceptable final hour bacteriological results as indicated in Table 10.2. Product that underwent a Modified Schedule will not be released to market during the evaluation phase, and may be relayed to a restricted or conditionally restricted area. All shellstock must be clearly identified as a depurated product at all stages of marketing. It is the processor's responsibility to ensure that buyers are aware of conditions for marketing depurated products (labelling and repacking restrictions).

Any final hour failures during the validation phase should be examined for cause and any proposed changes to the process or protocol as corrective action must be reviewed with CFIA. Product must be disposed of as per 10.2.10.

Changes to existing depuration facilities or the defined process parameters may require a complete re-evaluation of the system (examples are changed water flow, tank size, and density loading). The addition of identical tanks and systems in existing facilities with an approved process do not require re-evaluation on approval from the CFIA.

A written report with all data and parameters from the validation must be prepared and a copy sent to the CFIA. An additional copy shall be retained by the establishment.

10.2.8 Routine QMP Monitoring (Post-Validation) - Requirements

The processor must meet the following requirements:

a. Shellstock samples for bacteriological analysis must be taken from every lot at zero hour and at the final hour of depuration. Lots must meet the zero hour requirement (less than or equal to 2,300 faecal coliform/100 g or more for a modified schedule as validated at 10.2.7) and final hour limits stated in Table 10.2.

b. The minimum number of samples to be analysed from each lot at 0 hours and 44 hours Footnote 8 (or at completion of depuration) can be determined by the history of the performance of the depuration process, size of the lots depurated, the variation of the harvest area or areas, whether spatial or seasonal, and the initial levels of contamination.
A depuration facility which has high overall depuration performance and harvest areas with consistently low zero hour results, and is processing relatively small lots may, with CFIA approval have the number of zero and/or final (44-hour Footnote 8) samples reduced to 1. If such a facility were to find higher levels of initial faecal coliforms, experience deviations in final product results, or receive product from a new area, 5 zero hour samples would be required.
A facility which consistently shows initial faecal coliform counts of greater than or equal to 1,000, receives product from diverse harvest areas, receives product from areas which experience wide fluctuations in

contamination over time, would be required to analyse five (5) 44-hour[Footnote 8] (or end of depuration) samples.
If a modified schedule (72 hours) is used, five (5) final hour samples must be analysed.

Table 10.2 End Product Standards for Each Process Batch of Shellfish (Faecal coliforms/100 g)

Number of Samples	Shellfish Species	Geometric Mean not to Exceed	One Sample May Exceed	No Sample Shall Exceed
1	Soft clam	No value	No value	170
1	Oyster, hard clam, mussel	No value	No value	100
2	Soft clam	125	No value	170
2	Oyster, hard clam, mussel	75	No value	100
3	Soft clam	110	No value	170
3	Oyster, hard clam, mussel	45	No value	100
5	Soft clam	50	100	170
5	Oyster, hard clam, mussel	20	45	100
10	Soft clam	50	130	170
10	Oyster, hard clam, mussel	20	70	100

c. Samples of depuration water for bacteriological analysis must be taken at a frequency of at least one per day.

The depuration facility must keep records of all bacteriological results.

10.2.9 Process Deviations

Any process batch which shows a final hour faecal coliform count greater than 170/100 g for softshell clams or 100/100 g for all other shellfish will be considered as a **batch deviation**. If two consecutive process batches have counts greater than 130/100 g for softshell clams or 70/100 g for all other shellfish, this will indicate a **process deviation**. In either case, all information pertaining to the deviation shall be placed in a deviation file. The establishment must notify the CFIA Inspection Office immediately upon discovery of the deviation, and must initiate investigative action to determine the cause(s).

For lots that do not meet the zero hour requirement (less than or equal to 2300 faecal coliforms/100 g or as approved during process validation) or final hour limits (Table 10.2), the following options are available:

a. depurate using an approved Modified Schedule:

i. Lots with any zero hour result > 2300 may be purified using an approved Modified Schedule of not less than 72 hours. The lot shall be detained until the results of bacteriological analysis are complete. The lot will be released if the final hour results do not exceed the species limits in Table 10.2. If results exceed the species limit, the lot may be re-depurated using an approved Modified Schedule.

ii. Lots with final hour results which exceed limits in Table 10.2 may be purified by using an approved Modified Schedule of not less than 72 hours in addition to the original depuration cycle. The lot shall be detained until the results of bacteriological analysis are complete. The lot will be released if the final hour results do not exceed the species limits in Table 10.2. If results exceed the species limits, the lot will not be re-depurated, unless it is first returned to a restricted or conditionally restricted area for at least 14 days;

b. heat process (e.g.), canning) the bivalve molluscs if the faecal coliforms are < 4,000/100 g;

c. return to an area meeting the requirements of section 10.2.1. Product may not be re-harvested for depuration for at least 14 days;

d. have shellstock disposed of for other than human consumption.

Establishments are required to include overall depuration facility performance as evaluated using Table 10.1 in their Quality Management Plan self-verification.

Note: The end products of depuration operations must meet the guidelines as listed in Appendix II).

10.2.10 Product Release

Product that meets the final hour limits in Table 10.2 may be released to market. Product shall remain under the control of the establishment until released. During process validation, the product may be released, by the CFIA, to the market upon receipt of acceptable final hour bacteriological results as indicated in Table 10.2. Product that underwent a Modified Schedule will not be released to market during the process validation, and should be returned to a restricted or conditionally restricted area.

Footnotes

Footnote 8

Existing depuration facilities that are approved for a 48 hour depuration process must provide additional 20 lot process validation data to prove the depuration process can still consistently cleanse the shellfish if they wish to use a 44 hour process.

Return to footnote 8 referrer

10.3 Short Term Container Relay Protocols

All companies planning to carry out short term container relay (less than fourteen days), must undergo a process validation with the CFIA (see sections 10.1 and 10.2 for criteria).

10.3.1 Harvest Areas

Harvest areas must meet the requirements identified in Section 10.2.1.

10.3.2 Storage and Container Requirements

As in 10.2.2e)i) and 10.2.2e)ii)2)-5).

10.3.3 Shellstock Separation Requirements

Defined lots of relayed shellstock are separated by at least 10 metres from other shellstock on the lease during decontamination to avoid potential cross contamination.

10.3.4 Laboratory

As in 10.2.4.

10.3.5 Operational Controls

As in Section 10.2.5, a) through d), where applicable.

In the case of aquaculture leases, the criteria outlined in Chapter 12 must also be met.

10.3.6 Records

Up-to-date QMP records must be maintained at all times and be available for Compliance Verification purposes. Examples of records may be found in Annex 10A.

10.3.7 Process Validation for Short Term Container Relaying

The facility must prove with a minimum of 20 lots that the relay process is consistently cleansing the shellfish. In this assessment, each lot used must have zero hour results greater than or equal to a geometric mean of 230 faecal coliform/100 g, with no sample < 100. The number and location of samples to be drawn at zero, mid-cycle, and final hours will be approved by the CFIA. The services of an independent statistician may be used. The intent of these samples is to determine that all locations in the lot facilitate decontamination.

The maximum zero hour limit will be 2,300 faecal coliforms/100 g meat. If any zero hour sample exceeds this limit, the lot shall be relayed for a minimum of 14 days.

The CFIA will establish a minimum relay time of not less than 6 days and a maximum coliform level for each individual system.

10.3.8 Routine Container Relay Monitoring

One sample from every lot must be analysed for faecal coliforms at the final hour of decontamination.

a. Processor/grower records and bacteriological analysis results must be made available on request for QMPCompliance Verification purposes.
b. An annual review of the data will be required before the permit will be renewed.
c. Any laboratory used to perform the necessary analyses is required to be approved by a Lab Evaluation Officer.

10.3.9 Process Deviations

If the lot exceeds the species limit in Table 10.2, the following options are available:

a. use an approved modified schedule of not less than 14 days;
b. heat process the product if faecal coliforms are less than 4,000;
c. relay to another area classified as approved; or
d. have shellstock disposed of for other than human consumption.

10.3.10 Release

Product that meets the final hour limits in Table 10.2 may be released to market. Product shall remain under the control of the establishment until released. During process validation, the product may be released to the market, by the CFIA, upon receipt of acceptable final hour bacteriological results as indicated in Table 10.2.

10.4 Natural and Extended Container Relay Protocols

All companies engaged in a natural or extended container relay operation (greater than or equal to 14 days) must conform to the following criteria:

10.4.1 Shellfish Areas

Harvesting may occur in any area not classified as prohibited provided that the harvester is licensed under the Management of Contaminated Fisheries Regulations.

10.4.2 Storage Facilities

As in 10.2.2 c).

10.4.3 Shellstock Separation Requirements

Defined lots of relayed shellfish are separated by at least 10 metres to avoid cross contamination with other shellfish and to maintain the identity of relayed lots.

10.4.4 Laboratory

As in 10.2.4.

10.4.5 Operational Controls

See 10.2.5 a) and b) where applicable. Shellfish shall not be mishandled or subjected to thermal shock.

Lots of shellfish destined for natural/extended container relay must remain in water for a minimum of 14 days. When an area to which shellfish have been relayed has been placed in closed status due to an emergency event, the relay time of product in the affected area must be extended by an additional 14 days after the area is returned to open status.

Shellfish for relay must be placed in or on a shellfish lease and in an area that is clearly marked off to identify the relay site.

10.4.6 Records

As in Section 10.2.6 (see Annex 10A). Any federally registered facility processing this product must verify as part of their Critical Control Point (CCP) for incoming product that appropriate procedures have been followed.

10.4.7 Routine Natural/Extended Container Relay Monitoring

Lots of shellfish relayed from 14 to 21 days must be analysed for faecal coliforms with a minimum of 1 sample. Lots of shellfish that are relayed in excess of 21 days may be exempt from the testing requirement, at the discretion of the CFIA.

Processor/grower records and bacteriological analysis results must be made available upon request.

a. An annual review of the data will be required before the license issued under the Management of the Contaminated Fishery Regulations will be renewed.
b. All analyses are to be performed by a CSSP approved laboratory.

10.4.8 Process Deviations

A lot is acceptable if no sample has a faecal coliform count greater than 230/100 g (after the minimum 14-day relay period). All deviations must be immediately reported to the CFIA for product disposition.

If the lot exceeds this limit, the following options may be provided:

a. continue relaying for an extended period;
b. heat process the product if faecal coliform levels are less than 4,000;
c. relay to another area classified as approved; or
d. have shellstock disposed of for other than human consumption.

10.4.9 Release

Product that meets the final hour limits (referenced in Section 10.4.8) may be released to market. Product shall remain under the control of the establishment until released.

Annex 10A - Records

The following records must be kept and must be available for DFO audit.

10A.1 Per lot:

- date of harvest
- area of harvest
- harvesters' names
- quantity of shellfish harvested
- time and date received at storage Footnote 10
- time and date removed from storage Footnote 10
- pre-process storage temperature
- amount of culls, time and place of disposal
- time and date of arrival at facility
- lot number
- time and date of start of depuration
- time and date of removal from depuration system
- zero hour bacteriological results
- final hour bacteriological results
- destination of lot

10A.2 Daily Facility Records:

a. Depuration Water

- oxygen content
- salinity
- temperature
- turbidity
- coliform count

b. Plant Equipment

- tank number
- tank flow rate (measured twice daily and after adjustments are made to any tank)
- time (in depuration hours) that tanks and shellfish hosed down
- time of back flush
- temperature of dry storage
- ultraviolet lights (hours of use, percent efficiency, date replaced)
- water flow chart

10A.3 Other

Harvesting Site - salinity and water temperature of overlay water

Note: All records must be acknowledged by the responsible operator (by initialling records) and by a management check.

Footnote

Footnote10

If storage facility location is separate from cleansing facility.

Return to footnote 10 referrer

Annex 10B - Selected Examples of Tags and Record Forms

A. Lot Identity At Dig Site

Harvest Area and Sub-area and Area Number _____
Date of Harvest _____
Name(s) of Harvesters _____
Permit Number _____
Quantity of Clams _____
Lot Number _____
Processing Company Name, Address and Registration Number _____

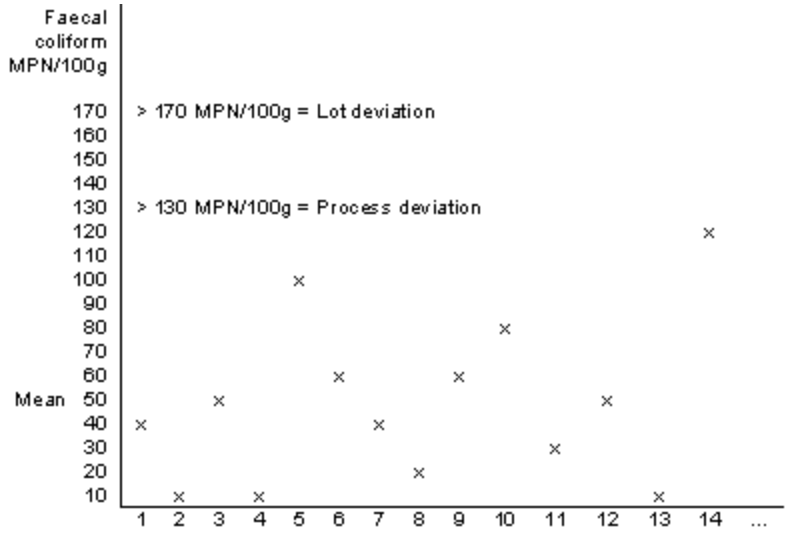
B. Lot Identity At Interim Storage Facility

Lot Number _____
Storage Temperature _____
Date Received _____
Quantity Received _____
Harvest Area and Number _____
Quantity Culled _____
Disposal Method _____
Disposal Date _____
Quantity Shipped _____
Date Shipped _____

C. Depuration Cycle

Cleansing (Depuration) Cycle _____
Lot Number _____
Date (Time) in: _____
Quantity _____
Container (Tank) Number _____
Container Position _____
Time of Wash Down _____
Date (Time) Out _____
Quantity _____
Disposal of Culls _____

D. Graph of Results per Lot (example - soft shell clam)



Description for Schematic - Graph of Results per Lot

Annex 10C - Example of Special Licence

Licence Number: _____

Pursuant to Section 4 of the Management of Contaminated Fisheries Regulations, permission is hereby granted to (name of company and responsible officer) and persons working under his/her supervision, to remove soft shelled clams from the following areas:

Those portions of the _____ as designated by the _____ **(DFO Office)**, _____, **(area)** for controlled purification or depuration.

1 - All operations will be carried out in compliance with the attached Memorandum of Agreement between _____, **(name of company)** and DFO for the harvesting of soft shell clams from restricted areas;

2 - A copy of the licence will be carried by those working on the harvesting of the clams and is to be available for inspection by a fisheries officer;

3 - That _____ (Fisheries Manager), _____ **(area)**, _____ **(telephone number)**, be kept advised of the details of the clam fishery;

4 - The method of harvesting shall conform with existing policies and applicable Regulations;

5 - Non-compliance with any condition of the attached agreement or this licence may result in the cancellation of the licence;

6 - DFO reserves the right to cancel all or part of this licence at any time; and

7 - The harvesting would be permitted from _____ to _____. (Maximum 1 Year)

Issued at _____ **(location, date)**_____.

_____ **(Name)**_____
Director-General

Annex 10D - Memorandum of Agreement

Memorandum of Agreement between (Company) and Fisheries and Oceans Canada for the Harvesting and Processing of Softshell Clams from Areas Classified as Restricted or Conditionally restricted

This agreement to be in effect from _____ (date) _____ to _____ (date) _____. The conditions of the agreement are detailed in Section 1, Harvesting, Transport and Storage, and Section 2, Processing.

The Fisheries and Oceans Canada reserves the right to amend the agreement during the effective period.

Signatures

_____
Company Representative

_____
Fisheries and Oceans Canada

Section 1. Harvesting, Transport and Storage

1.1 Designation of Areas

Fisheries and Oceans Canada, in consultation with Environment Canada, will designate areas or portions of areas from which bivalve molluscs may be harvested for controlled cleansing. Overlay waters from these areas must have a median faecal coliform count of less than 88 MPN/100 mL, with less than 10% of samples greater than 260 MPN/100mL.

1.2 Harvesting Licence

A special license issued under the authority of the Management of Contaminated Fishery Regulations will be required to harvest bivalve molluscs from restricted or conditionally restricted areas for controlled cleansing. The licence holder must comply with all requirements outlined in this agreement and the conditions specified in the licence.

1.3 Method of Harvesting (Applies to Mechanical Harvesters if permitted)

The licence holder must conform to all pertinent regulations with respect to mechanical harvesters and the mechanical harvester must be licensed under the authority of the applicable fishery regulations and the licence must be carried during the harvesting operations.

1.4 Notification of Intent to Harvest

The licence holder must provide the Conservation and Protection Office in the area of operation with at least one week's advance notice of the weekly harvesting plan. This plan will indicate what areas or portions of areas are to be harvested, when and by whom.

DFO reserves the right to restrict the number of areas being harvested and the number of harvesters operating at any one time.

1.5 Designation and Responsibilities of Harvesters

The licence holder must provide to DFO a list of digger representatives ("Master Harvesters") and diggers working under each representative. A written update of this list must be provided for any change of personnel. Each digger representative must be present during the entire harvesting operation and is responsible for designating the dig site using stakes or markers. The site must be no larger than that area which is in view of the representative at all times. During the harvesting operation each digger must carry a copy of the special licence issued to the depuration facility. The digger representative must also ensure that all clams harvested are placed in containers before they leave the dig site.

1.6 Identification of Shellstock

Harvested shellstock must be transported to their destination (storage facility or cleansing plant), in a sealed vehicle meeting the requirements of Schedule V of the Fish Inspection Regulations, in containers which are tagged to identify harvesting area, harvesting crew and amount harvested. The licence holder must ensure that records of lot identity are maintained.

1.7 Storage Facilities (Interim Storage Facilities - to Be Used When Cleansing Plant is Located Distant from Harvest Area)

The storage facility must be approved by the CFIA prior to the start of harvesting operations. The facility must have adequate security to prevent free access to shellstock and shall be large enough to allow the identity of the lots to be maintained.

In order to prevent thermal shock or an increase in bacterial levels, shellstock shall not be subjected to temperature fluctuations while in storage. Shellstock shall be maintained at a temperature not greater than the temperature of the process water and not more than 3°C lower than the process water.

Shellstock shall not be stored longer than three days including day of digging and day of transport to depuration plant.

1.8 Transportation of Shellfish

Containers of shellstock shall be transported directly to their destination (cleansing plant or storage facility) by the most direct route and immediately after harvesting.

Section 2 - Processing

2.1 Temperature Control

Shellstock held prior to processing shall be stored at a temperature not greater than that of the process water and not more than 3°C lower than the process water.

2.2 Culling and Washing

Shellstock shall be washed with approved water (less than 2 coliform/100 mL) to remove foreign matter and culled to remove all broken shelled, dead or gaping shellfish prior to the cleansing process.

2.3 Length of Cleansing

Shall be established on process evaluation data.

2.4 Equipment Cleaning

All equipment used to transport, hold or process shellfish must be maintained in good order and washed and sanitized after every use. The requirements of the Fish Inspection Regulations must be met.

2.5 Records

Records shall be maintained for the following:

1. daily harvesting activities including date of harvesting, harvesting area, and volume harvested;
2. placement of lot (one tides digging from one area) into tanks or cages, tank or cage identity and date and time of loading and unloading;
3. bacteriological analyses of water samples before and after bactericidal treatment;
4. bacteriological analyses of each lot showing basket or tank sampled and zero hour and final hour results. These results must be graphed as well as tabulated (Faecal Coliform versus Lot number); and
5. water temperature, salinity, rainfall data, oxygen content, turbidity, pH, waterflow and ultraviolet lights on a daily basis, as listed in Annex 10A.

Records must be kept up to date and must be available for audit by the CFIA.

2.6 Sampling and Laboratory Analysis (Depuration Operations)

The company will be required to analyze zero hour and final hour samples of each lot of shellstock for faecal coliform levels using approved methods.

The laboratory will be subject to periodic audits by the Canadian Food Inspection Agency (the policy on periodic audits and check samples program is being revised by the CFIA). The laboratory must participate in the split sample program operated by the CFIA and should participate in the check sample program.

2.7 Cleansing Process - Bacteriological Performance Criteria

The cleansing process will be considered satisfactory if faecal coliform analyses of samples of cleansed clams result in a MPN geometric mean value of 50/100 grams (g) or less and not more than 10% of the samples exceed a faecal coliform MPN of 130/100 g.

A lot will be considered acceptable if it has a faecal coliform MPN of 170/100 g or less.

CFIA will establish, based on demonstrated plant performance, a zero hour faecal coliform limit and a minimum depuration cycle time. If any zero hour sample has faecal coliform levels greater than the established maximum, the lot shall be:

1. purified using an approved modified schedule (not less than 72 hours for land-based depuration units) and detained by industry until the results of bacteriological analyses are complete; or
2. detained and sampled by industry. If industry final hour results are less than 170 faecal coliforms/100 g, the lot will be released; if greater than 170/100 g, the lot will remain detained, with

the plant having the option to re-depurate using a modified schedule, or heat-process (e.g., can) the clams; or
3. disposed of for other than human consumption; or
4. relayed to a restricted or conditionally restricted area.

2.8 Deviation File

If any depurated lot has a final hour faecal coliform count greater than 170/100 g or if two consecutive lots have counts greater than 130 faecal coliforms/100 g, all information pertaining to the lot, including dig site information, storage time, water quality and bacteriological data must be placed in a deviation file. The establishment must notify the CFIAInspection Office immediately upon discovery of the deviation as well as initiate investigative action to determine the cause. the CFIA will take appropriate action with regard to the lot of clams.

Chapter 11 - Control of Marine Biotoxins

Shellfish areas on both the Atlantic and Pacific coasts of Canada have been affected by marine biotoxins. The toxins are produced by certain species of naturally occurring microscopic algae that bloom under favourable hydrographic conditions. Filter-feeding bivalve shellfish accumulate the toxins when they ingest toxic algae as a food source. The consumption of toxic shellfish can lead to illness and even death. The toxins do not kill the shellfish nor cause any discernible changes in the appearance, smell or taste of shellfish that would alert consumers of toxicity. As conditions (e.g., water temperature, salinity, and nutrient levels) become less favourable, the bloom subsides and with time, shellfish rid themselves of toxin and are once again safe to eat.

Any filter feeding bivalve can acquire the toxins, and in Canada, many species of clams, oysters, mussels and scallops have been affected. The rates at which toxins are accumulated and eliminated varies with species. Also, animals that feed on bivalves may become toxic. Toxins have been detected in lobsters, crabs, and whelks and other predatory gastropods.

The following marine toxins have been found in Canadian shellfish: Paralytic Shellfish Poison (PSP), Amnesic Shellfish Poison (ASP) and Diarrhetic Shellfish Poison (DSP). The toxins are named for the most notable symptom they cause, i.e., paralysis, amnesia and diarrhea, respectively. Serious illness (as well as occasional deaths) have occurred as a result of consumption of bivalves contaminated with high levels of PSP and ASP; no deaths have been recorded for DSP.

In order to protect consumers, programs to monitor biotoxin levels and control the harvesting of toxic shellfish have been established. The Canadian Food Inspection Agency (CFIA) is responsible for collecting and analysing shellfish samples, and making recommendations for the opening and closing of shellfish areas to Fisheries and Oceans Canada (DFO) which implements and enforces closures.

11.1 Program responsibilities and Reporting

The CFIA is responsible for overall CSSP program implementation and management of shellfish sampling related to toxins. Reports of all activities are centrally maintained at the Regional level. Because of the risk of serious illness and death, reports of suspected cases of poisoning are closely investigated. All consumer illness information must be entered in the Issues Management System (IMS).

11.2 Sampling of Shellfish Areas

Each CFIA Region must have established sampling sites and frequencies to monitor changes in Paralytic Shellfish Poison (PSP), Amnesic Shellfish Poison (ASP) and Diarrhetic Shellfish Poison (DSP).

The toxicity levels in shellfish vary depending on the location of the actual sampling site. It is important that sampling sites for monitoring toxicity levels be chosen after evaluating the following criteria:

a. accessibility for sampling at all times of the year;
b. the amount of shellfish resource in the area;
c. the defined harvest area that the sample site represents; and
d. the history of toxicity in the area.

In order to maintain reliability of laboratory results, the period of time between the sampling of shellfish and extraction should be uniform and limited. Each sample must be properly packaged and identified with the area of harvest, the species, the date and time of sampling and the sampler's name. Samples should be

stored at refrigerated temperatures between 0° and 10°C until extracted; or samples should be frozen, then thawed and stored at refrigerated temperatures between 0° and 10°C until extracted.

In the case of offshore sites or aquaculture leases, shellfish samples may be collected at dockside or at registered establishments as long as the samples are handled appropriately and the identity is maintained.

Third party samplers can collect marine biotoxin samples for the CFIA as long as the CFIA provides oversight of the sample collection and handling process.

CFIA Regions must have in place a program to adequately monitor marine biotoxins. As levels begin to rise, sampling frequency may be increased in accordance with the speed of the rise to ensure timely closure. The objective is to ensure that shellfish areas are closed when:

i. PSP toxin levels reach 80 µg/100 g;
ii. ASP toxin levels reach 20 µg/g;
iii. DSP (okadaic acid and/or DTX, singly or in combination) toxin levels reach 0.2 µg/g or pectenotoxins levels reach 0.2 µg/g (whole tissue)

In certain circumstances it may be necessary for the CFIA to make a recommendation to DFO to close an area prior to reaching the standards above. These situations are usually limited to the following scenarios:

1. sampling indicates that the toxin levels are rising rapidly, though they have not exceeded the standard, and the next planned sample cannot be obtained and/or analysed within a reasonable time frame to ensure consumer safety.
2. sampling has shown a spike in toxin levels that are close to the standard, but have not yet exceeded it, and historical information on the area(s) indicate that rising levels will pose a significant threat to consumer safety.

Areas that are closed based on the scenarios above may be opened earlier than the standard 14 day closure if a subsequent sample(or samples) indicates that the biotoxin levels never reached regulatory standards and the toxicity levels have dissipated.

When departures from the scheduled sampling and/or analyses occur, factors such as previous toxic history, harvesting activity and other supporting results should be considered and documented in a derogation report for the justification in not closing an area.

11.3 Sampling from Processing Plants

As an additional safety measure samples may be taken for biotoxin analysis from shellfish processing establishments during compliance verification activities.

When bivalve shellfish samples are collected for biotoxin analysis at a registered processing establishment the following enforcement policy is applied:

a. Where a shellfish sample collected from a registered processing establishments shows a PSP level ≥ 80 µg/100 g, and/or an ASP level ≥ 20 µg/g, and/or DSP chemical analysis gives okadaic acid (OA) and/or DTX, singly or in combination, of ≥ 0.2 µg /g or pectenotoxins (PTX) are ≥ 0.2 µg /g of whole tissue, a recommendation to close the implicated harvest area(s) will be made to DFO provided the QMP controls for biotoxins are deemed to be in compliance. The production lot from which the sample was taken will be detained if the lot is still available at the establishment. If the lot is unavailable the inspector should consult with his/her supervisor on the need for a possible product recall. Any recalls should follow the appropriate CFIA Food Emergency Response Manual

requirements. Enforcement actions will be considered as appropriate in accordance with the CFIA's Enforcement Policy.

b. Additional harvest area samples will be taken to determine the status of the harvest area(s) as per section 11.5. The duration of closure will be dependent on the biotoxin results of samples from the implicated area and may be a minimum of 14 days.
c. Until such time as samples from the suspect shellfish area are analysed, all production lots (harvested from suspect area since date of last acceptable result) from **all** establishments should be detained and sampled.
d. Should the harvest area samples be acceptable and there are no additional high results in samples from other establishments, all efforts would be re-directed at the original establishment. A compliance verification is to be initiated and any additional lots sampled as part of the investigation or audit are to be detained until results have been received.

There are additional considerations for in-plant sampling with respect to sea scallops (Placopecten magellanicus). The adductor muscle of Placopecten magellanicus is free from toxin, however, the gonads and roe may be toxic. The marketing of Placopecten magellanicus with roe attached is not permitted in the Bay of Fundy. In addition, all lots of Placopecten magellanicus harvested in the Gulf of St. Lawrence, Northumberland Strait, George's Bank and other areas, and which are packed whole or with roe attached, must be sampled for toxicity content prior to release for market. To ensure adequate control of toxins, fish processing establishments must, prior to processing any species of scallop whole or with roe on, must consult with the CFIA.

Note: The purple-hinged rock scallop (Crassedoma giganteum / Hinnites multirugosus) accumulates PSP toxin in the adductor muscle.

11.4 Area/Regional/District Management of Marine Biotoxins

Each CFIA area, district or region must develop an annual marine biotoxin monitoring control plan which must include the following: a list of sampling sites and rationale for site selection, species, the frequency of sampling, who collects the samples, who receives and interprets the results during normal business hours and during non routine situations (evenings/weekends/holidays), how priority samples are determined and what communication channels are established with receiving laboratories for priority samples, if and how the results are disseminated to industry and to other interested parties, the process for recommending closure and openings to DFO, a communication plan for notification of recommendations of closures and openings to regulated parties and stakeholders and, how performance of the control plan is reported.

Any area, region or district that is considering any significant changes (addition of harvest sites, replacement of harvest sites, change to key sites, reduction of sites and/or samples) to their marine biotoxin monitoring control plan must:

- take into account the local known history of toxicity,
- review any relevant scientific literature, and
- consult appropriate CSSP program specialists.

The rationale for changes must be documented in the area, regional or district biotoxin monitoring control plan.

11.5 Standards Applied and Procedures for Controlling Harvesting

A PSP toxin level ≥ 80 µg/100 g, or ASP toxin level ≥ 20 µg/g, or okadaic acid and/or DTX, (DSP) singly or in combination, ≥ 0.2 microgram per gram (µg/g) or ≥ 0.2 µg/g pectenotoxins in a sample, will require

the area from which the sample is taken to be closed. The area may be re-opened only when three consecutive acceptable values are obtained during a minimum period of 14 days, i.e., 1st sample on day 1 and the 3rd sample no earlier than day 14. Test results must contain < 80 µg/100 g PSP or < 20 µg/g ASP or < 0.2 µg/g DSP (okadaic acid and/or DTX, singly or in combination) or < 0.2 µg/g pectenotoxins (whole tissue).

11.6 Shellfish Illness due to Marine Biotoxins

A shellfish harvest area may be placed in closed status as an interim measure when a marine biotoxin related shellfish illness is suspected or confirmed. The area to be closed will depend on the circumstances under investigation, and will remain closed until an investigation is complete and the area is deemed safe to harvest. The duration of closure will be dependent on the biotoxin results of samples from the implicated area and may be a minimum of 14 days.

11.7 The Status of Harvested Shellfish Products Upon Notification of an Area Biotoxin Closure

Shellfish areas will be placed in the closed status when marine biotoxin levels (PSP, ASP or DSP) exceed established standards. It is possible in some cases that shellfish can be harvested between the last acceptable sample and the date the area has been closed. In these cases, the following procedure will be used to determine if the shellfish are safe for consumption.

The safety of all bivalve shellfish harvested after the last acceptable sample is to be evaluated on a case by case basis.

The CFIA must analyze the situation (factors such as toxin level, timing, species profile/biology, history of harvest area, etc.). Inspectors must consult with their supervisor, Regional Program Officer, and the Area Program Network shellfish specialist to determine what, if any, measures should be taken. This may include detaining product affected by the closure. If it is decided that a risk assessment is required, the Area Recall Coordinator will be contacted to initiate the risk assessment process via the CFIA's Office of Food Safety and Recall (OFSR).

If affected shellfish is in distribution an IMS file will be opened. If there is no affected product in distribution product actions will be documented in the CFIA Fish Products Database (MCAP).

It is the responsibility of each registered shellfish processing facility to take appropriate corrective action in these circumstances to ensure shellfish are safe for consumption. Examples of acceptable corrective procedures may include but are not limited to:

- cease using the water for wet storage systems if it is sourced from a growing area that is placed in closed status due to elevated marine biotoxins, filter the water supply to remove any toxic phytoplankton (using a validated system), or switch to an alternate salt water supply not affected by the toxic phytoplankton (i.e., salt water well).
- hold and evaluate the safety of product in inventory and distribution and make a decision on disposition.
- testing shellfish that may be affected by the closure.
- disposing of shellfish with unacceptable results or returning them to the closed area (subject to CFIA and DFOapproval).

Shellfish kept in wet storage systems during marine biotoxin closures (and potentially placed under detention by the CFIA) would be evaluated for safety on a case by case basis by the processing facility and

by the CFIA. In these instances, the product remaining at the facility may be held and may be sampled by CFIA. Sampling by the CFIA would be conducted as per the procedures described in the CFIA Fish Products Standards and Methods Manual.

Chapter 12 - Shellfish Aquaculture

Shellfish aquaculture is an important industry in many coastal areas of Canada. It is important that the leasing and licensing authorities in each jurisdiction consult Fisheries and Oceans Canada, Environment Canada and the Canadian Food Inspection Agency for advice during the site approval, and lease and licence granting processes to ensure that all considerations relating to CSSP are captured.

12.1 Aquaculture Sites

The aquaculture of shellfish may be conducted in areas where:

a. the shellfish area complies with the requirements of Chapter 2 for approved or conditionally approved area classification and only when chemical or toxin levels do not reach or exceed the tolerances and/or action levels outlined in Appendix II;
b. the shellfish area complies with the requirements of Chapter 2 for restricted or conditionally restricted areas and only when chemical or toxin levels do not reach or exceed the tolerances and/or action levels outlined in Appendix II. Shellfish harvested from a restricted or conditionally restricted area requires a licence issued under the Management of Contaminated Fisheries Regulations (DFO, 1990) and are subject to a depuration or relay protocol prior to marketing as outlined in Chapter 10. Holders of leases within restricted or conditionally restricted areas may be required, at the discretion of CSSPShellfish Control Authorities, to have bacteriological analyses of overlay waters and/or chemical analysis of shellstock performed by ISO 17025:2005 - accredited third-party laboratories. The analyses will be per the requirements under Chapter 2 in order to demonstrate that the bacteriological quality of the lease site overlay water has not deteriorated and the shellstock have not been subjected to significant sources of chemical contamination.
c. the shellfish area is not within any prohibited area as described in Chapter 2 however, as described in Section 2.3.6, Seed and Spat Collection, seed and spat collection is allowed in prohibited areas with appropriate licences.

12.2 Integrated Multi-Trophic Aquaculture

For the purposes of the CSSP, integrated multi-trophic aquaculture refers to the raising of shellfish and finfish within a 125 metre radius of one another in the marine environment.

Special measures are required to ensure that the shellfish cultivated and harvested from such systems are not adversely affected by potential sources of pollution stemming from the culture operation and structures (see Chapter 2).

The aquaculture proponent who plans to cultivate and harvest shellfish within the 125 metre distance of a finfish net pen must:

- have a documented agreement with the authority responsible for land tenure and/or licensing aquaculture activities for the exploitation of the species grown on the site, as well as confirmation from Environment Canada that it has surveyed and classified the surrounding waters, and;
- submit an Integrated Multi-Trophic Aquaculture Management Plan (IMTAMP) to the Regional Interdepartmental Shellfish Committee (RISC).

The IMTAMP will be developed as described in Appendix XII, "Procedure for Development, Approval and Review of an Integrated Multi-Trophic Aquaculture Management Plan" and shall detail the operating

measures which ensure that cultivation and harvesting takes place only where sanitary conditions can be maintained (see Chapter 2, Appendix II, and Appendix III).

Failure to meet the conditions of the IMTAMP must be immediately reported to the Chair of the RISC.

12.3 Aquaculture Methods

Consideration must be given to culture shellfish in a manner that will ensure it is safe for consumption prior to harvesting for sale. When, in the opinion of a shellfish control authority, the technology used to grow shellfish could potentially create or attract significant sources of contamination, failure to develop adequate control measures could lead to the closure of an aquaculture site. Any shellstock cultured using this type of technology must be subject to QMPcontrols in a federally registered establishment, or the leaseholder must submit a harvest plan with appropriate control measures acceptable to the regional shellfish control authority.

Chapter 13 - Outbreaks of shellfish-related illness

13.1 Response to outbreaks

Public health authorities are responsible for the investigation and response to illness outbreaks. Provincial and local public health authorities lead the response to enteric illness outbreaks within their respective jurisdictions. The Public Health Agency of Canada leads the response to enteric illness outbreaks that span more than one Canadian province or territory or involve Canada as well as another country, pursuant to the Canada's Food-borne Illness Outbreak Response Protocol. When shellfish are implicated in an illness outbreak, the Canadian Shellfish Sanitation Programauthorities participate in the investigation response.

13.2 Epidemiological information and food safety investigations

Provincial public health authorities and the Public Health Agency of Canada provide the Canadian Food Inspection Agency (CFIA) with information respecting potential epidemiological associations between reported illnesses and shellfish consumption. The CFIA will use the epidemiological illness data in conjunction with evidence gathered as part of a CFIA led food safety investigation to assess the link between molluscan shellfish from a specific shellfish harvest area, landfile or lease and reported illnesses. The CFIA's food safety investigation will assess whether the illness is related to a shellfish harvest area (whole or part of), landfile or lease or is the result of processor post-harvest contamination.

13.3 Shellfish harvest area, landfile or lease closures – norovirus contamination

The CFIA will recommend to Fisheries and Oceans Canada (DFO) to place an implicated shellfish harvest area (whole or part of), landfile or lease in closed status if:

- shellfish from a specific area (whole or part of), landfile or lease are the suspected vector of infection and there are/is:
    - two single source illness clusters in a 21 day harvest period or,
    - one single source illness cluster and 2 multi-source illness clusters in a 21 day harvest period or,
    - a single source illness cluster comprised of a large number of illnesses resulting from a specific harvest for a public or private event.

or,

Environment and Climate Change Canada (ECCC) will recommend to DFO to place an implicated shellfish harvest area (whole or part of), landfile or lease in closed status if there has been a confirmed contamination event as per appendix VIII (Protocol for Emergency Closure of any Shellfish Growing Area).

Follow-up representative shellfish sampling at the harvest area, landfile or lease will be conducted to determine the level and extent of contamination. The shellfish area (whole or part of), landfile or lease remains in closed status when investigative samples from approved areas exceed any of the following criteria:

- E. coli (n=5, c=1, m=230 MPN/100 g, M=330 MPN/100 g)
- Norovirus (n=5 detected in any sample)

If samples are unacceptable for norovirus, the closure will be in effect for a minimum of 30 days. If sample results are unacceptable for E. coli only, the closure will remain in place for a minimum of 7 days.

A shellfish area (whole or part of), landfile or lease may return to open status if investigative sample results are acceptable.

13.4 Shellfish harvest area re-opening – norovirus contamination

a) For closures due to Norovirus

CFIA and ECCC will recommend to DFO that a shellfish harvest area, landfile or lease be returned to open status when:

- ECCC has confirmed that there is no evidence of new or ongoing sanitary concerns and,
- After 30 days, CFIA shellfish testing results meet the following criteria:
    - E. coli (n=5, c=1, m=230 MPN/100 g, M=330 MPN/100 g)
    - Norovirus (n=5 not detected)
- or,
- After 60 days, without testing, when the harvest area water temperature has remained at 10 degrees Celsius or higher.

b) For closures due to E. coli only

CFIA and ECCC will recommend to DFO that a shellfish harvest area, landfile or lease be returned to open status when:

- ECCC has confirmed that there is no evidence of new or ongoing sanitary concerns and
- After 7 days, CFIA shellfish testing results meet the following criterion:
    - E. coli (n=5, c=1, m=230 MPN/100 g, M=330 MPN/100 g)

13.5 Risk assessment

The CFIA will consult with Health Canada to determine the level of risk that any shellfish in distribution might pose and take follow-up action as required as per CFIA's Food Investigation and Response Manual.

Appendices

- Appendix I - Laboratory Procedures
- Appendix II - Action Levels, Tolerances and Other Values for Poisonous or Deleterious Substances in Seafood

Appendix I - Laboratory Procedures

PDF (53 kb)

This Appendix provides CSSP laboratories with information on: analytical methods and quality assurance procedures associated with the examination of seawater and shellfish; references and information necessary for conducting bacteriological, toxicological, chemical and physical tests; and guidance for development and implementation of quality assurance procedures. Adherence to the procedures identified in this Appendix will provide the uniformity necessary to produce reliable laboratory results upon which public health decisions can be made in determining whether shellfish are suitable for human consumption.

1. Bacteriological Procedures

The American Public Health Association (APHA) publications Laboratory Procedures for the Examination of Seawater and Shellfish (Greenburg and Hunt 1984) or Standard Methods for the Examination of Water and Wastewater (most recent edition) or equivalently Health Canada's Health Protection Branch Method MFHPB-19, Enumeration of Coliforms, Faecal coliforms and of E. coli in foods using the MPN method (Compendium of Analytical Methods, HPBMethods of Microbiological Analysis, Volume 2), shall be followed for the collection, transportation and examination of samples of shellfish and shellfish waters. The official reference for the examination of shellfish for Vibrio parahaemolyticus is Health Canada's Health Protection Branch Method MFLP-39a, Detection of Vibrio Species, (Compendium of Analytical Methods, HPB Methods of Microbiological Analysis, Laboratory Procedures for the Microbiological Analysis of Foods Volume 3) or equivalently, the U.S. Food and Drug Administration 2001 Bacteriological Analytical Manual Online. Laboratories should conduct the test for this organism when routine tests of marine foods suspected in food borne outbreaks fail to demonstrate other enteric pathogens or bacterial toxins (Ratcliffe and Wilt 1971).

The multiple tube fermentation technique is most commonly used to estimate bacterial numbers in seawater and shellfish. This technique uses the principle of dilution to extinction to estimate the number of bacteria in a sample. Decimal dilutions of the sample are introduced into replicate tubes of a medium designed to select for growth of the particular organism being enumerated. Thus it reasonably can be assumed that the maximum dilution at which growth occurs represents a volume containing a single organism. The results of

such an analysis are expressed in terms of the Most Probable Number (MPN). This represents an estimate based on probability formulae.

Any laboratory wishing to analyze regulatory samples in support of the CSSP must be accredited to the international standard ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories by a recognized accrediting body.

Bacteriological water quality standards, based on fecal coliform levels, as determined by the MPN method, are presently in use for the classification of shellfish growing waters. Bacteriological shellstock count standards based on fecal coliform levels, as determined by the MPN method, are presently in use for the evaluation of depuration effectiveness and verification data to open areas closed under a management plan.

Sample Condition

Initiate the bacteriological examination of water samples immediately after collection and preferably within 8 hours after collection. Under no circumstances however, shall bacteriological examination results from water samples held longer than 30 hours be considered valid for classification purposes. Keep samples between 0 and 10°C until examined. No other method of sample preservation is acceptable. A minimum of 100 mL of water sample is required for this test, and only sterile glass or polypropylene bottles should be used.

Shellstock samples should be collected in clean, waterproof and puncture resistant containers. Approximately 10-12 or more animals (sufficient to yield 150-250 g), free of open or cracked shells are required for each shellstock sample. Shellstock samples should be kept and transported in dry storage at 10°C or below but above 0°C until examined. Shellstock should not be allowed to come in direct contact with ice. Shellstock samples should be submitted to the laboratory as quickly as possible and analyzed within 24 hours of collection.

Interference

Bacteriostatic or bactericidal agents, such as chlorine, silver, lead, and various organic complexes, can significantly reduce bacterial densities in a sample. Contaminating nutrients can cause unwanted growth of organisms in the sample which would result in an overestimation of bacterial densities.

Both of these problems can be greatly reduced by insuring that:

a. all glassware used in the analyses is free from such substances;
b. distilled/deionized water used in media preparation is not contaminated with bacterial, fungal or algal growth; and
c. samples are processed as quickly as possible after collection.

Growth of certain organisms in the test media which are not of importance to the specific analysis performed can give false positive results, thereby overestimating the true bacterial density. However, the specificity of the test media normally eliminates most of these organisms. Incubation temperatures are critical, and slight changes can alter the kinds and numbers of bacteria growing in the test media.

Precision and Accuracy

The bacterial density calculated by the MPN method is a statistical estimation and should be treated as such. The 95 percent confidence limits for the 5-tube MPN test, range between 24% and 324% of the MPN; thus, the results of a single sample are by no means conclusive. Accuracy increases with increased sampling, and

normally a minimum of five samples are required at each sample location to better approximate the true bacterial density.

Apparatus

- Sterile 10.0 mL and 1.0 mL serological pipettes
- Sterile applicator sticks or 5 mm inoculating loops (platinum[Footnote 11])
- 35 ± 0.5°C air incubator
- 44.5 ± 0.2°C or dual temperature programmable waterbath
- Sterile 250 mL wide-mouth sample bottles[Footnote 11]
- 20 x 150 mm Pyrex test tubes and caps[Footnote 11]
- 16 x 150 mm Pyrex test tubes and caps[Footnote 11]
- 6 x 50 mm culture tubes (Durham tubes)
- Test tube racks
- Autoclave
- Sterile Pasteur pipettes
- Milk dilution bottles[Footnote 11], 160 mL
- Blender
- 1.0 L (minimum size) blender jars[Footnote 11].
- sterile shucking knife and/or scalpel.
- sterile stiff brush

Bacteriological Media and Reagents

With the exception of A-1 medium (which must be prepared from its individual components) and Modified MacConkey Agar (which may be prepared from its individual components), all other media listed are commercially available in a dehydrated form.

Lauryl Tryptose Broth (LTB)

This medium is commercially available.

- Tryptose - 20.0 g
- Lactose - 5.0 g
- K_2HPO_4 - 2.75 g
- KH_2PO_4 - 2.75 g
- NaCl - 5.0 g
- Sodium lauryl sulfate - 0.1 g
- Distilled/deionized water - 1.0 L

Suspend 35.6 g in 1.0 L of distilled or deionized water and warm slightly to dissolve completely. Double strength media is prepared using the above amounts dissolved in 500 mL of water. Dispense 10 mL aliquots into tubes containing inverted fermentation vials. Autoclave at 121°C for 15 minutes. The pH of the medium should be 6.8 after sterilization.

Brilliant Green Bile (BGB) 2% Broth

This medium is commercially available.

- Peptone - 10.0 g

- Lactose - 10.0 g
- Oxgall - 20.0 g
- Brilliant Green - 0.0133 g
- Distilled/deionized water - 1.0 L

Suspend 40 g in 1.0 L of distilled or deionized water and warm slightly to dissolve completely. Dispense 5 to 10 mLaliquots into tubes containing inverted fermentation vials. Autoclave at 121°C for 15 minutes. The pH of the medium should be 7.2 after sterilization.

EC Medium

This medium is commercially available.

- Tryptose or trypticase - 20.0 g
- Lactose - 5.0 g
- Bile salts No. 3 - 1.5 g
- K_2HPO_4 - 4.0 g
- KH_2PO_4 - 1.5 g
- NaCl - 5.0 g
- Distilled/deionized water - 1.0 L

Suspend 37 g of the powder in 1.0 L of distilled or deionized water and warm slightly to dissolve completely. Dispense 5 to 10 mL aliquots into tubes containing inverted fermentation vials. Autoclave at 121°C for 15 minutes. The pH of the medium should be 6.9 after sterilization.

A-1 Medium

- Lactose - 5.0 g
- Tryptone - 20.0 g
- NaCl - 5.0 g
- Salicin - 0.5 g
- Triton X-100 - 1.0 mL
- Distilled/deionized Water - 1.0 L

Suspend the above ingredients in 1.0 L of distilled or deionized water. Mix thoroughly then add 1 mL of Triton X-100 and continue mixing until dissolved completely. Double strength media is prepared using the above amounts dissolved in 500 mL of water. Dispense 10 mL aliquots into tubes containing inverted fermentation vials. Autoclave at 121°C for 10 minutes. The pH of the medium should be 6.9 after sterilization.

Levine's Eosin Methylene Blue Agar

This medium is commercially available.

- Pancreatic Digest of Gelatin - 10.0 g
- Lactose - 10.0 g
- K_2HPO_4 - 2.0 g
- Eosin Y - 0.4 g
- Methylene Blue - 0.065 g
- Agar - 15.0 g
- Distilled/deionized Water - 1.0 L

Suspend 37.4 g of the powder in 1.0 L of distilled or deionized water. Mix thoroughly. Heat with frequent agitation and boil for 1 minute to completely dissolve the powder. Autoclave at 121°C for 15 minutes. The pH of the medium should be 7.0 after sterilization. Allow to cool to approximately 45°C and pour into petri dishes. Allow plates to cool to room temperature.

Plate Count Agar (or Standards Methods Agar)

This medium is commercially available.

- Pancreatic Digest of Casein - 5.0 g
- Yeast extract - 2.5 g
- Dextrose - 1.0 g
- Agar - 15.0 g
- Distilled/deionized water - 1.0 L

Suspend 23.5 g of the powder in 1.0 L of distilled or deionized water. Mix thoroughly. Heat with frequent agitation and boil for 1 minute to completely dissolve the powder. Autoclave at 121°C for 15 minutes. The pH of the medium should be 7.0 after sterilization.

Modified MacConkey Agar (Double strength)

- Peptone - 34.0 g
- Polypeptone - 6.0 g
- Lactose - 20.0 g
- Bile Salts No. 3 - 1.5 g
- Agar - 27.0 g
- Neutral Red - 0.06 g
- Crystal Violet - 0.02 g
- Distilled/deionized Water - 1.0 L

Suspend the above ingredients in 1.0 L of distilled/deionized water. Mix thoroughly. Heat with frequent agitation until boiling. Remove from heat and boil again (do not autoclave). Temper in waterbath at 45 - 50°C for up to six hours.

Phosphate Buffer

This buffer is prepared from 2 stock buffer solutions:

- Stock phosphate buffer solution: dissolve 34.0 g of potassium dihydrogen phosphate (KH_2PO_4) in 500 mL distilled water, adjust to pH 7.2 with 1 N NaOH (approximately 150 to 175 mL of 1 N NaOH may be required to adjust to pH 7.2), and dilute to 1.0 L with distilled water.

Magnesium Chloride solution:

- Dissolve 81.1 g $MgSO_4 \cdot 6H_2O$ in 1.0 L distilled/deionized water

Final Phosphate buffer dilution water:

- 1.25 mL Stock phosphate buffer solution
- 5.0 mL Magnesium Chloride solution
- 1.0 L distilled/deionized water

Fill dilution bottles or tubes with dilution water so that after sterilization (autoclave at 121°C for 15 minutes) they will contain the quantity desired with a tolerance of ± 2%.

0.5% Peptone Water

- Peptone or gelysate - 5.0 g
- Distilled/deionized water - 1.0 L

Dissolve peptone in distilled/deionized water and fill dilution bottles or tubes with dilution water so that after sterilization (autoclave at 121°C for 15 minutes) they will contain the quantity desired with a tolerance of ± 2%.

Procedure

Water Analysis for Coliform and Fecal Coliform

Generally, five 10 mL aliquots, five 1.0 mL aliquots, and five 0.1 mL aliquots of the sample are aseptically inoculated into test tubes containing Lauryl Tryptose Broth (LTB). The 10 mL aliquots are inoculated into double strength LTB. It is necessary to perform serial 1/10 dilutions on some samples to prevent indeterminate results. Dilutions are made in phosphate buffered distilled water and should be chosen such that approximately half the tubes give positive results. The tubes are incubated at 35 ± 0.5°C and examined for the presence of growth accompanied by gas production at 24 (± 2) and 48 (± 4) hours. Growth and gas production are both necessary for a positive result. The MPN is calculated and results are expressed as "Presumptive Coliform MPN/100 mL".

To confirm the presence of coliforms, inocula from 24- and 48-hour positive presumptive tubes are aseptically transferred to tubes of Brilliant Green Bile (2%) Broth. Transfers are done at both 24 and 48 hours after the initial inoculation into Lauryl Tryptose Broth, dependent on time of gas formation in Lauryl Tryptose Broth. The tubes are incubated at 35 ± 0.5°C and examined for growth with gas production at 24 (± 2) and 48 (± 4) hours. Results are expressed as "Confirmed Coliform MPN/100 mL".

To enumerate fecal coliforms, inocula from 24- and 48-hour positive presumptive tubes are aseptically transferred to tubes of EC medium. These tubes are incubated at 44.5 ± 0.2°C for 24 ± 2 hours and examined for the presence of growth with gas production. Results are expressed as "Fecal Coliform MPN/100 mL".

Rapid Fecal Coliform MPN Test (Modified A-1 Method)

Inoculation and dilution procedures for this technique are identical to those described for lauryl tryptose broth in the preceding section except the medium used is A-1 medium. The tubes are incubated for 3 ± 0.5 hours at 35 ± 0.5°C and then transferred to a waterbath maintained at 44.5 ± 0.2°C for an additional 21 ± 2 hours incubation. As an alternative, laboratories can use programmable waterbaths to incubate the samples for the full 24 hours. At the completion of the 24 hour incubation period tubes are examined for the presence of both growth and gas. The MPN is calculated and results are expressed as "Fecal Coliform MPN/100 mL". The use of the A-1 medium for the rapid determination of fecal coliforms is presently restricted to fecal coliform enumeration in marine shellfish growing waters and is not applicable to other types of waters or effluents.

Shellfish Analysis

Prior to performing the standard MPN procedure on shellstock, the following sample preparation is required. Shellstock to be used is cleaned prior to shucking. Sterile shucking knives, brushes, and blender jars are used. Prior to shucking, shellstock are scrubbed with a stiff, sterile brush and rinsed under water of

drinking water quality. Shellstock are allowed to drain in a clean area prior to shucking. A minimum of 100 g (minimum of 10-12 animals) of shellstock sample (meat and liquor) is aseptically shucked into a sterile, tared blender jar using sterile shucking equipment. An equal weight of sterile phosphate-buffered dilution water is added to the blender jar, and the contents are blended at high speed for 90-120 seconds. Immediately after blending, 20 g of this mixture is aseptically added to 80 mL of dilution water resulting in a 1/10 dilution of the original sample. A 1/100 dilution is prepared by aseptically adding 10 mL of the 1/10 dilution into 90 mL of dilution water. The standard MPN procedure (using LTB/EC) is performed using these dilutions with 10 and 1 mL aliquots inoculated from the 1/10 dilution and 1 mL aliquots from the 1/100 dilution.

Calculations

MPN values, expressed as MPN/100 mL, for those tube codes which normally occur are presented in the applicable reference for 5-tube MPN procedures. If dilutions are performed on the sample, the MPN value appearing in the table is multiplied by the appropriate dilution factor.

2. Toxicological

Laboratories shall use either:

- official methods that have been verified to determine performance characteristics in each laboratory
- other methods that have been validated using internationally recognized protocol; or
- methods that have been approved as part of that lab's scope of accreditation

3. Chemical and Physical

a. Current AOAC and APHA official methods shall be followed in making chemical and physical determinations.
b. Results of all chemical and physical determinations shall be expressed in standard units. (For example, salinity should be expressed in parts per thousand rather than hydrometer readings.)

4. Quality Assurance

The CSSP laboratory (government or private) shall ensure that all samples are collected, preserved, transported and analyzed in a manner that assures the validity of the analytical results.

In conjunction with ISO requirements, the laboratory shall develop a Quality Assurance Plan specific to the laboratory. The Quality Assurance Plan shall include, but not be limited to, the following:

- A description of the organization of the laboratory;
- A description of staff training requirements and maintenance of records of training;
- Written Standard Operating Procedures (SOPs) for all procedures conducted by the laboratory;
- A description of internal quality control measures for equipment calibration, maintenance, repair and performance checks and maintenance of records;
- A description of laboratory safety issues and maintenance of applicable records (training, MSDS);
- A description of internal laboratory performance assessment and maintenance of records;
- A description of external laboratory performance assessment and maintenance of records.

All laboratories performing CSSP testing for regulatory purposes must be accredited to the international standard ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration

Laboratories by a recognized accrediting body. This standard requires that all applicant/accredited laboratories shall demonstrate their technical proficiency by their satisfactory participation in a suitable Proficiency Testing (PT) activity administered by a suitable PT Provider.

A joint CFIA- EC "CSSP Laboratory Committee" will serve as a key contact point for internal, external and international discussion and inquiries related to issues, methods and accreditation status.

Footnote

Footnote 11

Or suitable substitutes which meet or exceed CSSP requirements.

Return to footnote 11 referrer

Appendix II - Action Levels, Tolerances and Other Values for Poisonous or Deleterious Substances in Seafood

PDF (19 kb)

The types of poisonous or deleterious substances which have been recovered from shellfish include heavy metals, pesticides, petroleum products, polychlorinated biphenyls and naturally occurring marine biotoxins. The source of these contaminates may be from: industry, agriculture, mining, spillage, sewage, dredging operations, sludge dumps and naturally occurring marine organisms.

The Canadian guidelines for poisonous or deleterious substances are as follows:

- Total DDT > 5 ppm
- Polychlorinated Biphenyls (PCB) > 2 ppm
- Dioxin > 20 ppt
- Mercury > 0.5 ppm
- Mirex > 0.1 ppm
- PSP ≥ 80 µg/100 g
- Domoic Acid ≥ 20 µg/g
- Okadaic Acid (OA) + DTX-1 + DTX-2 + OA esters + DTX-1 esters + DTX-2 esters ≥ 0.2 µg/g (interim)
- Pectenotoxins: (PTX-1, PTX-2, PTX-3, PTX-4, PTX-6 and PTX-11) ≥ 0.2 µg/g

All other Agricultural Chemicals > 0.1 ppm

The United States FDA action levels/tolerances for fish products may be found on the CFIA Internet site, in the Certification Requirements section. The following levels of marine biotoxins also apply in the USA:

NSP - Non-detectable

The NSSP considers the presence of any NSP toxin to be hazardous to human health. The value for neurotoxic shellfish poison (NSP) is not an FDA action level or tolerance.

Appendix III - Procedures for Molluscs Exceeding CFIA Bacteriological Guidelines

PDF (25 kb)

Domestically processed shellfish or raw products derived therefrom, whether fresh or frozen, are considered bacteriologically acceptable for direct market when they are:

i. harvested from an approved or a conditionally approved area in the open status, and

ii. meet the CFIA's Bacteriological Guidelines for Fish and Fish Products.

These procedures (represented graphically in the PDF - 430 kb) apply to molluscan shellfish processed at federally registered establishments in Canada or sampled from approved or conditionally approved shellfish areas and will be followed by the federal CSSP partners where appropriate.

1. If a shellfish sample collected at a CFIA registered shellfish processing establishment fails to meet a bacteriological guideline and, upon verification, the Quality Management Program is deemed to be in control, the following actions will be taken by the CFIA:

i. collect five (5) sample units at the implicated harvest area as soon as possible.[Footnote 12]
ii. Contact the leasing authority (if applicable) to inform them of the situation, actions taken and potential outcomes.

2. Should results of sample units collected from the implicated shellfish area meet the CFIA's bacteriological guidelines, no harvest area action is taken.

3. If results of the shellfish area sampling (e.g., E. coli or Salmonella) do not meet the CFIA bacteriological guidelines, the CFIA will make a recommendation to DFO to place the implicated harvest area in the closed status. The size of the closure will be determined on a case by case basis.

i. The CFIA will contact EC and inform them of the unacceptable results. EC will review the status of the area and may conduct a shoreline sanitary survey and/or collect additional water quality samples based on the results of the review.

ii. The area may be re-sampled by the CFIA (five (5) sample units) after a minimum of seven (7) days. If the results are acceptable, the CFIA, in consultation with EC, will recommend to DFO to place the harvest area in the open status. This additional sampling is at the discretion of the CFIA (i.e. if the area was placed in the closed status, it may be kept as such and EC requested to re-evaluate the area as survey schedules permit). If the results are unacceptable the area will remain in the closed status.

Footnote

Footnote 12

If mutually agreed, harvest site samples may be collected by another federal or provincial department or individual. Sample units are to be taken from separate, randomly selected sites in the implicated area.

Return to footnote 12 referrer

Appendix IV - Canada-United States Bilateral Agreement on Shellfish

PDF (24 kb)

Regarding Sanitary Practices in the Shellfish Industries and Related Matters

I. The Canadian Embassy in the United States of America to the Department of State

Canadian Embassy, Washington, March 4, 1948

No. 106

The Canadian Ambassador presents his compliments to the Secretary of State and, on the instruction of his government, has the honour to inform him that, in order to improve sanitary practices in the shellfish industries of Canada and the United States and to facilitate the exchange of information with reference to endorsement of shellfish certifications, the Canadian Department of National Health and Welfare and the United States Public Health Service have agreed on the desirability of an Agreement being concluded on the points and in the terms set forth in the annexed memorandum.

If such an agreement is acceptable to the United States Government, it is the proposal of the Canadian Government that this note and its Annex together with a reply agreeing thereto, constitute an Agreement between the two Governments effective from the date of the reply and from the United States authorities.

Annex **1**
Memorandum of Agreement

In order to improve the sanitary practices prevailing in the shellfish industries of Canada and the United States, it is agreed as follows:

1. Whatever manual of recommended practice for sanitary control of the shellfish industry is approved by both the United States Public Health Service and the Canadian Department of National Health and Welfare, will be regarded as setting forth the sanitary principles that will govern the certification of shellfish shippers.
2. The degree of compliance with those principles obtained by the State authorities of the United States will be reported to the Canadian Department of National Health and Welfare by the United States Public Health Service, and the degree of compliance obtained by the Provincial and other competent authorities in Canada will be reported by the Canadian Department of National Health and Welfare to the United States Public Health Service.
3. Whenever inspections of shellfish handling facilities or of shellfish areas are desired by either party to this Agreement, the other party will endeavour to facilitate such inspections.
4. This agreement may be terminated by either party giving thirty days' notice.

II. The Department of State to the Canadian Embassy in the United States of America

Department of State

The Secretary of State presents his compliments to His Excellency the Ambassador of Canada and has the honour to refer to his note No. 106 of March 4, 1948, proposing that an agreement be entered into between the Governments of the United States of America and Canada in the following terms:

Memorandum of Agreement

In order to improve the sanitary practices prevailing in the shellfish industries of the United States and Canada, it is agreed as follows:

1. Whatever manual of recommended practice for sanitary control of the shellfish industry is approved by both the United States Public Health Service and the Canadian Department of National Health and Welfare will be regarded as setting forth the sanitary principles that will govern the certification of shellfish shippers.

2. The degree of compliance with those principles obtained by the State authorities of the United States will be reported to the Canadian Department of National Health and Welfare by the United States Public Health Service, and the degree of compliance obtained by the Provincial and other competent authorities in Canada will be reported by the Canadian Department of National Health and Welfare to the United States Public Health Service.
3. Whenever inspections of shellfish handling facilities or of shellfish areas are desired by either party to this Agreement, the other party will endeavour to facilitate such inspections.
4. This Agreement may be terminated by either party giving thirty days' notice.

The Memorandum of Agreement as set forth above is acceptable to the Government of the United States of America. As proposed in His Excellency's note, therefore, that note and the present reply are regarded as constituting an Agreement between the two Governments effective on the date of the present note.

Washington
April 30, 1948

Appendix V - Memorandum of Understanding between the Canadian Food Inspection Agency ("CFIA") and Fisheries and Oceans Canada ("DFO") and Environment Canada ("EC") Concerning the Canadian Shellfish Sanitation Program ("CSSP")

PDF (34 kb)

The CSSP is a shared responsibility of the Canadian Food Inspection Agency (CFIA), Fisheries and Oceans Canada (DFO) and Environment Canada (EC).

1. Purpose

This Memorandum of Understanding (MOU) recognizes:

a. the purpose of the CSSP, which is to provide reasonable assurance that molluscan shellfish (hereinafter referred to as shellfish) are safe for consumption as food by controlling the harvesting of all molluscs within the tidal waters of Canada;
b. the commitment that Canada has to the Bilateral Agreement between the United States Public Health Service and the Canadian Department of National Health and Welfare (now Health Canada), signed April 30, 1948, to improve the sanitary practices prevailing in the shellfish industries of the two countries;
c. the respective responsibilities of the CFIA, DFO and EC in delivering the CSSP in Canada, and the CFIA's responsibility as lead agency for liaison with foreign governments; and
d. the parties' mutual commitment to strive constantly to: enhance the efficiency and effectiveness of CSSP program delivery, address linkages to related issues, communicate and co-operate with each other and all stakeholders, conduct and/or participate in national and/or international audits, and take remedial action as required to implement improvements.

2. Responsibilities of the CFIA

The CFIA shall be the lead agency in the administration of the CSSP with regard to: the handling, processing, import and export of shellfish; the marine biotoxin monitoring program; and any other microbiological monitoring program not described in section 4 - "Responsibilities of EC".

The CFIA shall be responsible for:

a. inspecting and issuing certificates of federal registration to plants that meet federal regulatory requirements and are engaged in the processing, holding and export of shellfish;
b. licensing fish importers and inspecting imported shellfish;
c. administering the marine biotoxin monitoring program and any other shellfish micro-biological monitoring program not described under EC's responsibilities in section 4;
d. recommending to DFO the closing of shellfish areas because of unacceptable marine biotoxin, microbiological and chemical levels in shellfish stock, and advising DFO when shellfish areas are acceptable for the harvesting of shellfish;
e. reviewing referrals from DFO for the issuing of licences for harvesting from closed areas, for relaying or depuration purposes;
f. maintaining records, data bases and other documents in support of marine biotoxin, microbiological and chemical closures, recommended closure actions, and administrative evaluations by internal and external auditors;
g. ensuring proper application of prescribed analytical and reporting procedures in CFIA laboratories and private laboratories approved in accordance with the CSSP Manual of Operations, including adequate quality assurance, performance standards and quality control of the laboratory-generated data;
h. ensuring proper application of prescribed sampling procedures by qualified parties, including adequate quality assurance and quality control of the collected samples;
i. supporting DFO in its notification activity related to section 3(e), and providing or making available to interested parties information on program activities;
j. implementing CFIA elements of jointly developed Management Plans for "Conditionally Approved" areas; and
k. participating in the CSSP audit program, as well as in external audits by such bodies as Health Canada and the United States Food and Drug Administration.

3. Responsibilities of DFO

DFO shall be the lead agency in the administration of the CSSP with regard to the harvesting of shellfish and shall be responsible for:

a. opening and closing shellfish areas on the basis of:
    i. classification recommendations from EC, based on the sanitary and bacteriological water quality of the shellfish areas, and agreed to by the regional Shellfish Area Classification Committees; and
    ii. recommendations from the CFIA on marine biotoxin levels, and microbiological and chemical levels in shellfish areas;
b. posting, patrolling and enforcing shellfish closures in accordance with the Fisheries Act;
c. controlling shellfish relaying operations and harvesting for depuration operations;
d. implementing DFO elements of jointly developed Management Plans for "Conditionally Approved" areas;
e. providing notification to the CFIA, EC, stakeholders and other interested parties, on locations, boundaries and timing of harvesting closures and openings;
f. maintaining records of the opening and closure of shellfish areas, as well as records of enforcement patrols, in support of reviews by external or internal auditors, and providing the CFIA and EC with annual patrol enforcement activity reports;
g. consulting with the CFIA and EC prior to the commencement of any new developmental or exploratory shellfish fisheries, and/or the issuance of any new licences or permits thereto; and

h. participating in the CSSP audit program, as well as in external audits by such bodies as Health Canada and the U.S. Food and Drug Administration.

4. Responsibilities of EC

EC shall be the lead agency in the administration of the CSSP with regard to recommending the appropriate classification of shellfish growing waters based upon the sanitary and bacteriological water quality conditions of the area, and shall be responsible for:

a. conducting comprehensive sanitary and bacteriological water quality surveys of the shellfish areas in Canada, in accordance with the CSSP Manual of Operations criteria;
b. from the surveys, determining the sources of point and non-point pollution, the degree of contamination and the extent of area contamination, and recommending the location of closure lines;
c. recommending to the regional Shellfish Area Classification Committees specific classifications of areas and their boundaries, on the basis of survey results and the classification definitions in the CSSP Manual of Operations;
d. maintaining records, data bases, sectoral maps, survey reports, central files and other documents in support of classification action and administrative reviews by internal and external auditors;
e. ensuring proper application of prescribed analytical and reporting procedures in EC laboratories, private laboratories approved in accordance with the CSSP Manual of Operations, and laboratories under contract to EC, including adequate quality assurance and quality control of the laboratory-generated data;
f. ensuring proper application of prescribed sampling procedures by qualified parties, including adequate quality assurance and quality control of the collected samples;
g. promoting pollution prevention, regulatory compliance, remediation and restoration of shellfish areas, together with federal/ provincial/ municipal agencies and other stakeholders;
h. supporting DFO in its notification activity pursuant to section 3(e), and providing or making available to interested parties information on program activities;
i. upon request, providing to DFO available information on water quality for areas proposed;
j. implementing EC elements of jointly developed Management Plans for "Conditionally Approved" areas; and
k. participating in the CSSP audit program, as well as in external audits by such bodies as Health Canada and the U.S. Food and Drug Administration.

5. Administrative Arrangements

The Assistant Deputy Ministers of DFO and EC and the Vice-President of the CFIA hereby establish the Interdepartmental Shellfish Committee to implement this MOU. The Committee shall be composed of representatives of the CFIA, DFO and EC, as designated by Directors General from both national headquarters and regions across Canada.

a) The Interdepartmental Shellfish Committee shall meet as required, but at least once a year, to:

i. discuss the CSSP and review national shellfish-related legislative, regulatory, policy and procedural issues of mutual concern, including proposed amendments to the CSSP Manual of Operations;
ii. enhance communication and co-ordination of CSSP activities;
iii. create annexes to this MOU covering specific CSSP program delivery and operational issues of mutual concern;
iv. establish sub-committees and working groups as required to deal with specific issues, and develop appropriate policies and procedures for dealing with them;

v. advise senior executive management as required about the progress and effectiveness of the CSSP, and make appropriate recommendations;
vi. receive presentations by provinces, shellfish industry and other stakeholders on matters that have impact on all parties, and provide appropriate interdepartmental/ agency response; and
vii. produce an annual report.

b) The Interdepartmental Shellfish Committee Meetings shall be chaired on a rotating basis by each party, which shall be responsible for providing secretariat services. The meeting recommendations and the annual report on program delivery will be forwarded to the Directors General of the CFIA and EC and the Assistant Deputy Minister, Fisheries Management of DFO, for review and approval.

c) The Interdepartmental Shellfish Committee shall also evaluate new integrated systems-based management/inspection approaches to the CSSP, and is committed to consulting with stakeholders on the new approaches and how such approaches may be funded.

d) Regional Shellfish Area Classification Committees shall be organized in each region of Canada where shellfish are harvested. They shall be chaired by EC, meet as required but at least once a year, and shall be composed of appropriate regional CFIA, DFO, EC and provincial government representatives. Stakeholders may participate in working groups and be observers and/or make presentations to the Committees on specific issues.

6. Implementation and Termination

a) This Agreement will come into effect on March 1, 2000.

b) The operation of the Memorandum of Understanding shall be reviewed periodically by the Parties, and may be amended at any time by mutual consent of the Parties or terminated by any Party upon (90) days' advance written notice to the other Parties.

7. Review

The President of the Canadian Food Inspection Agency, the Deputy Minister of Fisheries and Oceans Canada and the Deputy Minister of Environment Canada may meet as required to review this Agreement.

8. Signatures

signed by P.S. Chamut

Assistant Deputy Minister
Fisheries Management
Fisheries and Oceans Canada

13/04/2000
Date

signed by Jean-Pierre Gauthier

Assistant Deputy Minister
Environmental Protection Service
Environment Canada

02/05/2000
Date

signed by André Gravel

Vice-President
Programs
Canadian Food Inspection Agency

13/04/2000
Date

Appendix VI - Selected References

PDF (34 kb)

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Footnote

Footnote 13

Available from: FDA Northeast Technical Service Unit, Building S-26 North Kingstown, RI 02852.

Return to footnote 13 referrer

Appendix VII - Management of Contaminated Fisheries Regulations

PDF (32 kb)

Operational Procedures

Purpose

Over the past 20 years or more, a number of regulations have been made to control harvesting shellfish that become toxic with paralytic shellfish poisoning (PSP) in certain waters and harvesting of shellfish from waters that become so contaminated as to render certain shellfish unsafe for human consumption. These regulations are the Sanitary Control of Shellfish Regulations and parts of the New Brunswick, Nova Scotia, Prince Edward Island and Quebec Fishery Regulations and the Pacific Shellfish Regulations. These provisions in some cases are inconsistent in approach, duplicating or conflicting. Recent testing of waters into which effluent from industrial activities is deposited, notably pulp and paper mills, indicate potential problems with the presence of dioxin which may render fish other than shellfish unsafe for human consumption. Existing regulations do not allow the Department to react quickly enough to close fisheries where such problems are identified. The Management of Contaminated Fisheries Regulations authorize a Regional Director General to issue orders prohibiting harvesting of fish (fin fish, molluscs and crustaceans) from areas where any kind of contamination or toxicity is present to an extent to be of public health significance. The regulations will give the Department the ability to quickly close fisheries where toxicity or contamination reach unacceptable levels.

Sampling

Areas where it is suspected that fish may be affected by contamination should be sampled in a manner that will be representative of the species and size of fish that are normally harvested by commercial and/or

recreational harvesters. In the case of bivalve molluscs, sampling should be conducted as outlined in the Regional Sampling Plan.

Closures

a) Chemical contaminants

i. The Regions of Newfoundland, Gulf, Scotia Fundy, Pacific and coastal areas of Quebec Region, Northwest Territories and the Yukon - closures will be implemented when the fish samples exceed Health and Welfare Canada, Health Protection Branch's (HPB) contaminant guidelines or standards to such an extent that HPB feels the product is of public health concern. When the contamination is the result of a specific industrial activity which is also present in other provinces, HPB and DFO consultation at NHQ level is required, e.g., dioxin issue associated with pulp mills in B.C.
ii. Ontario, Manitoba, Saskatchewan, Alberta and fresh water areas of Quebec Region - in order that the province may take appropriate action they will be advised when fish samples exceed the HPB contaminant guideline or standard, and that the particular fish species is not acceptable for the consumer market. (There may be some specific instances where a market exists in a country whose tolerances for the particular contaminant is higher than HPB's guideline. In such cases discussions should be held with the province and with the processor of the product that has the market, to arrive at a procedure that will not jeopardize the marketing of the product in that specific country). When the contamination is the result of a specific industrial activity which is also present in other provinces, HPB and DFO consultation at NHQ level is required.

b) Sanitary closures - Mollusc harvesting areas will be closed when Environment Canada classification surveys show that the waters exceed the applicable sanitary guidelines of the National Shellfish Sanitation Program (NSSP).

c) Toxic closures - Mollusc harvesting areas will be immediately closed when the following toxin levels are encountered:

i. PSP - 80 µg/100 g
ii. Domoic Acid - 20 µg/g and rising

Openings

a) Chemical contaminants

i. The Regions of Newfoundland, Scotia Fundy, Gulf, Pacific and the coastal areas of Quebec Region, Northwest Territories and the Yukon - repeal of this type of closure will be implemented when survey samples of the specified fish contain levels less than the applicable guidelines or standards.
ii. Ontario, Manitoba, Saskatchewan, Alberta and fresh water areas of Quebec Region - in order that the province may take appropriate action, they will be advised when the fish samples are less than the HPB contaminant guideline or standard and that the particular fish species is acceptable for the consumer market.

b) Sanitary closures - repeal of this type of closure will be implemented when Environment Canada classification surveys show that the waters meet the appropriate NSSP sanitary guidelines.

c) Toxic closures - repeal of closures will be issued when three consecutive acceptable values from the same specie of mollusc, taken at the key sampling station, are obtained during a minimum period of 14 days, i.e.,:

1st sample on day 1 and the 3rd sample no earlier than day 14. Mollusc samples from any other key sampling stations in the same area must also be acceptable.

Communications

A written procedure should be developed by each region to capture the appropriate information and to establish the communication links (who does what and when for openings/closures and licences to harvest in closed areas).

a) The laboratory results and recommendation are given to the appropriate Regional Director of the Branch, designating and describing the area, the species of fish and the reason the species is affected.

b) The Regional Director of the Branch will, as appropriate:

i. complete the closure order or repeal of closure order and forward it to the Regional Director General (RDG) for his/her signature. The Regional Director will advise the other directors, area managers, and the communication officer about the closure or opening. Alternatively the order may be prepared by the Fisheries and Habitat Management Branch, Regulations Unit for review by the Director of Inspection who in turn will forward it to the RDG;
or
ii. advise the provincial counterpart of the issue (see Closures a) ii)).

c) An information copy of the signed order and the following additional information should be sent to the Chief, Scientific and Technical Programs, Inspection, Regulations and Enforcements Directorate, NHQ (fax 990-4668):

i. the type of toxin(s) and the level(s); and
ii. the names of licence holders (if any licences have been issued to permit harvesting in the closed area).

Records

Information associated with openings/closures should be recorded centrally within the region and should include:

a) Copies of Closure Orders and Repeal of Closure Orders that are numbered consecutively and indicate the region, type of closure, and year. The following designations shall be applied:

- G - Gulf, S - Scotia Fundy, N - Newfoundland, Q - Quebec, P - Pacific, C - Central and Arctic
- CH - chemical, SN - sanitary, TN - toxin
  e.g., GCH-1990-1 would mean the first closure in 1990 for chemical reasons in the Gulf region;

b) The contaminant(s) and levels;

c) Names of those persons, if any, that have been issued licences to harvest in the closed area; and

d) Copies of letters to the provincial authorities (Ontario, Manitoba, Saskatchewan, Alberta and Quebec (for fresh water areas)).

Appendix VIII - Protocol for Emergency Closure of any Shellfish Growing Area

PDF (53 kb)

CSSP control agencies must be able to react quickly to an emergency situation in order to place an affected shellfish growing area in the closed status. An emergency situation may include, but is not limited to, events such as unusual weather, flooding, and spills of oil, toxic chemicals or sewage. Emergency closures do not include those resulting from elevated biotoxin levels, nor conditionally managed areas based on the operation of wastewater treatment and collection systems.

1. CSSP control agencies will advise, as soon as possible, all members of the appropriate RISC of their action in response to an emergency situation.

2. Subject to item 3, Upon notification of an emergency event or determination that changes in environmental conditions pose a risk of contamination to shellfish, EC and/or the CFIA will provide a recommendation, including closure boundaries, to DFO to place the affected shellfish growing area in the closed status and provide the closure boundaries for that area.

3. Where pre-determined impact areas and/or standing recommendations for closure boundaries have been provided by EC and/or the CFIA, and DFO has been notified of an emergency event within the impact area, DFO will place the affected shellfish growing areas in the closed status. (Shellfish harvesters and processors will be advised of closures through established communication procedures.)

4. EC and/or the CFIA will provide a recommendation to DFO if, based on further evaluation of information, there is a need to rescind or modify the size of the closure. DFO will modify or rescind the closure accordingly.

5. The closure of the affected area will remain in place for at least 7 days. At this time, EC and/or the CFIA will evaluate the situation and advise DFO if changes in the closure status are warranted. This may be achieved through sampling of water and shellstock to test for factors relevant to the conditions in the area that led to the closure recommendation. Shellstock are sampled from sites that are representative of the harvest area and shall not:

- exceed 230 faecal coliform MPN/100g in approved areas,
- exceed 2300 faecal coliform MPN/100g in restricted areas that are harvested for depuration and/or,
- be contaminated with poisonous or deleterious substances.

The number of shellstock sites to be sampled will be determined on a case by case basis and is dependent on the size of the area and the location of shellfish resource.

6. If the emergency closure is in response to a discharge of untreated or partially-treated sewage, the affected area may be re-opened upon recommendation either:

a. after a minimum of 7 days, based on sampling of water and shellstock from representative locations within the closed area, or
b. without sampling, following a 21 day period after cessation of the last discharge event.

7. Once satisfied that the quality of the water (by EC) and shellstock (by the CFIA) are deemed to no longer pose a health risk, each agency will recommend to DFO that the area may return to the open status.

Appendix IX - Protocol for the Management of a Conditional Area

PDF (70 kb)

1. Further to results of a sanitary assessment, Environment Canada (EC) may recommend that an area be classified as conditionally approved or conditionally restricted based on either the performance of a wastewater treatment or collection system, rainfall and/or seasonal conditions.

2. If the Regional Interdepartmental Shellfish Committee adopts the recommendation that the area be classified as conditionally approved or conditionally restricted, the area will remain in the closed status of its classification until an appropriate Conditional Management Plan (CMP) is developed. The conditional classification designation shall be re-evaluated by the regional interdepartmental shellfish committee if/when a conditional management plan cannot be implemented as described in sections 2.3.3 and 2.3.5 of Chapter 2.

3. Fisheries and Oceans Canada (DFO) closes the area under the Management of Contaminated Fisheries Regulations and provides copies of the closure notice to EC and the Canadian Food Inspection Agency (CFIA).

4. Where an interest is expressed to operate a conditional area, which is not based on the operation of a wastewater treatment and/or collection system, the following procedures are to be followed:

a. A CMP shall be developed which must include:

    i. a Harvesting Plan agreed to by all affected parties, identifying who will be harvesting and the harvest boundaries (provided by proponent);
    ii. background information, rationale for classification area and map (from EC classification report);
    iii. the methods and procedures to be employed in undertaking a shellstock sampling and testing regime. This section shall also include methods of recording and reporting data, criteria for opening and closing the area, reporting and auditing procedures (developed in consultation with the CFIA);
    iv. the methods and procedures to be employed in undertaking a water quality sampling and testing regime. This section shall also include methods of recording and reporting data, criteria for opening and closing the area reporting and auditing procedures (provided by EC);
    v. identification of appropriate enforcement, surveillance and control mechanism issues which may arise from the CMP (provided by DFO).

b. The proposed CMP shall be submitted to the DFO office for evaluation (or other agency by agreement with DFO). DFO shall coordinate the development of an agreement for the CMP and send it to EC, the CFIA, (and other agencies) and affected parties for review and signatures. Responsibilities for the evaluation and administration of the CMP are as follows:

    i. EC: responsible for approval of the water quality sampling and testing procedures, approval of the water quality criteria upon which opening and closure of the area is based, approval of procedures for communicating requests to DFO for opening and closure of the area;
    ii. CFIA: responsible for approval of shellstock sampling and analysis procedures, approval of shellstock criteria upon which opening and closure of the area is based, approval of procedures for communicating requests to DFO for opening and closure of the area;
    iii. DFO: responsible for ensuring that the Harvesting Plan is enforceable and that it is consistent with the integrated fisheries management plan for that species or group of species in that area.

c. A maximum of four weeks is recommended for the return of comments. During this time representatives of the CFIA, DFO and EC will work together to evaluate all aspects of the CMP. Following this evaluation, DFO (or other agency by agreement with DFO) will respond to the proponent, to advise that the CMP has been approved by the three agencies, or that the CMP has not

been approved. If changes to the CMP are required which will facilitate approval of the CMP the proponent shall be so advised.

d. Once the CMP has been approved, the Canadian Shellfish Sanitation Program (CSSP) partners will manage the area in accordance with the CMP. In the event of non-compliance with the CMP, the shellfish area may be closed immediately. Where either EC or the CFIA identifies water quality and/or shellfish in the area as being contaminated and communicates this concern to DFO, DFO will take the appropriate action as identified in the Management of Contaminated Fisheries Regulations.

e. The Regional Interdepartmental Shellfish Committee shall review at the regional classification meeting, an annual report on the management of the area provided by DFO (or other agency by agreement with DFO), with input from EC, the CFIA and other affected parties. This report shall consist of the following:

   i. Title Page - states area (provided by DFO);
   ii. Summary Page - Describes general area, includes map, potential open period, number of closures and openings throughout the year; surveillance, enforcement and control activity - number of patrols, number of incidents or violations (provided by DFO);
   iii. Details - description of conditional opening; criteria for opening and closure; copy of agreements for the area; copy of supporting documentation from DFO, the CFIA, EC or other agency for each opening and closure.

5. Where the conditionally approved or conditionally restricted area is based on the operation of a wastewater treatment and /or collection system, DFO will lead the development of a CMP with the collaboration and contribution of all parties involved.

a. The CMP for areas impacted by the operation of wastewater treatment and/ or collection systems will include the requirements from 4 a) ii) to v) above and will further include information as per the template Footnote 14 in Annex A to this Appendix.
b. Once the CMP has been approved, CSSP partners will manage the area in accordance with the CMP. In the event of non-compliance with the CMP, the CSSP partners will determine whether the area classification or status will be changed. Where the wastewater treatment and/or collection system operator notifies Footnote 15 DFO of a release or discharge, or either EC or CFIA identifies water quality and/or shellfish in the area as being contaminated and communicates this concern to DFO, DFO will take the appropriate action as identified in the Management of Contaminated Fisheries Regulations.
c. The Regional Interdepartmental Shellfish Committee shall review, at the regional classification meeting, an annual report from each signatory to the CMP; the template for the information required for the Annual report is outlined in Appendix B of the template CMP.

Annex A

Conditional Management Plan (CMP)

Between the:

Canadian Food Inspection Agency (CFIA)
Fisheries and Oceans Canada (DFO)
Environment Canada (EC)
Insert Provincial department or Municipality/WWTP Operator (if appropriate)

For the Management of Shellfish Harvesting in Conditionally Classified Shellfish Areas Adjacent to the Wastewater Treatment Plant Located at:

Insert Name of Municipality:

Introduction

The Canadian Shellfish Sanitation Program (CSSP) is delivered by three federal institutions, Fisheries and Oceans Canada (DFO), Environment Canada (EC) and the Canadian Food Inspection Agency (CFIA). The CSSP provides reasonable assurance that molluscan shellfish are safe for consumption, thus supporting the industry and providing confidence for Canadians and export markets. This Conditional Management Plan (CMP) between CSSP federal partner institutions, provinces, municipalities/WWTP operators and First Nations (when applicable) outlines the roles and responsibilities of the signatories' in the event of a WWTP release/discharge incident.

The present CMP does not affect legal requirements existing under Federal or Provincial statutes. For greater certainty, where there occurs a deposit of a deleterious substance out of the normal course of events in water frequented by fish, or a serious and imminent danger thereof, the person that causes or contributes to the deposit (or danger thereof) has a legal obligation to report such occurrences to a Fisheries Act inspector or to any other person or authority as is prescribed by regulations under subsection 38(4) of the Fisheries Act.

Duration of the Conditional Management Plan

This CMP shall come into effect on (insert date) and expire on (insert date) and is subject to each participant signing this CMP prior to coming into force.

1. Purpose and Scope

Full cooperation is required to achieve timely detection and notification of WWTP release/discharge incidents, along with the necessary response actions to ensure continued food safety of harvested bivalves. This initiative stems from the CSSP and the requirements related to Conditional Area Management (refer to the CSSP Manual). Conditional Area Management will be supplemented by Hazard Analysis Critical Control Points (HACCP) controls implemented by registered fish processing establishments.

This CMP provides enhanced management of the bivalve molluscan shellfish harvest waters adjacent to the WWTPlocated at (insert name), as described in Section 4.

The area described in Section 4 of this CMP has been classified based upon the area hydrographical data and the performance characteristics of the WWTP. A classification map of the harvest area is provided in Appendix A.

2. Background

2.1 Conditional Management

The CSSP Manual of Operations outlines the authorities (statutes and regulations), policies, procedures and activities governing the control of shellfish growing areas, and the harvesting, processing and distribution of shellfish.

Shellfish harvest areas that are subject to intermittent microbiological contamination may be classified as Conditionally Approved or Conditionally Restricted Areas. If the conditions set out in this CMP cannot be met, the CSSP partners will determine whether the area will be reclassified as Prohibited.

2.2 WWTP description

Insert a description of the type of treatment plant and what the limits are for faecal coliform discharge in the provincial permit/licence - to be completed by EC with input from Province and Municipality/WWTP Operator).

2.3 Description of the shellfish Fisheries (including aquaculture)

Insert a brief description of the fisheries in this shellfish harvest area including the harvesting location of all shellfish resources. This may include the resource management approach and its relationship to the implementation of this agreement. **To be completed by DFO and the Province.**

3. Roles and Responsibilities

The roles and responsibilities of each signatory participant are specified in Sections 5 to 8. Additional responsibilities for the CSSP partners can be found in Appendix 5 of the CSSP Manual of Operations. The roles and responsibilities of the (insert name of provincial Department) and the Municipality/WWTP Operator of (insert name) are as follows:

The (insert name of provincial Department) is responsible for the regulation of WWTP. The (insert name of provincial department) will:

- verify through an annual audit that the municipality/WWTP Operator of (insert name) is compliant with the operating permit issued by the department, and is reporting failures as described in section 5.2 of this CMP;
- determine through a review of the annual report submitted by the municipality/WWTP Operator, whether the final effluent quality at the (insert name) WWTP is in compliance with its current operating permit, including final effluent quality;
- provide an annual report of the results of all the activities listed above in relation to this CMP to (insert Department TBD) by April 1st of the following year including recommendations for changes to this CMP if required

The municipality/WWTP Operator of (insert name) is responsible for the operation of the WWTP located at (insert location). The municipality/WWTP Operator of (insert name) will:

- provide to the (insert name of provincial Department) and EC, a written confirmation that the WWTP is functioning properly, prior to the CSSP partners allowing the harvesting of shellfish within the conditionally classified area(s) herein described. This confirmation is required at the start of a harvest season and each time the area is to be re-opened after a closure event;
- maintain up-to-date records of the operations and maintenance of the wastewater collection and/or treatment facilities as per the requirements of the Certificate of Approval to operate issued by (insert name of provincial Department);
- provide the results of routine final effluent analysis to (insert name of provincial department) and EC, as described in the operating permit issued by the province;
- provide an annual report of the results of activities listed above to the (insert name of provincial Department) and EC. Propose recommendations for changes to this CMP if any are necessary

4. Description of Conditionally Classified Area(s)

This CMP deals specifically with the harvesting of shellfish in the Conditionally Approved and/or Conditionally Restricted Area(s) described as:

(To be completed by EC)

Provide a written description of each growing area classification type, including all boundary coordinates in either latitude-longitude or Universal Transverse Mercator (UTM) zone, easting and northing. In all cases, the North American Datum (NAD) and reference chart or map name must be included.

5. Detection/Notification/Response

An effective regime for the detection, notification and response as defined in the CSSP Manual of Operations to disruptions in the normal operation of a WWTP is a prerequisite to the harvest of shellfish in the conditionally classified areas described in this CMP.

5.1 Detection

The municipality/WWTP Operator must have in place and maintain a detection system by which untreated or un-disinfected sewage discharges (at the WWTP or lift stations) are noticed in a timely manner, therefore allowing corrective actions to be initiated without delay.

The conditional area described in Section 4 of this CMP may be closed to the harvesting of molluscan shellfish in response to any event or disruption that results in untreated sewage or sewage with insufficient or inadequate disinfection being released from the WWTP to, or adjacent to the area. The municipality/WWTP must be able to detect such discharges, which include, but are not limited to, the following, and to make the appropriate notifications:

- sewage that receives insufficient or inadequate treatment;
- sewage that receives insufficient or inadequate disinfection;
- sewage that receives no disinfection;
- sewage that bypasses the WWTP (including planned releases); or
- any disruptions that result in a discharge of sewage that cannot reasonably be expected to meet performance standards or values permitted by provincial regulators

The municipality/WWTP operator can provide additional definitions of release/discharge incident if it has the capacity to detect and properly measure the nature and extent of the event threshold which has been pre-determined to impact the growing area.

Event or disruption detection systems in place include the following: (Insert information on the WWTP pertaining to the release/discharge incident detection systems in place.) (To be completed by Province and EC.)

5.1.1 The positions responsible for monitoring release/discharge incident detection.

5.1.2 Description of the normal operating conditions (performance standards or values permitted by provincial regulators).

5.1.3 Description of the types of release/discharge incident scenarios that are reasonably likely to occur (lack of disinfection, bypass, power failure, overflow of lift stations that could impact the area, presence of a hazardous substance such as oil or gas, others).

5.1.4 Description of how each of the release/discharge incident types noted above are detected (SCADA, visual, others).

5.1.5 Time lines for detection of each release/discharge incident type, in hours, taking into account best and worst case scenarios (during and after working hours including weekends).

5.2 Notification

Any event or disruption described in 5.1 requires a notification of a Discharge of Wastewater Notice (Appendix C) be created and distributed by the WWTP operator.

Notification of WWTP release/discharge incident is as follows:

1. Immediately notify EC/DFO/CFIA when release/discharge incidents are detected as per section 5.1.

   Note: a notification under the current CMP does not replace or otherwise affect reporting to be done to a Fisheries Act inspector or to any other person or authority as is prescribed by regulations pursuant to subsection 38(4) of the Fisheries Act when there occurs a deposit of a deleterious substance out of the normal course of events in water frequented by fish, or a serious and imminent danger thereof.

2. E-mail and/or fax every representative listed on the Discharge of Wastewater Notice (Appendix C), of any planned or unplanned changes in operations of the municipality/WWTP Operator's WWTP (e.g. untreated sewage discharge, proposed maintenance work, etc.) which are likely to alter the normal effluent loading or location of discharge in or in proximity of the conditionally classified area(s) herein described.

3. Advise in writing (by email or fax) each representative of EC, the CFIA and DFO listed in the Discharge of Wastewater Notice when the sewage release has been terminated,

(This section will identify how and when the WWTP operator will notify DFO and other parties when monitoring detects a release/discharge incident condition. Insert the following info):

5.2.1 The positions responsible for approving and providing notification.

5.2.2 Description of how notification is provided all CSSP partners and other parties (phone/fax/email).

5.2.3 Description of the timelines for providing notification to CSSP partners in hours, taking into account all reasonable delays (e.g. during and after working hours, including weekends and holidays).

5.2.4 Contact information of the parties to be notified of closures during and after working hours, including weekends, as provided by the province, EC, and the CFIA.

5.3 Response

Upon receiving notification as outlined in section 5.2, each department/agency will respond as per respective authority.

- The regional office of DFO receiving notification of a discharge incident by the WWTP operator is to treat such a notification in the same manner as a formal recommendation for closure made by EC.
- Upon notification under section 5.2, DFO will set in motion an internal process which may result in the affected area being closed to harvesting. Where the notification provides the DFO Regional Director General with reasons to believe that fish of any species in any area are contaminated, he/she may issue an order prohibiting fishing in that area for that species.
- The CFIA will notify CFIA registered shellfish processing establishments in writing (email/fax) that the conditionally classified areas have been closed or are about to be closed to harvesting.

Response procedures are as follows:

Identify how and when measures will be taken to stop harvest, product distribution and to close the area once notification has been received. Insert the following information:

DFO will communicate to the parties herein (including First Nations and general public as appropriate) the issuance of a prohibition order and notice of the order will be published to inform harvesters to cease harvesting immediately in the area subject to the order.

5.3.1 Description of how affected stakeholders and First Nations are notified.

5.3.2 Contact information of the parties to be notified of closures during and after working hours, including weekends, as provided by the province, EC, and the CFIA.

6. Re-opening Criteria

The harvest areas described in this document will remain closed to harvesting until the re-opening criteria are met. After each release/discharge incident event, EC will determine if the size of the closure should be modified and make appropriate recommendations to DFO.

Areas will be returned to their classification status when conditions outlined in Chapter 2 of the CSSP Manual of Operations have been met.

The sampling methodology must comply with the established procedures outlined in Appendix 1 of the CSSP Manual of Operations and the Sampling Policy and Procedures found in the CFIA's Fish Products Standards and Methods Manual. The sample locations are identified on a map in Appendix A.

The samples must be analysed at CSSP - recognized laboratories.

In addition to the conditions above, describe the arrangement reached between the signatories to this CMP as to the process and responsibilities for collecting samples, sample locations, and where they are analyzed.

7. Annual Reporting

All signatories to this plan will provide input into an annual report on the management of the area as outlined in Appendix IX of the CSSP. The report will then be provided to the Regional Interdepartmental Shellfish Committee (RISC) for its review. This report shall include, as a minimum, the information outlined in Appendix B.

Insert the procedures to be followed at the local level in order to fill in report.

8. Amendment and Termination

If at any time any party to the Conditional Management Plan fails to fulfill the requirements as set forth in the Plan, the RISC will determine whether the area classification or status will be changed.

This CMP may be amended at any time subject to the written approval of all the parties.

9. Appendices

The Appendices herein form part of this CMP.

- Appendix A - Classification Map (including verification shellstock and water sampling locations)
- Appendix B - Example of Information for annual report
- Appendix C - Discharge of Wastewater Release/discharge incident Notice

- Appendix D - Example contact list

Approved at (insert city), this (insert date) day of (insert month). 200.

_____
Regional Director
Fisheries and Aquaculture Management
Fisheries and Oceans Canada

_____
Executive Director
Canadian Food Inspection Agency

_____
Director
Water Quality Monitoring
Environment Canada

_____
Province (insert title)

_____
Municipality/Waste Water Treatment Plant (insert title)

Appendix A - Insert classification map, to be provided by EC

The response line identified on the classification area map in Appendix A is relevant only for CFIA registered fish processing establishments. Further guidance of how registered fish processing establishments maintain control of shellfish harvested from areas situated between the prohibited area and the response line is contained in the CFIApolicy documents found in Bulletin 25 of the CFIA Fish, Seafood and Production Division's Facilities Inspection Manual.

Appendix B - Sample Annual Report

Name of Area
Conditional Shellfish Area Annual Report for (insert year)

Area

- Description/location with boundaries
- Map (with classification and sampling sites for water quality and shellstock)
- Closure criteria
- Potential time period for opening (if applicable)
- Species managed and harvesting restrictions/season (if applicable)

Summary of Activities

- Number of openings/closures during the year
- Prohibition order numbers and dates
- Supporting documentation used to make decision about closing Notices from WWTP Operator (Event, dates, duration)

- Supporting documentation used to make decision about opening Water and shellstock microbiological data to re-open the area (dates, results)
- Surveillance, enforcement, control activities: number of patrols, number of incidents, violations

Copy of Management Plan

- Attached

Report from Province

- Assessment that final effluent quality is in compliance with permit/licence

Report from Municipality/WWTP Operator

- Summary report of discharges and notifications

Concerns/ Recommendations (all signatories)

Appendix C

From: _____

Discharge of Wastewater Notice

To:	Representatives	E-mail completed notice to:	Direct call
Environment Canada			Direct call: 1st alternate: 2nd alternate:
CFIA			Direct call: 1st alternate: 2nd alternate:
DFO			Direct call: 1st alternate:

Discharge of Wastewater Notice

To:	Representatives	E-mail completed notice to:	Direct call
			2nd alternate:
(Provincial Environment)			Direct call: alternate:

Note: After office hours Monday to Friday or on weekends report emergency discharge by phone to Canadian Coast Guard at 1-800-565-1633 and e-mail this completed notice to all persons named above.

This is to notify your department of the following event:

- planned
- Treated wastewater
- in progress
- Untreated wastewater
- past event

Sample analysis required for planned discharge

Sample Date	BOD_5 (mg/L)	SS (mg/L)	Faecal (MPN/100 mL)

Name/Owner/Operator: _____

Location: _____ Map attached: _____

Receiving water: _____

Date / Duration of event: _____

Reason for discharge: _____

Period of discharge hrs: _____ Estimated low rate (unis): _____

Estimated BOD_5 - mg/L: _____ Estimated SS - mg/L: _____

Estimated faecal coliform MPN/100 mL: _____ Total Discharge: _____

All measurements are estimates only

Comments: _____

Sent By e-mail - Date: _____ By: _____

Phone: _____ Position: _____

Appendix D

Contact List

Department/Agency	Name	Position	Address	Telephone/Fax
Fisheries and Oceans Canada				
Canadian Food Inspection Agency				
Environment Canada				
(Provincial Environment)				
(Municipality/WWTP Operator)				

After Hours, Weekends and Holidays

Canadian Coast Guard - 1-800-565-1633

Footnotes

Footnote 14

The template is meant to be a guidance document for CMP; final versions may vary due to regional differences.

Return to footnote 14 referrer

Footnote 15

A notification under the current CMP does not replace or otherwise affect reporting to be done to a Fisheries Act inspector or to any other person or authority as is prescribed by regulations pursuant to subsection 38(4) of the Fisheries Act when there occurs a deposit of a deleterious substance out of the normal course of events in water frequented by fish, or a serious and imminent danger thereof.

Return to footnote 15 referrer

Appendix X - Protocol for CSSP Manual Amendments

PDF (16 kb)

This protocol outlines the procedure that manual amendments must follow; it builds on the interim Interdepartmental Shellfish Committee (ISC) terms of reference for roles, responsibilities, and time lines on decision-making. The Protocol works under two assumptions:

i. that new and revised CSSP policies/amendments must be channeled through the ISC and should be recorded in the Manual; and
ii. that those drafting the amendments have considered stakeholder input, if required.

All documents/information shall be simultaneously available in both official languages.

1. The sponsoring agency (Headquarters level) will circulate the proposed amendment to the other two CSSP agencies (Headquarters level) and to the Chairs of the Regional Interdepartmental Shellfish Committees (RISC) for review. Feedback should be provided within a period of four weeks of receiving the information. Should the reviewers need extra time to provide feedback, a written request should be sent to the sponsoring agency indicating the estimated time extension required.

2. Depending on the nature of the feedback received, the sponsoring agency may:

a. send a revised final draft to the ISC Chair, who will table the amendment at the next meeting/teleconference for discussion and final recommendation to the CSSP Directors General (DGs) Committee; or
b. revise or withdraw the amendment. If the sponsor chooses to revise, a new draft should be distributed for feedback. The other federal CSSP partners should provide feedback within 2 weeks of having received the revisions. Should the reviewers need extra time to provide feedback, a written request should be sent to the sponsoring agency indicating the estimated time extension required.

The sponsoring agency will then incorporate the comments/suggestions into a final document in both official languages and forward it to the ISC Chair, who will table the amendment at the next meeting/teleconference for discussion and final recommendation to the CSSP DGs Committee.

3. As per the ISC process, the Chair will communicate the recommendations to the CSSP DGs Committee and will follow up for a timely response.

4. The Chair will advise the ISC members of the CSSP DGs Committee decision. If the amendment recommendation is approved, the Chair will forward it to the CFIA for inclusion in the CSSP Manual.

Appendix XI - Protocol for Shellfish Brokers and Licensed Fish Importers Reshipping to and Within United States

PDF (56 kb)

1. Scope

This protocol outlines the policies and procedures governing the inspection and designation of parties, other than federally registered shellfish processors, who take ownership of live or raw bivalve shellfish products from facilities listed on the Interstate Certified Shellfish Shippers List (ICSSL) and transport them to, from and within the United States (U.S.) without any further processing.

Shellfish brokers or licensed fish importers that carry shellfish to the U.S. may bring back molluscs to Canada with their own transport vehicle; however, in order to do this, they need to be listed on the ICSSL and develop a Shellfish Shipment Control Program (SSCP). As the parties described in the above paragraph do not operate processing facilities subject to federal registration, this protocol provides a mechanism for implementing controls that would allow such parties to be recommended by CFIA for listing to the ICSSL as a Canadian "Reshipper".

Reshippers (RS) are defined as those who purchase shucked shellfish or shellstock from other certified shippers and sell the product without repacking or relabelling to other certified shippers, wholesalers, or retailers. As these reshippers are non-registered establishments, the operation fee for processing shellfish does not apply. As per the definition, the reshipper only reships processed and packaged product from an ICSSL plant therefore they are not required to protect their water against backflow and back siphonage.

This protocol does not apply to federally licensed importers utilizing common carriers to move shellfish from the U.S. to Canada.

This protocol is consistent with the controls and requirements as specified in the Canadian Shellfish Sanitation Program (CSSP) and the appropriate sections of the U.S. National Shellfish Sanitation Program Model Ordinance.

2. Authority and Reference Documents

Fish Inspection Act, R.S.C., 1970, c. F-12; Section 6
Fish Inspection Regulations, C.R.C., 1978, c. 802; (FIR)

Canadian Shellfish Sanitation Program - Manual of Operations
Facilities Inspection Manual
Canada - United States Bilateral Agreement on Shellfish Regarding Sanitary Practices in the Shellfish Industries and Related Matters
National Shellfish Sanitation Program, Model Ordinance (specifically Chapters X and XIV)

3. Policy

3.1 Shellfish brokers and licensed importers involved in shipping live or raw bivalve molluscs to, from and within the U.S., as defined above, will be assessed by the CFIA and recommended for an RS listing on the ICSSL when the following conditions have been met:

- the shellfish being transported have been processed in:
    a. a federally registered Canadian shellfish processing plant listed on the ICSSL or
    b. a shellfish processing plant listed on the ICSSL,
- the shellfish are identified with a tag as outlined in the Canadian Shellfish Sanitation Program Manual of Operations (or the U.S. Shellfish Model Ordinance for product originating from or destined to the U.S.),
- the shellfish are placed under temperature control until sale to the processor or final consumer,
- the shellfish shipments comply with all relevant requirements as contained in the Canadian Shellfish Sanitation Program Manual of Operations (or the U.S. Shellfish Model Ordinance for product originating from or destined to the U.S.) and,
- the requirements of this protocol have been implemented.

3.2 Shellfish brokers and licensed importers must develop and implement a Shellfish Shipment Control Program (SSCP). This SSCP must be submitted for review by the CFIA to verify that it meets the requirements of the protocol as detailed below.

3.3 Once the CFIA has determined that the SSCP meets the requirements of the protocol, a CFIA Inspector may conduct a review of any aspect of the SSCP at any time.

3.4 The CFIA may cancel the eligibility of a participant under this protocol at any time if the company does not meet the conditions outlined in the protocol.

4. Procedures

4.1 The SSCP submitted to the CFIA for review should document the procedures and controls in place for shellfish transport, and must include the following components:

a. background information, including company name, location, telephone number, primary contact, type of vehicle to be used to transport product, type of product to be shipped and any additional information related to the shipment of bivalve molluscs;
b. record-keeping procedures and formats which track all shellfish shipments to, from and within the United States. The requirement for comprehensive records is necessary in order to facilitate recalls and follow-up on reports of illness when required and should, at a minimum, include:
    i. species;
    ii. form (e.g., live, shucked, IQF);
    iii. source plant (including ICSSL registration number);
    iv. quantity;
    v. harvest date and location or production code;
    vi. consignee; and
    vii. transport information.

    All records must be retained by the reshipper for three years, or for a period of time that exceeds the shelf-life of the product if that is longer than three years. Copies of the forms to be used should be included in the submission (see example in Annex B).

c. control measures to ensure the safe, sanitary transport of the product. This must include, as a minimum, controls for maintaining, cleaning, sanitizing and inspecting the storage area of the transport vehicle, temperature controls, and the monitoring and record keeping associated with these activities.
d. the procedure for notifying the CFIA when a shipment is rejected or denied over a border by a regulatory authority.
e. the names of personnel responsible for the development and implementation of the SSCP.
f. a company representative's signature providing commitment to meeting the conditions of the protocol (see example in Annex A).

4.2 Instances of non-compliance may result in the broker/dealer being declared ineligible for this program. Recommendations for ineligibility will be forwarded to the Regional Director or designate for review and action. Ineligibility will result in removal of the company from the ICSSL.

Annex A
Company Declaration

I, the undersigned, hereby agree to the requirements of this protocol and will maintain the necessary controls and records to ensure compliance.

Company Name:

Company Official:

Name: (please print)

Title:

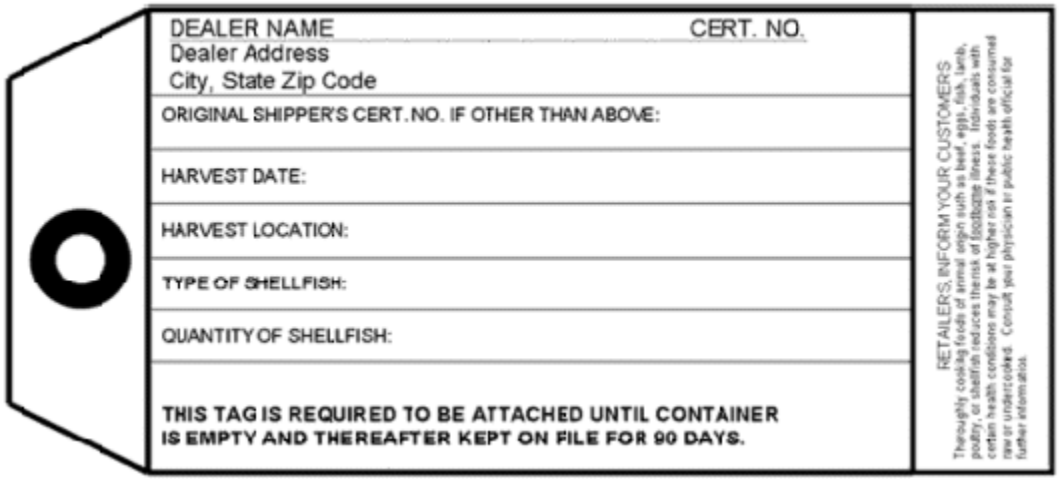
Date:

Signature:

Annex B
Examples

Labelling Example

This tag is an example of a dealer's tag with the minimum required NSSP information in the required order. Dealer means a person to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.



Description for United States shellfish dealer's shipping tag

Shellfish Shipment Control Program (SSCP) Ledger Example

Transport Info	Consignee	Processor / ICSSL No.	Harvest Location	Harvest date / Code	Packing Info	Qt
Yarmouth Transport Ltd. reefer truck	Caveat Emptor Seafood	XYZ Shellfish Co. Shellburne, NS NS 345 SS	NS 15, Okeover Inlet 15-4	Mar.1/03	6 sacks x 50 lb	30

Shellfish Shipment Control Program (SSCP) Ledger Example

Transport Info	Consignee	Processor / ICSSL No.	Harvest Location	Harvest date / Code	Packing Info	Qt
	Restaurant Buffalo, NY					
Alaska Airlines flight 789	Shangri-La Casino Las Vegas, NV	Hank's Prairie Oysters, Fort St. John, BC BC 1945 SP	BC 6.3, Harley Bay	Best before Mar.20/03	5 cs. x 20 x 8 oz.	50
Air Canada flight 2345	Honest Nat's Discount Seafood Boston, MA	Hank's Prairie Oysters, Fort St. John, BC BC 1945 SP	BC 6.1, Kitimat Arm	Best before Mar.20/03	10 cs. x 20 x 8 oz.	10
Silverdale Transport Ltd. freezer	The Fish Store at Pike Street Seattle, WA	Tofino Oyster Co. Tofino, BC BC 234 SP	BC 24.9, Lemmen's Inlet 24-9	Feb.28/03	10 cs. x 2 x 10 kg	20

Appendix XII - Procedure for Development, Approval and Review of an Integrated Multi-trophic Aquaculture Management Plan

PDF (24 kb)

1. Before integrated multi-trophic aquaculture commences, the proponent is required to have a documented agreement with the authority responsible for land tenure and/or licensing aquaculture activities for the exploitation of the species grown on the site, and confirmation from Environment Canada that they have surveyed and classified the surrounding waters.
2. The proponent will develop an Integrated Multi-Trophic Aquaculture Plan (IMTAMP) that shall include:
    a. location and dimensions of the tenure, including the specific location of the finfish net pens and of the shellstock products under culture, as well as any living accommodations at the site. If there is floating living accommodation on the site, shellstock products must not be located within 125 metres of living accommodation structures unless an approved zero-discharge waste management plan is in place (see Chapter 2);
    b. details of the species to be cultivated and harvested;

c. a process flow diagram which outlines all production steps at the aquaculture site in relation to all species to be cultivated and harvested;
d. a detailed hazard analysis for all steps identified in iii) above which identifies critical control points (CPP) at the tenured site pertaining to bivalve molluscs. The resulting site-specific on-farm HACCP plan will include, for each CCP, the control measures, monitoring and verification activities and record keeping of the bivalve molluscs grown on site. The HACCP plan must also include the appropriate sampling plan for monitoring water and/or shellstock product for toxins, pathogens, drugs, and chemical contaminants identified as potential waterborne sources of contamination: this should include methods for sampling, recording and reporting data. The action levels, tolerances and other values for poisonous or deleterious substances in seafood can be found in Appendix II;
e. controls for sanitation and pests;
f. a verification/audit system to ensure compliance to the management plan;
g. a clear description of the responsibilities/duties of involved parties;
h. a statement that all shellfish products destined for interprovincial or international trade be processed in a federally registered fish processing establishment as per the Fish Inspection Regulations.

3. The Canadian Food Inspection Agency (CFIA) will review the food safety component of the IMTAMP and data collected on-site for validation purposes or during the monitoring of toxins, chemicals, drugs, and/or microbiological contamination.
4. When documentation from both the aquaculture licensing authorities and the CFIA shows no objection to the project, the proponent will consult with Environment Canada (EC) to ensure a sampling regime can be implemented to maintain growing water classification of the defined area.
5. The proponent shall obtain written documentation from Fisheries and Oceans Canada (DFO) stating that all appropriate harvest licenses and/or orders, if required, to allow harvesting from the site where shellfish are being cultured, would be granted once the IMTAMP has been accepted.
6. The proponent will submit the IMTAMP for approval to the Regional Interdepartmental Shellfish Committee (RISC), with written documentation from DFO, EC, and the CFIA in support of the proposal.
7. The RISC will consider the information on the IMTAMP and the recommendations by DFO, EC and the CFIA and, where appropriate, will adopt the proposal that the area be:
    a. reclassified from prohibited to closed (depuration or relay permitted), or;
    b. approved for harvest upon acceptance of the implementation of the IMTAMP and the review of shellfish area assessments and shellfish data.
8. DFO will revise prohibition and/or variation order and, if required, will authorize the proponent to harvest bivalve molluscs in the newly classified area.
9. The CFIA will verify that any federally registered bivalve molluscs processing establishment receiving bivalve molluscs grown under an IMTAMP has amended its Quality Management Program (QMP) plan to address the potential hazards of Integrated Multi-Trophic Aquaculture. This may be done under a Supplier Quality Assurance (SQA) with the site operator or with a CCP at receipt of bivalve molluscs.
10. The proponent, with appropriate input from the federal, provincial or local authorities, shall submit an annual report documenting all data (as mentioned in section 2 iv) relating to the operation of the IMTAMP pertaining to bivalve molluscs. An annual audit shall be performed by an acceptable third party and a written audit report shall be submitted to the chair of the RISC.
11. The RISC shall review the proponent's annual report and the audit report. The RISC will determine if the IMTAMPis in compliance and if the proponent can continue with the operation of the Integrated Multi-Trophic Aquaculture site.
12. The RISC shall advise the aquaculture licence authority and DFO where the IMTAMP is not in compliance, and where closure of an Integrated Multi-Tropic Aquaculture site is recommended.

Appendix XIII - Procedure for Classification of New Shellfish Harvesting Areas

PDF (16 kb)

1) Proposals for classification of new shellfish harvest areas are to be submitted in writing by the proponent to the chairperson of the RISC. The proposal must include (but is not limited to):

a. a detailed description of the proposed harvest area with a map and precise graphics GPS coordinates;
b. intended use (wild harvest, aquaculture, Food, Social and Ceremonial (FSC), recreational, etc.) and benefits of having this area classified;
c. an indication of the resource availability in the area - species, amount per square metre, etc.;
d. accessibility of area for delivery of CSSP activities;
e. any other items requested by RISC for assessment purposes.

2) Following a review by the RISC, a decision will be made to:

a. Accept the proposal and direct CSSP authorities to proceed with the classification of the proposed area. EC, DFOand the CFIA will identify the work required by each respective department/agency and the conditions under which the classification work may be conducted (such as cost or in-kind suport borne by the proponent, timless, etc.), or
b. reject the proposal and notify the proponent, in writing, of the decision and the reason for the decision, or
c. defer a decision pending a request for further information from the proponent.

3) Once the proposal is accepted and EC, DFO and the CFIA have carried out their respective responsibilities for area classification, a recommendation is submitted to the RISC for a final decision.

Appendix XIV - Policy on the Use of Non-Government of Canada Samplers for the Canadian Shellfish Sanitation Program

PDF (111 kb)

1. Introduction

The Canadian Shellfish Sanitation Program (CSSP) is delivered by Fisheries and Oceans Canada (DFO), Environment and Climate Change Canada (ECCC) and the Canadian Food Inspection Agency (CFIA). ECCC and CFIA conduct testing of shellfish growing area marine waters and shellstock, respectively, for compliance with Canadian standards. The CSSP Manual of Operations describes how samples are collected by government (CSSP-mandated) employees in order to be acceptable to CSSP requirements and quality assurance programs. However, under certain circumstances, it is preferable that sampling be conducted by non-Government of Canada (GoC) samplers. Upon request by CFIA or ECCC, a sampling arrangement (agreement or contract) may be established between ECCC or CFIA and a non-GoCparty to support delivery of the CSSP. Non-GoC parties are advised that other policies (e.g. CSSP Appendix XIII – Procedures for Classification of New Shellfish Harvesting Areas) are taken into account when a decision is made on the establishment of a non-GoC sampling arrangement. The CSSP partners reserve the right to limit the number of non-GoC sampling arrangements on a regional or national basis.

2. Objective

The goal of this policy is to establish minimum criteria to enable the CSSP partners to enter into non-GoC sampling arrangements. Samples taken under such arrangements are deemed appropriate to be used by the shellfish control authority (SCA) to make a regulatory decision on the status of a shellfish growing area.

3. Scope

This policy applies to all marine water and shellstock sampling conducted by non-GoC samplers for submission to a CSSP laboratory. When sampling is conducted as described by the policy, the CSSP laboratory (Government or other) will deem the samples as acceptable for analysis.

Occasions when this policy may be applied include (but not limited to):

- routine sampling for monitoring programs (e.g. water quality, biotoxin);
- sampling to support revoking closures in conditional areas;
- sampling to support revoking closures in areas closed under appendix III (Procedures for Molluscs Exceeding CFIA Bacteriological Guidelines) or appendix VIII (Emergency Closures); and
- special sampling projects (e.g. scientific research, WWTP studies, sampling related to remediation work, new classification, or classification changes)

4. Policy Statement

The objective of the CSSP is to provide reasonable assurance that bivalve molluscs are safe for consumption through various means including the collection of marine growing waters and shellstock for laboratory testing of various parameters. The CSSP is committed to developing a policy whereby other parties (non-GoC) are able to collect and submit samples to a CSSP laboratory while meeting the requirements of the CSSP.

5. Policy Requirements

5.1 In order to ensure that sampling is conducted as per the CSSP, a formal arrangement must be completed between the applicable department and the sampler. The arrangement must stipulate the purpose, contributions to be made by each party, duties to be conducted by each party, terms and conditions, arrangements for initial and ongoing training, signatures from each party representative, a work plan and sampling schedule, sampling procedures (or a reference to existing ones), a reference to applicable provincial or federal Occupational Health and Safety (OHS) and any applicable Transport Canada vessel requirements. The arrangement will include an audit component to ensure that the samples are collected as per the sampling procedures found within.

5.2 Individual samplers will be deemed CSSP recognized (i.e. added to list of approved CSSP samplers) if they have completed a signed agreement, completed all prescribed training, and possess all applicable certifications and licenses. The list of prescribed training, certifications, and licenses will be provided by ECCC and/or CFIA to the interested parties.

5.3 The responsibility for recognition of non GoC samplers including arrangement development, training, and evaluation will be that of the individual department or agency. Such arrangements must be consistent with existing policies (e.g.CFIA Alternative Service Delivery, ECCC Third Party Safety Guide) in effect within each department/agency.