Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Environment Canada | Environnement Canada

Fisheries and Oceans | Pêches et Océans

CANADIAN SHELLFISH SANITATION PROGRAM

Manual of Operations

Canada

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), the Department of Fisheries and Oceans (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 CSSP and 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. 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.

Enquiries concerning processing and distribution should be directed to:

Senior Policy Analyst - CSSP
Canadian Food Inspection Agency
59 Camelot Drive
Nepean, Ontario
K1A 0Y9

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

Director, Marine Environment Branch
Environmental Protection Service
Environment Canada
351 St. Joseph Blvd.
Ottawa, ON
K1A 0H3

Enquiries concerning patrolling and harvesting should be directed to:

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

This manual is available to the fish processing industry and other interested parties upon request.

TO: All Holders of the Canadian Shellfish Sanitation Program Manual.

SUBJECT: REQUIREMENTS FOR CLASSIFICATION SURVEYS FOR "DEEPWATER" AND "OFFSHORE" SHELLFISH HARVESTING LOCATIONS

There are numerous "deepwater" (ie. below extreme low-tide level) and "offshore" locations where shellfish may be harvested. Because of their unique location there are times when full growing-area overlay-water surveys would be required and others where it would not be necessary. The following are some examples:

Area is Approved - No Survey Required

1. When the harvest area falls between two approved growing areas (eg. mainland and an island) and when no additional sources of pollution would impact on the area.

2. When the harvest area is seaward of an approved growing area and when no additional sources of pollution would impact on the area. Occasional bacteriological testing of harvested shellfish would be required at the plant level.

Full Growing-Area Classification Survey Required

3. When the harvest area falls between an approved growing area and a restricted or closed area.

4. When the harvest area is impacted by sources of pollution such as offshore or deepwater effluent pipes.

5. When the harvest area is immediately seaward of a restricted or closed growing area (i.e. adjacent to the outer boundary of the closure).

6. In situations where the deepwater or offshore area does not meet the examples described above the regional shellfish classification committee will decide, on a case by case basis, whether a full growing area survey would be required.

B.J. Emberley
Director General
Inspection Directorate

INTRODUCTION

The Canadian Shellfish Sanitation Program (CSSP) has been developed over the years as a direct result and response to an outbreak of typhoid fever in the United States during the winter of 1924-25. This outbreak involved 1500 cases and 150 deaths and was traced to consumption of contaminated oysters. Canada's concern for its consumers resulted in regulations under the Fish Inspection Act being passed on July 3, 1925 requiring that imported oysters be accompanied by a certificate to show that they were a "safe food product". The States of New York and Massachusetts also extended requirements for certification to all shipments consigned to their markets. The mutual concerns of Canada and the United States to protect the public from the consumption of contaminated bivalve molluscs led to a formal shellfish agreement on April 30, 1948 dealing with sanitary practices prevailing in the shellfish industries of both countries.

Initially, the Department of National Health and Welfare was the designated Canadian agency for administration of the 1948 Memorandum of Agreement between the United States and Canada, and was specifically responsible for: a) paralytic shellfish poison (PSP) bioassays and recommendations for closures; b) certification of the British Columbia Shellfish Program; c) issuance of plant certificates; and d) surveys of shellfish growing areas in the Atlantic Provinces and Quebec. The Department of Fisheries was responsible for: a) the inspection of plants and products; b) management of paralytic shellfish poison control programs in the Atlantic provinces and British Columbia, including the collection of shellfish samples, preparation of shellfish extracts for bioassay and advice to industry and the general public on the hazards; c) inspection of United States imports; d) patrol of closed areas to enforce contamination and PSP closures; e) preparation and promulgation of shellfish closure regulations; and f) land surveys for the installation of shellfish area closure boundary markers.

In 1971, as a result of a reorganization among various government departments, a reassignment of shellfish control responsibilities occurred. Environment Canada (formerly Department of Fisheries and Forestry) assumed operational responsibility for the entire shellfish sanitation program except for the bioassay portion of PSP control which continued to be the responsibility of Health and Welfare Canada. Environment Canada (Fisheries Service) was designated the Canadian agency responsible for honouring the 1948 Canada/U.S. Shellfish Agreement. In addition, Environment Canada assumed the administrative and operational responsibilities for the sanitary control of shellfish growing areas and the harvesting and processing of shellfish in British Columbia.

Environment Canada subsequently became Fisheries and Environment Canada and then a further reorganization in 1979 resulted in the formation of separate departments, Fisheries and Oceans (DFO) and Environment Canada. Shellfish control responsibilities were assigned to DFO except for those related to water quality in, and classification of, shellfish growing areas. These latter functions became the responsibility of the newly reorganized Department of the Environment. Health and Welfare Canada's responsibility for the bioassay portion of the paralytic shellfish poison control was incorporated with the responsibilities of DFO in 1988 to further improve necessary closure response times.

The purpose of the Canadian Shellfish Sanitation Program, Manual of Operations is to provide Departmental staff with the policies and procedures to be employed when applying the Fisheries Act, Fish Inspection Act and related regulations governing the control of shellfish growing areas, and the harvesting, processing and distribution of shellfish. It will contribute to uniformity of interpretation and consistency in the application of policies and regulations.

This manual is not intended to be all inclusive. It is to be used in conjunction with other appropriate source materials to provide the interpretation tools required by Departmental officials, inspectors and fishery officers who have enforcement responsibilities under the program. It is meant to be a reference source and not a training manual.

This manual does not contain chemical methods, organoleptic standards for shellfish products or the policies and procedures governing facility inspections. These topics are addressed in other Fisheries and Oceans publications (see DFO 1984, 1986, 1987, 1988, and 1990 in Appendix VI).

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 temporarily be made a closed area 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 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.

Closed Area - A growing area where the harvesting of shellfish is temporarily or permanently not permitted, except by special permit for specific purposes.

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.

Conditionally Approved Area - The classification of a shellfish growing area 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 management plan. A conditionally approved shellfish growing area is a closed area when the area does not meet the approved growing area criteria and is temporarily closed by the shellfish control authority.

Container - any bag, sack, tote, conveyance or other receptacle used for containing shellfish for holding or transporting.

Container Relaying - The transfer of shellfish from closed 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.

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 or closed growing areas and submits such shellstock to an approved controlled purification process.

Dry Storage - The storage of shellstock out of water.

Emergency Closure - An approved shellfish harvesting area may be closed when it is suspected that shellfish may be contaminated as a result of an emergency situation which is not predictable nor controllable under a routine monitoring program. 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 - transfer of shellfish from closed 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 facility 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.

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 permits issued to an individual, group or company by the Competent Authority.

LEO (Lab Evaluation Officer) - A laboratory manager standardised to evaluate laboratories wishing to analyse shellfish or water samples in support of the CSSP.

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.

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

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 & 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 - transfer of shellfish from closed areas to approved areas for natural biological cleansing, using the ambient environment as a treatment system (Houser, 1964) for periods of 14 days or greater.

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 - Distinct areas or areas within closed growing areas that are prohibited to shellfish harvesting for **any** purposes.

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.

Relaying - The transfer of shellfish from closed areas to approved areas for natural biological cleansing using the ambient environment as a treatment system (Houser 1964).

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.

Restricted for Controlled Purification - the median or geometric mean faecal coliform MPN of water does not exceed 88/100 mL and not more than 10% of the samples exceed a faecal coliform MPN of 260/100 mL, for a five-tube decimal dilution test.

Restricted for Relaying - areas within closed areas in which the median 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. These areas must not be within a prohibited area.

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.

Scheduled Controlled Purification Process - A process which places shellfish harvested from closed or approved waters into a controlled aquatic environment selected by the processor and approved by the shellfish control agency as adequate to effectively reduce the level of bacteria and viruses in live shellfish.

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 - Any submarket size bivalve shellfish that has been gathered 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* 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.

* Except for the adductor muscle

Shellstock - Shellfish in the shell.

Shellfish Control Agency - 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 and that have the responsibility to provide reasonable assurance that shellfish are safe for human consumption.

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 - transfer of shellfish from closed 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.

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 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.

CHAPTER 1

ADMINISTRATION

1.1 Administrative Responsibilities and Procedures

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

a) Canadian Food Inspection Agency

The CFIA is responsible for the control of handling, storage, transportation, processing and labelling of shellfish including imports (Fish Inspection Act and Regulations); the Marine Biotoxins Control Program (Fisheries Act and Regulations); and is the designated contact point for exchanges of information with the Division of Shellfish Sanitation, Bureau of Foods, Food and Drug Administration, Department of Health, Education and Welfare, Washington, DC, on matters covered by the Memorandum of Agreement of April 30, 1948.

b) Environment Canada

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

c) Department of Fisheries and Oceans

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

Program coordination is achieved through periodic

Interdepartmental meetings at National Headquarters and Shellfish Growing Area Survey and Classification Committees in the Atlantic, Quebec and Pacific regions. These regional committees are chaired by Environment Canada and are composed of representatives from the CFIA, DFO, Environment Canada and appropriate provincial government departments. The mandate of the regional committees is as follows:

a) to review growing area surveys and classify all shellfish growing areas;

b) to review the policies, procedures, criteria and regulations affecting the implementation and application of shellfish growing area classifications;

c) to recommend to DFO changes in regulations pertaining to the classification of shellfish growing areas; and

d) to make recommendations to the Regional Director, Environmental Protection, Environment Canada,regarding regional growing area survey needs and priorities.

The regulatory requirements and administrative arrangements are such that:

a) Shellfish Program requirements apply to all actual and potential shellfish growing areas.

b) Shellfish Program requirements apply to all shellfish harvesters.

c) Shellfish Program requirements apply to all persons handling the shellfish prior to its delivery to the certified shipper.

d) The following records of shellfish sanitation activities are maintained:

    i) laboratory quality assurance records and other related data;

    ii) individual growing area reports (see Chapter 2);

    iii) relay activities permitted and a record of supervision provided (see Chapter 10); and

    iv) patrol activity reports, including numbers of

arrests, prosecutions, and the results of prosecutions (see Chapter 3).

e) Records and reports are made available on request for authorised audits including those that may be conducted by U.S. officials in connection with the 1948 Shellfish Agreement.

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

NOTE:

Effective implementation of the regional shellfish program requires good liaison among the various federal and provincial agencies overseeing the shellfish industry. As a result, a provincial committee on shellfish has been established in each province of the Atlantic Region. The mandate of the provincial committee is as follows:

a) promotion of the exchange of information and liaison between agencies and groups involved in the shellfish fishery;

b) development of education and information programs on shellfish growing area problems and recommending implementation to the appropriate agency;

c) reviewing existing data on shellfish and recommending resource development projects and sanitary and water quality survey priorities;

d) monitoring progress in the development of plans and programs to eliminate or prevent pollution of shellfish growing areas and encouraging corrective action for specific problem areas; and

e) acting as an advisory group to Environment Canada and the provinces.

1.2 Legislation

The legal authority for the Canadian Shellfish Sanitation

Program is provided by the *Fisheries Act*, the Management of Contaminated Fisheries Regulations, the *Fish Inspection Act*, the Fish Inspection Regulations and the Canada - United States Bilateral Agreement on Shellfish (Appendix IV). The Acts, Regulations and the Memorandum of Understanding between the CFIA, DFO and Environment Canada enable the Departments to:

a) classify all actual and potential shellfish growing areas as to their suitability for shellfish harvesting on the basis of sanitary quality and safety of the public health. This authority allows the responsible department to designate as closed any actual and potential shellfish areas where classifications are based upon outdated information and are not representative of existing sanitary conditions;

b) control the harvesting of shellfish from areas which are classified as contaminated or otherwise closed. This authority allows the responsible department to:

   i) issue harvest licences;

   ii) patrol growing areas;

   iii) apprehend persons violating restrictions; and

   iv) effectively prosecute persons apprehended harvesting shellfish from closed areas;

c) regulate and supervise relaying, transplanting, cleansing and replanting of shellfish. This authority allows the responsible Departments to obtain copies of monitoring data and to require that the industry collect and maintain certain harvesting and processing records;

d) restrict harvesting of shellfish from actual and potentially affected growing areas in a public health emergency. Administrative procedures required in connection with such emergency actions are rapid and in general require no more than one day to complete;

e) prevent the sale, shipment or possession of shellfish which cannot be identified as having been produced in accordance with the regulatory requirements or which are otherwise unfit for human consumption, and to detain or seize such shellfish;

f) register, certify, inspect and audit each shellfish facility to determine the level of conformity with the Fish Inspection Regulations including verification and effectiveness of the QMP Plan and applicable provisions of this Manual. Inspection includes the authority to review and copy necessary records to determine whether compliance with the applicable requirements is being maintained;

g) regulate the shipping conditions and labelling requirements for shellstock to protect against contamination and to provide for accurate source identity. These controls apply to every person that handles shellfish from the point of harvest through each certified shipper and up to the retail point of sale;

h) regulate the export, import, processing, packaging, shipping, storage and repacking of shellfish to protect against contamination and product quality degradation, to maintain source and lot identity and integrity and to provide for proper labelling and packaging;

i) regulate the controlled purification of shellstock to prevent illegal diversions, ensure cleansing, protect against recontamination, verify product quality and purification effectiveness, maintain production and product quality records and provide for proper labelling and packaging;

j) suspend, revoke, void, or refuse to issue or renew a Certificate of Registration in accordance with the policies set out in the Facilities Inspection Manual;

k) evaluate laboratories performing shellfish analyses in accordance with the requirements of this Manual;

l) collect samples and conduct appropriate bacteriological, chemical and physical tests necessary to determine product quality and monitor the effectiveness and performance of process operations;

m) prohibit the export - or possession of - shellfish from: unidentified sources; uncertified dealers or unapproved growing areas; sources which did not harvest, transport, process or pack the shellfish in accordance with requirements of the Fish Inspection

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

1.3 Certification and Registration Procedures

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

a) The Shellfish Program requirements shall be applied to all commercial shellfish harvesters; all persons handling the shellfish prior to its delivery to the processor; all persons engaged in controlled purification, wet storage, shucking, packing and repacking; or other forms of processing for export.

b) Each facility shall be registered according to the procedures described in Chapter 2, Subject 1 of the Facilities Inspection Manual and, if applicable, certified to the Interstate Certified Shellfish Shippers List (ICSSL) according to Chapter 2, Subject 2 of the Facilities Inspection Manual, published and maintained by the Canadian Food Inspection Agency.

c) Compliance Verifications of registered facilities shall be conducted following the procedures described in Chapter 3, Subject 3 of the Facilities Inspection Manual.

d) Enforcement actions are taken as per the policies and procedures outlined in Chapter 7 of the Facilities Inspection Manual.

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

e) A shellfish facility whose Certificate of Registration has been removed for cause may not export. A Certificate of Registration may be reinstated once the CFIA has verified that all instances of non-compliance have been corrected and the requirements of the Fish Inspection Regulations have been met. The policy is set out in Chapter 2 of the Facilities Inspection

Manual. Upon reinstatement of a Certificate of Registration, the Canadian Food Inspection Agency in Ottawa shall notify the FDA immediately.

f) Adequate records documenting the degree of compliance with the registration requirements shall be maintained in a district office central file for at least three years and made available to the FDA upon request during an official program audit. These records will include:

i) inspection, systems verification and compliance verification reports of certified processors;

ii) notification letters and actions taken regarding compliance verifications and certification withdrawals;

iii) records of shellfish sample results and follow-up actions taken (see Appendix III - Enforcement Policy for Molluscs Exceeding Established Bacteriological Levels);

iv) records of complaints or inquiries and follow-up actions taken; and

v) records of prosecutions.

g) The CFIA is responsible for completing Form FDA 3038, Interstate Shellfish Dealer's Certificate, and forwarding the completed form to the FDA Division of Cooperative Programs for posting on the Interstate Certified Shellfish Shippers List web site. The shellfish certificates forwarded to the FDA for posting should provide the following information:

i) the usual business name and alternative names that should appear on the Interstate Certified Shellfish Shippers List (hereinafter referred to as the "List");

ii) a business address where inspections are conducted;

iii) a unique certificate number for each business unit consisting of a one to five digit arabic number preceded by the two letter provincial abbreviation and followed by the two letter

abbreviations for the type of operation the dealer is qualified to perform; shucker packer (SP), repacker (RP), shellstock shipper (SS), reshipper (RS), or controlled purification [depuration] (DP); and

iv) an expiration date that is preferably the same for all firms, and preferably the last day of a month.

h) The following guidelines are followed in managing the issuance of shellfish certificates:

i) when a change is made to an existing, unexpired certificate or a withdrawn certificate, a new corrected certificate is issued;

ii) shippers are informed by the certifying officer of the probable date their names will appear on the List and should be advised against making shipments prior to the date. If shipments must be made before the appearance of the shipper's name on the List, the certifying officer will notify the FDA headquarters' office;

iii) if CFIA officials cancel a shellfish shipper's Certificate of Registration, the FDA is notified immediately and a completed Form FDA 3038, is forwarded to the FDA Division of Cooperative Programs informing them that the shipper should no longer be listed on the ICSSL;

iv) ICSSL renewal certificates should be sent to the FDA so they are received by the FDA's Division of Cooperative Programs prior to the date of posting of the List (usually the 15th of the month) for the month that the original certificates expire. Certificates will be withdrawn automatically from the List on the date of expiration unless renewal forms have been received by the FDA; and

v) inspectors are provided with appropriate equipment and supplies to conduct inspections and compliance verifications of certified shippers.

CHAPTER 2

GROWING 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 growing areas be surveyed and that actual and potential sources of pollution be identified. Following such surveys, the growing areas are classified as to their suitability for the harvesting of shellfish according to accepted water quality standards and general sanitary conditions in the growing area. The following sections describe the various types of surveys used to assess shellfish growing areas, and the principles used in assigning specific classifications to these areas.

Environment Canada's Shellfish Water Quality Protection 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 growing 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 (Verber, 1983; Cameron and Hackney, 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)(Verber, 1983). The positive relationship between sewage pollution of shellfish growing areas and enteric disease has been discussed by Hackney and Pierson, 1994 and Burkhardt and Calci, 2000.

Pollution of shellfish growing 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 discharges from sewage treatment plants, pulp mills, food processing plants,

sewage lift station overflows, 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 growing 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.

The following sections of this Chapter outline the requirements for growing area surveys and classification. For more specific information please refer to the "Manual for Growing Area Surveys for the Canadian Shellfish Sanitation Program" (in process).

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 growing 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 growing 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 15 samples shall be collected at each station. In remote shellfish growing 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, 2002".

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 and/or bacteriological sampling at representative stations if deemed necessary.

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 growing area once every three years (this requirement may be modified in remote shellfish growing 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 growing 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[1].

b) A minimum of 5 samples shall be collected at each station.

c) The analysis of at least the last fifteen water samples from each representative station and other field works will be undertaken as deemed necessary to determine the appropriate classification for the area.

---

[1] 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, 2002.

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 agency for each classified shellfish area.

2.3 Classification of Growing Areas

The CSSP recognizes four major classification categories:

- Approved;
- Conditionally Approved;
- Closed; and
- Prohibited.

Specific area classifications, and their boundaries, are assigned to shellfish growing areas based on survey results.

2.3.1 Approved

General definition - Shellfish growing areas may be designated as "Approved" if the area is not contaminated with faecal material, pathogenic micro-organisms, poisonous or deleterious substances, or unacceptable levels of marine biotoxins 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[2]; or

b) the biotoxin, chemical and bacteriological levels meet the standards/tolerances outlined in Appendix II and

---

[2] 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, 2002.

Appendix III of this Manual.

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 category.

2.3.2 Conditionally Approved

General definition - Conditionally Approved is the classification of a shellfish growing area determined by the shellfish control authority to meet the Approved criteria for a predictable period. These growing areas are subject to intermittent pollution caused by discharges from wastewater treatment facilities, seasonal populations, non-point source pollution, or boating activity. The period meeting the Approved criteria is conditional upon established performance standards specified in a management plan. A conditionally approved shellfish growing area is a closed area when the area does not meet the approved growing area criteria and is temporarily closed by the shellfish control authority. An area may be designated as "Conditionally Approved" if the following conditions are met:

a) during those times when harvesting is permitted, the area meets all of the requirements of an "Approved" area;

b) conditions which preclude harvesting in areas designated "Conditionally Approved" must be:

   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) an applicant has developed a harvesting plan as described in Appendix IX, "Protocol for Implementation of the Management of Conditionally Approved Areas";

   ii) all necessary measures have been taken to ensure that performance standards will be met;

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; and

iv) a documented management plan for each conditionally approved area has been developed (refer to Appendix IX, "Protocol for Implementation of the Management of Conditionally Approved Areas"). This plan must contain a clear description of the responsibilities and duties of all parties.

b) The conditionally approved area shall be immediately closed to shellfish harvesting when the criteria established in the management plan are not met. A conditionally approved area which has been closed shall not be re-opened to shellfish harvesting until:

i) the criteria established in the management plan are fully met;

ii) a time has elapsed which is sufficient, under environmental conditions, to permit natural biological cleansing of the shellfish; and

iii) verification that the bacteriological quality of the water and shellfish has again met the approved standards.

c) Monitoring requirements. In addition to the verification monitoring previously outlined, monitoring is required to confirm the Approved status when open. When the conditional area management plan is based on the operation and performance of a wastewater treatment plant(s), combined sewer overflows, or other point sources of pollution, monthly samples (minimum 5) are required during the period when the area is in the open status. When the conditional area management plan is based on the effects of non-point pollution, such as rainfall events, stormwater run-off, and seasonal variations, a minimum of 5 water samples shall be collected during the period when the area is in the open status.

d) 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.

e) The conditionally approved area shall be evaluated at least once each year by the Regional Shellfish Area Classification 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.

f) 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, federal agencies should not approve the area for direct harvesting of market shellfish.

g) Any failure to meet the conditions of the Management Plan must be immediately reported to and acknowledged by the shellfish control agencies.

h) If it is discovered that a failure to meet criteria in the Management Plan has not been reported by the operator of the sewage treatment plant, the area will immediately revert to a closed classification.

i) If at any time any party to the Management Plan fails to fulfill the requirements as set forth in the Plan, the area will immediately revert to a closed classification.

j) All data relating to the operation of a conditionally approved area, including operation of sewage systems, will be maintained in a file by the shellfish control agency or agencies.

2.3.3 Closed

General Definition - A growing area where the harvesting of shellfish is not permitted, except by special licence for specific purposes, due to contamination by faecal material, pathogenic micro-organisms, poisonous or deleterious substances, or unacceptable levels of marine biotoxins to the extent that consumption of the shellfish might be hazardous.

Shellfish growing areas are classified as "Closed" 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;

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 (see footnote 2); or

c) the biotoxin, chemical or bacteriological levels exceed the standards/tolerances outlined in Appendix II and Appendix III of this Manual.

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 closed areas can be allowed on a limited basis by licence for the purpose of scientific investigation, for seed, or for spat.

b) The "closed" classification (or any sub-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.

c) 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 defined as Prohibited Areas (see Section 2.3.4).

d) If an area within a Closed classification is to be used for Depuration or for Short-term Container Relaying the following criteria must be met.

   i) The median or geometric mean faecal coliform MPN

of water does not exceed 88/100 mL and not more than 10% of the samples exceed a faecal coliform MPN of 260/100 mL, for a five-tube decimal dilution test (see footnote 2).

e) If an area within a Closed classification is to be used for Natural and Extended Container Relaying it must not be within a Prohibited Area.

2.3.4 Prohibited

General definition - shellfish shall not be harvested from prohibited areas for any purpose, with the exception of seed and spat which may be collected under special license.

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

   a) the area within a minimum 300 metre radius around industrial, municipal and sewage treatment plant outfall discharges;

   b) the area within a minimum 125 metre radius around marinas;

   c) areas where due to the degree of contamination in the growing waters (i.e., waters having excessive concentrations of faecal 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.

2.3.5 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.

2.3.6 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 the reports of the comprehensive and re-evaluation surveys and minutes of the regional meetings.

CHAPTER 3

CONTROL OF HARVESTING

The control of harvesting from growing 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 approved or conditionally approved areas, or from closed areas by licence. Potentially hazardous shellfish must be prevented from reaching the consumer. It is the responsibility of the Conservation and Protection Division/Fisheries Branch in each Fisheries and Oceans (DFO) Region to provide sufficient personnel and equipment for surveillance activities that will act as a deterrent to harvesting from closed areas.

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 harvesting from closed areas.

a) a patrol policy document shall contain the following provisions:

   i) method of identification of closed 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 Shellfish Agreement.

3.2 Licensing of Harvesters

It is not a requirement of the Fisheries Act to licence harvesters who fish for shellfish in open (i.e. approved) areas. Specific regulations under the Fisheries Act however may require licensing of harvesters; such a requirement exists for the licensing of clam diggers in the Pacific Region. Information with respect to opening and closing shellfish areas is conveyed to harvesters through the local media or by the posting of notices in affected areas and in post offices and at shellfish processing plants, if applicable.

In the case of closed areas (i.e. areas not approved for direct marketing) the following criteria apply:

a) licences may be issued to harvesters or processors for the taking of shellfish from closed areas. The licences shall be issued in accordance with the operating procedures specified in Chapter 2 of this manual concerning relaying and controlled purification;

b) DFO may renew licenses each year, or more frequently, as necessary;

c) harvesters shall have valid licences in their possession while engaged in shellfish harvesting activities in other than open areas. DFO shall prohibit any person from harvesting who does not have a valid licence; and

d) 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 and changes in applicable laws and regulations.

3.3 Identification of Closed Areas

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

a) the boundaries of the closed areas shall be marked by fixed objects or landmarks or are otherwise described in a manner which permits easy recognition of the boundaries and successful prosecution of any violators of closed areas; and

b) shellfish harvesters shall be notified of the location of closed areas by publication, posting of notices, or other effective means. The method of notification and identification shall be sufficient to permit the successful prosecution of persons harvesting shellfish from closed areas.

3.4 Prevention of Harvesting from Closed Areas

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 from closed areas, educational programs are developed to provide harvesters with information concerning the public health aspects of consuming shellfish harvested from closed areas. Other measures and programs are developed as necessary to prevent harvesting from closed areas;

b) closed shellfish growing areas are patrolled with due consideration given to night, weekend and holiday patrols;

c) patrol forces shall be so equipped that persons found harvesting shellfish in closed areas or processing shellfish from closed areas may be apprehended; and

d) complete records of patrol activities, including violations and court actions, are maintained in a central office of the Regional patrol agency.

3.5 Depletion of Closed Areas

In the United States, individual States are encouraged to deplete market size shellfish from closed areas to reduce the likelihood of contaminated shellfish reaching the marketplace. This practice is not a procedure recommended or endorsed by DFO as a means of controlling harvesting.

CHAPTER 4

HARVESTING AND HANDLING SHELLSTOCK

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

a) 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.

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

4.3 Disposal of Human Wastes

a) Human wastes, sewage or refuse shall not be discharged from harvest vessels while in an area approved for shellfish harvesting or those areas adjacent to the approved area.

b) Portable toilets, if provided, shall be used only for the purpose intended, and shall be so secured and located as to prevent contamination of the shellfish by spillage or leakage.

c) The contents of portable toilets shall be emptied only into an approved sewage disposal system, and portable

toilets shall be cleaned before being returned to the vessel. (Facilities used for cleaning food-processing equipment shall never be used for cleaning portable toilets).

4.4 Shellstock Identification

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

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

c) 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.

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

   i) the harvester's name;

   ii) 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);

   iii) the date of harvesting; and

   iv) the common name and quantity of shellfish.

e) 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 Temperature Control of Shellfish From Harvest 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.

CHAPTER 5

WET STORAGE

Temporary wet storage of live shellstock in nearshore floats, baskets, or sacks, and onshore in tanks is subject to the requirements of the Fish Inspection Act and Regulations. In order to provide reasonable assurance that shellfish are wholesome, the criteria which follow shall apply to wet storage facilities and operations. These requirements do not apply to transplant operations where shellfish are moved to new growing areas for conditioning or resource management.

5.1 Source of Shellfish

Shellfish for wet storage shall be harvested, identified and shipped in accordance with Chapter 7 of this Manual.

5.2 Storage Facilities

a) Each new wet storage site or facility shall be evaluated and approved by the CFIA on the basis of an evaluation* of the nearshore site, or for an onshore operation, the facility's QMP plan and an inspection of the storage site or facility. Factors to be considered include but are not limited to the following:

   i) the location of the nearshore storage site in an area classified as approved or conditionally approved (and in the approved status);

   ii) examination of the construction of shellstock containers (if used) and loading depth to ensure the free flow of water to all shellstock;

   iii) a plan giving the design of the onshore storage facility, source of water to be used for wet storage, and details of any water treatment system.

*** NOTE Environment Canada surveys may be used in the evaluation.**

b) Wet storage shall be practised only in compliance with the provisions described in each facility's QMP. Each registered facility must consider, and where applicable, incorporate the following components in the development and implementation of their Quality Management Program:

i) nearshore areas used for wet storage shall meet the approved area criteria and acceptable biotoxin levels at all times shellfish are being held for direct marketing;

ii) each onshore wet storage facility shall meet the applicable requirements of Schedules I and II of the *Fish Inspection Regulations* (FIR);

iii) storage tanks and related plumbing are fabricated of safe material and are easily cleanable. Tanks are constructed so as to be easily accessible for cleaning and inspection, to be self-draining or equivalent, and to meet food-contact surface requirements. Plumbing is designed and installed so that cleaning and sanitizing will be effective;

iv) unless the water to be used for tank storage and washing of shellfish meets the requirements of Section 14(3) of Schedule I of the FIR, and the storage tanks are set up and operated as a flow-through system, the holding/washing water shall be treated;

v) the water treatment system shall provide an adequate quantity and quality of water to carry out the intended purpose of the wet storage operation and the treatment shall not leave residues that may interfere with the process. The treated water supplied to wet storage tanks shall have no detectable levels of coliform organisms as measured by the standard five tube MPN test. The quality of the water prior to final disinfection shall not exceed a median or geometric mean of 88 faecal coliform/100 mL ($\leq$ 10% do not exceed 260 MPN/100 mL); and

vi) for water receiving UV disinfection, turbidity does not exceed 20 Jackson Turbidity Units (or equivalent Nephelometar turbidity units).

c) 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.

d) Shellfish from different harvest lots shall not be commingled during wet storage in tanks.

e) Bivalve molluscs shall not be commingled with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve molluscs and other species, process 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.

f) Tanks shall be cleaned and sanitized as necessary to prevent contamination of the tank and water.

g) Disinfection units shall be cleaned, serviced, and tested as frequently as is necessary to assure effective disinfection. A water sampling schedule shall be included in the facility's QMP and the water shall be tested according to the schedule. If a water supply with faecal coliform median or geometric mean MPN of 88 per 100 mL ($\leq$ 10 % exceeding 260 per 100 mL) is used, the sampling schedule should require daily water testing by an approved laboratory. Records of UV light efficiency and replacement and records of all water sampling shall be kept by the facility and made available to CFIA inspectors for examination during QMP compliance verifications.

h) Salt (food grade) added to increase salinity or produce synthetic seawater shall be free of any levels of poisonous or deleterious substances which may contaminate the shellfish.

i) Water from approved areas must not be used for onshore wet storage if there is a marine biotoxin closure in effect at the source unless an approved control system is implemented to filter the water supply.

5.3 Labelling Requirements

a) Product wet stored shall be labelled:

i) if wet stored for less than 14 days: the harvest site is the original harvest site prior to wet storage and the date of harvest is the date removed from the wet storage site;

ii) if wet stored for 14 days or greater: the harvest site is the wet storage site and the date of harvest is the date removed from the wet storage site.

b) In all cases records shall be maintained that clearly indicate 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 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 name and address of the processor or distributor; and

   iv) if the shucked shellfish originate from depurated shellstock then the label must indicate that they have been depurated.

b) The principal display panel on each package of fresh or frozen shucked shellfish shall contain the certification number of the packer and 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.

c) 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.

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

e) 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**.

f) 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

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 Source Identification

All shellstock shall originate from an approved source and be 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 d) or e)) 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) date of processing;

ii) the most precise description of the location from which they were harvested (harvest area) as is practical (e.g. NB16 Bar Road, BC18-4 Swanson Channel, QC Baie Laval N-4.1.2 etc.);

iii) name, address and registration number of the dealer performing the packing;

iv) 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 for 14 days or more shall be labelled with the harvest site identified as the relay site. Shellstock relayed for less than 14 days shall be labelled with the original harvest site identified as the harvest 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) 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**;

ii) the most precise description of the location from which they were harvested (harvest area) as is practical (eg. NB16 Bar Road, BC18-4 Swanson Channel QC Baie Laval N-4.1.2 etc.);

iii) name, address and registration number of the dealer performing the packing;

iv) type and quantity of shellfish;

v) if the shellstock are depurated then the tag or label shall include the depuration cycle code; and

vi) shellstock that has been relayed for 14 days or more shall be labelled with the harvest site identified as the relay site. Shellstock relayed for less than 14 days shall be labelled with a harvest site identified as the original harvest site.

3) Export to the United States

a) The dealers' tags shall be:

i) durable, waterproof and sanctioned by the Authority prior to use; and

ii) at least 2 5/8 inches by 5 1/4 inches (6.7 x 13.3 cm) in size.

b) The dealer's tag shall contain the following indelible, legible information in the order specified below:

i) the dealer's name and address;

ii) the dealer's certification number as assigned by the Authority and the original shellstock shipper's certification number;

iii) the date of harvest;

iv) the most precise identification of the harvest location as is practical including the initials of the province of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g., Long Bay, Decadent County, lease number, bed, or lot number);

v) the type and quantity of shellstock;

vi) the following statement in bold capitalised type on each tag:

"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

vii) all raw shellstock exported to the U.S. is required to carry a consumer advisory. The following or equivalent wording for the advisory is acceptable:

"RETAILERS, INFORM YOUR CUSTOMERS"
"Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

c) Retail packages of frozen in shell molluscan shellfish exported to the U.S. shall be labelled "frozen in shell" and shall have a tag on the master carton containing all the information identified above. There is no requirement that each retail package within the master container be tagged. However, there may be other U.S. retail labelling requirements that apply. Registered facilities should consult the U.S. Food and Drug Administration's Retail Food Program for specific requirements.

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 tranships 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 Chapters 6 and 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

Relay systems (natural or in containers) and land-based depuration establishments are efficient methods of achieving microbiologically safe bivalve molluscs that are harvested from closed areas with limited contamination. 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), the Department of Fisheries and Oceans (DFO) and Environment Canada (EC), 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 in closed areas can be issued. This is in addition to any commercial shellfish license required regionally.

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 harvesting 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 harvest 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, Section 2.3.3.1).

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 CFIA and when their efficacy has been proven through verification.

a) Water

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

i) the water must be from a source approved by 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 Nepholometar 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) marine biotoxin contamination in shellfish during depuration must not exceed the levels identified in Chapter 11.

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 seawater 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:

i) constructed of corrosion resistant, non-toxic, non-absorbent, easily cleanable material; and

ii) of a suitable size and shape to permit:

1) a mid-cycle washing of shellfish;
2) an adequate flow of water to all shellfish;
3) a maximum depth of Manila and littleneck clams of 10 cm (4 inches);
4) a maximum depth of soft-shelled clams in containers of 20 cm (8 inches); and
5) 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 verification 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 for restricted areas for controlled purification (see 10.2.1). 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

Any laboratory used to perform the necessary analyses is required to be approved by a Lab Evaluation Officer.

The requirements that microbiology and bioassay laboratories must meet are described in checklists found in Appendix I (Annex I - CSSP Microbiology laboratory evaluation checklist; Annex II - CSSP Bioassay laboratory evaluation checklist [to be issued at a later date]).

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:

1) the names of all harvesters;
2) the exact location in which they will be digging; and
3) 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:

1) the date of harvest;
2) the area of harvest;
3) the harvester's name;
4) the quantity harvested by each harvester; and
5) the harvest license number

These records must be maintained and available for review.

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.

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 CFIA and meet the requirements of Schedule V of the Fish Inspection Regulations (FIR). At no time shall product destined for depuration or relay be transported with product from Approved areas.

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:

1) greater than the temperature of the process water; and/or
2) more than 3 degree C below the process water temperature.

iii) Post-process storage temperature shall not exceed 4 degree 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 verification 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.

e) 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 Verification

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 ≥ 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-eight hours will be approved by 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 48 hours 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. 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 verification must be approved by 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% VALUE*
Soft Clam (*Mya arenaria*)	50	130
Hard Clam (*Mercenaria mercenaria, Protothaca staminea, Venerupis philippinarum*)	20	70
Blue Mussel (*Mytilus edulis*)	20	70
Oyster (*Crassostrea virginica, Crassostrea gigas*)	20	70

* 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.

During the evaluation period the product may be released, by 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 closed 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 verification 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 CFIA.

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

10.2.8 Routine QMP Monitoring (Post-Verification) - 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 (≤2300 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 48 hours (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 beaches with consistently low zero hour results, and is processing relatively small lots may, with CFIA approval have the number of zero and/or final (48-hour) 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 ≥1000, 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) 48-hour 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
	Oyster, hard clam, mussel	No value	No value	100
2	Soft clam	125	No value	170
	Oyster, hard clam, mussel	75	No value	100
3	Soft clam	110	No value	170
	Oyster, hard clam, mussel	45	No value	100
5	Soft clam	50	100	170
	Oyster, hard clam, mussel	20	45	100
10	Soft clam	50	130	170
	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

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 ($\leq$ 2300 faecal coliforms/100 g or as approved during process verification) 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 closed area for at least 14 days;

b) heat process (e.g., canning) the bivalve molluscs if the faecal coliforms are < 4000/100 g;

c) return to a closed 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 verification, the product may be released, by 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 verification, and should be returned to a closed area.

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 verification 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 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 Verification 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 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.

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 QMP Compliance 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 4000;

c) relay to another approved area; 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 verification, the product may be released to the market, by 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 Harvest Areas

Harvesting may occur in any classified areas not identified as prohibited.

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.

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 30 days must be analysed for faecal coliforms with a minimum of 1 sample. Lots of shellfish that are relayed in excess of 30 days may be exempt from the testing requirement, at the discretion of CFIA.

a) Processor/grower records and bacteriological analysis results must be made available on request for QMP Compliance Verification purposes or DFO audit 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.

10.4.8 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 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;

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, when applicable, and must be available for CFIA Compliance Verification purposes.

10A.1 Per lot:

- date of harvest
- area of harvest
- harvesters' names
- quantity of shellfish harvested
- time and date received at storage*
- time and date removed from storage*
- 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

* If storage facility location is separate from cleansing facility

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, % 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.

ANNEX 10B

SELECTED EXAMPLES OF TAGS AND RECORD FORMS

A. Lot Identity At Dig Site

HARVEST AREA AND SUB-AREA AND AREA # _____

DATE OF HARVEST _____

NAME(S) OF HARVESTERS _____

_____

PERMIT # _____

QUANTITY OF CLAMS _____

LOT # _____

PROCESSING CO. NAME, ADDRESS & REGISTRATION # _____

B. Lot Identity At Interim Storage Facility

LOT # ____ STORAGE TEMPERATURE ____ DATE RECEIVED _____

HARVEST AREA AND NUMBER _____

QUANTITY RECEIVED _____

QUANTITY CULLED _____

DISPOSAL METHOD _____

DISPOSAL DATE _____

QUANTITY SHIPPED _____

DATE SHIPPED _____

C. Depuration Cycle

CLEANSING (DEPURATION) CYCLE _____ LOT # _____

DATE (TIME) IN: _____ QUANTITY _____

CONTAINER (TANK) NUMBER _____

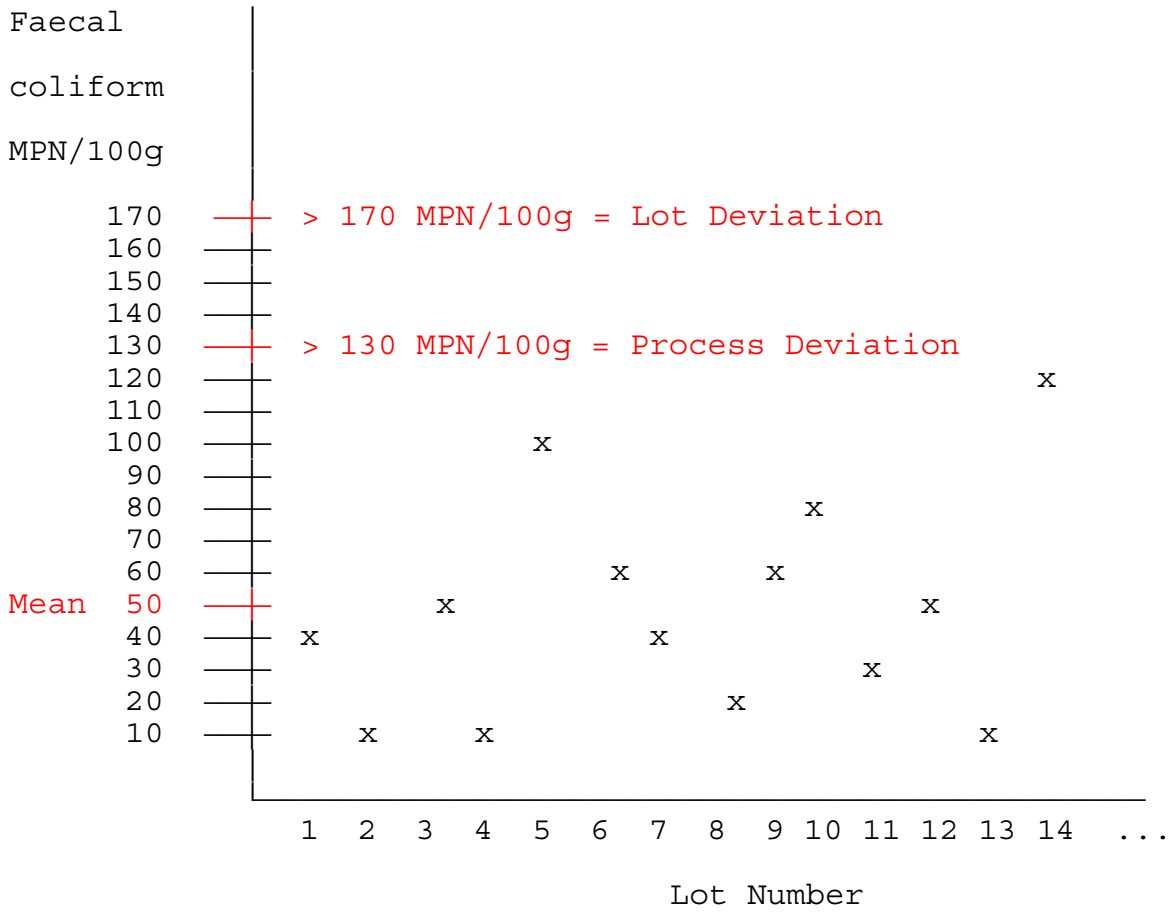
CONTAINER POSITION _____

TIME OF WASH DOWN _____

DATE (TIME) OUT _____ QUANTITY _____

DISPOSAL OF CULLS _____

D. Graph of results per lot (example - soft shell clam)



ANNEX 10C

EXAMPLE OF SPECIAL LICENCE

Licence No. _____

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 closed 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 shelled 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)_____, (phone 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

BETWEEN

_____

(Company)

AND

DEPARTMENT OF FISHERIES & OCEANS

FOR THE
HARVESTING AND PROCESSING OF SOFTSHELL CLAMS
FROM CLOSED AREAS

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 Department of Fisheries & Oceans reserves the right to amend the agreement during the effective period.

Signatures

_____
Company Representative

_____
Dept. of Fisheries & Oceans

SECTION 1. HARVESTING, TRANSPORT AND STORAGE

1.1 Designation of Closed Areas

The Department of Fisheries and Oceans, in consultation with the Department of the Environment, 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/100 mL.

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 closed 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 DFO Inspection Services 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 sanitised 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 vs. Lot#); 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 DFO.

2.6 Sampling and Laboratory Analysis (Depuration Operations)

The company will be required to analyse 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 Department of Fisheries and Oceans. The laboratory must participate in the split sample program operated by DFO 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.

DFO 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 DFO until the results of bacteriological analyses are complete; or

2) detained and sampled by DFO. If DFO 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 (eg. can) the clams; or

3) disposed of for other than human consumption; or

4) relayed to a closed 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 DFO Inspection Office immediately upon discovery of the deviation as well as initiate investigative action to determine the cause. DFO 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 molluscan shellfish accumulate the toxins when utilizing 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 hydrographic conditions 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, and toxins have been detected in lobsters, crabs, and whelks and other predatory gastropods.

Canadian shellfish have been contaminated with three types of biotoxins: 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. No deaths have been recorded for DSP, but deaths have resulted from PSP and ASP intoxications.

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 the Department of Fisheries and Oceans (DFO) which implements and enforces closures.

11.1 Program responsibilities and Reporting

The CFIA is responsible for overall program implementation while the Regional Inspection Divisions manage specific programs within their geographic limits, in cooperation

with DFO Fishery Officers responsible for enforcement and patrol.

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. A Consumer Complaint Record (Annex 11A) is required to be completed for each person who may have been involved. Any incident is to be reported to the Regional Director, CFIA by telephone and followed as soon as possible with a detailed report, including a Consumer Complaint Record.

11.2 Sampling of Harvesting Areas

Each Fisheries Region has established sampling stations and frequencies to monitor changes in PSP and ASP.

DSP testing will only occur in suspect harvesting areas or as a result of consumer complaints where symptoms would indicate possible DSP intoxication. If no DSP related illnesses occur within a year of initial testing, an area would not remain defined as suspect and sampling could be discontinued.

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 carefully chosen after a thorough analysis of toxicity score data.

The following conditions must be considered in site selection:

a) accessibility to the site at all times of the year;

b) the supply of shellfish available in a localised area;

c) a location which can be readily identified or marked; and

d) assessment of the site by past records of toxicity.

In order to maintain reliability of bioassay results, the period of time between the digging of shellfish and extraction should be uniform and limited. Each sample must be properly identified with the area of digging, the species, the date of digging and the sampling officer's name. Samples should be stored at refrigerated

temperatures 2 ° to 7 °C (35 ° to 45 °F) until extracted.

In the case of aquaculture operations, samples may be collected at the establishment if the same standards of continuity and sample handling are maintained.

Regions should have in place a monitoring program to adequately monitor marine biotoxins. As levels begin to rise, sampling frequency is to be increased in accordance with the speed of the rise to ensure timely closure. Areas that have been closed are to be monitored on a regular basis but with increased frequency as PSP scores decline toward acceptable levels. The objective is to ensure that shellfish areas are closed when:

i) PSP toxin levels reach 80 µg/100 g and are opened only when toxin levels are consistently below 80 µg/100 g;

ii) ASP toxin levels reach 20 µg/g and are opened only when toxin levels are consistently below 20 µg/g; and

iii) DSP chemical analysis gives okadaic acid and/or DTX-1, singly or in combination, of less than 1 microgram per gram (µg/g) of digestive tissue (equivalent to approximately 20 µg/100g soft tissue) and are opened only when consistently below this level.

Should departures from the scheduled sampling and/or analyses occur, due to weather conditions, absence of staff, diversion of sampling/analytical resources to areas of higher concern, then 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.

In addition to normal sampling, when certain species are used for canning (e.g., butter clams in British Columbia) a special Harvesting License (Annex 11B) is required, and the shellfish must be tested for PSP prior to release for sale.

11.3 Sampling from Processing Plants

As an additional safety measure samples are periodically taken for toxin analysis from plants processing shellfish. Shellstock shippers, shucker-packers and other registered shellfish plants are monitored and the following enforcement policy is applied.

a) Where a shellfish sample collected from a plant shows a PSP level ≥ 80 µg/100 g, and/or an ASP level ≥ 20 µg/g, and/or DSP chemical analysis gives okadaic acid and/or DTX-1, singly or in combination, of ≥ 1 microgram per gram (µg/g) of digestive tissue (equivalent to approximately 20 µg/100g soft tissue), the production lot should be detained if still available at the plant. 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. National Headquarters (National Manager, Product Inspection, and National Manager, Aquaculture and Shellfish Inspection) is to be advised with Regional recommendations and actions taken.

b) Recent results from the suspect harvest area should be reviewed and additional harvest area samples taken, if necessary, to determine if toxin levels have exceeded allowable limits. If limits have been exceeded then the area should be closed immediately.

c) Until such time as samples from the suspect harvest area are analysed, all production lots (originating from the suspect area) from all plants should be detained and sampled.

d) Should the harvest area samples be acceptable and there are no additional high results in samples from other plants, all efforts would be re-directed at the original plant. Detention and sampling shall continue at the original plant until three consecutive lots are shown to have less than 80 µg/100 g PSP or less than 20 µg/g ASP or DSP chemical analysis gives okadaic acid and/or DTX-1, singly or in combination, of less than 1 microgram per gram (µg/g) of digestive tissue (equivalent to approximately 20 µg/100g soft tissue).

e) If, throughout the fishing season there are five occurrences at a plant in which production had to be placed under detention as a result of lots being ≥ 80 µg/100 g PSP or ≥ 20 µg/g ASP, or DSP chemical analysis gives okadaic acid and/or DTX-1, singly or in combination, of ≥ 1 microgram per gram (µg/g) of digestive tissue (equivalent to approximately 20 µg/100g soft tissue), consideration will be given to taking further enforcement action under Section 10 of the Fish Inspection Act.

Note: For the purpose of this section each consecutive lot should be indicative of a "normal day's production". This would be equivalent to an average of the last 14 days' production.

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

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

11.4 Sample Priority

To ensure the timely analysis of samples, a system has been established to assist laboratory personnel in determining priorities for toxin analyses. The system is based upon immediate analysis of product that may go directly to the consumer.

Priority 1 - These are samples from a suspected illness, approved areas where toxicity may be increasing, samples that were delayed in analysis and from detained shellstock or fresh shucked product shipments. Samples are shipped by the most rapid means possible, are analysed immediately upon receipt and results are reported by telephone with mail or fax follow-up.

Priority 2 - These are samples from approved areas where levels are stable, closed areas which are showing changes, commercial lots of frozen products or heat-processed canned meats. Samples are shipped by regular means and are analysed within 24 hours of receipt.

Priority 3 - These are samples for research purposes, shipped by regular means and fitted into laboratory workloads.

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-1, singly or in combination, ≥ 1 microgram per gram (µg/g) of digestive tissue (equivalent to approximately 20 µg/100 g soft tissue) 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 okadaic acid and/or DTX-1, singly or in combination, of ≤ 1 microgram per gram (µg/g) of digestive tissue (equivalent to approximately 20 µg/100g soft tissue). In the past, grid samples taken at the end of the 14-day period have been found effective in some areas in reducing the likelihood of product having unacceptable biotoxin levels reaching the marketplace.

A closure or opening is implemented in the following manner.

a) Where mouse bioassay or chemical analysis results indicate an opening or closure is required, an order is prepared, under the Management of Contaminated Fisheries Regulations, for the signature of the Regional Director General (DFO) (see Appendix VII for details).

b) A news release is issued to local media. Departmental staff, fishermen's associations and shellfish processors are notified by telephone. All normal access points to the area are prominently posted with closure signs specifying the area affected or, closure signs are removed in the case of an opening.

c) Patrols are arranged to ensure effective closure.

As the canning process reduces PSP toxin, licences may be issued to harvest clams and mussels under the following specific criteria and conditions.

Soft shell clams and mussels (Atlantic) may be harvested

when PSP toxin levels exceed 80 µg/100 g and are less than 160 µg/100 g.

Butter clams on the West Coast may be harvested and canned, subject to the following conditions, when the PSP toxin levels (µg/100 g) are:

> 300 to ≤ 500 ..... entire siphon must be removed
> 80 to ≤ 300 .....distal half of the siphon must be removed
≤ 80 .....black tip of the siphon must be removed.

ANNEX 11A

Amend.no.1 25/03/94

INSTRUCTIONS FOR COMPLETING THE CONSUMER COMPLAINT RECORD

PLEASE PRINT ALL INFORMATION. WHEN NO INFORMATION IS AVAILABLE ENTER "N/A" (NOT AVAILABLE) IN THE BOX.

1. Enter the name of the Fisheries and Oceans laboratory or Inspection office and the region where the complaint was received.

2. Enter the date the complaint was received (e.g. Y/A 93 (1993); M 06 (June); D/J 15).

3. Enter the laboratory identification number. The ten-digit number is generated as follows:

   i) the first two digits identify the region and district where the complaint originated. The first digit is to indicate the region. The second digit should be zero (0) if the complaint was received at the Regional Office or the correct digit if the complaint was received in one of the area offices in the region.

i.e. Headquarters	NHQ	70
Newfoundland	NFLD	10
Scotia-Fundy	SCFU	20
Gulf	GULF	30
Central and Arctic	C+A	50
Pacific	PAC	60
Quebec	QUE	80

   ii) the third to eighth digits identify the date the complaint was recorded:

   - third and fourth digits - the year (e.g. 93)
   - fifth and sixth digits - the month (01 (January) to 12 (December))
   - seventh and eighth - the day of the month (01 to 31)

   iii) the ninth and tenth digits are used to indicate the number of the complaints in consecutive order as they are received each day (e.g. 50-930615-01 would mean the first complaint received by Central and Arctic regional office on the fifteenth of June, 1993).

   iv) trade complaints are to be identified by the addition of the letter T to the end of the consumer complaint number, (e.g. 50-930615-01T)

   If other than Canada, enter the country of origin in the

second part of box #3.

4. Check the box which indicates how the complaint was received. Did the consumer contact the department directly or was the complaint received through another department such as the Health Protection Branch (HPB) of Health Canada (HC), Industry Canada, a provincial ministry/department of health, etc.

5. If the complaint was received from another agency, enter the name and address.

6. Check if the complainant reported illness as a result of eating fish or fish products. If yes, complete the Supplementary Form for Suspected Food Poisoning (FP1580, reverse).

7. Print the complainant's name.

8. Print the complainant's home telephone number.

9. Print the complainant's home address.

10. Print the complainant's business telephone number.

11. Print the product brand name as printed on the product label.

12. Print the common name of the product including descriptive terms, noting the species name first (e.g. tuna chunk light, or shrimp peeled, deveined). Note packing medium (e.g. tuna chunk light vegetable broth).

13. Enter the net weight of the product package unit.

14. Enter the unit price of the item, or the retail price paid by the consumer.

15. Enter the manufacturer's container code placed on the packing carton or individual product package.

16. Identify the container pack type (e.g. canned, packaged, bulk).

17. Print the name and address of the manufacturer/distributor of the product as it appears on the product label. (If the manufacturer or distributor is also the responsible agent, enter "the same" on the form.)

18. Print the name and address of the dealer/vendor where the item was purchased.

19. Enter the date of purchase (e.g. Y/A 93 M 06 D/J 15).

20. Briefly describe the nature of the complaint, providing all pertinent details. If possible, the following terms should be used in the description:

    a) illness;
    b) odour/flavour;
    c) appearance;
    d) foreign material;
    e) extraneous matter;
    f) parasites;
    g) label;
    h) other.

21. Check if the original complaint sample was examined by Fisheries and Oceans personnel. Note under what conditions the sample was stored, e.g. unopened, frozen, refrigerated, etc.

22. Enter the date the sample was inspected or examined.

23. Check if additional sample units were taken for investigation from any of the locations listed. Note the number of additional samples taken and from where.

24. Record the results of the inspection of the original product and the additional sample units, providing observations, action and comments.

25. Check the method of communication used to advise the complainant of the inspection results.

26. The Inspector is to print his/her name and sign the form.

27. Record if the complaint was referred to the Regional Office, the distributor, the manufacturer, HPB, etc.

28. Enter the date the report was completed.

29. If illness was involved, complete the supplementary form for suspected food poisoning.

11	A-5	
New	31/03/92	

INSTRUCTIONS FOR COMPLETING THE SUPPLEMENTARY FORM FOR SUSPECTED FOOD POISONING

PLEASE PRINT ALL INFORMATION. WHEN NO INFORMATION IS AVAILABLE ENTER "N/A" (NOT AVAILABLE) IN THE BOX.

1. Enter the name of the Fisheries and Oceans laboratory or Inspection office and the region where the complaint was received.

2. Enter the date the complaint was received (e.g. Y/A 93 (1993); M 06 (June); D/J 15).

3. Enter the ten digit laboratory identification number (see Section 3, Appendix A of this chapter).

4. Enter the date the illness occurred (e.g. Y/A 93; M 06; D/J 15).

5. Enter the date the illness was reported (e.g. Y/A 93; M 06; D/J 15).

6. Record the number of people affected.

7. Record the total number of people that consumed the food containing fish or fish products.

8. Check the symptoms reported by the complainant. Print any other symptoms not listed but experienced by the complainant.

9. Indicate the length of time which elapsed from the time of eating to the time the symptoms occurred.

10. Indicate the length of time the illness lasted.

11. Check if a doctor was consulted.

12. Print the doctor's diagnosis.

13. Print the doctor's name, business address and business telephone.

14. Check where the food was eaten. If applicable, provide the name of the public establishment.

15. Check if the meal was catered.

16. Print: "see attached". On a separate page(s) list the complainant's 24-hour food recall noting all foods and beverages, including the food suspected of causing food poisoning, and all meals and snacks consumed immediately prior to the illness.

Note: Items 17 to 32 inclusive deal primarily with fish or fish products purchased and prepared at home or in a private residence.

17. Check the form in which the fish or fish product was purchased.

18. Indicate the period of time which elapsed from purchase to consumption (generally in hours for fresh product and in months for canned or frozen product).

19. Indicate the amount of time that elapsed following opening of the package until consumption.

20. Enter the cooking time in hours or minutes.

21. Enter the cooking temperature or microwave power level.

22. If frozen, indicate if the product was thawed prior to cooking.

23. Indicate how the product was thawed.

24. Describe how the product looked prior to cooking.

25. Record the size or approximate weight of the portions consumed.

26. Check if there was a noticeable "off" odour prior to cooking.

27. Record the method used for cooking, e.g. baking, broiling, frying, sautéeing, steaming.

28. Record the product odour when the food was served. The following examples may serve as a guide:

    Taint - rancid, abnormal, contaminated;
    Decomposition - fruity, vegetable, sour, yeasty fermented, ammonia, putrid or faecal.

29. Record in minutes, hours or days the time delay between cooking and serving.

30. Check if the product was refrigerated between cooking and serving.

31. Record in minutes, hours, days, etc., how long the product was refrigerated.

32. Check which ingredients were used in the food preparation. Note any special ingredients.

33. Check if a sample of the suspect product was collected for bacteriological or chemical testing.

34. Record the date the analysis was completed. (e.g. Y/A 93 M 06 D/J 15)

35. Summarise the results of the analyses indicating possible causative agents. Attach bacteriological and/or chemical work sheets, if available.

36. Evaluate the validity of the complaint and record action taken.

37. Enter the date of the report. (e.g. Y/A 93 M 06 D/J 06)

38. The officer finalizing the investigation is to print his/her name and sign the report.

ANNEX 11B

EXAMPLE

MOLLUSCS HARVESTING LICENCE

Pursuant to Section 4(1) of the Management of Contaminated Fisheries Regulations made under the Fisheries Act, permission is hereby granted to harvest_____ _____, for _____ _____ subject to the following conditions:

1) That the vessel and/or digger be duly registered with the Department of Fisheries & Oceans.

2) That the local Fishery Officer be advised when the molluscs are to be harvested.

3) That, in the case of harvesting for canning purposes, all molluscs be used for canning only, and are not to be sold as fresh.

4) That the identity of the molluscs harvested under this licence must be maintained at all times, from the time they are harvested until they are in possession of the buyer.

5) That the Licence be produced immediately for examination, upon demand by a Fishery Officer.

6) That this License will not be valid when PSP scores exceed _____ µg/100 g and/or when Domoic Acid scores exceed _____ µg/ g.

7) That the area of operation be _____.

8) That non-compliance with any of the conditions of this Permit or pertinent Regulations will result in its immediate cancellation (Section 9 of the Fisheries Act).

Issued at _____ this _____ day of _____ 19__

_____ _____

Holder Fisheries Officer

CHAPTER 12

SHELLFISH AQUACULTURE

Shellfish aquaculture is fast becoming a very important part of the shellfish fishing industry. The granting of shellfish aquaculture leases is the mandate of provincial governments; however, both DFO and Environment Canada can provide advice to provincial authorities during both the site approval and lease granting processes.

12.1 Aquaculture Sites

The aquaculture of shellfish may be conducted in areas where:

a) the water quality complies with the approved area classification and is free from point and non-point pollution sources (see Sections 2.3.1 and 2.3.3.3) and only when chemical or toxin levels do not reach or exceed the tolerances and/or action levels outlined in Appendix II;

b) the water quality complies with the requirements of Section 2.3.3 Administrative Requirements b) i) and the shellfish are subjected to a depuration protocol as outlined in Sections 10.2. - 10.2.11;

c) the site is not within any prohibited area as described in Section 2.3.3.3 and the shellfish are subjected to a natural or container relaying to approved areas for sufficient time and under adequate environmental conditions to allow purification to occur (see also Section 2.3.3 Administrative Requirements b) ii)); and

d) all requirements of Annex 12A - Criteria for Shellfish Aquaculture Leases in Bacteriologically Contaminated Areas are met.

12.2 Polyculture

Shellfish and finfish should not be raised in close proximity as netpens have the potential to be point-sources of pollution due to human activity and poor husbandry practices. There should be a minimum of a 125m prohibited area surrounding netpens. The size of this area will be dependent on the size of the finfish site and on the hydrography surrounding the site (see Section

2.3.3.3 b) ii)).

Note: This does not preclude the use of netpens as sources of shellstock spat or seed (see 12.3 below).

12.3 Other Aquaculture Activities

Although aquaculture-raised shellfish are destined for human consumption there are a number of activities that may be carried out in advance of final harvesting, processing and sale. These activities can include spat and seed collection. Shellstock spat and seed may be collected, for grow-out, from bacteriologically contaminated areas 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. This grow-out period must be a minimum of six months or longer.

ANNEX 12A

CRITERIA FOR SHELLFISH AQUACULTURE LEASES IN BACTERIOLOGICALLY CONTAMINATED AREAS

1. All bivalve molluscan shellfish raised in bacteriologically contaminated areas must go through an approved depuration (controlled purification) or relay process before being marketed.

   In the case of "conditionally approved" areas, shellfish may be harvested for direct marketing only when the area meets the "approved-area" status and provided that a management plan is in place. Product harvested from these areas during periods when the area does not meet "approved-area" status must be depurated or relayed.

2. No lease shall be issued within the boundaries of any closure zone around point sources of pollution (eg. pipes, streams, wharves, sewage treatment plants, marinas etc.).

3. All new lease holders in previously unused areas must go through a species-specific verification process, acceptable to DFO and DOE, for whichever purification process (depuration or relaying) is intended.

4. All lease holders must, subject to DOE and/or DFO approval, have analyses of overlay waters and/or shellstock performed by third-party laboratories in order to demonstrate that the bacteriological quality of the lease site overlay water and shellstock have not deteriorated.

   Third-party laboratories performing the analyses will be subject to a DOE or DFO verification process.

5. All activities related to the harvesting and transportation of bacteriologically contaminated shellstock destined for depuration and/or relaying must be supervised and verified and carried out under conditions detailed in a management plan or Memorandum of Understanding (MOU).

APPENDIX I

LABORATORY PROCEDURES

This Appendix provides Shellfish Program 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

American Public Health Association (APHA) *Laboratory Procedures for the Examination of Seawater and Shellfish* 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, HPB Methods of Microbiological Analysis, Volume 2), shall be followed for the collection, transportation and examination of samples of shellfish and shellfish waters (Greenburg & Hunt 1984). 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, Volume 3) or equivalently, the U.S. Food and Drug Administration 2001 Bacteriological Analytical Manual Online. Available at: http://www.cfsan.fda.gov/~ebam-9.html [2001, June 15]. Laboratories should conduct the test for this organism when routine tests of marine foods suspected in foodborne outbreaks fail to demonstrate other enteric pathogens or bacterial toxins (Ratcliffe & 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.

The laboratory must be evaluated and approved triennially by a DOE or CFIA Laboratory Evaluation Officer (LEO) using the most recent CSSP Laboratory Evaluation Checklist (Annex 1). Quality assurance guidelines to be used are established below. In addition, the laboratory shall take part in an inter-laboratory analysis program (samples of unknown source) at least once per year.

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. Bacteriological shellstock count standards based on *E. coli* levels as determined by the MPN method, are presently in use for the evaluation of a facility's Quality Management Program (QMP).

Sample Condition

All water samples are to be held at a temperature below 10° C during a maximum transport time of 6 hours. Refrigerate these samples upon receipt in the laboratory and process within 2 h. When local conditions necessitate delays in delivery of samples longer than 6 h, consider making field examinations using field laboratory facilities located at the site of collection. 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. A complete list of sampling requirements can be found in the CSSP Water Sample Collection Checklist (Annex 2 - to be issued at a later date).

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 analysed 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*).
- 35 ± 0.5° C air incubator.
- 44.5 ± 0.2° C or dual temperature programmable waterbath.
- Sterile 250 mL wide-mouth sample bottles*.
- 20 x 150 mm Pyrex test tubes and caps*.
- 16 x 150 mm Pyrex test tubes and caps*.

- 6 x 50 mm culture tubes (Durham tubes).
- Test tube racks.
- Autoclave.
- Sterile Pasteur pipettes.
- Milk dilution bottles*, 160 mL.
- Blender.
- 1.0 L (minimum size) blender jars*.
- sterile shucking knife and/or scalpel.
- sterile stiff brush

* Or suitable substitutes which meet or exceed CSSP Laboratory Evaluation requirements

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 2% Broth (BGB)

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 mL aliquots 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 grams 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 following Table 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.

MOST PROBABLE NUMBERS (MPN)
per 100 mL of sample
planting 5 portions in each of 3 dilutions in geometric series

No. of Positive tubes 10 1 .1 (mL)	MPN	No. of Positive tubes 10 1 .1 (mL)	MPN	No. of Positive tubes 10 1 .1 (mL)	MPN	No. of Positive tubes 10 1 .1 (mL)	MPN	No. of Positive tubes 10 1 .1 (mL)	MPN	No. of Positive tubes 10 1 .1 (mL)	MPN
0 0 0		1 0 0	2.0	2 0 0	4.5	3 0 0	7.8	4 0 0	13	5 0 0	23
0 0 1	1.8	1 0 1	4.0	2 0 1	6.8	3 0 1	11	4 0 1	17	5 0 1	31
0 0 2	3.6	1 0 2	6.0	2 0 2	9.1	3 0 2	13	4 0 2	21	5 0 2	43
0 0 3	5.4	1 0 3	8.0	2 0 3	12	3 0 3	16	4 0 3	25	5 0 3	58
0 0 4	7.2	1 0 4	10	2 0 4	14	3 0 4	20	4 0 4	30	5 0 4	76
0 0 5	9.0	1 0 5	12	2 0 5	16	3 0 5	23	4 0 5	36	5 0 5	95
0 1 0	1.8	1 1 0	4	2 1 0	6.8	3 1 0	11	4 1 0	17	5 1 0	33
0 1 1	3.6	1 1 1	6.1	2 1 1	9.2	3 1 1	14	4 1 1	21	5 1 1	46
0 1 2	5.5	1 1 2	8.1	2 1 2	12	3 1 2	17	4 1 2	26	5 1 2	64
0 1 3	7.3	1 1 3	10	2 1 3	14	3 1 3	20	4 1 3	31	5 1 3	84
0 1 4	9.1	1 1 4	12	2 1 4	17	3 1 4	23	4 1 4	36	5 1 4	110
0 1 5	11	1 1 5	14	2 1 5	19	3 1 5	27	4 1 5	42	5 1 5	130
0 2 0	3.7	1 2 0	6.1	2 2 0	9.3	3 2 0	14	4 2 0	22	5 2 0	49
0 2 1	5.5	1 2 1	8.2	2 2 1	12	3 2 1	17	4 2 1	26	5 2 1	70
0 2 2	7.4	1 2 2	10	2 2 2	14	3 2 2	20	4 2 2	32	5 2 2	95
0 2 3	9.2	1 2 3	12	2 2 3	17	3 2 3	24	4 2 3	38	5 2 3	120
0 2 4	11	1 2 4	15	2 2 4	19	3 2 4	27	4 2 4	44	5 2 4	150
0 2 5	13	1 2 5	17	2 2 5	22	3 2 5	31	4 2 5	50	5 2 5	180
0 3 0	5.6	1 3 0	8.3	2 3 0	12	3 3 0	17	4 3 0	27	5 3 0	79
0 3 1	7.4	1 3 1	10	2 3 1	14	3 3 1	21	4 3 1	33	5 3 1	110
0 3 2	9.3	1 3 2	13	2 3 2	17	3 3 2	24	4 3 2	39	5 3 2	140
0 3 3	11	1 3 3	15	2 3 3	20	3 3 3	28	4 3 3	45	5 3 3	180
0 3 4	13	1 3 4	17	2 3 4	22	3 3 4	31	4 3 4	52	5 3 4	210
0 3 5	15	1 3 5	19	2 3 5	25	3 3 5	35	4 3 5	59	5 3 5	250
0 4 0	7.5	1 4 0	11	2 4 0	15	3 4 0	21	4 4 0	34	5 4 0	130
0 4 1	9.4	1 4 1	13	2 4 1	17	3 4 1	24	4 4 1	40	5 4 1	170
0 4 2	11	1 4 2	15	2 4 2	20	3 4 2	28	4 4 2	47	5 4 2	220
0 4 3	13	1 4 3	17	2 4 3	23	3 4 3	32	4 4 3	54	5 4 3	280
0 4 4	15	1 4 4	19	2 4 4	25	3 4 4	36	4 4 4	62	5 4 4	350
0 4 5	17	1 4 5	22	2 4 5	28	3 4 5	40	4 4 5	69	5 4 5	430
0 5 0	9.4	1 5 0	13	2 5 0	17	3 5 0	25	4 5 0	41	5 5 0	240
0 5 1	11	1 5 1	15	2 5 1	20	3 5 1	29	4 5 1	48	5 5 1	350
0 5 2	13	1 5 2	17	2 5 2	23	3 5 2	32	4 5 2	56	5 5 2	540
0 5 3	15	1 5 3	19	2 5 3	26	3 5 3	37	4 5 3	64	5 5 3	920
0 5 4	17	1 5 4	22	2 5 4	29	3 5 4	41	4 5 4	72	5 5 4	1600
0 5 5	19	1 5 5	24	2 5 5	32	3 5 5	45	4 5 5	81	5 5 5	>1600

Recommended Procedures for the Examination of Sea Water and Shellfish, 4th edition, 1970

2. Toxicological

Current Association of Official Analytical Chemists (AOAC) and APHA official methods shall be followed in the bioassay for PSP (Greenburg & Hunt 1984, AOAC 1995). Methods validated by Canadian Food Inspection Agency laboratories shall be followed for the determination of Domoic Acid.

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 analysed in a manner that assures the validity of the analytical results. To ensure this, the CSSP laboratory shall:

a) Develop a quality assurance plan specific to the laboratory. The QA plan shall:

- describe the organization of the laboratory;
- describe staff training requirements and maintain records of training;
- include written Standard Operating Procedures (SOP’s) for all procedures conducted by the laboratory;
- describe and maintain records for internal quality control measures for equipment calibration, maintenance, repair and performance checks;
- describe laboratory safety issues and maintain applicable records (training, MSDS’s);
- describe and maintain records of internal laboratory performance assessment;
- describe and maintain records of external laboratory performance assessment.

b) Participate in annual proficiency testing programs. For example, each March, the FDA Laboratory Quality Assurance Branch (Summit Argo, Illinois) sponsors an annual shellfish split sample program whereby samples of a mashed potato matrix containing unknown amounts of various bacteria are

shipped to all participating shellfish laboratories. Participating laboratories must comply with biocontainment level 2. The service is free and international in scope.

c) Participate in triennial onsite laboratory evaluations. Continued acceptance of microbiological data in support of the CSSP from any operating CSSP laboratory (government or private) is contingent upon being found to conform or provisionally conform to CSSP requirements as determined during the most recent laboratory evaluation using the most recent version of the CSSP Shellfish Laboratory Evaluation Checklist (see last page of checklist for laboratory approval criteria) This checklist is used during triennial laboratory evaluations conducted by an FDA Laboratory Evaluation Officer (LEO) or a CSSP LEO.

ANNEX IA

CANADIAN SHELLFISH SANITATION PROGRAM

LABORATORY EVALUATION OFFICER

NAME:_____ **AFFILIATION:** _____

REGION: _____

ADDRESS: _____ **Phone:** _____

_____ **Fax:** _____

_____ **E-MAIL:** _____

SHELLFISH LABORATORY EVALUATION CHECKLIST

LABORATORY:		
ADDRESS:		
TELEPHONE:	FAX:	
DATE OF EVALUATION	DATE OF REPORT	LAST EVALUATION
LABORATORY REPRESENTED BY:	TITLE:	
OTHER OFFICIALS PRESENT:	TITLE:	

The CSSP Shellfish Laboratory Evaluation Checklist is based upon references cited in the References section at the end of this Annex. To facilitate the application of the Canada / United States Shellfish Agreement of 1948, this checklist incorporates material from the NSSP Form LAB-100 rev. 8-21-95 and NSSP Form LAB-100 rev. 2001-11-17 checklists with modifications to reflect differences between the CSSP and the NSSP.

The CSSP Laboratory Checklist specifies the operating requirements for laboratories conducting analyses within the confines of the Canadian Shellfish Sanitation Program for the classification of shellfish growing areas and the processing of shellfish for market.

Items which do not conform are noted by: **C - Critical** K - Key O - Other	NA - Not Applicable	Conformity is noted by a check "✓"

CSSP ver. 1-31-02

Check the applicable analytical methods:	
	Multiple Tube Fermentation Technique for Seawater (APHA) [PART II]
	Multiple Tube Fermentation Technique for Seawater using MA-1 [PART II]
	Multiple Tube Fermentation Technique for Shellfish Meats (APHA) [PART III]
	Standard Plate Count for Shellfish Meats [PART III]
	Elevated Temperature Coliform Plate Method for Shellfish Meats [PART III]

PART I -		**QUALITY ASSURANCE**	
CODE	**REF.**	**ITEM**	
K	8, 11	**Quality Assurance Plan**	
			1. Written Plan ***(Check those items which apply)***
			a. Organization of the laboratory.
			b. Staff training requirements.
			c. Standard operating procedures.
			d. Internal quality control measures for equipment calibration, maintenance, repair and for performance checks.
			e. Laboratory safety.
			f Internal performance assessment.
			g. External performance assessment.
K	8		2. QA Plan Implemented.
O	11		3. Participates in a proficiency testing program annually. Specify Program(s) _____

CODE	**REF.**	**Work Area**	
O	8,11		1. Adequate for workload and storage.
K	11		2. Clean, well lighted.
K	11		3. Adequate temperature control.
O	11		4. All work surfaces are nonporous, easily cleaned and disinfected.
K	11		5. Microbiological quality and density of air is < 15 colonies/plate in a 15 minute exposure determined monthly and results recorded.
K	11		6. Pipette aid used, mouth pipetting not permitted.

CODE	REF.	Equipment		
O	9		1.	To determine the pH of prepared media, the pH meter has a standard accuracy of 0.1 pH unit.
O	6		2.	pH electrodes, consisting of pH half cell and reference half cell or equivalent combination electrode (free from Ag/AgCl or contains an ion exchange barrier preventing passage of Ag ions into the medium which may effect the accuracy of the pH reading).
K	6		3.	The effect of temperature on the pH is compensated for by an ATC probe or by manual adjustment.
K	8		4.	pH meter is calibrated daily or with each use and records are maintained.
K	6		5.	A minimum of two standard buffer solutions are used to calibrate the pH meter. The first must be near the electrode isopotential point (pH7). The second near the expected sample pH (i.e., pH 4 or pH 10). (Standard buffer solutions are used once daily and discarded.)
O	8		6.	Electrode effectiveness is determined daily or with each use. Method of determination _____
K	9		7.	Balance provides a sensitivity of at least 0.1 g at a load of 150 g.
K	11		8.	Balance calibrated monthly using NIST Class S or ASTM Class I or 2 weights or equivalent and records are maintained.
K	8		9.	Refrigerator temperature(s) monitored at least once daily and recorded.
K	1		10.	Refrigerator temperature maintained at 0° to 4°C,
C	**9**		**11.**	**The temperature of the incubator is maintained at 35° ± 0.5°C.**
C	**11**		**12.**	**Thermometers used in the air incubator(s) are graduated at no greater than 0.5°C increments.**
K	9		13.	A sufficient number of working thermometers are to be located throughout air incubators in areas of use.
C	**11**		**14.**	**Temperature of the waterbath is maintained at 44.5° ± 0.2°C under any loading capacity (if programmable waterbaths are used, must have capability of also maintaining 35° ± 0.5°C).**
C	**9**		**15.**	**The thermometers used in the waterbath are graduated in 0.1 °C increments.**
O	13		16.	The waterbath has adequate capacity for workload.
K	9		17.	The level of water in the waterbath covers the level of liquid in the incubating tubes.
K	8,11		18.	Air incubator/waterbath temperatures are taken twice daily and recorded (if programmable waterbaths are used, two high setting and one low setting readings shall be taken).
K	13		19.	Working thermometers are tagged with identification, date of calibration, calibrated temperature and correction factor.
K	4		20.	All working thermometers are appropriately immersed.
K	11		21.	A standards thermometer has been calibrated by NIST or one of equivalent accuracy at the points O°, 35° and 44.5°C (45.5°C for ETCP). Calibration records maintained.
K	9		22.	Standards thermometer is checked annually for accuracy by ice point determination. Results recorded and maintained Date of most recent determination _____
K	9		23.	Incubator and waterbath working thermometers are checked annually against the standards thermometer at the temperatures at which they are used. Records maintained.

CODE	REF.		Labware and Glassware Washing
O	9		1. Utensils and containers are clean borosilicate glass, stainless steel or other non-corroding material.
K	9		2. Culture tubes are of a suitable size to accommodate the volume for nutritive ingredients and samples.
K	9		3. Sample containers are made of glass or some other inert material (i.e.. polypropylene).
O	9		4. Dilution bottles and tubes are made of borosilicate glass or plastic and closed with rubber stoppers, caps or screw caps with non-toxic liners.
K	9		5. Graduations are indelibly marked on dilution bottles and tubes or an acceptable alternative method is used to ensure appropriate volumes.
K	9		6. Pipettes used to inoculate the sample deliver accurate aliquots, have unbroken tips and are appropriately graduated. Pipettes larger than 10 mL are not used to deliver 1 mL; nor, are pipettes larger than 1 mL used to deliver 0.1 mL.
K	9		7 Reusable sample containers are capable of being properly washed and sterilized.
K	9		8. In washing reusable pipettes, a succession of at least three fresh water rinses plus a final rinse of distilled/deionized water is used to thoroughly rinse off all the detergent.
C	**9**		**9. In washing reusable sample containers, glassware and plasticware the effectiveness of the rinsing procedure is established annually or when detergent (brand or lot) is changed by the Inhibitory Residue Test as described in the current edition of *Standard Methods for the Examination of Water and Wastewater.* Records are kept.** **Date of most recent testing _____** **Average difference between Groups A and B _____** **Average difference between Groups B and D _____** **Detergent brand_____ Lot _____**
K	11		10. Once during each day of washing several pieces of glassware (pipettes, sample bottles, etc.) from one batch are tested for residual acid or alkali w/aqueous 0.04% bromthymol blue. Records are maintained.

CODE	REF.		Sterilization and Decontamination
O	9		1. Autoclave(s) are of sufficient size to accommodate the workload.
O	8		2. Routine autoclave maintenance performed (e.g. pressure relief values, exhaust trap, chamber drain) and records maintained.
O	8		3. Autoclave(s) and/or steam generators serviced annually or as needed by a qualified technician and records maintained.
C	**11**		**4. Autoclave(s) provides a sterilizing temperature of 121°C (tolerance 121 ± 2°C) as determined weekly using a calibrated working maximum registering thermometer or equivalent (thermocouples, platinum resistance thermometers).**
K	8		5. An autoclave standards thermometer has been calibrated by the National Institute of Standards and Technology (NIST) or its equivalent at 121° C.
K	2		6. The autoclave standards thermometer is checked every five years for accuracy at either 121°C or at the steampoint. Date of most recent determination_____

CODE	REF.		Sterilization and Decontamination
K	11		7. Working autoclave thermometers are checked against the autoclave standards thermometer at 121 °C yearly. Date of last check _____ Method _____
K	11		8. Spore suspensions are used monthly to evaluate the effectiveness of the autoclave sterilization process. Results are recorded.
O	2		9. Heat sensitive tape is used with each autoclave batch.
K	8		10. Autoclave sterilization records including length of sterilization, total exposure time and chamber temperature are maintained. Type of record: autoclave log, computer printout or chart recorder tracings. ***(circle appropriate type or types).***
K	11		11. For dry heat sterilized materials, the hot air sterilizing oven provides heating and sterilizing temperature in the range of 160 ° to 180 °C.
K	9		12. A thermometer capable of determining temperatures accurately in the range of 160 ° to 180°C is used to monitor the operation of the hot-air sterilizing oven when in use.
K	8		13. Records of temperatures and exposure times are maintained for the operation of the hot-air sterilizing oven during use.
K	11		14. Spore strips are used quarterly to evaluate the effectiveness of the sterilization process in the hot-air oven. Records are maintained.
K	8		15. Reusable sample containers are sterilized for 60 minutes at 170°C in a hot-air sterilizing oven or autoclaved for 15 minutes at 121 °C.
O	1		16 The sterility of reusable sample containers is determined for each batch/lot.
K	9		17. Reusable pipettes are stored and sterilized in aluminum or stainless steel canisters or equivalent alternative.
K	9		18. Reusable pipettes (in canisters) are sterilized in a hot-air oven at 170°C for 2 hours.
O	2		19. The sterility of reusable pipettes is determined with each batch/lot. Results are recorded and maintained.
K	11		20. Hardwood applicator transfer sticks are properly sterilized.
O	13		21. Spent broth cultures and agar plates are decontaminated by autoclaving for at least 30 minutes before conventional disposal.

CODE	REF		Media Preparation
K	9		1. Media is commercially dehydrated except in the case of medium A-1 which is prepared from the individual components and modified MacConkey Agar which may be prepared from its components.
O	11		2. Dehydrated media and media components properly stored in cool, clean, dry place.
O	11		3. Dehydrated media are labeled with date of receipt and date opened.
C	**12**		**4. Caked or expired media are discarded.**
C	**11**		**5. Make-up water is distilled or deionized (circle one) and exceeds 0.5 megohm resistance or is less than 2 mSiemens/cm conductivity at 25°C to be tested and recorded monthly for resistance or conductivity*(circle the appropriate).***

CODE	REF.		Media Preparation
C	**11**		**6. Make-up water is analyzed for residual chlorine monthly and is at a non-detectable level (< O.1 mg/L). Records are maintained. Specify method of determination_____**
K	11		7. Make-up water is free from trace (< 0.05mg/L) dissolved metals specifically Cd, Cr, Cu, Ni, Pb, and Zn as determined annually with total heavy metal content ≤ 0.1 mg/L and records are maintained.
K	11		8. Make-up water contains < 1000 CFU/mL as determined monthly using the heterotrophic plate count method and records are maintained.
K	11		9. Media are sterilized according to the manufacturer's instructions.
K	9		10. Volume and concentration of media in the tube are suitable for the amount of sample inoculated.
C	**11**		**11. Total time of exposure of sugar broths to autoclave temperatures does not exceed 45 minutes.**
C	**1**		**12. Media sterility and positive and negative controls are run with each lot of commercially prepared media or run with each batch of media prepared from its components as a check for media productivity. Results recorded and records maintained.**
O	9		13. Sterile phosphate buffered dilution water or 0.5% peptone water is used as the sample diluent. *(circle appropriate choice)*
K	11		14. pH is determined after sterilization to ensure that it is consistent with manufacturer's requirements and records are maintained.

CODE	REF.		Storage of Prepared Culture Media
O	9		1. Prepared culture media are stored in a cool, clean, dry space where excessive evaporation and the danger of contamination are minimized.
K	5,11		2. Brilliant green bile 2% broth and A-1 are stored in the dark.
K	13		3. Stored media are labeled with expiration date or sterilization date.
O	9		4. Storage of prepared culture media at room temperature does not exceed 7 days.
O	2		5. Storage under refrigeration of prepared media with loose fitting closures shall not exceed 1 month.
O	11		6. Storage under refrigeration of prepared media with screw cap closures does not exceed 3 months.
K	9		7. All prepared media stored under refrigeration are held at room temperature overnight prior to use. Culture tubes containing any type of precipitate or Durham tubes containing air bubbles are discarded.

PART II - SEAWATER SAMPLES				
CODE	**REF.**	**ITEM**		
		Collection and Transportation of Samples		
C	**11**		**1.**	**Containers are of suitable size to contain at least 100 mL and to allow head space for shaking. Seawater samples are collected in clean, sterile, water tight, properly labeled sample containers.**
K	1		2.	Sample identified with collectors name, harvest area, time and date of collection.
C	**9**		**3.**	**After collection, seawater samples shall be immediately placed in a cooler which is maintained between 0°C and 10°C until examined. Samples are to be delivered to the laboratory within 6 hours of collection of the first sample.**
K	1		4.	A temperature blank is used to determine the temperature of samples upon receipt at the laboratory. Results are recorded and maintained.
C	**9**		**5.**	**Examination of the sample is initiated as soon as possible after collection. However, seawater samples are not to be tested if they are held beyond 8 hours of collection, regardless of refrigeration.**

CSSP ver. 1-31-02

CODE	REF.		Bacteriological Examination of Seawater by the APHA MPN
C	**9**		**1. Lactose broth or lauryl tryptose broth is used as the presumptive medium. *(circle appropriate one)***
C	**9**		**2. Sample and dilutions of sample are mixed vigorously (25 times in a 30cm arc in 7 seconds) before inoculation.**
C	**9**		**3. In a multiple dilution series 5 tubes per dilution are used.**
C	**6**		**4. For depuration, a single dilution series of between 5 and 12 tubes may be used.**
K	6		5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN _____ Strength of media used _____
K	9		6. Inoculated media are placed in an air incubator at 35 ° ± 0.5 °C for up to 48 ± 3 hours.
C	**2**		**7. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained. Positive Control _____ Negative Control _____**
K	9		8. Inoculated media are read after 24 ± 2 hours and 48 ± 3 hours of incubation and transferred at both intervals if positive for gas.

CODE	REF.		Confirmed Test for Seawater by APHA MPN
C	**9**		**1. Brilliant green bile 2% broth (BGB) is used as the confirmatory medium for total coliforms.**
C	**9**		**2. EC medium is used as the confirmatory medium for fecal coliforms.**
K	9,11		3. Transfers are made to BGB/EC by either sterile loop or sterile hardwood applicator stick from positive presumptives incubated for 24 and 48 hours ***(circle the method of transfer).***
K	2		4. When the inoculation of both EC and BGB broths is performed using the same loop or transfer stick, the order or inoculation is; EC first followed by BGB.
C	**9**		**5. BGB tubes are incubated at 35° ± 0.5 ° C.**
K	9		6. BGB tubes are read after 48 ± 3 hours of incubation.
C	**9**		**7. EC tubes are incubated in a circulating waterbath at 44.5 ± 0.2° C for 24 ± 2 hours.**
C	**9**		**8. The presence of any amount of gas or effervescence in the culture tube constitutes a positive test.**

CODE	REF.		Computation of results
K	9		1 . Results of multiple dilution tests are read from tables in *Recommended Procedures,* 4th Edition.
K	7		2. Results from single dilution series are calculated from Hoskins equation or interpolated from figure 1 Public Health Report 1621 entitled “Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation tube Method.
K	7,9		3. Results are reported as MPN/100 mL of sample.

CODE	REF.		Bacteriological Examination of Seawater by the MA-1 Method
C	**5**		**1. Medium A-1 sterilized for 10 minutes at 121°C.**
C	**9**		**2. Sample and dilutions of sample are mixed vigorously (25 times in a 30 cm arc in 7 seconds) before inoculation.**
C	**9**		**3. In a multiple dilution series 5 tubes per dilution are used.**
C	**6**		**4. For depuration, a single dilution series of between 5 and 12 tubes may be used.**
K	6		5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated_____ Range of MPN ___ _____ Strength of media used_____ _____
C	**11**		**6. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained.** **Positive control _____ Negative control _____**
C	**5**		**7. Inoculated media are incubated at 35° ± 0.5°C for 3 ± 0.5 hours of resuscitation.**
C	**5**		**8. After 3 ± 0.5 hours resuscitation at 35°C, inoculated media are incubated at 44.5 ± 0.2°C in a circulating waterbath for the remainder of the 24 ± 2 hours.**
C	**5**		**9. The presence of any amount of gas or effervescence in the culture tube constitutes a positive test.**

CODE	REF.		Computation of results
K	9		1. Results of multiple dilution tests are read from tables in Recommended Procedures, 4th Edition.
K	7		2. Results from single dilution series are calculated from Hoskins equation or interpolated from figure 1 Public Health Report 1621 entitled “Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation tube Method.
K	7,9		3. Results are reported as MPN/100 mL of sample.

PART III - SHELLFISH SAMPLES				
CODE	**REF.**		**ITEM**	
		Collection and Transportation of Samples		
C	**9**		**1.**	**A representative sample of shellstock is collected (minimum 10 - 12 live animals).**
K	9		2.	Shellstock is collected in clean, waterproof, puncture resistant containers.
K	9		3.	Shellstock labeled with collector's name, type of shellstock, the source, the harvest area, time, date and place (if market sample) of collection.
C	**9**		**4.**	**Shellstock samples are maintained in dry storage between O° and 10° C until examined.**
C	**1**		**5.**	**Examination of the sample is initiated as soon as possible after collection. However, shellfish samples are not examined if the time interval between collection and examination exceeds 24 hours.**

CODE	**REF.**	**Preparation of Shellstock for Examination**		
K	2		1.	Shucking knives, scrub brushes, and blender jar are (autoclave) sterilized for 15 minutes prior to use.
O	2		2.	Blades of shucking knives are not corroded.
O	9		3.	Prior to scrubbing and rinsing debris off shellstock, the hands of the analyst are thoroughly washed with soap and water.
O	2		4.	The faucet used to provide the potable water for rinsing the shellstock does not contain an aerator.
K	9		5.	Shellstock are scrubbed with a stiff, sterile brush and rinsed under water of drinking water quality.
O	9		6.	Shellstock are allowed to drain in a clean container or on clean towels prior to opening.
K	9		7.	Prior to opening, the hands (or gloved hands) of the analyst are thoroughly washed with soap and water and rinsed in 70% alcohol.
K	9		8.	Shellstock are not shucked directly through the hinge.
C	**9**		**9.**	**Contents of shellstock (liquor and meat) are shucked into a sterile, tared blender jar or other sterile container.**
K	9		10.	At least 100 grams of shellfish meat is used for analysis (based on a minimum of 10 - 12 live animals).
K	9		11.	The sample is weighed to the nearest gram and an equal amount by weight of (tempered for ETCP) diluent is added (to produce a 1 in 2 dilution).
O	9		12.	Sterile phosphate buffered dilution water or 0.5% peptone water is used as the sample diluent ***(circle appropriate choice)***
K	13		13.	Sterile phosphate buffered saline is used as a sample diluent for ETCP procedure
C	**9**		**14.**	**Samples are blended at high speed for 60 to 120 seconds.**
K	9		15.	For other than shellstock, APHA *Recommended Procedures* are followed for the examination of freshly shucked and frozen shellfish meats.

CODE	REF.		MPN Analysis for Fecal Coliform Organisms, Presumptive Test APHA	
C	**9**		1.	**Appropriate strength lactose or lauryl tryptose broth is used as presumptive media in the analysis. *(Circle appropriate choice)***
K	9		2.	Immediately (within 2 minutes) after blending, the ground sample is diluted and inoculated into tubes of presumptive media.
C	**9**		**3.**	**No fewer than 5 tubes per dilution are used in a multiple dilution MPN series.**
C	**9**		**4.**	**From the initial 1 in 2 dilution, a 1 in 10 dilution is prepared (20 g of 1 in 2 dilution added to 80 g diluent). From the 1 in 10 dilution a 1 in 100 dilution is prepared (10 g of 1 in 10 dilution added to 90 g diluent). A 5 tube dilution series is inoculated using 10 mL and 1 mL from the 1 in 10 dilution and 1 mL from the 1 in 100 dilution.**
K	6		5.	In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN _____ Strength of media used_____
C	**11**		**6.**	**Positive and negative control cultures accompany samples throughout the procedure. Records maintained. Positive control _____ Negative control _____**
K	9		7.	Inoculated media are incubated at 35° ± 0.5°C.
K	10		8.	Presumptive tubes are read at 24 ± 2 hours of incubation and transferred if positive.

CODE	REF.		Confirmed Test For Fecal Coliform - APHA	
C	**9**		**1.**	**EC medium is used as the confirmatory medium.**
K	9,11		2.	Transfers are made to EC medium by either sterile loop or hardwood sterile applicator sticks from positive presumptives incubated for 24 hours ***(circle the method of transfer).***
C	**9**		**3.**	**EC tubes are incubated in a circulating waterbath at 44.5° ± 0.2°C. for 24 ± 2 hours.**
K	9		4.	EC tubes are read for gas production after 24 ± 2 hours of incubation.
C	**9**		**5.**	**The presence of any amount of gas or effervescence in the Durham tube constitutes a positive test.**

CODE	REF.		Computation of results	
K	9		1.	Results of multiple dilution tests are read from tables in Recommended Procedures, 4th Edition and multiplied by the appropriate dilution factor.
K	7		2.	Results from single dilution series are calculated from Hoskins equation or interpolated from figure 1- Public Health Report 1621 entitled “Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation tube Method."
K	9		3.	Results are reported as MPN/100 g of sample.

CODE	REF.		Standard Plate Count Method	
K	9		1.	In the standard plate count procedure at least four plates, duplicates of two dilutions, are used to provide 30 to 300 colonies per plate.
K	9		2.	15 to 20 mL of tempered sterile plate count agar is used.
K	9		3.	Agar tempering bath maintains the agar at 44° to 46°C.
O	9		4.	Temperature control of the plate count agar is used in the tempering bath.
K	11		5.	Not more than 1 mL nor less than 0.1 mL of sample or sample dilution is plated.
C	**9**		**6.**	**Samples or sample dilutions to be plated are mixed vigorously (25 times in a 30 cm arc in 7 seconds) before plating.**
K	9		7.	Control plates are used to check the sterility of the air, agar and the diluent.
K	9		8.	Solidified plates are incubated at 35° ± 0.5°C for 48 ± 3 hours inverted and stacked not more than 4 high.
K	9		9.	Quebec Colony Counter or its equivalent is used to provide the necessary magnification and visibility for counting plates.
K	13		10.	A hand tally or its equivalent is used for accuracy in counting.

CODE	REF.		Computation of Results	
K	9		1.	Colony counts determined in accordance with Part III, A, Sections 4.31 through 4.33 *Recommended Procedures,* 4th Edition.
O	9		2.	Colony counts reported as APC/g of sample.

CSSP ver. 1-31-02

CODE	REF.		Bacteriological Examination of Shellfish Using the ETCP
K	9		1. Sample homogenate is cultured within 2 minutes of blending.
K	3		2. Double strength Modified MacConkey Agar is used.
C	**3**		**3. Hydrated double strength Modified MacConkey Agar is heated to boiling, removed from the heat, and boiled again. This agar is never autoclaved.**
K	3		4. Twice boiled, double strength Modified MacConkey Agar and sterile phosphate buffered saline are maintained in a tempering bath at 45° to 50°C until used. Prepared Modified MacConkey Agar is used on the day it is made.
C	**3**		**5. The equivalent of 6 grams of the homogenate is placed into a sterile container and the contents brought up to 60 mL with tempered, sterile phosphate buffered saline.**
K	3		6. Sixty (60) mL of tempered, twice boiled double strength modified MacConkey Agar is added.
K	3		7. Container is gently swirled or rotated to mix contents which are then distributed uniformly over 6 to 8 petri plates.
C	**1**		**8. Media and diluent sterility is determined with each use. Results recorded and records maintained.**
C	**1**		**9. To determine media productivity, positive and negative control cultures are pour plated in an appropriate concentration to accompany samples throughout the procedure.** **Positive control _____ Negative control _____**
C	**3**		**10. Plates are incubated inverted within 3 hours of plating in air at 45.5° ± O.5°C for 18 to 30 hours. Plates are stacked not more than four high.**
C	**3**		**11. Incubator temperature maintained at 45.5° ± 0.5°C.**

CODE	REF.		Expression of Results
K	11		1. Quebec Colony Counter or its equivalent is used to provide the necessary magnification and visibility.
O	13		2. A hand tally or its equivalent is used to aid in counting.
C	**3**		**3. All brick red colonies greater than 0.5 mm in diameter are totaled over all the plates and multiplied by a factor of 16.7 to report results as CFU/100 grams of sample.**

CSSP ver. 1-31-02

REFERENCES

1 Compendium of Methods for the Microbiological Examination of Foods, 2nd Edition, APHA, 1984

2 Good Laboratory Practice.

3 Interim Guides for the Depuration of the Northern Quahog *Mercenaria mercenaria,* Northeast Marine Health Sciences Laboratory, North Kingstown, RI, 1968.

4 NBS Monograph 150, U.S. Department of Commerce, Washington, D.C., 1976.

5 Official Methods of Analyses of the Association of Official Analytical Chemists, 15th Edition, 1990.

6 Proceeding 8th National Shellfish Sanitation Workshop, 1984.

7 Public Health Service, Public Health Report, Reprint # 1621, 1947.

8 Quality Assurance Principles for Analytical Laboratories, Association of Official Analytical Chemists, 1991.

9 Recommended Procedures for the Examination of Sea Water and Shellfish, 4th Edition, American Public Health Association, 1970.

10 Shellfish Sanitation Interpretation #SS-39, Interstate Shellfish Sanitation Conference, 1986.

11 Standard Methods for the Examination of Water and Wastewater, 18th Edition, APHA/WEF/AWWA, 1992.

12 Title 21, Code of Federal Regulations, Part 58, Good Laboratory Practice for Non-clinical Laboratory Study, Washington, D.C.

13 Standard Methods for the Examination of Dairy Products, 16th Edition, APHA, 1992.

LABORATORY:			DATE OF EVALUATION
SHELLFISH LABORATORY EVALUATION CHECKLIST SUMMARY OF NON-CONFORMITIES			
Page	**Item**	**Observation**	**Documentation Required**

LABORATORY STATUS	
LABORATORY:	DATE:
LABORATORY REPRESENTATIVE:	

MICROBIOLOGICAL COMPONENT: (PART I - III)

A. Results

Total # of Critical (C) Non-conformities in Parts I through III _____

Total # of Key (K) Non-conformities in Parts I through III _____

Total # of Critical, Key & Other (O) Non-conformities in Parts I through III _____

B. Criteria for Determining Laboratory Status of the Microbiological Component

1 - Does Not Conform Status: The microbiological component of this laboratory is not in conformity with NSSP requirements if:

a) The total # of Critical non-conformities is ≥4 or

b) The total # of Key non-conformities is ≥13 or

c) The total # of Critical, Key, and Other is ≥18 (not to exceed the Critical and Key Criteria)

2. Provisionally Conforms Status; The microbiological component of this laboratory is determined to be provisionally conforming to NSSP requirements if the number of critical non-conformities is ,≥1 but ≤ 3 (not to exceed Key and Total criteria.)

C. Laboratory Status *(circle appropriate)*

Does Not Conform Provisionally Conforms Conforms

Acknowledgment by Laboratory Director/Supervisor:

All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____

Laboratory Signature: _____ Date _____

LEO Signature: _____ Date _____

CSSP ver. 1-31-02

APPENDIX II

ACTION LEVELS, TOLERANCES AND OTHER VALUES FOR POISONOUS OR DELETERIOUS SUBSTANCES IN SEAFOOD

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 and/or DTX-1..... ≥ 1 ug/g* of digestive tissue

All other Agricultural Chemicals .....> 0.1 ppm

The United States FDA action levels/tolerances for fish products may be found in Chapter 10 of the DFO Fish Products Inspection Manual. The following levels of marine biotoxins also apply in the USA:

PSP.....≥ 80 µg/100 g
Ptychodiscus brevis.....20 mouse units/100 g meats

The value for P. brevis toxin(s) represents a level which is deemed by NSSP to be potentially unsafe for human consumption. The value is not an FDA action level or tolerance.

* Health Canada interim standard.

APPENDIX III

ENFORCEMENT POLICY FOR MOLLUSCS EXCEEDING ESTABLISHED BACTERIOLOGICAL LEVELS

1. Domestic molluscan shellfish (except scallop adductor muscles) or raw products derived therefrom, whether fresh or frozen, are considered satisfactory when they are harvested from an approved or conditionally approved area and the E. coli (for end-of-line product) or faecal coliform (product prior to processing) counts conform to the current DFO Bacteriological Guidelines for Fish and Fish Products. The following policy (step 2) is graphically represented in the attached flow diagram (***in the diagram, all QMP steps are italicized and bold***).

2. a) Should a shellfish sample taken at the plant fail the bacteriological guideline, a QMP review will occur to:

   i) verify that the processor ensures that all shellfish which are accepted are harvested from open areas*;

   ***NOTE**: Should the suspect product originate from another federally registered plant a QMP review should also occur at the originating plant.

   ii) verify that the operation complies with Schedule II, section 14.1 (records for bivalve molluscs (except scallop adductor muscles)); and

   iii) in the case of failure of end-of-line products - verify that all plant records, monitoring and corrective actions have been properly recorded and implemented.

   b) If, after a product failure, a review of the plant's QMP indicates that the plant appears in control of its operation, ten (10) sample units will be taken by DFO at the implicated harvest area for faecal coliform analysis*.

   ***NOTE**: If there is reason to believe that the harvest area classification of the implicated site is not current, the area may be closed without on-site sampling.

   i) Should results from sample units collected from the implicated harvest area be bacteriologically acceptable, no QMP enforcement action shall be implemented*; however, product from the suspect area should be targeted for bacteriological sampling during

the next QMP inspection;

***NOTE**: If the on-site sample confirms approved area status, and the plant has 2 or more rejects out of the five most recent QMP samples, the "incoming product" CCP will be rated as not in control and the plant corrective action(s) taken considered ineffective.

ii) If following the harvest area sampling greater than 10% of the samples exceed 230 (or one sample exceeds 2300) faecal coliforms, the area shall be closed.

The area may be re-sampled* by DFO (10 sample units) after a minimum of 7 days and if results are acceptable the area shall be re-opened.

***NOTE**: This additional sampling is at the discretion of DFO and does not have to be carried out. The area may be kept closed and DOE requested to re-evaluate the area as survey schedules permit.

c) If, after a product failure, a detailed review of the plant's QMP indicates that the plant appears to not be in control of its operation the appropriate QMP action will be implemented (see most recent QMP Enforcement Policy).

3. **Imported** bivalve molluscan shellfish (except scallop adductor muscles) must comply with Section 6.(1)(b) of the Fish Inspection Regulations, i.e. they must originate from a source approved by the Minister. Satisfactory compliance with this requirement, for imported product, shall be in accordance with the Fish Products Inspection Manual (FPIM) Chapter 3, Subject 1.

DFO must receive proper notification of all imported shellfish. This information must be entered into the Inspection Import Management System (INIM) as per the FPIM Chapter 3, Subject 1. If the product is inspected, then all inspection results must also be entered into INIM.

Where an imported lot meets the above requirements but is found to exceed the current DFO Bacteriological Guidelines for Fish and Fish Products:

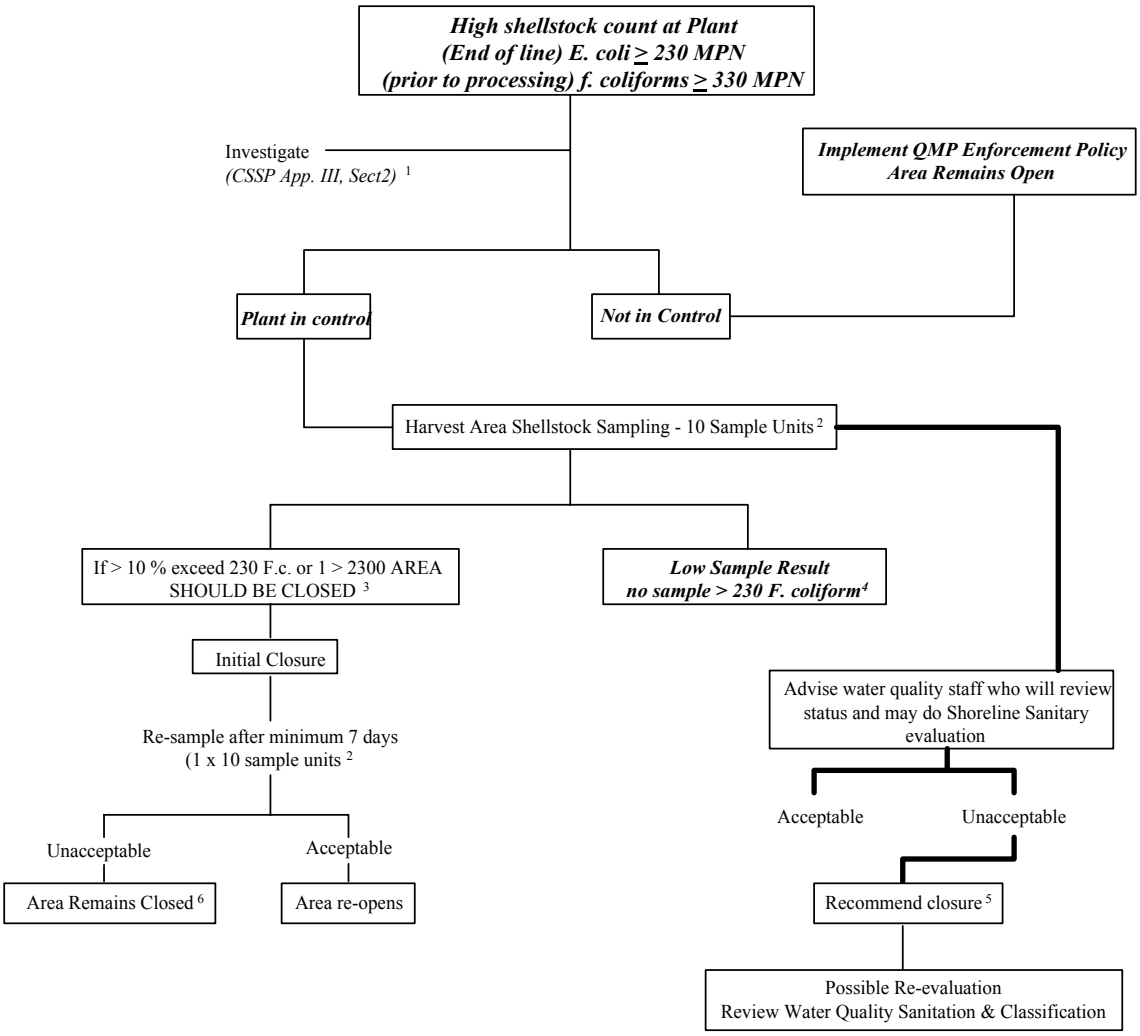
a) the licensed importer shall immediately be notified in writing of the high count using the Fish Inspection Report. The product will then be listed on the Mandatory Inspection List (MIL) until such time as **four** (4) consecutive shipments are satisfactory;

b) NHQ must be informed immediately of the details; and

c) appropriate regulatory officials in the source country shall be informed, by NHQ, of the counts, shipment details and subsequent action proposed.

4. Product detained for exceeding the *E. coli* count may be **reconditioned** by canning if counts do not exceed 4000 *E. coli*/100 grams, or may be disposed of, under DFO supervision, for other than human food purposes.

ENFORCEMENT POLICY FOR MOLLUSCS EXCEEDING ESTABLISHED BACTERIOLOGICAL LEVELS



[1] This includes investigation of originating federally registered plant if that is the source of implicated product.

[2] Samples are to be taken from separate, randomly selected sites in the implicated area.

[3] Where area exceeds faecal coliform bacteriological guideline take no plant action.

[4] When there is no apparent contamination problem at the beach, efforts should be made to target product from the suspect area for bacteriological analysis during the next QMP inspection. If the on-site sample confirms approved area stuatus and the plant has 2 or more rejects out of the five most recent QMP samples, the "incoming product" CCP will be rated as not in control and the corrective action taken considered ineffective.

[5] If water quality staff recommend closure, additional Harvest Area Shellstock Samples need not be taken.

[6] Local Inspection staff need not re-sample area indefinitely. The area may be kept closed and DOE requested to re-evaluate the area as survey schedules permit.

APPENDIX IV

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 growing 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 growing 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

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

CANADIAN FOOD INSPECTION AGENCY ("CFIA")

AND THE

DEPARTMENT OF FISHERIES AND OCEANS ("DFO")

AND

ENVIRONMENT CANADA ("EC")

CONCERNING

THE CANADIAN SHELLFISH SANITATION PROGRAM ("CSSP")

PROTOCOLE D'ENTENTE

ENTRE LE

L'AGENCE CANADIENNE D'INSPECTION DES ALIMENTS (« ACIA »)

ET LE

MINISTÈRE DES PÊCHES ET DES OCÉANS (« MPO »)

ET

ENVIRONNEMENT CANADA (« EC »)

CONCERNANT

LE PROGRAMME CANADIEN DE CONTRÔLE DE LA SALUBRITÉ DES MOLLUSQUES (« PCCSM »)

MEMORANDUM OF UNDERSTANDING

BETWEEN THE CANADIAN FOOD INSPECTION AGENCY ("CFIA")

AND THE

DEPARTMENT OF FISHERIES AND OCEANS ("DFO")

AND

ENVIRONMENT CANADA ("EC")

CONCERNING

THE CANADIAN SHELLFISH SANITATION PROGRAM ("CSSP")

The CSSP is a shared responsibility of the Canadian Food Inspection Agency (CFIA), the Department of Fisheries and Oceans (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

PROTOCOLE D'ENTENTE

ENTRE L'AGENCE CANADIENNE D'INSPECTION DES ALIMENTS (« ACIA »)

ET LE

MINISTÈRE DES PÊCHES ET DES OCÉANS (« MPO »)

ET

ENVIRONNEMENT CANADA (« EC »)

CONCERNANT

LE PROGRAMME CANADIEN DE CONTRÔLE DE LA SALUBRITÉ DES MOLLUSQUES (« PCCSM »)

Le PCCSM relève de la responsabilité commune de l'Agence canadienne d'inspection des aliments (ACIA), du ministère des Pêches et des Océans (MPO) et d'Environnement Canada (EC).

1. OBJET

Le présent Protocole d’entente (PE) reconnaît:

a) que le PCCSM vise à donner une assurance raisonnable que les mollusques constituent des aliments sains, en permettant de contrôler la récolte de tous les mollusques qui se retrouvent dans les eaux de marée du Canada;

b) l’engagement que le

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;

Canada a contracté dans l'Accord bilatéral entre le Public Health Service des États-Unis et le ministère canadien de la Santé et du Bien-être social (maintenant Santé Canada), signé le 30 avril 1948, en vue d'améliorer les mesures d'hygiène adoptées par l'industrie des mollusques des deux pays;

c) the respective responsibilities of CFIA, DFO and EC in delivering the CSSP in Canada, and CFIA's responsibility as lead agency for liaison with foreign governments; and

c) les responsabilités respectives de l'ACIA, du MPO et d'EC dans l'exécution du PCCSM au Canada et la responsabilité de l'ACIA comme organisme compétent pour assurer la liaison avec les gouvernements étrangers;

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.

d) l'engagement mutuel des parties à s'efforcer continuellement d'améliorer l'efficience et l'efficacité de l'exécution du PCCSM, d'aborder les liens avec les enjeux connexes, de communiquer et de collaborer l'une avec l'autre et avec tous les intervenants, de procéder et/ou de participer à des vérifications nationales et/ou internationales et de prendre les mesures de redressement voulues pour apporter les améliorations qui s'imposent.

2. RESPONSIBILITIES OF CFIA

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".

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;

2. RESPONSABILITÉS DE l'ACIA

L'ACIA est l'organisme compétent pour l'administration du PCCSM en ce qui concerne la manutention, la transformation, l'importation et l'exportation des mollusques, le programme de surveillance des biotoxines marines et tout autre programme de surveillance microbiologique non décrit autrement à la section 4 « Responsabilités d'EC ».

L'ACIA est chargée :

a) d'inspecter les usines et de délivrer des certificats d'enregistrement fédéral à celles qui assurent la transformation, la rétention et l'exportation de mollusques selon les exigences réglementaires fédérales;

b) de délivrer des permis aux importateurs de poisson et d'inspecter les mollusques importés;

c) d'administrer le programme de surveillance des biotoxines marines et tout autre programme de surveillance microbiologique des mollusques non autrement décrit à la section 4 - « Responsabilités d'EC »;

d) recommending to DFO the closing of harvesting areas because of unacceptable marine biotoxin, microbiological and chemical levels in shellfish stock, and advising DFO when harvesting areas are acceptable for the harvesting of shellfish;

d) de recommander au MPO la fermeture de secteurs de récolte à cause de niveaux inacceptables de biotoxines marines, de dégradation microbiologique et de substances chimiques dans le stock de mollusques et d'aviser le MPO lorsque les secteurs de récolte sont acceptables pour la pêche des mollusques;

e) reviewing referrals from DFO for the issuing of licences for harvesting from closed areas, for relaying or depuration purposes;

e) de revoir les renvois du MPO pour la délivrance de permis de récolte dans des secteurs fermés à des fins de repar**C**age ou de dépuration;

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;

f) de tenir les dossiers, les bases de données et autres documents justifiant les fermetures pour cause de biotoxines marines, de dégradation microbiologique et de substances chimiques, recommander des mesures de fermeture et des évaluations administratives par des vérificateurs internes et externes;

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

g) d'assurer l'application appropriée des procédures d'analyse et de rapport prescrites dans les laboratoires de l'ACIA et les laboratoires privés approuvés conformément au Manuel des opérations du PCCSM, y compris l'assurance et le

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.

contrôle de la qualité et les normes de rendement des données produites en laboratoire;

h) d'assurer l'application appropriée des procédures prescrites d'échantillonnage par des parties qualifiées, y compris l'assurance et le contrôle de la qualité des échantillons prélevés;

i) d'aider le MPO à mener son activité de notification prévue au paragraphe (3e) et de fournir ou de rendre disponibles aux intéressés des renseignements sur les activités du programme;

j) de mettre en oeuvre les éléments ACIA des plans de gestion élaborés en commun pour les secteurs « agréés sous condition »;

k) de participer au programme de vérification du PCCSM ainsi qu'aux vérifications externes menées par des organismes comme Santé Canada et la Food and Drug Administration des États-Unis.

3. RESPONSIBILITIES OF DFO

DFO shall be the lead agency in the administration of the CSSP

3. RESPONSIBILITÉS DU MPO

Le MPO est l'organisme compétent pour l'administration du PCCSM

with regard to the harvesting of shellfish and shall be responsible for:

a) opening and closing shellfish growing areas on the basis of :

   i) classification recommendations from EC, based on the sanitary and bacteriological water quality of the growing areas, and agreed to by the regional Shellfish Growing Area Classification Committees; and

   ii) recommendations from CFIA on marine biotoxin levels, and microbiological and chemical levels in shellfish growing areas;

b) posting, patrolling and enforcing shellfish closures in accordance with the Fisheries Act;

c) controlling shellfish relaying operations and harvesting for

en ce qui concerne la récolte des mollusques et est chargé :

a) d'ouvrir et de fermer les secteurs de croissance des mollusques d'après :

   i) les recommandations en matière de classification formulées par EC en fonction de la qualité sanitaire et bactériologique des eaux des secteurs de croissance et acceptées par les comités régionaux de classification des secteurs décroissance des mollusques;

   ii) les recommandations de l'ACIA sur les niveaux des biotoxines marines, de la dégradation microbiologique et des substances chimiques dans les secteurs de croissance des mollusques;

b) d'annoncer, de faire patrouiller et de faire observer les fermetures de secteurs de croissance des mollusques conformément à la Loi sur les pêches;

c) de contrôler les opérations de reparcage des mollusques et la

depuration operations;

d) implementing DFO elements of jointly developed Management Plans for "Conditionally Approved" areas;

e) providing notification to 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 growing areas, as well as records of enforcement patrols, in support of reviews by external or internal auditors, and providing CFIA and EC with annual patrol enforcement activity reports;

g) consulting with 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

récolte à des fins de dépuration;

d) de mettre en oeuvre les éléments MPO des plans de gestion élaborés en commun pour les secteurs « agréés sous condition »;

e) de fournir à l'ACIA, à EC, aux intervenants et aux autres intéressés des avis sur les emplacements, les limites et les calendriers des fermetures et des ouvertures de la récolte;

f) de tenir des dossiers sur les ouvertures et les fermetures des secteurs de croissance de mollusques ainsi que sur les patrouilles de surveillance,en soutien pour revues par des vérificateurs externes ou internes, et fournir à l'ACIA et à EC des rapports annuels sur les activités des patrouilles;

g) de consulter l'ACIA et EC avant de commencer toute nouvelle pêche de développement ou d'exploration des mollusques et/ou de délivrer toute nouvelle licence ou tout nouveau permis à cette fin;

h) de participer au programme de vérification du PCCSM

audits by such bodies as Health Canada and the U.S. Food and Drug Administration.

ainsi qu'aux vérifications externes menées par des organismes comme Santé Canada et la Food and Drug Administration des États-Unis.

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 growing 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 Growing Area Classification

4. RESPONSIBILITÉS D'EC

EC est l'organisme compétent pour l'administration du PCCSM en ce qui concerne les recommandations de classification des eaux de croissance des mollusques en fonction des conditions sanitaires et bactériologiques qui y règnent et est chargé :

a) d'effectuer des relevés détaillés de la qualité sanitaire et bactériologique des eaux des secteurs de croissance des mollusques au Canada, selon les critères du Manuel des opérations du PCCSM;

b) de déterminer, à partir des relevés, les sources de pollution ponctuelle et diffuse, le degré et l'étendue de la contamination du secteur, et de recommander l'emplacement des limites des secteurs fermées;

c) de recommander aux comités régionaux de classification des secteurs de croissance

Committees specific classifications of growing areas and their boundaries, on the basis of survey results and the classification definitions in the CSSP Manual of Operations;

des mollusques des classifications des secteurs de croissance et leurs limites en fonction des résultats des relevés, et des définitions à des fins de classification dans le Manuel des opérations du PCCSM;

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;

d) de tenir des dossiers, des bases de données, des cartes sectorielles, des rapports de relevés, des fichiers centraux et d'autres documents justifiant les mesures de classification et les revues administratives par des vérificateurs internes et externes;

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;

e) d'assurer l'application appropriée des procédures d'analyse et de rapports prescrites dans les laboratoires d'EC, les laboratoires privés agréés conformément au Manuel des opérations du PCCSM et les laboratoires sous-contrat avec y compris l'assurance et le contrôle de la qualité des données produites en laboratoire;

f) ensuring proper application of prescribed sampling procedures by qualified parties, including adequate quality assurance and quality control of the collected samples;

f) d'assurer l'application appropriée des procédures prescrites d'échantillonnage par les parties qualifiées, y compris l'assurance et le contrôle de la qualité des échantillons prélevés;

g) promoting pollution prevention, regulatory compliance, remediation and restoration of shellfish growing areas, together with federal/provincial/municipal agencies and other stakeholders;

g) de promouvoir la prévention de la pollution, la conformité aux règlements, la récupération et la restauration des secteurs de croissance des mollusques, de concert avec des organismes fédéraux, provinciaux, municipaux et autres intervenants;

h) supporting DFO in its notification activity pursuant to section 3(e), and providing or making available to interested parties information on program activities;

h) d'aider le MPO à exécuter son activité de notification conformément au paragraphe (3e) et de fournir ou de rendre disponibles aux intéressés des renseignements sur les activités du programme;

i) upon request, providing to DFO available information on water quality for areas proposed;

i) de remettre au MPO, sur demande, les renseignements disponibles sur la qualité des eaux des secteurs proposés à des fins de repar**C**age;

j) implementing EC elements of jointly developed Management Plans for "Conditionally Approved" areas; and

j) de mettre en oeuvre les éléments EC dans les plans de gestion élaborés conjointement pour les secteurs « agréés sous condition »;

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.

k) de participer au programme de vérification du PCCSM ainsi qu'aux vérifications externes menées par des organismes comme Santé Canada et la Food and Drug Administration des

5. ADMINISTRATIVE ARRANGEMENTS

The Assistant Deputy Ministers of DFO and EC and the Vice-President of CFIA hereby establish the Interdepartmental Shellfish Committee to implement this MOU. The Committee shall be composed of representatives of 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

États-Unis.

5. MODALITÉS ADMINISTRATIVES

Le sous-ministre adjoint du MPO et d'EC et le Vice-président de l'ACIA établissent le Comité interministériel des mollusques et le chargent de mettre en oeuvre le présent PE. Le Comité comprend des représentants de l'ACIA, du MPO et d'EC désignés par les directeurs généraux, les administrations centrales nationales et des régions de tout le Canada.

a) Le Comité interministériel des mollusques se réunit si nécessaire mais au moins une fois l'an, pour:

i) discuter du PCCSM et revoir des questions législatives, réglementaires, générales et procédurales nationales d'intérêt commun liées aux mollusques, y compris les modifications proposées au Manuel des opérations du PCCSM;

ii) améliorer la communication et la coordination des activités du PCCSM;

iii) créer des annexes

this MOU covering specific CSSP program delivery and operational issues of mutual concern;

au présent PE portant sur l'exécution d'activités particulières du PCCSM et des questions opérationnelles d'intérêt commun;

iv) establish sub-committees and working groups as required to deal with specific issues, and develop appropriate policies and procedures for dealing with them;

iv) constituer les sous-comités et les groupes de travail requis pour examiner des questions particulières et élaborer les politiques et procédures appropriées à leur égard;

v) advise senior executive management as required about the progress and effectiveness of the CSSP, and make appropriate recommendations;

v) conseiller, la haute direction, au besoin, sur l'état et l'efficacité du PCCSM et formuler les recommandations appropriées;

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

vi) recevoir les mémoires des provinces, de l'industrie des mollusques et des autres intervenants qui se répercutent sur toutes les parties et fournir la réponse interministérielle ou organisationnelle appropriée;

vii) produce an annual

vii) produire un rapport

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 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 Growing 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

annuel.

b) Les réunions du Comité interministériel des mollusques sont présidées, à tour de rôle, par chaque partie, qui en assure le secrétariat. Les recommandations des réunions et le rapport annuel sur l'exécution du Programme sont transmis aux directeurs généraux de l'ACIA et d'EC et au SMA de la Gestion des pêches du MPO pour revue et approbation.

c) Le Comité interministériel des mollusques évalue également les nouveaux modes intégrés et analytiques de gestion et d'inspection du PCCSM et s'engage à consulter les intervenants à leur sujet et sur la façon dont ils pourraient être financés.

d) Des comités régionaux de classification des secteurs de croissance des mollusques sont constitués dans chaque région du Canada où sont récoltés des mollusques. Ils sont présidés par EC, se réunissent si nécessaire, mais au moins une fois l'an, et comprennent les représentants régionaux appropriés de l'ACIA, du

representatives. Stakeholders may participate in working groups and be observers and/or make presentations to the Committees on specific issues.

MPO, d'EC et du gouvernement provincial. Les intervenants peuvent participer aux travaux des groupes de travail et y être des observateurs et/ou présenter aux comités des mémoires sur des questions particulières.

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.

6. MISE EN OEUVRE ET RÉSILIATION

a) Le présent PE entrera en vigueur le Mars 1, 2000.

b) Les parties revoient périodiquement le PE et peuvent le modifier à tout moment par consentement mutuel de chaque partie ou peuvent le résilier sur préavis écrit de 90 jours transmis aux autres.

7. REVIEW

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

7. REVUE

Le président de l'Agence canadienne d'inspection des aliments, le sous-ministre du ministère des Pêches et des Océans et le sous-ministre d'Environnement Canada se réuniront si nécessaire pour revoir le présent protocole d'entente.

8. SIGNATURES

signed by/signé par P.S. Chamut

Assistant Deputy Minister
Fisheries Management
Department of Fisheries
and Oceans

Sous-ministre adjoint
Gestion des pêches
Ministère des Pêches et
des Océans

13/04/2000
Date

signed by/signé par Jean-Pierre Gauthier

Assistant Deputy Minister
Environmental Protection
Service
Environment Canada

Sous-ministre adjoint
Service de la protection
de l'environnement
Environnement Canada

02/05/2000
Date

signed by/signé par André Gravel

Vice-President
Programs
Canadian Food Inspection Agency

Vice-président
Programmes
Agence canadienne
d'inspection des aliments

13/04/2000
Date

8. SIGNATURES

APPENDIX VI

Section 1

SELECTED REFERENCES

AOAC 1990, Official Methods of Analysis of the Association of Official Analytical Chemists. 15th ed. Arlington, VA. Association of Official Analytical Chemists.

Bond, R.M. 1975. Management of PSP in Canada. **In** Proceedings of the First International Conference on Toxic Dinoflagellate Blooms (V.R. LoCicero, ed.), Massachusetts Science and Technology Foundation, pp. 473-482.

Devlin, I.H. 1973. Oyster Depuration Plant-Ladysmith, B.C. Operation Report.

Devlin, I.H. and N. Neufield 1971. Oyster Depuration Plant-Ladysmith, B.C. Operation Report.

DFO 1984a. Fishing Vessel Certification Requirements, Handbook of Compliance, Department of Fisheries & Oceans, 200 Kent St., Ottawa, Ontario, K1A 0E6.

DFO 1984b. Unloading, Handling, Holding and Transportation Requirements, Handbook of Compliance, Department of Fisheries & Oceans, 200 Kent St., Ottawa, Ontario, K1A 0E6.

DFO 1986. Chemical Methods Manual, Department of Fisheries & Oceans, 200 Kent St., Ottawa, Ontario, K1A 0E6.

DFO 1987. Fish Inspection Regulations, Schedules I and II, Handbook of Compliance, Department of Fisheries & Oceans, 200 Kent St., Ottawa, Ontario, K1A 0E6.

DFO 1988. Standard Procedures for Bacteriological Analysis, 3rd edition, Department of Fisheries & Oceans, 200 Kent St. Ottawa, Ontario, K1A 0E6.

DFO 1989. Fish Products Inspection Manual, Department of Fisheries & Oceans, 200 Kent St., Ottawa, Ontario, K1A 0E6.

DFO 1990. Facilities Inspection Manual Vol. 1. Department of Fisheries & Oceans, 200 Kent St., Ottawa, Ontario, K1A 0E6.

DFO Minutes, Interdepartmental Shellfish Committee, 1967 to present, available for review at Inspection Directorate, Ottawa.

Frost, W. J. 1925. Report of Committee on sanitary control of the shellfish industry in the United States. Supplement No. 53, Public Health Reports, Nov. 6, 1925, 17 pp.*

Greenberg, A.E. and D.A. Hunt 1985. Laboratory Procedures for the Examination of Seawater and Shellfish. 5th ed. Washington, D.C. The American Public Health Association, 155 pp..

Health Canada, 1989. Health Protection Branch Laboratories Method HPB-FC-11 March 1989, Liquid Chromatographic Determination of Domoic Acid in Mussels.

Houser, L.S. (ed.) 1964. Proceedings of Fifth National Shellfish Sanitation Workshop, 1964, November 17-19; Washington D.C., 239 p.*

Jensen, E.T. 1955. The 1954 national conference on shellfish sanitation, (first national workshop). Public Health Reports, 79(9).

Jensen, E.T. 1956. Proceedings - 1956 Shellfish Sanitation Workshop, (second national workshop) 1956, August 27-28; Washington, D.C. 143 p.*

Jensen, E.T. 1958. Proceedings - 1958 Shellfish Sanitation workshop, (third national workshop) 1958, August 26-27; Washington, D.C. 72 p.*

Jensen, E.T. 1961. Proceedings - 1961 Shellfish Sanitation Workshop, (fourth national workshop) 1961, November 28-30; Washington, D.C. 288 p.*

Morrison, G. (ed.) 1968. Proceedings of Sixth National Shellfish Sanitation Workshop, 1968, February 7-9; Washington D.C. 115 p.*

Morrison, G. 1977. Memorandum, manual interpretation S.S. 31, Subject: evaluation of independent laboratories. Food and Drug Administration, Bureau of Foods, Washington, D.C., 1977, May 13. Available from: FDA, Shellfish Sanitation Branch, 200 C Street, S.W., Washington, DC 20204.

Neufield, N., Tremblett, A and K. Jackson 1975. Clam Depuration Project, Ladysmith, B.C.

NSSP (see U.S. Food and Drug Administration).

Prakash, A., J. C. Medcof and A.D. Tennant 1977. Paralytic shellfish poisoning in Eastern Canada. Bulletin 177. Fisheries Research Board of Canada, Ottawa, Canada.

Quayle, D. B. 1969. Paralytic shellfish poisoning in British Columbia. Bulletin 168. Fisheries Research Board of Canada, Nanaimo, B.C., Ottawa, Canada.

Ratcliffe, S.D. and D. S. Wilt (ed.) 1971. Proceedings of Seventh National Shellfish Sanitation Workshop, 1971, October 20-22; Washington D.C. 412 p.*

U.S. Food and Drug Administration, 1990 Revision. National Shellfish Sanitation Program Manual of Operations. Part I, Sanitation of Shellfish Growing Areas. Interstate Shellfish Sanitation Conference, P.O. Box 4460, Austin Texas 78765.

U.S. Food and Drug Administration, 1990 Revision. National Shellfish Sanitation Program Manual of Operations. Part II, Sanitation of the Harvesting, Processing and Distribution of Shellfish. Interstate Shellfish Sanitation Conference, P.O. Box 4460, Austin, Texas 78765.

U.S. Food and Drug Administration, 1993 Revision. National Shellfish Sanitation Program Manual of Operations. Part I, Sanitation of Shellfish Growing Areas. Interstate Shellfish Sanitation Conference, P.O. Box 4460, Austin Texas 78765.

U.S. Food and Drug Administration, 1993 Revision. National Shellfish Sanitation Program Manual of Operations. Part II, Sanitation of the Harvesting, Processing and Distribution of Shellfish. Interstate Shellfish Sanitation Conference, P.O. Box 4460, Austin, Texas 78765.

Wilt, D.S. (ed.) 1974. Proceedings of Eighth National Shellfish Sanitation Workshop, 1974, January 16-18; New Orleans LA 158 p.*

Wilt, D.S. 1975. Proceedings of Ninth National Shellfish Sanitation Workshop, 1975, June 25-26; Charleston, SC 150 p.*

Wilt, D.S. 1977. Proceedings of Tenth National Shellfish Sanitation Workshop, 1977, June 29-30; Hunt Valley MD 236 p.*

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

Section 2

GROWING AREA SURVEY AND CLASSIFICATION REFERENCES

APHA 1980. Standard Methods for the Examination of Water and Wastewater. 13th edition. APHA Washington, D.C. (1980).

Bordner, R. and John Winter,(eds.), 1978. Microbiological Methods for Monitoring the Environment: Water and Wastes. U.S. Environmental Protection Agency EPA-600/8-78/017.

Chandler, Linda A., 1982. Indicator organisms. Northeast Technical Services Unit, Shellfish Sanitation Branch, U.S. Food and Drug Administration.

Environment Canada, 1993. Marina Basin Closure Study. Prepared by Bion Research Inc. for the Canadian Shellfish Sanitation Program. 25p plus appendices.

Faust, M.A., 1976. Coliform Bacteria from Diffuse Sources as a Factor in Estuarine Pollution. Water Research, 10: 619-627.

Furfari, S.A., 1979a. Monitoring Programs for Shellfish Growing Areas. In: Shellfish Growing Area Survey and Evaluation Training Course, Lexington, Mass., May 17-21, 1982. U.S. Food and Drug Administration, Northeast Technical Services Unit.

Furfari, S.A., 1979b. Bacteriological Data Analysis. In: Shellfish Growing Area Survey and Evaluation Training Course, Lexington, Mass., May 17-21, 1982.

Furfari, S.A., 1979c. Training Course Manual. Non-point Pollution and Shellfish Sanitation. Department of Health, Eduction, and Welfare, Public Health Service, Food and Drug Administration Northeast Technical Services Unit, Davisville, Rhode Island.

Gameson, A.L.H. (ed.) 1975. Discharge of Sewage from Sea Outfalls. Pergamon Press.

Hoadley, A.W. and B.J. Dutka (eds.), 1977. Bacterial Indicators/Health Hazards Associated with Water, ASTM STP635. American Society for Testing and Materials.

Hunt, D.A., 1977. Indicators of Quality for Shellfish Waters, In: Bacterial Indicators/Health Hazards Associated with Water, ASTM STP635. A.W. Hoadley and B.J. Dutka, eds., pp. 337-345.

Hunt, D.A. and J. Springer, 1977. Comparison of Two Rapid Test Procedures with the Standard EC Test for the Recovery of Faecal Coliform Bacteria from Shellfish Growing Waters. J. Assoc. Off. Anal. Chem. 61(6):1317.

Kay, B.H., 1978. Evaluation of the A-1 Medium for Rapid Recovery of Faecal Coliforms from Marine Waters. Environmental Protection Service Regional Program Report 78-9, Fisheries and Environment Canada.

Menon, A.S., 1977. Evaluation of A-1 Medium for the Rapid Recovery of Faecal Coliforms from Marine Waters. Environmental Protection Service Technology Development Report EPS-4-AR-75.

Mitchell, R. (ed.) 1978. Water Pollution Microbiology. Vol. 2. John Wiley and sons, Inc.

NETSU, 1975. Training Course - Field Techniques in Tracing Sewage Effluents. Prepared by Northeast Technical Service Unit, Food and Drug Administration, Davisville, Rhode Island.

NSSP (see U.S. Food and Drug Administration).

U.S. Environmental Protection Agency, 1990. Technical Guidance Manual for Performing Waste Load Allocations, Book III - Estuaries, Part I - Estuaries and Waste Load Allocation Models. Washington, D.C.

U.S. Food and Drug Administration, 1965. National Shellfish Sanitation Program Manual of Operations. Part 1: Sanitation of Shellfish Growing Areas. U.S. Department of Health, Eduction and Welfare.

Verber, J.L., 1983. Shellfish-Borne Disease Outbreaks. Food and Drug Administration, Northeast Technical Services Unit, Davisville, Rhode Island, USA.

Velz, C.J., 1981. Graphical Approach to Statistics. Reprinted from Water and Sewage Works.

Waller, D.H., 1977. Shellfish Area Contamination in the Maritime Provinces (Vol. 1). Report to Environmental Protection Service, Environment Canada, Atlantic Region, Dartmouth, Nova Scotia.

Woodward, R.L., 1957. How Probable is the Most Probable Number. Journal AWWA 449: 1060-1068.

Section 3

DEPURATION REFERENCES

Arcisz, W., and C.B. Kelly, 1955. Self-purification of the soft clam, Mya arenaria. Public Health Report, 70 (6): 605-14.

Ayres, P.A., 1978. Shellfish purification in installations using ultraviolet light. Lab. Leaflet MAFF Direct. Fish. Res. Lowestaft, (43), 20 pp.

Cabelli, Victor, and W. Paul Heffernan, 1970. Elimination of bacteria by the soft shell clam, Mya arenaria. Journal of the Fisheries Research Board of Canada, 27:1579-87.

Fisheries and Marine Service, and Environmental Protection Service, 1973. Regional guidelines for depuration of shellfish. Unpublished Manuscript 24 pp + VIII.

Furfari, S.A., 1976. Depuration Plant Design. U.S. Department of Health, Education and Welfare. Public Health Service, National Shellfish Sanitation Program, Washington, D.C., 119 pp.

Kelly, C.B., 1961. Disinfection of sea water by Ultraviolet Radiation. American Journal of Public Health, 51 (11): 1670-80.

Menon, A.S., B.J. Richard, and J.P. Donnely, 1983. A Sanitary and bacteriological water quality resurvey of the St. Croix and Estuary. Environmental Protection Service, Environment Canada. Manuscript Report No. AR-83-1.

NSSP (see U.S. Food and Drug Administration).

Piel, Edward, A. Russell Ceurvels, John Der Hovanesian, Jr., and John Pow, 197_. Analysis of depuration for soft-shelled clams at Newburyport, Massachusetts and a program for bacteriological standards. Ches. Sci. 15 (1): 49-52.

Richard, B.J., J.P. Donnelly and A.S. Menon, 1983. Sanitary and bacteriological resurveys, Charlotte County, New Brunswick. Shellfish areas N.B. 9, 10, 12 and 16, 1982, Environmental Protection Service, Environment Canada. Manuscript Report No., AR-82-2.

Rowell, T.W., G. Robert, K.B. Swansburg and R. Davis, 1976. Soft shell clam depuration, Digby, Nova Scotia. Fisheries and Marine Services, Technical Report No. 687 1X + 121 pp.

U.S. Dept. of Health, Education and Welfare, 1982. Shellfish Sanitation, training course manual. Public Health Service, Division of Environmental Engineering and Food Protection.

U.S. Food and Drug Administration, 1986. Sanitation of shellfish growing areas. 1986 Revision. National Shellfish Sanitation Program, Manual of Operations Part I.

U.S. Food and Drug Administration, 1987. Sanitation of the Harvesting, Processing and Distribution of Shellfish. 1987 Revision, National Shellfish Sanitation Program, Manual of Operations Part II.

APPENDIX VII

MANAGEMENT OF CONTAMINATED FISHERIES REGULATIONS

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 specie(s) 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 ug/100g

ii) Domoic Acid - 20 ug/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 specie(s) 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 specie(s) of fish and the reason the specie(s) 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	CH - chemical
S - Scotia Fundy	SN - sanitary
N - Newfoundland	TN - toxin
Q - Quebec	
P - Pacific	
C - Central & Arctic	

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)).

New 20/02/03

APPENDIX VIII

PROTOCOL FOR EMERGENCY CLOSURE OF ANY SHELLFISH GROWING AREA

1. A notification system must be in place to allow DFO to react quickly to close a shellfish growing area that may be affected by an emergency situation such as spill of deleterious substances*.

2. The notification process should require the reporting agency to advise the representatives of shellfish control agencies (DFO, EC, CFIA and appropriate provincial department(s)) in the event of an emergency situation involving a spill of deleterious substances* into a shellfish growing area.

3. During normal working hours, upon notification of the emergency situation, EC will advise DFO if there is a need to implement an emergency closure in the affected shellfish growing area.

4. Outside normal working hours, upon notification of the emergency situation, DFO shall immediately close the affected shellfish growing area as a precautionary measure until further notice from EC and/or CFIA.

5. EC and/or CFIA will advise DFO if there is a need to rescind or modify the size of the precautionary shellfish closure upon receiving more detailed information from the reporting agency. DFO will modify the closure accordingly.

6. The closure will remain in place for at least 7 days. At this time, EC and/or CFIA will evaluate the situation and advise DFO on the status of the closure, as well as a plan for continued evaluation. Once the bacteriological and chemical quality of the water and shellstock is satisfactory, CFIA and EC will advise DFO to reopen the area and notify the provinces of their findings and any further follow-up.

** "deleterious substance" as defined under the Fisheries Act, Section 34 (1).*

APPENDIX IX

PROTOCOL FOR THE MANAGEMENT OF A CONDITIONALLY APPROVED AREA

1. Environment Canada (EC) surveys and recommends that an area be closed but finds that it could be classified as a conditionally approved shellfish growing area. EC defines the water quality criteria for opening and closure of the area based on either the performance of the sewage treatment plant, rainfall and/or seasonal conditions.

2. The Regional Shellfish Classification Committee adopts the recommendation that the area be closed but that upon development and implementation of an appropriate Conditionally Approved Area Management Plan (CAAMP) the area may operate as a conditionally approved area.

3. The Department of Fisheries and Oceans (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 conditionally approved area, the following procedures are to be followed:

    a) A CAAMP 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 and area description (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 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) where there are sewage treatment facilities in the area, the proponent shall ensure that the appropriate federal/provincial/municipal authorities have been consulted and that the CAAMP includes provisions to ensure that all agencies are notified of any spill or release from the facility(ies);

vi) identification of appropriate enforcement, surveillance and control mechanism issues which may arise from the CAAMP (provided by DFO);

b) The proposed CAAMP 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 CAAMP and send to EC, CFIA, (and other agencies) and affected parties for review and signatures. Responsibilities for the evaluation and administration of the CAAMP are as follows:

i) Environment Canada: 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 CFIA, DFO and EC will work together to evaluate all aspects of the CAAMP. Following this evaluation, DFO (or other agency by agreement with DFO) will respond to the proponent, to advise that the CAAMP has been approved

by the three agencies, or that the CAAMP has not been approved. If changes to the CAAMP are required which will facilitate approval of the CAAMP the proponent shall be so advised.

d) Once the CAAMP has been approved, DFO will manage the area in accordance with the CAAMP. In the event of non-compliance with the CAAMP, the harvest area may be closed immediately. Where 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.

e) The Regional Shellfish Classification 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, 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, CFIA, EC or other agency for each opening and closure.

APPENDIX X

PROTOCOL FOR CSSP MANUAL AMENDMENTS

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.