CHAPTER 11

CONTROL OF MARINE BIOTOXINS

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

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

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

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

11.1 Program Responsibilities and Reporting

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

11.2 Sampling of Shellfish Areas

Each CFIA Region must have established sampling sites and frequencies to monitor changes in PSP, ASP and DSP.

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

a. accessibility for sampling at all times of the year;

b. the supply of shellfish available in the area;

c. the defined harvest area that the sample site represents and,

d. the history of toxicity in the area.

In order to maintain reliability of laboratory results, the period of time between the sampling of shellfish and extraction should be uniform and limited. Each sample must be properly packaged and identified with the area of harvest, the species, the date and time of sampling and the sampler's name. Samples should be stored at refrigerated temperatures between 0 ° and 10 °C until extracted.

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

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

CFIA Regions must have in place a program to adequately monitor marine biotoxins. As levels begin to rise, sampling frequency may be increased in accordance with the speed of

the rise to ensure timely closure. The objective is to ensure that shellfish areas are closed when:

i) PSP toxin levels reach 80 µg/100 g

ii) ASP toxin levels reach 20 µg/g

iii) DSP (okadaic acid and/or DTX-1, singly or in combination)toxin levels reach 0.2 µg/g or pectenotoxins levels reach 0.2 µg/g(whole tissue)

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

1) sampling indicates that the toxin levels are rising rapidly, though they have not exceeded the standard, and the next planned sample cannot be obtained and/or analysed within a reasonable timeframe to ensure consumer safety.

2) sampling has shown a spike in toxin levels that are close to the standard, but have not yet exceeded it, and historical information on the area(s) indicate that rising levels will pose a significant threat to consumer safety.

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

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

11.3 Sampling from Processing Plants

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

When registered shellfish processing establishments are monitored the following enforcement policy is applied:

a) Where a shellfish sample collected from a registered processing establishment 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, ≥ 0.2 µg/g or pectenotoxins are ≥ 0.2 µg/g of whole tissue, the production lot should be detained if still available at the plant establishment. If the lot is unavailable the inspector should consult with his/her supervisor on the need for a possible product recall. Any recalls should follow the appropriate CFIA Food Emergency Response Manual requirements. CFIA National Headquarters Fish, Seafood and Production Division National managers are to be advised through the local program manager, on regional recommendations and actions taken. Enforcement actions will be considered as appropriate in accordance with CFIA's Enforcement Policy.

b) Recent results from the suspect shellfish 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 CFIA will recommend that the area should be closed immediately.

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

d) Should the harvest area samples be acceptable and there are no additional high results in samples from other establishments all efforts would be re-directed at the original establishment. A compliance verification is to be initiated and any additional lots sampled as part of the investigation or audit are to be detained until results have been received.

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

species of scallop whole or with roe on, must consult with the CFIA.

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

11.4 Area/Regional/District Management of Marine Biotoxins

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

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

11.6 The status of Harvested Shellfish Products Upon Notification of an Area Biotoxin Closure.

Shellfish areas will be placed in the closed status when marine biotoxin levels (PSP, ASP or DSP) exceed established guidelines. It

is possible in some cases that shellfish can be harvested between the last acceptable sample and the date the area has been closed. In these cases, the following procedures will be used to determine if the shellfish are safe for consumption.

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

CFIA inspectors/specialists must analyze the situation (factors such as toxin level, and timing, species profile/biology, history of harvest area etc.) with their supervisor and the Area Program Network shellfish specialist to determine what, if any, measures should be taken. This may include detaining product affected by the closure. If it is decided a risk assessment is needed it would be done by the National Manager of Technical Standards (FSPD), Senior Policy Analyst for the CSSP, the Program Network Shellfish Specialists, and if applicable, Health Canada and the Office of Food Safety Recall (OFSR)[1].

If affected shellfish is in distribution an IMS file will be opened and the Area Recall Coordinator will be contacted as soon as possible. If there is no affected product in distribution product actions will be documented in the CFIA Fish Products Database(MCAP).

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

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

[1]OFSR involvement is only necessary when products of concern have left the control of the shellfish processing establishment.

returning to the closed area.

Shellfish kept in wet storage systems during marine biotoxin closures (and potentially placed under detention by CFIA) would be evaluated for safety on a case by case basis by the processing facility and by CFIA. In these instances, the product remaining at the facility may be held and may be sampled by CFIA. Sampling by the CFIA would be conducted as per the procedures described in the CFIA Fish Products Standards and Methods Manual.

ANNEX 11A

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 Fisheries and Oceans Canada.

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 licence issued under MCFR or pertinent Regulations will result in its immediate cancellation (Section 9 of the *Fisheries Act)*.

Issued at _____ this _____ day of _____ 2___

_____ Holder

_____ Fisheries Officer