Chapter 11
Control of Marine Biotoxins

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

Any filter feeding bivalve can acquire the toxins, and in Canada, many species of clams, oysters, mussels and scallops have been affected. The rates at which toxins are accumulated and eliminated vary 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) has 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;
b. the amount of shellfish resource in the area;
c. the defined harvest area that the sample site represents; and
d. the history of toxicity in the area.

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

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

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

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

1. sampling indicates that the toxin levels are rising rapidly, though they have not exceeded the standard, and the next planned sample cannot be obtained and/or analysed within a reasonable time frame to ensure consumer safety.
2. sampling has shown a spike in toxin levels that are close to the standard, but have not yet exceeded it, and historical information on the area(s) indicate that rising levels will pose a significant threat to consumer safety.
Areas that are closed based on the scenarios above may be opened earlier than the standard 14 day closure if a subsequent sample (or samples) indicates that the biotoxin levels never reached regulatory standards and the toxicity levels have dissipated.

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

### 11.3 Sampling from Processing Plants

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

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

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

b. Additional harvest area samples will be taken to determine the status of the harvest area(s) as per section 11.5. The duration of closure will be dependent on the biotoxin results of samples from the implicated area and may be a minimum of 14 days.

c. Until such time as samples from the suspect shellfish area are analysed, all production lots (harvested from suspect area since date of last acceptable result) from all establishments should be detained and sampled.

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

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

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

### 11.4 Area/Regional/District Management of Marine Biotoxins

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

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

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

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

### 11.5 Standards Applied and Procedures for Controlling Harvesting

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

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

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

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

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

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

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

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

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