ISSC 2019
Committee Report

Committee Name : Biotoxin
Chairperson: Darcie Couture
Date of Meeting: Multiple Conference Calls 2018-2019

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Charges

Charge 1: Proposal 13-116: Shellfish Quarantine Guidance Document

- Develop a Guidance Document for the use of end product testing in open and closed shellfish harvesting waters.
- Review the March 15, 2017 Biotoxin Workshop Report to better understand how end product testing is currently being used in approved shellfish growing areas.

Findings/Conclusions:

The Committee reviewed both Proposal 13-116 and the March 15, 2017 Biotoxin Workshop Report. The Committee developed a guidance document and also determined there was a need to revise Model Ordinance Chapter IV.

Recommendations:

To allow the Committee to discuss and propose changes to the NSSP Guide, the ISSC Executive Office submitted Proposal 19-149. The Committee recommends Proposal 19-149 language be substituted as below.

Section II. Model Ordinance

Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

A. General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.
(1) Emergency Conditions…
(2) Classification of All…
(3) Boundaries…
(4) Revision of Classifications…
(5) Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be open, closed, controlled access in the case of biotoxins or inactive for the harvesting of shellstock. Supporting information for all changes in the status of growing areas shall be documented by a written record in the central file.
(a) Open Status…
(b) Closed Status…
(c) Controlled Access Status. This status can be applied to allow harvesting in areas with biotoxin concerns where routine monitoring or pre-harvest testing is not practical.
~~(c)~~(d) Reopened Status...
(e) Inactive Status…
(f) Remote Status...
(g) Seasonally Remote/Approved Status...

@.04 Marine Biotoxin Control

A. Contingency Plan.
(1) The Authority shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas addressing the management of PSP, ASP, NSP, diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (AZP) in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred or an illness outbreak caused by marine biotoxins.
(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:
(a) Initiate an emergency shellfish sampling ~~and assay~~ program;
(b) Close growing areas and embargo shellfish;
(c) Prevent harvesting of contaminated species;
(d) Provide for product recall;
(e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent States and federal partners, shellfish industry, and local health agencies;
(f) Coordinate control actions taken by Authorities and Federal agencies; and
(g) Establish reopening criteria including the number of samples over what period of time.

~~**NOTE:** The plan may include other requirements, as deemed necessary by the Authority in the State of landing, to ensure adequate public health protection under the NSSP.~~

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .062

B. Marine Biotoxin Management Plan.
In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton ~~are known~~ have been documented to occur, ~~and~~ the toxins are prone to accumulate in shellfish, and ~~when appropriate at those~~during times when marine biotoxins ~~can be reasonably predicted~~are likely to occur, representative samples of ~~the~~ water ~~may be collected~~ and/or shellfish shall be collected during harvest periods in accordance with one or a combination of the marine biotoxin management strategies listed below in 4. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. ~~The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples may be assayed for the presence of toxin-producing phytoplankton and shellfish meat samples shall be assayed for the presence of toxins.~~

~~**NOTE:** In situations in which the toxin of concern has an established cell count standard, such as *Karenia brevis*, water and shellfish samples would not be required. Management decisions could be made on either water or shellfish sampling results.~~

(1) The Authority shall develop and adopt a marine biotoxin management plan for all marine and estuarine shellfish growing areas if there is a history of biotoxin closures related to PSP, ASP, NSP, DSP, and/or AZP; if toxin-producing phytoplankton ~~are known~~have been documented to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur.

(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:

(a) Maintain a toxin-producing phytoplankton and/or shellfish sampling as described below in (4). It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~Maintain a routine shellfish sampling and assay program including;~~

~~i.Establishment of appropriate shellfish screening levels;~~
~~ii.Establishment of appropriate shellfish screening and testing methods;~~
~~iii.Establishment of appropriate laboratories/analysts to conduct shellfish screening and testing methods;~~
~~iv.Establishment of a sampling plan for both (i) and (ii) above; and~~

~~v.~~i. ~~Other controls as necessary to ensure that shellstock are not harvested when levels of marine biotoxins meet or exceed the established criteria in Section C.~~

(b) Close growing areas and embargo shellfish;

(c) Prevent harvesting of contaminated species;

(d) Provide for product recall;

(e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent States, shellfish industry, and local health agencies;

(f) Coordinate control actions taken by Authorities and Federal agencies; ~~and~~

(g) Establish reopening criteria~~;~~. and

(h) Ensure that all shellfish harvested from growing areas or portion(s) of growing areas placed in the controlled access status meets all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing or product holds.

(3) The Authority may use precautionary closures based on shellfish toxicity screening or phytoplankton sample results as defined in their marine biotoxin management ~~program~~plan. Precautionary closures may be lifted immediately:

(a) if confirmatory testing using an approved method shows the level of biotoxin present in shellfish meats is not equal to or above established criteria as described below in ~~Section~~ C; or

(b) when shellfish toxicity screening or phytoplankton sample results indicate that the precautionary closure was not necessary.

(4) Marine biotoxin management strategies are as follows:~~Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine biotoxins or so remote that adequate sampling cannot be achieved and thus the situation cannot be safely managed, the presence of marine biotoxins shall not affect the classification of the shellfish growing area under Section @.03. The Authority may use the conditionally approved classification for areas affected by marine biotoxins.~~

(a) Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species known or suspected to produce marine biotoxins. This is a complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish and must be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(b) Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species specific shellfish testing is conducted, the highest risk species shall be used. This strategy may be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(c) Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvest. This strategy, if used independent of any other strategy, shall permit harvest for a short period of time following testing. This strategy may be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(d) Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

(e) Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(5) The marine biotoxin management plan ~~may~~ shall include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in ~~designated parts of~~ a ~~State~~ growing area ~~while other parts of the same growing area are~~that is placed in the controlled access~~closed~~ status. Such ~~controlled~~ harvesting shall be conducted with strict assurances of safety and in accordance with the marine biotoxin management strategies listed in (4). ~~In State growing areas or designated portions of State growing waters that are closed, the Authority may allow for harvesting if an end product testing program is developed and samples of each lot are tested and found to be below the action levels specified in Section C.~~

~~The program must include at a minimum:~~

~~(a) Establishment of appropriate pre-harvest screening levels;~~

~~(b) Establishment of appropriate screening and end product testing methods;~~

~~(c) Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods;~~

(d)Establishment of representative sampling plan for both (a) and (b) above;

(e) Disposal of shellfish should end product test results meet or exceed established criteria specified in Section C; and

(f) Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.

(6) Prior to allowing the landing of shellfish harvested from Federal waters where routine monitoring of toxin levels is not conducted, in addition to following State requirements in the Model Ordinance, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:

(a) Harvest permit requirements;

(b) Training for individuals conducting onboard toxicity screening using NSSP methods;

(c) Vessel monitoring;

(d) Identification of shellfish for each harvesting trip to include:

(i) Vessel name and owner;

(ii) Captain's name;

(iii) Person conducting onboard screening tests;

(iv) Port of departure name and date;

(v) Port of landing name and date;

(vi) Latitude and longitude coordinates of designated harvest area;

(vii) Onboard screening test results;

(viii)Volume and species of shellfish harvested;

(ix) Intended processing facility name, address and certification number; and

(x) Captain's signature and date;

(e) Pre-harvested (onboard) sampling that includes a minimum of five (5) samples from the intended harvest area be tested for toxins that are likely to be present harvesting shall not be permitted if any of the pre-harvested samples contain toxin levels in excess of half of the established criteria listed in Chapter IV@.04(1) (e.g., 44 µg/l00 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test for PSP toxins);

~~(f) Submittal of onboard screening homogenates and test results to the Authority in the State of landing;~~

~~(g) The collection of a minimum of seven (7) dockside samples by the Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory; the Authority may require more samples based on the size of the vessel and the volume of shellfish harvested;~~

~~(h) Holding and providing separation until dockside samples verify that toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins);~~

~~(i) Disposal of shellfish when dockside test results meet or exceed the established criteria in Chapter IV@.04C.(1) (e.g., 80 µg /100 g for PSP toxins);~~

~~(j) Notification prior to unloading;~~

~~(k) Unloading schedule;~~

~~(l) Access for Dockside Sampling;~~

~~(m) Record Keeping; and~~

~~(n) Early Warning/Alert System.~~

~~NOTE: The plan may include other requirements, as deemed necessary by the Authority in the State of landing, to ensure adequate public health protection under the NSSP.~~

C. Closed or Controlled Access Status of Growing Areas.

(1) A growing area, or portion(s) thereof as provided in Section A.(4), shall be placed in the closed status for the taking of shellstock when the Authority determines that the number of toxin-forming organisms in the growing waters and/or the level of biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:

(a) PSP - 80 µg saxitoxin equivalents/100 grams
(b) NSP - ~~5,000 cells/L or~~ 20 MU/100 grams (0.8 mg brevetoxin-2 equivalents/kg)
(c) AZP - 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm)
(d) DSP – 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm)
(e) ASP - 2 mg domoic acid/100 grams (20 ppm)

(2) For any marine biotoxin ~~producing organism~~ for which criteria have not been established under this Ordinance, either cell counts of the toxin producing organism in the water column or biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock.

(3) When sufficient data exist to establish that certain shellfish species can be safely exempted ~~from the marine biotoxin management plan~~, the closed status for harvesting may be applied selectively to some shellfish species and not others.

(4) The closed status shall remain in effect until the Authority has data to show that the toxin content of the shellfish in the growing area is below the level established for closing the area.

(5) The determination to return a growing area to the open status shall consider whether toxin levels in the shellfish from adjacent areas are declining.

(6) The analysis upon which a decision to return a growing area to the open status is based shall be adequately documented.

~~(6)~~(7) A growing area, or portion(s) thereof, shall be placed in the controlled access status for the taking of shellstock when the Authority determines that additional requirements are necessary to ensure the safe harvest of product. Controlled access status is a designation of an approved area. Additional requirements shall be included in harvest permit conditions. All shellstock harvested from growing areas in the controlled access status shall be tagged with Restricted Shellstock tags.

D. Heat Processing. If heat processing is practiced, a control procedure shall be developed. This procedure shall define the following:
(1) Toxicity limits for processing;
(2) Controls for harvesting and transporting the shellstock to processor;
(3) Special marking for unprocessed shellstock;
(4) Scheduled processes; and
(5) End product controls on the processed shellfish.

E. Records. The Authority shall maintain a copy of all of the following records.
(1) All information, including monitoring data, relating to the levels of marine biotoxins in the shellfish growing areas;
(2) Copies of notices placing growing areas in the closed status;
(3) Evaluation reports; and
(4) Copies of notices returning growing areas to the open status.

Section IV. Guidance Documents

Chapter II. Growing Areas

.02 Guidance for Developing Marine Biotoxin Plans

Section to be added:

Marine Biotoxin Management Strategies

It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. The Authority initiating biotoxin management plans should employ sampling in accordance with the strategies below until a baseline dataset of at least 36 samples per growing area or hydrographically linked waterbodies is developed. These samples should cover representative environmental conditions and a time span of at least three years. Once this dataset is developed, the Authority may consider modifying sample numbers and frequency in the marine biotoxin management plan in accordance with the strategies below.

A. Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species documented or suspected to produce marine biotoxins. This

complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish must be used in combination with other management strategies.

The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of toxin-producing phytoplankton may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies for a time span of at least three years of phytoplankton counts, comparing with the onset of shellfish toxicity when toxic phytoplankton are present, should be developed before the biotoxin monitoring plan may be modified.

Phytoplankton monitoring can be applied to all growing areas where collecting, transporting and processing water samples is logistically feasible, taking into consideration effects of zooplankton grazing and durability of various cell types to temperature and transport. This management strategy may be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible wild harvest areas and aquaculture sites in state waters or aquaculture sites in federal waters.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

The phytoplankton monitoring strategy shall be used together with one or more of the other biotoxin management strategies. If it were used as the sole management strategy, phytoplankton monitoring would likely misrepresent the actual risk of marine biotoxins. Cell counts, as measured per liter of water, are often used to trigger additional testing of shellfish in biotoxin monitoring programs. These cell count criteria can only be established with a robust data set; therefore, new monitoring programs should employ low cell count criteria to trigger shellfish toxicity samples to establish or refine the cell concentrations responsible for toxins accumulating in shellfish.

When an early warning system such as phytoplankton monitoring detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program. If a plan consists of water sampling for phytoplankton cell counts as surveillance, the Authority should identify its plan to be able to initiate shellfish sampling.

Considerations should be made for how sampling is conducted such as phytoplankton net tows, filtered surface water, or whole water samples. The depth of water sampled should also be considered and evaluated for all species of phytoplankton being targeted. Some species of phytoplankton are known to

display diurnal, vertical migration patterns within the water column, while other species are known to occur in dense patches.

Laboratory and field methods may include, but are not limited to light microscopy, flowcytometry, DNA fingerprinting, rapid toxin detection tests, and PCR assays. Analysts should be trained in each method employed and consideration should be given to complimentary methods of analysis such as light microscopy with phytoplankton identification confirmed by a rapid test at least in the initial phases of the monitoring program.

An appropriate sampling plan, station location, and sampling frequency should all factor in the location and type of the resource being monitored, the species of phytoplankton anticipated or observed, and the environmental conditions that might result in a rapid bloom or trigger the production of toxicity in an existing population. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxic phytoplankton are most likely to first appear, based either on experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Historical occurrences and fluctuations in coastal phytoplankton populations due to the influence of meteorological and hydrographic events are also significant. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom, or a hurricane may drive an offshore phytoplankton bloom onshore. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites.

B. Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species-specific shellfish testing is conducted, the highest risk species (e.g. species that metabolizes toxin most quickly) occurring in the growing area shall be used. Many biotoxin monitoring programs have found mussels to be the best sentential species. This strategy may be used alone or in combination with other management strategies.

The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year.

This management strategy can be applied to all growing areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to, easily accessible wild harvest areas and aquaculture sites in state waters or wild harvest areas and aquaculture sites in federal waters.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

The routine shellfish toxicity monitoring strategy may be used independently or together with one or more of the other biotoxin management strategies. If used as the sole management strategy, predicting future toxicity levels in shellfish and the appropriate sampling frequency can be difficult. Long-term databases can provide valuable historic information on the timing of toxicity occurring in shellfish as well as toxicity depuration from shellfish. Shellfish toxin levels that are below the regulatory levels may trigger emergency or expanded testing, or precautionary closures. Growing areas should be placed in the closed status at a level that provides an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be considered. Precautionary closures can be made in order to prevent the harvest of potentially toxic shellfish while sample results are being collected and processed.

Consideration should be given to the different species of shellfish present in a growing area, the intensity and duration of harmful algal blooms and the uptake and depuration rates of specific toxins from all species of shellfish harvested from the growing areastoxins (e.g., sea scallops).

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14. The Authority should identify laboratories that can perform approved methods for marine biotoxins and identify laboratory capacity.

An appropriate sampling plan, station location and sampling frequency should factor in the location and type of the resource being monitored, the species of shellfish harvested in the growing area and environmental conditions that might affect toxin uptake, such as water temperatures. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxin is most likely to first appear, based either on past experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration.

Sample collection, sample transportation, and sample analysis procedures should be developed, and predictable timeframes established between collection and results. The Authority should ensure that in an emergency, such as a suspected biotoxin illness, the normal timeframe can be compressed, and sample results known as quickly as possible. It is important to consider emergency coverage schedules for staff and lab availability outside of normal office hours during harmful algal bloom events.

When an early warning system detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

C. Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvesting. This strategy, if used independent of any other strategy, shall permit harvest in specific geographic locations and for short durations. This strategy may also be used in combination with other management strategies and should be considered as a complementary strategy while developing datasets for alternative management strategies (e.g. pre-harvest shellfish toxicity testing in combination with phytoplankton monitoring which can evolve into a robust shellfish toxicity monitoring strategy).

This strategy requires representative samples that cover the spatial distribution of the area to be harvested. The duration of permitted harvest following sampling will vary based on the species being tested and the historical database available to inform the sampling strategy. A dataset with at least 36 samples per harvest area shall be developed before the biotoxin monitoring plan may be modified. Without at least 36 samples per harvest area over the span of at least three years, the short duration of permitted harvest shall not exceed three days from the time of shellfish collection for toxicity testing to harvest. The dataset could then be used to modify the duration of permitted harvest.

This management strategy can be applied to harvest areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters. If toxicity in excess of the established threshold in C is detected, the growing area must be either be placed in the closed or controlled access status.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- appropriate duration for permitted harvesting subsequent to sampling.

This strategy is specifically for permitting harvest following shellfish testing. The duration of permitted harvesting will depend on the species being tested, the risk of increasing toxicity and the timing of additional sampling. Samples must be representative of the harvest area.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14.

D. Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

This strategy requires representative samples for each lot of harvested shellstock. Lot testing shall be permitted in growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests are available. A dataset with at least 36 samples per harvest area over the span of at least three years shall be developed before the biotoxin monitoring plan may be modified.

This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency, and;
- representative number of samples per lot.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14.

E. Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing or receipt at the initial certified dealer.

This strategy shall permit harvest in specific geographic locations from growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the growing area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.

This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,

- appropriate sampling frequency,
- a defined harvest area, and;
- representative number of samples.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14.

Section IV. Guidance Documents

Chapter II. Growing Areas

~~**.06 Protocol for the Landing of Shellfish from Federal Waters**~~

~~Harvest of molluscan shellfish in Federal Waters not routinely monitored for toxins in shellfish (such as the Federal waters on Georges Bank closed due to PSP risks) may be authorized provided the Authority in the State of landing in cooperation with appropriate Federal agencies shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The following guidance provides descriptions of the specific information to be included in the protocol.~~

~~A. Harvest Permit Requirements~~

~~If harvesting from Federal waters closed due to toxins, the Authority in the landing State will only allow the landing of shellfish from vessels in possession of an appropriate Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS) by vessels participating in the Federal Vessel Monitoring System (VMS). The NMFS shall receive concurrence from the Authority in the State of landing. Vessels operating in open Federal waters will also need applicable permits.~~

~~B. Training~~

~~The Authority shall ensure that all shipboard persons conducting onboard testing have been trained by a U.S. FDA LEO (LEO) or an FDA marine biotoxin expert to conduct onboard toxin screening using an NSSP recognized method(s). Shipboard persons conducting onboard toxin testing must receive refresher training every three (3) years. A designee of the FDA LEO or FDA marine biotoxin expert may be appointed in writing to provide the training and/or refresher training.~~

~~C. Vessel Monitoring~~

The Authority shall monitor the harvesting location(s) of each landing vessel.

D. Identification of Shellfish

Prior to landing each vessel Captain or Mate shall provide the Authority with a Harvest Record, which may be electronic provided that it is made available to the authorized individual at dockside, for each harvesting trip identifying each lot of shellfish as follows:

1. Vessel name and Federal Fishing Permit number;
2. Name and telephone number of the vessel Captain and vessel owner;
3. Date(s) of harvest;
4. Number of lots and volume of catch per lot or number of containers per lot;
5. Location(s) of harvest (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds);
6. Identification of each harvest lot, including cage tag numbers for surf clams and ocean quahogs, and container numbers or identification codes for other shellfish species;
7. Location (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds) of each toxin screening sample;
8. Results of each toxin screening test; and
9. Destination(s) and purchaser(s) of each lot and amount of each lot to each destination

The Captain or Mate shall sign the Harvest Record. The Harvest Record shall be checked by the individual authorized to sample the harvested shellfish. Failure to provide complete and accurate information will result in revocation or suspension of the NMFS EFP and rejection of the entire lot(s) of harvested shellfish. Four (4) copies of the Harvest Record shall be prepared. One (1) copy shall remain with the vessel, one (1) copy shall be provided to the Authority in the State of landing, one (1) copy shall accompany the catch to the processing firm(s), and one (1) copy shall be retained by the laboratory authorized to conduct lot sample analyses.

Container Labeling:

Each container of shellfish shall be clearly labeled (indelible and legible) with the following NSSP required information at the time of harvest:

1. Surf clams and ocean quahogs existing NMFS tagging requirements.
2. All other molluscan shellfish (including Stimpson clams also known as Arctic surf clams) using durable, waterproof, Authority sanctioned prior to use tags:
   a. Vessel name;
   b. Type and quantity of shellfish;
   c. Date of harvest; and
   d. Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds.

E. Pre-Harvest Sampling

Prior to harvesting of molluscan shellfish, a minimum of five (5) screening samples shall be collected within each area of intended harvest (lot area) and tested for marine biotoxins that are likely to occur in accordance with an NSSP recognized method. Each screening sample shall be collected during a separate and distinct gear tow. Screening sample tows shall be conducted in a manner that evenly distributes the five (5) samples throughout the intended harvest area for each area of intended harvest (see Section H.). Only shipboard officials trained by an FDA LEO or FDA marine biotoxin expert (or their designee as expressly indicated in writing) in the use of the designated NSSP method may conduct these tests. Each of the five (5) samples must test negative for toxins (i.e., below half of the established criteria in Section II. Model Ordinance Chapter IV @04.C. (1)). A positive result from any one (1) sample shall render the lot area unacceptable for harvest. The harvest vessel Captain shall immediately report all positive screening test results, by telephone or email, to the Authority within the intended State of landing, the FDA Shellfish Specialist, and the processor. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s). For each screening test, whether positive or negative, the remaining sample material (homogenate) shall be maintained under refrigeration for later use should the Authority in the State of landing request confirmatory testing using an NSSP recognized method.

Each screening sample shall be comprised of at least twelve (12) whole animals with the exception of mussels and “whole” or “roe-on” scallops. For mussels each sample shall be comprised of thirty (30) animals. For “whole” scallops each sample shall be comprised of twenty (20) scallop viscera and gonads. For “roe-on” scallops each sample shall be comprised of twenty (20) scallop gonads.

F. Submittal of Onboard Screening Homogenates and Test Results

All screening results shall be recorded on the Harvest Record as stipulated in Section D. of this Protocol. Upon landing of the harvest vessel, the Harvest Record and screening homogenates shall be provided to the Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory in the State of landing authorized to sample the harvested shellfish as described in Section G. of this Protocol.

G. Dockside Sampling

~~After dockside samples are collected by the Authority or designee, molluscan shellfish may be processed while awaiting toxin results. Each lot must be identified and segregated during storage while awaiting dockside sample test results. Under no circumstances will product be released from the processor prior to receiving satisfactory toxin results that demonstrate that toxin levels are below the established criteria in Section II. Model Ordinance Chapter IV @04.C.(1).~~

~~The dockside sampling protocol for molluscan shellfish shall be as follows:~~

1. ~~For each lot of molluscan shellfish, a minimum of seven (7) composite samples, each comprised of at least twelve (12) whole animals, shall be taken at random by the individual authorized by the Authority to sample, with the following exceptions:~~
   a. ~~For each lot of mussels, a minimum of seven (7) composite samples, each comprised of at least thirty (30) whole animals, shall be taken at random by the individual authorized to sample.~~
   b. ~~For each lot of "whole" scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop viscera and gonads, shall be taken at random by the individual authorized to sample.~~
   c. ~~For each lot of "roe-on" scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop gonads, shall be taken at random by the individual authorized to sample.~~
2. ~~Shellfish samples collected in accordance with G.1 shall be tested for the presence of toxins using an NSSP recognized method(s).~~
3. ~~Laboratory test results for each lot of shellfish shall be forwarded to the Authority in the State in which the shellfish is being held prior to the product being released by the Authority in the State of landing, or if processed in another State, the Authority in the State of processing.~~

~~H. Holding and Lot Separation~~

~~A harvest lot is defined as all molluscan shellfish harvested during a single period of uninterrupted harvest activity within a geographic area not to exceed three (3) square miles. Once harvesting has ceased and the harvest vessel moves to another location, regardless of the distance, a new harvest lot will be established. Any harvest vessel containing more than one (1)lot shall clearly mark and segregate each lot while at sea, during off loading, and during transportation to a processing facility. Prior to harvesting in Federal waters, each harvest vessel shall submit to the NMFS a written onboard lot segregation plan. The Authority in the intended State of landing and the FDA Shellfish Specialist must approve the proposed lot segregation plan.~~

~~I. Disposal of Shellfish~~

If test results of any one (1) of the seven (7) samples collected in accordance with G.1 equal or exceed the established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) (e.g., 80 µg /100 g for PSP toxins)(n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the Authority in accordance with State laws and regulations except when:

A lot of "whole" or "roe-on" scallops equals or exceeds the established criteria in Section II. Model Ordinance Chapter IV@.04C.(1), the adductor muscle may be shucked from the viscera and/or gonad and marketed. The remaining materials (viscera and/or gonad) must be discarded or destroyed under supervision of the Authority in accordance with State laws and regulations.

Dockside toxin testing shall be according to NSSP recognized methods and shall be conducted by laboratories evaluated in accordance with NSSP guidelines. Private laboratories may be used if evaluated by an LEO in accordance with NSSP guidelines.

J. Notification Prior to Unloading

Prior to the issuance of an EFP, the harvester shall be responsible for notifying the Authority in the State of landing and in a manner approved by the Authority that molluscan shellfish is being harvested for delivery to the intended receiving processor.

Each vessel shall give at least twelve (12) hours' notice to the individual authorized to sample prior to unloading shellfish. Notice of less than twelve (12) hours may be approved by the authorized individual at his/her discretion. Authorities may appoint a designee in writing for sampling and sample transport to the NSSP certified testing laboratory in accordance with the practices and procedures used by the Authority under the NSSP. The procedures, as well as training and certification records, must be available for evaluation.

Shellfish from a Federal water harvest area(s) must be kept separate and not sold until so authorized by the Authority in the State of landing or, if processed in another State, the Authority in the State of processing.

Failure to comply with the provisions of this Protocol will result in the suspension or revocation of the vessel's permits through the NMFS.

K. Unloading Schedule

~~Unloading shall take place between 7:00 A.M. and 5:00 P.M. Monday through Friday, unless otherwise mutually agreed upon by the individual authorized to sample, the processing plant manager, the harvest vessel captain, and the Authority in the State of landing.~~

~~L. Access for Dockside Sampling~~

~~Individuals authorized to sample shall be provided access to the catch of shellfish.~~

~~M. Record Keeping~~

~~Record keeping requirements shall be as follows:~~

~~1. The vessel shall maintain Harvest Records for at least one (1) year.~~
~~2. The processor(s) shall maintain Harvest Records for at least one (1) year or two (2) years if the product is frozen.~~
~~3. The Authority in the State of landing shall retain Harvest Records for at least two (2) years.~~

~~N. Early Warning/Alert System~~

~~Toxin data acquired as a result of onboard screening and dockside testing shall be transmitted to the FDA. These data, both screening and dockside, shall be transmitted to the FDA by the NSSP certified laboratory conducting toxin testing of the sampled lot(s) within one (1) week of the completion of the toxin analyses. The data provided shall include the following:~~

~~1. Shellfish species;~~
~~2. Harvest location name and coordinates (GPS or latitude/longitude);~~
~~3. Harvest date;~~
~~4. Onboard screening test method, date, and results; and~~
~~5. Laboratory test date, test method, and test results for dockside samples.~~

~~Results of all samples having acceptable levels of toxins (e.g.,<80 µg/100 g for PSP toxins) shall immediately be reported to the Authority in the State of landing. If the results of any one (1) sample equal or exceed the established criteria in Chapter IV @.04(c)(1) the testing laboratory shall immediately notify the FDA Shellfish Specialist, the Authority, and the processor by telephone. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s).~~

~~NOTE: Due to the resources necessary to meet the requirements of this Protocol, Authorities (may find it necessary to require industry to fund associated costs. These costs may include sample collection, screening, transportation, analysis, inspection, enforcement, and other related expenses.~~