

	<p>Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting</p>	<p>a. <input checked="" type="checkbox"/> Growing Area b. <input type="checkbox"/> Harvesting/Handling/Distribution c. <input type="checkbox"/> Administrative</p>
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Proposal Subject	Marine Biotoxin Control	
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.01 A. Chapter IV. Shellstock Growing Area @.04	
Text of Proposal/ Requested Action	<p>Section II. Model Ordinance</p> <p>Chapter II. Risk Assessment and Risk Management</p> <p>@.01 Outbreaks of Shellfish-Related Illness.</p> <p style="margin-left: 40px;">A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish<u>shellfish toxicity associated with marine biotoxins (PSP)</u>), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:</p> <ul style="list-style-type: none"> (1) Each consumer's food history; (2) Shellfish handling practices by the consumer and/or retailer; (3) Whether the disease has the potential or is known to be transmitted by shellfish; and (4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent. <p>Chapter IV. Shellstock Growing Areas Management</p> <p>@.04 Marine Biotoxin Control.</p> <p style="margin-left: 40px;">A. Contingency Plan.</p> <ul style="list-style-type: none"> (1) The Authority shall develop and adopt a marine Biotoxin contingency plan for all marine and estuarine shellfish growing areas <u>addressing the management of PSP, ASP, NSP, DSP and 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.</u> (2) The plan shall define the administrative procedures and resources necessary to accomplish the following: <ul style="list-style-type: none"> (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, shellfish industry, and local health agencies; ~~and~~

(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.

~~(3) Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine Biotoxins that 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.~~

~~(4) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a State growing area while other parts of the same growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety. 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; and~~

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

~~(5) Prior to allowing the landing of shellfish harvested from federal waters closed due to periodic toxic algal blooms associated with PSP, and where routine monitoring of saxitoxin levels is not conducted, 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~~
- ~~(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 saxitoxins. Harvesting shall not be permitted if any of the pre harvested samples contain saxitoxin levels in excess of 44 µg/100 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test.~~
- ~~(f) Submittal of onboard screening homogenates and test results to the authority in the state of landing.~~
- ~~(g) The collection and saxitoxin level testing of a minimum of seven (7) dockside samples. The SSCA 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 saxitoxin levels are below 80 µg/100 g.~~
- ~~(i) Disposal of shellfish should dockside test results exceed 80 µg /100 g.~~
- ~~(j) Notification prior to unloading.~~
- ~~(k) Unloading schedule.~~
- ~~(l) Access for Dockside Sampling.~~
- ~~(m) Record Keeping.~~
- ~~(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.

B. Marine Biotoxin Monitoring Management Plan .

In those areas that have been implicated in an illness outbreak or where toxin-~~producing forming phytoplankton organisms~~ are known to occur ~~periodically~~ and the toxins are prone to accumulate in shellfish, and when appropriate at those times when marine ~~B~~biotoxins can be reasonably predicted to occur, representative samples of the water may be collected and/or shellfish shall be collected during harvest periods. The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples ~~will~~may be assayed for the presence of toxin-~~producing forming organisms phytoplankton~~ and shellfish meat samples shall be assayed for the presence of toxins.

(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, or AZP; if toxin-producing phytoplankton are known 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 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. 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.

(3) The Authority may use precautionary closures based on screening or water sample results as defined in their marine biotoxin management program. Precautionary closures may be lifted immediately if confirmatory testing using an approved method shows toxin-producing phytoplankton in the growing waters and/or the level of biotoxin present in shellfish meats are not equal to or above established criteria in Section C.

(4) 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.

(5) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a State growing area while other parts of the

same growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety. 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.
- (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 closed due to periodic toxic algal blooms associated with PSP, and where routine monitoring of saxitoxin levels is not conducted, 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
 - (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 saxitoxins. Harvesting shall not be permitted if any of the pre-harvested samples contain saxitoxin levels in excess of 44 $\mu\text{g}/100\text{ g}$ when using a quantitative test or a positive at a limit of detection of 40 $\mu\text{g}/100\text{ g}$ for the qualitative screening test.

(f) Submittal of onboard screening homogenates and test results to the authority in the state of landing.

(g) The collection and saxitoxin level testing of a minimum of seven (7) dockside samples.

The SSCA 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 saxitoxin levels are

below 80 µg/100 g.

(i) Disposal of shellfish should dockside test results exceed 80 µg /100 g.

(j) Notification prior to unloading.

(k) Unloading schedule.

(l) Access for Dockside Sampling.

(m) Record Keeping.

(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 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 Biotxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:

(a) PSP - ~~cells/L n/a;~~ 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 - ~~cells/L n/a;~~ 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm)

(d) DSP – ~~cells/L n/a;~~ 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm)

(e) ASP - ~~cells/L n/a;~~ 2 mg domoic acid/100 grams (20 ppm)

~~(f) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 µg per 100 g of edible portion of raw shellfish; or~~

~~(g) For neurotoxic shellfish poisoning (NSP), the harvesting of shellstock shall not be allowed~~

~~when:~~

~~(i) The concentration of NSP equals or exceeds 20 mouse units per 100 grams of edible portion of raw shellfish; or~~

~~(ii) The cell counts for *Karenia brevis* organisms in the water column exceed 5,000 per liter; or~~

~~(h) For domoic acid, the toxin concentration shall not be equal to or exceed 20 ppm in the~~

~~edible portion of raw shellfish.~~

~~(i) For azaspiracid shellfish poisoning (AZP), the concentration of azaspiracids shall not be equal to or exceed 0.16 mg/kg (AZA-1 equiv.) in the edible portion of raw shellfish.~~

~~(j) For diarrhetic shellfish poisoning (DSP), the concentration of DSP toxins shall not be equal to or exceed 0.16 mg/kg (OA equiv.) in the edible portion of raw shellfish.~~

(2) For any marine Biotoxin producing organism for which criteria have not been established under this Ordinance, either cell counts 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 ~~B~~biotoxin ~~management~~contingency 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.

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.

<p>Public Health Significance</p>	<p>In response to the ISSC 2015 Summary of Actions, the USFDA requested the ISSC and FDA begin discussion regarding establishment of minimum requirements for sample collection and analysis for safely reopening areas following Biotoxin closures. This effort should include examination of existing practices and the level of safety they provide.</p> <p>In response to this request, the ISSC Executive Board agreed to host a Biotoxin meeting to discuss the Biotoxin issues listed above. States that are frequently involved in Biotoxin closures and reopenings were invited to discuss present state efforts to implement the NSSP Model Ordinance requirements for biotoxin management. The participants agreed that changes should be made to the Model Ordinance and existing biotoxin guidance. These proposed changes were provided to the Biotoxin Committee for comments. This proposal reflects the recommendation developed from that review process.</p>
<p>Cost Information</p>	