

 <p><b>Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting</b></p>	<p>a. <input checked="" type="checkbox"/> Growing Area</p> <p>b. <input type="checkbox"/> Harvesting/Handling/Distribution</p> <p>c. <input type="checkbox"/> Administrative</p>
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Proposal Subject	Marine Biototoxin Control Guidance
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II .02
Text of Proposal/ Requested Action	<p><b>Chapter II. Growing Areas</b> <b>.02 Guidance for Developing Marine Biototoxin <span style="color: blue;">Contingency</span> Plans.</b></p> <p>NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, <span style="color: red;"><u>which includes the requirements of the program and summaries of the requirements for that component.</u></span> NSSP <i>Model Ordinance</i> requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.</p> <p><b>Introduction</b></p> <p><span style="color: red;"><u>Shellfish are filter feeders and, therefore, they have the ability to concentrate toxigenic dinoflagellates toxic phytoplankton</u></span> from the water column when present in shellfish growing waters. The toxins produced by <span style="color: blue;"><u>these dinoflagellates certain species of phytoplankton</u></span> can cause illness and death in humans. Toxins are accumulated in the viscera and/or other tissues of shellfish and <span style="color: blue;"><u>are transferred to humans exposure occurs</u></span> when the shellfish are eaten (Gordan <i>et al.</i>, 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. <span style="color: blue;"><u>Most of these toxins are detected through animal testing. However, some involve the use of instrument based or biochemical analyses for detection. Since the dinoflagellates are naturally occurring, their</u></span>The presence <span style="color: red;"><u>of toxic phytoplankton</u></span> in the water column or traces of their toxin in shellfish meat does not necessarily constitute a health risk, as toxicity is dependent on concentration (dose) in the shellfish. To protect the consumer, the Authority must evaluate the concentration of toxin present in the shellfish or the <span style="color: blue;"><u>dinoflagellate toxic phytoplankton</u></span> concentration in the water column against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken.</p> <p><span style="color: red;"><u>There are a wide range of methodologies developed for screening and confirmation of toxic phytoplankton and their toxins. Only methods adopted into the NSSP can be implemented for the purpose of confirming toxin concentration levels and making decisions to close or reopen growing areas. Additionally, some screening methods</u></span></p>

have been evaluated by the ISSC and found fit for purpose for the NSSP, thereby providing confidence in their use for specific screening purposes. Toxin methods fall into two categories in the NSSP: Approved Methods for Marine Biotxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 2.) and Approved Limited Use Methods for Marine Biotxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 4.). These methods range from mouse bioassays to immunochromatography and other antibody based platforms to chemical analytical methods such as high performance liquid chromatography (HPLC). Information available in the referenced Tables above provides references for the methods and, as applicable, what limitations are placed on the use of the method within the NSSP. For toxins that have no method adopted into the NSSP, best available science is employed.

There are ~~three (3)~~five (5) types of shellfish poisonings which are specifically addressed in the NSSP Model Ordinance: Paralytic Shellfish Poisoning (PSP), Neurotoxic Shellfish Poisoning (NSP), ~~and~~ Amnesic Shellfish Poisoning (ASP), also known as Domoic Acid poisoning, Diarrhetic Shellfish Poisoning (DSP) and Azaspiracid Shellfish Poisoning (AZP). ~~All three (3)~~Of these five (5) types of shellfish poisoning, PSP, NSP and ASP are the most dangerous. ~~toxins, and~~ PSP and ASP ~~or domoic acid~~ can cause death at sufficiently high ~~exposure concentrations.~~ In addition, ASP can cause lasting neurological damage. PSP is caused by saxitoxins produced by the dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*). The dinoflagellate *Pyrodinium bahamense* is also a producer of saxitoxins. NSP is caused by brevetoxins produced by the dinoflagellates of the genus *Karenia* (formerly *Gymnodinium*). ASP is caused by domoic acid and is produced by diatoms of the genus *Pseudonitzschia*. Certain *Dinophysis* spp. and *Prorocentrum* spp. produce okadaic acid and dinophysin toxins that cause DSP. *Azadinium* spp. is the producer of azaspiracids, which cause AZP.

Both *Alexandrium* and *Karenia* can produce "red tides", i.e. discolorations of seawater caused by blooms of the algae; however, they may also reach concentrations that cause toxic shellfish without imparting any water discoloration. Toxic blooms of these dinoflagellates can occur unexpectedly or follow predictable patterns. The unpredictability in occurrence of toxic blooms was demonstrated in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses (Schwalm, 1973). Historically, *Alexandrium* blooms have occurred between April and October along the Pacific coasts from Alaska to California and in the Northeast from the Canadian Provinces to Long Island Sound (U.S. Public Health Service, 1958); but these patterns may be changing. The blooms generally last only a few weeks and most shellfish (with the exception of some species of clams and scallops which retain the toxin for longer periods) clear themselves rapidly of the toxin once the bloom dissipates. Occurrence of *Karenia* blooms NSP, which is less common, has occurred extends from the Carolinas south and extends throughout the Gulf Coast states. It shows no indication of regular recurrence and shellfish generally take longer to eliminate the toxin (Liston, 1994). DSP and AZP cause similar symptoms mostly related to diarrhea and abdominal pain. DSP toxin-producing phytoplankton have been documented to occur off the coasts of Washington (Trainer et al. 2013) and

Texas (Deeds et al. 2010) as well as off the coast in the Northeast (e.g., Massachusetts [Tong et al. 2015]). While AZP has occurred in the U.S., the contaminated shellfish was imported (Klontz et al. 2009). Harvesting closures in the U.S. have not been documented due to AZP toxins.

The minimum concentration of PSP toxin that will cause intoxication in susceptible persons is not known. Epidemiological investigations of PSP in Canada, however, have indicated 200 to 600 micrograms of PSP toxin will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of PSP toxin. Investigations indicate that lesser amounts of the toxin have no deleterious effects on humans. Shellfish growing areas should be closed at a PSP toxin level, which provides an adequate margin of safety, since in many instances PSP toxicity levels can change rapidly.

The NSSP Model Ordinance requires that growing areas be placed in the closed status when the PSP toxin concentration is equal to or exceeds the action level of 80 micrograms per 100 grams of ~~edible portion of~~ raw shellfish (FDA, 1977; FDA, 1985).

In shellfish growing areas where low levels of PSP ~~toxin~~ routinely occur, harvesting for thermal processing purposes may be an alternative to consider. Thermal processing as defined by applicable FDA regulations (21 CFR 113) will reduce ~~but not entirely destroy~~ the PSP ~~toxin concentration content~~ of the shellfish via dilution, not destruction. If thermal processing is practiced, the Authority must develop and implement procedures to control the harvesting and transportation of the affected shellfish to the processing plant.

In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karenia brevis*. The most common public health problem associated with *Karenia* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karenia brevis* blooms have been reported in Florida (Center for Disease Control, 1973 [a] and [b]). Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat. The NSSP Model Ordinance mandates that growing areas be placed in the closed status when any NSP toxin is found in shellfish meat at or above 20 MU per 100 grams of shellfish, or when the cell counts for members of the genus *Karenia* in the water column equal or exceed 5,000 cells per liter of water.

ASP is caused by domoic acid, which is produced by diatoms of the genus *Pseudo-nitzschia*. Blooms of *Pseudo-nitzschia* are of ~~relatively short duration~~ varying intensity, duration and extent. ~~However, during the~~ 1991-1992 incident in Washington and a 2015 event on the west coast from Washington to California, high toxin levels persisted for several months (Liston, 1994; McCabe et al. 2016). There was also an extensive event in the Northeast from Maine to Rhode Island in 2016, with different regions showing varying toxicity and species dominance within the bloom. The event started in late September in eastern Maine and ended in October; however, Rhode Island experienced another bloom in February of 2017. The NSSP Model Ordinance requires that growing

areas be placed in the closed status when the domoic acid concentration is equal to or exceeds 20 parts per million in ~~the edible portion of~~ raw shellfish.

The suitability of some growing areas for shellfish harvesting is periodically influenced by the presence of marine biotoxins such as those responsible for PSP, NSP, domoic acid, ASP, DSP and AZP ~~or other marine Biotoxins~~. The occurrence of these toxins is often unpredictable, and the potential for them to occur exists along most coastlines of the United States and other countries having shellfish sanitation Memoranda of Understanding (MOU) agreements with the United States. As a result, states or countries with MOUs with the U.S. need to have management plans and/or make contingency plans to address shellfish-borne intoxications.

### **Controlling Marine Biotoxins in Shellfish**

There are two types of plans defined in the NSSP MO for the control of marine biotoxins. A contingency plan is developed by an Authority that has no history or reason to expect toxin-producing phytoplankton in their growing areas. A marine biotoxin management plan is developed by an Authority that has historic occurrence of toxin-producing phytoplankton and toxicity in shellfish from their growing areas.

#### The Contingency Plan

The contingency plan is primarily for reactive management to an illness outbreak or an emergence of a toxin-producing phytoplankton in a growing area that has not historically occurred before. The contingency plan must describe administrative procedures, laboratory support, sample collection procedures, ~~and~~ patrol procedures to be implemented on an emergency basis and reopening criteria ~~in the event of the occurrence of shellfish toxicity~~ (Wilt, 1974). The contingency plan is only appropriate for a shellfish Authority that has no history or reason to expect toxin-producing phytoplankton in their growing areas. The primary goal of ~~this planning the~~ contingency plan should be to ensure that maximum public health protection is provided. To achieve this goal the following ~~objectives~~ elements should be ~~met~~ included:

- A process for immediate precautionary closures;
- A sampling plan that considers water samples to evaluate the extent and intensity of the toxic phytoplankton distribution;
- A sampling plan that considers species-specific shellfish sampling;
- Access to biotoxin tests: both screening and approved methods;
- Trained staff to carry out sample collection and testing if necessary; and
- A reopening criteria.

~~\*An early warning system should be developed and implemented.~~

~~\*Procedures should be established to define the severity of occurrences.~~

~~\*The state or MOU country should be able to respond effectively to minimize illness.~~

~~\*Adequate intelligence and surveillance information should be gathered~~

~~and evaluated by the Authority.~~

~~\*Procedures should be instituted to return the Biotoxin contaminated areas to the open status of their growing area classification.~~

Under the certification provisions of the NSSP, FDA and receiver states should have the assurance that shellfish producing states or MOU countries are taking and can take adequate measures to prevent harvesting, shipping, and consumption of toxic shellfish. To provide this assurance, the NSSP requires the Authority to develop and adopt a marine Biotoxin contingency plan for all marine and estuarine shellfish growing areas. The Authority's plan should specify how each of the objectives listed above will be accomplished. This document provides recommended guidelines to be used in preparing a plan to meet these objectives.

### The Marine Biotoxin Management Plan

The marine biotoxin management plan is primarily for proactive management of marine biotoxins for growing areas with a history of toxin-producing phytoplankton and toxicity in shellfish and/or a previous illness event or outbreak. The management plan must describe an early warning system, administrative procedures, laboratory support, sample collection procedures, patrol procedures to be implemented and reopening criteria (Wilt, 1974). A management plan is required for a shellfish Authority that has a history of toxin-producing phytoplankton, toxicity in shellfish and/or an illness event or outbreak attributed to their growing areas. A shellfish Authority might have a management plan for certain marine biotoxins like PSP toxins but a contingency plan for toxins like AZP toxins. The primary goal of the management plan should be to prevent illnesses from toxic shellfish and ensure that maximum public health protection is provided. To achieve this goal the following elements should be included:

- An early warning system should be developed and implemented.
- Procedures should be established to define the severity of occurrences.
- The Authority should be able to respond effectively to minimize risk of illness.
- Adequate intelligence and surveillance information should be gathered and evaluated by the Authority.
- Procedures should be instituted to return the biotoxin contaminated areas to the open status of their growing area classification.

### **Recommended Contingency Plan Guidelines**

*\* Provide an early warning system:*

1. Communication procedures should be established with other

appropriate agencies to rapidly report to the Authority any abnormal environmental phenomenon that might be associated with shellfish growing areas such as bird or fish kills, water discoloration or abnormal behavior of shellfish or marine scavengers.

2. The Authorities should establish procedures for health agencies to report any toxin-like illnesses.
3. An early warning phytoplankton and/or shellfish-monitoring program should be implemented.

These monitoring programs should use the "key primary station" (for both phytoplankton and shellfish monitoring) and "critical species" concepts (for shellfish monitoring).

- \* Sampling stations (primary stations) should be located at sites where past experience has shown toxin is most likely to appear first.

- \* When monitoring shellfish, samples should be collected of species which are most likely to

reveal the early presence of toxin and which are most likely to show the highest toxin levels (critical species). For example, mussels have been found to be useful for early PSP detection. Sampling design should always consider what species are present in the growing area and commercially harvested.

- \* The frequencies and ~~periods~~ geographic distribution for collection of samples should be established recognizing the randomness of PSP toxic algal blooms. This assumes several years of baseline data in order to establish stations and sampling plans.

- \* Frequency and geographic distribution of sampling should be adequate to monitor for fluctuations in coastal phytoplankton populations and the influence of meteorological and hydrographic events. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom or a hurricane may drive offshore phytoplankton blooms onshore.

4. Channels of communication concerning shellfish toxicity should be established with other states, countries (in the case of MOU countries), FDA, and other responsible officials. A marine Biotoxin control official should be designated by the Authority to receive and distribute all marine

Biotoxin related information. Consultation with adjacent jurisdictions, marine biologists and

other environmental officials ~~might also be~~ is also useful (Felsing, 1966; Quayle, 1969; Prakash *et al.*, 1971).

\* *Define the severity of the problem:*

1. A procedure should be established to promptly expand the sampling program for marine Biotoxins in the event of increased toxicity/cell counts at any indicator monitoring stations identified within the plan. Sampling stations and frequencies of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing. The procedure should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

2. Information should be available concerning the location of commercial shellfish resource areas and species present in the state.
3. Criteria should be developed to define the circumstances under which growing areas will be placed in the closed status because of marine Biotoxin contamination. The criteria should integrate public health, conservation, and economic considerations. Principal items of concern include consideration of the rapidity with which toxin levels can increase to excessive levels, the inherent delays in sample collection and results, the number of samples required to initiate action, the size of the area to be closed (including a safety zone), and the type of harvesting restrictions to be invoked (all species or specific species). It may be appropriate to close harvesting areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.
4. Procedures should be established to promptly identify which shellfish products or lots might be potentially contaminated, and to determine the distribution of these products or lots.

*\* Respond effectively to minimize illness:*

1. A summary should be provided citing the laws and regulations in the state (or MOU country) that promptly and effectively allow the Authority to restrict harvesting, withdraw interstate shipping permits, and to embargo/recall any potentially toxic shellfish already on the market in the event of a marine Bbiotoxin episodeevent. The plan should clearly define the timeframe involved in taking appropriate legal action.
2. The administrative procedures necessary to place growing areas in the closed status, to withdraw interstate certification of dealers, and to embargo and recall shellfish should be delineated. The timeframe necessary to accomplish these actions should also be specified.
3. A plan should be developed which will define what type of patrol program is necessary to properly control harvesting in toxin contaminated growing areas. The program should be tested to ensure prompt implementation in the event it is needed.
4. Procedures should be developed to promptly disseminate information on the occurrences of toxic phytoplankton blooms to the industry and local health agencies. It is helpful to establish relationships and procedures with other agencies such as the state CDC and Poison Control and authorities in advance of any serious biotoxin event.
5. Procedures should be established to coordinate control activities taken by state and federal agencies or departments and district, regional, or local health authorities.

*\* Gather follow-up data:*

1. Appropriate records of illnesses should be compiled and maintained by the Authority. These records should include data on the incidence of illness and appropriate case history data. This information may be

important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.

2. Records of shellfish sample results from toxin testing should include analysis of trends, detoxification curves, phytoplankton and water sample analyses, and pertinent environmental observations.

3. Whenever possible the Authority should archive shellfish homogenates for additional analysis.

\* *Return growing areas to the open status of their NSSP classification:*

1. Once a growing area is placed in the closed status because of marine Biotoxin contamination, a procedure should be instituted to gather data necessary to decide when the area can be returned to the open status of its classification. A system of representative samples to establish detoxification curves should be part of this procedure.
2. The Authority should develop a set of criteria that must be met before a growing area can be returned to the open status. These criteria should integrate public health, conservation, and economic considerations, and employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin or cell counts are below the closure level. For example, experience has shown that appropriate reopening criteria for PSP include a minimum of three (3) samples collected over a period of at least fourteen (14) days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams of shellfish tissue.
3. A program of consumer education should be continued as long as any area remains in the closed status because of marine Biotoxin contamination.

**References**

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<p>Public Health Significance</p>	<p>This proposal includes modifications to Guidance Document .02 Guidance for Developing Marine Biotxin Contingency Plans. This proposal includes guidance document modifications which support Proposal 17-122.</p>
<p>Cost Information</p>	