**Proposal No. 19-124**

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| **Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting** | 1. a. ☒ Growing Area<br>b. ☐ Harvesting/Handling/Distribution<br>c. ☐ Administrative |

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| 10. Proposal Subject | Marine Biotoxin Control – Guidance Document |
| 11. Specific NSSP Guide Reference | Section IV Guidance Documents Chapter II. Growing Areas Chapter IV. Shellstock Growing Areas .02 |
| 12. Text of Proposal/ Requested Action | **.02 Guidance for Developing Marine Biotoxin Contingency and Management Plans.**<br><br>Regardless of whether a growing area has a history of toxin-producing phytoplankto being able to detect occurrences and take appropriate action to prevent contaminated product from entering commerce is an important part of marine biotoxin control.<br><br>There are two types of plans defined in the NSSP MO for the control of marine biotoxins: a *contingency plan* and a *management plan*.<br><br>The *contingency plan* is primarily for reactive management to an illness outbreak or emergence of a toxin-producing phytoplankton in a growing area that has not historically occurred before. The contingency plan is only appropriate for a shellfish Authority that has no history or reason to expect toxin-producing phytoplankton in th growing areas. The primary goal of the contingency plan is to detect emerging toxins and to outline response activities necessary to prevent additional illnesses (if illness h already occurred) and protect the public's health.<br><br>The *management plan* is primarily for proactive management of marine biotoxins in growing areas with a history of toxin-producing phytoplankton and toxicity in shellfi and/or a previous illness event or outbreak. 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.<br><br>A shellfish authority might have a management plan for certain marine biotoxins, lik PSP toxins, but a contingency plan for toxins like AZP toxins.<br><br>**General Plan Elements**<br><br>Whether the authority is developing a plan to manage biotoxins, or a contingency pla for the unexpected, the plan should address the following elements:<br><br>• Statutory and/or Regulatory Authorities<br>• Resource/Growing Areas and Species |

- Communication
- Control & Response
- Growing Area Reopening Criteria
- Recordkeeping
- Post Event Actions
- Plan Testing, Post Event Activities

**Recommended General Plan Guidelines**

**Statutory and/or Regulatory Authorities*

The authority should prepare a summary of the laws and regulations in the state (or MOU country) that allow the authority to promptly and effectively take actions to prevent or remove potentially toxic shellfish from commerce in the event of a marine biotoxin event, including:

1. close a growing area to harvest;
2. embargo shellfish that has not entered commerce;
3. prevent harvesting of contaminated species;
4. provide for embargo and/or recall of any potentially toxic shellfish already o the market; and
5. withdraw interstate shipping permits.

**Resource/Growing Areas and Species*

As is the case in several aspects of the NSSP MO, the plan should include a list or reference to a list of locations of classified shellfish growing areas and the species present in the area. This is especially important if the authority intends to implement species-specific biotoxin closures as part of the plan.

**Communication*

Information-sharing among government and non-government agencies is critical as p of an effective biotoxin plan, whether contingency or management. As such, the authority should establish and formalize channels of communication with appropriat partner agencies (e.g., wildlife, epidemiology, local health, public safety, public heal and environmental), research or academic organizations (e.g., marine biologists), adjacent shellfish control authorities, industry, and other similar partners in advance any serious biotoxin event.

Information to be communicated includes that which is relevant to early warning as v as control and response, including:

1. abnormal environmental phenomenon that may be associated with a shellfish growing area (e.g., bird, fish, or marine mammal die-offs or abnormal behavior, or water discoloration);
2. occurrences of toxic phytoplankton blooms;
3. toxin-like illness reports in humans;
4. growing area closures (specifically, disseminating information on occurrences and/or toxicity in shellfish meats to adjacent states, industry and local health agencies);

5. coordination of control activities taken by state and federal agencies or departments and district, regional, or local health authorities (e.g., patrol legal actions); and
6. consumer educational outreach during growing area closure periods.

This aspect of the plan may include references to Memoranda of Understanding and tables that outline each partner's roles and responsibilities, and procedures that defin how agencies will maintain contact lists. Model press releases, email notifications, a similar templates may also be useful.

**Control and Response Activities*

An authority's plan should include the following elements to address control and response activities:

1. Growing Area Closure Criteria

   An authority's plan (either contingency or management) should define the circumstances under which the authority will place a growing area in the clo status due to marine biotoxin contamination. The criteria should integrate pu health and economic considerations. Principle considerations include

   * The rapidity with which toxin levels can increase to excessive levels
   * 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 (it may be appropriate to close harvesting areas adjacent to known toxic areas u increased sampling can establish which areas are toxin free and that toxin levels have stabilized); and
   * The type of harvesting restrictions to be invoked (all species or spec species).

   The biotoxin level governing the need to place the growing area in the close status may vary depending on the species of phytoplankton and the species o bivalve shellfish. Since the ability to concentrate biotoxins varies among species, it is possible for one species in a growing area to have safe levels of biotoxin while another species in the same growing area will have dangerous biotoxin concentrations. In this situation, the authority may allow the harves of one species with no adverse public health consequences while prohibiting harvest of another species. In these situations, the authority must closely monitor the growing area and develop a sufficient database for use in makin this determination.

2. Administrative Actions

   The authority should specify the administrative procedures, including timeframes, necessary to place growing areas in the closed status, identify potentially contaminated shellfish products, determine the distribution of the products, and initiate embargo and/or recall activities.

3. Other Control Activities.

   If the authority's statutes or regulation do not allow for a certain administrati action and/or the authority must seek a court order or other legal action, the authority should define the procedures and timeframes, where applicable.

The authority should also refer to, or describe patrol activities relative to growing area closures due to marine toxins.

**Growing Area Reopening Criteria*

The authority's plan should describe how the authority determines that shellfish for commercial harvest in a growing area are safe for harvest and distribution into commerce for human consumption following an event. The protocol should reflect th authority's consideration of the public's health, and economic consequences.

A system of representative samples and other environmental indices are typically use to establish detoxification curves indicating that the level of toxin or cell counts have decreased to acceptable levels. Several authorities require that three (3) samples collected over a period of fourteen (14) days show results below the quarantine limit before reopening the affected area.

**Routine Monitoring Program*

A routine surveillance monitoring program (also referred to as an early warning phytoplankton and/or shellfish-monitoring program) is recommended as part of a marine biotoxin control plan to detect the presence of a "bloom." In describing this program, the authority should include:

1. Geographic Distribution of Primary Sampling Stations
   For both phytoplankton and shellfish monitoring plans, primary sampling stations (also referred to as indicator or sentinel stations) should be located a sites where toxin is most likely to first appear, based either on past experienc or knowledge of site conditions. The geographic distribution for collection o samples should take into consideration the randomness of toxic algal blooms For these reasons, several years of baseline data are often necessary in order establish stations. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites.
2. Determination of Species to be Sampled
   For a monitoring plan, sampling design should always take into account wha commercially-harvested species are present in the growing area and samples should be collected of species which are most likely to reveal the early prese of toxin and are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early detection of an event.
3. Frequency and Timing of Sample Collection
4. Just as location of sampling sites should be carefully considered, the authorit should establish the frequency and period for collection of samples in order t identify an event as early as possible. Historical occurrences and fluctuations coastal phytoplankton populations due to the influence of meteorological and hydrographic events are important considerations. 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 bloom onshore. As well, uptake rates for various species of shellfish being tested is critical in terms of timing.
5. Sample Collection Procedures
6. 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.

7. Identification of Laboratories/Analysts;
   Biotoxin sample results must be provided by an NSSP conforming lab that is utilizing an approved or limited use method. For checklist requirements and additional guidance regarding laboratory evaluation for conformance, see Chapter II Growing Areas. For NSSP requirements, see Section II MO, Chap I Shellfish Sanitation Program, @.03(B).

   The Authority should consider where they can access sample processing for biotoxins that occur or may occur within their jurisdiction, and identify alternative laboratory support, should that support become necessary.

8. Description of Testing Methods, Which May Include Approved Limited Use and Approved Methods
   To control marine biotoxins, the authority must evaluate the concentration of toxin present in the shellfish. In the case of NSP, phytoplankton must be monitored as well as shellfish. Approved and limited use methods are listed the NSSP Guidance Documents.

9. Establishment of Appropriate Screening Levels
   Though the NSSP establishes the toxin levels in shellfish at which a growing area must be closed, many programs implementing early warning systems include phytoplankton cell counts. Additionally, shellfish toxin levels that a below the regulatory levels may trigger emergency or expanded testing, or precautionary closures. Growing areas should be closed at a level that provid an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be conside Precautionary closures can be made in order to prevent the harvest of potentially toxic shellfish while sample results are being collected and processed.

10. Procedures to Expand Sampling if Toxin Levels or Cell Counts Indicate a Harmful Algal Bloom.
    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 station and/or increase the frequency of sampling for marine biotoxins. The procedu 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 an emergency shellfish sampling program

**Recordkeeping*

Records generated as part of a marine biotoxin program may be important in definin the severity of an event, as well as for retrospectively evaluating the adequacy of the

entire control program.

The NSSP requires certain biotoxin-related records be maintained. As such, authority plan should define records to be generated, reviewed, and maintained. Required reco include:

* Monitoring data, including shellfish and phytoplankton and water sample analyses results, relating to levels of marine biotoxins in each growing area;
* Closure and reopening notices;
* Investigation-related documents, including sample results;
* Recall-related records, including public warnings, notification to other states involved in the recall, FDA, and ISSC, recall status reports in accordance with Section II, Chapter II Risk Assessment and Risk Management, @.01(I); and
* Evaluation reports, which may include analyses of trends and detoxification curves.

An authority may also consider maintaining

- Records of reported illnesses that include data on the incidence of illness and appropriate case history data; and
- Pertinent environmental observations.

Whenever possible, the authority's servicing laboratory should archive shellfish homogenates for additional analysis.

**Plan Testing, Post Event Activities*

The authority should test the plan periodically to ensure prompt implementation in th event it is needed. As well, the authority should routinely review data post-event to improve aspects of the authority's plan. Because historical information plays such a critical role in the authority's plan, authorities are highly encouraged to document rationale for significant changes.

**Heat Processing.**

In shellfish growing areas where low levels of PSP 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 the toxin concentration of certain toxins in 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; and must require that the processor provide adequate demonstration of the destruction of the biotoxin and adequate controls to assure that the end product is safe for human consumption.

~~NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, which includes the requirement~~

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| | the program . NSSP *Model Ordinance* requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up-date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.<br><br>**Introductin**<br><br>Shellfish are filter feeders and, therefore, they have the ability to concentrate toxic phytoplankton from the water column when present in shellfish growing waters. T toxins produced by certain species of phytoplankton can cause illness and death in humans. Toxins are accumulated in the viscera and/or other tissues of shellfish and are transferred to humans when the shellfish are eaten (Gordan *et al*., 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected taste. The presence of toxic phytoplankton in the water column or traces of their to in shellfish meat does not necessarily constitute a health risk, as toxicity is depende on concentration (dose) in the shellfish. To protect the consumer, the Authority m evaluate the concentration of toxin present in the shellfish or the toxic phytoplankte concentration in the water column against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken.<br><br>While there is a wide range of methodologies developed for screening and confirmat of toxic phytoplankton and their toxins, methods must be adopted into the NSSP if th are to be implemented for the confirmation of toxins for making decisions to reopen growing areas. Additionally, there are screening methods that have been evaluated b the ISSC and found fit for purpose for the NSSP, thereby providing confidence in the methods for specific screening purposes. Toxin methods fall into two categories in t NSSP: Approved Methods for Marine Biotoxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 2.) and Approved Limited Use Methods for Marine Biotoxin 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, and limitations placed on the use of the method within the NSSP. For tox that have no method adopted into the NSSP, best available science is employed.<br>There are five (5) types of shellfish poisonings which are specifically addressed in th NSSP Model Ordinance: Paralytic Shellfish Poisoning (PSP), Neurotoxic Shellfish Poisoning (NSP), Amnesic Shellfish Poisoning (ASP), also known as Domoic Acid poisoning, Diarrhetic Shellfish Poisoning (DSP) and Azaspiracid Shellfish Poisoning (AZP). Of these five (5) types of shellfish poisoning, PSP, NSP and ASP are the mo dangerous PSP and ASP can cause death at sufficiently high concentrations. In addition, ASP can cause lasting neurological damage. PSP is caused by saxitoxins produced by the dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*). Th dinoflagellate *Pyrodinium bahamense* is also a producer of saxitoxins. NSP is caus 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 Pseudonitzchia. Certain *Dinophysis* spp. and *Prorocentrum* spp. produce okadaic acid and dinophysis toxins that cause DSP. *Azadinium* spp. is the producer o azaspiracids, which cause AZP.Both *Alexandrium* and *Karenia* can produce "red tide i.e. discolorations of seawater caused by blooms of the algae; however, they may als |

~~reach concentrations that may result in toxic shellfish without imparting any water discoloration. Toxic blooms of these dinoflagellates can occur unexpectedly or follo 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 (Schwal 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 th 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. NSP has occurred from the Carolinas and extends throughout the Gulf Coast states. It shows no indication of regular recurrence and shellfish generally tak 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) an Texas (Deeds et al. 2010) as well as off the coast in the northeast (e.g., Massachuset [Tong et al. 2015]).While AZP has occurred in the U.S., the contaminated shellfish v 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, ha 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 PSP toxin. Investigations indicate that lesser amounts of the toxin have no deleterio effects on humans. Shellfish growing areas should be closed at a PSP toxin level, wh provides an adequate margin of safety, since in many instances PSP toxicity levels c change rapidly.~~

~~The NSSP Model Ordinance requires that growing areas be placed in the closed statu 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, 198~~

~~In shellfish growing areas where low levels of PSP 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 PSP toxin concentration 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 Mod Ordinance mandates that growing areas be placed in the closed status when any NS toxin is found in shellfish meat at or above 20 MU per 100 grams of shellfish, or w~~

~~the cell counts for members of the genus *Karenia* in the water column equal or exce~~
~~5,000 cells per liter of water.~~

~~ASP is caused by domoic acid, which is produced by diatoms of the genus *Pseudonitzachia*. Blooms of *Pseudonitzachia* are of varying intensity, duration and extent.. During the 1991-1992 incident in Washington and the 2015 event on the w 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 vary toxicity and species dominance within the bloom. The event started in late Septem in eastern Maine and ended in October; however, Rhode Island experienced anothe bloom in February of 2017.The NSSP Model Ordinance requires that growing area placed in the closed status when the domoic acid concentration is equal to or exceed 20 parts per million 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, ASP, DSP and AZP. The occurrence of these toxins is often unpredictable, a 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 contingency plans to address shellf borne intoxications.~~

**~~Controlling Marine Biotoxins in Shellfish~~**

~~There are two types of plans defined in the NSSP MO for the control of marine biotoxins~~

~~The contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxicity (Wilt, 1974) The primary goal of this planning should be to ensure that maximum public health protection is provided. To achieve this goal the following objectives should be met~~

- ~~*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 a evaluated by the Authority.~~
- ~~*Procedures should be instituted to return the Biotoxin contaminated areas to th open status of their growing area classification.~~

~~Under the certification provisions of the NSSP, FDA and receiver states should hav the assurance that shellfish producing states or MOU countries are taking and can t adequate measures to prevent harvesting, shipping, and consumption of toxic shellf 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 are 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.

**Recommended Contingency Plan Guidelines**

- The process for precautionary closures:
- A sampling plan that considers water samples to evaluate t extent and intensity of the bloom
- A sampling plan that considers species specific shellfish sampling
- Access to screening tests; both rapid and approved method
- Trained staff to carry out sample collection and testing if necessary
- A reopening criteria

*The Marine Biotoxin Management Plan*

The marine biotoxin management plan is primarily for proactive management of marine biotoxins based on a history of toxin-producing phytoplankton and toxicity 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 a history of toxin-producing phytoplankton, toxicity in shellfish and/or an illness ev 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 pl 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 objectives should be met

- 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 illness.
  - Adequate intelligence and surveillance information should be gathe and evaluated by the
  - Authority.
  - Procedures should be instituted to return the biotoxin contaminated area the open status of their
  - growing area classification.

** 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 an toxin-like illnesses.
3. An early warning phytoplankton and/or shellfish monitoring program shoul be implemented.

   These monitoring programs should use the "key station" (for both

phytoplankton and shellfish monitoring) and "critical species" concepts (fo shellfish monitoring).

* Sampling stations should be located at sites where past experience ha 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 th highest toxin levels. For example, mussels have been found to be usefu for early PSP detection.
* The frequencies and periods for collection of samples should be established recognizing the randomness of PSP blooms. This assumes several years of baseline data in order to establish stations and samplin plans.
* Frequency of sampling should be adequate to monitor for fluctuation coastal phytoplankton populations.

4. Channels of communication concerning shellfish toxicity should be establis with other states, countries (in the case of MOU countries), FDA, and other responsible officials. A marine Biotoxin control official should be designa 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 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 count 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. T 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 grow areas will be placed in the closed status because of marine Biotoxin contamination. The criteria should integrate public health, conservation, a economic considerations. Principal items of concern include consideration 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 safe zone), and the type of harvesting restrictions to be invoked (all species or specific species). It may be appropriate to close harvesting areas adjacent t known toxic areas until increased sampling can establish which areas are to free and that toxin levels have stabilized.
4. Procedures should be established to promptly identify which shellfish produ 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 ( 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 Biotoxin event. The plan should clearly define the timeframe involved in taking appropriate legal action.
2. The administrative procedures necessary to place growing areas in the close status, to withdraw interstate certification of dealers, and to embargo and recall shellfish should be delineated. The timeframe necessary to accompli these actions should also be specified.
3. A plan should be developed which will define what type of patrol program necessary to properly control harvesting in toxin contaminated growing are The program should be tested to ensure prompt implementation in the even is needed.
4. Procedures should be developed to promptly disseminate information on th 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 advar of any serious biotoxin event.
5. Procedures should be established to coordinate control activities taken by st and federal
   agencies or departments and district, regional, or local health authorities.

** 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 Biotox 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. system of representative samples to establish detoxification curves should b 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 criter for PSP include a minimum of three (3) samples collected over a period of least fourteen (14) days. These samples should show the absence of PSP o 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**
**Title 21 CFR Part 7**
**References**

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| | 1. Center for Disease Control (a). 1973. Shellfish Poisoning - Florida. *Morbid. Mortal. Weekly Rep*.22(48):397-398.<br>2. Center For Disease Control (b). 1973. Neurotoxic Shellfish Poisoning - Florida. *Morbid. Mortal.Weekly Rep*. 22(48):397-398.<br>3. Felsing, W.A., Jr. 1966. Proceedings of Joint Seminar on North Pacific Cla September 24-25,1965. U.S. Public Health Service, Washington, D.C.<br>4. Food and Drug Administration. 1977. Poisonous or Deleterious Substances Food. *FederalRegister* 42(190):52814-52819.<br>5. Food and Drug Administration. 1985. Action Levels For Poisonous or Deleterious Substances in Human Food and Animal Feed. U.S. Department of Health and Human Services, Public Health Service, Washington, D.C. 20204. 1 pages.<br>6. Gordon, K., M.D., *et al*. 1973. Shellfish Poisoning. *Morbid. Mortal. Weekly Rep*. 22, (48):397-398.<br>7. Liston, J. 1994. Association of *Vibrionaceae*, natural toxins, and parasites v fecal indicators, p.215-216. In Hackney, C.R. and M.D. Pierson (eds.), *Environmental Indicators and Shellfish Safety*. Chapman and Hall, New York,<br>8. Prakash, A., J.C. Medcof, and A. D. Tennant. 1971. Paralytic shellfish poisoning in easternCanada. Bulletin 177, Fisheries Research Board of Canada. Ottawa, Canada.<br>9. Quayle, D.B. 1969. Paralytic shellfish poisoning in British Columbia. Bulle 168, FisheriesResearch Board of Canada. Ottawa, Canada.<br>10. Schwalm, D.J. 1973. The 1972 PSP outbreak in New England. FDA Report Boston, MA. U.S.Food and Drug Administration, Washington, D.C.<br>11. U.S. Public Health Service (PHS). 1958. Proceedings: 1957 Conference on Shellfish Poison. U.S.PHS, Washington, D.C. 125 pages.<br>12. Wilt, D.S. (ed). 1974. Proceedings of Eighth National Shellfish Sanitation Workshop. January 16-18. New Orleans, LA. National Technical Information Services (PB8-6 236916/AS), U.S. Dept. of Commerce, Springfield, VA. 158 p |
| 13. Public Health Significance | Marine biotoxins can cause injury, illness, or death. More clearly presented guidance will assist control authorities in developing marine biotoxin contingency and management plans. |
| 14. Cost Information | None |