Interstate Shellfish Sanitation Conference (ISSC)
Biotoxin Workshop Report
March 14-15, 2017 – Washington, D.C.

I. Purpose

In 2015, the ISSC debated Proposal 15-105 which addressed the National Shellfish Sanitation Program (NSSP) requirements for marine biotoxin sampling for opening growing areas closed due to biotoxins. Although the ISSC voting delegates elected to take "no action" on the proposal, it became apparent from Task Force I discussions that there was a need for a broader understanding of State efforts to address issues associated with biotoxins in molluscan shellfish.

In response to the ISSC 2015 Summary of Actions, the U.S. Food and Drug Administration (FDA) requested the ISSC and FDA begin discussion regarding establishment of minimum requirements for sample collection and analysis for safely reopening areas following marine biotoxin closures. The Summary of Actions stated that this effort should include examination of existing practices and the level of safety they provide.

In response to this request, the ISSC Executive Board agreed to host a Biotoxin Workshop to discuss the biotoxin issues listed above. States that are frequently involved in biotoxin closures and reopenings were invited to participate. The Biotoxin Workshop was held on March 14 & 15, 2017 in Washington, DC.

II. Introduction

The current biotoxin knowledge base in the U.S. appears to be regional and toxin-specific. The ISSC nor the NSSP have a collective repository of information describing the various toxins and control strategies being used by each State to address biotoxins in molluscan shellfish. Many of the toxins presently being managed are not well addressed in the NSSP. Current NSSP language focuses primarily on paralytic shellfish poisoning toxins. The goals of the Biotoxin Workshop were to initiate the development of an information source for biotoxins and control strategies and determine if criteria for reopening growing areas following biotoxin closures could be standardized. The workshop was not intended to identify individual program deficiencies or non-compliance. Each State was asked to provide an overview of their Biotoxin Program. A list of specific questions to be addressed in their overview presentation was provided to each State in advance (see section VII. below for the list of questions). During the workshop, the adequacy and usefulness of both existing Model Ordinance requirements and NSSP Guidance were also discussed.

III. Relevance to Molluscan Shellfish

Shellfish are filter feeders and, therefore, they have the ability to concentrate toxic phytoplankton from the water column when present in shellfish growing waters. The 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 human exposure occurs when the shellfish are eaten (Gordan *et al.,* 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. The presence of toxic phytoplankton 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 Shellfish Control Authority must evaluate the concentration of toxin present in the shellfish, or the toxic phytoplankton concentration in the water column, against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken.

IV. Invitees

The ISSC invited Shellfish Control Authority managers with expertise in biotoxin management to discuss individual state biotoxin management strategies. The invitees are listed below.

A.	Drew Sheehan	Alabama
B.	Kim Stryker	Alaska
C.	Jill Fleiger	Florida
D.	Kohl Kanwit	Maine
E.	Mike Hickey	Massachusetts
F.	Chris Nash	New Hampshire
G.	Alex Manderson	Oregon
H.	Kirk Wiles	Texas
I.	Jerry Borchert	Washington
J.	Vanessa Zubkousky-White	California

V. Format

Welcome & Purpose and Meeting Format & Objectives

Review of Biotoxin Matrix

State Program Reports

FDA Biotoxin Role in the NSSP

Discussion of Existing NSSP Model Ordinance Requirements

Discussion of NSSP Guidance

Discussion of State Programs/Presentations

Discussion of Recommendations for Improving the Model Ordinance and NSSP Guidance

VI. Meeting Objectives

The objectives of the meeting were to facilitate a broad discussion and better understanding of state efforts to manage the public health impacts of marine biotoxins on molluscan shellfish. The workshop was the beginning of efforts to develop a repository of biotoxin management information which could be available to all states. An overview of each state program has been developed and will be included on the ISSC website (Attachment 1).

VII. State Biotoxin Program Information Presented

1. a. Do you have a phytoplankton sampling program for algae that produce toxins that impact molluscan shellfish?
   b. Is the monitoring program routine for the purpose of an early warning system or is it event monitoring?
   c. Are phytoplankton sampling results used for reopening? If yes, explain.
   d. Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?
   e. For which algal species?
2. a. Do you routinely monitor for biotoxins in shellfish meats?
   b. For which biotoxins?
   c. In which shellfish species?
   d. Is the monitoring program routine for the purpose of an early warning system, used as a follow-up to phytoplankton information, or is it event monitoring?
   e. How often do you monitor?
   f. Does the frequency change? If so, what is the frequency change based on?
   g. Please describe use of sentinel species/stations, if applicable.
3. Do you utilize partnerships with other agencies or entities in your phytoplankton or meat sampling programs? Please name the partners and describe the partnership.
4. a. Our records indicate that you have instituted closure(s) in the past ten (10) years
   b. What biotoxin was responsible for the closure?
   c. What information did you use to close the harvest area?
5. a. What are your reopening criteria and procedures?
   b. Provide rationale for the closure period.
   c. How did you determine the number and distribution of meat

samples for reopening?

d. Did you use screening tests for reopening? Which ones?

e. How were they used?

f. How do you determine the size of your closure area?

6. What laboratory methods were used for each laboratory test conducted for re-opening?

7. If cell counts were used, how were they used and what cell counting techniques did you employ?

8. Did you conduct recalls in conjunction with the closures?

9. What other information/experiences have you used to improve HAB management?

VIII. Workshop Conclusions

It was apparent from the presentations that states have developed biotoxin management programs that are uniquely different. These differences are the result of the individual state responses to new and evolving toxins. Many different biotoxin challenges have emerged in recent years and states have found themselves using a variety of sources for technical advice in developing response and control strategies. Many of the challenges have been regional in nature and public health responses have been influenced by the limited resources available to the states.

There was consensus that although the programs were often very different, all seemed to provide an acceptable level of public health protection. Given the different toxins and geographical challenges, states need the flexibility to develop management strategies that are cost effective and practical given the nature of the risk posed by biotoxins in their respective states. While it was clear that developing standardized criteria for reopening growing areas following biootoxin closures was not the best approach, the participants concluded that updates to the Model Ordinance and Guidance Documents were appropriate to reflect the current state of science as well as current state management strategies.

IX. Workshop Recommendations

The workshop participants recommended Model Ordinance modifications which were included in ISSC Proposal 17-122 (Attachment 2). Additionally, updates on Guidance Documents were recommended and included in ISSC Proposal 17-123 (Attachment 3). These proposals were provided to the ISSC Biotoxin Committee for review and comment.

The participants discussed the public health significance language that is included in the NSSP. It was suggested that the public health significance language be reviewed following conference action on Proposals 17-122 and 17-123.

Attachment 1

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STATE OF ALABAMA

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	Yes
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	Routine and early alert
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	Yes, >5000 cells/L Karenia brevis triggers a closure
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	Yes, Screening prior to shellfish meat sampling
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	Quantitative (cell counts)
f.	For which algal species?	Karenia brevis
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	No
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	
c.	For which Biotoxins?	Karenia brevis, ASP
d.	In which shellfish species?	Oysters
e.	How often do you monitor for early alert if applicable?	As necessary to : 1) evaluate impact of events 2) reopen
f.	Does the frequency change? If so, what is the frequency change based on?	N/A
g.	Please describe use of sentinel species or sentinel stations, if applicable.	Dictated by location of events
3.	Do you utilize partnerships with other	Yes

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STATE OF ALABAMA

	agencies or entities in your phytoplankton or meat sampling programs?	
4.	Number of closure(s) in the past ten (10) years	5
a.	What Biotoxin was responsible for the closure?	Karenia brevis (4), Pseudo-nitzschia (1)
b.	What information did you use to close the harvest area?	Cell counts
c.	What are your reopening procedures?	Determine when cell counts have diminished and test shellfish meats to determine levels are 20MU/100 g or below
	i. Provide rationale for the closure period.	Cell count reductions
	ii. How did you determine the number and distribution of meat samples for reopening?	We take meat samples from the farm nearest to the highest cell counts in each area
d.	Do you use rapid screening tests prior to reopening?	Yes
	i. Which ones?	Elisa
	ii. How were they used?	Screening before sending meat sample to be tested
e.	Do you use phytoplankton for screening prior to reopening?	
	i. Which ones?	Cell count techniques
	ii. How were they used?	To quantify number of cells
f.	How do you determine the size of your closure area?	5,000 cells/L Karenia brevis closes all state waters
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	Mouse bioassay
6.	Did you conduct recalls in conjunction with the closures?	Yes, we were able to collect the sacks before they were processed and put them back on the reef
7.	What other information/experiences have you used to improve HAB management?	We monitor all the testing being done in FL and we share our results with NOAA https://tidesandcurrents.noaa.gov/hab/development.html

Attachment 1

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STATE OF ALASKA

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	No, the State of Alaska does not have a statewide monitoring program for commercial molluscan shellfish. However, there are some non-government organizations that monitor phytoplankton and some growers have microscopes to self-monitor their specific site.
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	N/A
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	No closure initiated by regulatory agency; however, some farmers that self-monitor voluntarily cease harvest activities.
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	No
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	N/A
f.	For which algal species?	N/A
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	Yes
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	Sampling is conducted prior to harvest in harvesting areas or farm.
c.	For which Biotoxins?	PST, ASP toxins
d.	In which shellfish species?	PST – Pacific oysters, blue mussels, razor clams, geoduck clams, littleneck clams ASP –routine in razor clams, non-routine for all other species commercially harvested in AK
e.	How often do you monitor for early alert if applicable?	Based on harvest
f.	Does the frequency change? If so, what is the frequency change based on?	N/A
g.	Please describe use of sentinel species or sentinel stations, if applicable.	N/A

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STATE OF ALASKA

3.	Do you utilize partnerships with other agencies or entities in your phytoplankton or meat sampling programs?	Yes, we do work with non-profit, non-governmental agencies for general information regarding phytoplankton and recreational shellfish meat information. However, the data are not always reflective of commercial growing/harvest areas.
4.	Number of closure(s) in the past ten (10) years	For geoduck, the area is only opened for harvest following an acceptable sample (areas are not opened for continuous harvest; rather, openings are typically restricted to fewer than 10 hours). For species other than geoduck, since 2007, 18 closures.
a.	What Biotoxin was responsible for the closure?	PST, due to *Alexandrium catenella*
b.	What information did you use to close the harvest area?	Sample results for PST in shellfish meat
c.	What are your reopening procedures?	For species other than geoduck, three subsequent sample results show acceptable levels of PST.
	i. Provide rationale for the closure period.	Data for all species, except geoduck, historically have demonstrated a regressive curve following a bloom event that causes toxicity. For all species, except geoduck, depuration is somewhat predictable.
	ii. How did you determine the number and distribution of meat samples for reopening?	Historical data.
d.	Do you use rapid screening tests prior to reopening?	No, not for regulatory purposes. Though at least one oyster farmer has stated that she utilizes a rapid test.
	i. Which ones?	N/A
	ii. How were they used?	N/A
e.	Do you use phytoplankton for screening prior to reopening?	No
	i. How were they used?	N/A
f.	How do you determine the size of your closure area?	Blooms are localized, so each farm or subarea is required to undergo shellfish meat testing (pre-harvest,

		weekly, or lot sampling) and results are used for that specific farm/subarea (which is oftentimes, a smaller area within a classified growing/harvest area).
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	Mouse Bioassay
6.	Did you conduct recalls in conjunction with the closures?	Yes, where product has been released into commerce.
7.	What other information/experiences have you used to improve HAB management?	Our partnerships have been quite valuable in understanding phytoplankton blooms throughout the state; however, we are vast in geography and limited in resources, making a more full understanding of the occurrence and the subsequent toxicity of certain species of shellfish quite difficult. Though certain areas have a history of toxicity, for the most part, blooms tend to be localized and very unpredictable. Alaska is unique in many ways and its shellfish program reflects adaptation to regulatory language that works well and reflects practices familiar to states where shoreline is limited, blooms are predictable, and a significant body of literature is available for the species harvested. That said, though Alaska has seen many PSP illnesses associated with personal harvest of indigenous shellfish, there has never been a PSP case associated with its commercially harvested product.

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STATE OF CALIFORNIA

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	Yes
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	Routine
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	No, phytoplankton results are used for screening
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	No
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	Qualitative. Determine percent abundance and calculate a relative abundance index.
f.	For which algal species?	*Alexandrium* *Pseudo-nitzschia* *Dinophysis*
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	Yes
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	Routine and event.
c.	For which Biotoxins?	Saxitoxins (PSP) Domoic acid (ASP) PSP is routine for all samples. Domoic acid (DA) is routine for areas with a history of DA events and event monitoring for other areas when increased abundance of *Pesudo-nitzschia* is detected in plankton samples.
d.	In which shellfish species?	Mussels and oysters. During a biotoxin event, all commercially harvestable species can be sampled.
e.	How often do you monitor for early alert if applicable?	Weekly
f.	Does the frequency change? If so, what is the frequency change based on?	Yes, can increase to twice a week when levels are above detection and below closure level.
g.	Please describe use of sentinel species or sentinel	Mussels are used as sentinel species at set stations

STATE OF CALIFORNIA

	stations, if applicable.	near the mouth of bays for some commercial growing areas.
3.	Do you utilize partnerships with other agencies or entities in your phytoplankton or meat sampling programs?	Monitoring for plankton and shellfish in commercial growing areas is collected by the growers. For recreational monitoring in the rest of the state, we have a volunteer network and partner with local counties, tribes, and other agencies.
4.	Number of closure(s) in the past ten (10) years	Approximately 17 closures.
a.	What Biotoxin was responsible for the closure?	PSP and ASP
b.	What information did you use to close the harvest area?	Biotoxin levels exceeding NSSP Active level
c.	What are your reopening procedures?	2 satisfactory samples at least 3 days apart
	i. Provide rationale for the closure period.	Shellfish sample results
	ii. How did you determine the number and distribution of meat samples for reopening?	Representative monitoring locations, size and location of growing area (bay vs. open ocean), distance between leases in a single growing area, and historical data.
d.	Do you use rapid screening tests prior to reopening?	No
	i. Which ones?	Only use SRT for PSP for screening, not for reopening samples.
	ii. How were they used?	
e.	Do you use phytoplankton for screening prior to reopening?	No
	i. How were they used?	
f.	How do you determine the size of your closure area?	Initial closure is usually entire growing area, unless there is data to support a different strategy.
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	PSP: MBA ASP/DA: HP-LC
6.	Did you conduct recalls in conjunction with the closures?	Yes, if product has been distributed.

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STATE OF CALIFORNIA

7.	What other information/experiences have you used to improve HAB management?	

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STATE OF FLORIDA

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	Yes
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	Routine
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	Yes. Closures occur: *Karenia brevis* – cell counts exceed 5,000 cells/liter *Pseudo Nitzschia* – cell counts over 1,000,000 cells/liter trigger meat sample collection or water sample analyses to determine if toxin is being produced *Pyrodinium Bahamense* – collect meat samples when any cell count is present (mostly over 5,000 cells/liter)
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	No
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	Quantitative
f.	For which algal species?	*Karenia brevis, Pyrodinium bahamense, Pseudo nitzschia*
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	Yes
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	Event and starting routine in some harvest areas.
c.	For which Biotoxins?	NSP, ASP and PSP
d.	In which shellfish species?	Oysters, clams
e.	How often do you monitor for early alert if applicable?	As necessary to evaluate extent of event
f.	Does the frequency change? If so, what is the frequency change based on?	Yes, extent of event
g.	Please describe use of sentinel species or sentinel stations, if applicable.	N/A
3.	Do you utilize partnerships with other agencies	Yes

STATE OF FLORIDA

	or entities in your phytoplankton or meat sampling programs?	
4.	Number of closure(s) in the past ten (10) years	Depends on harvest area
a.	What Biotoxin was responsible for the closure?	*Karenia brevis, Pyrodinium bahamense, Pseudo nitzschia*
b.	What information did you use to close the harvest area?	Cell counts and meat test
c.	What are your reopening procedures?	NSP - Cell concentrations fall to less than or equal to 5,000 cells per L and shellfish meat samples are less than 20 MU; Concentrations of PSP fall below 80 ug per 100 g on 2 consecutive meat samples at least 7 days apart; Concentrations of DA fall below 2 mg per 100 g on 2 consecutive meat samples at least 7 days apart
	i. Provide rationale for the closure period.	Water and meat sampling results
	ii. How did you determine the number and distribution of meat samples for reopening?	Aquaculture Use Zones and wild resource locations.
d.	Do you use rapid screening tests prior to reopening?	Yes
	i. Which ones?	ELISA
	ii. How were they used?	They were used to determine when samples should be tested by mouse bioassay
e.	Do you use phytoplankton for screening prior to reopening?	Yes
	i. How were they used?	To determine when event is over
f.	How do you determine the size of your closure area?	Affected area
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	NSP – ELISA (screening)/Mouse Bioassay ASP – Neogen (screening)/HPLC PSP – Scotia (screening)/Mouse Bioassay
6.	Did you conduct recalls in conjunction with the closures?	No

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STATE OF FLORIDA

7.	What other information/experiences have you used to improve HAB management?	

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STATE OF MAINE

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	yes
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	Routine Early Alert Event Monitoring
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	no
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	Yes, to show trend of bloom and inform meat results For screening only
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	both
f.	For which algal species?	Alexandrium, Pseudonitzschia, Prorocentrum, Dinophysis
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	yes
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	Routine event monitoring follow-up to Phytoplankton
c.	For which Biotoxins?	Saxitoxins PSP Domoic Acid ASP Okadaic Acid DSP
d.	In which shellfish species?	Clams, Mussels, Oysters, Scallops
e.	How often do you monitor for early alert if applicable?	Monthly Nov – Feb Weekly March - Oct
f.	Does the frequency change? If so, what is the frequency change based on?	Yes – changes in blooms events; as frequently as twice a week and lot testing
g.	Please describe use of sentinel species or sentinel stations, if applicable.	Mussels are used at primary stations to monitor toxin pre and post bloom
3.	Do you utilize partnerships with other agencies or entities in your phytoplankton or meat sampling programs?	Yes – highly trained volunteer phytoplankton network, communication with Canada and other states, contract with private lab for PSP, ASP and DSP sample processing
4.	Number of closure(s) in the past ten (10) years	Regional mussel closures implemented in early May each year, species specific closures according to toxin levels. Several distinct closures each year.
a.	What Biotoxin was responsible for the closure?	All above
b.	What information did you use to close the harvest area?	Biotoxin levels in SF PSP ASP DSP
c.	What are your reopening procedures?	2 consecutive samples no less than 7 days apart
	i. Provide rationale for the closure period.	2 samples over 7 days insures problem has diminished
	ii. How did you determine the number and distribution of meat samples for reopening?	Historic data, bloom patterns, commercial resource and fishery

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STATE OF MAINE

d.	Do you use rapid screening tests prior to reopening?	No, rapid screening methods are only used to indicate the presence of toxin in phytoplankton leading up to closures
	i. Which ones?	PSP ASP
	ii. How were they used?	These rapid tests help with target cell identification (Alexandrium) and blooms that only sometimes develop toxin (Pseudo-nitzschia)
e.	Do you use phytoplankton for screening prior to reopening?	Yes
	i. How were they used?	Phytoplankton sampling was used to determine bloom status
f.	How do you determine the size of your closure area?	Phyto sampling coupled with meat sampling, closure goes to next clean station
7.	What laboratory methods were used for each laboratory test conducted for re-opening?	HPLC PCOX & MBA (PSP) HPLC UV (ASP) LCMS/MS (DSP)
8.	If cell counts were used for reopening, what cell counting techniques did you employ?	N/A trend data only
9.	Did you conduct recalls in conjunction with the closures?	Yes for ASP in 2016
10.	What other information/experiences have you used to improve HAB management?	Regional mussel closures during the peak season provides the best protection to public health in remote areas and allows sampling to focus on most important commercial resources. Transition to chemical method provides early warning of toxin increasing at lower levels. Extensive phytoplankton monitoring provides early warning and confidence in reopening after the bloom.

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STATE OF MASSACHUSETTS

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	Yes
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	Routine
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	No
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	No
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	Both
f.	For which algal species?	*Alexandrium, Pseudonitzschia, Prorocentrum, Dinophysis*
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	Yes
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	Early alert Event monitoring
c.	For which Biotoxins?	PSP
d.	In which shellfish species?	Mussels weekly throughout the season, other species as needed during a bloom.
e.	How often do you monitor for early alert if applicable?	Weekly
f.	Does the frequency change? If so, what is the frequency change based on?	Yes, more frequent as toxin levels in shellfish increase
g.	Please describe use of sentinel species or sentinel stations, if applicable.	MA monitors 16 primary stations for toxicity in blue mussels weekly throughout April-October.
3.	Do you utilize partnerships with other agencies or entities in your phytoplankton or meat sampling programs?	Yes
		Annually

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STATE OF MASSACHUSETTS

4.	Number of closure(s) in the past ten (10) years	
a.	What Biotoxin was responsible for the closure?	PSP , ASP, and DSP
b.	What information did you use to close the harvest area?	Levels of toxin in shellfish that are approaching NSSP Standards for closure.
c.	What are your reopening procedures?	Three consecutive shellfish samples in not less than 14 days below 80 ug per 100 g and descending. Evidence that the bloom has subsided.
	i. Provide rationale for the closure period.	Suggested in NSSP Guidance
	ii. How did you determine the number and distribution of meat samples for reopening?	This has been the practice in MA since before 1988.
d.	Do you use rapid screening tests prior to reopening?	Yes
	i. Which ones?	Scotia
	ii. How were they used?	Screening
e.	Do you use phytoplankton for screening prior to reopening?	Yes
	i. How were they used?	To monitor presence and extent of blooms; reopenings are based on toxicity in shellfish.
f.	How do you determine the size of your closure area?	Based on shellfish samples and the extent of a bloom.
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	MBA for PSP. HPLC for ASP.
6.	Did you conduct recalls in conjunction with the closures?	MA has but rarely because we have a conservative approach to closures. Ma closes shellfish areas prior to reaching violative levels of toxin in shellfish to avoid the need for recalls.
7.	What other information/experiences have you used to improve HAB management?	Maintaining communication with other states and institutions regarding blooms , toxin levels and closures.

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STATE OF NEW HAMPSHIRE

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	Yes
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	Volunteer routine
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	No – screening only
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	No – screening only
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	Quantitative
f.	For which algal species?	Alexandrium fundyense, Pseudo-nitzschia (large cells and small cells), Dinophysis spp (acuminate, norvegica, tripos)., Prorocentrum lima. Several other species are enumerated, but not year round.
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	Yes
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	routine (weekly PSP biotoxin monitoring at two locations)
c.	For which Biotoxins?	PSP
d.	In which shellfish species?	Blue mussels are the primary species. Other species monitored as needed depending on location of bloom and time of year. Other species include softshell clam, surf clam, and American oyster.
e.	How often do you monitor for early alert if applicable?	Weekly blue mussel tissue samples for PSP at two locations.
f.	Does the frequency change? If so, what is the frequency change based on?	if toxins are rising but have not risen to the closure criterion, additional shellfish tissue tests are performed.
g.	Please describe use of sentinel species or sentinel stations, if applicable.	the two primary blue mussel stations used in the program are sentinel stations (transplants needed).

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3.	Do you utilize partnerships with other agencies or entities in your phytoplankton or meat sampling programs?	NH DHHS performs laboratory analyses. Star Island Corporation occasionally assists with blue mussel sample collection. Phytoplankton monitoring is done a by a private citizen volunteer
4.	Number of closure(s) in the past ten (10) years	3
a.	What Biotoxin was responsible for the closure?	Saxitoxins (PSP)
b.	What information did you use to close the harvest area?	Levels exceeded 80 ug/ 100 g
c.	What are your reopening procedures?	3 weekly samples below 80 ug/ 100 g
	i. Provide rationale for the closure period.	3 weeks adequate to protect Public Health
	ii. How did you determine the number and distribution of meat samples for reopening?	Used primary stations and typical weekly monitoring protocol
d.	Do you use rapid screening tests prior to reopening?	No
	i. Which ones?	n/a
	ii. How were they used	n/a
e.	Do you use phytoplankton for screening prior to reopening?	yes
	i. How were they used?	To determine when event is over
f.	How do you determine the size of your closure area?	Based on pre-determined growing area boundaries.
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	MBA
6.	Did you conduct recalls in conjunction with the closures?	No. only recreational areas were affected.
7.	What other information/experiences have you used to improve HAB management?	Woods Hole PSP listserve to improve information sharing. Extensive discussions with other state to expand phytoplankton monitoring and phyto toxin screening kits for ASP and DSP (began 2017)

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1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	No
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	N/A
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	N/A
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	N/A
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	N/A
f.	For which algal species?	N/A
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	Yes
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	Early alert
c.	For which Biotoxins?	PSP Domoic Acid
d.	In which shellfish species?	Razor clams Bay clams Mussels Oysters (during events)
e.	How often do you monitor for early alert if applicable?	Routine twice monthly
f.	Does the frequency change? If so, what is the frequency change based on?	More frequency as levels increase
g.	Please describe use of sentinel species or sentinel stations, if applicable.	Stations cover entire coast line
3.	Do you utilize partnerships with other agencies or entities in your phytoplankton or meat	YES. Oregon Dept. Fish and Wildlife for meat sample collection.

STATE OF OREGON

	sampling programs?	
4.	Number of closure(s) in the past ten (10) years	More than 5.
a.	What Biotoxin was responsible for the closure?	Domoic acid.
b.	What information did you use to close the harvest area?	Levels exceed NSSP standard
c.	What are your reopening procedures?	80 PSP 20 Domoic Acid Minumum of two clean samples collected from site/s that caused the closure. These will always be a minimum of one week apart and, more typicall, will be two weeks apart each. In otherwords, an area usually won't open for a month after an initial closure.
	i. Provide rationale for the closure period.	Conservative approach to ensure the trend is consistent.
	ii. How did you determine the number and distribution of meat samples for reopening?	Sampled in affected areas
d.	Do you use rapid screening tests prior to reopening?	No
	i. Which ones?	N/A
	ii. How were they used?	N/A
e.	Do you use phytoplankton for screening prior to reopening?	No
	i. How were they used?	N/A
f.	How do you determine the size of your closure area?	Go to the next clean sampling site to both the north and south of the site that tested above the closure limit . Distance will vary depending on the location of the next sites in relation to the hot one. ?
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	MBA - PSP HPLC – Domoic Acid
6.	Did you conduct recalls in conjunction with the closures?	No. The 'closures' conincided with periods where this fishery was already closed for annual conservational closures.

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7.	What other information/experiences have you used to improve HAB management?	Communication with neighboring states.

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STATE OF TEXAS

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	Yes
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	Cytobot early alert Cell counting when cells appear
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	Yes
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	No
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	Both
f.	For which algal species?	Karenia Brevis Domoic acid
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	No
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	Event monitoring
c.	For which Biotoxins?	Domoic acid
d.	In which shellfish species?	Oysters
e.	How often do you monitor for early alert if applicable?	N/A
f.	Does the frequency change? If so, what is the frequency change based on?	Cell counts
g.	Please describe use of sentinel species or sentinel stations, if applicable.	Stations are located at entrance to embankments
3.	Do you utilize partnerships with other agencies or entities in your phytoplankton or meat sampling programs?	Yes
4.	Number of closure(s) in the past ten (10) years	10

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a.	What Biotoxin was responsible for the closure?	NSP Okadaic Acid
b.	What information did you use to close the harvest area?	Cell counts
c.	What are your reopening procedures?	Screen with cell counts followed by meat samples
	i. Provide rationale for the closure period.	Based on cell counts less than 5
	ii. How did you determine the number and distribution of meat samples for reopening?	Based on size of affected area
d.	Do you use rapid screening tests prior to reopening?	No
	i. Which ones?	N/A
	ii. How were they used?	
e.	Do you use phytoplankton for screening prior to reopening?	Yes
	i. How were they used?	To determine when cell counts were less than 5
f.	How do you determine the size of your closure area?	Cell counts and close any waters that are hydrologically linked to the impacted area.
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	MBA HPLC
6.	Did you conduct recalls in conjunction with the closures?	1 recall
7.	What other information/experiences have you used to improve HAB management?	

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STATE OF WASHINGTON

1.	Phytoplankton Monitoring	
a.	Do you have a phytoplankton sampling program for toxins associated with molluscan shellfish?	Yes
b.	Type of phytoplankton monitoring program? routine/early alert/event monitoring	Early warning
c.	Is phytoplankton sampling results used for establishing closures? If yes, explain.	Normally no; yes if high cell counts
d.	Is phytoplankton sampling results used for reopening? If yes, explain.	No
e.	Is the phytoplankton monitoring qualitative (presence/absence) or quantitative (cell concentrations are determined)?	both
f.	For which algal species?	*Alexandrium catenella, Pseudonitzschia spp.; Dinophysis spp.; Heterosigma akashiwo*
2.	Shellfish Meat Monitoring	
a.	Do you monitor for Biotoxins in shellfish meats?	Yes
b.	Type of monitoring program? routine/early alert/event monitoring/follow-up to phytoplankton monitoring	Routine event monitoring
c.	For which Biotoxins?	Saxitoxins (PSP), Domoic Acid (ASP), Okadaic/Dinophysis (DSP)
d.	In which shellfish species?	Mussels, oysters, clams geoduck
e.	How often do you monitor for early alert if applicable?	Mussels are collected biweekly (no toxins) or increased to weekly when elevated levels of toxin are detected. Geoduck are tested weekly in areas with a history of elevated PSP toxin risk or biweekly in areas with low PSP toxin risk. Other species are tested if mussels are not available in the growing area.
f.	Does the frequency change? If so, what is the frequency change based on?	Increased to weekly as level increase

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g.	Please describe use of sentinel species or sentinel stations, if applicable.	Approximately 80 sentinel mussel sites are located in Puget Sound and coastal bays. These sites are located near commercial shellfish harvest areas, public beaches and Tribal centers. There are annual sites and seasonal sites (May – September). If any elevated levels of biotoxin are detected the industry is notified and required to submit commercial species for testing if harvesting or planning to harvest in growing area.
3.	Do you utilize partnerships with other agencies or entities in your phytoplankton or meat sampling programs?	Yes, state agencies, LHJ's, Tribes , shellfish industry, citizen scientists (volunteers)
4.	Number of closure(s) in the past ten (10) years	2016 17 2015 27 2014 33 2013 32 2012 29 2011 11 2010 31 2009 21 2008 25 2007 37 Total = 263
a.	What Biotoxin was responsible for the closure?	PSP DSP ASP
b.	What information did you use to close the harvest area?	When levels exceed the action level; Geoduck viscera sample tests above the action levels; another shellfish species tests above the action levels; reported illness from shellfish from area
c.	What are your reopening procedures?	At times 3 samples may be required if the previous toxin results (2 samples) don't demonstrate a decline in toxin levels or phytoplankton monitoring results show increased HAB species.
	i. Provide rationale for the closure period.	Historical data
	ii. How did you determine the number and distribution of meat samples for reopening?	Historical data
d.	Do you use rapid screening tests prior to reopening?	No, but rapid screening tests are being evaluated for DSP toxins.
	i. Which ones?	PP2A

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	ii. How were they used?	Screening prior to meat sampling on a seasonal (winter) basis is being considered.
e.	Do you use phytoplankton for screening prior to reopening?	Yes
	i. How were they used?	To determine when event is over and adequate purging has occurred
f.	How do you determine the size of your closure area?	Cell counts and meat sampling
5.	What laboratory methods were used for each laboratory test conducted for re-opening?	MBA – PSP, evaluating RBA HPLC - ASP LCMSMS - DSP
6.	Did you conduct recalls in conjunction with the closures?	Yes
7.	What other information/experiences have you used to improve HAB management?	Working with NOAA and local universities to evaluate new screening tools, analytical methods and better understand HAB's and bloom prediction.

Attachment 2

Proposal No. 17-122

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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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	**Section II. Model Ordinance** **Chapter II. Risk Assessment and Risk Management** **@.01 Outbreaks of Shellfish-Related Illness.** 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~~shellfish toxicity poisoning associated with marine biotoxins ~~[PSP])~~, the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing: (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. **Chapter IV. Shellstock Growing Areas Management** **@.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, 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. (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, 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 safety 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 safety 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 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.

(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 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 - ~~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~~
t~~o 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.

Attachment 2

Proposal No. **17-122**

Public Health Significance	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. 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.
Cost Information	

Attachment 3

Proposal No. 17-123

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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Proposal Subject	Marine Biotoxin Control Guidance
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II .02
Text of Proposal/ Requested Action	**Chapter II. Growing Areas** **.02 Guidance for Developing Marine Biotoxin ~~Contingency~~ Plans.** NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, which includes the requirements of the program ~~and summaries of the requirements for that component~~. NSSP *Model Ordinance* 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. **Introduction** Shellfish are filter feeders and, therefore, they have the ability to concentrate ~~toxigenic dinoflagellates~~toxic phytoplankton from the water column when present in shellfish growing waters. The toxins produced by ~~these dinoflagellates~~ 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 exposure occurs when the shellfish are eaten (Gordan *et al.*, 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. ~~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~~The presence of toxic phytoplankton 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 ~~dinoflagellate~~toxic phytoplankton concentration in the water column against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken. 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

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 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, 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 Pseudonitzchia. Certain *Dinophysis* spp. and *Prorocentrum* spp. produce okadaic acid and dinophysis 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. Occurance 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).

~~I~~n 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-nitzs~~a~~chia*. Blooms of *Pseudo-nitzs~~a~~chia* are of ~~relatively short duration~~varying intensity, duration and extent.. ~~However, d~~During ~~the~~a 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 ~~B~~biotoxin ~~episode~~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 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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Public Health Significance	This proposal includes modifications to Guidance Document .02 Guidance for Developing Marine Biotoxin Contingency Plans. This proposal includes guidance document modifications which support Proposal 17-122.
Cost Information	