

Proposal Subject: Control of Marine Biotoxins

Specific NSSP Section II Model Ordinance Chapter IV. Shellstock Growing Areas
Guide Reference: @. 04. Marine Biotoxin Control
 D. Controlled Harvest From Closed Federal Waters

Section IV Guidance Documents Chapter II. Growing Areas
 .03 Example of Protocol for Onboard Screening and Dockside Testing for PSP in Closed Federal Waters

Text of Proposal/ Requested Action: Chapter IV Shellfish Growing Areas @.04 Marine Biotoxin Control. Insert new item A. (5)

(5) Prior to allowing the landing of shellfish harvested from 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 memorandums of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memorandums of understanding shall provide strict safety assurances. At a minimum agreements or memorandums 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 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 44ug/100g.
- (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 80ug/100g.
- (i) Disposal of shellfish should dockside test results exceed 80ug /100g.
- (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.

Insert new Additional Guidance reference at Model Ordinance Chapter IV@ .04. A. (5) as follows:

Additional Guidance – Section IV Guidance Documents Chapter II. Growing Areas .03 Protocol for the Landing of Shellfish from Federally Closed Waters due to PSP

Add new guidance to Section IV. Guidance Documents, Chapter II. Growing Areas .03 and re-number Section IV. Guidance Documents, Chapter II. Growing Areas .03 through .15 as .04 through .16.

Protocol for the Landing of Shellfish from Federally Closed Waters due to PSP

When the harvest of molluscan shellfish is closed in Federal Waters due to Paralytic Shellfish Poison (PSP), exceptions to the prohibitions may be authorized provided the Authority in the State of landing in cooperation with appropriate Federal agencies shall develop agreements or memorandums of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. This guidance provides descriptions of the specific information to be included in the protocol.

A. Harvest Permit Requirements

The Authority in the landing state will only allow the landing of shellfish from federal waters closed due to PSP from vessels in possession of an appropriate Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS). The NMFS shall receive concurrence from the SSCA in the State of landing.

B. Training

The Authority shall ensure that all shipboard persons conducting onboard sampling have been trained by a National Shellfish Sanitation Program (NSSP) Laboratory Evaluation Officer (LEO) or a US Food and Drug Administration (FDA) marine biotoxin expert to conduct onboard PSP screening using a NSSP recognized method(s).

C. Vessel Monitoring

The Authority shall ensure that the harvesting location(s) of each landing vessel has been appropriately monitored. This requirement may be met by the vessel participating in the Federal Vessel Monitoring System (VMS).

D. Identification of Shellfish

Prior to landing each vessel shall provide the Authority with a record identifying each lot of shellfish as follows: For each harvesting trip the Captain or Mate shall record the following information on a “Harvest Record.” Electronic logging of this information may be permitted provided it is made available to the authorized individual at dockside.

1. Vessel name and Federal Fishing Permit number
2. Name and telephone number of the vessel Captain and vessel owner
3. Date(s) of harvest
4. Number of lots and volume of catch per lot or number of containers per lot
5. Location(s) of harvest (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds)
6. Identification of each harvest lot, including cage tag numbers for surfclams and ocean quahogs, and container numbers or identification codes for other shellfish species.
7. Location (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds) of each PSP screening sample
8. Results of each PSP screening test. Screening test kits for each sample shall be submitted to the authorized authority along with the “Harvest Record” as stated in Section D.
9. Destination(s) and purchaser(s) of each lot and amount of each lot to each destination

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

CONTAINER LABELING:

Each container of shellfish shall be clearly labeled with the following NSSP required information at the time of harvest:

1. For surfclams and ocean quahogs existing NMFS tagging requirements
2. For all other molluscan shellfish (including Stimpson clams also known as Arctic surfclams) using Tyvek tags:
 - a. Vessel name
 - b. Type and quantity of shellfish
 - c. Date of harvest
 - d. Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds

E. Pre-Harvest Sampling

Prior to commercial harvesting of molluscan shellfish, a minimum of five (5) screening samples shall be collected within each area of intended harvest (lot area) and tested for PSP toxins in accordance with a NSSP recognized screening method. Each screening sample shall be collected during a separate and distinct gear tow. Screening sample tows shall be conducted in a manner that evenly distributes the five (5) samples throughout the intended harvest area for each area of intended harvest (see Section H.). Only shipboard officials trained in the use of the designated NSSP screening method may conduct these tests. Each of the five (5) samples must test negative for PSP toxins. A positive result from any one (1) sample shall render the “lot area” unacceptable for harvest. The harvest vessel

captain shall immediately report all positive screening test results, by telephone, to the SSCA within the intended state of landing and the NMFS. The Captain should also notify other permitted harvest vessels of the positive screening test and advise them to avoid the questionable area. For each screening test, positive and negative, the remaining sample material (homogenate) shall be maintained under refrigeration. Test kits, positive and negative, shall accompany the remaining sample homogenates to the certified laboratory. Confirmatory testing shall be performed on homogenate from each positive screening test using a NSSP recognized test method. Upon request by the SSCA in the state of landing, confirmatory testing of homogenate from negative screening tests shall be conducted using a NSSP recognized test method.

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

F. Submittal of Onboard Screening Homogenates and Test Results

All screening results shall be recorded on the “Harvest Record” as stipulated in Section D. of this Protocol. Test kits used to screen each lot shall accompany the “Harvest Record”. Upon landing of the harvest vessel, the “Harvest Record” and accompanying test kits shall be provided to the individual (state shellfish official, FDA official, NMFS official) authorized to sample the harvested shellfish as described in Section G. of this Protocol.

G. Dockside Sampling

After dockside samples are collected, molluscan shellfish may be processed while awaiting PSP analytical results. Each lot must be identified and segregated during storage while awaiting dockside sample test results. Under no circumstances will product be released from the processor prior to receiving satisfactory paralytic shellfish toxin test results.

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

1. For each lot of molluscan shellfish, a minimum of seven (7) composite samples, each comprised of at least twelve (12) whole animals, shall be taken at random by the individual authorized to sample, with the following exceptions:
 - a. For each lot of mussels, a minimum of seven (7) composite samples, each comprised of at least thirty (30) whole animals, shall be taken at random by the individual authorized to sample.
 - b. For each lot of “whole” scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop viscera and gonads, shall be taken at random by the individual authorized to sample.
 - c. For each lot of “roe-on” scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop gonads, shall be taken at random by the individual authorized to sample.
2. Shellfish samples collected in accordance with G.1 shall be tested for the presence of paralytic shellfish toxins using NSSP recognized methods.
3. Laboratory test results for each lot of shellfish shall be forwarded to the

SSCA in the state in which the shellfish is being held prior to the product being released by the SSCA.

H. Holding and Lot Separation

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

I. Disposal of Shellfish

If test results of any one (1) of the seven (7) samples collected in accordance with G.1 equal or exceed 80ug of paralytic shellfish toxins/100g of shellfish tissue (n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the SSCA in accordance with state laws and regulations except when:

A lot of “whole” or “roe-on” scallops equals or exceeds 80ug paralytic shellfish toxins/100g of tissue, the adductor muscle may be shucked from the viscera and/or gonad and marketed. The remaining materials (viscera and/or gonad) must be discarded or destroyed under supervision of the SSCA in accordance with state laws and regulations.

Confirmatory PSP analyses shall be according to NSSP recognized methods and shall be conducted by laboratories certified in accordance with NSSP guidelines. Private laboratories may be used if certified by a Federal or state shellfish Laboratory Evaluation Officer (LEO) in accordance with NSSP guidelines.

J. Notification Prior to Unloading

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

Each vessel shall give at least twelve (12) hours notice to the individual authorized to sample prior to unloading shellfish. Notice of less than twelve (12) hours may be approved by the authorized individual at his/her discretion. SSCAs may approve industry sampling and sample transport to the NSSP certified testing laboratory in accordance with the practices and procedures used by the SSCA under the NSSP. Such procedures may be approved by the SSCA only when sample collection and sample transport training is provided by the SSCA.

Shellfish from a federally closed harvest area must be kept separate and not sold until so authorized by the SSCA.

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

K. Unloading Schedule

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

L. Access for Dockside Sampling

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

M. Record Keeping

Record keeping requirements shall be as follows:

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

N. Early Warning/Alert System

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

1. shellfish species
2. harvest location name and coordinates (GPS or latitude/longitude)
3. harvest date
4. onboard screening test method, date, and results
5. laboratory test date and test results

Results of all samples having acceptable levels of paralytic shellfish toxins (<80ug/100g) shall immediately be reported to the SSCA in the state of landing. If the results of any one (1) sample equal or exceed 80ug/100g the testing laboratory shall immediately notify the FDA Regional Shellfish Specialist, the SSCA, and the processor by telephone. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s).

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

**Public Health
Significance:**

The surf clam and ocean quahog fishery is one of the largest shellfish fisheries in the U.S. producing up to 130 million pounds of meats per year, generating about \$75 million ex-vessel per year.

Atlantic surf clams and ocean quahogs are found in the North Atlantic from North Carolina to the Gulf of St. Lawrence. The surf clam and ocean quahog fisheries in the U.S. are managed by the National Marine Fisheries Services (NMFS) in accordance with a management plan prepared by the Mid Atlantic Fishery Management Council under an individual transferable quota system implemented in 1990.

The management plan includes requirements for trip announcements, landings time and port, and each vessel is equipped with a Vessel Monitoring System (VMS). The VMS allows the regulators to identify, tracked locations of harvest within 100 feet and steaming speed, for every clam vessel authorized to operate in federal waters.

Allocations are issued to quota holders each year in the form of specifically identified tags that must be attached to containers of surf clams or ocean quahogs. Ownership of the tags and harvest activities are closely monitored by NOAA Fisheries.

Surf clams and ocean quahogs are processed for use in strips, soups, chowders, and sauces. Although surf clams and ocean quahogs are not consumed raw they are shipped alive in interstate commerce and are subject to NSSP regulation. Thirteen processing facilities are located in six states: MA, RI, NJ, DE, MD, and VA. A fleet of approximately 40 vessels land their catch in five states; MA, RI, NJ, MD, and NY.

Because the U.S. FDA does not have the resources necessary to routinely monitor the Northwest Atlantic Ocean where Alexandrium blooms responsible for PSP have historically occurred, waters of the Northwestern Atlantic west of 69.00° W Longitude have been closed since 1990. In 2005 federal waters east of 69.00° W Longitude and north of 40.00° N Latitude were also closed in response to an unprecedented toxic algal bloom (PSP) that occurred throughout the Northwest Atlantic Ocean, affecting state and federal waters. Much of this area remains closed today to the harvest of all molluscan shellfish, all of the area remains closed to the harvest of whole and roe-on scallops. These areas combined represent approximately 50% of the total surf and ocean quahog resource along the Atlantic coast. The result has been increased pressure on the remaining resource and economic loss to the fishery and its affiliated land based components.

Beginning in 2008, a pilot program was initiated to evaluate the Onboard Screening and Dockside Testing Protocol (Protocol), outlined in this ISSC Proposal and developed by FDA, NMFS, EPA, North and Mid Atlantic State shellfish authorities, and representatives of the Atlantic Fishery Management Council. The purpose of the pilot, which was given ISSC Executive Board concurrence, was to test the effectiveness of the Protocol for ensuring the safe harvest of shellfish harvested from Federal waters closed because of the historical occurrence of significant PSP episodes. Harvesting was conducted under an Experimental Fishing Permit issued to a single vessel by NMFS. Four States participated in the Pilot including NJ, DE, RI, and MA.

Under the Pilot, shellfish are tested at sea to ensure that harvest levels do not exceed 44ug PSP/100g meat. Once landed the shellfish is again tested using the traditional Mouse Bioassay (MBA) and only permitted to leave the processing facility for entry into the commercial market when all samples have demonstrated PSP levels compliant with NSSP requirements. To date there have been over 70 successful harvest trips to offshore Federal waters on Georges Bank, accounting for the safe landing of approximately 330,000

bushels of clams. The Pilot has demonstrated the efficacy of the Protocol in all regards.

Adoption of this Proposal by the ISSC will pave the way for additional vessels, operating under NMFS permit in accordance with Protocol requirements, to safely harvest from offshore Federal waters closed as a result of historical episodes of toxic PSP blooms.

**Cost Information
(if available):**

**Action by 2011
Task Force I**

Recommended adoption of Proposal 11-116 as amended.

Chapter IV Shellfish Growing Areas @.04 Marine Biotoxin Control. Insert new item A. (5)

(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 memorandums of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memorandums of understanding shall provide strict safety assurances. At a minimum agreements or memorandums 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 44ug/100g -when using a quantitative test or a positive at a limit of detection of 40ug/100g 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 80ug/100g.
- (i) Disposal of shellfish should dockside test results exceed 80ug /100g.
- (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.

Insert new Additional Guidance reference at Model Ordinance Chapter IV@ .04. A. (5) as follows:

Additional Guidance – Section IV Guidance Documents Chapter II. Growing Areas .03 Protocol for the Landing of Shellfish from Federally Closed Waters due to PSP

Add new guidance to Section IV. Guidance Documents, Chapter II. Growing Areas .03 and re-number Section IV. Guidance Documents, Chapter II. Growing Areas .03 through .15 as .04 through .16.

Protocol for the Landing of Shellfish from Federally Closed Waters due to PSP

When the harvest of molluscan shellfish is closed in Federal Waters due to Paralytic Shellfish Poison (PSP), exceptions to the prohibitions may be authorized provided the Authority in the State of landing in cooperation with appropriate Federal agencies shall develop agreements or memorandums of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. This guidance provides descriptions of the specific information to be included in the protocol.

A. Harvest Permit Requirements

The Authority in the landing state will only allow the landing of shellfish from federal waters closed due to PSP from vessels in possession of an appropriate Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS). The NMFS shall receive concurrence from the SSCA in the State of landing.

B. Training

The Authority shall ensure that all shipboard persons conducting onboard sampling have been trained by a National Shellfish Sanitation Program (NSSP) Laboratory Evaluation Officer (LEO) or a US Food and Drug Administration (FDA) marine biotoxin expert to conduct onboard PSP screening using a NSSP recognized method(s).

C. Vessel Monitoring

The Authority shall ensure that the harvesting location(s) of each landing vessel has been appropriately monitored. This requirement may be met by the vessel participating in the Federal Vessel Monitoring System (VMS).

D. Identification of Shellfish

Prior to landing each vessel shall provide the Authority with a record identifying each lot of shellfish as follows: For each harvesting trip the Captain or Mate shall record the following information on a "Harvest Record." Electronic logging of this

information may be permitted provided it is made available to the authorized individual at dockside.

1. Vessel name and Federal Fishing Permit number
2. Name and telephone number of the vessel Captain and vessel owner
3. Date(s) of harvest
4. Number of lots and volume of catch per lot or number of containers per lot
5. Location(s) of harvest (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds)
6. Identification of each harvest lot, including cage tag numbers for surfclams and ocean quahogs, and container numbers or identification codes for other shellfish species.
7. Location (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds) of each PSP screening sample
8. Results of each PSP screening test. ~~Screening test kits for each sample shall be submitted to the authorized authority along with the "Harvest Record" as stated in Section D.~~
9. Destination(s) and purchaser(s) of each lot and amount of each lot to each destination

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

CONTAINER LABELING:

Each container of shellfish shall be clearly labeled with the following NSSP required information at the time of harvest:

1. For surfclams and ocean quahogs existing NMFS tagging requirements
2. For all other molluscan shellfish (including Stimpson clams also known as Arctic surfclams) using Tyvek tags:
 - a. Vessel name
 - b. Type and quantity of shellfish
 - c. Date of harvest
 - d. Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds

E. Pre-Harvest Sampling

Prior to commercial harvesting of molluscan shellfish, a minimum of five (5) screening samples shall be collected within each area of intended harvest (lot area) and tested for PSP toxins in accordance with a NSSP recognized screening method. Each screening sample shall be collected during a separate and distinct gear tow. Screening sample tows shall be conducted in a manner that evenly distributes the five (5) samples throughout the intended harvest area for each area of intended harvest (see Section H.). Only shipboard officials trained in the use of the

designated NSSP screening method may conduct these tests. Each of the five (5) samples must test negative for PSP toxins. A positive result from any one (1) sample shall render the “lot area” unacceptable for harvest. The harvest vessel captain shall immediately report all positive screening test results, by telephone, to the SSCA within the intended state of landing and the NMFS. The Captain should also notify other permitted harvest vessels of the positive screening test and advise them to avoid the questionable area. For each screening test, positive and negative, the remaining sample material (homogenate) shall be maintained under refrigeration. Test kits, positive and negative, shall accompany the remaining sample homogenates to the certified laboratory. Confirmatory testing shall be performed on homogenate from each positive screening test using a NSSP recognized test method. Upon request by the SSCA in the state of landing, confirmatory testing of homogenate from negative screening tests shall be conducted using a NSSP recognized test method.

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

F. Submittal of Onboard Screening Homogenates and Test Results

All screening results shall be recorded on the “Harvest Record” as stipulated in Section D. of this Protocol. Test kits used to screen each lot shall accompany the “Harvest Record”. Upon landing of the harvest vessel, the “Harvest Record” and accompanying test kits shall be provided to the individual (state shellfish official, FDA official, NMFS official) authorized to sample the harvested shellfish as described in Section G. of this Protocol.

G. Dockside Sampling

After dockside samples are collected, molluscan shellfish may be processed while awaiting PSP analytical results. Each lot must be identified and segregated during storage while awaiting dockside sample test results. Under no circumstances will product be released from the processor prior to receiving satisfactory paralytic shellfish toxin test results.

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

1. For each lot of molluscan shellfish, a minimum of seven (7) composite samples, each comprised of at least twelve (12) whole animals, shall be taken at random by the individual authorized to sample, with the following exceptions:
 - a. For each lot of mussels, a minimum of seven (7) composite samples, each comprised of at least thirty (30) whole animals, shall be taken at random by the individual authorized to sample.
 - b. For each lot of “whole” scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop viscera and gonads, shall be taken at random by the individual authorized to sample.
 - c. For each lot of “roe-on” scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop gonads, shall be taken at random by the individual authorized to sample.

2. Shellfish samples collected in accordance with G.1 shall be tested for the presence of paralytic shellfish toxins using NSSP recognized methods.
3. Laboratory test results for each lot of shellfish shall be forwarded to the SSCA in the state in which the shellfish is being held prior to the product being released by the SSCA.

H. Holding and Lot Separation

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

I. Disposal of Shellfish

If test results of any one (1) of the seven (7) samples collected in accordance with G.1 equal or exceed 80ug of paralytic shellfish toxins/100g of shellfish tissue (n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the SSCA in accordance with state laws and regulations except when:

A lot of “whole” or “roe-on” scallops equals or exceeds 80ug paralytic shellfish toxins/100g of tissue, the adductor muscle may be shucked from the viscera and/or gonad and marketed. The remaining materials (viscera and/or gonad) must be discarded or destroyed under supervision of the SSCA in accordance with state laws and regulations.

Confirmatory PSP analyses shall be according to NSSP recognized methods and shall be conducted by laboratories certified in accordance with NSSP guidelines. Private laboratories may be used if certified by a Federal or state shellfish Laboratory Evaluation Officer (LEO) in accordance with NSSP guidelines.

J. Notification Prior to Unloading

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

Each vessel shall give at least twelve (12) hours notice to the individual authorized to sample prior to unloading shellfish. Notice of less than twelve (12) hours may be approved by the authorized individual at his/her discretion. SSCAs may approve industry sampling and sample transport to the NSSP certified testing laboratory in accordance with the practices and procedures used by the SSCA under the NSSP. Such procedures may be approved by the SSCA only when sample collection and sample transport training is provided by the SSCA.

Shellfish from a federally closed harvest area must be kept separate and not sold until so authorized by the SSCA.

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

K. Unloading Schedule

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

L. Access for Dockside Sampling

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

M. Record Keeping

Record keeping requirements shall be as follows:

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

N. Early Warning/Alert System

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

1. shellfish species
2. harvest location name and coordinates (GPS or latitude/longitude)
3. harvest date
4. onboard screening test method, date, and results
5. laboratory test date and test results

Results of all samples having acceptable levels of paralytic shellfish toxins (<80ug/100g) shall immediately be reported to the SSCA in the state of landing. If the results of any one (1) sample equal or exceed 80ug/100g the testing laboratory shall immediately notify the FDA Regional Shellfish Specialist, the SSCA, and the processor by telephone. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s).

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

**Action by 2011
General Assembly**

Adopted recommendation of 2011 Task Force I on Proposal 11-116.

**Action by FDA
February 26, 2012**

Concurred with Conference action on Proposal 11-116 with the following recommendation.

FDA concurs with Conference action to adopt Proposal 11-116 to approve use of the Onboard Screening and Dockside Testing Protocol for controlling PSP in closed Federal waters. In the adopted Model Ordinance language the Protocol requires delivery of all onboard screening homogenates and test results to the authority in the State of landing. However, there is a discrepancy between what the adopted Model Ordinance language requires and what the adopted Guidance Document language recommends. To be consistent with the Model Ordinance requirement for onboard screening homogenates and test results to be submitted to the authority in the State of landing, the Guidance Document should be amended as follows: (strikethrough = *deleted text*, underline = *added text*)

Change Guidance Document item “E” first paragraph to read, “*Prior to commercial harvesting of molluscan shellfish, a minimum of five (5) screening samples shall be collected... For each screening test, positive and negative, the remaining sample material (Homogenate) shall be maintained under refrigeration for later use should the SSCA in the State of landing request confirmatory testing using a NSSP recognized test method. ~~Test kits, positive and negative, shall accompany the remaining sample homogenates to the certified laboratory. Confirmatory testing shall be performed on homogenate from each positive screening test using a NSSP recognized test method. Upon request by the SSCA in the state of landing, confirmatory testing of homogenate from negative screening tests shall be conducted using a NSSP recognized test method.~~”*

Change Guidance Document item “F” to read, “*All screening results shall be recorded on the “Harvest Record” as stipulated in Section D. of this Protocol. ~~Test kits used to screen each lot shall accompany the “Harvest Record”.~~ Upon landing of the harvest vessel, the “harvest Record” ~~and accompanying test kits~~ and screening homogenates shall be provided to the ~~individual (state shellfish official, FDA official, NMFS official)~~ authority in the State of landing authorized to sample the harvested shellfish as described in Section G. of this Protocol.*