

 <p>Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting</p>	<p>a. <input checked="" type="checkbox"/> Growing Area b. <input type="checkbox"/> Harvesting/Handling/Distribution c. <input type="checkbox"/> Administrative</p>
Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	U.S. Food and Drug Administration (FDA)
Address Line 1	5001 Campus Drive
Address Line 2	HFS-325
City, State, Zip	College Park, MD 20740
Phone	240-402-1401
Fax	301-436-2601
Email	Melissa.abbott@fda.hhs.gov
Proposal Subject	Update the Control of Marine Biotoxins in Federal Waters
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IV Shellstock Growing Areas @.04 Marine Biotoxin Control A(5) Section IV Guidance Documents Chapter II Growing Areas .06 Protocol for the Landing of Shellfish from Federally Closed Waters Due to PSP
Text of Proposal/ Requested Action	<p>Update the language as indicated below for Section II Model Ordinance Chapter IV Shellstock Growing Areas @.04 Marine Biotoxin Control A. Contingency Plan</p> <p>(5) Prior to allowing the landing of shellfish harvested from fFederal waters closed due to periodic toxic algal blooms associated with PSP, and where routine monitoring of saxitoxin levels is not conducted, <u>in addition to following all other requirements in the Model Ordinance</u>, 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:</p> <ul style="list-style-type: none"> (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: <ul style="list-style-type: none"> (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 ~~saxi~~toxins that are likely to be present. Harvesting shall not be permitted if any of the pre-harvested samples contain ~~saxi~~toxin levels in excess of half of the established criteria listen in Chapter IV @.04@(1) (e.g., 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 for PSP toxins).

(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 by the SSCA or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming Laboratory.

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 ~~saxi~~toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins).

(i) Disposal of shellfish ~~when should~~ dockside test results meet or exceed the established criteria in Chapter IV@.04(c)(1) (e.g., 2 mg domoic acid 80 µg/100 g for ASP toxins).

(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.

Update the language as indicated below for Section IV Guidance Documents
Chapter II Growing Areas

.06 Protocol for the Landing of Shellfish from Federally ~~Closed~~ Waters Due to PSP

~~When the h~~Harvest of molluscan shellfish ~~is closed~~ in Federal Waters not routinely monitored for toxins in shellfish (such as the Federal waters on Georges Bank closed due to Paralytic Shellfish Poison (PSP) risks); ~~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 memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. ~~The~~ is following 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~~ If harvesting from ~~f~~Federal waters closed due to PSP toxins, the Authority in the landing state will only allow the landing of shellfish from vessels in possession of an appropriate

	<p>Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS) <u>by vessels participating in the Federal Vessel Monitoring Systems (VMS)</u>. The NMFS shall receive concurrence from the SSCA in the State of landing. <u>Vessels operating in open Federal waters will also need applicable permits.</u></p> <p>B. Training</p> <p>The Authority shall ensure that all shipboard persons conducting onboard <u>sampling-testing</u> have been trained by a <u>U.S. Food and Drug Administration (FDA) National Shellfish Sanitation Program (NSSP) Laboratory Evaluation Officer (LEO) or an US Food and Drug Administration (FDA) marine Bbiotoxin expert to conduct onboard <u>PSP-toxin</u> screening using an <u>NSSP recognized method(s)</u>. <u>Shipboard persons conducting onboard toxin testing must receive refresher training every 3 years. A designee of the FDA LEO or FDA marine biotoxin expert may be appointed in writing to provide the training and/or refresher training.</u></u></p> <p>C. Vessel Monitoring</p> <p>The Authority shall <u>ensure that monitor</u> 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).</p> <p>D. Identification of Shellfish</p> <p>Prior to landing, each vessel <u>Captain or Mate</u> shall provide the Authority with a <u>Harvest Record, which may be electronic provided that it is made available to the authorized individual at dockside, for each harvesting trip record</u> identifying each lot of shellfish as follows: For each harvesting trip the Captain or Mate shall record the following information on a "Harvest Record." <u>Electronic logging of this information may be permitted provided it is made available to the authorized individual at dockside</u></p> <ol style="list-style-type: none"> 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 surf clams 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 <u>PSP</u>
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- 8. toxin screening sample
- 8. Results of each PSP-toxin screening test
- 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 (indelible and legible) with the following NSSP required information at the time of harvest:

- 1. ~~For s~~ Surf clams and ocean quahogs existing NMFS tagging requirements.
- 2. ~~For a~~ All other molluscan shellfish (including Stimpson clams also known as Arctic surf clams) using durable, waterproof, Authority sanctioned prior to use Tyvek-tags:
 - a. Vessel name;
 - b. Type and quantity of shellfish;
 - c. Date of harvest; and
 - 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-marine biotoxins that are likely to occur in accordance with an 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 by an FDA LEI or FDA marine biotoxin expert (or their designee as expressly indicated in writing) 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 (i.e., below half of the established criteria in Chapter IV). A positive result from any one (1) sample shall render the “lot area” unacceptable for harvest. The harvest vessel ~~e~~Captain shall immediately report all positive screening test results, by telephone or email, to the SSCA within the

intended state of landing, the FDA Shellfish Specialist, and the processor-NMFS. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area (s). 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, whether positive and-or 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 an 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. Upon landing of the harvest vessel, the “Harvest Record” and screening homogenates shall be provided to the SSCA or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory authority in the State of landing authorized to sample the harvested shellfish as described in Section G. of this Protocol.

G. Dockside Sampling

After dockside samples are collected by the SSCA or designee, molluscan shellfish may be processed while awaiting PSP analytical toxin 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 that demonstrate that toxin levels are below the established criteria in Chapter IV@.04(c)(1).

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 by the SSCA 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 an 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 in the state of landing, or if processed in another state, the SSCA in the state of processing.

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 the established criteria in Chapter IV@.04(c)(1) (e.g., 80 µg of paralytic shellfish toxins/100 g for PSP toxins) 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 the established criteria in Chapter IV @.04©(1) 80 µg paralytic shellfish toxins/100 g 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.

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

	<p>NSSP guidelines.</p> <p>J. Notification Prior to Unloading</p> <p>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.</p> <p>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 <u>appoint a designee in writing for</u> sampling and sample transport to the NSSP certified testing laboratory in accordance with the practices and procedures used by the SSCA under the NSSP. <u>The procedures, as well as training and certification records, must be available for evaluation.</u> Such procedures may be approved by the SSCA only when sample collection and sample transport training is provided by the SSCA.</p> <p>Shellfish from a federally closed <u>Federal water</u> harvest area(s) must be kept separate and not sold until so authorized by the SSCA <u>in the state of landing or, if processed in another state, the SSCA in the state of processing.</u></p> <p>Failure to comply with the provisions of this Protocol will result in the suspension or revocation of the vessel's EFP <u>permits through the NMFS.</u></p> <p>K. Unloading Schedule</p> <p>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.</p> <p>L. Access for Dockside Sampling</p> <p>Individuals authorized to sample shall be provided access to the catch of shellfish.</p> <p>M. Record Keeping</p> <p>Record keeping requirements shall be as follows:</p> <ol style="list-style-type: none"> 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
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	<p style="text-align: center;">least two (2) years.</p> <p>N. Early Warning/Alert System</p> <p>PSP sample Toxin 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 dockside, shall be transmitted to the FDA by the NSSP certified laboratory conducting PSP analyses toxin testing of the sampled lot(s) within one (1) week of the completion of the PSP-toxin analyses. The data provided shall include the following:</p> <ol style="list-style-type: none"> 1. Shellfish species; 2. Harvest location name and coordinates (GPS or latitude/longitude); 3. Harvest date; 4. Onboard screening test method, date, and results; <u>and</u> 5. Laboratory test date, <u>test method</u>, and test results <u>for dockside samples</u>. <p>Results of all samples having acceptable levels of paralytic shellfish toxins (e.g., <80 µg/100 g <u>for PSP toxins</u>) shall immediately be reported to the SSCA in the state of landing. If the results of any one (1) sample equal or exceed <u>the established criteria in Chapter IV @.04(c)(1) 80 µg/100 g</u> 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).</p> <p>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.</p>
<p>Public Health Significance</p>	<p>The protocol adopted by the ISSC in 2011 to allow the harvest of surf clams and ocean quahogs from Federal waters closed due to the risk of paralytic shellfish poisoning (PSP) toxins has granted access to valuable shellfish resources with measures in place to protect public health. While the protocol, referred to as onboard screening dockside testing, was designed for surf clam and ocean quahog harvests on Georges Bank, its success has demonstrated its applicability to other Federal waters where routine monitoring for marine biotoxins is not feasible.</p> <p>The goal of this proposal and the requested updates to the language in the Model Ordinance and Guidance Documents is to broaden the application of this successful protocol to other regions and for other toxins as they emerge into the regions of interest, thereby safely expanding access to shellfish resources in Federal waters.</p>
<p>Cost Information</p>	<p>N/A</p>