

UNITED STATES DEPARTMENT OF COMMERCE National Oceanic and Atmospheric Administration NATIONAL MARINE FISHERIES SERVICE

NORTHEAST REGION
55 Great Republic Drive
Gloucester, MA 01930-2276

Interstate Shellfish Sanitation Conference 209-2 Dawson Road Columbia, SC 29223 SEP 04 2012

RE: Proposed Rule to Re-Open a Portion of the Georges Bank (GB) Closure Area for the Harvest of Atlantic Surfclams and Ocean Quahogs

NOAA's Fisheries Service is proposing a Federal action regarding re-opening a portion of the GB Closed Area for the harvest of surfclams and ocean quahogs under the terms and conditions of the paralytic shellfish poisoning (PSP) testing protocol. We are taking this action under authority provided at 50 CFR 648.76(c) and at the request of the Mid-Atlantic Fishery Management Council (Council).

We previously proposed to re-open a portion of the GB Closed Area, but withdrew the proposal due to comments received from the public stating that the area should not be open without an approved testing protocol in place. We have issued exempted fishing permits (EFP) since 2008 to surfclam and ocean quahog vessels to conduct research in the closure area. Testing of clams in the GB Closed Area by the U.S. Food and Drug Administration (FDA), in cooperation with NMFS and the fishing industry under the EFPs, demonstrate that PSP toxin levels have been well below the regulatory limit established for public health safety. The FDA and NMFS have also developed a Protocol for Onboard Screening and Dockside Testing in Molluscan Shellfish that is designed to test and verify that clams harvested from the GB Closed Area are safe. The protocol was formally adopted into the National Shellfish Sanitation Program at the October 2011 Interstate Shellfish Sanitation Conference. Now that a testing protocol has been approved, NMFS, at the request of the Council, is proposing to re-open a portion of the GB Closed Area, provided all harvest is conducted under the terms of the PSP testing protocol.

A copy of the <u>Federal Register</u> notice is attached for your review, along with a copy of the approved PSP testing protocol. The comment period for this proposed rule ends on October 1, 2012. If you have any questions regarding this action, please contact Jason Berthiaume, Fishery Management Specialist, at 978-281-9177 or Jason.Berthiaume@noaa.gov

Sincerely,

Daniel S. Morris

Acting Regional Administrator

Enclosure







Federal Communications Commission. Bulah P. Wheeler,

Deputy Manager, Office of the Secretary, Office of Managing Director.

[FR Doc. 2012–21478 Filed 8–30–12; 8:45 am] BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 214

[Docket No. FRA-2008-0059, Notice No. 6] RIN 2130-AC37

Railroad Workplace Safety; Adjacent-Track On-Track Safety for Roadway Workers

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Petitions for reconsideration; response status.

summary: This document provides notice that, due to the complex issues raised in both the petitions for reconsideration of the final rule published November 30, 2011, and the comments received on the petitions, FRA continues to formulate an appropriate response to the petitions and comments. FRA's response will be published as soon as practicable and will be filed in the same docket.

FOR FURTHER INFORMATION CONTACT: Kenneth Rusk, Staff Director, Track Division, Office of Safety Assurance and Gompliance, FRA, 1200 New Jersey Avenue SE., RRS-15, Mail Stop 25, Washington, DC 20590 (telephone 202-493-6236); or Anna Winkle, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue SE., RCC-12, Mail Stop 10, Washington, DC 20590 (telephone 202-493-6166 or 202-493-6052).

SUPPLEMENTARY INFORMATION: On November 30, 2011, FRA published a final rule concerning adjacent-track ontrack safety for roadway workers. See Docket No. FRA—2008—0059, Notice No. 4 at 76 FR 74586. In response, FRA received two petitions for reconsideration (Petitions) that raised substantive issues. One of the Petitions included a request for a delay in the effective date of the final rule until July 1, 2013.

On March 8, 2012, FRA published a final rule delaying the effective date of the November 30, 2011, final rule until July 1, 2013, and establishing a 60-day comment period in order to permit interested parties an opportunity to

respond to the Petitions. See 77 FR 13978. FRA received five comments on the Petitions, some of which raise additional substantive issues or provide further detailed information on the issues already raised. The Petitions and comments on the Petitions are available for review in the docket for this rulemaking, and have been assigned identification numbers of FRA-2008-0059-0031 and FRA-2008-0059-0032, for the Petitions, and identification numbers of FRA-2008-0059-0034, FRA-2008-0059-0035, FRA-2008-0059-0036, FRA-2008-0059-0037, and FRA-2008-0059-0038, for the comments on the Petitions.

Due to the complex issues raised and extensive estimates provided in the Petitions and comments, FRA continues to formulate an appropriate response. FRA's response to the Petitions and comments will be published as soon as practicable and will be filed in the same docket.

Issued in Washington, DC, on August 27, 2012.

Jo Strang,

Associate Administrator for Railroad Safety/ Chief Safety Officer.

[FR Doc. 2012-21585 Filed 8-30-12; 8:45 am]
BILLING CODE 4910-06-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 120604138-2289-01] RIN 0648-BC21

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Atlantic Surfclam and Ocean Quahog Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

summary: NMFS proposes to re-open a portion of the Georges Bank Closed Area to the harvest of Atlantic surfclams and ocean quahogs. The area has been closed since 1990 due to the presence of toxins known to cause paralytic shellfish poisoning. The proposed re-opening is based on a request from the Mid-Atlantic Fishery Management Council and the recent adoption of a testing protocol into the National Shellfish Sanitation Program.

DATES: Written comments must be received no later than 5 p.m. eastern standard time, on October 1, 2012.

ADDRESSES: You may submit comments, identified by NOAA-NMFS-2012-0121, by any of the following methods:

• Electronic Submissions: Submit all electronic public comments via the Federal e-Rulemaking portal http://www.regulations.gov.

• Fax: (978) 281–9177, Attn: Jason Berthiaume.

 Mail: Daniel S. Morris, Acting Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930.
 Mark the outside of the envelope: "Comments on Proposed Opening of GB PSP Closed Area."

Instructions: All comments received are part of the public record and will generally be posted to http://www.regulations.gov without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted via Microsoft Word, Microsoft Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Jason Berthiaume, Fishery Management Specialist, phone (978) 281–9177, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION:

Background

The Georges Bank (GB) Closed Area, located in the Exclusive Economic Zone east of 69°00' W. long. and south of 42°20' N. lat., has been closed to the harvest of surfclams and ocean quahogs since 1990 due to red tide blooms that cause paralytic shellfish poisoning (PSP). The closure was implemented based on advice from the U.S. Food and Drug Administration (FDA) after samples tested positive for toxins (saxitoxins) that cause PSP. These toxins are produced by the alga-Alexandrium fundyense, which can form blooms commonly referred to as red tides, or harmful algal blooms, and can produce toxins that accumulate in water column filter-feeding shellfish. Shellfish contaminated with the toxin, if eaten in large enough quantity, can cause illness or death in humans.

Due to inadequate testing or monitoring of this area for the presence of PSP-causing toxins, the closure was made permanent in 1999, under Amendment 12 to the Atlantic Surfclam and Ocean Quahog Fishery Management Plan (FMP). Since the implementation of the closure, NOAA's National Ocean Service has provided grants to the FDA, the states of Maine, New Hampshire, and Massachusetts, and a clam industry representative to collect water and shellfish samples from Federal waters off southern New England. NMFS has also issued exempted fishing permits (EFPs) since 2008 to surfclam and ocean quahog vessels to conduct research in the closure area. Testing of clams on GB by the FDA in cooperation with NMFS and the fishing industry under the EFPs demonstrate that PSP toxin levels have been well below the regulatory limit established for public health safety

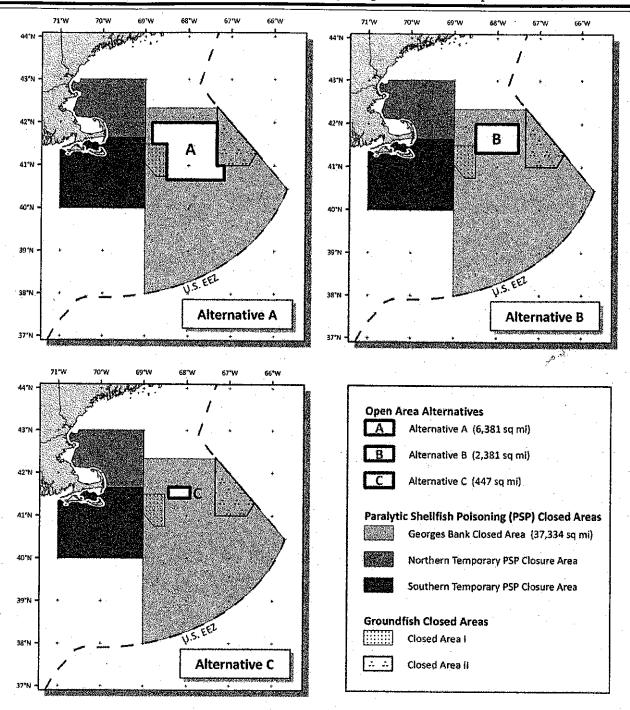
(FDA 2010). The FDA and NMFS also developed a Protocol for Onboard Screening and Dockside Testing in Molluscan Shellfish that is designed to test and verify that clams harvested from GB are safe. The protocol was formally adopted into the National Shellfish Sanitation Program at the October 2011 Interstate Shellfish Sanitation Conference.

On June 30, 2010, NMFS published a similar proposal in the Federal Register (75 FR 37745) to re-open a portion of the GB Closed Area. This proposed rule was later withdrawn due to public comments that opposed re-opening the GB Closed Area without having a testing protocol in place. Now that the protocol has been formally adopted, NMFS is proposing to re-open a portion of the GB

Closed Area with the requirement that the protocol be used on all fishing trips into the area.

Three areas are being considered for re-opening. To allow the industry to access as much of the area as possible and to generate public comment on all options, NMFS is proposing to re-open the largest of the three areas (Alternative A). The Alternative A area reflects the largest area that was previously permitted for sampling under an EFP, and the other alternatives areas are smaller subsets of the larger Alternative A area. The area proposed for reopening is defined in the table below and the remaining portion of the GB Closed Area would remain closed. BILLING CODE 3510-22-P

Coordinate of the Area Proposed for Opening (Alternative A)		
Point	Latitude	Longitude
1	42°00'	68°50'
2	42°00°	67°20'
3	41°00'	67°20'
4	41°00°	67°10'
5	40°40'	67°10'
6	40°40'	68°30'
7	41°30'	68°30'
8	41°30°	68°50'



BILLING CODE 3510-22-C

There have been no recent PSP toxin measurements recorded above regulatory limits, and PSP toxin monitoring would be conducted under the terms of the protocol for all trips into the area. Further, NMFS has the authority to close any area to harvesting of surfclams and ocean quahogs to prevent contaminated shellfish from entering the market. Any future closures or openings within the GB Closed Area will be based upon PSP toxin testing

results conducted under the terms of the protocol, the advice of the FDA, and the most current information available.

NMFS proposes to re-open the portion of the GB Closed Area to the harvest of surfclams and ocean quahogs, under its authority at § 648.76(c). However, we will continue to defer to the FDA in matters of public health and, should we receive new advice from the FDA, we will reconsider which portion of the GB

Closed Area should be opened for harvesting.

In addition, while NMFS proposes to re-open a portion of the GB Closed Area as requested by the Mid-Atlantic Fishery Management Council, NMFS also recognizes that red-tide events can vary inter-annually. For that reason, NMFS has prepared an environmental assessment (EA) that analyzes the proposed re-opening and two smaller area alternatives within the GB Closed

Area, to cover the possibility that the proposed opening could shift or vary, depending on a change in conditions or if new information becomes available. Given the temporal nature of PSP conditions, NMFS is seeking public comment on whether this proposed reopening should be implemented and, if so, which of the three areas should be re-opened (Alternatives A, B, or C).

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator for Fisheries, NOAA, has determined that this proposed rule is consistent with the Atlantic Surfclam and Ocean Quahog FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

NMFS prepared a draft EA for this action that analyzes the impacts of this proposed rule. A copy of the draft EA is available from the Federal e-Rulemaking portal http://www.regulations.gov. Type "NOAA-NMFS-2012-0121" in the Enter Keyword or ID field and click search. A copy of the EA is also available upon request from NMFS Northeast Acting Regional Administrator, Daniel S. Morris (see ADDRESSES).

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is as follows.

The proposed measures would only affect vessels holding an active Federal open access surfclam and/or ocean quahog permit. In 2011, there were 47 Federal open-access surfclam and/or ocean quahog permitted vessels that landed surfclams and/or ocean quahogs. All of these vessels fall within the SBA's definition of a small business. This action proposes to re-open an area that has previously been closed. The surfclam and ocean quahog fishery is managed under an Individual Transferable Quota system, and, since overall quotas are not being changed as a result of this action, no additional harvest would be permitted with this action. Participating vessels would still be able to fish in any of the existing areas open to the harvest of surfclams

and ocean quahogs. Those vessels that may fish in the area proposed to be opened may experience increased operational costs, if they choose to fish there; however, these costs may be offset due to increased productivity and efficiency of the fishing effort because of greater abundance of surfclams and ocean quahogs in the GB Closed Area. Regardless, any increased costs would not be considered significant.

In addition, for the past 5 years, NMFS has issued EFPs allowing the harvest of surfclams using the FDAapproved Protocol for Onboard Screening and Dockside Testing in Molluscan Shellfish. Because NMFS has issued EFPs to harvest surfclams within the GB Closure Area, and given that surfclams are more valuable than ocean quahogs, it is likely that vessels would continue this trend of targeting surfclams from the GB Closed Area, Due to the seasonal variability of PSP toxin levels, any or all of the areas associated with this action could open or close based on PSP conditions. Given this uncertainty as to whether the area would remain open, it is not anticipated that there would be an overall increase in participation in the surfclam and ocean quahog fishery due to the opening of this area. Therefore, because this action only proposes to re-open an area that has previously been closed, and because no net change in fishing effort, participation in the fishery, or fishery expenses is expected, this action will not have a significant economic effect on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: August 28, 2012.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 et seq.

2. In § 648.76, paragraph (a)(4) is revised to read as follows:

§ 648.76 Closed areas.

(a) * * *

(4) Georges Bank. The paralytic shellfish poisoning (PSP) contaminated area, which is located on Georges Bank, and is located east of 69° W. long., and south of 42°20′ N., lat., is closed to the harvest of surfclams and ocean quahogs. A portion of the Georges Bank Closed Area is open to harvest surfclams and ocean quahogs provided the vessel complies with the requirements specified in paragraph (a)(4)(i) of this section. The open portion of the Georges Bank Closed Area is defined by straight lines connecting the following points in the order stated:

OPEN PORTION OF THE GEORGES
BANK CLOSED AREA

Point	N. Latitude	W. Longitude
1	42°00′	68°50′
2	42°00′, 🗟	67°20'
3	41°00′ຶ	67°20'
4	41°00′	67°10′
5	40°40'	67°10′
6	40°40′	68°30′
7	41°30′	68°30'
8	41°30′	68°50'

- (i) Requirements for Vessels Fishing in the Open Portion of the Georges Bank Closed Area. A vessel may fish in the open portion of the Georges Bank Closed Area as specified in this paragraph (a)(4), provided it complies with the following terms and conditions:
- (A) A valid letter of authorization issued by the Regional Administrator must be onboard the vessel; and
- (B) The vessel must adhere to the terms and conditions of the PSP testing protocol as adopted into the National Shellfish Sanitation Program by the Interstate Shellfish Sanitation Conference. All surfclams and ocean quahogs harvested from the area must be handled in accordance with the terms and conditions of the protocol from the first point of harvest through completion of testing and release by the State Shellfish Control Authority as required by the PSP testing protocol; and
- (C) Prior to leaving port at the start of a fishing trip, the vessels' owner or operator must declare its intent to fish in the area through the vessel's vessel monitoring system.

[FR Doc. 2012-21586 Filed 8-30-12; 8:45 am]

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

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.
- 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 for later use should the SSCA in the State of landing request confirmatory testing 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. Upon landing of the harvest vessel, the "Harvest Record" and screening homogenates shall be provided to the 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, 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.