

MID-ATLANTIC FISHERY MANAGEMENT COUNCIL

Richard B. Robins, Jr.
Chairman

Lee G. Anderson
Vice Chairman

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Christopher M. Moore, Ph.D.
Executive Director

MEMO TO: Surfclam/Ocean Quahog and Tilefish Committee (Anderson, Himchak, Berg, King, Schafer, Gilmore)

MEMO FROM: Tom Hoff and Jose Montanez *TBH*

DATE: January 21, 2011

SUBJECT: February Council meeting.

The Clam Committee will meet on Wednesday February 9 from 8:00 to 9:00 AM at the New Bern, NC Council meeting. We have one agenda item. The Council received Regional Administrator Kurkul's letter of December 6, 2010 (Attachment 1) which informs the Council that the Agency has withdrawn the proposed rule to open a portion of the Georges Bank Closed Area that has been closed because of paralytic shellfish poisoning (PSP). The RA's December 8 letter to federal permit holders and dealers is also included (Attachment 2). Council's letters of support for this reopening (Attachment 3) and encouraging the development of a PSP protocol (Attachment 4) are also attached.

As identified in the last paragraph of Ms. Kurkul's December 6 letter, the Agency does not have independent authority to implement a formal testing protocol as a condition of re-opening a portion of the Georges Bank Closed Area and she mentions the Council could give her this authority through an Amendment. Staff contacts with Regional Office staff and General Counsel seem to indicate that addition of a PSP testing protocol to Amendment 15 could be possible and would not likely delay the ongoing work on this document.

Amendment 15 Update

Scoping for Amendment 15 was conducted nearly 2 years ago. The Amendment has 5 issues: 1) essential fish habitat (EFH) update, 2) new ocean quahog overfishing definition, 3) cost recovery, 4) excessive shares, and 5) data collection. The Committee and Council have reviewed and approved alternatives for EFH and the OQ overfishing. The excessive shares issue has been a very difficult one for both the FMAT and Committee, but it appears some sort of resolution is near. Last summer the Agency assigned \$80K for a contract which is being run by the Social Science Branch at Woods Hole. A 6 month contract was awarded and a report is to be generated by early February with presentation and WEBINAR review in early March. It is expected that a CIE review panel will convene and review the report in June. Development of a Draft Environmental Assessment with preferred alternatives should occur by October with the Council approving a public hearing draft by December. It is not expected that

inclusion of this issue -- implementing a mandatory testing protocol with the Agency monitoring it, would delay the Council's submission of Amendment 15 to the Service.

2010 Landings Update

You will recall that, at the quota setting meeting last June, there was a lot of concern over the surfclam landings with the majority coming from off of New Jersey. Surfclam landings in 2010 were only 60% of the allowable quota and totaled only a little more than 2 million bushels (Attachment 5).

Sea Watch fished on Georges Bank with an Exempted Fishery Permit for all of 2010. More than 200,000 bushels or more than 10% of the total coast-wide landings came from Georges Bank. Sea Watch again has received an Exempted Fishery Permit for 2011 and is expected to continue fishing on Georges Bank. Any one can apply and become part of the Exempted Fishery as long as they comply with existing rules and regulations. Thus, anyone can still fish on Georges Bank.

PSP Protocol for Testing and Industry Activities

Industry, NMFS, FDA and several States worked on the 2007 *Protocol for Onboard Screening and Dockside Testing for PSP Toxins in Molluscan Shellfish in Federally Closed Waters* for nearly a decade (Attachment 6). Council (Attachment 4) fully supported those efforts.

Industry continues to work with individual States. Please see attached series of emails between Tom Alspach and me documenting that the Commonwealth of Massachusetts now has formally agreed to permit the landing of surfclams harvested from Georges Bank in New Bedford. Previous landings by the Exempted Fishery were mostly in New Jersey.

Staff Recommendation

Staff recommends that the Surfclam/Ocean Quahog and Tilefish Committee recommend to the Council inclusion of language to give NMFS the independent authority to implement a formal testing protocol as a condition of re-opening a portion of the Georges Bank Closed Area. The language in the regulation could read something like: "The Assistant Administrator may impose additional conditions on the reopening of any area closed due to the presence of the paralytic shellfish poisoning toxin in order to protect public health."

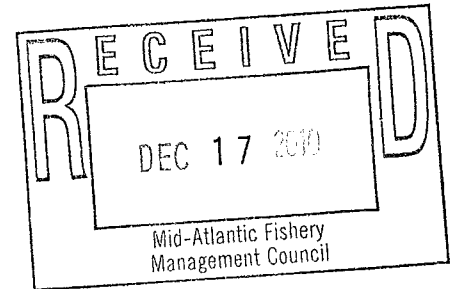
I look forward to seeing everyone on Wednesday February 9.



UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
NATIONAL MARINE FISHERIES SERVICE
NORTHEAST REGION
55 Great Republic Drive
Gloucester, MA 01930-2276

DEC - 6 2010

Richard B. Robins, Jr., Chairman
Mid-Atlantic Fishery Management Council
Suite 201
800 North State Street
Dover, DE 19901



Dear Rick:

This letter is to notify you that NOAA's National Marine Fisheries Service (NMFS) has withdrawn the proposed rule to open a portion of the Georges Bank (GB) Closed Area to the harvest of Atlantic surfclams and ocean quahogs.

The proposed rule was developed in response to a request from the U.S. Food and Drug Administration (FDA) on January 21, 2010, requesting that NMFS re-open a portion of the GB Closed Area, known Cultivator Shoal. The FDA indicated that recent testing of clams harvested from this area were below the regulatory limit established for public health safety and determined that the clams from this area are once again safe for human consumption.

Unfortunately, NMFS cannot move forward at this time with the FDA's request to re-open a portion of the GB Closed Area. During the public comment period, NMFS received substantive comments from experts in PSP that raised serious concerns with the proposed re-opening. These experts question the validity of the data on which the proposed re-opening is based, and strongly caution NMFS against re-opening the area without a rigorous testing protocol designed to protect the public health. Comments were also received from industry members who supported the re-opening but with the use of the FDA-approved Protocol for Onboard Screening and Dockside Testing in Molluscan Shellfish (Protocol). The Protocol was developed by the FDA, NMFS, and several states, and is designed to test whether clams harvested from the GB are safe. This Protocol is currently being used by one fishing vessel issued an exempted fishing permit to test the efficacy of harvesting surfclams and ocean quahogs from the GB Closed Area.

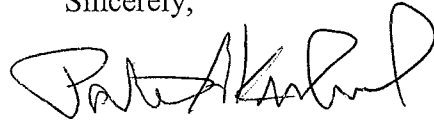
NMFS agrees that such a testing protocol is necessary to ensure that clams harvested from the area remain safe for human consumption; however, under the existing regulations for the surfclam and ocean quahog Fishery Management Plan (FMP), NMFS does not have that authority to implement such a monitoring requirement. Therefore, based on the review of the public comments, and given the significant health risks associated with opening the area without a testing protocol, NMFS has withdrawn the proposed rule.

Although NMFS does not have independent authority to implement a formal testing protocol as a condition of re-opening a portion of the GB Closed Area, this could be done through a Council



action to amend the Atlantic Surfclam and Ocean Quahog FMP. I encourage the council to consider initiating such an FMP amendment and, as always, my staff stands ready to assist the Council as necessary.

Sincerely,

A handwritten signature in black ink, appearing to read 'Patricia A. Kurkul', written in a cursive style.

Patricia A. Kurkul
Regional Administrator



UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
NATIONAL MARINE FISHERIES SERVICE
NORTHEAST REGION
55 Great Republic Drive
Gloucester, MA 01930-2276

DEC 08 2010

**-GEORGES BANK CLOSED AREA REMAINS CLOSED TO THE HARVEST OF
ATLANTIC SURFLAMS AND OCEAN QUAHOGS-**

Dear Federal Permit Holder or Dealer:

This letter is to inform you that that the Georges Bank (GB) Closed Area remains closed to the harvest of Atlantic surfclams (surfclams) and ocean quahogs.

NOAA's National Marine Fisheries Service (NMFS) on December 8, 2010, withdrew the proposed rule that was published on June 30, 2010, to solicit public comments on a re-opening a portion of the Georges Bank Closed Area, known as Cultivator Shoal. NMFS published this rule in response to a request from the U.S. Food and Drug Administration (FDA). Significant comments were received from experts in Paralytic Shellfish Poisoning (PSP) who cautioned against re-opening the area without a rigorous testing protocol to ensure the clams harvested from the GB are safe for human consumption. Comments were also received from industry members who supported the use of the FDA-approved Protocol for Onboard Screening and Dockside Testing in Molluscan Shellfish (Protocol). NMFS agrees that a testing protocol is needed to ensure that clams harvested from the GB area are safe; however, the agency does not have the authority to implement a monitoring program under the existing regulations for the surfclam and ocean quahog fishery.

Therefore, based on the comments received, and given the significant risk to the public health associated with re-opening the area without a testing protocol, NMFS has withdrawn the proposed rule and the GB Closed Area will remain closed.

The GB Closed Area is located east of 69°00' W. Longitude, and south of 42°20' N. Latitude and remains closed to the harvest of surfclams and ocean quahogs. *See chart of the closure area on the reverse side.*

A copy of the withdrawal of this rule is available at NMFS's Northeast Regional Office Web Site: <http://www.nero.noaa.gov>. If you have any questions on the withdrawal of this action, please call Anna Macan at (978) 281-9165.

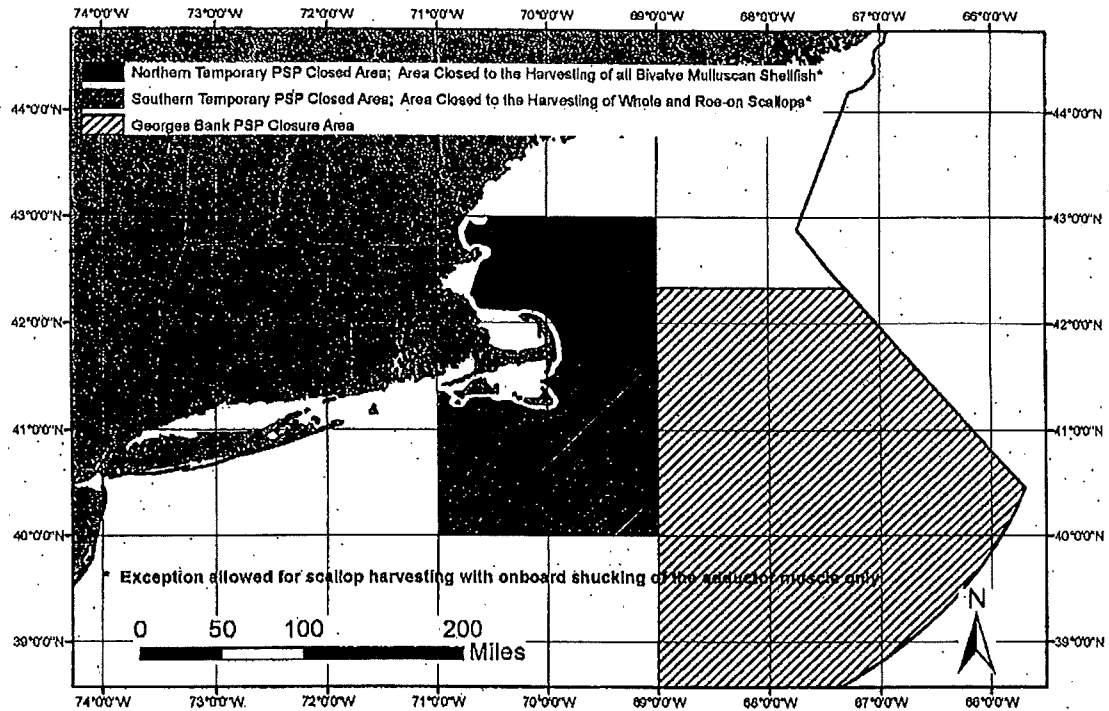
Sincerely,

Patricia A. Kurkul
Regional Administrator



This small entity compliance guide complies with section 212 of the Small Business Regulatory Fairness Act of 1996.

Federal Waters Closed Due to the Presence of the Toxin that Causes Paralytic Shellfish Poisoning



MID-ATLANTIC FISHERY MANAGEMENT COUNCIL

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Richard Seagraves
Acting Executive Director

Ms. Patricia A. Kurkul, Regional Administrator
NMFS, NERO
55 Great Republic Drive
Gloucester, MA 01930

July 14, 2010

Dear Pat,

The Mid-Atlantic Fishery Management Council (Council) offers the following comments in support of the proposed rule published in the *Federal Register* on June 30, 2010 that would open a portion of the Georges Bank (GB) Closed Area to the harvest of Atlantic surfclams and ocean quahogs. Our support for the proposed opening is based on the US Food and Drug Administration's (the Agency responsible for public seafood safety) determination that recent testing of clams collected from this portion of the GB Closed Area, known as Cultivator Shoal, has demonstrated that paralytic shellfish poisoning (PSP) toxin levels are well below the regulatory limit established for public health safety.

The Council has supported industry's efforts during the past several years to monitor PSP levels in New England and get a portion of the Closed Area opened if warranted. As you are well aware, surfclams and ocean quahogs are not overfished and overfishing is not occurring, but there are concerns regarding the spatial concentration of fishing effort on the surfclam resource and declining landings per unit of effort (LPUE) in the area off of New Jersey. The most recent stock assessments indicate that nearly half of both of these resources are distributed on GB and opening Cultivator Shoal should substantially alleviate the declining LPUE off of New Jersey for surfclams since we anticipate that effort will shift to GB where the catch rates in the Exempted Fishery are very high.

An opening of GB also will be consistent with the FMP where the management unit is all surfclams and ocean quahogs in the Atlantic EEZ. Finally, we support this proposed opening action because of the conclusions of the Programmatic Environmental Assessment which clearly concludes that any adverse habitat impacts will be temporary and minimal due to the predominantly high energy sandy bottom environment that exists on GB in the proposed open area.

Thank you for your consideration of our comments. Please do not hesitate to call Dr. Tom Hoff of Council staff should you have any questions.

Sincerely,

Richard B. Robins, Jr.
Chairman

cc: Anderson, Seagraves, Moore, Hoff

MID-ATLANTIC FISHERY MANAGEMENT COUNCIL

W. Peter Jensen
Chairman

Dr. Gene Kray
Vice Chairman

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Daniel T. Furlong
Executive Director

August 14, 2007

Ms. Pat Kurkul
Regional Administrator, Northeast Region
National Marine Fisheries Service
One Blackburn Drive
Gloucester, MA 01930

Dear Pat,

The Council at its August meeting last week, unanimously passed the following motion:

Move that the MAFMC write a letter to the FDA, NMFS, and northern states requesting that the FDA and NMFS facilitate talks with the states to establish a process and agreement under which NMFS could issue a permit with FDA concurrence to implement the PSP protocol.

The Council has been following the PSP closure for the shellfish harvesting on Georges Banks since 1990 and is concerned that more than a decade has passed since the original 1995 PSP protocol requirements to incorporate the latest scientific understanding and technology. This year's revisions to the protocol agreement (attached) should have facilitated the fishing industry's ability to harvest shellfish (i.e., scallops, surfclams, ocean quahogs, and mussels), but so far the protocol has not been enacted. The FDA and the Interstate Shellfish Sanitation Commission have ratified the protocol.

Obviously, we are concerned for our managed species of surfclams and ocean quahogs. Slightly more than 40% of each of these two EEZ resources are currently found on Georges Bank. This region has continued to increase its relative percentage of the biomass for each species as the clam industry has concentrated its efforts to regions south and west of Georges Bank.

Thank you for your attention to this request. If we can do anything to assist in the opening of Georges Bank for the harvest of our managed shellfish species, please to not hesitate to contact our Council Chairman or Dr. Thomas Hoff on staff.

Sincerely

Daniel T. Furlong
Executive Director

cc: Jensen and Kray

2010 Surfclam/Ocean Quahog Quota Report

Report run on:
For data reported
through:

January 4, 2011
December 31,
2010

Species	Bushels*	Percent of Quota*	Quota (Bushels)
SURFCLAM	2,071,458	60.9	3,400,000
OCEAN QUAHOG	3,382,767	63.4	5,333,000
MAINE QUAHOG	52,154	52.2	100,000

For Maine Quahog closures, click on the following link:
[Maine Quahog Closures Page](#)



**National
Oceanic and
Atmospheric
Administration**

Data are provided by the Northeast Region/Fishery Statistics Office of NOAA Fisheries. These figures are based on the 2010 dealer/processor shellfish reports for purchases made through December 31, 2010 and may be preliminary. Maine bushels have been converted to standard bushels for the 'Ocean Quahog' data but remain in Maine bushels for the 'Maine Quahog' data.

*The landings in these fields exclude 'Confidential' data.

2010 Surfclam/Ocean Quahog Landings by period

Period	Begin Date	End Date	Surfclam Bushels	Surfclam Bushels (Cumulative)	Ocean Quahog Bushels	Ocean Quahog Bushels (Cumulative)	Maine Quahog Bushels	Maine Quahog Bushels (Cumulative)
01	01-JAN	15-JAN	133,184	133,184	142,648	142,648	1,289	1,289
02	16-JAN	31-JAN	82,336	215,520	151,765	294,414	1,441	2,730
03	01-FEB	15-FEB	77,769	293,289	170,162	464,576	1,484	4,214
04	16-FEB	28-FEB	43,280	336,569	115,128	579,705	1,157	5,371
05	01-MAR	15-MAR	130,048	466,617	173,025	752,730	1,126	6,497
06	16-MAR	31-MAR	75,488	542,105	138,446	891,176	1,581	8,078
07	01-APR	15-APR	146,848	688,953	172,689	1,063,866	1,959	10,037
08	16-APR	30-APR	104,192	793,145	139,005	1,202,872	1,614	11,651
09	01-MAY	15-MAY	98,176	891,321	157,685	1,360,557	2,235	13,886
10	16-MAY	31-MAY	83,616	974,937	166,369	1,526,926	5,990	19,876
11	01-JUN	15-JUN	123,680	1,098,617	103,336	1,630,263	3,051	22,927
12	16-JUN	30-JUN	106,464	1,205,081	174,384	1,804,647	6,555	29,482
13	01-JUL	15-JUL	87,872	1,292,953	137,945	1,942,592	520	30,002
14	16-JUL	31-JUL	78,352	1,371,305	160,530	2,103,123	2,215	32,217
15	01-AUG	15-AUG	95,649	1,466,954	134,217	2,237,341	3,024	35,241
16	16-AUG	31-AUG	87,008	1,553,962	150,527	2,387,868	3,955	39,196
17	01-SEP	15-SEP	96,104	1,650,066	108,781	2,496,650	2,962	42,158
18	16-SEP	30-SEP	77,824	1,727,890	113,308	2,609,958	1,614	43,772
19	01-OCT	15-OCT	94,208	1,822,098	153,424	2,763,383	1,365	45,137
20	16-OCT	31-OCT	73,744	1,895,842	128,895	2,892,279	1,414	46,551

21	01- NOV	15- NOV	52,896	1,948,738	119,098	3,011,377	1,117	47,668
22	16- NOV	30- NOV	81,152	2,029,890	159,422	3,170,799	1,299	48,967
23	01- DEC	15- DEC	26,784	2,056,674	129,770	3,300,570	1,660	50,627
24	16- DEC	31- DEC	14,784	2,071,458	82,197	3,382,767	1,527	52,154
<i>Totals:*</i>			2,071,458		3,382,767		52,154	



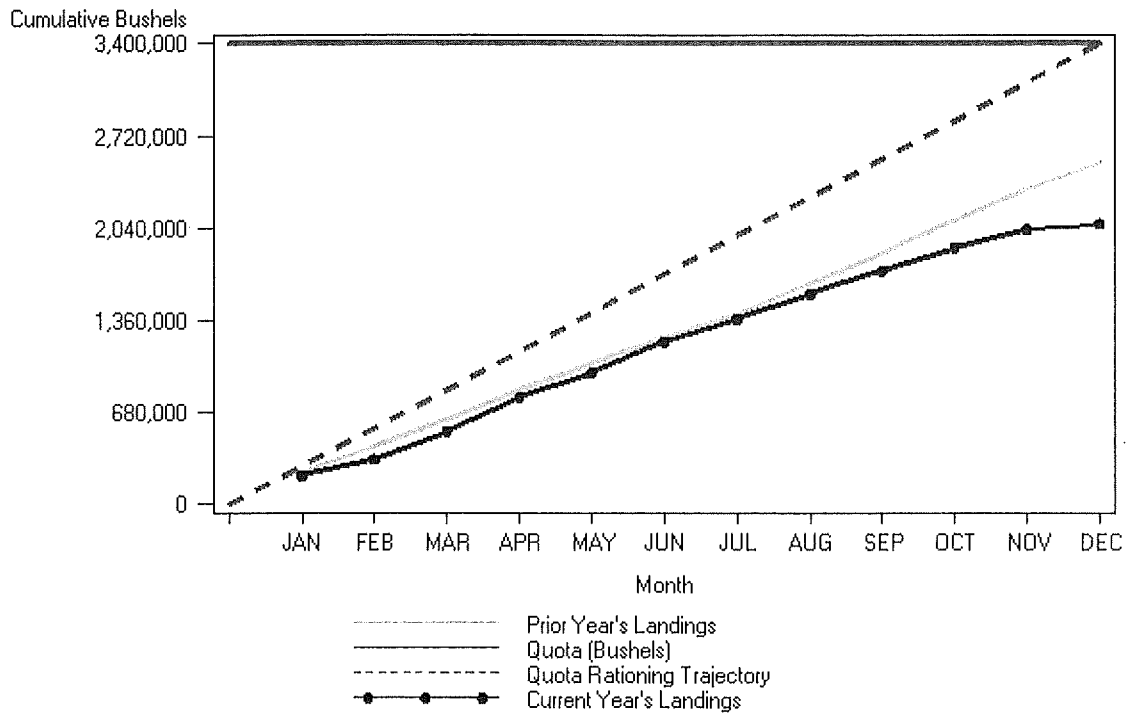
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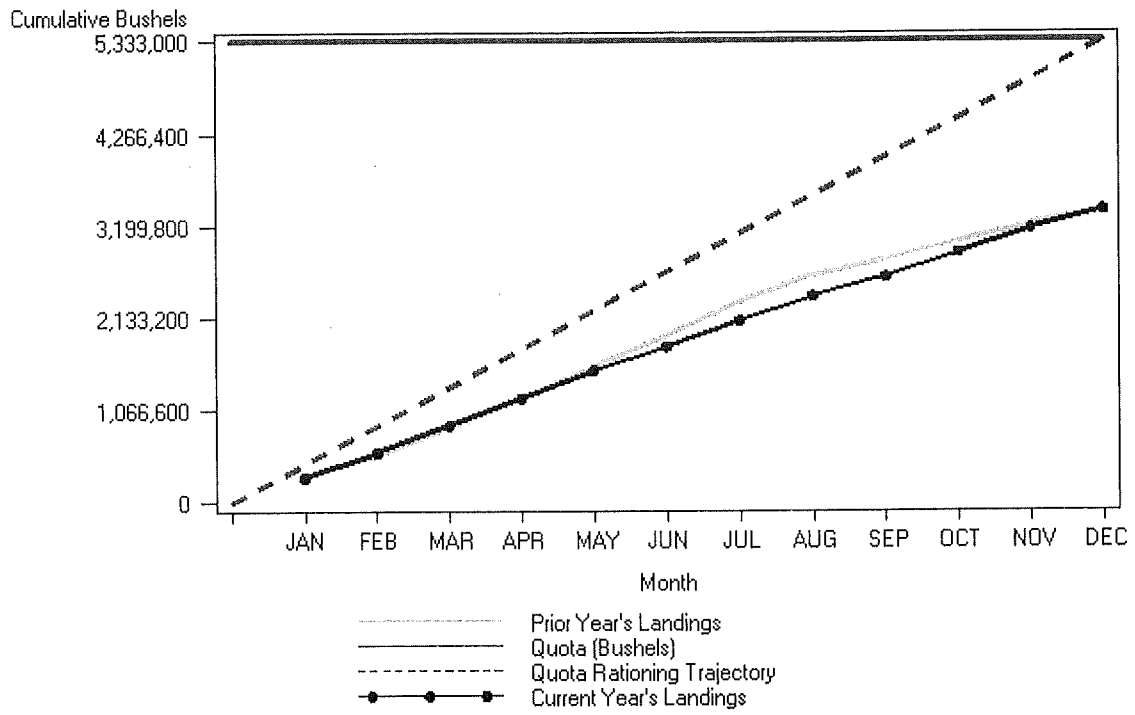
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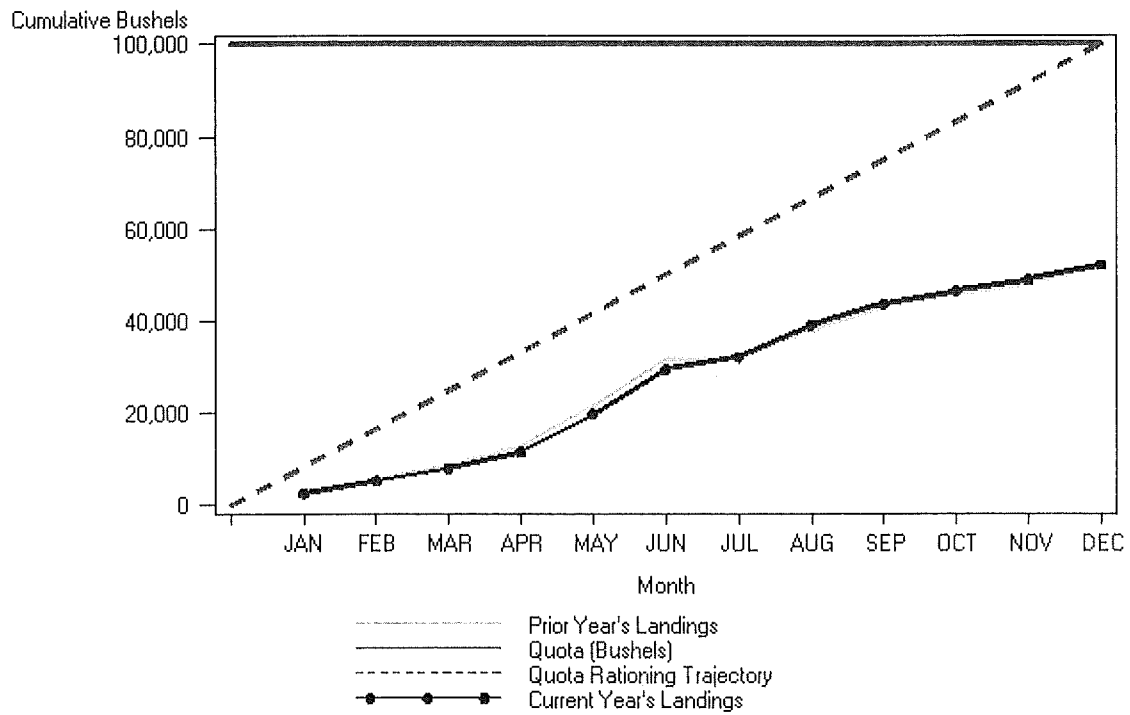
2010 SURFCLAM LANDINGS REPORT



2010 OCEAN QUAHOG LANDINGS REPORT



2010 MAINE QUAHOG LANDINGS REPORT



Protocol for Onboard Screening and Dockside Testing for PSP
Toxins in Molluscan Shellfish in Federally Closed Waters
November 2007

When the harvest of molluscan shellfish is prohibited due to Paralytic Shellfish Poison (PSP), exceptions to the prohibitions may be authorized provided that such harvests are subject to onboard screening and dockside lot testing for paralytic shellfish toxins in accordance with the following *Onboard Screening and Dockside Testing Protocol for PSP*, hereafter referred to as the Protocol.

I. PERMIT REQUIREMENTS:

Only vessels in possession of an appropriate Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS) may harvest molluscan shellfish from Federal waters closed because of PSP. Vessels granted an EFP must participate in the NMFS Vessel Monitoring System (VMS). All requests for permission to harvest in closed Federal waters must include a statement identifying the shipboard person(s) who has 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). Requests for permission to harvest shall also include a signed statement from the intended receiving processor affirming that he/she understands that each lot of shellfish from a Federally closed harvest area must be kept separate, not sold, and not processed until so authorized by the State Shellfish Control Authority (SSCA). Concurrence from the SSCA in the state of landing shall be obtained by NMFS prior to the issuance of an EFP. Under 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.

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

Costs associated with meeting the requirements of this Protocol, including sample collection, screening, transportation, analysis, etc., shall be borne by the industry user.

II. HARVEST LOT:

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.

III. ONBOARD PSP SCREENING PRIOR TO COMMERCIAL HARVESTING

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 (lot area). 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.

All screening results shall be recorded on the "Declaration of Harvest Record" as stipulated in Section V of this Protocol. Test kits used to screen each lot shall accompany the "Declaration of Harvest Record". Upon landing of the harvest vessel, the "Declaration of 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 V of this Protocol.

IV. APPROVED LABORATORIES:

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.

V. DECLARATION OF HARVEST RECORD:

For each harvesting trip the Captain or Mate shall record the following information on a "Declaration of Harvest Record." Electronic logging of this information may be permitted provided it is made available to the authorized individual at dockside.

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

The Captain or Mate shall sign the "Declaration of Harvest Record." The "Declaration of 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 "Declaration of 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.

VI. CONTAINER LABELING:

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

- a) For surfclams and ocean quahogs existing NMFS tagging requirements
- b) For all other molluscan shellfish (including Stimpson clams also known as Arctic surfclams) using Tyvek tags:
 - Vessel name
 - Type and quantity of shellfish

- Date of harvest
- Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds

VII. NOTIFICATION PRIOR TO UNLOADING:

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.

VIII. 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.

IX. ACCESS FOR DOCKSIDE SAMPLING:

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

X. DOCKSIDE SAMPLING, TESTING, AND PRODUCT DISPOSITION:

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, 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, 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, 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, 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 X.1 shall be tested for the presence of paralytic shellfish toxins using NSSP recognized methods.
3. If test results of any one (1) of the seven (7) samples collected in accordance with X.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.
4. 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 for processing by the SSCA.

XI. RECORD KEEPING:

Record keeping requirements shall be as follows:

- a) The vessel shall maintain the "Declaration of Harvest Record" for at least one year.
- b) The processor(s) shall maintain the "Declaration of Harvest Record" for at least one year or two years if the product is frozen.
- c) The SSCA in the state of landing shall retain the "Declaration of Harvest Record" for at least two years.
- d) FDA shall maintain records of all onboard screening tests and laboratory tests. These data shall be transmitted to the FDA in accordance with Section XII.

XII. 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:

- a) shellfish species
- b) harvest location name and coordinates (GPS or latitude/longitude)
- c) harvest date
- d) onboard screening test method, date, and results
- e) 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).

XIII. FEDERAL WATERS UNDER THE JURISDICTION OF THE STATE OF MAINE

The NMFS will not issue an EFP to fish Federal waters of the Maine Mahogany Quahog Zone unless the state of Maine concurs with the issuance of such a permit.

XIV. PROTOCOL EVALUATION:

The protocol and the data it generates will be evaluated annually. The evaluation will be conducted by a work group comprised of state and Federal agencies and the shellfish industry. The evaluation will assess the Protocol's effectiveness in providing public health protection and the need for possible modifications. The evaluation will also allow the possible incorporation of new technology and innovation.

Hoff, Thomas B.

From: Thomas T. Alspach [talspach@goeaston.net]
Sent: Thursday, January 06, 2011 12:32 PM
To: Hoff, Thomas B.
Subject: Re: Georges Bank/Opening of New Bedford
Feel free to share with the Council. Will be back to you soon on the harvest info.

TTA

----- Original Message -----

From: Hoff, Thomas B.
To: Alspach, Tom
Sent: Thursday, January 06, 2011 11:44 AM
Subject: RE: Georges Bank/Opening of New Bedford

Thank you Tom. This is wonderful. I am assuming that with your statement about me being able to distribute these to any interested parties, that I can share this completely with the Council, correct?

Look forward to your answer on the volume of clams harvested on GB. If there is any problem on your end, I am sure I can work around the specific number with generalities.

Again, thanks for the very informative update.

Tom

From: Thomas T. Alspach [mailto:talspach@goeaston.net]
Sent: Thursday, January 06, 2011 11:13 AM
To: Hoff, Thomas B.
Subject: Georges Bank/Opening of New Bedford

Tom –

Confirming our telephone conversation this morning, I wanted you to know that the Commonwealth of Massachusetts now has formally agreed to permit the landing of surf clams harvested from GB in New Bedford, pursuant to a slightly modified dockside testing protocol adapted from the previously approved FDA protocol for the experimental fishing now occurring in federal waters.

I am attaching the following which you may want to distribute to any interested parties:

Press release from the Massachusetts Governor's office announcing the new protocol and opening of New Bedford;

Letter from Massachusetts DPH to Bob Brennan, President of Sea Watch, confirming granting of variance from existing restrictions on landing of GB clams in New Bedford, pursuant to the terms of the new protocol; and

A copy of the new Massachusetts protocol as adopted.

Concerning the last document you will see that the only slight modification Massachusetts is

requiring in order to land in New Bedford is found in section X, which states that 11 samples must be tested (as opposed to the seven samples required by the FDA protocol). This standard was discussed in detail at multiple meetings among DPH, FDA and Sea Watch representatives, and Sea Watch is entirely comfortable with the need to do these several additional samplings at the dock. As you know, we have already been fishing for some time on GB and there have been no instances of tainted clams being brought ashore, so we are confident that landings will continue even with the additional samples required.

Finally, you will see that this protocol pertains only to surf clams, which is all that Sea Watch requested at the present time. We have been assured by Mass DPH, however, that the program can be expanded to include quahogs if we make application for that additional coverage if and when we desire to harvest quahogs from the GB area.

I know you share the concern that the Surf Clam Committee be satisfied that clams are being actively harvested from Georges Bank, so that that resource may be considered for quota setting purposes, as it should be. I will also pass your request about release of the volume of resources harvested to the responsible Sea Watch officials, as I am confident I can get permission to provide this information which is already fairly widely known.

Thank you for your continuing interest in all of this.

TTA

Thomas T. Alspach
295 Bay Street, Suite One
P.O. Box 1358
Easton, MD 21601
410-822-9100

Confidentiality Notice

The information in this transmission is intended only for the individual or entity named above. It may be legally privileged and confidential. If you have received this information in error, please notify us immediately by calling our operator at the number set out above and permanently delete the sent message. If the reader of this message is not the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of this communication or its contents is strictly prohibited.

APPENDIX – B

Protocol for Onboard Screening and Dockside Testing for PSP Toxins in Molluscan Shellfish in Federally Closed Waters November 2007

Massachusetts revisions – October 2010

When the harvest of molluscan shellfish is prohibited due to Paralytic Shellfish Poison (PSP), exceptions to the prohibitions may be authorized provided that such harvests are subject to onboard screening and dockside lot testing for paralytic shellfish toxins in accordance with the following *Onboard Screening and Dockside Testing Protocol for PSP*, hereafter referred to as the Protocol.

I. PERMIT REQUIREMENTS:

Only vessels in possession of an appropriate Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS) may harvest molluscan shellfish from Federal waters closed because of PSP. Vessels granted an EFP must participate in the NMFS Vessel Monitoring System (VMS). All requests for permission to harvest in closed Federal waters must include a statement identifying the shipboard person(s) who has 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). Requests for permission to harvest shall also include a signed statement from the intended receiving processor affirming that he/she understands that each lot of shellfish from a Federally closed harvest area must be kept separate, not sold, and not processed until so authorized by the State Shellfish Control Authority (SSCA). Concurrence from the SSCA in the state of landing shall be obtained by NMFS prior to the issuance of an EFP. Under 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.

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

Costs associated with meeting the requirements of this Protocol, including sample collection, screening, transportation, analysis, etc., shall be borne by the industry user.

II. HARVEST LOT:

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.

III. ONBOARD PSP SCREENING PRIOR TO COMMERCIAL HARVESTING

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.

Note: in Massachusetts, harvest decisions are to be made based upon concurrent use of the Abraxis and Jellet onboard screening tests as authorized in the ISSC letter dated June 17, 2009 from Ken B. Moore to Patricia Kurkul, Regional Administrator, National Marine Fisheries Service.

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 (lot area). 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.

Note: in Massachusetts – use of this Protocol for harvesting of molluscan shellfish species other than surf clams must be reviewed and approved in advance by the Massachusetts Department of Public Health.

All screening results shall be recorded on the "Declaration of Harvest Record" as stipulated in Section V of this Protocol. Test kits used to screen each lot shall accompany the "Declaration of Harvest Record". Upon landing of the harvest vessel, the "Declaration of 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 V of this Protocol.

IV. APPROVED LABORATORIES:

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.

V. DECLARATION OF HARVEST RECORD:

For each harvesting trip the Captain or Mate shall record the following information on a "Declaration of Harvest Record." Electronic logging of this information may be permitted provided it is made available to the authorized individual at dockside.

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

The Captain or Mate shall sign the "Declaration of Harvest Record." The "Declaration of 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 "Declaration of 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.

VI. CONTAINER LABELING:

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

- a) For surfclams and ocean quahogs existing NMFS tagging requirements
- b) For all other molluscan shellfish (including Stimpson clams also known as Arctic surfclams) using Tyvek tags:

- Vessel name
- Type and quantity of shellfish
- Date of harvest
- Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds

VII. NOTIFICATION PRIOR TO UNLOADING:

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.

VIII. 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.

IX. ACCESS FOR DOCKSIDE SAMPLING:

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

X. DOCKSIDE SAMPLING, TESTING, AND PRODUCT DISPOSITION:

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, **eleven (11)** 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, **eleven (11)** 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, **eleven (11)** 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, **eleven (11)** composite samples, each comprised of twenty (20) scallop gonads, shall be taken at random by the individual authorized to sample.

Note: clarification – if the harvest vessel has harvested shellfish from more than one harvest area, each area constitutes a separate “lot” and eleven (11) composite samples shall be taken from each lot.

Note: in Massachusetts – use of this protocol for harvesting of molluscan shellfish species other than surf clams must be reviewed and approved in advance by the Massachusetts Department of Public Health. Expansion of harvest to species other than surf clams also requires notification by the harvester to the SSCA.

2. Shellfish samples collected in accordance with X.1 shall be tested for the presence of paralytic shellfish toxins using NSSP recognized methods.
3. If test results of any one (1) of the **eleven (11)** samples collected in accordance with X.1 equal or exceed 80ug of paralytic shellfish toxins/100g of shellfish tissue (**n=11, 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.

4. 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 for processing by the SSCA.

XI. RECORD KEEPING:

Record keeping requirements shall be as follows:

- a) The vessel shall maintain the “Declaration of Harvest Record” for at least one year.
- b) The processor(s) shall maintain the “Declaration of Harvest Record” for at least one year or two years if the product is frozen.
- c) The SSCA in the state of landing shall retain the “Declaration of Harvest Record” for at least two years.
- d) FDA shall maintain records of all onboard screening tests and laboratory tests. These data shall be transmitted to the FDA in accordance with Section XII.

XII. 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:

- a) shellfish species
- b) harvest location name and coordinates (GPS or latitude/longitude)
- c) harvest date
- d) onboard screening test method, date, and results
- e) laboratory test date and test results

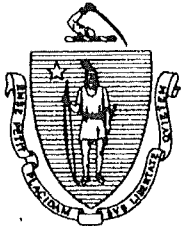
Results of all samples having acceptable levels of paralytic shellfish toxins (<80ug/100g) shall immediately be reported to the SSCA in the state of landing. If the results of any one (1) sample equal or exceed 80ug/100g the testing laboratory shall immediately notify the FDA Regional Shellfish Specialist, 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).

XIII. FEDERAL WATERS UNDER THE JURISDICTION OF THE STATE OF MAINE

The NMFS will not issue an EFP to fish Federal waters of the Maine Mahogany Quahog Zone unless the state of Maine concurs with the issuance of such a permit.

XIV. PROTOCOL EVALUATION:

The protocol and the data it generates will be evaluated annually. The evaluation will be conducted by a work group comprised of state and Federal agencies and the shellfish industry. The evaluation will assess the Protocol's effectiveness in providing public health protection and the need for possible modifications. The evaluation will also allow the possible incorporation of new technology and innovation.



DEVAL L. PATRICK
GOVERNOR

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JOHN AUERBACH
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Department of Public Health
Bureau of Environmental Health
Food Protection Program
305 South Street, Jamaica Plain, MA 02130-3597
(617) 983-6712 (617) 524-8062 - Fax

December 21, 2010

Robert Brennan, President
Sea Watch International, Inc.
8978 Glebe Park Drive
Easton, MD 21601-7004

Dear Mr. Brennan:

The Massachusetts Department of Public Health (DPH), Food Protection Program has reviewed documents pertaining to the pilot program for Onboard Screening and Dockside Testing for PSP Toxins in Molluscan Shellfish in Federally Closed Waters, including your letter dated March 10, 2010 in which you requested a variance from certain provisions of the DPH regulations governing shellfish. This letter sets forth the conditions under which such a variance is issued.

As you know, the pilot program is proceeding under the authority of Exempted Fishing Permit (EFP) 9273, issued by the National Marine Fisheries Service on December 10, 2009, and the November 2007 Protocol for Onboard Screening and Dockside Testing for PSP Toxins in Molluscan Shellfish in Federally Closed Waters ("the Protocol"), approved by the federal Food and Drug Administration and the National Marine Fisheries Service, as revised by Massachusetts in October, 2010. In brief summary, the Protocol provides that samples of shellfish from each specific area to be harvested will be tested for the presence of paralytic shellfish poison (PSP) onboard the Sea Watch vessel. If the samples "pass," the specific area may be harvested. Once landed, the shellfish are subject to dockside sampling and laboratory testing. Only if the laboratory testing indicates that the shellfish are safe for human consumption may they enter the marketplace.

In order for clams to be landed legally in Massachusetts under the Protocol, additional requirements as detailed in Sections III (Onboard PSP Screening Prior to Commercial Harvesting) and X (Dockside Sampling, Testing, and Product Disposition) of the attached Protocol must be observed. Further, DPH has reviewed and approved additional requirements

that are contained in the following attached documents received from Sea Watch International, Inc.:

- 1) SWI Training protocol
- 2) Check Sheet – Georges Banks
- 3) Georges Banks SOPs
- 4) HACCP Plan (Georges Banks revisions)
- 5) HACCP Hazard Analysis Worksheet (Georges Banks revisions)
- 6) Declaration of Harvest – Protocol for Onboard Screening and Dockside Testing for PSP Toxins (October 2010 revision)
- 7) SWI Clam Cage Loading Diagram for SeaWatcher I

DPH regulations at 105 CMR 533.000, Fish and Fishery Products, set forth various requirements that must be met by handlers and processors of shellfish. Section 533.030 provides that DPH may vary the application of any provision of the regulations with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice, provided that the decision of the Department does not conflict with the spirit of the regulations. With respect to the pilot program, there are two sections of the regulations that are appropriate for a variance.

Section 533.006 includes in the definition of “Critical Violation or Critical Deficiency,” any seafood from an unapproved source. Although the federally closed waters from which the shellfish will be harvested are an unapproved source, strict adherence to the requirements of the EFP, the Protocol, and the other requirements described above will ensure that the shellfish are safe for human consumption. Therefore, a variance from this requirement is warranted.

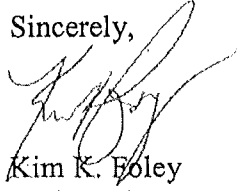
Section 533.008(A) states the “market standard” for shellfish sold in Massachusetts. This regulation provides: “Any shellfish, fresh or frozen, shall be deemed to meet the market standard for shellfish sold in Massachusetts if:

- (1) It was harvested from an approved area; or
- (2) It was harvested from a restricted area and was subjected to a process of controlled purification approved by the Department; and
- (3) Approved analytical methods indicate that it meets the NSSP standards for fecal and pathogenic contamination.”

The shellfish harvested pursuant to the Protocol will be harvested from an unapproved area, and they will not be subjected to a controlled purification process. However, as noted by you in your variance request, the Protocol and the Massachusetts requirements described above entail rigorous testing and sampling of the shellfish. The shellfish will not enter the marketplace unless they meet the testing standards established by these requirements. In the event that the tests show that the shellfish are not safe for human consumption, they will not be “purified” but will be destroyed or otherwise disposed of pursuant to established procedures. Therefore, a variance from 105 CMR 533.008(A) is warranted.

Variations from 105 CMR 533.006 and 533.008(A) as discussed above are hereby granted with respect to surf clams¹, subject to the conditions that the EFP, the Protocol, and the above-described requirements are adhered to at all times by Sea Watch.

Sincerely,



Kim K. Foley
Acting Director
Food Protection Program

CC: Suzanne K. Condon, Associate Commissioner/Director, MDPH/BEH
Michael Hickey, MA Division of Marine Fisheries
Anna Macan, Northeast Region, National Marine Fisheries Services

¹ Under the Protocol, the harvesting of molluscan shellfish species other than surf clams must be reviewed and approved in advance by the Massachusetts Department of Public Health.