

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 648**

[Docket No. 050613158-5158-01; I.D. 061305B]

RIN 0648-AT48

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Emergency Fishery Closure Due to the Presence of the Toxin that Causes Paralytic Shellfish Poisoning (PSP)

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

ACTION: Emergency action; request for comments.

SUMMARY: NMFS is promulgating emergency regulations, at the request of the Food and Drug Administration (FDA), to close portions of Federal waters of the Gulf of Maine, Georges Bank, and southern New England to the harvest of shellfish (bivalves), with the exception of sea scallop adductor muscles harvested and shucked at sea, due to the presence in those waters of the toxin that causes paralytic shellfish poisoning (PSP). The concentrations of the toxin in the Federal waters is great enough to warrant a public health emergency. The closure will remain in effect until September 30, 2005, with the possibility of a reduction or an extension of the closure based upon FDA's determination that the concentration of the toxin in shellfish is at a level that is safe or unsafe, respectively, for human consumption.

DATES: Effective June 14, 2005 through September 30, 2005. Comments must be received by July 18, 2005.

ADDRESSES: Comments may be submitted by any of the following methods:

- E-mail: PSPClosure@NOAA.gov.

Include in the subject line the following: "Comments on the Emergency Rule for Area Closure Due to PSP."

- Federal e-Rulemaking Portal: <http://www.regulations.gov>.

- Mail: Paper, disk, or CD-ROM comments should be sent to Patricia A. Kurkul, Regional Administrator, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on the Emergency Rule for Area Closure Due to PSP."

- Fax: (978) 281-9135.

Copies of the emergency rule are available from Patricia A. Kurkul, Regional Administrator, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930.

FOR FURTHER INFORMATION CONTACT:

Brian Hooker, Fishery Policy Analyst, phone: (978) 281-9220, fax: (978) 281-9135.

SUPPLEMENTARY INFORMATION:**Background**

On June 10, 2005, FDA requested that NMFS close an area of Federal waters off the coasts of New Hampshire and Massachusetts to any harvesting of shellfish (bivalves) intended for human consumption. This includes surfclams, ocean quahogs, unshucked or "roe-on" scallops, and mussels. The only exception to this closure is for Atlantic sea scallops harvested for onboard shucking of the adductor muscle or "meat" which is unaffected by the toxin. The text of the June 10, 2005, FDA request is as follows:

June 10, 2005
Rebecca Lent, Ph.D.
Deputy Administrator
National Marine Fisheries Service
1315 East West Highway
Silver Spring, MD 20910

Dear Dr. Lent:

On behalf of Michael O. Leavitt, Secretary of Health and Human Services (HHS), the Food and Drug Administration (FDA) is requesting that the National Oceanic and Atmospheric Administration (NOAA)/National Marine Fisheries Service (NMFS) of the Department of Commerce close waters of the north western Atlantic Ocean, as described below, to the harvesting of bivalve molluscan shellfish intended for human consumption. The States of Massachusetts, New Hampshire, and Maine are experiencing one of the largest toxic algal blooms (red tides) in their history. The red tide, which is responsible for the production of marine biotoxins that cause Paralytic Shellfish Poisoning (PSP) in persons consuming affected shellfish, has spread from State waters to Federal waters further offshore. In accordance with the National Shellfish Sanitation Program (NSSP), the States have closed affected waters within their jurisdiction. Closure of Federal waters is also necessary to address this public health emergency by ensuring that potentially unsafe bivalve molluscan shellfish are not harvested for human consumption.

FDA is requesting that NMFS close all waters south of 43 degrees north latitude, west of 69 degrees west longitude, north of 40 degrees north latitude, and east of 71 degrees west longitude. This area is to be closed to the harvesting of all species of bivalve molluscan shellfish with the only exception of scallops that are harvested for onboard shucking of the adductor muscle. While FDA cannot

predict how long the closure should remain in effect, it is reasonable that closure should at least extend for 2 to 3 months. Reopening the area should be based on test results from shellfish collected within the closed area. The closure does not include Federal waters off the coast of Maine because cell counts of the organism responsible for production of the dangerous marine biotoxin are at lower levels and the small fishery in these waters has been controlled through State and industry actions.

Given the severity of the illness associated with PSP, FDA requests that NMFS moves as quickly as possible to implement the closure. FDA stands ready to assist NMFS in whatever way it can. Please contact Paul DiStefano at 301-436-1410, of my staff, or me should you have any questions or need further assistance.

As always, FDA appreciates the support and cooperation provided by NMFS in our joint efforts to protect public health. We look forward to working with you to collect samples from the closure to better define the level of toxicity in shellfish meats and in our joint efforts to once again reopen the area for commercial harvest.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs.

According to FDA, portions of the north western Atlantic Ocean are experiencing one of the largest toxic algal blooms (red tides) in history. The red tide is responsible for the production of marine biotoxins that cause PSP in persons consuming affected shellfish. It has spread from State waters to Federal waters further offshore. In accordance with the FDA's National Shellfish Sanitation Program (NSSP), the States have closed affected waters within their jurisdiction. Closure of the Federal waters is also necessary to address the public health emergency.

While it is difficult to predict precisely how long the closure should remain in effect, FDA estimates that the closure should remain in effect at least 2 to 3 months. Thus, this closure will remain in effect until September 30, 2005, with the possibility of a reduction or an extension of the closure based upon FDA's determination that the concentration of the toxin in shellfish is at a level that is safe or unsafe, respectively, for human consumption.

This action temporarily closes all Federal waters of the Exclusive Economic Zone (EEZ) of the Northeastern United States to any shellfish harvesting, with the exception of Atlantic sea scallops shucked at sea for their adductor muscles, in the area bound by the following coordinates in the order stated: (1) 43°00' N. lat., 71°00'

W. long.; (2) 43°00' N. lat., 69°00' W. long.; (3) 40°00' N. lat., 69°00' W. long.; (4) 40°00' N. lat., 71°00' W. long., and then ending at the first point.

Classification

This action is issued pursuant to section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1855(c).

This rule has been determined to be not significant under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA (AA), finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment for this action, as prior notice and comment would be impracticable and contrary to the public interest. The action is in response to a public health emergency. The FDA has requested that NMFS move as quickly as possible to close a specified area to the harvest of shellfish, as shellfish harvested from that area could pose a public health risk if consumed. Any delay in implementing this rule could pose serious health risks to the public. For the reasons stated above, the AA also

finds good cause to waive the delayed effectiveness period pursuant to 5 U.S.C. 553(d)(3).

Since this emergency action is necessary to protect public health, a Regulatory Impact Review (RIR) in accordance with Executive Order 12866 has not been completed. The RIR will be made available to the public once it has been completed.

Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: June 14, 2005.

Rebecca Lent

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 648 is amended to read 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 § 648.14, paragraph (a)(166) is added to read as follows:

§ 648.14 Prohibitions.

(a) * * *

(166) Fish for, harvest, catch, possess, or attempt to fish for, harvest, catch, or possess any bivalve shellfish, including Atlantic surfclams, ocean quahogs, and mussels, with the exception of sea scallops harvested only for adductor muscles and shucked at sea, in the area of the U.S. Exclusive Economic Zone bound by the following coordinates in the order stated: 43°00' N. lat., 71°00' W. long.; 43°00' N. lat., 69°00' W. long.; 40°00' N. lat., 69°00' W. long.; 40°00' N. lat., 71°00' W. long., and then ending at the first point.

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