



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

October 16, 2006

William T. Hogarth, Ph.D.
Director
National Marine Fisheries Services
1315 East West Highway
Silver Spring, Maryland 20910

Dear Dr. Hogarth:

The Food and Drug Administration (FDA) has been working jointly with the National Marine Fisheries Service (NMFS), the Environmental Protection Agency (EPA), state health and fisheries agencies, the Interstate Shellfish Sanitation Conference (ISSC), and the molluscan shellfish industry to develop and implement an "Onboard Screening and Dockside Testing Protocol". The purpose of the Protocol is to establish a public health control strategy to enable the safe harvesting and marketing of shellfish from Federal waters closed due to the presence in bivalve mollusks of paralytic shellfish toxins associated with the periodic occurrence of hazardous algal blooms. The threat of Paralytic Shellfish Poisoning (PSP) associated with these naturally occurring toxins resulted in the closure of Federal waters off the northeast coast, in the area known as Georges Bank, to molluscan shellfish harvesting in May 1990. In June 2005 the closure was extended to include Federal waters lying between Georges Bank and state waters which extend three miles beyond the coast. Without sufficient analytical data and the resources necessary to routinely monitor the safety of affected shellfish, these areas remain closed to harvesting with no reasonable expectation for their status to change.

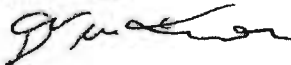
The "Onboard Screening and Dockside Testing Protocol" offers a comprehensive approach to safely harvest and market shellfish from Federal waters closed because of PSP. The Protocol outlines specific requirements, using test methods recognized by the National Shellfish Sanitation Program (NSSP). Under these requirements, fishermen would conduct toxicity screening of shellfish onboard harvest vessels to ensure product safety prior to harvest and landing. Once landed, state or other recognized health authorities would conduct confirmatory toxicity testing of shellfish prior to its release for marketing. In addition, the Protocol outlines a notification process to ensure that appropriate Federal and state regulatory authorities are kept apprised of product disposition throughout harvesting, landing, and processing.

FDA has concluded that the Protocol provides adequate control for the food safety risks associated with PSP, while providing economic opportunities for shellfish fishermen. Toward this end, FDA supports the issuance of an "Exempted Fishing Permit" (EFP) to a single fishing entity, in accordance with the conditions and requirements of the Protocol, as a pilot project. Upon conclusion of the pilot project, FDA, in cooperation with the other parties, will assess whether the pilot project demonstrated that the Protocol functioned as intended and ensured the harvest of safe molluscan shellfish, and whether it would be appropriate to support action by NMFS to open its EFP process to additional harvesters.

While the Protocol has full support from FDA, with concurrence from other Federal and state authorities, state health and fisheries authorities will exercise final approval for allowing molluscan shellfish harvested and handled in accordance with the Protocol to be landed within their state. This is in keeping with the National Shellfish Sanitation Program (NSSP), which is administered by FDA. Under the NSSP, states are responsible for regulating the molluscan shellfish industry within their jurisdiction and for ensuring the safety of shellfish harvested within or entering their borders. For this reason it is essential that prior to implementation of the Protocol for shellfish intended to be landed within a given state, issuance of an EFP by NMFS must be approved by the affected state control authority. The Protocol is explicit in this regard.

FDA appreciates the support and cooperation provided by NMFS in our joint efforts to protect public health. The dedicated efforts of your Agency to work hand in hand with FDA to bring this important public health safety Protocol to fruition have been most rewarding. Without those efforts, the rich shellfish resource of the northwestern Atlantic Ocean would likely remain closed to the fishery indefinitely.

Sincerely,



Donald W. Kraemer
Acting Director
Office of Seafood
Center for Food Safety and Applied Nutrition
US Food and Drug Administration

Enclosure:

cc:

HFS-1, (Brackett)

HFS-3 (Oliver)

HFS-415 (Jones)

HFS-417, (DiStefano)

HFS-600, (Baca, Smith)

HFS-628, (Watkins)

Kevin Chu, NMFS

Brian Hooker, NMFS

Spencer Garrett, NOAA

Alan Risenhoover, NOAA

Ken Moore, ISSC