

Section IV. Guidance Documents**Chapter II. Growing Areas**

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.02 Guidance for Developing Marine Biotoxin Contingency Plans

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP *Model Ordinance* requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Introduction

Shellfish are filter feeders and, therefore, they have the ability to concentrate toxigenic dinoflagellates from the water column when present in shellfish growing waters. The toxins produced by these dinoflagellates can cause illness and death in humans. Toxins are accumulated in the viscera and/or other tissues of shellfish and are transferred to humans when the shellfish are eaten (Gordan et al, 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. Most of these toxins are detected through animal testing. However, some involve the use of instrument based or biochemical analyses for detection. Since the dinoflagellates are naturally occurring, their presence in the water column or traces of their toxin in shellfish meat does not necessarily constitute a health risk, as toxicity is dependent on concentration (dose) in the shellfish. To protect the consumer, the Authority must evaluate the concentration of toxin present in the shellfish or the dinoflagellate concentration in the water column against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken.

There are three types of shellfish poisonings which are specifically addressed in the NSSP Model Ordinance: paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP) and amnesic shellfish poisoning (ASP), also known as domoic acid poisoning. All three are dangerous toxins, and PSP and ASP or domoic acid can cause death at sufficiently high concentrations. In addition, ASP can cause lasting neurological damage. PSP is caused by dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*). NSP is caused by brevetoxins produced by the dinoflagellates of the genus *Karenia* (formerly *Gymnodinium*). Both of these dinoflagellates can produce "red tides", i.e. discolorations of seawater caused by blooms of the algae. Toxic blooms of these dinoflagellates can occur unexpectedly or follow predictable patterns. The unpredictability in occurrence of toxic blooms was demonstrated in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses (Schwalm, 1973). Historically, *Alexandrium* blooms have occurred between April and October along the Pacific coasts from Alaska to California and in the Northeast from the Canadian Provinces to Long Island Sound (U.S. Public Health Service, 1958); but these patterns may be changing. The blooms generally last only a few weeks and most shellfish (with the exception of clams which retain the toxin for longer periods) clear themselves rapidly of the toxin once the bloom dissipates. NSP, which is less common, has occurred from the Carolinas and extends throughout the Gulf Coast states. It shows no indication of regular recurrence and shellfish generally take longer to eliminate the toxin (Liston, 1994).

The minimum concentration of PSP toxin that will cause intoxication in susceptible persons is not known. Epidemiological investigations of PSP in Canada, however, have indicated 200 to 600 micrograms of PSP toxin will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of PSP toxin. Investigations indicate that lesser amounts of the toxin have no deleterious effects on humans. Shellfish growing areas should be closed at a PSP toxin level, which provides an adequate margin of safety, since in many instances PSP toxicity levels can change rapidly. The NSSP Model Ordinance requires that growing areas be placed in the closed status when the PSP toxin concentration is equal to or exceeds the action level of 80 micrograms per 100 grams of edible portion of raw shellfish (FDA, 1977; FDA, 1985).

In shellfish growing areas where low levels of PSP routinely occur, harvesting for thermal processing purposes may be an alternative to consider. Thermal processing as defined by applicable FDA regulations (21 CFR 113) will reduce but not entirely destroy the PSP content of the shellfish. If thermal processing is practiced, the Authority must develop and implement procedures to control the harvesting and transportation of the affected shellfish to the processing plant.

In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karenia brevis*. The most common public health problem associated with *Karenia* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karenia brevis* blooms have been reported in Florida (Center for Disease Control, 1973 [a] and [b]). Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat. The NSSP Model Ordinance mandates that growing areas be placed in the closed status when any NSP toxin is found in shellfish meat, or when the cell counts for members of the genus *Karenia* in the water column exceed 5,000 cells per liter of water.

ASP is caused by domoic acid, which is produced by diatoms of the genus *Pseudonitzschia*. Blooms of *Pseudonitzschia* are of relatively short duration. However, during the 1991-1992 incident in Washington, high toxin levels persisted for several months (Liston, 1994). The NSSP Model Ordinance requires that growing areas be placed in the closed status when the domoic acid concentration is equal to or exceeds 20 parts per million in the edible portion of raw shellfish.

The suitability of some growing areas for shellfish harvesting is periodically influenced by the presence of PSP, NSP, domoic acid, or other marine biotoxins. The occurrence of these toxins is often unpredictable, and the potential for them to occur exists along most coastlines of the United States and other countries having shellfish sanitation Memoranda of Understanding (MOU) agreements with the United States. As a result, states or countries with MOUs with the U.S. need to make contingency plans to address shellfish-borne intoxications.

Controlling Marine Biotoxins in Shellfish

The contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxicity (Wilt, 1974). The primary goal of this planning should be to ensure that maximum public health protection is provided. To achieve this goal the following objectives should be met:

- * An early warning system should be developed and implemented.
- * Procedures should be established to define the severity of occurrences.

- * The state or MOU country should be able to respond effectively to minimize illness.
- * Adequate intelligence and surveillance information should be gathered and evaluated by the Authority.
- * Procedures should be instituted to return the biotoxin contaminated areas to the open status of their growing area classification.

Under the certification provisions of the NSSP, FDA and receiver states should have the assurance that shellfish producing states or MOU countries are taking and can take adequate measures to prevent harvesting, shipping, and consumption of toxic shellfish. To provide this assurance, the NSSP requires the Authority to develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas. The Authority's plan should specify how each of the objectives listed above will be accomplished. This document provides recommended guidelines to be used in preparing a plan to meet these objectives.

Recommended Contingency Plan Guidelines

** Provide an early warning system:*

1. Communication procedures should be established with other appropriate agencies to rapidly report to the Authority any abnormal environmental phenomenon that might be associated with shellfish growing areas such as bird or fish kills, water discoloration or abnormal behavior of shellfish or marine scavengers.
2. The Authorities should establish procedures for health agencies to report any toxin-like illnesses.
3. An early warning phytoplankton and/or shellfish-monitoring program should be implemented. These monitoring programs should use the "key station" (for both phytoplankton and shellfish monitoring) and "critical species" concepts (for shellfish monitoring).
 - * Sampling stations should be located at sites where past experience has shown toxin is most likely to appear first.
 - * When monitoring shellfish, samples should be collected of species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early PSP detection.
 - * The frequencies and periods for collection of samples should be established recognizing the randomness of PSP blooms. This assumes several years of baseline data in order to establish stations and sampling plans.
 - * Frequency of sampling should be adequate to monitor for fluctuations in coastal phytoplankton populations.
4. Channels of communication concerning shellfish toxicity should be established with other states, countries (in the case of MOU countries), FDA, and other responsible officials. A marine biotoxin control official should be designated by the Authority to receive and distribute all marine biotoxin related information. Consultation with adjacent jurisdictions, marine biologists and other environmental officials might also be useful (Felsing, 1966; Quayle, 1969; Prakash et al., 1971)

** Define the severity of the problem:*

1. A procedure should be established to promptly expand the sampling program for marine biotoxins in the event of increased toxicity/cell counts at any indicator monitoring stations identified within the plan. Sampling stations and frequencies of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing. The

procedure should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

2. Information should be available concerning the location of commercial shellfish resource areas in the state.
3. Criteria should be developed to define the circumstances under which growing areas will be placed in the closed status because of marine biotoxin contamination. The criteria should integrate public health, conservation, and economic considerations. Principal items of concern include consideration of the rapidity with which toxin levels can increase to excessive levels, the inherent delays in sample collection, the number of samples required to initiate action, the size of the area to be closed (including a safety zone), and the type of harvesting restrictions to be invoked (all species or specific species). It may be appropriate to close harvesting areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.
4. Procedures should be established to promptly identify which shellfish products or lots might be potentially contaminated, and to determine the distribution of these products or lots.

** Respond effectively to minimize illness:*

1. A summary should be provided citing the laws and regulations in the state (or MOU country) that promptly and effectively allow the Authority to restrict harvesting, withdraw interstate shipping permits, and to embargo/recall any potentially toxic shellfish already on the market in the event of a marine biotoxin episode. The plan should clearly define the timeframe involved in taking appropriate legal action.
2. The administrative procedures necessary to place growing areas in the closed status, to withdraw interstate certification of dealers, and to embargo and recall shellfish should be delineated. The timeframe necessary to accomplish these actions should also be specified.
3. A plan should be developed which will define what type of patrol program is necessary to properly control harvesting in toxin contaminated growing areas. The program should be tested to ensure prompt implementation in the event it is needed.
4. Procedures should be developed to promptly disseminate information on the occurrences of toxic phytoplankton blooms to the industry and local health agencies.
5. Procedures should be established to coordinate control activities taken by state and federal agencies or departments and district, regional, or local health authorities.

** Gather follow-up data:*

1. Appropriate records of illnesses should be compiled and maintained by the Authority. These records should include data on the incidence of illness and appropriate case history data. This information may be important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.
2. Records of shellfish sample results from toxin testing should include analysis of trends, detoxification curves, phytoplankton and water sample analyses, and pertinent environmental observations.

** Return growing areas to the open status of their NSSP classification:*

1. Once a growing area is placed in the closed status because of marine biotoxin contamination, a procedure should be instituted to gather data necessary to decide when the area can be returned to the open status of its classification. A system of representative samples to establish detoxification curves should be part of this procedure.

2. The Authority should develop a set of criteria that must be met before a growing area can be returned to the open status. These criteria should integrate public health, conservation, and economic considerations, and employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin or cell counts are below the closure level. For example, experience has shown that appropriate reopening criteria for PSP include a minimum of three samples collected over a period of at least 14 days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams of shellfish tissue.
3. A program of consumer education should be continued as long as any area remains in the closed status because of marine biotoxin contamination.

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