Proposal Subject Marine Biotoxin Control

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control. B. and C.

Text of Proposal/ Requested Action

B. Marine Biotoxin Monitoring.
In those areas where **and at those times when** marine biotoxins are likely to occur in shellfish, representative samples of shellfish **and/or water** shall be collected during all harvest periods. Samples shall be collected from indicator stations at intervals determined by the Authority, and assayed for the presence of toxins **and/or toxin-forming organisms** in accordance with §C.

C. Closed Status of Growing Areas
(1) A growing area, or portions thereof as provided in §A. (4), shall be placed in closed status for the taking of shellstock when the Authority determines that the level of biotoxin present in shellfish meats **and/or the level of toxin forming organisms in the growing area** is sufficient to cause a health risk. The closed status shall be established based on the following criteria:
(a) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 micrograms per 100 grams of edible portion of raw shellfish; or
(b) For neurotoxic shellfish poison (NSP), the harvesting of shellstock shall not be allowed when:
(ix) ~~Any NSP toxin is found in shellfish meats~~ **The concentration of NSP equals or exceeds 20 mouse units per 100 grams of edible portion of raw shellfish**; or
(ii) The cell counts of ~~Gymnodinium breve~~ Karenia brevis organisms in the water column exceed 5,000 per liter.

Public Health Significance

The Chapter IV. @. 04 B Requirements for Marine Biotoxin Monitoring does not allow for marine biotoxin hazard monitoring through the use of water sampling. However, it does refer to §C and §C contains a water quality criterion for NSP-forming Gymnodinium breve (now Karenia brevis) as well as a provision (IV. @. 04 C (2)) that "For any marine biotoxin producing organism for which criteria have not been established under this Ordinance, either cell counts in the water column or biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock."

A number of states currently utilize monitoring of K. brevis cell counts in the water column rather than shellfish tissues and the FDA has accepted practice.

States that utilize water quality monitoring to assess the K. brevis hazard also utilize a variety of early warming systems, such as aerial surveillance, satellite imagery, interstate communication, and conditions conducive to proliferation of K. brevis to alert them to the impending occurrence of unacceptable concentrations of the organism. In some cases, sampling is conducted only when early warning systems indicate that unacceptable K. brevis concentrations are likely to occur rather than during "…all harvest period." The FDA has also accepted that approach.

Finally, there are circumstances in which the mouse bioassay for NSP results in the death of one or more mice and the laboratory reporting < 20 mouse units per 100 grams of shellfish tissue. In practice, though this could indicate the presence of

some NSP, growing areas have not been closed or held in closed status on the basis of mouse bioassay results unless mice die and a determination of ≥ 20 mouse units per 100 grams of shellfish tissue is made. That practice has been consistent with FDA advice.

Therefore, the following changes are suggested for the accompanying reasons:
1. Add "…and at those times when…" to IV. @ .04 B. as indicated in the proposed changes to allow for the use of early warning systems to initiate sampling as opposed to

sampling during all harvest periods regardless of indications that a marine biotoxin hazard is not likely to occur.

2. Add "…and/or water…" and "and/or toxin forming organisms…" to IV. @ .04 B. as indicated in the proposed changes to allow fro the use of the water sampling alternative.
3. Add "…and/or the level of toxin forming organisms in the growing area…" to IV. @ .04 C. (1) as indicated in the proposed changes to allow for scenarios in which water sampling rather than meat sampling is used.
4. Replace "Any NSSP toxin is found in shellfish meats" with "The concentration of NSP equals or exceeds 20 mouse units per 100 grams of edible portion of raw shellfish" in IV. @ .04 C (1) (b) (i) as indicated in the proposed changes to allow for circumstances in which there are some indications that some NSP toxin may be present but not enough to precipitate the "20 mouse units" determination.

The NSP method stipulates the reporting language to be used. The method can provide results of "toxin present less than 20 mouse units". The current manual requirement of no toxin present would result in areas remaining closed if toxin is present at less than 20 mouse units. The public health significance of toxin less than 20 mouse units is debatable. However, the low levels could increase closure period without affording any additional public health problems.

Cost Information (if available)

None submitted.

Action by 2003 Task Force I

Recommended referral of Proposal 03-105 to appropriate committee as determined by the Conference Chairman and requests that FDA share APHA guidance from 1989 discussions.

Action by 2003 General Assembly

Adopted recommendation of 2003 Task Force I.

Action by USFDA

Concurred with Conference action.

Action by 2005 Biotoxin Committee

Recommended adoption of Proposal 03-105 as amended by the Committee.

Comments

The Committee recognized that the ISSC Conference, during it's deliberations in 1989, adopted a 6-hour or 15.5 observation in conducting mouse bioassays for Karina breve which changed the standard to <20 mouse units or <10 mouse units, dependent on the observation time. This change was recommended on an interim basis until the publication of a new APHA Lab Procedures for Seawater and Shellfish. This did not happen and the change was never officially recognized in the NSSP as approved Laboratory Procedures. The limit of no detectable toxin in 24 hours remained the standard even though the change had been adopted by the Conference in 1989.

Model Ordinance Text

B. Marine Biotoxin Monitoring.
In those areas where **toxin-forming organisms are known to occur periodically and the toxins are prone to accumulate in shellfish, and when appropriate at those times when marine biotoxins can be reasonably predicted to occur,** representative samples of **the water and/or** shellfish shall be collected during ~~all~~ harvest periods. **The** samples shall be collected from indicator stations at intervals determined by the Authority. ~~, and assayed for the presence of toxins, in accordance with §C.~~ **Water samples will be assayed for the presence of toxin-forming organisms and shellfish meat samples shall be assayed for the presence of toxins.**

C. Closed Status of Growing Areas

(1) A growing area, or portions thereof as provided in §A. (4), shall be placed in closed status for the taking of shellstock when the Authority determines that the **number of toxin-forming organisms in the growing waters and/or the** level of biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:

PSP – cells/L n/a; 80 µg/100 grams
NSP – 5,000 cells/L or 20 MU (approximate as 80 µg/100 g)
ASP – cells/L n/a; 2 mg/100 grams (20 ppm)

(a) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 micrograms per 100 grams of edible portion of raw shellfish; or

(b) For neurotoxic shellfish poison (NSP), the harvesting of shellstock shall not be allowed when:

~~(i) Any NSP toxin is found in shellfish meats~~ **The concentration of NSP equals or exceeds 20 mouse units per 100 grams of edible portion of raw shellfish**; or

(ii) The cell counts of ~~Gymnodinium breve~~ Karenia brevis organisms in the water column exceed 5,000 per liter.

Action by 2005 Task Force I Recommended adoption of the Biotoxin Committee recommendation on Proposal 03-105.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force I.

Action by USFDA Concurred with Conference action.