

	<p>Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting</p>	<p>a. <input checked="" type="checkbox"/> Growing Area b. <input type="checkbox"/> Harvesting/Handling/Distribution c. <input type="checkbox"/> Administrative</p>
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<p>Proposal Subject</p>	<p>Shellfish Quarantine Guidance Document</p>	
<p>Specific NSSP Guide Reference</p>	<p>Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control</p> <p>Section IV. Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans</p>	
<p>Text of Proposal/ Requested Action</p>	<p>Model Ordinance Chapter IV. Shellstock Growing Areas</p> <p>@.04 Marine Biotoxin Control</p> <p>Section A. (4) describes agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting during marine Biotoxin closures under specific, controlled conditions. The State of Florida has successfully implemented such an agreement to address Neurotoxic Shellfish Poisoning (NSP) for over a decade. This pilot project, developed in consultation with FDA, has resulted in zero cases of NSP in commercially harvested shellfish from Florida waters. NSP may affect any Gulf or South Atlantic state and therefore Florida wishes to provide ISSC member states with a proven quarantine protocol template for incorporation into the Model Ordinance Section IV. Guidance Documents.</p> <p>Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans.</p> <p>Text of the proposed guidance is as follows:</p> <p><u>Example Protocol for Quarantine Harvest of Shellfish from Aquaculture Leases During <i>Karenia brevis</i> Closures:</u></p> <p><u>A. Closure of an entire shellfish growing area due to <i>Karenia brevis</i> shall be in accordance with Model Ordinance Chapter IV. @.04 C. (1).</u></p> <p><u>B. When a shellfish growing area is closed due to <i>Karenia brevis</i>, the Authority may allow harvest of shellfish from selected aquaculture leases within a specific zone by authorized harvesters and subsequent controlled quarantine at a certified shucker packer or shellstock shipper. This option would not be</u></p>	

available if any Authority collected water samples in the specific zone exceeded 200,000 cells per liter of *Karenia brevis*. Zone is defined as an Authority delineated geographic area within a Conditionally Approved or Approved classified shellfish growing area.

Controlled quarantine conditions:

The Authority will determine and plot the specific zones. Certified processors possessing a valid shellfish processing plant certification license must have written permission from the Authority to engage in this activity. To be eligible for participation in the quarantine program, the certified processor must:

- (1) Provide the Authority with written and signed agreements the processor has with shellfish aquaculture leaseholders who would be supplying the shellfish and;
- (2) Notate on their application letter which FDA-approved marine Biotoxin laboratory will be used to conduct the approved mouse bioassay and;
- (3) Provide the Authority with the cooler capacity, physical address and current certification number of the facility to be used for controlled quarantine of shellfish. All quarantine coolers must be non-mobile, secure from unauthorized access and equipped with warning signs in a language readily understood by all employees.

Participation in each week's quarantine program is only possible for certified processors who:

- (1) Have written permission on file with the Authority and are on an Authority-controlled document listing current approved quarantine program processors and;
- (2) Possess emailed permission granted by the Authority the day before harvest for that one specific quarantine and;
- (3) Propose harvesting a quantity of shellfish that meets the Authority established minimum number but does not exceed the maximum allowed number of shellfish of one specific species for that day.

Under no circumstances may any approved processor participate in any quarantine until they possess written (emailed) documentation sent by the Authority before each specific quarantine event.

- The authorization email sent by the Authority shall explicitly state the permissible species that may be harvested by that approved processor.
- The Authority will notify the appropriate law enforcement entity in charge of patrol of shellfish growing areas with a list of participants in that specific day's harvest.
- Persons harvesting a species not authorized for that day's harvest will be subject to seizure of that harvest by the Authority. In addition, the Authority will immediately seize and destroy product

which is improperly tagged, violates any National Shellfish Sanitation Program (NSSP) Model Ordinance regulations, state laws or is from non-authorized participants.

- Co-mingling of species is not allowed to make up an individual lot.

Violation of the terms of this protocol may result in the termination of the participant's future eligibility in the quarantine program, as determined by the Authority.

Prior to being considered for participation in any specific quarantine event, approved processors shall be contacted by the Authority and asked to provide the name of the species they plan to harvest and the quantity they plan on harvesting. Quantities shall be described as approximate total number by species in addition to total number of baskets, containers, bags, etc. with specific weights (if applicable) for those baskets, containers, bags, etc.

Eligible processors should be aware that daily implementation of this program is contingent on marine Biotoxin laboratory availability as well as Authority staffing considerations given staff time necessary to fulfill the requirements of the program.

Regulatory considerations on behalf of the Authority and staffing considerations on behalf of the marine Biotoxin lab necessitate an Authority developed maximum number of samples that could be potentially tested on any given week.

The Authority may implement a lottery, random rotation or similar procedure to ensure a fair distribution of testing opportunities among the eligible processors. It is suggested that the Authority develop this procedure with industry involvement.

Once specific permission is received from the Authority, the processor:

- (2) May receive properly tagged shellfish from eligible aquaculturists only as indicated in the Authority's authorization email;
- (3) Must upon receipt of shellfish, separate and maintain the shellfish into specific lots [A Lot is defined as shellfish of one species from no more than one day's harvest from a specific zone within a shellfish growing area];
- (4) Must place shellfish under proper controls and quarantine; Proper controls and quarantine are defined by bold, clear, warning signage signaling the properly tagged and segregated shellfish within the processor's cooler are under quarantine and must not be moved until Authority permission is obtained pending outcome of laboratory testing. The signage should be such that it is clear to anyone entering the cooler (including facility employees and/or regulatory inspectors) that the affected shellfish are under quarantine. Wrapping of the entire lot with a single bright red or yellow ribbon or equivalent attached to the bold warning sign will

	<p style="text-align: center;"><u>further reinforce the warning message.</u></p> <p>(5) <u>Must allow the Authority to take two (2) random samples [minimum of twenty (20) shellfish per each sample] from each lot and deliver to the approved laboratory for approved mouse bioassay;</u></p> <p>(6) <u>Must hold all shellfish in quarantine at the approved processor's certified facility until receiving official written test result notice from the Authority via email or fax that the shellfish are cleared for sale;</u></p> <p>(7) <u>Must either return shellfish to aquaculture lease(s) in the zone(s) from where harvested if any sample in a lot is 20 Mouse Units / 100 grams or greater or destroy the shellfish, both activities of which must be witnessed and documented by the Authority;</u></p> <p>(8) <u>Must cease this activity if any Authority collected red tide cell counts in the specific zone exceeds 200,000 cells per liter of <i>Karenia brevis</i>; and</u></p> <p>(9) <u>Must document all of the requirements listed above in the approved facility HACCP plan.</u></p> <p><u>C. If cell counts in all water samples fall to 5,000 cells/L or less <i>Karenia brevis</i> in the entire area, the Authority will collect shellfish meat samples for toxicity testing and the entire Shellfish Harvesting Area will be reopened if results of all samples are <20 MU/100g.</u></p> <p><u>I _____ (print name) have received a copy of this quarantine protocol and I agree to abide by all terms and conditions. I understand I am bound by the terms of this agreement during the period of time that I am processing shellfish from a shellfish growing area that is currently in the closed status due to <i>Karenia brevis</i>.</u></p> <p>_____</p> <p><u>Signed _____ Date _____</u></p>
<p>13. Public Health Significance</p>	<p>Closures of shellfish growing areas due to Neurotoxic Shellfish Poisoning (NSP) may occur at any time in the Gulf of Mexico and to a lesser degree, the Atlantic coast. Well established procedures for detecting and responding to <i>Karenia brevis</i> blooms have safeguarded public health. Clear early warning signs, a cell count action level with a high factor of safety and established sampling networks provide excellent public health protection. A very real impact of <i>Karenia brevis</i> blooms is the resulting long-term closures of shellfish growing areas and severe economic impact to commercial shellfish operations. Florida addressed this issue after studying years of water quality samples and mouse bioassay results from shellfish growing areas. Hydrodynamic studies linked to water samples obtained from fixed stations over an extended period of time established clear patterns in distribution of <i>Karenia brevis</i>. Working in conjunction with harmful algal bloom researchers, shellfish growing area managers, FDA and industry, Florida developed a NSP quarantine protocol that has resulted in the retention of a shellfish industry in one of the most severely impacted HAB regions of the Gulf while protecting public health as required by the Model Ordinance. An enormous amount of data has been generated and reviewed during the years this protocol has been used. Repeated mouse bioassay testing on shellfish exposed to different levels of <i>Karenia brevis</i></p>

	<p>has provided Florida with sufficient data to refine the protocol into a powerful management tool. Florida’s experience pre-quarantine protocol was unfortunate, as several fledgling businesses failed due to repeated NSP closures. It was this economic damage that spurred the aforementioned collaborative effort between leading edge HAB researchers, shellfish growing area managers, FDA and industry. If adopted, shellfish producing states impacted by <i>Karenia brevis</i> could reference this protocol in the Guidance Document and use it to effectively manage NSP closures.</p>
<p>Cost Information</p>	<p>The estimated cost for a full 96-well plate assay is ~\$95.00. Including standards and samples with triplicate measurements (as well as three dilutions per sample to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitative results would be ~\$13.60. If running multiple plates or in screening mode, sample costs would be reduced. Further, the filter plates used in the RBA differ from ELISA plates in that all reagents are added to each well as needed rather than already being a component of the plate, making it more practical and cost-effective to analyze samples when there is less than a full plate.</p>
<p>Action by 2013 Task Force I</p>	<p>Recommended referral of Proposal 13-116 to an appropriate committee as determined by the Conference Chairman</p>
<p>Action by 2013 General Assembly</p>	<p>Adopted recommendation of 2013 Task Force I on Proposal 13-116.</p>
<p>Action by FDA May 5, 2014</p>	<p>Concurred with Conference action on Proposal 13-116.</p>
<p>Action by 2015 Biotoxin Committee</p>	<p>Recommended adoption of Proposal 13-116 with substitute language as follows:</p> <p>(4) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a <u>state</u> growing area while other parts of the same <u>the</u> growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety. <u>In state growing areas or designated portions of state growing waters that are closed, the authority may allow for harvesting if an end product testing program is developed and, such as by batch release of shellfish lots only after</u> samples of each lot are tested and found to be below the action levels specified in Section C.</p> <p><u>The program must include at a minimum:</u></p> <ul style="list-style-type: none"> <u>i. Establishment of appropriate pre-harvest screening levels;</u> <u>ii. Establishment of appropriate screening and end product testing methods;</u> <u>iii. Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods;</u> <u>iv. Establishment of representative sampling plan for both i. and ii. above;</u> <u>and</u> <u>v. Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.</u> <p>Should the above amended proposal be adopted by the conference, then the Biotoxin Committee should develop a Guidance Document that includes guidance for development of end-product testing programs to address biotoxins in closed state waters.</p>
<p>Action by 2015 Task</p>	<p>Recommends adoption of Biotoxin Committee recommendation on Proposal 13-</p>

Force I	116.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-116.
Action by 2017 Task Force I	Recommended the Biotxin Committee should develop a Guidance Document that includes guidance for development of end-product testing programs to address Biotoxins in closed State waters.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-116.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-116.