

 <p>Proposal for Task Force Consideration at the ISSC 2017 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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Proposal Subject	ISSC Method Application and Single Lab Validation of an Enzyme-linked Immunosorbent Assay (ELISA) method for the determination of Neurotoxic Shellfish Poisoning (NSP) toxins in hard clams, sunray venus clams, and oysters.
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas. 14 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	<p>This submission proposes that the MARBIONC brevetoxin ELISA be approved for limited use in NSP testing such that samples with negative results by ELISA (≤ 1.6 ppm in hard clams and sunray venus clams and ≤ 1.80 ppm in oysters) would pass, while samples with positive results by ELISA (greater than these levels) would require additional testing by an Approved Method. Samples passing by ELISA would enable the same management actions as samples passing by NSP mouse bioassay (i.e., Growing Area closing or re-opening, controlled relay, and end product testing of controlled harvest as permitted within a State Authority's marine biotoxin contingency program). Samples failing by ELISA would either require additional testing by an Approved Method or could support the same management actions as samples failing by an Approved Method. ELISA could also be used as a screening method to initiate precautionary closures.</p> <p>Requested changes:</p> <p>Section IV. Guidance Documents Chapter II. Growing Areas. 14 Approved NSSP Laboratory Tests</p> <p>4. Approved Limited Use Methods for Marine Biotoxin Testing Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP)</p> <p>Add columns for Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP) and for Application: Controlled Harvest end product testing</p> <p>Add MARBIONC brevetoxin ELISA to table for all applications except Dockside Testing with the following footnote:</p> <p style="margin-left: 40px;">MARBIONC Brevetoxin ELISA, MARBIONC Development Group, LLC. Method can be used in place of an Approved Method for oysters, hard clams, and sunray venus clams within these parameters:</p> <p style="margin-left: 80px;">a. A negative result (≤ 1.6 ppm in hard clams and sunray venus clams and ≤ 1.80 ppm in oysters) can substitute for testing by an Approved Method for the purposes of controlled relaying,</p>

	<p>controlled harvest end-product testing, or to re-open a previously closed area.</p> <p>b. A positive result (> 1.6 ppm in hard clams and sunray venus clams and > 1.80 ppm in oysters) requires additional testing by an Approved Method or could support the same management actions as samples failing by an Approved Method.</p> <p>See attached proposed revisions to Table 4. Approved Limited Use Methods for Marine Biotoxin Testing</p>
<p>Public Health Significance</p>	<p>Brevetoxins produced by <i>K. brevis</i> are toxic to humans. Filter-feeding bivalves accumulate brevetoxins during blooms, and ingestion of contaminated shellfish can cause NSP in humans. Symptoms of NSP typically begin three to six hours after ingestion and may include nausea, diarrhea, tingling of lips or tongue, muscle ache, lack of coordination, temperature reversal, and vertigo. In severe cases, a feeling of constriction in the throat may occur. Individuals with NSP may require hospitalization but usually recover within days. To prevent NSP, shellfish harvesting areas are closed when <i>K. brevis</i> concentrations exceed 5,000 cells/L and are re-opened once <i>K. brevis</i> levels decrease and testing demonstrates that shellfish are no longer toxic. However, the APHA mouse bioassay - the only approved method for NSP testing - has many drawbacks, and the delays caused by the time required to analyze samples (two days) and low sample throughput compound economic losses. To mitigate economic harm to the shellfish industry and ensure the continued protection of public health, rapid alternative methods for NSP testing are needed.</p>
<p>Cost Information</p>	<p>Kit reagents are sold in bulk. The cost of reagents is currently \$2,400 for 15 plates and \$1,000 for 5 plates. The cost of additional consumables and reagents not included is approximately \$20 per plate. Therefore cost per sample is \$36-44 for full quantitation (5 samples per plate) and less than \$6 per sample for qualitative screening (40 samples per plate).</p>