

 Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting		a. <input checked="" type="checkbox"/> Growing Area b. <input type="checkbox"/> Harvesting/Handling/Distribution c. <input type="checkbox"/> Administrative
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Proposal Subject	High Pressure Liquid Chromatography (HPLC) test method for Domoic Acid (Amnesic Shellfish Poison)	
Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter II. Growing Areas, 4. Approved Limited Use Methods for Marine Biotoxin Testing, HPLC entry for Biotoxin Type: Amnesic Shellfish Poisoning (ASP), p. 263 The method reference is in the footnote of the Approved Limited Use Methods for Marine Biotoxin Testing table that includes use of HPLC to detect ASP in shellfish references the method used by M.A. Quilliam, et al, to publish the Technical Report, "Rapid Extraction and Cleanup Procedure for the Determination of Domoic Acid in Tissue Samples" in 1991. At the time of publication, however, the Report did not include a full operating procedure.	
Text of Proposal/ Requested Action	The Washington State Shellfish Biotoxins Laboratory proposes to perform a Single Laboratory Validation (SLV) for the detection of ASP by the HPLC method that was developed at the WA Public Health Laboratories (WAPHL) in 1991, modified in 1996 and which is currently used in the Laboratory, running the CFSAN recommended method (Quilliam et. al 1991) in tandem with the WAPHL method.	
Public Health Significance	<p>Marine biotoxins are poisons that are produced by certain kinds of microscopic algae (a type of phytoplankton) that are naturally present in marine waters, normally in amounts too small to be harmful. Molluscan shellfish (shellfish with hinged shells such as oysters, clams, and mussels) are filter feeders and ingest any particles, both good and bad, that's in the surrounding water. Algae is a food source for them, and HABs create a plentiful food supply. When shellfish eat toxin producing algae, the toxin remains in their system; large amounts of algae means more toxin can concentrate in their tissue. Biotoxins don't harm shellfish, but they can accumulate in shellfish to levels that can cause illness or death in humans and other mammals that eat them.</p> <p>Domoic Acid, the agent responsible for Amnesic Shellfish Poisoning, is a naturally occurring shellfish biotoxin. It is one of several potent neurotoxins that acts as agonists to glutamate, a neurotransmitter in our central nervous systems.</p> <p>It is imperative that modern, rapid and accurate laboratory testing methods be developed or refined to assure that adequate monitoring programs are in place to protect public health.</p>	
Cost Information	There is no significant difference in cost between the two methods.	
Research Needs Information		
a. Proposed specific research need/	Between the 1991 time of publication and adoption of the CFSAN procedural interpretation of this particular method by the ISSC in 2014 most state laboratories	

<p>problem to be addressed</p>	<p>that needed to screen for Amnesic shellfish Poisoning have developed their own in house HPLC methods, which were roughly based on the Quilliam report. Over time, the methods have been updated with minor changes and modernizations in the technology which has increased sensitivity and throughput of the method. Because of the increased speed and accuracy of the WAPHL method, protection of public health will be increased as compared with the CFSAN recommended method.</p> <p>The FDA is now insisting that all laboratories standardize on the CFSAN Procedure, which has demonstrated lower sensitivity and longer sample cycle times than the current method used by the proposing laboratory. Changing to the CFSAN method at this time, while there are increased ASP concentrations on the Pacific Coast and therefore higher sample loads at the laboratory is viewed as detrimental to public health in Washington State.</p> <p>CFSAN needs to be satisfied that the methods in place at the labs testing for ASP are robust and may not need reversion to 25-year old technology and the ISSC SLV is the proper mechanism for this demonstration. Unfortunately there is currently no Proficiency Testing program offered by CFSAN for biotoxins which would also lend itself to demonstrating the comparability of the different methods.</p>
<p>b. Explain the relationship between proposed research need and program change recommended in the proposal</p>	<p>The SLV is the mechanism by which the laboratories of the ISSC can demonstrate new methodology and technologies. The Washington State Shellfish Biotoxins Laboratory feels the method they have used since 1996 is superior to the CFSAN procedural interpretation of Quilliam’s 1991 work. Furthermore, the CFSAN recommended procedure has not undergone a published ISSC SLV and its adoption by the FDA seems premature.</p>
<p>c. Estimated cost</p>	<p>The cost of this study will be borne by the Washington State Public Health Laboratories.</p>
<p>d. Proposed sources of funding</p>	<p>N/A</p>
<p>e. Time frame anticipated</p>	<p>2 years</p>
<p><i>For Research Guidance Committee Use Only</i></p>	<p>Relative priority rank in terms of resolving research need</p> <ul style="list-style-type: none"> <input type="checkbox"/> Immediate <input type="checkbox"/> Required <input type="checkbox"/> Valuable <input type="checkbox"/> Important <input type="checkbox"/> Other