Proposal No. **13-110**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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Proposal Subject	Immunoassay Method for Detection of Saxitoxin (PSP) from Shellfish
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	2. Approved Methods for Marine Biotoxin Testing and 4. Approved Limited Use Methods for Marine Biotoxin Testing. Review the validation for Saxitoxin (PSP) Microtiter Plate Test Kit by the Proposal Review Committee. Single Laboratory Validation Protocol for Method Approval attached.
Public Health Significance	Rapid screening method can handle numerous samples and screen out negative samples so that it reduces the size of sample to be confirmed with regulatory methods such as mouse bioassay (MBA) or liquid chromatography with post-column oxidation (PCOX). This results in saving resources of the laboratories, and makes the laboratories able to provide rapid warning. References attached.
Cost Information	Approximate cost for the basic set up of the method is $3600.
Action by 2013 Laboratory Methods and Quality Assurance Review Committee	Recommended referral of Proposal 13-110 to an appropriate committee as determined by the Conference Chairman and directs the Executive Office send a letter to the submitter requesting additional information as requested by the Laboratory Methods Review and Quality Assurance Committee.
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-110.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-110.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-110.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-110 to the appropriate committee as determined by the Conference Chair until additional data are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-110.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-110.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-110.