

Proposal Subject:	Immunoassay Method for Detection of Saxitoxin (PSP) from Shellfish
Specific NSSP Guide Reference:	NSSP Guide Section IV. Guidance Document Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests, 2. Approved Methods for Marine Biotoxin Testing and 4. Approved Limited Use Methods for Marine Biotoxin Testing.
Text of Proposal/ Requested Action	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 make the laboratories enable to provide rapid warning. References attached.
Cost Information (if available):	Approximate cost for the basic set up of the method is \$3600
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended Proposal 13-110 be referred to an appropriate committee as determined by the Conference Chairman and direct 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.
NOTE:	Click here for Proposal 13-110 Supporting Documentation