

Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		×	Growing Area
			Harvesting/Handling/Distribution
			Administrative
Submitter	Byungchul Kim		
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Proposal Subject	Immunoassay Method for Detection of Saxitoxin (PSP) from Shellfish		
Specific NSSP	Section IV. Guidance Documents		
Guide Reference	Chapter II. Growing Areas		
	.11 Approved NSSP Laboratory Tests		
Text of Proposal/	2. Approved Methods for Marine Biotoxin Testing and		
Requested Action	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	Rapid screening method can handle numerous samples and screen out negative		
Significance	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	Recommended Proposal 13-110 be referred to an appropriate committee as		
Laboratory Methods and	determined by the Conference Chairman and direct the Executive Office send a letter		
Quality Assurance	to the submitter requesting additional information as requested by the Laboratory		
Review Committee	Methods Review and Quality Assurance Committee.		
Action by 2013	Recommended adoption of Laboratory Method Review and Quality Assurance		
Task Force I	Committee recommendation on Proposal 13-110.		
Action by 2013	Adopted recommendation of 2013 Task Force I on Proposal 13-110.		
General Assembly			
Action by FDA	Concurred with Conference action on Proposal 13-110.		
May 5, 2014			

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