



Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input checked="" type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Submitter	Matthew Forester and Jacqueline Knue with the support of the Pacific Region Laboratory Evaluation Officers and Managers (PARLEOM) Cooperative Agreement Group	
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Proposal Subject	Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination	
Specific NSSP Guide Reference	2011 NSSP Section IV. Guidance Documents Chapter II. Growing Areas .12 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers including Laboratory Evaluation Checklist-Laboratory Checklist-PSP	
Text of Proposal/ Requested Action	Establish a PSP Laboratory Evaluation Checklist for the HPLC-PCOX method. Please find the HPLC-PCOX checklist attached-word document titled "PSP HPLC PCOX checklist.docx" There is no summary of changes as no previous checklist exists for this procedure	
Public Health Significance	The HPLC-PCOX method has been an approved limited use method since 2009, yet no checklist exists to allow evaluation of laboratories who utilize this method. Use of this method provides states much more detailed toxin profiles as well as helping eliminate animal testing. It is important that the checklist items and quality assurance requirements are clear and understandable.	
Cost Information	For laboratories that do not already possess a HPLC post column reaction system, the upfront cost can be significant. Once in place, the costs per test are not significantly different than that imposed by the capital cost of the mouse bioassay.	
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended Proposal 13-115 be referred to an appropriate committee as determined by the Conference Chairman.	
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-115.	
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-115.	
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-115.	