Proposal No. 27-126

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	**Method Modification Request: Receptor Binding Assay for the Detection of Paralytic Shellfish Poisoning Toxins: porcine tissue option for use as a receptor source.**
Specific NSSP Guide Reference	**2023 NSSP Guide for the Control of Molluscan Shellfish** Section IV Guidance Documents – Chapter IV. Chapter III. Laboratory Page | 266 SHELLFISH LABORATORY EVALUATION CHECKLIST Receptor Binding Assay for Paralytic Shellfish Poisoning (RBA PSP) https://www.issc.org/sites/default/files/uploads/-2023/2023-guide-docs/11-rba-psp-checklist-with-comments.pdf Part I Quality Assurance 1.5 Reference Solution Reagent Storage, Preparation and Security 1.5.8 Commercial porcine brain homogenate is stored according to the manufactures specification and is properly labeled with received date and expiration date. 1.7 ~~Rat Brain~~ Membrane Tissue Preparation 1.7.1 The protein/receptor concentration of the rat or porcine membrane tissue preparation is determined for each new commercial lot or batch or using a Pierce Micro BCA Protein Assay Reagent Kit No. 23235 (micro plate method) or No. 23225 (tube method) or equivalent. 1.7.2 The dilution of the protein/receptor concentration of the rat or porcine brain membrane tissue preparation needed to obtain a working stock of 1 mg/mL is determined by either titration to meet the required 'top' value or by generating a tissue linearity curve. 1.7.3 Dilutions of the protein/receptor concentration of the rat or porcine brain membrane tissue preparation of less than 1:4 are not used as they may be too viscous

Text of Proposal/ Requested Action	This submission presents the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination for consideration to offer an optional tissue type as a receptor source. We propose that the Interstate Shellfish Sanitation Conference (ISSC) approve a modification to the Receptor Binding Assay (RBA) method [SLV (2023;Proposal13-114] for the detection of Paralytic Shellfish Poisoning (PSP) toxins. The proposed modification would allow the use of porcine brain tissue as an alternative source of receptorsto rat brain tissue for the RBA. This modification would provide an additional tissue source for preparation of the receptor material while maintaining the established principles and intended analytical application of the RBA method. The proposed modification would be supported by appropriate method validation data demonstrating that the use of porcine brain tissue provides comparable analytical performance to the currently specified rat brain tissue.
Public Health Significance	The Receptor Binding Assay (RBA) provides a sensitive and efficient method for detecting Paralytic Shellfish Poisoning (PSP) toxins in shellfish and supports timely public health decisions related to shellfish safety and harvest closures. Maintaining reliable access to the tissue required for the assay is important to ensure continued laboratory capacity for routine monitoring and response to PSP events. Allowing the use of porcine brain tissue as an alternative to rat brain tissue would provide laboratories with a commercially accessible source of receptors, which reduces the cost associated with obtaining and preparing the receptor material. This modification could therefore reduce the overall cost and ease of performing the RBA while supporting the sustainability and availability of the method. The proposed modification would not change the intended use of the RBA for detection of PSP toxins. Use of porcine brain tissue would be supported by appropriate validation demonstrating comparable analytical performance to the established rat brain tissue source. Providing laboratories with an additional, readily available and cost effective receptor source would strengthen the long term sustainability of the RBA and support continued, timely public health monitoring of shellfish for PSP toxins.
Cost Information	The estimated cost per 96-well plate using porcine is ~$235. Including standards and samples with triplicate measurements (as well as three dilutions per sample [ranging from 3.5-600 µg STX eq 100 g-1] to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitation would be ~$35. In contrast, the estimated cost for a 96-well plate using rat brain is ~$300 with a cost per sample for quantitation of ~$40. For a potential savings of ~$5 per sample while using porcine. If running multiple plates or in screening mode, sample costs would be reduced for both receptor protein sources." In 2025, the Washington State Public Health Laboratories (WA PHL) analyzed approximately 3,000 PSP samples. The use of less expensive porcine tissue in the Receptor Binding Assay would have resulted in an estimated cost savings of approximately $15,000 that year.