Proposal No. 27-125

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

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Proposal Subject	Matrix Extensions for the Receptor Binding Assay for detecting Paralytic Shellfish Poisoning [SLV (2023;Proposal13-114)]
Specific NSSP Guide Reference	Section IV Guidance Documents – Chapter IV. Growing Areas Paralytic Shellfish Poisoning (PSP) Shellfish Lab Methods page 351
Text of Proposal/ Requested Action	This submission presents the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination for consideration to upgrade its current limited use status to an NSSP Fully Approved Use Method from mussels (*Mytilus species*) to include Pacific geoduck clam (*Panopea generosa*) gutball, whole Pacific oysters (*Crassostrea gigas*), northern razor clam (*Siliqua patula*) meat only, and whole hard clams, comprising three species: butter clams (*Saxidomus gigantea*), Pacific littleneck clams (*Protothaca staminea*), and Japanese littleneck clams (also known as Manila clams; *Venerupis philippinarum).* The mouse bioassay (MBA) remains the most widely accepted method for detecting saxitoxins worldwide and has been demonstrated to adequately protect public health. The receptor binding assay (RBA) is a competitive assay in which radiolabeled saxitoxin competes with unlabeled saxitoxin for a finite number of available receptor sites. The resulting measurement provides an estimate of overall PSP toxicity in a shellfish sample (Van Dolah et al., 2009). The RBA was approved for use with mussels and approved for limited use with clams and scallops in 2014. To support full implementation of the RBA, Washington State conducted matrix extension studies to evaluate and expand the use of the method to additional species of molluscan shellfish. The validation and matrix extension study report is included with this proposal submission. The requested action is to expand the NSSP approved use of the RBA to include mussels, clams, geoduck clams (gutball), razor clam (meat), and oysters as a fully approved use method for PSP toxicity determination. **Paralytic Shellfish Poisoning (PSP) Toxins**

Shellfish Lab Methods	The mouse bioassay is still the most widely accepted detection method for the saxitoxins around the world and has been shown to adequately protect the public's health. In 2009, the Interstate Shellfish Sanitation Conference approved a post-column oxidation HPLC- PCOX method, making it the newest regulatory method available for PSP toxins in the U.S. The receptor binding assay (RBA), a competition assay whereby radiolabeled saxitoxin competes with unlabeled saxitoxin for a finite number of available receptor sites, provides a measure of

		overall PSP toxicity in a sample (Van Dolah et al., 2009). The RBA was approved for mussels in 2014, Pacific geoduck gutball, whole Pacific oysters, northern razor clam (meat only), and whole hard clams, comprising three species: butter clams, Pacific littleneck clams and Japanese littleneck clams in 2026 and approved limited use for ~~clams~~ and scallops in 2014.
Public Health Significance	**Public Health Significance:** Paralytic shellfish poisoning (PSP) is a serious public health concern because exposure to paralytic shellfish toxins can cause severe illness and, in some cases, death. The receptor binding assay (RBA) provides a more sensitive and efficient approach for detecting saxitoxin and related toxins in shellfish. The RBA can detect toxins at approximately five times lower concentrations than the mouse bioassay, providing an earlier warning of toxin accumulation. This increased sensitivity supports more timely public health actions, including increased sampling, harvest closures, and reopening decisions, helping reduce the potential for contaminated shellfish to reach consumers and recreational harvesters. The implementation of the RBA strengthens Washington's ability to protect public health while supporting efficient, sustainable shellfish monitoring.	
Cost Information	The estimated cost per 96-well plate assay is ~$300. 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 ~$40. If running multiple plates or in screening mode (single dilutions), sample costs could be reduced significantly. A microplate scintillation counter is needed as a one-time purchase, and the cost is ~$70-250K for a new counter, depending on the brand and number of simultaneous detectors. However, used instruments can be purchased for ~$13K. In 2025, the Washington State Public Health Laboratories (WA PHL) analyzed approximately 3,000 paralytic shellfish poisoning (PSP) samples. Replacing the more costly Mouse Bioassay ($145 per sample) with the less expensive Receptor Binding Assay (RBA) ($40 per sample) could have resulted in an estimated savings of approximately $315,000 in a single year. Expanding the use of the RBA offers significant potential for long term cost savings while maintaining the capacity needed to support ongoing public health surveillance and shellfish safety testing.	