Proposal No. 2 7 - 1 3 0

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☑ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	AOAC OMA 2005.06, Determination of Paralytic Shellfish Poisoning Toxins in Shellfish Using Prechromatographic Oxidation and Liquid Chromatography with Fluorescence Detection
10. Specific NSSP Guide Reference	Section IV Guidance Documents – Chapter III. Laboratory @.02 Methods 0.1 Approved NSSP Laboratory Tests 2. Approved Methods for Marine Biotoxin Testing
11. Text of Proposal/ Requested Action	Adoption of AOAC Official Method 2005.06 (OMA 2005.06) as an Approved Method of PSP testing in mussels, clams, oysters, and scallops. In the ISSC Constitution Bylaws and Procedures, updated July 22, 2024, Procedure XV. Procedure for the approval of analytical methods for the NSSP, section vii(a) states that: *AOAC approved methods that have undergone the AOAC Official Methods of Analysis (OMA) or FDA Office of Foods Level 3 or 4 validations may be accepted as an NSSP method without Single Lab Validation providing the AOAC or FDA multi-laboratory validation was performed in the raw molluscan shellfish matrix for which the Conference intends it to be used and is deemed by ISSC as fit for purpose.* The European Union (EU) integrated OMA 2005.06 into its regulatory monitoring in 2006, and in 2019, officially adopted OMA 2005.06 as the EU Reference Method for the detection of PSP toxins in shellfish. This method has been rigorously vetted and validated and has been deemed to be fit for purpose across the EU. This proposal is for adoption of OMA 2005.06 as published. Subsequent refinements and improvements (including additional toxins), as adopted by the EU, will be submitted as method extensions in future submissions.
12. Public Health Significance	Paralytic Shellfish Poisoning (PSP) occurs worldwide and poses a serious threat to shellfish consumers. Currently approved methods in the NSSP include the APHA Mouse Bioassay (for all matrices covered by the NSSP), the Receptor Binding Assay (for mussels only), and the PCOX HPLC method (for mussels, clams, oysters, and scallops). Each method has its advantages and drawbacks, and NSSP laboratories benefit from choices that may be driven by access to equipment, the matrices of interest, or local PSP profiles.

13. Cost Information	$94,000 – $240,000 for equipment. $14 - $25 per sample for consumables, depending on the toxins present.
14. Changes Needed to Guidance (if proposed change is adopted)	Section IV Guidance Documents – Chapter III. Laboratory @.02 Methods 0.1 Approved NSSP Laboratory Tests Add to table: 2. Approved Methods for Marine Biotoxin Testing AOAC Official Method 2005.06[6] Indicate applicability to columns: Biotoxin Type Paralytic Shellfish Poisoning (PSP) Application: Growing Area Survey & Classification Sample Type: Shellfish Application: Dockside Testing Program Sample Type: Shellfish Application: Controlled Relaying Sample Type: Shellfish Add to Footnotes: 6. AOAC International. (2005). AOAC Official Method 2005.06: Paralytic Shellfish Poisoning Toxins in Shellfish: Prechromatographic Oxidation and Liquid Chromatography with Fluorescence Detection. In Official Methods of Analysis of AOAC International. Gaithersburg, MD: AOAC International. doi: 10.1093/9780197610145.003.4019. Applicable to the determination of STX; NEO; GTX2,3; GTX1,4; dcSTX; B-1/GTX5; C1,2; and C3,4 in mussels, clams, oysters, and scallops.