Proposal No. **13-109**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	Executive Office
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Proposal Subject	Expanding the use of the Abraxis Shipboard ELISA for the determination of paralytic shellfish poisoning (PSP) toxins
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	4. Approved Limited Use Methods for Marine Biotoxin Testing This submission presents the Abraxis Shipboard ELISA for paralytic shellfish poisoning (PSP) toxins as a screening method for consideration as an NSSP Approved Limited Use Method. Currently the Abraxis Shipboard ELISA is approved for limited use in conjunction with the Jellett Rapid Extraction (mixture of rubbing alcohol and vinegar) and specifically for the onboard testing protocol. This proposal presents more data on the Abraxis test using the rapid extraction and also provides new data and comparisons of the test when AOAC extractions (boiling with hydrochloric acid) are performed. The data presented supports expanding the use of the Abraxis Shipboard ELISA to (1) allow for the rapid extraction OR the AOAC extraction method and (2) allow the kit to be used as a screening method beyond the onboard screening protocol
Public Health Significance	Paralytic shellfish poisoning intoxications result from the consumption of seafood (primarily bivalve molluscs) contaminated with neurotoxins known as paralytic shellfish toxins (PSTs). To protect public health, harvesting closures are implemented when toxicity exceeds the guidance level of 80 micrograms saxitoxin equivalents per 100 grams of shellfish tissue. As such, accurate screening and analytical methods are needed to monitor shellfish toxicity for making decisions regarding opening and closing shellfish growing areas accordingly. While the Abraxis Shipboard ELISA is already an NSSP Approved Limited Use Method for PSP toxicity determination, being able to use AOAC extractions with this kit would allow for the same extraction to be used with this method during screening and with the MBA as necessary for confirmation (without requiring a second extraction). Further expanding the use of the method beyond the onboard screening protocol would be beneficial as it would make the Abraxis Shipboard ELISA available for use by monitoring laboratories.
Cost Information	Each 96 well plate costs ~$500.
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended referral of Proposal 13-109 to an appropriate committee as determined by the Conference Chairman.

Action by 2013 Task Force I	Recommended adoption of Laboratory Method and Quality Assurance Review Committee recommendation on Proposal 13-109.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-109.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-109.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-109 to an appropriate committee as determined by the Conference Chair until data that supports the use of the Abraxis ELISA beyond the use of the onboard procedure is made available.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-109.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-109.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-109.