Proposal Subject:	Update PSP Laboratory Evaluation Checklist
Specific NSSP Guide Reference:	NSSP Section IV. Guidance Documents Chapter II. Growing Areas .12 Evaluation of Laboratories By State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists-Laboratory Evaluation Checklist - PSP
Text of Proposal/ Requested Action	Update PSP Laboratory Evaluation Checklist. Please find the updated PSP Laboratory Checklist attached - word document titled "Revised PSP Checklist 11-08-2010.doc". A summary of the changes is: • Added the checklist items for Jellett Rapid Test for PSP • Renumbered checklist items to accommodate proposed additions and deletions and to better identify each checklist item. • Added, deleted or changed language for checklist items to be consistent with the microbiology laboratory evaluation checklist including added laboratory education and experience requirements • Deleted the requirement for metals testing on reagent water • Clarified and defined requirements for laboratory equipment, reagents and the mouse bioassay method.
Public Health Significance:	The current PSP laboratory checklist was last revised in 2005. Since that time the Jellett Rapid Test has received approval and is not in the checklist. Deficiencies have been identified while using the PSP checklist in evaluation of laboratories and the PSP checklist is inconsistent with some requirements in the microbiology checklist which has more recently been revised . It is important that the checklist items and quality assurance requirements are clear and understandable. It is important that quality assurance requirements among the different laboratory evaluation checklists remain as consistent as possible since many monitoring laboratories perform multiple types of tests and are evaluated using multiple checklists; inconsistencies among the checklist cause confusion, extra expense and work for the laboratories.
Cost Information (if available):	None
Action by 2011 LMRC	Recommended Proposal 11-109 be referred to the appropriate committee as determined by the Conference Chairman.
Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 11-109.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-109.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-109.
Action by 2013 Laboratory Method Review & Quality Assurance Committee	Recommended Proposal 11-09 be referred to the appropriate committee as determined by the Conference Chairman.
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 11-109.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-109.

Action by FDA
May 5, 2014

Concurred with Conference action on Proposal 11-109.