

 Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting		a. <input checked="" type="checkbox"/> Growing Area b. <input type="checkbox"/> Harvesting/Handling/Distribution c. <input type="checkbox"/> Administrative
Submitter	U.S. Food and Drug Administration (FDA)	
Affiliation	FDA	
Address Line 1	5001 Campus Drive	
Address Line 2	HFS-325	
City, State, Zip	College Park, MD 20740	
Phone	240-402-1401	
Fax	301-436-2601	
Email	Melissa.abbott@fda.hhs.gov	
Proposal Subject	Alkaline Phosphatase Probe Method for <i>Vibrio vulnificus</i> and <i>Vibrio parahaemolyticus</i> Detection in Oysters - Laboratory Evaluation Checklist	
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists	
Text of Proposal/ Requested Action	The requested action is to adopt the text of the attached checklist for the probe method for detecting <i>Vibrio vulnificus</i> (Vv) and <i>Vibrio parahaemolyticus</i> (Vp) in oysters and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.	
Public Health Significance	Currently, there is no checklist adopted by the ISSC for the probe method for detecting Vv and Vp in oysters. The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing this method in support of the NSSP. The checklist documents the number of critical, key or other nonconformities and how overall laboratory status for the method is determined.	
Cost Information	NA	
Action By 2017 Laboratory Committee	Recommended Proposal 17-110 be referred to an appropriate committee as determined by the Conference Chair.	
Action By 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-110.	
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-110.	
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-110.	