Proposal No. 17-111

-	Γask Force Consideration a.  □ Growing Area   017 Biennial Meeting b. □ Harvesting/Handling/Distribution   c. □ Administrative
Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	FDA
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Proposal Subject	MPN Real-Time PCR Method for Vibrio vulnificus and Vibrio parahaemolyticus
	Detection in Oysters - Laboratory Evaluation Checklist
Specific NSSP	Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of
Guide Reference	Laboratories by State Shellfish Laboratory Evaluation Officers Including
	Laboratory Evaluation Checklists
Text of Proposal/	The requested action is to adopt the text of the attached checklist for the MPN real-
Requested Action	time PCR method for detecting Vibrio vulnificus (Vv) and Vibrio parahaemolyticus
	(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
7 11 77 11	Checklists.
Public Health	Currently, there is no checklist adopted by the ISSC for the MPN real-time PCR
Significance	method for detecting Vv and Vp in oysters that is approved in the NSSP for Vibrio
	enumeration. 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	
Cost Information	NA