Proposal for Task Force Consideration at the 2009 Biennial Meeting Interstate Shellfish Sanitation Conference	☒ **Growing Area** ☐ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	ISSC *Vibrio parahaemolyticus* Methodology Workgroup
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Proposal Subject:	Real Time PCR Method for Determining Levels of *V. parahaemolyticus*
Specific NSSP Guide Reference:	Section IV Guidance Document, Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods
Text of Proposal/ Requested Action	With the advent of real-time PCR assays, it is now possible to conduct more rapid and accurate screening for *Vibrio parahaemolyticus* within 24 hour time frame. Real-time PCR assays are generally less labor intensive and less time consuming then the traditional biochemical assays that have been used to detect total *Vibrio parahaemolyticus.* The State of Washington Department of Health has developed a multiplex real time PCR assay for the detection of *Vibrio parahaemolyticus* (VP) using the Applied Biosystem Taqman Platform. This assay targets two species identification markers (*tlh* and *gyrase B*) for total VP, the virulence marker (*tdh*), and a *16S* target that is specific for five species (V. *parahaemolyticus*, V. *alginolyticus*, V. *furnissii*, V. *harveyi*, V. *fluvialis*) within the genus.
Public Health Significance:	*Vibrio parahaemolyticus* continues to cause food borne outbreaks globally due to the consumption of raw or undercooked oysters[i, ii]. Current molecular methods can of differentiate between pathogenic (tlh+, tdh+) and non-pathogenic (tlh+, tdh-) organisms but real-time PCR procedures are not fully approved by the ISSC. This real-time PCR assay, if approved, would improve the turn around time for results for public health protection and seafood safety. [i]Wong, H.C., S. H. Liu, et al. (2000). Characteristics of Vibrio parahaemolyticus O3:K6 from Asia." Appl Environ Microbiol **66**(9): 3981-6. [ii]DePaola, A., C. A. Kaysner, et al. (2000). "Environmental investigations of Vibrio parahaemolyticus in oysers after outbreaks in Washington, Texas, and New York (1997 and 1998)." Appl Environ Microbiol **66**(11): 4649-54.
Cost Information (if available):	None
Action by 2005 Laboratory Methods Review Committee	Recommended Proposal 05-108 be referred to the appropriate committee as determined by the Conference Chairman, with further direction to the Executive Office to organize a meeting of the Laboratory Methods Committee within six (6) months of the conclusion of this Biennial Meeting.
Action by 2005 Task Force I	Recommended adoption of the Lab Methods Review Committee recommendation on Proposal 05-108.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.

Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended no action on Proposal 05-108. Rationale – Inadequate data submission. The methods proposed in Proposal 05-108 would be very useful to the NSSP. The submitter will be requested to provide additional data to the Executive Office for approval consistent with Procedure XVI.
Action by 2007 Task Force I	Recommended referral of Proposal 05-108 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action with the following comments and recommendations for ISSC consideration. The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP. At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the Executive Office for methods approval consistent with Procedure XVI, clearly recognized the importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.