

*Vibrio vulnificus*  
Post Harvest Processing  
Validation and Verification  
Laboratory Methods Approval

Getting There

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# Validation and Approval of New Methods in the NSSP

- Emerging Methods are great!
  - Take less time than conventional identification microbiology
  - Using molecular technologies that are routinely employed in criminal science, genome projects, and disease diagnosis
  - Can be combined with conventional culture technique to eliminate false positives due to molecular target persistence

# Validation and Approval of New Methods in the NSSP

- What's taking so long to get these methods into the NSSP Approved Methods?

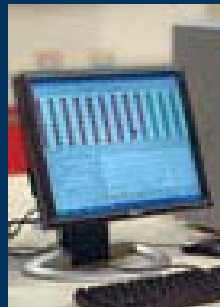
# Validation and Approval of New Methods in the NSSP

- The process
  - An approval process was developed and adopted in the ISSC Constitution By-Laws and Procedures
  - We now have

## Procedure XVI

# Validation and Approval of New Methods in the NSSP Procedure XVI

- The process requires that methods proposed for use in the NSSP meet certain criteria for
  - Accuracy
  - Sensitivity
  - Precision
  - Specificity
  - Comparability to existing methods
  - And much, much more!



# Validation and Approval of New Methods in the NSSP Procedure XVI

These checks assure that the methods accepted within the NSSP are fit for the purpose and needs found in Shellfish Sanitation programs

# Validation and Approval of New Methods in the NSSP Procedure XVI

➤ Methods developers are required to supply

- Information mentioned previously such as specificity and sensitivity
- Reagent and equipment requirements
- A single lab demonstration using conventional statistical analysis that the method works
- A checklist with the critical control points in the method so that evaluations may be made with consistency

# Validation and Approval of New Methods for Vibrios in PHP products

- Methods have been developed and are presently being employed by the industry to validate PH processes
- Several have been proposed to the ISSC for Lab Methods Review, Executive Board and final Conference approval
- The Lab Methods review committee is waiting for all necessary information to be submitted so that the approval process can advance.

# Validation and Approval of New Methods for Vibrios in PHP products

Here is more on some of these methods that are in the approval process for acceptance into the NSSP