Proposal No. 17-110

| -                                     | ask Force Consideration 17 Biennial Meeting  a.   Growing Area  b.   Harvesting/Handling/Distribution  c.   Administrative  |
|---------------------------------------|---|
| Submitter                             | U.S. Food and Drug Administration (FDA)   |
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| Proposal Subject                      | Alkaline Phosphatase Probe Method for <i>Vibrio vulnificus</i> and <i>Vibrio parahaemolyticus</i> 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/<br>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                         | Currently, there is no checklist adopted by the ISSC for the probe method for   |
| Significance                          | 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  |