

<b>Proposal Subject</b>	Establish a <i>Vibrio vulnificus</i> Illness Review Subcommittee within the Vibrio Management Committee
<b>Specific NSSP Guide Reference</b>	Chapter IV. Naturally Occurring Pathogens
<b>Text of Proposal/ Requested Action</b>	.02 <i>Vibrio vulnificus</i> Management Plan  Insert a new section (d) and re-letter the remaining sections.  (d) Creation of a working group to work collectively with the FDA and CDC to review and approve all <i>Vibrio vulnificus</i> illness information prior to it being presented to the <i>Vibrio vulnificus</i> subcommittee.
<b>Public Health Significance</b>	With illness reduction goals in place the Conference should, through a working group, review and approve all of the <i>Vibrio vulnificus</i> illness cases that the FDA and CDC are presenting to the <i>Vibrio vulnificus</i> subcommittee.
<b>Cost Information (if available)</b>	None
<b>Action by 2005 Task Force I</b>	Recommends adoption of Proposal 05-101 as submitted.
<b>Action by 2005 General Assembly</b>	Recommended referral of Proposal 05-101 to the appropriate committee as determined by the Conference Chairperson.
<b>Action by USFDA</b>	Concurred with Conference action.
<b>Action by Vv Illness Criteria Review Workgroup</b>	Recommended adoption of Vv Illness Criteria (see below).

**CRITERIA FOR INCLUDING VV CASES IN ILLNESS REDUCTION CALCULATIONS AND DETERMINING SOURCE STATES**

1. Each case that is considered must be reported on a Center for Disease Control and Prevention Cholera *Vibrio* Illness Surveillance Report (COVIS) Form CDC 52.79.
2. Each case must also be listed be on the FDA (Glatzer’s) database (NSSP Guide for the Control of Molluscan Shellfish Guidance Documents Chapter IV .02).
3. The ISSC committee to review reported Vv illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations must have access to the COVIS form for each case (patient names and other necessary information appropriately redacted). The ISSC addendum form is also provided, where available. This access to the COVIS form is critical for adequate interpretation of the data collected during the state epidemiological investigation.
4. The ISSC Vv Illness Review Committee will complete the following criteria table for each case. These tables serve as documentation.
5. For cases to be included in illness reduction calculations the following criteria must be met:
  - Item 1-4 and 5a must be answered yes.
  - Should the COVIS form include information that suggests other exposures that may be responsible for the Vv illness further investigation may occur. Consultation with State Shellfish Control Authorities and Epidemiologist from the state is encouraged to determine which exposure should be recorded as the cause of illness. Should oyster consumption not be determined to be the cause of illness the case will not be counted. Should there be disagreements with the inclusion of a case; the disagreeing party may request a review. The request must include a rationale for the review and should be addressed to the Executive Board Chairman.

- If 5b is no, other exposures should be considered. If no other exposures exist, case will not be counted.
- Should the only exposure be consumption of cooked oysters or unknown 5b will be checked yes.

<i>Vibrio vulnificus</i> Criteria Table				
Case Identifier / Number	Criteria	Criteria Status Determination		
		Yes	No	Unknown
1.	<b>Etiologically Confirmed</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<b>Septicemia Illness</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<b>Reporting State (CA, FL, LA, TX)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<b>Commercial Harvest from US Production</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	<b>Exposures</b>			
a.	Onset Consistent with Consumption of Oysters (within last 4 days)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	Raw or undercooked oysters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	<b>Traceback Information</b>			
a.	Were shipping tags available or was other traceback information reported	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	State of harvest and harvest area (s)			<input type="checkbox"/>
c.	Harvest date (s)			<input type="checkbox"/>
d.	From what State waters did the oysters originate			<input type="checkbox"/>
7.	<b>Case Determination</b>			
a.	Is case included in Vv illness reduction Calculations	<input type="checkbox"/>	<input type="checkbox"/>	
b.	Is case attributed to a single source state	<input type="checkbox"/>	<input type="checkbox"/>	
Instructions for completing Criteria Table:				
<ul style="list-style-type: none"> <li>• Check YES if Criterion is confirmed from the COVIS form or addendum.</li> <li>• Check NO if Criterion is not confirmed from the COVIS form or addendum.</li> <li>• Check UNKNOWN if Criterion is not clear or absent from the COVIS form or addendum.</li> <li>• No Criterion can have more than one check entered.</li> <li>• Each Criterion must have one check entered (YES, NO, or UNKNOWN).</li> </ul>				
These criteria tables will be used to review reported Vv illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations and will also be used for identifying other source states.				

**Action by 2007 Vibrio Management Committee**

Recommended adoption of Proposal 05-101 as amended. In addition, the Vibrio Management Committee recommended appointment of a committee that will consist of three (3) epidemiologists and advisors as appropriate. The Committee will use this form to screen cases for the purposes of determining if a case is attributable to a single source state as well as whether the case is includable in the Vv Illness Reduction Goals. In addition, to ensure uniformity, the form shall be used for screening 2007-2008 cases and that cases from the baseline will be screened using the same form. See below.

**CRITERIA FOR INCLUDING VV CASES IN ILLNESS REDUCTION CALCULATIONS AND DETERMINING SOURCE STATES**

1. Each case that is considered must be reported on a Center for Disease Control and Prevention Cholera *Vibrio* Illness Surveillance Report (COVIS) Form CDC 52.79.
2. Each case must also be listed be on the FDA (Glatzer’s) database (NSSP Guide for the Control of Molluscan Shellfish Guidance Documents Chapter IV .02).
3. The ISSC committee to review reported Vv illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations must have access to the COVIS form for each case (patient names and other necessary information appropriately redacted). The ISSC addendum form is also provided, where available. This access to the COVIS form is critical for adequate interpretation of the data collected during the state epidemiological investigation.
4. The ISSC Vv Illness Review Committee will complete the following criteria table for each case. These tables serve as documentation.

5. For cases to be included in illness reduction calculations the following criteria must be met:
- Item 1-4 and 5a must be answered yes.
  - Should the COVIS form include information that suggests other exposures that may be responsible for the Vv illness further investigation may occur. Consultation with State Shellfish Control Authorities and Epidemiologist from the state is encouraged to determine which exposure should be recorded as the cause of illness. Should oyster consumption not be determined to be the cause of illness the case will not be counted. Should there be disagreements with the inclusion of a case; the disagreeing party may request a review. The request must include a rationale for the review and should be addressed to the Executive Board Chairman.
  - If 5b is no, other exposures should be considered. If no other exposures exist, case will not be counted.
  - Should the only exposure be consumption of cooked oysters or unknown 5b will be checked yes.

***Vibrio vulnificus* Criteria Table**

Case Identifier / Number	Criteria	Criteria Status Determination		
		Yes	No	Unknown
<b>1.</b>	<b>Etiologically Confirmed</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2.</b>	<b>Septicemia Illness</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>3.</b>	<b>Reporting State (CA, FL, LA, TX)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>4.</b>	<b>Commercial Harvest from US Production</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>5.</b>	<b>Exposures</b>			
a.	Onset Consistent with Consumption of Oysters (within last 4 days)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	Raw or undercooked oysters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>6.</b>	<b>Traceback Information</b>			
a.	Were shipping tags available or was other traceback information reported	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	State of harvest and harvest area (s)			<input type="checkbox"/>
c.	Harvest date (s)			<input type="checkbox"/>
d.	From what State waters did the oysters originate			<input type="checkbox"/>
<b>7.</b>	<b>Case Determination</b>			
a.	Is case included in Vv illness reduction Calculations	<input type="checkbox"/>	<input type="checkbox"/>	
b.	Is case attributed to a single source state	<input type="checkbox"/>	<input type="checkbox"/>	
Instructions for completing Criteria Table: <ul style="list-style-type: none"> <li>• Check YES if Criterion is confirmed from the COVIS form or addendum.</li> <li>• Check NO if Criterion is not confirmed from the COVIS form or addendum.</li> <li>• Check UNKNOWN if Criterion is not clear or absent from the COVIS form or addendum.</li> <li>• No Criterion can have more than one check entered.</li> <li>• Each Criterion must have one check entered (YES, NO, or UNKNOWN).</li> </ul> These criteria tables will be used to review reported Vv illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations and will also be used for identifying other source states.				

**Action by 2007 Task Force I** Recommended adoption of the Vibrio Management Committee recommendation on Proposal 05-101.

**Action by 2007 General Assembly** Adopted recommendation of 2007 Task Force I.

**Action by USFDA** December 20, 2007  
Concurred with Conference action.