

 <p>Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting</p>	<input type="checkbox"/> Growing Area <input checked="" type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
Address Line 1	5001 Campus Drive
Address Line 2	CPK1, HFS-325
City, State, Zip	College Park, MD 20740
Phone	240-402-1401
Fax	301-436-2601
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Shellfish Illness Response Associated with <i>Vibrio parahaemolyticus</i> (V.p.)
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with V.p.
Text of Proposal/ Requested Action	<p><u>A.</u> When the investigation outlined shellfish are implicated in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen <i>Vibrio parahaemolyticus</i> (V.p.), the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows <u>whether an epidemiological association exists between the illness(es) and shellfish consumption by reviewing:</u></p> <p style="margin-left: 20px;">(1) <u>Each consumer's food history;</u></p> <p style="margin-left: 20px;">(2) <u>Shellfish handling practices by the consumer and/or retailer.</u></p> <p><u>B.</u> <u>When the Authority has determined an epidemiological association between V.p. illness(es) and shellfish, including illnesses described as sporadic, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and span of time as follows:</u></p> <p>(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30)<u>seven (7)</u> day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure and evaluate compliance with the existing State Vibrio Control Management Plan. If at least two (2) cases occur from a single harvest day, the Authority shall refer to @.02 B. (3).</p> <p>(2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4)<u>two (2)</u> but not more than ten (10)<u>four (4)</u> over a thirty (30) day time period <u>greater than seven (7) but less than thirty (30) days,</u> from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area, the Authority shall:</p> <p style="margin-left: 20px;">(a) Determine the extent of the implicated area; and</p> <p style="margin-left: 20px;">(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and</p> <p style="margin-left: 20px;">(c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish.</p>

	<p>(3) When the number of cases exceeds ten (10) <u>four (4)</u> illnesses within a thirty (30) day period <u>or two (2) illnesses within a seven (7) day period</u> from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall:</p> <ul style="list-style-type: none"> (a) Determine the extent of the implicated area; and (b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and <u>(c) As soon as determined by the Authority, transmit to the ISSC, FDA, and receiving States information identifying the dealers shipping the implicated shellfish.</u> <u>(e) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.</u> <u>(e) Issue a consumer advisory for all shellfish (or species implicated in the illness).</u> <p>(4) When a growing area has been closed as a result of <i>V.p.</i> cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:</p> <ul style="list-style-type: none"> (a) The area will remain closed for a minimum of fourteen (14) days, when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area. (b) The area will remain closed for a minimum of twenty one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area <p>(5) Prior to reopening an area closed as a result of the number of cases exceeding ten (10) <u>four (4)</u> illnesses within thirty (30) days or <u>two (2) within seven (7) days or two (2)</u> cases from a single harvest date from the implicated area, the Authority shall:</p> <ul style="list-style-type: none"> (a) Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies; <u>or</u> (b) Ensure that environmental conditions have returned to levels not associated with <i>V.p.</i> cases. <p>(6) Shellfish harvesting may occur in an area closed as a result of <i>V.p.</i> illnesses when the Authority implements one or more of the following controls:</p> <ul style="list-style-type: none"> (a) Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total <i>Vibrio parahaemolyticus</i> for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams; (b) Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing; (c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of <i>V.p.</i> illness is no
--	--

	<p style="text-align: center;">longer reasonably likely to occur, as approved by the Authority. <u>(7) Molluscan shellfish recalled as a result of V.p. illnesses may be reconditioned as described in Chapter II. @.01 J.</u></p>
<p>Public Health Significance</p>	<p>The national trend with regard to Vp illnesses has not improved over the past several years. This proposal intends to improve the effectiveness of response to Vp illnesses. This proposal retains the tiered approach for response to Vp illnesses, but requires closure of implicated areas and recall for situations where multiple illnesses occur over a short period of time, suggesting a higher risk situation.</p> <p>The requirement to close for a minimum of fourteen (14) days and to collect and analyze water samples prior to re-opening is expected to decrease the numbers of V.p. illnesses occurring from particularly high risk growing areas.</p> <p>A reference to @.01 J has been added for clarification.</p>
<p>Cost Information</p>	