



Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input type="checkbox"/> Growing Area <input checked="" type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Submitter	Executive Office	
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)	
Address Line 1	209 Dawson Road	
Address Line 2	Suite 1	
City, State, Zip	Columbia, SC 29223-1740	
Phone	803-788-7559	
Fax	803-788-7576	
Email	issc@issc.org	
Proposal Subject	Shellfish Related Illnesses Associated with <i>V.p.</i>	
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment & Risk Management @.02 Shellfish Related Illnesses Associated with <i>Vibrio parahaemolyticus</i> (<i>V.p.</i>)	
Text of Proposal/ Requested Action	<p>Amend Model Ordinance Chapter II. Risk Assessment & Risk Management @.02 A. (4) (a) to provide clarification regarding closures associated with sporadic cases that 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) day period from an implicated area in which no two (2) cases occurred from a single harvest day. Two (2) options are offered below that could provide needed clarification.</p> <p>Option 1:</p> <p>@.02 Shellfish Related Illnesses Associated with <i>Vibrio parahaemolyticus</i> (<i>V.p.</i>)</p> <p>A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen <i>Vibrio parahaemolyticus</i> (<i>V.p.</i>), 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.</p> <p><u>(1)</u> 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) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall:</p> <p><u>(a)</u> Determine the extent of the implicated area; and</p> <p><u>(b)</u> Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and</p> <p><u>(c)</u> The Authority will mMake reasonable attempts to ensure compliance with the existing Vibrio Management Plan.</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) but not more than ten (10) 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 day from the implicated area, the Authority shall:</p> <p>(a) Determine the extent of the implicated area; and</p> <p>(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and</p>	

	<ul style="list-style-type: none"> (c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish. (3) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall: <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 (c) 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. (d) Issue a consumer advisory for all shellfish (or species implicated in the illness). (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: <ul style="list-style-type: none"> (a) The area will remain closed for a minimum of seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area. (b) 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. (c) 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 (5) Prior to reopening an area closed as a result of the number of cases exceeding ten (10) illnesses within thirty (30) days or four (4) cases from a single harvest date from the implicated area, the Authority shall: <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. (b) Ensure that environmental conditions have returned to levels not associated with <i>V.p.</i> cases. (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
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	<p>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 longer reasonably likely to occur, as approved by the Authority. <p>Option 2:</p> <p>@.02 Shellfish Related Illnesses Associated with <i>Vibrio parahaemolyticus</i> (<i>V.p.</i>)</p> <p>A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen <i>Vibrio parahaemolyticus</i> (<i>V.p.</i>), 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.</p> <ul style="list-style-type: none"> (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) 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 compliance with the existing Vibrio Management Plan. (2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) 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 day from the implicated area, the Authority shall: <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 (c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish. (3) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall: <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 (c) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless
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	<p>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.</p> <p>(d) Issue a consumer advisory for all shellfish (or species implicated in the illness).</p> <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> <p>(a) The area will remain closed for a minimum of seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area.</p> <p>(b) <u>(a)</u> 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.</p> <p>(c) <u>(b)</u> 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> <p>(5) Prior to reopening an area closed as a result of the number of cases exceeding ten (10) illnesses within thirty (30) days or four (4) cases from a single harvest date from the implicated area, the Authority shall:</p> <p>(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.</p> <p>(b) Ensure that environmental conditions have returned to levels not associated with <i>V.p.</i> cases.</p> <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> <p>(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;</p> <p>(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;</p> <p>(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 longer reasonably likely to occur, as approved by the</p>
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Public Health Significance	<p>Following the adoption of Proposal 13-202 at the 2013 Biennial Meeting, the Executive Board was asked to clarify the language of the proposal associated with sporadic cases that 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) day period from an implicated area in which no two (2) cases occurred from a single harvest day.</p> <p>To address this concern, the Executive Board, with FDA concurrence, took interim action to delay the implementation of the closure requirement associated with @.02 A. (4) (a). The intent of this Board action was to allow the ISSC to discuss the intent of @.02 A. (4) (a).</p>
Cost Information	