

		Growing Area			
Proposal for Task Force Consideration at the		Harvesting/Handling/Distribution			
ISSC 2015 Biennial N	leeting				
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 V.p.				
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment & Risk Management @.02 Shellfish Related Illnesses Associated with <i>Vibrio parahaemolyticus (V.p.)</i>				
Text of Proposal/ Requested Action	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.				
	Option 1: @.02 Shellfish Related Illnesses Associated with <i>Vibrio parahaemolyticus (V.p.)</i>				
	 are associated with the nation (V.p.), the Authority shall cases epidemiologically as by the Authority will be bar follows. (1) When sporadic carring area in which no two Authority shall: (a)	butlined in Section @.01 A. indicates the illness(es) atturally occurring pathogen <i>Vibrio parahaemolyticus</i> all determine the number of laboratory confirmed associated with the implicated area and actions taken based on the number of cases and the span of time as cases do not exceed a risk of one (1) illness per or involves at least two (2) but not more than four ng within a thirty (30) day period from an implicated two (2) cases occurred from a single harvest day, the ne the extent of the implicated area; and ely place the implicated portion(s) of the harvest the closed status; and hority will mMake reasonable attempts to ensure ce with the existing Vibrio Management Plan. acceeds one (1) illness per 100,000 servings within a eriod or when cases exceed four (4) but not more r a thirty (30) day period from the implicated area or cases but less than four (4) cases occur from a single the implicated area, the Authority shall: he the extent of the implicated area; and tely place the implicated portion(s) of the harvest the implicated area, and the place the implicated portion(s) of the harvest the implicated area, and tely place the implicated portion(s) of the harvest 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:
	(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
	(d) Issue a consumer advisory for all shellfish (or species
	(d) Issue a consumer advisory for all shellfish (or species
(4)	implicated in the illness). When a growing area has been closed as a result of <i>V.p.</i> cases, the
(4)	Authority shall keep the area closed for the following periods of time
	to determine if additional illnesses have occurred:
	(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 (20) days or four (4) cases accur from a
	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 (10) illumination (10) illumination (10) is the set of the s
	exceeding ten (10) illnesses within thirty (30) days or four (4) cases
	from a single harvest date from the implicated area, the Authority shall:
	(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 V.p. cases.
(6)	Shellfish harvesting may occur in an area closed as a result of V.p.
	illnesses when the Authority implements one or more of the



following controls:	
(a) Post-harvest processing validated to achieve a two total Vibrio parahaemoly.	using a process that has been to (2) log reduction in the levels of <i>ticus</i> for Gulf and Atlantic Coast and a three (3) log reduction for or hard clams;
labeled for shucking by a	nard clam harvest to product that is certified dealer, or other means to ressed by further processing;
(c) Other control measures the studies are designed to en	hat based on appropriate scientific issure that the risk of $V.p$. illness is ely to occur, as approved by the
Option 2:	
@.02 Shellfish Related Illnesses Associated with V	Vibrio parahaemolyticus (V.p.)
A. When the investigation outlined in Section are associated with the naturally occurring (<i>V.p.</i>), the Authority shall determine the cases epidemiologically associated with the by the Authority will be based on the numb follows.	pathogen <i>Vibrio parahaemolyticus</i> e number of laboratory confirmed e implicated area and actions taken
 (1) When sporadic cases do not exceed a servings or involves at least two (2) occurring within a thirty (30) day period no two (2) cases occurred from a sing determine the extent of the implicate reasonable attempts to ensure comp Management Plan. 	but not more than four (4) cases of from an implicated area in which gle harvest day, the Authority shall of area. The Authority will make pliance with the existing Vibrio
 thirty (30) day period or when cathan ten (10) over a thirty (30) day two (2) or more cases but less than harvest day from the implicated are (a) Determine the extent of the (b) Immediately place the imarea(s) in the closed status (c) As soon as determined by 	e implicated area; and nplicated portion(s) of the harvest ; and the Authority, transmit to the FDA formation identifying the dealers
 (30) day period from the implication occurred from a single harvest data Authority shall: (a) Determine the extent of the 	-
(c) area(s) in the closed status (c) Promptly initiate a volunt	nplicated portion(s) of the harvest ; and tary industry recall consistent with 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)	Author	a growing area has been closed as a result of <i>V.p.</i> cases, the rity shall keep the area closed for the following periods of time rmine if additional illnesses have occurred: 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) (a)	^
	(0) <u>(u)</u>	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) (b)	*
	· · · <u>· · · ·</u>	(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 t	o reopening an area closed as a result of the number of cases
		ling ten (10) illnesses within thirty (30) days or four (4) cases a single harvest date from the implicated area, the Authority
	(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)	Shellfi	sh harvesting may occur in an area closed as a result of <i>V.p.</i>
	illness	es when the Authority implements one or more of the
		ing controls:
	(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.	
Public Health Significance	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.	
	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).	
Cost Information		