Proposal No. **17-206**

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Proposal Subject	Shellfish Illness Response Associated with *Vibrio parahaemolyticus* (*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	A. When ~~the investigation outlined~~ shellfish are implicated in ~~Section @.01 A. indicates the~~ illness(es) ~~are~~ associated with the naturally occurring pathogen *Vibrio parahaemolyticus (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~~ whether an epidemiological association exists between the illness(es) and shellfish consumption by reviewing:. (1) Each consumer's food history; (2) Shellfish handling practices by the consumer and/or retailer. B. 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: (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)~~seven (7) 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). (2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed ~~four (4)~~two (2) but not more than ~~ten (10)~~four (4) over a ~~thirty (30) day~~ time period greater than seven (7) but less than thirty (30) days, 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: (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)~~ four (4) illnesses within a thirty (30) day period or two (2) illnesses within a seven (7) day period from the implicated area ~~or four (4) or more cases occurred from a single harvest date from the implicated area~~, ~~T~~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)~~ As soon as determined by the Authority, transmit to the ISSC, FDA, and receiving States information identifying the dealers shipping the implicated shellfish.

(~~d~~) 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~~e) 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 *V.p.* cases, the Authority shall keep the area closed for ~~the following periods of time to determine if additional illnesses have occurred:~~

~~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.~~

~~(a) 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)~~ four (4) illnesses within thirty (30) days or ~~four (4)~~ two (2) within seven (7) days or two (2) 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.; or

(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 using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* 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 *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority. (7) Molluscan shellfish recalled as a result of *V.p.* illnesses may be reconditioned as described in Chapter II. @.01 J.
Public Health Significance	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. 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. A reference to @ .01 J has been added for clarification.
Cost Information	
Action by 2017 Task Force II	Recommended referral of Proposal 17-206 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-206.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-206.
Action by 2019 *V.p.* Illness Response Committee	Recommended: 1) the language of proposal 17-206 be replaced with substitute language presented by FDA (included below) for the purpose of referral to an appropriate committee **Section II. Model Ordinance** **Chapter II. Risk Assessment and Risk Management** **@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)***

	A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (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 (1) lllness per 100,000 servings or…. (2) … (3) … (4) … (5) … (6) … (7) Culture-Independent Diagnostic Test (CIDT) positive results not confirmed by reflex culture (probable case) will be considered a confirmed case **if:** a) more than (>) 2 CIDT positive cases, with symptoms corresponding to Vp, originate from the same growing area within a 30-day period; b) CIDT positive cases originate from areas where confirmed Vp cases are occurring within a 30-days period. If either of these scenarios present themselves, the presumptive CIDT cases will be treated as confirmed Vp cases *Vibrio parahaemolyticus* Illness Attribution Committee will attribute multisource illnesses, if the Authority is unable to attribute a case to a growing area within 24 hrs of the completion of the illness investigation. This committee will assign cases and percentages of cases to state growing areas if a single source cannot be identified. State members of the committee may not vote on illnesses potentially attributed to their own state. 2) Proposal 17-206, as amended, be referred by the Conference Chairman to an appropriate committee, requesting that the committee charge and appointments be made prior to the 2020 ISSC Spring Executive Board meeting.
Action by 2019 Task Force II	Recommended adoption of substitute language of Proposal 17-206 with referral to an appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 17-206.
Action by FDA February 21, 2020	FDA concurred with the Conference's action to refer Proposal 17-206 to committee. FDA suggests this committee be formed as soon as possible and that the Executive Board consider the committee's recommendations on appropriate changes to the June 22, 2018 Guidance which was provided to states. The critical issues that should be considered by the committee are counting of culture independent diagnostic testing (CIDT) positive cases and case attribution where multiple sources are identified. The committee would deliberate and decide on appropriate attribution. The attribution of illnesses is a great public health concern as it impacts closure and harvest controls; and thus, prevention of further illnesses. The FDA encourages the expeditious formation of the committee and looks forward to continued engagement in this process.
Action by *V.p.* Illness Response Committee, 2023	Recommends sending proposal 17-206 to the appropriate committee as determined by the conference chair, and the committee continue its work in the interim prior to the next conference.
Action by Task Force II, 2023	Recommends accept *V.p.* Illness Response Committee's recommendation to send proposal 17-206 back to the appropriate committee along with proposa1 15-226.

Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 17-206
Action by FDA July 7,2023	Concurred with Conference action on Proposal 17-206.