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	Reducing the Risk of Vibrio Illnesses
Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish
Text of Proposal/ Requested Action	A Vibrio workshop was held in Dauphin Island, Alabama in November 2012 to discuss possible solutions for addressing illness risks. State Shellfish Control Authority representatives, Vibrio researchers, and the USFDA participated in the two-day workshop. The participants identified several topics (listed below) that are related to Vibrio controls. These topics should be addressed by the collective participants of the ISSC. The purpose of this proposal is to request the ISSC Executive Board work collaboratively with the USFDA to address the information gaps that are obstacles to identifying effective control strategies for reducing the risk of illness associated with Vibrioses. Requested Action Items: 1. Rewrite Chapter II. Risk Assessment *V.p.* (section 05). 2. Incorporate salinity (and other environment factors?) into *V.v.* and *V.p.* risk calculators. 3. Develop protocol for validating the effectiveness of non-labeling PHPs. 4. Develop protocol for ensuring that growing/harvest/handling (production) practices do not increase risk of Vibrio illness. 5. Request FDA to develop sampling protocol for closing versus reopening growing areas after outbreaks including the development of resources to sustain the present capabilities. 6. Develop new labeling/tagging system for oysters produced under conditions achieve equivalent levels as validated PHP (for labeling), including validation protocol. 7. ISSC request FDA to reexamine risk assessments and risk calculators (*V.p.* and *V.v.*). 8. ISSC request FDA to reexamine illness and landings data to determine observed risk per serving. 9. Develop the process for using local data to refine calculators to more accurately reflect risk in the region or state. 10. Determine how best to estimate national consumption patterns for molluscan bivalves. Mega study. 12. ISSC request FDA technical assistance for enhancing state vibrio programs (data management, laboratory support, think tank, BMPs, evaluation of

	effectiveness of new controls, statistical support) . 13. States request FDA assistance with developing approved method(s) to temper clams. 14. Draft proposal for acceptance of laboratory methods validated by other accrediting bodies.
Public Health Significance	The ISSC continues to struggle with identifying practical cost effective strategies for reducing the risk of Vibrio illnesses associated with the consumption of molluscan shellfish. This proposal identifies information needs that are obstacles to the development of control strategies.
Cost Information	
Research Needs Information Proposed (specific research need/problem to be addressed)	1. Is total *V.v.* a valid indicator of risk? 2. Are there differential effects of validated PHP on virulent subpopulations? 3. How do environmental factors affect levels of virulent subpopulations? 4. Compile collection of *V.v.* for future virulence research. 5. Do other species react to controls the same as *V.v.* and *V.p.*? 6. Determine relative virulence of *V.p.* subpopulations. 7. What are Vibrio (total and virulent) levels at harvest (in oysters and clams)? 8. How much Vibrio (total and virulent) growth results from the current time/temperature controls (in oysters and clams)? Priorities: 1. What information is needed to supply more tools to the "toolbox"? 2. What regional information is needed to refine risk assessments and risk calculator tools for implementation of effective control plans? 3. What is the significance of salinity to Vibrio levels in shellfish? 4. Is there a salinity/temperature matrix that determines Vibrio levels? 5. What are the key virulence factors (or combination thereof) for *V.v.* and *V.p.*? 6. Need to know dose response of different Vibrio strains and populations 7. What are the regional differences in pathogenic strains of *V.v.* and *V.p.*? 8. What is the percentage of pathogenic strains of Vibrio in growing waters? 9. Should the "viable but not culturable" state in pathogenic Vibrios be a concern?
Explain the relationship between proposed research need and program change recommended in the proposal	
Estimated cost	
Proposed sources of funding	
Time frame anticipated	
For Research Guidance	Relative priority rank in terms of resolving research need ☐ Immediate ☐ Required ☐ Valuable ☐ Important ☐ Other

Committee Use Only	
Action by 2013 Task Force II	Recommended referral of Proposal 13-200 to an appropriate committee as determined by the Conference Chairman with instructions to the committee as follows: 1. Request that FDA reexamine its risk assessments and risk calculators (*V.p.*) and (*V.v.*) and present the results to ISSC, including the factors and methodology used to calculate risk per serving. 2. Develop a process for using local data including regional or state illness and landings information, to more accurately reflect risk in a region or state. 3. Determine how best to estimate consumption patterns, including collection data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods. 4. Evaluate existing NSSP regulations to reduce risk of Vibrio illness caused by improper handling, storing, or transportation of shellstock and the effectiveness of existing enforcement mechanisms. 5. Provide recommendations to ISSC based on the results of the above study and evaluation.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-200.
Action by FDA May 5, 2014	FDA concurred with Conference action on Proposal 13-200 with the following comments and recommendations. FDA concurs with ISSC referral of Proposal 13-200 to Committee. As appropriate, FDA will provide support to the Committee via participation of Agency Vibrio research and risk assessment experts to assist in addressing Committee charges as set forth in Proposal 13-200. The Agency will look to the Conference to advance recommendations made by the Committee for purposes of implementing appropriate controls to reduce the Vibrio risk. Results of ISSC actions in response to Proposal 13-204 will be integral to answering key questions associated with the Committee's charges.
Action by 2015 Vibrio Management Committee	Recommended the following action on Proposal 13-200: That the ISSC recognize the new *V.v.* and *V.p.* calculators as a tool available to calculate the actual risk and assess the effectiveness of state controls. Continue to monitor the activities addressed in items 2 & 3 and report annually to the VMC regarding progress. That a workgroup be formed to evaluate the effectiveness of existing NSSP regulations to reduce risk of Vibrio illnesses caused by improper handling, storing, or transportation of shellstock; to identify areas within the NSSP needing improvement; and make recommendations to the ISSC. The workgroup will consist of FDA, state and industry representatives.

Action by 2015 Task Force II	Recommended adoption of VMC recommendations 2. And 3. with referral of Proposal 13-200 to an appropriate committee with a recommendation that States be allowed to pilot the new *V.v.* and *V.p.* calculators and to provide input to the FDA and report back to VMC prior to the next ISSC meeting.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-200.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-200.
Action by 2017 Vibrio Management Committee	a. Monitor the development of processes for using local data including regional or state illnesses and landings information, to more accurately reflect risk in a region or state. Recommendation: The VMC recommended the Conference support and promote the collection of production data and recommends in every case possible the data be provided in product form. b. Monitor activities to estimate consumption patterns, including collection of data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods. Recommendations: 1. The VMC recommended that the ISSC continue to identify funding to collect data regarding shellfish consumption patterns to include serving size and product form and also distribution patterns. 2. VMC recommended the Conference identify funding to conduct pilots in each region of the country to gather information on consumption patterns, including collection of data regarding the number of shellfish consumed per serving. c. Evaluate the effectiveness of existing NSSP guidelines in reducing the risk of Vibrio illness caused by improper handling, storing or transportation of shellstock and effectiveness of existing enforcement mechanisms. Recommendation: VMC recommended no action. Rationale: This charge is part of VMC ongoing mission.
Action by 2017 Task Force II	Recommended adoption of Vibrio Management Committee recommendations on Proposal 13-200 as submitted.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 13-200.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-200.
Action by 2019	

Vibrio Management Committee	
Action by 2019 Task Force II	No Task Force Action is necessary on Proposal 13-200. This proposal was included for informational purposes only. The VMC has pending recommendations in their committee report that are included in the VMC Committee Report. These recommendations do not involve any changes to the NSSP Guide.

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	*V.p.* Illness Response Guidance Document
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter V. Illness Outbreaks and Recall Guidance
Text of Proposal/ Requested Action	Add new section: .03 *V.p.* Illness Response Guidance Document I. Introduction Chapter II @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*) is intended to address three (3) distinct *V.p.* illness situations as follows: A. Traditional sporadic cases from a State in which single cases occur that most often do not involve a single growing area and occur weeks or months apart. The occurrences of these types of illnesses have historically been considered as an acceptable risk in the National Shellfish Sanitation Program (NSSP) and have not involved closures or recalls. B. Frequent sporadic cases which often begin when water temperatures reach a level which supports reproduction of *V.p.* to levels which can cause illness. The illness risk usually persists until the environmental conditions no longer support *V.p.* levels of illness causing potential. This illness situation involves clusters of sporadic cases in multiple individual growing areas or may be limited to a single growing area when the environmental conditions are favorable for the persistence of illness causing levels of *V.p.* C. A true outbreak with multiple cases with multiple harvest areas and varying routes of transportation indicates a more widespread contamination of a growing area. The outbreak may be characterized by a high attack rate. In this situation, a single growing area is usually involved with multiple cases of illness occurring from a single harvest day or from a relatively short harvest time frame. The strains of *V.p.* associated with these different illness situations are not the same. The attack rates are very different and the reported illnesses reflect the differences in attack rates. Although strain identification is time consuming, knowing the strain aids the Shellfish Control Authority in addressing the problem. II. Illness Investigation 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.

The Shellfish Control Authority is encouraged to coordinate the investigation and response with other appropriate State entities and the US Food and Drug Administration (FDA) to facilitate and streamline the reporting process to promote prompt and appropriate regulatory responses to illness.

III. Risk per Serving Determinations

In determining a risk per serving, the Shellfish Control Authority should use a recognized serving size and credible landing data. The period of time for evaluating the risk per serving should be consistent with the time of harvest of the shellfish that was associated with the illness (es) and should not exceed thirty (30) days

IV. Regulatory Response

When a case(s) is reported, the State Shellfish Control Authority will determine the number of cases and the time period between the harvest dates of reported cases and the extent of the implicated area.

When determining the number of illnesses in the thirty (30) day period, the harvest date will be used. When an illness occurs, the Shellfish Control Authority will determine the number of cases that have occurred during the previous thirty (30) days. Every subsequent harvest associated with a new reported case will require a review of the previous thirty (30) days.

A. Should the number of cases and the period of time result in a risk that is less than one (1) per 100,000 servings or involves at least two (2) but not more than four (4) cases in which no two of these were from a single harvest day from an implicated area, the State Shellfish Control Authority will evaluate and attempt to ensure compliance, where appropriate, with the existing Vibrio Management Plan. Regulatory response to multiple illnesses occurring from a single harvest day from an implicated area are addressed in IV. B and IV. C.

B. Should the number of cases and the period of time result in a risk that exceeds one (1) illness per 100,000 servings or if the number of cases within a thirty (30) day period from the implicated area is more than four (4) but less than ten (10) or if two (2) or more but less than four (4) cases occur from a single harvest day from the implicated area, the Shellfish Control Authority is required to:

(1) Determine the extent of the implicated area; and

(2) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and

(3) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish

The notification is intended to facilitate the reporting of other illnesses that may have occurred associated with the implicated harvest area. Although the State is not required to report this information to the Interstate Shellfish Sanitation Conference (ISSC), if requested, the ISSC will assist the States with notification.

C. Should the number of cases exceed ten (10) within a thirty (30) day period or four (4) or more cases occurred from a single harvest day from the implicated area, the Shellfish Control Authority is required to:

(1) Determine the extent of the implicated area; and

(2) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and

(3) 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; and

(4) Issue a consumer advisory for all shellfish (or species implicated in the illness). The consumer advisory shall be in the form of a news release and will be shared with the State Shellfish Control Authorities in all states receiving the implicated shellfish.

V. Closure Periods

A. 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 the Shellfish Control Authority will close the implicated growing area. The area will remain closed for a minimum of fourteen (14) days.

B. 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 the Shellfish Control Authority will close the implicated growing area. The area will remain closed for a minimum of twenty-one (21) days.

VI. Reopening of Closed Areas

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:

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.

C. Implicated areas that have been closed 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 do not require sampling or review of environmental conditions prior to reopening.

VII. Harvesting From Closed Areas

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. VIII. Laboratory All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Office or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP. IX. Approved Laboratory Methods Methods for the analyses of shellfish and shellfish growing or harvest waters shall be: The Approved NSSP Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI. of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the NSSP Guide for the Control of Molluscan Shellfish Section IV Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.
Public Health Significance	The purpose of this document is to provide guidance to States in implementing the requirements of Chapter II. @.02 Shellfish Related Illnesses Associated with Vibrio parahaemolyticus (V.p.).
Cost Information	
Action by 2015 Task Force II	Recommended referral of Proposal 15-226 to an appropriate committee as determined by the Conference Chair with instruction to remove this section from the NSSP Guide as interim guidance.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-226.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-226.
Action by 2017	The Vibrio Management Committee recommended that the Conference Chairperson

Vibrio Management Committee	appoint an appropriate workgroup to amend the *Vibrio parahaemolyticus* Illness Response guidance document to submit to the Executive Board as interim approval following the Biennial Meeting.
Action by 2017 Task Force II	Recommended adoption of Vibrio Management Committee recommendation on Proposal 15-226.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 15-226.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 15-226.
Action by 2019 Illness Response Committee	Recommends Proposal 15-226 be referred back to Committee by the Conference Chairperson so that any changes in Vp response requirements can be considered when developing the NSSP guidance document.
Action by Task 2019 Force II	Recommends referral of Proposal 15-226 to the appropriate committee as determined by the Conference Chair.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
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	Notices of Illness Outbreaks, Recalls and Closures
Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish Section II. Chapter II. Risk Assessment and Risk Management @.01 Outbreaks of Shellfish-Related Illnesses
Text of Proposal/ Requested Action	@.01 Outbreaks of Shellfish-Related Illness B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall: (1) Notify the FDA Regional Shellfish Specialist that a shellfish related outbreak has occurred. (~~1~~2) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling. (~~2~~3) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products. C. When the investigation outlined in Model Ordinance Chapter II. @.04 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall: (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; (2) Notify ~~receiving states~~, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area; ~~(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and~~ (3~~4~~) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21CFR Part 7. The recall shall include all implicated products. (4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish. (5) The ISSC will notify States and FDA Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information

	identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information. D. When the investigation outlined in Model Ordinance Chapter II. @.04 B. demonstrates that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall: (1) Notify ~~receiving states,~~ the ISSC and the FDA Regional Shellfish Specialist of the problem; and (2) Initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products. (3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish. (4) The ISSC will notify States and FDA Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.
Public Health Significance	The proposed language in Section B. would ensure that FDA is immediately aware of shellfish related outbreaks. The proposed language changes in Section C. would more clearly outline the responsibility associated with notification to FDA and States. Currently notification requirements are not included for recalls associated with post-harvest contamination. Additionally, there are no requirements for notification to States that are not identified as a State receiving recalled product. It is important that all States be notified of recalls. In many cases the complete list of States cannot be determined by identifying the initial dealers. The proposed change would also establish an inventory of closures and recalls. Without an inventory it is difficult to assess program trends.
Cost Information	
Action by 2017 Task Force II	Recommended adoption of Proposal 17-201 with recommendations to the ISSC Executive Board to appoint a committee to develop guidance which details recall and closure information sharing.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-201.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-201.
Action by 2019 Illness Notification Committee	The committee recommends the following examples be added to Section IV, Chapter V (Illness Outbreaks and Recall Guidance):

Example Notification

NOTICE OF POTENTIAL HEALTH RISK ASSOCIATED WITH AN IMPLICATED GROWING AREA (Ch II@.01(C)(2))

On **(DATE)**, **(NAME OF AUTHORITY)** determined that an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption existed and began an investigation of the outbreak to determine whether the illness was growing-area related or was the result of post-harvest contamination or mishandling. We have determined that this outbreak is growing-area related and this email serves to notify ISSC and the FDA Shellfish Specialist of these findings.

On **(DATE)**, the **(IMPLICATED HARVEST/GROWING AREA)** was closed to harvest and recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 are being initiated to recall all implicated **(SPECIES)** harvested from **(DATES OF HARVEST)**.

The Point of Contact for this matter is **(NAME OF KEY PERSON WITHIN AUTHORITY AND CONTACT INFORMATION)**.

Example Notification

DISTRIBUTION INFORMATION
RE: PRODUCT RECALL ASSOCIATED WITH OUTBREAK (Ch II@.01(C)(4))

On **(DATE)**, **(NAME OF AUTHORITY)** determined an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption, determined that this outbreak is growing-area related, and initiated recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 to recall all implicated **(SPECIES)** harvested **from (IMPLICATED HARVEST/GROWING AREA)** from **(DATES OF HARVEST)**. This email serves to provide distribution information to ISSC and FDA.

Recalled product was distributed to dealers and/or retailers in the following states: **(NAME OF EACH STATE)**. In accordance with Ch II@.01(I), we have notified each of the receiving states.

The Point of Contact for this matter is **(NAME OF KEY PERSON WITHIN AUTHORITY AND CONTACT INFORMATION)**.

Distribution information is as follows:

Shipping Dealer #1 **Name & ICSSL #:**								
Harvest Area	**Harvest Date**	**Receiving Dealer, Retailer, or Food Service** *(include ICSSL #, if known or applicable)*	**City, State**	**Sale Date**	**Lot No. or Date Shucked**	**Qty Sold**	**Product Description**	**Status** *(consumed, destroyed, returned)*

Shipping Dealer #2 **Name & ICSSL #:**								
Harvest Area	**Harvest Date**	**Receiving Dealer, Retailer, or Food Service** *(include ICSSL #, if known/applicable)*	**City, State**	**Sale Date**	**Lot No. or Date Shucked**	**Qty Sold**	**Product Description**	**Status** *(consumed, destroyed, returned)*

(include as many tables as needed, depending on number of shipping dealers involved in recall)

Attachments:

Action by 2019 Task Force II	Recommends adoption of the Illness Notification Committee recommendation on Proposal 17-201.

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 *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.

(~~c~~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	Recommends: 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.)*** **@.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	Recommends adoption of substitute language of Proposal 17-206 with referral to an appropriate committee as determined by the Conference Chair.

Submitter	John A. Tesvich
Affiliation	Louisiana Oyster Task Force
Address Line 1	2021 Lakeshore Drive Suite 300
Address Line 2	
City, State, Zip	New Orleans, LA 70122
Phone	504-912-2750
Fax	504-564-2733
Email	jatesvich@yahoo.com
Proposal Subject	*V. vulnificus* Control Plan
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management Requirements for the Authority @.06 *Vibrio vulnificus* Control Plan (Effective January 1, 2012) E. Control Plan (1)
Text of Proposal/ Requested Action	Add Section @.06 E. (1) (c) (c) A state has the option to implement a *Vibrio vulnificus* Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70°F. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below: Action Level | Water Temperature | Maximum hours from Exposure to Temperature Control Level 1 | <65°F | 36 hours Level 2 | 65°F - 70°F (18°C – 23°C | 14 hours
Public Health Significance	In the Gulf there has been no significant risk of *V.v.* illness during the coldest months, Dec-Feb. This will allow a state with a *Vibrio vulnificus* Control Plan to more effectively tailor a comprehensive harvesting time-temp control plan without a 70 degree F average maximum water temperature limit.
Cost Information	No expected increase in cost.
Action by 2017 Task Force II	Recommended referral of Proposal 17-207 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-207.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-207.
Action by 2019 Time	Recommends adoption of Proposal 17-207 as amended.

<table>
<tr><td>Temperature Committee</td><td>Add Section @.06 E. (1) (c)

(c) A state has the option to implement a Vibrio vulnificus Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70°F. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below:

<table>
<tr><th>Action Level</th><th>~~Water Temperature~~ Month</th><th>Maximum hours from Exposure to Temperature Control</th></tr>
<tr><td>Level 1</td><td>~~<65°F~~December, January, February</td><td>36 hours</td></tr>
<tr><td>Level 2</td><td>~~65°F - 70°F (18°C – 23°C~~March, November</td><td>14 hours</td></tr>
</table>
</td></tr>
<tr><td>Action by 2019 Task Force II</td><td>Recommends adoption of Temperature Committee recommendations on Proposal 17-207 as amended

Add Section @.06 E. (1) (c)

(a) A state has the option to implement a Vibrio vulnificus Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70°F. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below:

<table>
<tr><th>Action Level</th><th>Water Temperature</th><th>Maximum hours from Exposure to Temperature Control</th></tr>
<tr><td>Level 1</td><td><65°F</td><td>36 hours</td></tr>
<tr><td>Level 2</td><td>65°F - 70°F (18°C – 23°C</td><td>14 hours</td></tr>
</table>
(b) All shellstock harvested according to a Vibrio vulnificus control plan shall be cooled to an internal temperature of 55F (12.7 C) or less within 10 hours of being placed into temperature control.</td></tr>
<tr><td>(</td><td></td></tr>
</table>

Proposal No. **17-209**

<table>
<tr><td>Submitter</td><td>John A. Tesvich</td></tr>
<tr><td>Affiliation</td><td>Louisiana Oyster Task Force</td></tr>
<tr><td>Address Line 1</td><td>2021 Lakeshore Drive Suite 300</td></tr>
<tr><td>Address Line 2</td><td></td></tr>
<tr><td>City, State, Zip</td><td>New Orleans, LA 70122</td></tr>
<tr><td>Phone</td><td>504-912-2750</td></tr>
<tr><td>Fax</td><td>504-564-1733</td></tr>
<tr><td>Email</td><td>jatesvich@yahoo.com</td></tr>
<tr><td>Proposal Subject</td><td>Shellstock Time to Temperature Controls</td></tr>
<tr><td>Specific NSSP Guide Reference</td><td>Section II Model Ordinance Chapter VIII. Control of Shellfish Harvesting
@.02 Shellstock Time to Temperature Controls.</td></tr>
<tr><td>Text of Proposal/ Requested Action</td><td>A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one of the following:

(1) The State Vibrio vulnificus Control Plan as outlined in Chapter II. @.06; or
(2) The State Vibrio parahaemolyticus Plan as outlined in Chapter II. @.07; or
(3) All other shellstock shall comply with one of the ~~matrix~~ matrices below:

<table>
<tr><th>Action Level</th><th>Average Monthly Maximum Air Temperature</th><th>Maximum Hours from Exposure to Receipt at a Dealer’s Facility</th></tr>
<tr><td>Level 1</td><td><50 °F (10 °C)</td><td>36 hours</td></tr>
<tr><td>Level 2</td><td>50 °F - 60 °F (10 °C - 15 °C)</td><td>24 hours</td></tr>
<tr><td>Level 3</td><td>>60 °F - 80 °F (15 °C - 27 °C)</td><td>18 hours</td></tr>
<tr><td>Level 4</td><td>>80 °F (≥27 °C)</td><td>12 hours</td></tr>
</table>

<table>
<tr><th>Action Level</th><th>Water Temperature</th><th>Maximum Hours from Exposure to Temperature Control</th></tr>
<tr><td>Level 1</td><td><65 °F</td><td>36 hours</td></tr>
<tr><td>Level 2</td><td>65 °F - 74 °F (18 °C - 23 °C)</td><td>14 hours</td></tr>
<tr><td>Level 3</td><td>>74 °F - 84 °F (>23 °C - 28 °C)</td><td>12 hours</td></tr>
<tr><td>Level 4</td><td>> 84 °F (>28 °C)</td><td>10 hours</td></tr>
</table>
</td></tr>
<tr><td>Public Health Significance</td><td>No adverse public health significance. Gulf states have had no significant historical bacterial based risk during cold water months Dec-Feb. This will allow states the option to have the harvest time to temperature controls based on Average Monthly Maximum water temperature instead of only Average Monthly Maximum Air Temperature, (as it was prior to 2012)</td></tr>
<tr><td>Cost Information</td><td>None</td></tr>
</table>

Action by 2017 Task Force II	Recommended referral of Proposal 17-209 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-209.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-209.
Action by 2019 Time Temperature Committee	Recommends Task Force II to take no action on Proposal 17-209. Rationale this issue is resolved by action on Proposal 17-207.
Action by 2019 Task Force II	Recommends no action on Proposal 17-209. Rationale: Adequately addressed by the action taken on Proposal 17-207.

Proposal No. **17-217**

Submitter	Susan Ritchie
Affiliation	New York State Department of Environmental Conservation
Address Line 1	Division of Marine Resources, Bureau of Shellfisheries
Address Line 2	205 North Belle Mead Road, Suite 1
City, State, Zip	East Setauket, NY 11733
Phone	631-444-0494
Fax	631-444-0484
Email	susan.ritchie@dec.ny.gov
Proposal Subject	Removal of Harvester Tags being Shipped by Shellfish Dealers
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers .05 Shellstock Identification
Text of Proposal/ Requested Action	B. Tags (1) The dealers' tags… (2) The dealer's tag… (3) ~~When both the dealer and harvester tag appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.~~ The harvester tag must be removed from each container prior to being shipped. The harvester tag shall be replaced with a dealer tag and shall meet the requirements in Section .05 B. (4) If the shellstock… (5) Country of origin… (6) When shellstock intended… (7) If a shellfish…
Public Health Significance	There should not be any harvester tags at restaurants because only harvesters who are also certified dealers can sell directly to retail or ship interstate making harvesters an unapproved source. When both tags are affixed to the container, there will also be a blank dealer's tag that may potentially be used by an unauthorized person. Excerpt from Shellfish Plant Sanitation Course. "Shellfish harvesters are authorized to: grow and harvest shellstock. Wash, sort, bag and tag harvested shellstock. Sell the product to certified dealers in the State, depending on the State's regulations. Only a harvester who is also a certified dealer can sell directly to retail or ship interstate." https://www.accessdata.fda.gov/ORAU/ShellfishPlantSanitation/SPS_01_000.htm
Cost Information	$0.00
Action by 2017 Task Force II	Recommended adoption of Proposal 17-217 as submitted.
Action by 2017 General	Adopted the recommendation of Task Force II on Proposal 17-217.

Assembly	
Action by FDA February 7, 2018	Did not concur with Conference action on proposal 17-217. FDA recommended alternative language. (See February 7, 2018 FDA response to ISSC Summary of Actions)
Action by ISSC Executive Board	Did not accept the FDA recommended language. Referred Proposal 17-217 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Shellfish Tagging Committee	Recommends adoption of Proposal 17-217 as amended. B. Tags (1) The dealers' tags… (2) The dealer's tag… (3) ~~The harvester tag must be removed from each container prior to being shipped. The harvester tag shall be replaced with a dealer tag and shall meet the requirements in Section .05 B.~~If a dual-purpose tag is used (harvester or dealer), duplicate information is not required on both sides of the tag. (4) If a two-tag system is used, the dealer tag shall meet the requirements in .05 B. (~~4~~5) If the shellstock… (~~5~~6) Country of origin… (~~6~~7) When shellstock intended… (~~7~~8) If a shellfish…
Action by 2019 Task Force II	Recommends adoption of Proposal 17-217 as amended. B. Tags (1) The dealers' tags… (2) The dealer's tag… (3) If a dual-purpose tag is used (harvester and ~~or~~ dealer), duplicate information is not required on both sides of the tag, or~~-~~ (4) If a two~~-~~tag system is used, the dealer tag shall meet the requirements in .05 B. (5) If the shellstock… (6) Country of origin… (7) When shellstock intended… (8) If a shellfish…

Proposal No. **17-220**

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	Hand Sanitizer
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. .02 D. (4); Section II. Model Ordinance Chapter XII. .02 D. (1) (c); Section II. Model Ordinance Chapter XIII. .02 D. (1) (b); Section II. Model Ordinance Chapter XIV. .02 D. (1) (b); and Section II. Model Ordinance Chapter XV. .02 D. (3)
Text of Proposal/ Requested Action	Chapter XI. Shucking and Packing .02 Sanitation D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities. (1) Hand washing facilities… (2) Hand washing facilities… (3) The dealer shall… (4) The dealer shall provide at each hand washing facility: (a) Supply of hand cleansing soap or detergent; [K] (b) Supply of hand sanitizer; **[K]** (c~~b~~) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O] (d~~c~~) Easily cleanable waste receptacle; and [O] (e~~d~~) Hand washing signs in a language understood by the employees; [O] (5) Sewage [C] and liquid… (6) The dealer shall provide… Chapter XII. Repacking of Shucked Shellfish .02 Sanitation. D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities. (1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$] (a) Hand washing facilities… (b) The dealer shall… (c) The dealer shall provide at each hand washing facility: (i) Supply of hand cleansing soap or detergent; [K] (ii) Supply of hand sanitizer; **[K]** (iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(iv~~ii~~) Easily cleanable waste receptacle; and [O]

(~~i~~v) Hand washing signs in a language understood by the employees; [O]

(2) Sewage [C] and liquid…

(3) The dealer shall…

Chapter XIII. Shellstock Shipping .02 Sanitation.

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]

(a) Handwashing facilities shall…

(b) The dealer shall provide at each handwashing facility:

(i) Supply of hand cleansing soap or detergent; [K]

(ii) Supply of hand sanitizer; **[K]**

(iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(iv~~ii~~) Easily cleanable waste receptacle; and [O]

(~~i~~v) Handwashing signs in a language understood by the employees; [O]

(2) Sewage [K] and liquid…

(3) The dealer shall…

Chapter XIV. Reshipping .02 Sanitation.

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]

(a) Handwashing facilities shall…

(b) The dealer shall provide at each handwashing facility:

(i) Supply of hand cleansing soap or detergent; [K]

(ii) Supply of hand sanitizer; **[K]**

(iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(iv~~ii~~) Easily cleanable waste receptacle; and [O]

(~~i~~v) Handwashing signs in a language understood by the employees; [O]

(2) Liquid disposable wastes…

(3) The dealer shall…

Chapter XV. Depuration .02 Sanitation

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities

	(1) Hand washing facilities… (2) Hand washing facilities… (3) The dealer shall provide at each hand washing facility; (a) Supply of hand cleansing soap or detergent; [K] (b) Supply of hand sanitizer; **[K]** (c~~b~~) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O] (d~~c~~) Easily cleanable waste receptacle; and [O] (e~~d~~) Hand washing signs in a language understood by the employees; [O] (4) Sewage [C] and liquid…
Public Health Significance	Current Model Ordinance language in Chapters XI-XV .02 C. Prevention of Cross Contamination, requires that employees wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility. Currently D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities addresses an adequate supply of hand cleaning soap or detergent, but does not address an adequate supply of hand sanitizer. Adding the new language in will make current language more consistent and enforceable by State inspectors.
Cost Information	Minimal cost.
Action by 2017 Task Force II	Recommended referral of Proposal 17-220 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-220.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-220.
Action by 2019 Sanitation Committee	Recommends adoption of Proposal 17-217 as amended. **Section II.** **Chapter XI. Shucking and Packing** .02 Sanitation D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities. (1) Hand washing facilities… (2) Hand washing facilities… (3) The dealer shall… (4) The dealer shall provide at each hand washing facility: (a) Supply of hand cleansing soap or detergent; [K] (b) Supply of FDA approved hand antiseptic~~sanitizer~~; **[K]** (c) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O] (d) Easily cleanable waste receptacle; and [O]

	(e) Hand washing signs in a language understood by the employees; [O] (5) Sewage [C] and liquid… (6) The dealer shall provide… Chapter XII. Repacking of Shucked Shellfish .02 Sanitation. D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities. (1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$] (a) Hand washing facilities… (b) The dealer shall… (c) The dealer shall provide at each hand washing facility: (i) Supply of hand cleansing soap or detergent; [K] (ii) Supply of FDA approved hand antiseptic~~sanitizer~~; **[K]** (iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O] (iv) Easily cleanable waste receptacle; and [O] (v) Hand washing signs in a language understood by the employees; [O] (2) Sewage [C] and liquid… (3) The dealer shall… No changes will be made to Chapters XIII, XIV, or XV
Action by 2019 Task Force II	Recommends adoption of Proposal of 17-220 as amended. 17-220 Hand Sanitizer Substitute Text of Proposal/Requested Action Section II – Chapter X. General Requirements for Dealers .02 General Sanitation Requirements A... (4) Maintenance of hand washing, ~~hand sanitizing~~, and toilet facilities, hereinafter referred to as: Maintenance of Hand Washing, ~~Hand Sanitizing~~ and Toilet Facilities; Section II – Chapter XI. Shucking and Packing .02 Sanitation C. Prevention of Cross Contamination. (3) Employee practices. (b) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~ in an adequate hand washing facility:

	D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities. Section II - Chapter XII. Repacking of Shucked Shellfish .02 Sanitation C. Prevention of Cross Contamination. (b) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~ in an adequate hand washing facility: D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities. Section II – Chapter XIII. Shellstock Shipping .02 Sanitation (C) Prevention of Cross Contamination (2) Employee practices. (a) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~ in an adequate handwashing facility: D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities. Section II. XIV. Reshipping .02 Sanitation (C) Prevention of Cross Contamination (2) Employee practices. (a) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~in an adequate handwashing facility: D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities. Section II. Chapter XV. Depuration .02 Sanitation (C) Prevention of Cross Contamination (3) Employee practices. (a) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~ in an adequate hand washing facility: D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities. Section III. Public Health Reasons and Explanations – Chapters XI., XII., XIII., and XIV. Shellfish Processing and Handling Requirements for Dealers .02 General Sanitation Requirements General Sanitation Requirements apply to Chapters XI., XII., XIII., XIV., and XV. as appropriate to the activity being conducted and as required in the NSSP Model Ordinance: (1) Safety of Water for Processing and Ice Production; (2) Condition and Cleanliness of Food Contact Surfaces; (3) Prevention of Cross Contamination; (4) Maintenance of Hand Washing~~, Hand Sanitizing~~, and Toilet Facilities; (5) Protection from Adulterants; (6) Proper Labeling, Storage, and Use of Toxin Compounds; (7) Control of Employees with Adverse Health Conditions; (8) Exclusion of Pests.

	D. Maintenance of Hand Washing~~, Hand Sanitizing~~, and Toilet Facilities. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand drying device improves the ~~sanitizing~~ sanitation of the hands. Disease-causing microorganisms may be present in body discharges of employees that are cases or carriers of communicable disease organisms. When sewage disposal facilities are of a satisfactory type, there is less possibility that the shellfish being processed may become contaminated with fecal material carried by flies, rodents, or by other means. .03 Other Model Ordinance Requirements L. Personnel. Disease producing agents may be carried on the hands of shuckers and packers unless proper hand washing is practiced. Finger cots, gloves, and shields, unless effectively sanitized periodically, will accumulate bacteria that may contaminate the shucked shellfish. ~~Employees handling shucked shellfish need to sanitize their hands as an added public health control practice.~~ Requirements for the Depuration Processor .02 Sanitation D. Maintenance of Hand Washing~~, Hand Sanitizing~~, and Toilet Facilities. Adequate toilet, and hand washing ~~and sanitizing~~ facilities must be provided. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash their hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand-drying device improves the ~~sanitizing~~ sanitation of the hands. Section IV. Guidance Documents Chapter III Harvesting, handling, processing, and distribution .02 Shellfish Plant Inspection Standardization Procedures NSSP Standardized Shellfish Processing Plant Inspection Form Chapter IV Performance Criteria for Field Standardization INTRODUCTION (d.) Although there will be no written report left, with the firm, if there are significant findings they will be brought to the attention of the PERSON IN CHARGE during the Exit Interview. In addition to verbal and written communication, the Candidate shall also use the inspection process to communicate and demonstrate FOOD SAFETY concepts by example. Activities such as proper hand washing~~, and sanitizing~~, insuring the thermometer is cleaned and sanitized before every use and wearing proper clean outer garments and a ~~heave~~head cover will reinforce your spoken and written communications.

Proposal No. 17-225

Submitter	Chris Shriver, GM and Daniel Cohen, President
Affiliation	Atlantic Capes Fisheries, Inc.
Address Line 1	16 Broadcommon Road
Address Line 2	
City, State, Zip	Bristol, Rhode Island 02809
Phone	401-253-3030
Fax	401-253-9207
Email	cshriver@atlanticcapes.com and dcohen@atlanticcapes.com
Proposal Subject	Clarification of Surf Clams and Ocean Quahogs Exemption from Time/Temperature Requirements whcn "intended for thermal processing".
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls G. Section IV. Guidance Documents Chapter II. Handling, Processing, and Distributing B.
Text of Proposal/ Requested Action	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls G. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempt from this temperature control plan when these products are intended for thermal processing, which includes when a Processor represents, labels, or intends for the products to be cooked prior to consumption pursuant to the Processor's HACCP Plan as defined in FDA 21 CFR Part 123 Seafood HACCP regulations. For clarity, if Surf Clams or Ocean Quahogs are distributed live with the intention they could eaten raw, those Surf Clams and Ocean Quahogs are not exempt from this temperature control plan. Section IV. Guidance Documents Chapter III. Handling, Processing and Distributing B. Ocean Quahogs (*Arctica islandia*) and Surf Clams (*Spisula solidissima*) are excluded from the time to temperature controls of State Vibrio Control Plans or the matrix outlined in Chapter VIII. @.02 A. (1) (2) and (3). This exclusion applies only when these products are intended for thermal processing, which includes when a Processor represents, labels, or intends for the product to be cooked prior to consumption pursuant to the Processor's HACCP Plan as defined in FDA 21 CFR Part 123 Seafood HACCP regulations. Authorities may exclude other species when intended for thermal processing. For clarity, if Surf Clams or Ocean Quahogs are distributed live with the intention they could eaten raw, those Surf Clams and Ocean Quahogs are not exempt from this temperature control plan.
Public Health Significance	There is no adverse public health significance by this clarification of the meaning of the exemption for surf Clams and Ocean Quahogs *"intended for thermal processing"*. There will be no change from current practices, which include HACCP process controls adopted by each Processor. The additional wording merely clarifies a misinterpretation that the definition of *"intended for thermal processing"* is limited to low acid canning of 21 CFR 113.3(o). The Surf Clam and Ocean Quahog

	processors have been shucking surf clams and selling them in the uncooked state (both as fresh clam meats and frozen clam meats) for decades to customers with the intention that all of their customers will fully cook the Surf Clam meats and Ocean Quahogs prior to consumption. Thermal processing and cooked is not limited to only low aid canning, but also includes other forms of cooking and thermal processing as defined in the NSSP MO in Definitions (B) (94). Intended use guidance and controls are already established, this proposal simply clarifies and documents current practices, and aligns with common use of Surf Clams and Ocean Quahogs. As per FDA 21 CFR Part 123 Seafood HACCP regulations the Surf Clam and Ocean Quahog processors shall identify the intended use of their products. Additionally the Surf Clam and Ocean Quahog processors shall be required, consistent with their HACCP Plans, to issue annual HACCP Compliance Letters to all their customers which also identify the intended use of their products.
Cost Information	None. There will be no additional cost to industry, public, or the regulators by this clarification.
Action by 2017 Task Force II	Recommended referral of Proposal 17-225 to an appropriate committee as determined by the Conference Chair. Task Force Member Joe Jewell (Mississippi) requested the record reflect he abstained from the vote.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-225.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-225.
Action by 2019 Time Temperature Committee	Recommends Task Force II refer Proposal 17-225 back to the committee as the Subcommittee is still collecting data needed to make a recommendation.
Action by 2019 Task Force II	Recommends referral of Proposal 17-225 back to Time Temperature Committee with instruction to develop a definition for thermal processing and to request FDA to extend the exemption from the time temperature requirements until the study is completed.

Submitter	David Fyfe[1] & Tamara Gage[2]
Affiliation	Northwest Indian Fisheries Commission[1] & Port Gamble Tribe[2]
Address Line 1	19472 Powder Hill Place NE[1]
Address Line 2	Suite 210
City, State, Zip	Poulsbo, WA 98370
Phone	360-878-1350
Fax	360-297-3413
Email	dfyfe@nwifc.org
Proposal Subject	Impact of water quality in wet storage
Specific NSSP Guide Reference	Not Applicable
Text of Proposal/ Requested Action	There are very specific conditions associated with moving shellfish from one body of water to another for the purposes of relay or depuration. These processes 1. Always move shellfish into water that is considered better quality, from a health standpoint, and 2. Are specifically designed to reduce bacterial loads resulting from human contamination i.e. coliforms For decades now, public health concerns have increasingly focused on vibrios, which are naturally occurring, and less predictable. Wet storage, which is not designed to reduce bacterial load, is given little attention, provided that the shellfish move between Approved growing areas. Vibrios, however, could be at a higher concentration in the originating waters or where the wet storage occurs, so with time, vibrio levels may increase or decrease while in wet storage. With public health in mind, it is probably safe to assume that when shellfish are exposed to higher bacterial levels, their uptake is relatively quick and when bacterial levels are low, 'purging' is relatively slow. This is because uptake simply involves filtration and reduction involves emptying of the gut. When a vibrio illness occurs due to the consumption of shellfish that have been wet stored, both bodies of water are noted on the associated tags and thereby become associated with a vibrio problem, if not directly implicated. Shellfish which have been raised in waters with no recorded vibrio illnesses, could be wet stored in a growing area that has a history of vibrio illnesses, now implicating the former and possibly resulting in stricter harvesting and handling standards. In an extreme case, that growing area could be considered the sole source of an illness, if wet storage only occurred for a few days. This proposal asks that a committee be charged with examining this situation for the purposes of providing guidance as to how much weight should be given to the relative history of vibrios in both the growing area and the wet storage area, when implicating one or both, after an illness.
Public Health	Individual subjectivity could result in low risk areas being implicated and/or high risk

Significance	areas being cleared, based on perception as to how long shellfish must remain in a wet storage area in order to significantly uptake or purge vibrios. Guidance resulting from Committee deliberations, possibly including a recommendation for a multisource determination in certain circumstances, is requested.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-200 as submitted.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Definition of Certification Number
Specific NSSP Guide Reference	Section I. Purpose and Definitions B. Definition of Terms
Text of Proposal/ Requested Action	**(17) Certification Number** means the unique identification number issued by the Authority to each dealer for each location. Each certification number shall consist of a one (1) to five (5) digit Arabic number preceded by the two letter State abbreviation and followed by a two (2) letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with Chapter X. .04 B. The certification type will be followed by applicable permit designation as indicated in Chapter I. @.02 E.1. ~~this Ordinance using the following terms:~~ ~~(a) Shellstock shipper (SS);~~ ~~(b) Shucker-packer (SP);~~ ~~(c) Repacker (RP);~~ ~~(d) Reshipper (RS); and~~ ~~(e)~~(a) ~~Depuration processor (DP).~~
Public Health Significance	The new language creates consistencies with Proposal 19-204 and includes both certification type and permit designations.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-201 as submitted.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Definition of Restricted Shellstock
Specific NSSP Guide Reference	Section I. Purpose and Definitions B. Definition of Terms
Text of Proposal/ Requested Action	**(18) Restricted ~~Use~~ Shellstock** means shellstock that is harvested from growing areas classified as approved or conditionally approved in the open status and under conditions that do not allow the sale of the shellstock for direct marketing for raw consumption. Restricted use shellstock is identified with a tag indicating that the shellstock ~~is intended for~~has restrictions requiring further processing or testing prior to distribution. ~~to retail or food service.~~ NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommends to adopt Proposal 19-202 as amended: **(17) Restricted Shellstock** means shellstock that is harvested from growing areas classified as approved or conditionally approved in the open status and under conditions that do not allow the sale of the shellstock for direct marketing for raw consumption. Restricted ~~use~~

	shellstock is identified with a tag indicating that the shellstock has restrictions requiring further processing or testing prior to distribution. And also to refer to an appropriate committee as determined by the Conference Chair to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Foreign Country and Federal Waters Authority
Specific NSSP Guide Reference	Section II, Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority
Text of Proposal/ Requested Action	**@.01 Administration** A. Scope. (1) The Authority shall establish a statewide shellfish safety and sanitation program to regulate: (a) The classification of shellfish growing areas; (b) The harvesting of shellfish; (c) Shellfish processing procedures and facilities; (d) Product labeling; (e) Storage, handling and packing; (f) Shellfish shipment in interstate commerce; (g) Shellfish dealers; and (h) Bivalve aquaculture (2) All foreign countries shipping shellfish into the United States will have a memorandum of understanding or an equivalency agreement with the United States. (3) The regulatory responsibility for growing area and harvest control in federal waters will be the responsibility of the FDA and NOAA. B. State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A. Federal Agencies shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of growing area and harvest control. C. Records. The Authority… D. Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities. In the case of Federal Waters, if more than one agency is involved in the administration of the shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities E. Administrative Procedures. (1) The Authority shall have administrative procedures sufficient to: (a) Regulate shellfish harvesting, sale, and shipment;

	(b) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the State from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its State to purchase the shellstock; (c) Detain, condemn, seize, and embargo shellfish; and (d) Assure compliance with Shellfish Plant Inspection Standardization (2) In the case of Federal Waters, the FDA and NOAA shall have administrative procedures sufficient to regulate growing areas and harvest control. NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-203 as submitted.

<table>
<tr><td>Submitter</td><td>ISSC Executive Office</td></tr>
<tr><td>Affiliation</td><td>Interstate Shellfish Sanitation Conference</td></tr>
<tr><td>Address Line 1</td><td>209 Dawson Road</td></tr>
<tr><td>Address Line 2</td><td>Suite 1</td></tr>
<tr><td>City, State, Zip</td><td>Columbia, SC 29223</td></tr>
<tr><td>Phone</td><td>(803) 788-7559</td></tr>
<tr><td>Fax</td><td>(803) 788-7576</td></tr>
<tr><td>Email</td><td>issc@issc.org</td></tr>
<tr><td>Proposal Subject</td><td>ICSSL Certification Type</td></tr>
<tr><td>Specific NSSP Guide Reference</td><td>Section II. Model Ordinance Chapter I. Shellfish Sanitation Program for the Authority @.02 E. 1.</td></tr>
<tr><td>Text of Proposal/ Requested Action</td><td>E. Interstate Certified Shellfish Shippers List (ICSSL).
(1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The Authority shall include the certification type and any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038.

Designations:

<table>
<tr><th>Certification</th><th>Permit</th></tr>
<tr><td>SP – Shucker Packer</td><td>PHP – Post-Harvest Processing</td></tr>
<tr><td>RP – Repacker</td><td>AQ – Aquaculture</td></tr>
<tr><td>SS – Shellstock Shipper</td><td>WS – Wet Storage</td></tr>
<tr><td>RS – Reshipper</td><td></td></tr>
<tr><td>DP – Depuration</td><td></td></tr>
</table>
(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate or permit is:
(a) Suspended; or
(b) Revoked.</td></tr>
<tr><td>Public Health Significance</td><td>This language is intended to address an omission. Authorities currently include certification type when submitting 3038 forms.</td></tr>
<tr><td>Cost Information</td><td></td></tr>
<tr><td>Action by 2019 Task Force II</td><td>Recommends adoption of Proposal 19-204 as submitted.</td></tr>
</table>

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Dealer Inspection Requirements for States
Specific NSSP Guide Reference	Section II Model Ordinance Chapter I Shellfish Sanitation Program for the Authority @.02 F.
Text of Proposal/ Requested Action	F. Inspections. (1) After any person is certified, the Authority shall make unannounced inspections of the dealer's facilities: (a) During periods of activity; and (b) At the following minimum frequencies: (i) Within thirty (30) days of beginning activities if the dealer was certified on the basis of a pre-operational inspection; (ii) At least monthly for dealer facilities certified as depuration processors; (iii) At least quarterly for dealer's activities certified as shucker-packer or repacker; and (iv) At least semiannually for other dealer activities. (2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation at the time of inspection. The inspection form shall contain a listing of deficiencies by area in the operation and inspection item with corresponding citations to this Model Ordinance. ~~(2)~~(3) The plant inspection shall be conducted by the State Shellfish Standardization Inspector using the appropriate inspection form.
Public Health Significance	Model Ordinance Chapter I @.02 A. states that certification inspections can only be conducted by a State Shellfish Standardization Inspector using the appropriate inspection form. Chapter I @.02 F., which addresses routine inspections, does not state that routine inspections must be conducted by a standardized inspector. This was probably an unintentional omission. This proposal is intended to create consistency within the program.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-205 as submitted.

Submitter	ISSC Illness Outbreak Guidance Committee
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Illness Outbreak Response
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	**@.01 Outbreaks of Shellfish-Related Illness** A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the ~~Authority~~ determination of ~~shall determine~~ whether an epidemiological association exists between the illness and the shellfish consumption will be made by the state or local epidemiologist in the state in which the outbreak occurs. The determination will be made by reviewing: (1) ~~Each consumer's f~~Food history; ~~(2) Shellfish handling practices by the consumer and/or retailer;~~ ~~(3)~~(2) Whether the disease has the potential or is known to be transmitted by shellfish; and ~~(4)~~(3) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent. NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*. B. When the state or local epidemiologist in the state in which the outbreak occurs~~Authority~~ has determined an epidemiological association between an illness outbreak and shellfish consumption, the appropriate ~~Authority~~ Authorities shall: (1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred. (2) ~~Conduct an investigation of the illness outbreak w~~Within twenty-four (24) hours ~~to~~ determine whether the illness is growing area related or is the result of post-harvest contamination, ~~or~~ mishandling, or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple authorities in multiple states. The determination of the illness being growing area related will be conducted by the source state. ~~Determine whether to initiate a voluntary recall by firms. If a~~

~~firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.~~

C. When the Authorities determine that the outbreak is not the result~~investigation outlined in Model Ordinance Chapter II. @.04 B. does not indicate~~ a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;

(2) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;

(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.

(4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(5) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

D. When the appropriate Authorities determine~~investigation outlined in Model Ordinance Chapter II. @.04 B. demonstrates~~ that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination, mishandling or illegal harvesting from a closed area shall:

(1) Notify the ISSC and the FDA Shellfish Specialist of the problem; and

(2) ~~Initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use~~ Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.

(3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(4) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

E. When the Authority can not complete the determination outlined in Chapter II @.01 B ~~investigation outlined in Model Ordinance Chapter II. @.04 B. cannot be completed~~ within 24 hours, the Authority in the source state shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status. ~~Follow the closure procedure outlined in Chapter II @.01 C.; and if the investigation does not indicate a growing area problem, the area may be immediately reopened and product recall terminated.~~

(2) Should the Authorities later determine that the illnesses are related to post harvest contamination, or mishandling, or harvesting from a closed area, the suspected growing area can be reopened.

~~(1)~~(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products

~~F. Upon closing an implicated area for problems other than naturally occurring pathogens and/or biotoxins, the Authority shall review the growing area classification and determine if a growing area classification problem exists. The review shall include at a minimum:~~

~~(1) A review of the growing area classification file records;~~

~~(2) A field review of existing pollution sources;~~

~~(3) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and~~

(4) ~~Examination of water quality subsequent to the illness outbreak~~.

~~G.~~F. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:

(1) Shall follow an existing marine biotoxin contingency/management plan, if appropriate.

(2) Shall collect and analyze samples relevant to the investigation, if appropriate.

(3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.

(4) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

~~H.~~G. When the growing area is determined the problem, the Authority shall:

(1) Place the growing area in the closed status until:

(a) The Authority verifies that the area is properly classified by conducting a review of the growing area to include:

(i) ~~, using~~ current data, in compliance with the NSSP Model Ordinance; ~~or~~

(ii) A field review of existing pollution sources;

(iii) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems. If the review indicates that a previously unknown pollution source exists, the area shall be reclassified. If the previously unknown pollution source can be corrected, the closure period ~~should~~ shall be extended to allow for natural depuration following correction of the pollution source; and

	~~(i)~~(iv) Examination of water quality subsequent to the illness outbreak. (b) ~~Shellfish from the growing area are confirmed as the cause of illness but i~~It has been determined that the event which caused the contamination no longer exists and sufficient time has elapsed for natural depuration; (2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and (3) Develop a written report summarizing the findings of the investigation and actions taken. ~~I.~~H. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, ISSC and the Authorities in other States involved in the recall. The Authority shall submit periodic recall status reports to the FDA Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 CFR Part 7, Subpart C, Section 7.53 (b) (1- 6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the State of product origin regarding recall efforts within their State until such time that the Authority in the State of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any State involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate. ~~J.~~I. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v.* or *V.p.* may be reconditioned. Validated reconditioning processes include subjecting product to validated post-harvest processing (PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority.
Public Health Significance	Following outbreaks in Maryland and Washington, the states requested clarification regarding the requirements of Chapter II. @.01 "Outbreaks from Shellfish Related Illness". In response, the ISSC Executive Board directed the establishment of a committee to provide clarification. The committee was also tasked to develop proposals to revise Chapter II language to provide requirement clarification. The committee was also requested to address appropriate outbreak response to multi-source outbreaks.
Cost Information	

Action by 2019 Task Force II	Recommend adoption of Proposal 19-208 as amended. Task Force II requests the development of a decision tree reflecting the requirements of 19-208 to be presented at the Spring 2020 Board Meeting. **@.01 Outbreaks of Shellfish-Related Illness** A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the determination of whether an epidemiological association exists between the illness and the shellfish consumption will be made by the state or local epidemiologist in the state in which the outbreak occurs. The determination will be made by reviewing: (1) Food history; (2) Whether the disease has the potential or is known to be transmitted by shellfish; and (3) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent. NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*. B. When the state or local epidemiologist in the state in which the outbreak occurs has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption, the appropriate Authorities shall: (1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred. (2) Within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling, or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple authorities in multiple states. The determination of the illness being growing area related will be conducted by the source state. C. When the Authorities determine that the outbreak is not the result a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall: (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; (2) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area; (3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include

all implicated products.

(4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(5) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

D. When the appropriate Authorities determine that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination, mishandling or illegal harvesting from a closed area shall:

(1) Notify the ISSC and the FDA Shellfish Specialist of the problem; and

(2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.

(3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(4) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

E. When the Authority can not complete the determination outlined in Chapter II @.01 B within 24 hours, the Authority in the source state shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status.
Should the Authorities later determine that the illnesses are related to post harvest contamination, or mishandling, or harvesting from a closed area, the suspected growing area can be reopened.

(2) ~~Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products~~ Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate.

(3)
~~(2)~~ Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority can document a rationale that a recall would be effective.

~~F. .~~

~~G.~~F. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:

(1) Shall follow an existing marine biotoxin contingency/management plan, if appropriate.
(2) Shall collect and analyze samples relevant to the investigation, if appropriate.
(3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.
(4) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

~~H.~~G. When the growing area is determined the problem, the Authority shall:
(1) Place the growing area in the closed status until:
(a) The Authority verifies that the area is properly classified by conducting a review of the growing area to include:
(i) current data, in compliance with the NSSP Model Ordinance;
(ii) A field review of existing pollution sources;
(iii) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems. ~~If the review indicates that a previously unknown pollution source exists, the area shall be reclassified.~~ If ~~the~~ a previously unknown pollution source can be corrected, the closure period ~~should~~ shall be extended to allow for natural depuration following correction of the pollution source; and
(iv) Examination of water quality subsequent to the illness outbreak.
(b) It has been determined that the event which caused the contamination no longer exists and sufficient time has elapsed for natural depuration;
(2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and
(3) Develop a written report summarizing the findings of the investigation and actions taken.

~~I.~~H. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, ISSC and the Authorities in other States involved in the recall. The Authority shall submit periodic recall status reports to the FDA Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 CFR Part 7, Subpart C, Section 7.53 (b) (1- 6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the State of product origin regarding recall efforts within their State until such time that the Authority in the State of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any State involved in the recall fails to

	implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate. ~~J.~~ I. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v.* or *V.p.* may be reconditioned. Validated reconditioning processes include subjecting product to validated post-harvest processing (PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority.

Submitter	ISSC Illness Outbreak Guidance Committee
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Illness Outbreak Response
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	**@.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. States will not be expected to close growing areas based on *V.p.* cases that are reported more than sixty (60) days after harvest. ~~and a~~Actions taken by the Authority will be based on the number of cases and the 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) 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:

(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:

(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 the number of cases and the span of time reach the thresholds outlined above, prior to implementing the controls above, the Authority shall conduct an investigation of the illnesses within seventy-two (72) hours of reaching any one of the thresholds of Chapter II @.02 . 1, 2 or 3 to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling such as time temperature abuse.

(5) When the investigation outlined in Model Ordinance Chapter II. @.02 A.4. demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:

(a) Notify the ISSC and the FDA Shellfish Specialist of the problem; and

(b) Determine the appropriateness of initiating a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

(c) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish; Should closures and recalls be necessary the ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(6) When the investigation outlined in Model Ordinance Chapter II. @.02 A.4. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(a) Follow the procedures outlined in Chapter II @.02 A. 1, 2 and 3.

(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;

(c) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;

(d) Promptly initiate recall procedures consistent with the

Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

(e) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

~~(e)~~(f) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(7) When the State Authority investigating the laboratory confirmed *V.p.* cases does not provide information to identify a single growing area and multiple growing areas are implicated, the State Authorities in the states with implicated growing areas shall evaluate to determine if the illness should be attributed to the implicated area(s). Evaluations may include but are not limited to:

(a) Vibrio levels in the growing area around the time and date of harvest

(b) Comparison of other single source illnesses attributed to a growing area(s) involved in a multiple source outbreak. The purpose of this comparison would be to determine if a common growing area can be identified.

(c) Environmental conditions which could increase the risk of *V.p.* at the time of harvest. This could include conditions such as water temperature, air temperature and tidal stage.

(d) Genetic typing the implicates a common growing area or rules out implicated growing areas

(8) If conditions in (7) identify higher risk for *Vibrio parahaemolyticus* then the Shellfish Authority shall take actions outlined in A, above.

~~(4)~~(9) 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:

(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

~~(5)~~(10) 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: (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)~~(11) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls: (a) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* 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.
Public Health Significance	Following outbreaks in Maryland and Washington, the states requested clarification regarding the requirements of Chapter II. @.01 "Outbreaks from Shellfish Related Illness". In response, the ISSC Executive Board directed the establishment of a committee to provide clarification. The committee was also tasked to develop proposals to revise Chapter II language to provide requirement clarification. The committee was also requested to address appropriate outbreak response to multi-source outbreaks.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-209 as amended. **@.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. States will not be expected to close growing areas based on *V.p.* cases that are reported more than sixty (60) days after harvest ~~.~~ or when environmental parameters have changed or monitoring indicates the *V.p.* risk is reduced. Actions taken by the Authority will be based on the number of cases and the 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) 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:

(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:

(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 the number of cases and the span of time reach the thresholds outlined above, prior to implementing the controls above, the Authority shall conduct an investigation of the illnesses within seventy-two (72) hours of reaching any one of the thresholds of Chapter II @.02 . 1, 2 or 3 to determine whether the illness is growing area related or is the result of post-harvest ~~contamination~~ abuse or mishandling such as time temperature abuse.

(a) If the conditions in Chapter II @.02 (2) or (3) are met and the investigation cannot be completed within 72 hours, immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status.

(b) Should the Authority later determine that the illnesses are related to post harvest abuse or mishandling the implicated harvest area(s) can be immediately reopened.

(5) When the investigation outlined in Model Ordinance Chapter II. @.02 A.4. demonstrates that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:

(a) Notify the ISSC and the FDA Shellfish Specialist of the problem; and

(b) Determine the appropriateness of initiating a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

(c) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish; Should closures and recalls be necessary the ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(6) When the investigation outlined in Model Ordinance Chapter II. @.02 A.4. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(a) Follow the procedures outlined in Chapter II @.02 A. 1, 2 and 3.

~~(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;~~

~~(c)~~(b) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;

(c) ~~Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.~~If a recall is required by Chapter II @.02 A. 3

i. Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

ii. The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(7) When the State Authority investigating the laboratory

confirmed *V.p.* cases does not provide information to identify a single growing area and multiple growing areas are implicated, the State Authorities in the states with implicated growing areas shall evaluate to determine if the illness should be attributed to the implicated area(s). Evaluations may include but are not limited to:

(a) Vibrio levels in the growing area around the time and date of harvest

(b) Comparison of other single source illnesses attributed to a growing area(s) involved in a multiple source outbreak. The purpose of this comparison would be to determine if a common growing area can be identified.

(c) Environmental conditions which could increase the risk of *V.p.* at the time of harvest. This could include conditions such as water temperature, air temperature and tidal stage.

(d) Genetic typing of clinical isolets ~~the~~ implicates a common growing area or rules out implicated growing areas

(8) If the~~conditions~~ evaluation in (7) provides sufficient information to implicate a single area, ~~identify higher risk for *Vibrio parahaemolyticus*~~ then the Shellfish Authority shall take actions outlined in A, above.

(9) 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:

(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

(10) 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:

(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.

(11) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements

Submitter	ISSC Illness Outbreak Guidance Committee
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Illness Investigation Response for Multi-Source Cases
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	**@.01 Outbreaks of Shellfish-Related Illness** ~~K.~~J. When shellfish are… ~~L.~~K. When the Authority… C. When the post-harvest contamination investigation ~~i~~involving multiple sources (either harvesters/processors or growing areas) does not indicate post-harvest contamination problem or illegal harvesting from a closed area the Authorities in the source states shall immediately place the implicated portion(s) of the harvest area(s) in a precautionary closure. A specific growing area placed in a precautionary closed status under this section can be immediately re- opened when one or more of the following conditions are met: (1) When the investigation, conducted in consultation with epidemiologist(s) in the state(s) in which the outbreak occurs, determines that the shellfish which caused the outbreak did not come from one or more of the implicated growing areas in question based on consumption data provided by victims or other relevant data provided by state investigators. This would include an additional illness(es) that matches one or more of the implicated areas and allows for a more precise identification of the growing area(s) which caused the outbreak. (2) When an investigation, in accordance with Chapter II @ .01 H, of an implicated growing area identifies an actual or potential pollution source(s) in a specific growing area and no source(s) are identified in other implicated growing areas, the precautionary closures in other implicated growing areas can be reopened. The reopening can only occur in a growing area after the investigation referenced above does not indicate an actual or potential pollution sources that could be the cause of the outbreak. (3) When the investigation, conducted in consultation with the epidemeiologists in the state(s) in which the illnesses occur and the Authorities in the state from which the shellfish were harvested, provides information that may include but shall not be limited to: a) Volume or distribution information which would implicate a specific growing area; b) Illness reporting from immediately adjacent growing areas; c) Pollution source investigation in conjunction with growing area

	evaluation does not identify a pollution source. d) Epidemiological tools that would link cases based on genetic similarity. D. When precautionary closures are established to address an illness outbreak involving multiple sources, Authorities will not be required to initiate voluntary recalls until the investigations indicate a single source. Existing C-J renumbered.
Public Health Significance	Following outbreaks in Maryland and Washington, the states requested clarification regarding the requirements of Chapter II. @.01 "Outbreaks from Shellfish Related Illness". In response, the ISSC Executive Board directed the establishment of a committee to provide clarification. The committee was also tasked to develop proposals to revise Chapter II language to provide requirement clarification. The committee was also requested to address appropriate outbreak response to multi-source outbreaks.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-210 as submitted.

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	Frequency of *Vibrio vulnificus* Control Plan evaluation.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan E.(2)(a).
Text of Proposal/ Requested Action	(a) The State Authority will conduct annual~~an~~ evaluations of the plan.
Public Health Significance	Current Model Ordinance language does not specify a frequency for *Vibrio vulnificus* Control Plan evaluation. II.@.06E.(2)(a)(i) requires that the evaluation include "The annual number of *Vibrio vulnificus* cases associated with the State's growing waters and the amount of shellstock sold for half shell consumption to determine risk per servings for each temperature period." However, the Authority could meet that requirement by, for example, conducting an overall evaluation once every 10 years while including information on each of the previous 10 years' cases and risk per servings estimates.
Cost Information	No cost.
Action by 2019 Task Force II	Recommends adoption of Proposal 19-211 as submitted.

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	Restricted use language *Vibrio vulnificus* Control Plan.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan E.(1)(b)(i).
Text of Proposal/ Requested Action	(i) Labeling oysters as being ~~F~~for shucking by a certified dealer~~.~~ or for approved post-harvest processing to control the *Vibrio vulnificus* hazard when the Average Monthly Maximum Water Temperature exceeds 70 °F.
Public Health Significance	Using quotes with the language "For shucking by a certified dealers" technically means that exact language must appear. States frequently use language like "For Shucking by a Certified Dealer or Post Harvest Processing" only.
Cost Information	No cost.
Action by 2019 Task Force II	Recommends adoption of Proposal 19-212 as submitted.

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	Restricted use language *Vibrio parahaemolyticus* Control Plan.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.07 *Vibrio parahaemolyticus* Control Plan B.(4)(c).
Text of Proposal/ Requested Action	(c) Require the original dealer to cool oysters and/or hard clams to an internal temperature of 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *V.p.* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters and/or hard clams has reached 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering. Oysters and/or hard clams without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled as being for shucking by a certified dealer or for approved post-harvest processing to control the *Vibrio parahaemolyticus* hazard~~*only*", or other means to allow the hazard to be addressed by further processing.~~
Public Health Significance	Using quotes with the language *"for shucking only"* technically means that exact language must appear. States frequently use language like "For shucking by a certified dealer or Post Harvest Processing" only.
Cost Information	No cost.
Action by 2019 Task Force II	Recommends adoption of Proposal 19-213 as submitted.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Permitting of Federal Waters Harvesting
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellfish Growing Areas @04 b 6 Chapter VIII. Control of Shellfish Harvesting
Text of Proposal/ Requested Action	Section II. Model Ordinance Chapter IV. Shellfish Growing Areas @04 b 6 ~~(6) Prior to allowing the landing of shellfish harvested from Federal waters where routine monitoring of toxin levels is not conducted, in addition to following State requirements in the Model Ordinance, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:~~ ~~(a) Harvest permit requirements;~~ ~~(b) Training for individuals conducting onboard toxicity screening using NSSP methods;~~ ~~(c) Vessel monitoring;~~ ~~(d) Identification of shellfish for each harvesting trip to include:~~ ~~(i) Vessel name and owner;~~ ~~(ii) Captain's name;~~ ~~(iii) Person conducting onboard screening tests;~~ ~~(iv) Port of departure name and date;~~ ~~(v) Port of landing name and date;~~ ~~(vi) Latitude and longitude coordinates of designated harvest area;~~ ~~(vii) Onboard screening test results;~~ ~~(viii)Volume and species of shellfish harvested;~~ ~~(ix) Intended processing facility name, address and certification number; and~~ ~~(x) Captain's signature and date;~~ ~~(e) Pre-harvested (onboard) sampling that includes a minimum of five (5) samples from the intended harvest area be tested for toxins that are likely to be present harvesting shall not be permitted if any of the pre-harvested samples contain toxin levels in excess of half of the established criteria listed in Chapter IV@.04(1) (e.g., 44 µg/100 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test for PSP toxins);~~ ~~(f) Submittal of onboard screening homogenates and test results to the Authority in the State of landing;~~

	~~(g) The collection of a minimum of seven (7) dockside samples by the Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory; the Authority may require more samples based on the size of the vessel and the volume of shellfish harvested;~~ ~~(h) Holding and providing separation until dockside samples verify that toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins);~~ ~~(i) Disposal of shellfish when dockside test results meet or exceed the established criteria in Chapter IV@.04C.(1) (e.g., 80 µg /100 g for PSP toxins);~~ ~~(j) Notification prior to unloading;~~ ~~(k) Unloading schedule;~~ ~~(l) Access for Dockside Sampling;~~ ~~(m) Record Keeping; and~~ ~~(n) Early Warning/Alert System.~~ Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting **.01 General…** **.02. Shellstock Harvesting and Handling…** **.03. Shellstock Harvesting in Federal Waters** A. Prior to harvesting shellfish in Federal waters that have been implicated in an illness outbreak or where toxin producing phytoplankton are known to occur and the toxins are known to accumulate in shellfish and where routine monitoring of toxin levels is not conducted, the harvester shall; (1) Obtain a harvester license from NOAA that explains the condition for harvest and includes harvest restriction ~~(1)~~(2) Be a party to agreements or memorandum of understanding between the Authority, the landing state, NOAA and the shellfish dealers receiving the shellfish. NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-

	203, 19-214, 19-223, 19-228, and 19-229. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-214 as submitted.

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	Ingredients Used in Shellstock during Wet Storage
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas .04 C.(1)(f) Chapter X. General Requirements for Dealers .05 B.(2)(k)
Text of Proposal/ Requested Action	Chapter VII. .04 C.(1): C. Wet Storage Source Water (1) General. (a) Except for wells… (b) Any well used… (c) Except when the… (d) Results of water… (e) Disinfection or other... (f) Ingredients intended to alter the taste, texture, or quality of live shellstock shall not be used in wet storage process water unless such ingredients are GRAS or otherwise authorized by the FDA for direct food use in the quantities used and are labeled on the tag in accordance with NSSP MO X. .05 B.(2)(k). (g)~~(f)~~ Disinfected process water… (h)~~(g)~~ When the laboratory… Chapter X. .05 B.(2): .05 Shellstock Identification B. Tags. … (2) The dealer's tag shall contain the following indelible, legible information in the order specified below: (a) The dealer's name… (b) The dealer's certification… (c) The original shellstock… (d) The harvest date… (e) If wet stored… (f) The most precise… (g) The type and… (h) The following statement… (i) All shellstock intended… (j) The statement "Keep … (k) The words "Added Ingredients:" and the common or usual name (not the brand name or trade name) of any ingredient and sub-ingredients unless otherwise exempt. An ingredient may be added to impart or alter the taste, flavor, texture, or quality of live shellstock via wet storage process water or otherwise added to shellstock. Additionally, ingredient labeling shall comply

	with applicable sections of 21 CFR 101 and the Food Allergen Labeling and Consumer Protection Act.
Public Health Significance	Current Model Ordinance language in Chapter VII addresses disinfection ~~with salt~~ or other water treatment that can leave residues, but it does not address the direct addition of ingredients, such as liquid smoke flavors or flavored salts, to wet storage water for the purpose of modifying the taste/quality of live molluscan shellfish. The FDA has received inquiries regarding what ingredients are permitted to be used in live molluscan shellfish and how such ingredients should be labeled. The purpose of this proposal is to address these inquiries to ensure compliance with 21 CFR 101 and 21 CFR 172-189.
Cost Information	Minimal Cost
Action by 2019 Task Force II	Recommends referral of Proposal 19-215 to an appropriate committee as determined by the Conference Chair.

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	Storage of Toxic Compounds on Harvester Vessels
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting .02 C.(1)
Text of Proposal/ Requested Action	Chapter VIII. .02 C.(1): .02 Shellstock Harvesting and Handling C. Vessels. (1) The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock. (a) Decks and storage… (b) Bilge pump discharges… (c) Containers used for… (d) Boat decks and… (e) Vessels and all… (f) When necessary… (g) Toxic compounds shall be stored to prevent contamination of shellstock onboard the vessel. Such compounds include, but are not limited to, lubricants, oils, cleaners, paints, anti-freeze, and road salts.
Public Health Significance	Current Model Ordinance language in Chapter VIII .02 C.(1) addresses prevention of contamination due to bilge water, unsafe/unclean storage materials, hot sun, birds, and animals, but it does not address how to prevent contamination of shellstock due to the improper storage and use of toxic compounds frequently stored onboard harvester boats, such as oils, cleaners, paints, anti-freeze, road salts, etc. In many cases, these chemicals are stored in close proximity to shellstock onboard the vessel. There are specific requirements for dealers regarding the "Proper labeling, storage, and use of toxic compounds" (Chapter X. .02 A.(6)) in order to prevent shellstock from becoming contaminated by these chemicals in the dealer facility. On a harvester boat, the potential risk of chemical contamination (e.g., spills or leaks) is even greater, due to the movement of the boat and adverse weather conditions. By requiring toxic compounds onboard a harvester vessel to be stored in a manner that will prevent contamination of shellstock in the event of a leak or spill, this proposal will help reduce the potential risk posed by these chemicals.
Cost Information	Plastic boxes/containers can be purchased at the following costs, based on https://www.usplastic.com/: 6 Quart Plastic Box - $2.08 16 Quart Plastic Box - $5.07

	18 Quart Plastic Box - $8.25 30 Quart Plastic Box - $8.53 48 Quart Plastic Box - $12.07 Harvesters would also have the option to store chemicals below deck, to elevate shellstock, or to use other means to safely store chemicals, minus the use of a box, due to the proposed language "or otherwise stored to prevent contamination of shellstock onboard the vessel".
Action by 2019 Task Force II	Recommends adoption of Proposal 19-216 as submitted.

<table>
<tr><td>Submitter</td><td>ISSC Executive Office</td></tr>
<tr><td>Affiliation</td><td>Interstate Shellfish Sanitation Conference</td></tr>
<tr><td>Address Line 1</td><td>209 Dawson Road</td></tr>
<tr><td>City, State, Zip</td><td>Columbia, SC 29223</td></tr>
<tr><td>Phone</td><td>(803) 788-7559</td></tr>
<tr><td>Fax</td><td>(803) 788-7576</td></tr>
<tr><td>Email</td><td>issc@issc.org</td></tr>
<tr><td>Proposal Subject</td><td>Time to Temperature Controls Clarification</td></tr>
<tr><td>Specific NSSP Guide Reference</td><td>Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting</td></tr>
<tr><td>Text of Proposal/ Requested Action</td><td>
@.02 Shellstock Time to Temperature Controls

A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one (1) of the following:
(1) The State V.v. Control Plan as outlined in Chapter II. @.06; or
(2) The State V.p. Plan as outlined in Chapter II. @.07; or
(3) All other shellstock shall comply with the matrix below:

<table>
<tr><th>Action Level</th><th>Average Monthly Maximum Air Temperature</th><th>Maximum Hours from Exposure to Receipt at a Dealer's Facility</th></tr>
<tr><td>Level 1</td><td><50 °F (10 °C)</td><td>36 hours</td></tr>
<tr><td>Level 2</td><td>50 - 60 °F (10 - 15 °C)</td><td>24 hours</td></tr>
<tr><td>Level 3</td><td>>60 - 80 °F (15 - 27 °C)</td><td>18 hours</td></tr>
<tr><td>Level 4</td><td>>80 °F (27 °C)</td><td>12 hours</td></tr>
</table>
B. For the purposes of this section, temperature control is defined as the management of the temperature of shellstock by means of ice, mechanical refrigeration or other approved means necessary to lower and maintain the temperature of the shellstock to comply with Chapters XI., XIII., or XIV.
C. The Authority shall establish the water ~~or air~~ temperature required in the vibrio plans outlined in A.(1) and A.(2) above. The authority shall establish the air temperature required in A (3) above. These temperatures shall be established ~~to be applied to the requirements above~~ for each growing area by averaging the previous five (5) years maximum monthly ~~water or air~~ temperatures.
</td></tr>
<tr><td>Public Health Significance</td><td>The purpose of this proposal is to provide clarification regarding the circumstances in which air temperature and water temperature measurements are used to meet the requirements of Chapter VIII @.02 A.</td></tr>
<tr><td>Cost Information</td><td></td></tr>
<tr><td>Action by 2019 Task Force II</td><td>Recommends adoption of Proposal 19-217 as submitted.</td></tr>
</table>

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	Ice used on Harvester Vessels
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting .02 H
Text of Proposal/ Requested Action	.02 Shellstock Harvesting and Handling H. Ice production: (1) Any ice used in the storage or cooling of shellfish during harvest shall: (a) Be made from a potable water source or from a growing area in the approved classification or in the open status of the conditionally approved classification; or (b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. (c) Protected from contamination
Public Health Significance	Harvesters are using ice during harvest to meet the shellstock cooling requirements of State *Vibrio vulnificus* and *Vibrio parahaemolyticus* management plans. The source of ice used during these cooling activities is not referenced in NSSP MO Chapter VIII. NSSP MO Chapter VIII does reference that water used for washing shellfish shall be from a potable water source or from a growing area in the approved status or in the open status of the conditionally approved classification. This proposal just clarifies that water used in the production of ice must meet the same requirements of water (potable) being used to wash shellfish.
Cost Information	NA. Harvesters using ice are already purchasing or making ice. This requirement only ensures that the water used in the production of ice is potable or has come from a facility sanctioned by the Authority or the appropriate regulatory agency.
Action by 2019 Task Force II	Recommends adoption of 19-218 as amended. .02 Shellstock Harvesting and Handling H. Ice production: (1) Any ice used in the storage or cooling of shellfish during harvest shall: (a) Be made from a potable water source or from a growing area in the approved classification or in the open status of the conditionally approved classification; or (b) Come from a facility ~~sanctioned~~ approved by the Authority or the appropriate regulatory agency: and~~.~~ (c) Be ~~P~~protected from contamination

Submitter	Susan Ritchie, New York State Department of Environmental Conservation David Carey, Connecticut Department of Agriculture Kristin DeRosia-Banick, Connecticut Department of Agriculture Alissa Dragan, Connecticut Department of Agriculture
Affiliation	State Agencies
Address Line 1	Division of Marine Resources, Bureau of Shellfisheries
Address Line 2	205 North Belle Mead Road, Suite 1
City, State, Zip	East Setauket, NY 11733
Phone	631-444-0494
Fax	631-444-0484
Email	susan.ritchie@dec.ny.gov
Proposal Subject	Shipping Temperatures
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IX. Transportation .04 Shipping Temperatures
Text of Proposal/ Requested Action	.04 Shipping Temperatures Shellfish dealers shall ship shellfish adequately iced; or in a conveyance ~~pre-chilled~~ maintained at or below 45°F (7.2°C) ambient air temperature. Geoduck clams (*Panopea generosa*) are exempt from these requirements.
Public Health Significance	This change from "pre-chilled" to "maintained" will provide consistency between the shellstock shipping requirements of Chapter IX. And the shellstock receiving critical control points in Chapters XI, XIII and XIV. Pre-chilling of conveyances does not provide additional health protection for shellfish consumers and directly conflicts with many States' statutes and regulations regarding idling vehicles (see attachment). Idling also wastes money by burning millions of gallons of fuel each year and risks public health by releasing thousands of tons of pollution into the air (excerpt by American Lung Association of the City of New York). The manufacturers of refrigeration units recommended that the unit be turned off during loading to avoid condensation, and to maintain optimal function of the unit. Conveyances are not designed to lower product temperature; they are designed to maintain the desired temperature of the conveyance. In order for the conveyance to maintain ambient temperatures of 45°F or less, shellstock must be cooled prior to shipping. Warm shellstock placed into a conveyance that is set to 45°F may overwhelm the ability of the conveyance to maintain that temperature and subsequently fail to achieve continuous cooling of product as required under Chapter XIII. @.01 A. (3), for VIII. @.02 A. (3) shellstock that has not been cooled to an internal temperature of 50°F (10°C). Conversely, a conveyance with a properly functioning refrigeration unit maintaining an ambient temperature of 45°F or less should be able to maintain the internal temperatures of shellstock. This proposal should be considered along with the 2019 proposal regarding Transportation Records (Section II Model Ordinance Chapter IX .05).
Cost Information	No cost will be incurred by the industry or State regulatory agencies.
Action by 2019 Task Force II	Recommends referral of Proposal 19-220 to an appropriate committee as determined by the Conference Chair.

Submitter	Susan Ritchie, New York State Department of Environmental Conservation David Carey, Connecticut Department of Agriculture Kristin DeRosia-Banick, Connecticut Department of Agriculture Alissa Dragan, Connecticut Department of Agriculture
Affiliation	State Agencies
Address Line 1	Division of Marine Resources, Bureau of Shellfisheries
Address Line 2	205 North Belle Mead Road, Suite 1
City, State, Zip	East Setauket, NY 11733
Phone	631-444-0494
Fax	631-444-0484
Email	susan.ritchie@dec.ny.gov
Proposal Subject	Transportation Records
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IX. Transportation .05 Transportation Records
Text of Proposal/ Requested Action	05 Transportation Records ~~All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that that all shipping conveyances comply with the requirements of Chapter IX. This documentation must include a notice of all shellstock harvested under the requirements of Chapter VIII. @02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) and indicate the presence of a time/temperature recording device.~~ A. All shipments of shellstock shall be accompanied with documentation indicating the following: (1) Date and time of shipment; and (2) The temperature of the shellstock recorded by the shipping dealer at the time of shipment. B. For shipments of shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) prior to shipping and where the shipping time is greater than four (4) hours, the documentation shall also indicate the presence of a time/temperature recording device. C. Geoduck clams (*Panopea generosa*) are exempt from these requirements. If adopted, the receiving critical control points under Chapter XI. and XIII. .01 A. (2) (b) and Chapter XIV. 01 A. (2) would need to be updated to read: (2) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c), (d) or (e). The product must be accompanied with documentation as outlined in Chapter IX. .05 A. and B. and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature recording device or comply with Chapter XIII. 01. A. (2) (c), (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter IX. 05. A.
Public Health	There is no public health significance associated with the .05 Transportation Records as originally adopted. The transportation document has been a requirement since the

Significance	2015 Model Ordinance was published and has done nothing but create problems for industry and State regulatory agencies. Rather than "a notice of shellstock that has not been cooled to an internal temperature of 50°F," recording an actual shellstock temperature prior to shipping provides a mechanism for the receiving dealer to readily document and verify that continuous cooling was achieved for all shipments, not only those that are shipped prior to cooling. For the VIII. @.02 A. (3) product that has not been cooled prior to shipping, the temperature prior to shipping and the temperature recorded by the receiving dealer upon receipt, provides a verifiable value, that when considered with the TTRD data (for shipments greater than four (4) hours, allows both inspectors and dealers to readily verify the conditions that the shipment has been subject to. This documentation will also no longer comply with the requirements of Section II Model Ordinance Chapter IX. 04 should the new 2019 proposal regarding shipping temperatures be adopted. See new 2019 Proposal regarding Shipping Temperatures (Section II Model Ordinance Chapter IX. 04).
Cost Information	No cost will be incurred by the industry or State regulatory agencies.
Action by 2019 Task Force II	Recommends adoption of Proposal 19-221 as submitted.

Submitter	Susan Ritchie, New York State Department of Environmental Conservation Alissa Dragan, Connecticut Department of Agriculture
Affiliation	State Agencies
Address Line 1	Division of Marine Resources, Bureau of Shellfisheries
Address Line 2	205 North Belle Mead Road, Suite 1
City, State, Zip	East Setauket, NY 11733
Phone	631-444-0494
Fax	631-444-0484
Email	susan.ritchie@dec.ny.gov
Proposal Subject	Shellstock Identification
Specific NSSP Guide Reference	Section II Model Ordinance Chapter X. General Requirements for Dealers .05 Shellstock Identification A. General.
Text of Proposal/ Requested Action	(1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is: (a) Shipped with his/her dealer tag affixed to each container of shellstock; or (b) Emptied to wash, grade, or pack the shellstock. (2) When the dealer is also the harvester and he elects not to use a harvest tag, the dealer shall affix his dealer tag to each container of shellstock prior to shipment. (3) The dealer shall not give, receive, or possess any shellfish tag or label that belongs to another dealer, except for the tag required to be affixed to containers of shellstock that meets the requirements in Section .05 B. through E. with the following exceptions: (a) When a written MOU/MOA has been established between the State Shellfish Control Authority and the dealers to allow the possession of another dealer's tag within the State; or (b) When a written MOU/MOA has been established between State Shellfish Control Authorities to allow the possession of a dealer's tag from another State. (4) The dealer shall not give, sell or allow any person who has not been certified as a dealer in accordance with the requirement of Section .04 A. (1) to possess any shellfish dealer tag or label, except for the tag required to be affixed to containers of shellstock that meets the requirements in Section .05B through E.
Public Health Significance	If a shellfish dealer possesses a tag that belongs to another shellfish dealer, it allows opportunity for other dealers or persons to misrepresent the actual harvest location, harvest date, etc. This makes traceback nearly impossible. In the event of a shellfish related illness, the illness is reported to the shellfish authority of the state indicated on the tag along with the harvest information which may incorrectly implicate that state as the origin of the shellfish. In October 2018, a confirmed *Vv*-related death resulted from the consumption of oyster. In this case, the shellfish dealer in one state arranged for shipments of oysters from two other states to be shipped to a fourth state (the receiving state). Following a lengthy investigation, all four states conferred with each other and determined that the retagging of oysters occurred in the receiving state using tags that implicated the shellfish dealer in the state that arranged the shipments of oysters to the receiving state. An investigation by the receiving state shellfish authority revealed that the person who received the oysters and retagged them was not a certified shellfish dealer in any

	state. The receiving state shellfish authority was also told by the non-certified shellfish dealer that the oysters were stored in a refrigerated truck for two days. The receiving state shellfish authority managed to acquire the original tags from the non-certified shellfish dealer. The authority sent the original tags to the growing area states for further investigation. To complicate things further, an investigation by one of the growing area states revealed that one of their certified dealers had allowed another one of their certified shellfish dealers to use their tags. The shellfish authority from this state determined that the harvest area indicated on the tag was not a harvest area that the dealer using the other dealer's tags harvests. Following this investigation, it was then discovered that a previous unconfirmed shellfish related illness, which occurred in May 2018, involved some of the same people and states. The tags for this case had been taken at face value, and no investigation ensued. The above incidents highlight the possible consequences of one shellfish dealer using tags that belong to another and support the addition of the proposed text.
Cost Information	No cost will be incurred by the industry or State regulatory agencies.
Action by 2019 Task Force II	Recommends referral of Proposal 19-222 to an appropriate committee as determined by the Conference Chair.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Restricted Shellstock
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers .05. E.
Text of Proposal/ Requested Action	B. All restricted ~~use~~ shellstock shall include a tag containing all information required in Section .05 of Model Ordinance Chapter X. In addition, the tag will include specific language detailing the restrictions requiring further processing or testing prior to distribution.~~intended use of the shellstock until processed consistent with the stated purpose~~. NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229 . The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of 19-223 as submitted and recommends that a committee as appointed by the Conference Chair to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.

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	Restricted use tag language General Requirements for Dealers.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers .05 Shellstock Identification B.7.
Text of Proposal/ Requested Action	(7) If a shellfish producing State selects to implement Chapter II. @.06 E. (1) (b) (i), ~~the~~a statement indicating that the shellstock are "~~F~~for shucking by a certified dealer" or for approved post-harvest processing to control the *Vibrio vulnificus* hazard ~~or an equivalent statement~~ shall be included on the tag. When this statement is included, the shellstock shall ultimately be sold to or processed by a certified shucker-packer or post-harvest processor for the purpose of shucking or post-harvest processing~~only~~.
Public Health Significance	The existing language allows for language equivalent to quoted language. However, States frequently use language such a "For Shucking by a Certified Dealer or Post Harvest Processing" on restricted use tags and such language may not be equivalent to "For shucking by a certified dealer."
Cost Information	No cost.
Action by 2019 Task Force II	Recommends adoption of Proposal 19-224 as amended. (7) If a shellfish producing State selects to implement Chapter II. @.06 E. (1) (b) (i), a statement indicating that the shellstock are for shucking by a certified dealer and/ or for approved post-harvest processing to control the *Vibrio vulnificus* hazard shall be included on the tag. When this statement is included, the shellstock shall ultimately be sold to or processed by a certified shucker-packer or post-harvest processor for the purpose of shucking or post-harvest processing.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Add Depuration Processor Certification
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers .04 B
Text of Proposal/ Requested Action	B. Types of Certification. (1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer. (2) Repacker. (a) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker; (b) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker- packer, or repacker; (c) A repacker shall not shuck shellfish. (3) Shellstock Shipper. Any person who ships and receives shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer. (4) Reshipper. Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers shall be certified as a reshipper. ~~(4)~~(5) Depuration Processor. Any person who harvests or receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process.
Public Health Significance	Depuration is a recognized type of certification that is currently not included in this section.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-225 as submitted.

Submitter	Jon C Strauss
Affiliation	Colorado Dept. of Public Health and Environment
Address Line 1	4300 Cherry Creek Drive South
Address Line 2	A-2
City, State, Zip	Denver, CO 80246
Phone	303.692.3654
Fax	
Email	jon.strauss@comcast.net
Proposal Subject	Deletion of requirement for a suitable holder for toilet paper roll.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing Chapter XII. Repacking of Shucked Shellfish Chapter XIII. Shellstock Shipping Chapter XIV. Reshipping Chapter XV. Depuration
Text of Proposal/ Requested Action	Chapter XI @.02 D (6) The dealer shall provide: (a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]** (b) An adequate number of conveniently located, toilets; and **[K]** (c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder~~. ~~**[S$^{K/O}$]**~~ Chapter XII @.02 D (3) The dealer shall provide: (a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]** (b) An adequate number of conveniently located, toilets; and **[K]** (c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder~~. ~~**[S$^{K/O}$]**~~ Chapter XIII @.02 D (3) The dealer shall provide: (a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]** (b) An adequate number of conveniently located, toilets; and **[K]** (c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder~~. ~~**[S$^{K/O}$]**~~ Chapter XIV @.02 D (3) The dealer shall provide: (a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]** (b) An adequate number of conveniently located, toilets; and **[K]** (c) Each toilet facility with an adequate supply of toilet paper **[K]**

	~~in a suitable holder.~~ ~~[S^K/O]~~ Chapter XV @.02 D (5) The dealer shall provide: (a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]** (b) An adequate number of conveniently located, toilets; and **[K]** (c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder.~~ ~~[S^K/O]~~
Public Health Significance	The Food Code and the Grade "A" Pasteurized Milk Ordinance (PMO) do not require toilet paper to be on an appropriate holder. Many inland state inspectors who work in multiple programs have noted this disparity. The authors of this proposal do not seek to limit or eliminate toilet paper holders/dispensers, nor do they advocate for facilities to forgo use of existing toilet paper holders/dispensers. The developers of the proposal only seek to eliminate citing deficiencies when one or more unwrapped toilet paper rolls are found set upon the top of the toilet paper holder or on top of the toilet, in a stall or restroom that has a suitable holder/dispenser. Accordingly, it would be a deficiency if the stall/bathroom lacked toilet paper or if the toilet paper roll(s) were stored on the floor. Based upon how this situation is treated in other food safety programs, the developers of this proposal believe it is in the best interest of the ISSC to adopt this proposal and improve uniformity between food safety programs nation-wide.
Cost Information	No cost.
Action by 2019 Task Force II	Recommends adoption of Proposal 19-226 as submitted.

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	Proper Use of Devices to Prevent Backflow and Back Siphonage
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing Chapter XII. Repacking of Shucked Shellfish Chapter XIII. Shellstock Shipping Chapter XIV. Reshipping Chapter XV. Depuration Section IV: Guidance Documents Chapter III. Harvesting, Handling, Processing and Distribution
Text of Proposal/ Requested Action	**Chapter XI .02 Sanitation** B. Safety of Water for Processing and Ice Production. (1) Water Supply… (2) Ice Production… (3) Shellstock Washing… (4) Plumbing and Related Facilities. (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to: (i) Prevent contamination of water supplies; **[S$^{C/K}$]** (ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. **[S$^{C/K}$]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]** **Chapter XII .02 Sanitation** A. Safety of Water for Processing and Ice Production. (1) Water Supply… (2) Ice Production… (3) Plumbing and Related Facilities. (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to: (i) Prevent contamination of water supplies and [S$^{C/K}$] (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [S$^{C/K}$] The dealer shall install and maintain in good

working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]**

Chapter XIII .02 Sanitation

A. Safety of Water for Processing and Ice Production.
(1) Water Supply…
(2) Ice Production…
(3) Shellstock Washing…
(4) Plumbing and Related Facilities. The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(a) Prevent contamination of water supplies; [$S^{C/K}$]
(b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source [$S^{C/K}$] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]**

Chapter XIV .02 Sanitation

A. Safety of Water for Processing and Ice Production.
(1) Water Supply…
(2) Ice Production…
(3) Plumbing and Related Facilities. The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(a) Prevent contamination of water supplies; **[$S^{C/K}$]**
(b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[$S^{C/K}$]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]**

Chapter XV .02 Sanitation

A. Safety of Water for Processing and Ice Production
(1) Water Supply…
(2) Ice Production…
(3) Shellstock Washing…
(4) Depuration Process Water…
(5) Plumbing and Related Facilities.
(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(i) Prevent contamination of water supplies; **[$S^{C/K}$]** and
(ii) Prevent any cross-connection between the pressurized

potable water supply and water from an unacceptable source. **[S$^{C/K}$]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]**

(b) Depuration Plant Design and Construction. The dealer shall ensure that:

(i) Depuration tanks, processing containers, and piping are fabricated from non-toxic corrosion-resistant materials and are easily cleanable; **[K]**

(ii) Depuration tank design, hydraulics, and typical container configuration are such that process water is evenly circulated throughout all the shellfish containers within a given tank; and **[K]**

(iii) Shellfish containers allow process water to flow freely and uniformly to all shellfish within each container. **[K]**

(6) No change.

Section IV Guidance Documents – Chapter III

VIII. Backflow Prevention

Preventing contamination of potable water supplies through proper backflow prevention is a responsibility of every shellfish dealer. Different varieties of backflow and back siphonage devices are designed for specific conditions, thus dealers should work with their plumber to select the proper device for the proper application. Simple hose bib vacuum breakers are designed to protect against back siphon only. As such, they are to be used downstream of all shut-off valves. Their manufacturer's design criteria specify they must not be subjected to continuous pressure, for example, a shut-off valve or shut-off sprayer nozzle being installed downstream from the hose bib vacuum breaker. Observation of water being randomly expelled from vents in the simple hose bib vacuum breaker provides evidence that the device is being subjected to continuous pressure and dealers should be aware the simple devices are prone to failure. The internal mechanism is not robust and will fail under continuous pressure, leading to a loss of back siphonage protection. Hose bib vacuum breakers are inexpensive and ideal for applications where a simple hose is attached to them, without a shut-off sprayer nozzle attached to the end of the hose. In contrast, dual check valve (with or without intermediate atmospheric vent) backflow preventers are specifically designed for service in continuous pressure systems. As such, they are ideal when located upstream from shut-off sprayer nozzles. Dual check valve backflow preventers are designed to protect against back siphon and pressurized backflow. Shellfish dealers have access to different, free resources for plumbing design questions. A simple query made to the manufacturer of the backflow device in question should provide the dealer with critical information, describing the proper installation, application, and maintenance of the device.

Public Health Significance	Backflow and back siphonage are easily prevented public health threats that can lead to contamination of the plant water supply. Devices used to prevent backflow and back siphonage have specific application criteria that must be adhered to, for proper operation of the devices. For example, the simple hose bib vacuum breaker is designed to prevent back siphon only and is not designed for continuous pressure, per the manufacture and the International Association of Plumbing and Mechanical Officials, American National Standard, 2018 Uniform Plumbing Code.
Cost Information	Hose bib vacuum breakers may continue to be used, provided they are not subjected to continuous pressure. For example, a simple hose attached to a hose bib, which is in turn connected to a faucet is acceptable. Cost is approximately $6. If, however, a shut-off spray nozzle is added, the hose bib should be removed and a device capable of protecting against backflow and back siphonage under pressure should be installed upstream of the faucet valve. Cost per replacement device varies. For example, a ¾" Watts® LF7R lead free dual check valve, capable of protecting against backflow and back siphonage under continuous pressure in potable water systems, whether mounted vertically or horizontally, will cost approximately $40. Addition of an atmospheric vent to the dual check valve assembly will increase the cost.
Action by 2019 Task Force II	Recommends referral of Proposal 19-227 to the appropriate committee as determined by the Conference Chair.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Harvest of Restricted Shellstock In Federal Waters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .01 A
Text of Proposal/ Requested Action	A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and **[C]** ~~(a)~~(b) Harvested restricted shellstock from Federal waters and properly tagged with information describing the restriction. ~~(b)~~(c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and **[C]** ~~(c)~~(d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) **[C].** NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229,. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	

Action by 2019 Task Force II	Recommends adoption of Proposal 19-228 as amended. A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and **[C]** (b) Harvested restricted shellstock from Federal waters and properly tagged with information describing the restriction**[C]**. (c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and **[C]** (d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) **[C].**

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Restricted Shellstock From Federal Waters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .03 I. Section II. Model Ordinance Chapter XIII. Shellstock Shipping .02 I.
Text of Proposal/ Requested Action	Section II. Model Ordinance Chapter XI. Shucking and Packing .03 I. I. Restricted Shellstock from Federal Waters. The dealer shall: 1. Obtain permission from the Authority to receive restricted shellstock prior to receipt. 2. Develop agreements or memorandum of understanding between the Authority, National Oceanic Atmospheric Administration (NOAA) and the individual harvesters as necessary to comply with the biotoxin controls outlined in Chapter IV. Section II. Model Ordinance Chapter XIII. Shellstock Shipping .03 I. I. Restricted Shellstock from Federal Waters. The dealer shall: 1. Obtain permission from the Authority to receive restricted shellstock prior to receipt. 2. Develop agreements or memorandum of understanding between the Authority, National Oceanic Atmospheric Administration (NOAA) and the individual harvesters as necessary to comply with the biotoxin controls outlined in Chapter IV. NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC

	Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229,. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of 19-229 as amended. Section II. Model Ordinance Chapter X~~I~~. ~~Shucking and Packing .03 I.~~General Requirements for Dealers .09 ~~I.~~ Restricted Shellstock from Federal Waters. The dealer shall: 1. Obtain permission from the Authority to receive restricted shellstock prior to receipt. 2. Develop agreements or memorandum of understanding between the Authority, National Oceanic Atmospheric Administration (NOAA) and the individual harvesters as necessary to comply with the biotoxin controls outlined in Chapter IV. ~~Section II. Model Ordinance Chapter XIII. Shellstock Shipping .03 I.~~ ~~I. Restricted Shellstock from Federal Waters.~~ ~~The dealer shall:~~ ~~1. Obtain permission from the Authority to receive restricted shellstock prior to receipt.~~ ~~2. Develop agreements or memorandum of understanding between the Authority, National Oceanic Atmospheric Administration (NOAA) and the individual harvesters as necessary to comply with the biotoxin controls outlined in Chapter IV.~~ And refer to the appropriate committee as determined by the Conference Chair with instruction to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.

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	Shellstock Shipping facility requirements.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping *Exceptions.*
Text of Proposal/ Requested Action	~~*Exceptions. Shellstock Shippers are not required to pack shellstock in a building that complies with Sections .02 and .03 of this chapter when the Authority has determined that a shellstock shipper's practices and conditions do not warrant requiring shellstock to be packed in a building.*~~ *Exceptions. Shellstock Shippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a Shellstock Shipper's practices and conditions do not warrant requiring a building.*
Public Health Significance	This is suggested to make it clear that, depending on practices, Shellstock Shipping may not require a building complying with Section .02 and .03 requirements. Some dealer operations consist of receiving shellstock from harvesters in harvest containers then selling them immediately without handling them in any way other than unloading harvest containers from vessels and loading them onto trucks or possibly into standby coolers if necessary. They must be certified to purchase shellstock from harvesters but there is no reason to require that they have facilities required for Shellstock Shippers who wash, cull, and repack the shellstock. Allowance for dealers without buildings meeting Section .02 and .03 requirements is effectively indicated by XIII.03F, which references provisions for "A dealer whose activity consists of trucks or docking facilities only."
Cost Information	No cost.
Action by 2019 Task Force II	Recommends adoption of Proposal 19-230 as submitted.

Submitter	Blake Millett / Jon Strauss
Affiliation	Utah Department of Agriculture and Food / Colorado Department of Public Health & Envm
Address Line 1	350 N Redwood Road / 4300 Cherry Creek Drive South A-2
Address Line 2	
City, State, Zip	Salt Lake City, UT 84114 / Denver, CO 80246
Phone	801-706-9202 / 303-692-3654
Fax	801-538-4949 / 303-753-6809
Email	bmillett@utah.gov / jon.strauss@state.co.us
Proposal Subject	Addition of shipping CCP
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping Chapter XIV. Reshipping
Text of Proposal/ Requested Action	**Chapter XIII Shellstock Shipping** **.01 Critical Control Points** D. Shellstock Shipping Critical Control Point- The dealer shall ensure that (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. The transaction record shall indicate the quantity of restricted use shellstock containers.**[C]** (2) All shellstock is cooled to meet the requirements outlined in .01 B. (3) and (4) above prior to shipment. The original dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) prior to achieving the internal temperature of 50 °F (10 °C). Should the original dealer choose this option the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. **[C]** (3) All shellstock shipments to other certified dealers shall be accompanied by documentation in accordance with Chapter IX. .05 [C] **Chapter XIV Reshipping** **.01 Critical Control Points** E. Shellstock Shipping Critical Control Point. The dealer shall ensure that: (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. The transaction record shall indicate the quantity of restricted use shellstock containers. **[C]** (2) All shellstock received from a dealer which elected to ship restricted use shellstock or shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) prior to achieving the internal temperature of 50 °F (10 °C) must be cooled to an internal temperature of 50 °F (10 °C) prior to shipment. The dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A.

	(3) prior to achieving the internal temperature of 50 °F (10 °C). Should the dealer choose this option the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. **[C]** (4) All shellstock shipments to other certified dealers shall be accompanied by documentation in accordance with Chapter IX. .05[C]
Public Health Significance	When a dealer receives shellstock from another dealer, without the required time and pre-chill temperature documentation, then under Chapter XI.01.A.(2)(b), Chapter XIII.01.B, Chapter XIV.01.A.(1).(b), or Chapter XV.01.A.(2).(b), the receiving firm receives a Critical violation if that product is still present at the receiving firm during the Authority's inspection. Currently, the dealer who ships product without the required time and pre-chill temperature only receives a Key violation under Chapter IX. .04 and .05. Recall the issue that led to modifications of Chapter IX was the discovery of one or more original shippers loading shellstock into hot trailers. It is unclear how penalizing all receiving dealers, (who until the scandal broke, were unknowingly receiving product that was initially temperature abused), was a logical solution to halting a problem caused by a few original shippers. This proposal would create an equal penalty for a dealer who fails to add the required time and pre-chill temperature information to the transportation documents. There have been recurrent, unintended consequences from Chapter IX. Receiving dealers are failing recertifications for receiving shipments that do not contain the time and pre-chill temperature on the shipping documents, if that particular shipment of shellstock is present in the facility during inspection. While it is the receiving dealer's responsibility to reject these noncompliant shipments, responsibility should fall equally on the dealer who sends out noncompliant shipments. By creating a requirement for a shipping CCP, dealers who ship product without the time and pre-chill temperature as required will receive the same Critical violation that the receiving dealer gets on their inspection. The public health significance of this proposal is that by fairly and equally sharing the responsibility for those shipping and those receiving product, we are placing a stronger emphasis on the importance of keeping product safe during transportation from one dealer to another. The way that the MO is currently written, with the receiving firm getting cited for a Critical deficiency and the shipping firm getting a Key, we are essentially sanctioning the passing of risk to the receiving firm. As further evidence of passing risk to the end user, FDA has gone on record to state that if the Authority's inspection discovers a receiving dealer lacks proper documentation required by Chapter IX but the live shellfish shipment in question has been shipped out to another dealer and is thus not present in the receiving dealer's facility, the Critical deficiency becomes a Key.

	Proponents of the original change to Chapter IX insist the receiving firm should take responsibility and reject the product. In this way, the shipping firms would have to comply or risk shipments being rejected. History has shown that is not the case. The original change to Chapter IX, adding special shipping document requirements for shellstock to all receiving dealer CCPs, was put into place in 2011. Eight years later, we are still having national issues with some certified shippers not including this required documentation. This proposal will fix these issues.
Cost Information	No cost.
Action by 2019 Task Force II	Recommends referral of Proposal 19-231 to the appropriate committee as determined by the Conference Chair.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Public Health Explanation of Depuration
Specific NSSP Guide Reference	Section III Public Health Reasons and Explanations Chapter XV. Depuration
Text of Proposal/ Requested Action	**@.01 Administration** Depuration is intended to reduce the number of pathogenic organisms that may be present in shellfish harvested from moderately polluted (restricted) waters to such levels that the shellfish will be acceptable for human consumption without further processing. The process is not intended for shellfish from heavily polluted (prohibited) waters ~~nor to reduce the levels of poisonous or deleterious substances that the shellfish may have accumulated from their environment~~. The acceptability of the depuration process is contingent upon the Authority exercising very stringent supervision over all phases of the process.
Public Health Significance	This statement is not accurate.
Cost Information	
Action by 2019 Task Force II	Recommends no action on Proposal 19-232. Rationale: Submitter requests no action.

Submitter	Tom Dameron
Affiliation	Surfside Foods
Address Line 1	2838 High St
Address Line 2	
City, State, Zip	Port Norris, NJ, 08349
Phone	(856) 785-2115
Fax	
Email	capttomd@gmail.com
Proposal Subject	Shellstock Receiving and Shipping
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program for the Authority @.01 E
Text of Proposal/ Requested Action	~~E.~~F. Administrative Procedures. The Authority shall have administrative procedures sufficient to: (1) Regulate shellfish harvesting, sale, and shipment; ~~(2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the State from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its State to purchase the shellstock;~~ ~~(3)~~(2) Detain, condemn, seize, and embargo shellfish; and ~~(4)~~(3) Assure compliance with Shellfish Plant Inspection Standardization.
Public Health Significance	There is no public health significance associated with this requirement. Dealer receiving critical control points address the source of the shellfish. There is no public health reason for prohibiting a company which has a harvester license and is certified as a dealer from landing in one state and trucking shellfish to their dealer location in another state.
Cost Information	
Action by 2019 Task Force II	Recommends referral of Proposal 19-235 to an appropriate committee as determined by the Conference Chair.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Aquaculture Operational Plan for Birds and/or Mammals
Specific NSSP Guide Reference	Section II . Model Ordinance Chapter VI. Shellfish Aquaculture .04
Text of Proposal/ Requested Action	**.04 Aquaculture That Attracts Birds or Mammals** A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) A description of the design and activities of the culture facility; (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted; (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters; (4) The species of shellfish to be cultured and harvested; (5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities; and (6) An evaluation of the potential pollution impact of the birds and/or mammals. (~~6~~7) Maintenance of the required records.
Public Health Significance	As currently written section .04 does not require a pollution assessment.
Cost Information	
Action by 2019 Task Force II	Recommends adoption of proposal 19-236 as amended. **.04 Aquaculture That Attracts Birds or Mammals** A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) A description of the design and activities of the culture facility; (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted; (3) The types and locations of any structures, including rafts, pens,

	cages, nets, or floats which will be placed in the waters; (4) The species of shellfish to be cultured and harvested; (5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities; and (6) ~~An evaluation~~ A description of the mitigation or deterrent measures to minimize the potential pollution impact of ~~the~~ birds and/or mammals. (7) Maintenance of the required records.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Dealer Receiving Critical Control Points
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .01 A. (2) Chapter XIII. Shellstock Shipping .01 A (2). Chapter XIV. Reshipping .01 A (1)
Text of Proposal/ Requested Action	**Chapter XI. Shucking and Packing** **.01 Critical Control Points** B. Receiving Critical Control Point - Critical Limits. (1) The dealer shall… (2) The dealer shall shuck and pack only shellstock obtained and transported from a dealer who has: (a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); and **[C]** (b) Provided documentation as required in Chapter IX. .05; and **[C]** (c) Adequately iced the shellstock; or **[C]** (d) Shipped the shellstock in a conveyance ~~maintained~~ at or below 45 °F (7.2 °C) ambient air temperature; ~~or~~ and **[C]** (e) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less.[C] **Chapter XIII. Shellstock Shipping** **.01 Critical Control Points** B. Receiving Critical Control Point - Critical Limits. (1) The dealer shall… (2) The dealer shall ship or repack only shellstock obtained and transported from a dealer who has: (a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05; and **[C]** (b) Provided documentation as required in Chapter IX. .05; and **[C]** (c) Adequately iced the shellstock; or **[C]** (d) Shipped the shellstock in a conveyance ~~maintained~~ at or below 45 °F (7.2 °C) ambient air temperature; ~~or~~ and **[C]** (e) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. **[C]** **Chapter XIV. Reshipping**

	.01 Critical Control Points B. Receiving Critical Control Point - Critical Limits. (1) The dealer shall reship only shellfish obtained and transported from a dealer who has: (a) Identified the shellstock with a tag as outlined in Chapter X. .05, identified the in-shell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and **[C]** (b) Provided documentation as required in Chapter IX. .05; and **[C]** (c) Adequately iced the shellstock; or **[C]** (d) Shipped the shellstock in a conveyance ~~maintained~~ at or below 45 °F (7.2 °C) ambient air temperature; ~~or~~ and **[C]** (e) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less; **[C]** or (f) Shipped the shucked shellfish and/or in-shell product adequately iced or in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature. **[C]**
Public Health Significance	A record to document that the temperature has been maintained would require a time/temperature recording device in all shellstock. The requirement in (2) (e) was never intended to be an option at receiving. This is a shellstock storage critical control point at
Cost Information	
Action by 2019 Task Force II	Recommends adoption of Proposal 19-237 as submitted.

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223
Phone	(803) 788-7559
Fax	(803) 788-7576
Email	issc@issc.org
Proposal Subject	Definition of Processed Shellfish
Specific NSSP Guide Reference	Section I Definitions
Text of Proposal/ Requested Action	The National Shellfish Sanitation Program (NSSP) is the Federal/State cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and whole or roe-on scallops) moving in interstate commerce through Federal/State cooperation and uniformity of State shellfish programs. Only shellfish harvested under the NSSP is allowed for market access, whether consumed raw or transformed by further processing post-harvest (e.g. breading, canning, cooking, marinating, smoking, etc.). Shellfish subjected to further processing by which the organoleptic characteristics have been altered are beyond the scope of the NSSP controls for safe handling of raw shellfish and subject to the Seafood HACCP regulations (21CFR123). Historically the recognized purpose of the NSSP was to address shellfish as defined in Definition (112) as follows: (112) Shellfish means all species of: (a) Oysters, clams or mussels, whether: (i) Shucked or in the shell; (ii)Raw, including post-harvest processed; (iii) Frozen or unfrozen; (iv) Whole or in part; and (b) Scallops in any form, except when the final product form is the adductor muscle only. There are other definitions included in the Guide for the Control of Molluscan Shellfish that suggest that the NSSP includes certain types of processed shellfish. Below are two examples: (91) Processing means any activity associated with the handling, shucking, freezing, packing, labeling or storing of shellfish in preparation for distribution. This would include the activities of a shellstock shipper, shucker packer, repacker, reshipper, or depuration processor. (from NSSP Guide Section IV, Chapter III .01 Shellfish Industry Equipment Construction Guide) 27. Molluscan Shellfish - All edible species of oysters, clams, mussels and whole scallops or roe-on scallops (scallops are excluded when the final product is the shucked adductor muscle only). Shellfish products which may contain any material other than the meats and /or shell liquor of oysters, clams, mussels or scallops will be regarded as a ”processed food” and

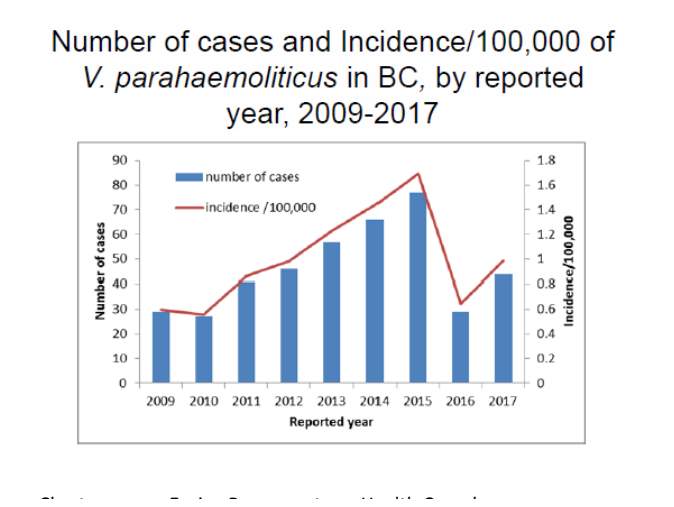
	will not be included in the Cooperative Program. The FDA will be recommending language for inclusion in Section I. Purpose of the NSSP Guide to clearly define the shellfish product forms to which the NSSP should apply.
Public Health Significance	The purpose of this proposal is to provide consistent language throughout the NSS Guide and clarity on the types of shellfish products that the NSSP Guide is intended to cover, while giving consideration to the advances in shellfish processing that have occurred over time.
Cost Information	
Action by 2019 Task Force	Recommends adoption of Proposal 19-238 as substituted. NSSP Guide Section I. Purpose and Definitions FIRST CHANGE: Purpose (page 2) First paragraph The National Shellfish Sanitation Program (NSSP) is the Federal/State cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of bivalve molluscan shellfish (hereinafter referred to as shellfish) produced and sold for human consumption. The purpose of the NSSP… Fourth paragraph The NSSP Guide for the Control of Molluscan Shellfish consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the Program. The Model Ordinance includes guidelines to ensure that the shellfish produced in States in compliance with the guidelines are safe and sanitary. The Model Ordinance provides readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish. The Model Ordinance is intended to cover molluscan shellfish that are raw (live, fresh or fresh frozen) and molluscan shellfish subjected to post-harvest processing (PHP) as defined in this Guide. Cooked shellfish, shellfish subject to 21 CFR part 113 or 114, or raw shellfish packaged with the explicit intent that they will be cooked by the end consumer (such as breaded or marinated) are generally recognized as products that are beyond the scope of the NSSP and are subject to the Seafood HACCP regulations (21 CFR 123). However, such shellfish products intended for interstate commerce are still subject to the appropriate harvest and/or approved source controls outlined in this Guide when they are necessary to control a food safety hazard." SECOND CHANGE: **(95) Raw** means shellfish that have not been heated ~~thermally processed: (a)~~ to an internal temperature of 145 °Fahrenheit or greater for 15 seconds (or equivalent~~);~~

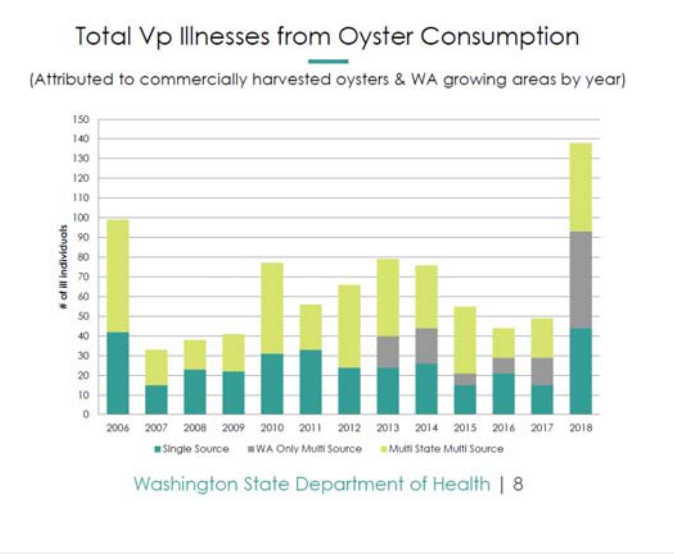
	~~or (b) altering the organoleptic characteristics~~. THIRD CHANGE: Section IV, Chapter III .01 Shellfish Industry Equipment Construction Guide ~~27. Molluscan Shellfish – All edible species of oysters, clams, mussels and whole scallops or roe-on scallops (scallops are excluded when the final product is the shucked adductor muscle only). Shellfish products which may contain any material other than the meats and/or shell liquor of oysters, clams, mussels or scallops will be regarded as a "processed food" and will not be included in the Cooperative Program.~~

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	Updating epidemiological investigation reference.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.01 Outbreaks of Shellfish-Related Illness A NOTE.
Text of Proposal/ Requested Action	NOTE: For additional guidance refer to the International Association for Food Protection ~~of Milk, Food, and Environmental Sanitarians'~~ *Procedures to Investigate Food Borne Illness*.
Public Health Significance	The name of the organization producing the referenced publication has changed.
Cost Information	No cost.
Action by 2019 Task Force II	Recommends adoption of Proposal 19-239 as submitted.

Submitter	Bill Dewey
Affiliation	Taylor Shellfish Farms
Address Line 1	130 SE Lynch Rd
Address Line 2	
City, State, Zip	Shelton, WA 98584
Phone	360-790-2330
Fax	360-432-3344
Email	billd@taylorshellfish.com
Proposal Subject	Alternative for allowing harvest for raw consumption from a growing area closed due to *V.p.*
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*), Section A. (6)
Text of Proposal/ Requested Action	(6) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls: (a) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* 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) Implementing a process that has been validated to achieve <100 mpn/gram total *V.p.*; ~~(b)~~(c) 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)~~(d) 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.
Public Health Significance	The Center for Disease control estimates 45,000 people get ill each year in the United States from *V.p.*. In an effort to reduce *V.p.* illnesses SSCAs have developed and implemented vibrio control plans and industry has diligently implemented strict temperature controls and harvest practices. Despite these efforts *V.p.* illnesses persist. There are several possible explanations for this. It could be the result of more oysters being produced for raw consumption and therefore greater exposure or because the adopted controls are ineffective or because of improper handling during retail distribution and sale at facilities beyond the authority of ISSC to control or because of increased reporting of illnesses because of improved awareness or changes in reporting procedures. Regardless of the reason, the fact is consumers continue to get ill from eating raw shellfish contaminated with *V.p.* bacteria and it is incumbent on the ISSC to consider all options for reducing *V,p.* illnesses. With this proposal we hope to enlighten ISSC participants to the apparent efficacy of utilizing a < 100 MPN/gram tlh standard to reduce V.p. illnesses and establish the standard as an option for states to use.

While based in Washington State, Taylor Shellfish Farms has farms, a processing facility and oyster bar in British Columbia. Because of this we are familiar with Canadian *V.p.* regulations. Following a *V.p.* outbreak in 2015 Canada implemented a requirement for processors to reduce total V.p. (tlh) levels below 100 MPN/gram prior to sale or distribution. This new regulation appears to have been effective at reducing *V.p.* illnesses while adjacent Washington State continues to see significant *V.p.* illnesses despite a vibrio control plan updated in 2015 with stringent harvest controls and time to documented temperature reduction.





On Taylor Shellfish farms in British Columbia (d.b.a. Fanny Bay Oyster) we can

	predictably achieve the < 100 MPN/gram Canadian standard by holding oysters in culture trays at growing densities in 12-15 C water for 5 to 7 days. In Washington, we are achieving similar results after holding shellfish in a chilled recirculating wet storage system at 15 C for 3 days. The current Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*), Section A. (6)(c) allows for harvest from areas closed due to *V.p.* with "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". This could provide the opportunity for a SSCA to allow the use of the < 100 MPN/gram to permit harvest. We are submitting this proposal to draw attention to the effectiveness of the < 100 MPN/gram tlh standard and clearly state that it is an option for inclusion in state vibrio control plans. As proposed, it is our understanding and intent that this would be an option and not mandatory. If adopted it would provide companies with an option to continue harvesting and distribution of a reduced risk product during V.p. closures. The International Commission on Microbiological Standards for Foods (ICMSF) advises that < 100 MPN/gram would be of acceptable quality in live bivalve Mollusca. Other countries, including Japan for fresh/frozen fish and shellfish and Hong Kong, Australia, New Zealand in Ready to Eat (RTE) foods and Russia (for imported shellfish) have adopted the 100 MPN/gram standard. U.S. companies exporting live shellfish to countries that have adopted this standard already have to demonstrate their product achieves the standard. This is yet another reason we feel it makes sense for the U.S. to consider including it as an option in the Model Ordinance. As a major seafood and shellfish consumer Japan has had a history of large numbers of *V.p.* illnesses. Their response warrants review as it appears to have been very effective at reducing illnesses. Following a peak in 1998 with 839 outbreaks and 12,318 cases, Japan's Ministry of Health, Labor and Welfare (MHLW) instituted a series of regulations from production through consumption including adoption of a ≤ 100 MPN/gram standard. Subsequently, the number of cases and out- breaks of *V. parahaemolyticus* infections decreased by an unprecedented 99- and 93-fold, respectively, from 1998 to 2012. The 2014 paper: Impact of seafood regulations for *Vibrio parahaemolyticus* infection and verification by analyses of seafood contamination and infection by Kara-Kudo and Kumagai reviews Japan's response including an explanation of how they arrived at the ≤ 100 MPN/gram tlh standard while considering various serotypes and pathogenic thermostable direct haemolysin (TDH) and/or TDH-related haemolysin (TRH)-positive strains. Further, according to Kara-Kudo and Kumagai's review article total V.

	parahaemolyticus levels in seafood associated with 11 outbreaks from 1998 were analyzed. The contamination levels in 8 out of 11 outbreaks were >100 V. parahaemolyticus MPN/g food, suggesting that the regulatory level of ≤100 V. parahaemolyticus MPN/g is effective for food control. Taylor Shellfish Farms is confident based on recommendations from the International Commission on Microbiological Standards for Foods (ICMSF), that results seen in BC and documented in Japan that the < 100 MPN/gram tlh standard provides considerable *V.p.* illness risk reduction. So much so that we have begun construction of a 90,000 gallon chilled live holding system at our Shelton, Washington processing facility with the goal of ensuring all our shellfish destined for raw consumption meets this standard.
Cost Information	If adopted as intended, it would be optional for states to include it in their vibrio control plans and for companies to pursue validation of a process to achieve the standard. It is anticipated that the tests associated with the validation process and periodic verification would be at the expense of the participating company. The costs would only be incurred if a company opted to pursue validation of their process. It is anticipated that states would recoup the cost of the validation tests if they were performed at a state operated laboratory. Presumably SSCAs could also impose fees to cover cost associated with overseeing validation of a company's process and periodic verification. Costs incurred by companies would theoretically be recouped by having the advantage of continued sales when growing areas might otherwise be closed due to *V.p.*.
Action by 2019 Task Force II	Recommends referral of Proposal 19-240 to the appropriate committee as determined by the Conference Chair.

Submitter	Centers for Disease Control and Prevention (CDC)
Affiliation	CDC
Address Line 1	1600 Clifton Road
Address Line 2	MS H24-9
City, State, Zip	Atlanta, GA 30329
Phone	404-718-1175
Fax	404-235-1735
Email	Estokes@cdc.gov
Proposal Subject	*Vibrio vulnificus* risk evaluation
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan Section III. Public Health Reasons and Explanations Chapter IV. Shellstock Growing Areas @.01 Sanitary Survey ISSC Constitution, Bylaws & Procedures Procedure XVI. Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures
Text of Proposal/ Requested Action	**Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan** C. All States not currently implementing a *V.v.* Control Plan shall develop and implement a *V.v.* Control Plan ~~should~~ if the risk evaluation indicates two (2) or more etiologically confirmed, and epidemiologically linked *V.v.* ~~septicemia~~ illnesses from ~~the~~ consumption of commercially harvested ~~raw or undercooked~~ oysters that originated from the growing waters of that State within the previous ten (10) years **Section III. Public Health Reasons and Explanations Chapter IV. Shellstock Growing Areas @.01 Sanitary Survey** **A.** General. One of the goals of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times. Shellfish-borne infectious diseases are generally transmitted via a fecal-oral route. The pathway can become quite circuitous. The cycle usually begins with fecal contamination of the growing waters. Feces deposited on land surfaces can release pathogens into surface waters via runoff. Most freshwater streams eventually empty into an estuary where fecal bacteria and viruses may accumulate in sediment and subsequently can be re-suspended. Shellfish pump large quantities of water through their bodies during the normal feeding process. During this process the shellfish also concentrate microorganisms, which may include pathogenic microorganisms. Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct numerical correlation between the bacteriological quality of water and the degree of hazard to health. Investigations made from 1914 to 1925 by the States and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish

harvested from water in which not more than fifty (50) percent of the one (1) cc portions of water examined were positive for coliforms (an MPN of approximately seventy [70] per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not be revealed by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the United States, the NSSP was initiated by the States, the Public Health Service, and the shellfish industry. Water quality criteria were then stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli- aerogenes group of bacteria in one (1) cc dilution of the growing area water. Once the standards were adopted in the United States in 1925, reliance on this three-part standard for evaluating the safety of shellfish harvesting areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. Similar water quality criteria have been used in other countries with favorable results.

Nevertheless, some indicators and pathogens are capable of persisting in terrestrial soil, fresh and marine waters, and aquatic sediment for many days while others are even capable of growth external to a host. A small number of shellfish-borne illnesses have also been associated with bacteria of the genus Vibrio. The *Vibrio spp.* are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters.
Among the marine *Vibrio spp.* classified as pathogenic are strains of non-01 *Vibrio cholerae*, *V. parahaemolyticus*, and *V. vulnificus*. All three (3) species have been recovered from coastal waters in the United States and other parts of the world. These and other *Vibrio spp.* have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform.
In general, shellfish-borne Vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and *Vibrio* spp. counts were higher. *V. parahaemolyticus* and non-~~01~~O1 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish. In contrast, *V. vulnificus* has been related to ~~two (2) distinct syndromes:~~ wound infections, invasive disease usually characterized by bacteremia, and less commonly diarrheal illness associated with the consumption of seafood. ~~often with tissue necrosis and bacteremia, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy. Increasing e~~Evidence shows that individuals with such chronic diseases such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy are susceptible to ~~septicemia~~ severe illness and death from raw seafood, especially raw oysters. Shellfish-borne Vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60 °C or higher) or cold (4 °C or lower) temperatures. If oysters and other seafood are to be eaten raw, consumers are probably at lower risk to Vibrio infection during months when seawater is cold than when it is warm.

In addition to pathogenic microorganisms, poisonous or deleterious substances may enter shellfish growing areas via industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land or geochemical reactions. The potential public health hazard posed by these substances must also be considered in assessing the safety

of shellfish growing areas.

The primary responsibility of the Authority is to ensure the public health safety of the shellfish growing areas through compliance with the NSSP Model Ordinance. The Authority must perform a sanitary survey that collects and evaluates information concerning actual and potential pollution sources that may adversely affect the water quality in each growing area. Based on the sanitary survey information, the authority determines what use can be made of the shellstock from the growing area and assigns the growing area to one (1) of five (5) classifications. The survey information must be updated periodically to ensure that it remains current and must be readily accessible to both the Authority and the harvester. Experience has shown that the minimum sanitary survey components required in this chapter are necessary for a reliable sanitary survey. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2017).

ISSC Constitution, Bylaws & Procedures Procedure XVI. Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures

Section 1. Committee Charge

The *V.v.* Illness Review Committee will annually review all *V.v.* cases involving the consumption of shellfish which are reported to FDA regional specialists and the Center for Disease Control (CDC). The Committee will determine which cases meet the case definition of a National Shellfish Sanitation Program (NSSP) *V.v.* case as outlined in Model Ordinance Section II. Chapter II. @.05. All cases meeting the NSSP definition will be included in an annual report which will be presented to the Interstate Shellfish Sanitation Conference (ISSC) Executive Board and the Vibrio Management Committee. Following ISSC Executive Board approval the report will be made available to the ISSC membership and posted on the ISSC website. This data is expected to be used by USFDA, State Authorities, and the ISSC for the following purposes:

Subdivision a. Conducting annual *V.v.* Risk Evaluations;

Subdivision b. Risk per serving determinations;

Subdivision c. *V.v.* Control Plan Evaluations;

Subdivision d. *V.v.* Contingency Plan Evaluations; and

Subdivision e. Reviewing illness trends.

Section 2. Procedures.

Subdivision a. The Committee will only consider cases that are reported on a CDC and Prevention Cholera Vibrio Illness Surveillance Report (COVIS) Form CDC 52.79 or other means.

Subdivision b. FDA will coordinate the collection of cases and COVIS forms, and other information and after redacting identifying information will make this information available to the Committee.

Subdivision c. The information from the COVIS forms will be

shared with the *V.v.* Illness Review Committee for review.

Subdivision d. The *V.v.* Illness Review Committee will review the cases and incorporate the appropriate information into a chart which will serve as the Committee report.

Subdivision e. The report will be presented to the ISSC Executive Board for approval and then forwarded to the Vibrio Management Committee.

Subdivision f. The availability of the report will be announced to the ISSC membership.

A copy of the report will be posted on the ISSC website.

Section 3. Criteria and Guidelines.

The Committee will use the following criteria and guidelines in reviewing reported cases:

Subdivision a. Was the illness etiologically confirmed? In this context "etiologically confirmed "shall mean laboratory confirmation by wound, stool or blood culture. Confirmation may be by a laboratory otherthan a State laboratory."

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean "associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

Subdivision c. Were the shellfish consumed?

Subdivision d~~e~~. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in commerce. Commercial harvest will include those cases involving a foreign state.

~~Subdivision d. Were the shellfish raw or undercooked? If the victim developed *V.v.* septicemia after consumption the shellfish are considered to have been raw or undercooked.~~

Subdivision e. From what State was the shellfish harvested?

Subdivision f. ~~Did the case involve septicemia from consumption:~~

~~The following guidance will be used in determining if the case is a septicemia or a gastroenteritis case. Clinical signs and~~

		~~symptoms *V.v.* septicemia include:~~ A case of severe *V.v.* is defined as illness in a person who had V. vulnificus infection confirmed by bacterial culture and either of the following:	
		Subdivision i.	*V. vulnificus* was isolated from blood or a site that likely indicates invasive disease (see specimen source table).~~*V.v.* bacteria isolated from blood~~.
		Subdivision ii.	Any of the following were indicated on the COVIS case report form: 1. Fever 2. Septic Shock 3. Death Any of the following sequelae: necrosis; or invasive procedure, such as surgery, amputation, skin graft, wound debridement, fasciotomy, or incision and drainage~~Fever measured as above 100 degree Fahrenheit~~.
		~~Subdivision iii.~~	~~Death as outcome (septicemia has a mortality rate of over 50% - 70%).~~
		~~Subdivision iv.~~	~~Bullae (blood filled blisters) but this also can occur after a wound infection which becomes septic.~~
		~~Subdivision v.~~	~~Shock because of the sepsis (again this can happen also because of a wound infection).~~
	~~Subdivision g.~~	~~Indications case may not be *V.v.* septicemia from consumption:~~	
		~~Subdivision i.~~	~~Bacteria are only isolated from wound fluid or stool and no clinical evidence of septicemia.~~
		~~Subdivision ii.~~	~~Cellulitis. Since cellulitis is a localized or diffuse inflammation of connective tissue with severe inflammation of dermal and subcutaneous layers of the skin (bacteria entering bodies through the skin,~~

~~there might be a visible wound or just a small scratch), therefore more likely a wound infection.~~

~~Subdivision iii.~~ ~~History of pre-existing and sustained wound infection (If both wound and oyster/seafood consumption is documented and happened within the incubation period, there is no way to differentiate why the patient is septic.)~~

~~Subdivision iv.~~ ~~Septicemia has a much shorter incubation period compared to gastroenteritis, according to CDC data. *V.v.* septicemia has an incubation period between 12-72 hours, although we have seen cases with shorter incubation periods.~~

Section 4. Challenges to Committee Findings.
Persons wishing to challenge the information included in the report must notify the ISSC Executive Director within sixty (60) days of the posting of the report on the ISSC website. The ISSC Executive Board will review all challenges at the next scheduled Executive Board meeting.

Section 5. *V.v.* Case Appeal Procedure

Subdivision a. Appropriate V.v. information will be provided to the reporting and source States at least 60 days prior to committee review. The States will be given 30 days from the date of receipt to respond.

Subdivision b. Following V.v. Illness Review Committee review, each source State with a countable case will be notified.

Subdivision c. Should a source State disagree with the Committee determination on a specific case, the source State will be provided thirty (30) days to file an appeal.

Subdivision d. Should the Committee, based on the information provided by the appellant, conclude that the original determination should be reversed, the appellant will be notified.

Subdivision e. Should the Committee, based on the information provided by the appellant, conclude that the

original determination was appropriate; the Committee will provide the appellant an opportunity to state their position. This opportunity will be either by telephone conference call or in person. The choice of venue will be determined by the Committee and will not exceed fifteen (15) minutes.

Subdivision f. The Committee will consider information presented by the appellant in the oral presentation. The appellant will be notified of the final decision of the Committee.

Subdivision g. The appellant will receive a final decision from the Committee no more than 30 days after the date the appeal is submitted; if a decision can NOT be made after 30 days, then an appeal extension must be granted by the committee, or the appeal will be considered denied.

Table: Specimen sources that likely reflect invasive disease

ISSC *Vibrio vulnificus* Illness Review Criteria Table

Review Date: _____

Blood: Includes plasma and blood components
Vascular: Includes heart, heart valves, aorta, blood vessels
Lymphatic: Includes lymph, lymph nodes, thymus
Spleen: Includes spleen, splenic abscesses
Bone: Includes bone, bone marrow
Placenta and products of conception: Includes fetus, cord blood
Nervous system Cerebrospinal fluid (CSF) Other nervous tissue; includes brain abscess
Pleural fluid
Peritoneal fluid
Joint: includes synovial/joint fluid
Hepatobiliary: Gallbladder, bile, liver (includes abscesses)
Pancreas: Includes pancreas, pancreatic cysts, and abscesses
Reproductive: Ovary, fallopian tube, uterus (includes cysts and abscesses in these sites), pelvic abscesses, amniotic fluid
Kidney: Includes renal and perinephric abscess

Case Identifier/Number:	Criteria Status		
Criteria	Yes	No	Unknown
1. Etiologically Confirmed? ~~Blood Stool~~			

2. Epidemiologically Linked?				
3. ~~Septicemia~~ Severe Illness?				
4. Reporting State?				
5. Commercial Harvest?				
6. Were shellfish consumed?				
a. Specify shellfish consumed:		Oysters	Clams	Specify Other
b. Date of consumption: _____				
c. Is onset consistent with consumption of shellfish? Date of onset _____				
7. Trace-back Information				
a. Were shipping tags available? If other trace-back information reported, list:				
b. State of harvest, harvest area (s), and harvest date (list all reported).				

Harvest Area	Harvest State	Harvest Date	Species	Comment

Public Health Significance	Septicemia is an outdated term no longer commonly used in medicine or public health. An alternative strategy of considering only "severe" cases to reflect the magnitude of risk from food is problematic, because 1) the severity of an illness may depend on factors other than the food, such as the patient's age, underlying health conditions, access to healthcare, bacterial load ingested, and appropriateness of medical treatment, and 2) data collection practices, state resources, and availability of data can vary by geography and over time. This makes the reporting of "severe" cases potentially inconsistent.

	Surveillance data on method of preparation can be limited and subjective. Any oyster that transmits illness can be considered insufficiently cooked; consumers may not realize they have eaten an undercooked food. Counting all etiologically confirmed cases associated with consumption of commercially harvested oysters is the most clear and consistent measure of *V. vulnificus* illness risk to the public.
Cost Information	NA
Action by 2019 Task Force II	Recommends to referral of Proposal 19-241 to the appropriate committee as directed by the Conference Chair.

Submitter	Steve Fleetwood
Affiliation	Bivalve Packing Company
Address Line 1	6957 Miller Ave
Address Line 2	
City, State, Zip	Port Norris, NJ 08349
Phone	856-785-0270
Fax	856-785-1406
Email	eastpointoysters@aol.com
Proposal Subject	Vv Illness Reporting
Specific NSSP Guide Reference	Not Applicable
Text of Proposal/ Requested Action	The CDC reported 493 *Vibrio vulnificus* cases for the years 2011-2014. The 493 cases resulted in 407 hospitalizations and 121 deaths. Although most illnesses are associated with persons at high risk, the outcomes are very severe. To address the illnesses associated with the consumption of raw or undercooked molluscan shellfish, the ISSC adopted control measures in an attempt to minimize *V.v.* cases associated with shellfish. Additionally the ISSC, FDA, states and the industry have developed and participated in education programs to inform at risk individuals of the risk of vibrio illness. This proposal is being presented to request the ISSC and FDA encourage the CDC and state epidemiologist to amend the current COVIS form to include a field to be used to determine if individuals who have contracted illnesses are aware of *V.v.* and the risk of illness posed to at risk individuals.
Public Health Significance	The inclusion of this request on the COVIS form would provide public health officials with information to determine if additional education programs should be developed to advise at risk consumers of all types of *V.v.* exposures.
Cost Information	N/A
Action by 2019 Task Force II	Recommends referral of Proposal 19-242 to the appropriate committee as appointed by the Conference Chair with additional instructions to encourage the conference to continue to address education efforts and specifically to consider target audiences and a needs assessment and potentially develop a data collection tool to determine existing knowledge of at risk individuals associated with *Vibriosis* illnesses.

Submitter	Steve Fleetwood
Affiliation	Bivalve Packing Company
Address Line 1	6957 Miller Ave
Address Line 2	
City, State, Zip	Port Norris, NJ 08349
Phone	856-785-0270
Fax	856-785-1406
Email	eastpointoysters@aol.com
Proposal Subject	Vp Illness Reporting
Specific NSSP Guide Reference	Not Applicable
Text of Proposal/ Requested Action	For the past several years, the CDC has reported increased *Vibrio parahaemolyticus* cases. To address the illnesses associated with the consumption of raw or undercooked molluscan shellfish, the ISSC has adopted control measures in an attempt to minimize *V.p.* cases associated with shellfish. Additionally the ISSC, FDA, states and the industry have developed and participated in education programs. This proposal is being presented to request the ISSC and FDA encourage the CDC and state epidemiologist to amend the current COVIS form to include a field to be used to determine if individuals who have contracted *V.p. have* illness conditions or are taking medications that place them at a higher risk of contracting *V.p*
Public Health Significance	The inclusion of this request on the COVIS form would provide public health officials with information to determine if additional education programs should be developed to advise consumers of *V.p.* risk.
Cost Information	N/A
Action by 2019 Task Force II	Recommends no action on Proposal 19-243. Rationale: Proposal is adequately covered by Proposal 19-242.

Submitter	Catalina Sea Ranch, LLC (CSR)
Affiliation	Catalina Sea Ranch, LLC (CSR)
Address Line 1	2303 S. Signal street, Berth 58
City, State, Zip	San Pedro, CA 90731
Phone	844-922-8254
Email	maria@catalinasearanch.com
Proposal Subject	Update the Protocol for Marine Biotoxin Control
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.04 B.
Text of Proposal/ Requested Action	**@.04 Marine Biotoxin Control** B. Marine Biotoxin Management Plan. In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton are known to occur and the toxins are prone to accumulate in shellfish, and when appropriate at those times when marine biotoxins can be reasonably predicted to occur, representative samples of the water may be collected and shellfish shall be collected during harvest periods. The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples may be assayed for the presence of toxin-producing phytoplankton and shellfish meat samples shall be assayed for the presence of toxins. **NOTE:** In situations in which the toxin of concern has an established cell count standard, such as *Karenia brevis,* water and shellfish samples would not be required. Management decisions could be made on either water or shellfish sampling results. (1) The Authority shall develop and adopt a marine biotoxin management plan for all marine and estuarine shellfish growing areas if there is a history of biotoxin closures related to PSP, ASP, NSP, DSP, or AZP; if toxin-producing phytoplankton are known to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur. (2) For Federal waters harvesters, each company is considered an Authority and must develop and adopt their own plan. (~~2~~3) The plan shall… (~~3~~4) The Authority may… (~~4~~5) Except that the… (~~5~~6) The plan may… (~~6~~7) Prior to allowing…
Public Health Significance	This proposal would expand the definition of Authority to include harvesters in the definition of Authority.
Cost Information	
Action by 2019 Task Force II	Recommends no action on Proposal 19-152. Rationale: This proposal was addressed by Task Force action on Proposal 19-203.