ISSC Task Force II
2023 Proposal Inventory

Proposal No. 15-226

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

Submitter	Executive Office
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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	Recommended 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	Recommended referral of Proposal 15-226 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 15-226.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 15-226.

Proposal No. **17-206**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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Proposal Subject	Shellfish Illness Response Associated with *Vibrio parahaemolyticus* (*V.p.*)
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *V.p.*
Text of Proposal/ Requested Action	A. When ~~the investigation outlined~~ shellfish are implicated in ~~Section @.01 A. indicates the~~ illness(es) ~~are~~ associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine ~~the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows~~ whether an epidemiological association exists between the illness(es) and shellfish consumption by reviewing:. (1) Each consumer's food history; (2) Shellfish handling practices by the consumer and/or retailer. B. When the Authority has determined an epidemiological association between *V.p.* illness(es) and shellfish, including illnesses described as sporadic, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and span of time as follows: (1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) ~~but not more than four (4)~~ cases occurring within a ~~thirty (30)~~seven (7) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. ~~The Authority will make reasonable attempts to ensure~~ and evaluate compliance with the ~~existing~~ State Vibrio Control ~~Management~~ Plan. If at least two (2) cases occur from a single harvest day, the Authority shall refer to @.02 B. (3). (2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed ~~four (4)~~two (2) but not more than ~~ten (10)~~four (4) over a ~~thirty (30) day~~ time period greater than seven (7) but less than thirty (30) days, from the implicated area ~~or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area,~~ the Authority shall: (a) Determine the extent of the implicated area; and (b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and (c) As soon as determined by the Authority, transmit to the FDA and

receiving States information identifying the dealers shipping the implicated shellfish.

(3) When the number of cases exceeds ~~ten (10)~~ (four (4) illnesses within a thirty (30) day period or two (2) illnesses within a seven (7) day period from the implicated area ~~or four (4) or more cases occurred from a single harvest date from the implicated area~~, ~~T~~the Authority shall:

~~(a)~~ Determine the extent of the implicated area; and

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

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

(~~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	Recommended: 1) the language of proposal 17-206 be replaced with substitute language presented by FDA (included below) for the purpose of referral to an appropriate committee **Section II. Model Ordinance** **Chapter II. Risk Assessment and Risk Management** **@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*** **@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)***

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

Proposal No. 17-225

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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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	Recommended 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	Recommended 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.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 17-225.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-225.

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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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	Recommended adoption of Proposal 19-200 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-200.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-200.

Proposal No. 19-202

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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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	Recommended 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.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-202.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-202.

Proposal No. 19-215

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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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	Recommended referral of Proposal 19-215 to an appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-215.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-215.

Proposal No. 19-220

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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
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Address Line 2	205 North Belle Mead Road, Suite 1
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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	Recommended referral of Proposal 19-220 to an appropriate committee as determined by the Conference Chair.

Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-220.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-220.

Proposal No. 19-222

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

Submitter	Susan Ritchie, New York State Department of Environmental Conservation Alissa Dragan, Connecticut Department of Agriculture
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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	Recommended referral of Proposal 19-222 to an appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-222.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-222.

Proposal No. 19-223

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
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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	Recommended adoption of 19-223 as submitted and Recommended 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.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-223.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-223.

Proposal No. 19-227

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
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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	Recommended referral of Proposal 19-227 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-227.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-227.

Proposal No. 19-229

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
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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	Recommended adoption of 19-229 as amended. Section II. Model Ordinance Chapter XI. ~~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.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-229.
Action by FDA February 21, 2020	FDA concurs with Conference Action on Proposal 19-229.
Action by 2022 Federal Waters Committee	Recommend adoption of the following language: .06 FEDERAL WATERS GUIDANCE I. INTRODUCTION Requirements for Federal waters shellfish harvesters, dealers, the State of Landing Authority and FDA and NOAA are listed in multiple sections throughout the NSSP Model Ordinance. The following guidance provides additional information to assist in meeting these requirements.

II. HARVESTER REQUIREMENTS

A. HARVESTER LICENSING AND TRACEABILITY

The Food and Drug Administration (FDA) and the National Oceanographic Atmospheric Administration (NOAA) are the federal agencies responsible for shellfish growing areas and harvest control in Federal waters. The State of Landing Authority, through agreements and in coordination with the FDA and NOAA, may also take the lead and/or take on responsibilities in the management, control of harvest, and/or marine biotoxin control associated with commercial shellfish harvested from Federal waters and landed in their state.

The NOAA Seafood Inspection Program (SIP) is the primary contact for all commercial shellfish harvesting activities in Federal waters. This does not supersede the harvester's responsibilities to contact other federal agencies related to federal fisheries permits and aquaculture siting permits.

To meet the requirement in the NSSP MO, Chapter VIII .03A. for Federal waters, the NOAA SIP utilizes the NOAA SIP contract that serves as the mechanism for the control of harvest and traceability for all commercial shellfish grown and harvested from Federal waters. It is the responsibility of shellfish harvesters to contact the NOAA SIP to obtain a NOAA SIP contract, which is the identified mechanism for authorizing harvesters to land shellfish harvested from Federal waters at a state certified dealer. The NOAA SIP contract also provides the unique identifier number that will be used on Federal waters shellfish harvester tags.

The NOAA SIP contract application process requires that the harvester provide their contact information as well as the intended Federal waters harvest and/or aquaculture site location information to the NOAA SIP. Harvester contact information will be used to contact each harvester in the event of an emergency closure (e.g., oil spill, hurricane, severe storm, chemical spill, WWTP spill, or ship discharge) and reopening, status change, classification change, and/or product recall.

The NOAA SIP will generate and maintain a NOAA SIP Contract Harvester List which can be accessed through the Interstate Shellfish Sanitation Conference (ISSC) website for reference. The NOAA SIP will coordinate with the FDA regarding meeting the requirements related to the growing area classification, control of harvest, and marine biotoxin control of the intended area of harvest as well as shellfish aquaculture operation and initial siting evaluation.

B. FEDERAL WATERS SHELLFISH CLASSIFICATION

The FDA is responsible for the classification of Federal waters shellfish growing areas (NSSP MO, Section II, Chapter IV @.03 F.). Federal waters are considered generally free from bacterial and chemical pollution and are therefore classified as approved for shellfish harvesting unless such areas are known to be polluted and involve commercial shellfish resources (Verber, 1977). Areas known to be polluted or are considered potential sources of pollution in Federal waters may include but are not limited to ocean dump sites designated for the disposal of contaminated wastes, areas where major estuarine complexes discharge large quantities of sewage

effluents or other contaminants, wastewater treatment plant effluent pipes, commercial shipping channels and anchorages, and oil platforms.

When applying for the NOAA SIP contract, the harvester will provide the intended harvest location(s) to the NOAA SIP using either the 10-minute latitude and longitude grid number(s), the NOAA National Marine Fisheries Statistical grid, or the latitude(s) and longitude(s). The NOAA SIP will coordinate and provide the FDA with the intended harvest site location(s).

For shellfish harvest areas of concern, the FDA will conduct a site-specific sanitary survey in accordance with NSSP MO, Chapter IV. @.01. Once the sanitary survey is completed, the FDA will coordinate with the NOAA SIP to notify the harvester of the sanitary survey findings, any growing area classification and/or status change, and if warranted, any microbiological and/or biotoxin monitoring requirements.

C. MARINE BIOTOXINS

To meet the NSSP MO, Chapter IV. @.04 requirements, once the harvester notifies the NOAA SIP of the intended harvest location(s) in Federal waters, through coordination with the NOAA SIP, the FDA will review available data and determine if marine biotoxins are of concern and which marine biotoxin requirements apply to the harvester for the intended harvest and/or aquaculture site locations. The harvester will then be notified by the NOAA SIP of any marine biotoxin requirements.

If the harvester is harvesting from a location in Federal waters where the associated State of Landing Authority has agreed to be responsible for marine biotoxin control, the harvester must abide by the State of Landing Authority marine biotoxin contingency plan and if applicable, marine biotoxin management plan.

i. MARINE BIOTOXIN CONTINGENCY PLAN

To meet the NSSP MO, Chapter IV. @.04 A. requirements, as a default, each harvester will abide by the FDA/NOAA SIP Marine Biotoxin Contingency Plan that addresses the management of paralytic shellfish poisoning (PSP), amnesic shellfish poisoning (ASP), neurotoxic shellfish poisoning (NSP), diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (AZP) in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred, or an illness outbreak caused by marine biotoxins.

If applicable, in the case where the State of Landing Authority chooses to be responsible for the control of marine biotoxins in Federal waters, the harvester will follow the State of Landing marine biotoxin contingency plan. The FDA will review the Federal waters component in the State of Landing Authority's marine biotoxin contingency plan during the state program growing area evaluation process.

ii. MARINE BIOTOXIN MANAGEMENT PLAN

To meet the NSSP MO, Chapter IV. @.04 B. requirements (and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans), the FDA and NOAA SIP will work with other federal and associated state agencies as well as the shellfish industry to

collect and review all available data to assist in identifying and delineating shellfish growing areas in Federal waters that meet(s) the criteria and requirement for a marine biotoxin management plan. If harvesting in these designated areas, each harvester must utilize the FDA/NOAA SIP Marine Biotoxin Management Plan template and specify and abide by the marine biotoxin management strategy(ies) of choice, intended state of landing, and the laboratory to be used for marine biotoxin sample analysis.

In the case where the State of Landing Authority has agreed to be responsible for the management of biotoxins and/or has an established a biotoxin management strategy(ies) for shellfish landed in their state from Federal waters, each harvester must coordinate with the State of Landing Authority to meet the marine biotoxin management plan requirements.

In coordination with the NOAA SIP, the FDA will review all harvester marine biotoxin management plans for compliance with NSSP MO, Chapter IV. @.04 B. For marine biotoxin management plans associated with Federal waters managed by the State of Landing Authority, the FDA will evaluate these management plans during the State of Landing growing area program evaluation.

In addition, to meet the requirements for marine biotoxin management strategies that include shellfish lot testing or pre-harvest shellfish toxicity screening coupled with lot testing [NSSP MO, Chapter IV. @.04 B.(4)(d) & (e) and (5)] and allow the landing of shellfish harvested in a growing area that is placed in the controlled access status, the harvester will be required to enter into an agreement or memoranda of understanding (MOU) between the State of Landing Authority, individual growers, individual shellfish dealers, and NOAA SIP. At a minimum, the agreement or MOU should reference the marine biotoxin management plan and include language indicating that all signatories agree with and will abide by the marine biotoxin management plan. The FDA and NOAA SIP will review the agreement or MOU for NSSP compliance.

To meet the restricted tag requirement of the NSSP MO, Chapter IV. @.04 C. (7), all shellstock harvested from growing areas in the controlled access status shall be tagged with restricted shellstock tags. Information included on the restricted shellstock tag should include specific details defining the restriction.

iii. LABORATORY REQUIREMENTS FOR SAMPLE ANALYSES

To meet the laboratory requirements for the analysis of regulatory samples from Federal waters, the harvester will be responsible for identifying and using a laboratory with an operational status of conforming or provisionally conforming to the requirements set forth by the NSSP and implement NSSP approved and/or approved limited use method for fecal coliform and marine biotoxin analysis. For guidance on available laboratories, the harvester may refer to the Interstate Shellfish Sanitation Conference (ISSC) website for the Domestic NSSP Laboratory List (https://www.issc.org/laboratory-1).

D. VIBRIO RISK ASSESSMENT & TIME/TEMPERATURE CONTROL

The harvester is responsible for meeting the requirements in the NSSP MO, Chapter VIII. @.02 & Chapter II. @.06 & @.07. To meet this requirement, the harvester must

meet the time to temperature matrix found in the NSSP MO, Chapter VIII. @.02 A. (3) or if the risk of Vibrio Parahaemolyticus or Vibrio Vulnificus illness has been determined to be reasonably likely to occur, then they must meet the defined Vibrio Control Plan for the area.

E. HARVESTER TRAINING

To meet the NSSP MO, Chapter VIII. .01 B. harvester training requirement, each harvester will be provided an electronic harvester training document during the application process for the NOAA SIP contract.

F. SHELLFISH AQUACULTURE OPERATIONAL PLAN

Per the NSSP MO, Chapter VI .07 B., each Federal waters shellfish aquaculture site is required to develop and maintain a site-specific Operational Plan. During the NOAA SIP contract application process, each Operational Plan will be provided to the NOAA SIP by the harvester for review by the FDA and NOAA SIP to ensure that it meets the NSSP requirements. The Operational Plan must at a minimum, include all items from the NSSP MO, Chapter VI. .05 A. and Chapter VI. .07 B.

G. FINALIZE NOAA SIP CONTRACT

Once all the harvester requirements have been reviewed and found to conform with the NSSP MO by the FDA and NOAA SIP, the NOAA SIP contract may be finalized with signatures, an effective date, and the contract number assigned by NOAA SIP to be used as the shellfish harvester's tag number. The finalized NOAA SIP contract will be added to the NOAA SIP Contract Harvester List located on the ISSC website.

III. DEALER REQUIREMENTS

To meet the requirement for state shellfish dealers listed on the Interstate Certified Shellfish Shippers List (ICSSL) List to only accept shellfish harvested from Federal waters from a harvester with a NOAA SIP contract, the dealer may go to the ISSC website and review the NOAA SIP Contract Harvester List to verify that a Federal waters harvester has a valid NOAA SIP contract.

When receiving shellstock harvested from Federal waters in the controlled access status, the dealer must agree to be a signatory to an agreement or MOU to abide by the marine biotoxin management plan. In addition, the biotoxin management plan will include specific language detailing the use of the restricted shellstock tag(s) as well as restrictions that require further processing and testing prior to the distribution of the shellstock into commerce.

IV. REFERENCES/SOURCES/LINKS

- Verber, 1977, Classification of Offshore Waters, James L. Verber
- NOAA SIP CONTRACT:
  - NOAA SIP Contract information:
    TBD Website: https://www.fisheries.noaa.gov/resource/document/us-department-commerce-approved-establishments
  - HARVESTER CONTRACT LIST: Discuss about adding this list to the ICSSL as well. It can just be a one-stop shop, as opposed to dealers and

	harvesters going to multiple sites for different things. • Link to state of landing shellfish contacts: https://www.cfsanappsexternal.fda.gov/scripts/shellfish/sh/shellfish.cfm#state • FDA/NOAA SIP MARINE BIOTOXIN CONTINGENCY and MANAGEMENT PLAN o Link: TBD • NSSP Conforming Laboratories, ISSC Website: https://www.issc.org/laboratory-1

Proposal No. 19-231

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

Submitter	Blake Millett / Jon Strauss
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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	Recommended referral of Proposal 19-231 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-231.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-231.

Proposal No. 19-240

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

Submitter	Bill Dewey
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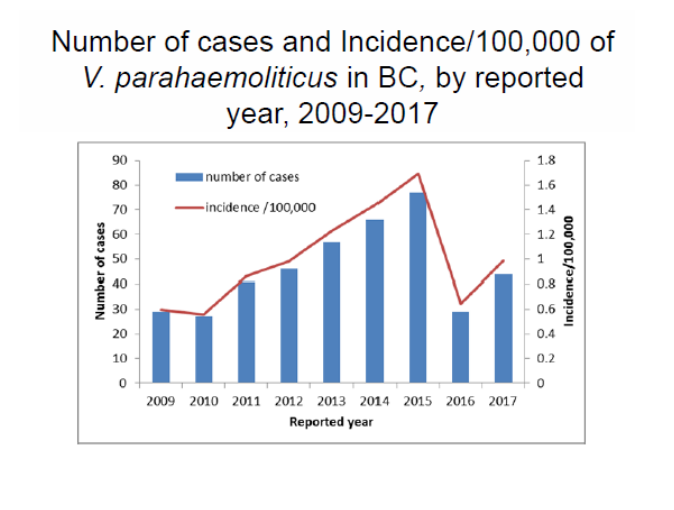
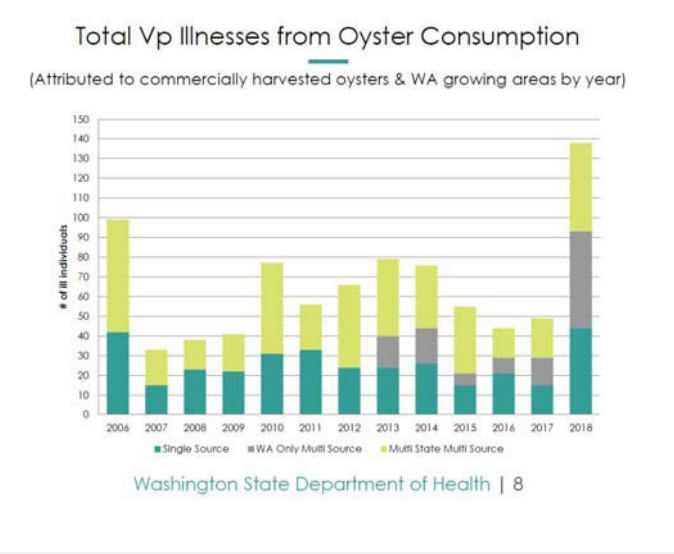
Proposal Subject	Alternative for allowing harvest for raw consumption from a growing area closed due to *V.p.*
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*), 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	Recommended referral of Proposal 19-240 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-240.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-240.

Proposal No. 19-241

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

Submitter	Centers for Disease Control and Prevention (CDC)
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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	Recommended to referral of Proposal 19-241 to the appropriate committee as directed by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-241.
Action by FDA February 21, 2020	FDA concurred with the Conference's action to refer Proposal 19-241 to committee. FDA would like to encourage the Conference Chair to direct the Vv Illness Review (VvIR) committee to begin discussions on proposal 19-241 as soon as possible. Identification of more appropriate metrics to assign Vibrio vulnificus (Vv) cases will greatly facilitate the VvlR committee's standing charge. The ISSC with FDA concurrence has opted not to accept each Vv case that is reported but to critique the merits to determine if each case is indeed septicemia from a commercial oyster consumption illness. As the uses of Vv data have changed over the life of the committee, this metric has become less useful. Ifthe committee is to continue to be useful in their role, each case must be deliberated in a standardized manner, not by examining for septicemia, but determining if each case meets a clinical definition. FDA supports this CDC drafted proposal intended to eliminate the septicemia qualification from Procedure XVI when case counting for Vv illness review. The suggested new metric to be used would be severe illness in the form of bacteremia, not blood infection. The proposal language includes cooked oysters and eliminates the question of how well the oysters are cooked. Additionally, the language considers only clinical symptoms such as fever, shock, listed sequelae or death. This proposal includes a table of specimen sources likely to indicate invasive disease rather than discounting stool or wound specimens.

Proposal No. **23-200**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Definition of Harvest
Specific NSSP Guide Reference	Section I Definitions (52) Harvest
Text of Proposal/ Requested Action	(52) Harvest means the act of (1) placing shellstock on or in a container which remains at the harvest site for sale to a dealer or (2) removing shellstock from a harvest site for sale or wet storage .
Public Health Significance	Currently, some operations gather **shellstock** and place it in bags, totes or cages and that **shellstock** is then sold, on-site, to a **dealer** who is either better equipped to move large quantities of **shellstock**, or who simply prefers to conduct business this way. Whatever the reason, since the current definition of **harvest** requires both placement on or in a **conveyance** AND removal from a **growing area**, technically, in the example above, **harvest** has not occurred. Other terms such as **growing area**, have intentionally not been used here because they are problematic. A **growing area**, for example, can be huge. If **shellstock** is merely moved up or down the beach to a stand, for sale to the public, it has never left the **growing area**, and thus technically, has never been **harveste**d. And if removal from the water is the criterion for removal from a **growing area**, **shellstock** is often gathered after or as the tide recedes, and thus the **shellstock** has already left the **growing area** at a low tide. This proposed definition change solves the problem outlined in the example above, removes some ambiguity and should not impose new regulations on approved, existing operations.
Cost Information	There should be no increased costs associated with this change as it is intended to merely clarify what is already occurring.

Proposal No. **23-201**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Inspection Frequency/Inspection Report
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority @.02 Dealer Certification (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~~ triannually for dealer's activities certified as shucker-packer or repacker; and (iv) At least semiannually for other dealer activities or annually for seasonal other dealer activities that are only certified for 6 months or less. (2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation ~~at the~~ within a reasonable time of completing ~~time of~~ the 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. (3) The plant inspection shall be conducted by the SSO or SSI using the appropriate inspection form.
Public Health Significance	Many shucker-packer or repacker operations operate on a seasonal basis. In most instances, the third and fourth inspections at these facilities are when the firm is not operating at all or is only operating as a shipper and not a shucker-packer or repacker. By reducing the minimum inspection frequency to once every 4 months from once every 3 months, this will allow state Authorities to focus limited resources where they are most valuable without jeopardizing public health. Currently the FDA inspects high priority food manufacturing plants once every three years. This proposal still has a shucker-packer or repacker being minimally inspected at a rate 9 times that frequency. This proposal also clarifies that a firm that is only certified for 6 months or less will minimally be inspected once per year. Without this clarification, state Authories are expected to inspect these firms twice during the 6 month period that they are certified each year. This proposal also would allow for the inspection report to be provided to the dealer by email

	once the report is completed because many states now use electronic inspection reports and are no longer hand writing the inspections.
Cost Information	No cost

Proposal No. 23-202

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Sampling for reopening following *Vp* illness closure
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 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) Shall follow the procedure outlined in Chapter II @ .02 (10)(a) for closures resulting from V.p. illnesses. (45) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific. G. When the growing area is… @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)* A… (10) Prior to reopening an area closed as a result of @.02 A. (9)(a) or (b) ~~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. (i) Samples shall be collected to be representative of the growing area, harvest/culture practices, and shellfish types. (ii) Multiple sample collection events shall span the closure time period in @.02 A. (9)(a) or (b) and be collected at intervals necessary to determine trends in the implicated harvest area. (b) Ensure that environmental conditions have returned to levels not associated with V.p. cases. (11) Shellfish harvesting may…
Public Health Significance	Following growing area closures due to *Vibrio parahaemolyticus* illnesses, it is essential to ensuring public health that the Program has confidence that the risk of illness from product has subsided. A representative and robust reopening sampling approach is critical to providing that confidence. The proposed language is intended to provide general recommendations for these sampling approaches.
Cost Information	Dependent on the number of samples collected.

Proposal No. **23-203**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Commingling in Wet Storage
Specific NSSP Guide Reference	Section II Model Ordinance, Ch. VII. Wet Storage in Approved and Conditionally Approved Growing Areas: @.03 Wet Storage Sites in Natural Bodies of Water (Offshore) C. @.04 Wet Storage in Artificial Bodies of Water (Land-Based) D.(2)
Text of Proposal/ Requested Action	@.03 Wet Storage Sites in Natural Bodies of Water (Offshore) C.: ~~C. Different lots of shellstock shall not be commingled in wet storage. If more than one (1) lot of shellstock is held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.~~ @.04 Wet Storage in Artificial Bodies of Water (Land-Based) D.(2): ~~(2) Unless the dealer is in the Authority's commingling plan under Chapter I. @.01 G., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one (1) lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.~~
Public Health Significance	Deletion of the commingling sections in .03 and .04 will not impact in any way the ability for a state to allow commingling under their Commingling Plan. This simply clarifies what is already allowed under the .02 General section H. The proposed strikethrough language was an omission when the original language for Wet Storage in Artificial Bodies of Water was added, or when Commingling became permissible. This proposal is simply correcting and mirroring language already used in the Chapter under @.04 Wet Storage in Artificial Bodies of Water (Land-Based) D. Shellstock Handling (2) "Unless the dealer is in the Authority's commingling plan under Chapter I. @.01 G., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one (1) lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained." This is redundant language and already provided in @.02 General allowing for commingling under the Authority's commingling plan.
Cost Information	N/A

Proposal No. **23-204**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Proposal for Clarifying Wet Storage Holding Temperatures for Shipped Shellstock
Specific NSSP Guide Reference	Chapter XIII. Shellstock Shipping .01 Critical Control Points (A) (2)(d) and (B)(2)(b)
Text of Proposal/ Requested Action	Under the current language in the Model Ordinance, shellstock shipped to another approved dealer, must be held under 45F. Per Chapter XIII. .01 B. (2) (b); "…be placed in a storage area or conveyance maintained at 45 F or less. Additionally, per Chapter XIII. .01 A (2) (d) "Shipped the shellstock in a conveyance at or below 45 F ambient air temperature; and (e) Cooled the shellstock to an internal temperature of 50F". It seems the primary concern in holding pre-chilled shellstock is an internal temperature of less than 50F. However, these rules are written under the language of Cold Storage, or chilled conveyances, this language does not consider validated artificial wet storage systems. To maintain an internal temperature of less than 50 F in Cold Storage, the temperature of the cold storage system must be set to less than 45 as the difference between the chiller and the internal temperature will vary by a few degrees. In an artificial wet storage system, the temperature of the chiller and the internal temperature of the animal will vary by ~1 degree. So, in theory you are not permanently raising the holding temperature of pre-chilled shellstock by putting them in wet storage of 50 F or less. Local authority has been clear to our company that holding temperatures of shipped shellstock must be held at 45 F or less, as to match the temperature of the conveyance it was shipped on. We are requesting guidance documents or language changes to Chapter XIII. .01 B that would allow pre chilled shipped shellstock to be held in a validated Wet Storage system at 50 F or less.
Public Health Significance	Maintaining the internal temperature of shipped shellstock within a wet storage system.
Cost Information	No cost to authorities, potentially significant cost savings to shippers with energy savings.

Proposal No. **23-205**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Recirculating Wet Storage Water Quality Threshold
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas Section .04 Wet Storage in Artificial Bodies of Water (Land-Based) C.Wet Storage Source Water (1) General. (3) Recirculating Water System. Section IV Guidance Documents – Chapter III. Harvesting, Handling, Processing, and Distribution .05 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body
Text of Proposal/ Requested Action	Section II Model Ordinance – Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas Section .04 Wet Storage in Artificial Bodies of Water (Land-Based) C.Wet Storage Source Water (1) General. (f) Disinfected process water entering the wet storage tanks shall have ~~no detectable levels~~ less than or equal to 2 cfu/100ml of the coliform group as measured by an approved NSSP method appropriate for UV process water and follow the protocol of the Decision Tree (Section IV. Guidance Documents Chapter III. .05) (g) When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows ~~any~~ a ~~positive~~ result above 2 cfu/100ml for the coliform group daily sampling shall be immediately instituted until the problem is identified and eliminated. (h) When the problem that is causing disinfected process water to show positive results above 2 cfu/100ml for the coliform group is eliminated, the effectiveness of the correction shall be verified on the first operating day following correction through the collection, over a twenty-four (24) hour period, of a set of three (3) samples of disinfected process water. (3) Recirculating Water System. (b) Once sanctioned for use, the recirculating process water system shall be sampled weekly to demonstrate that the disinfected water is ~~negative~~ less than or equal to 2 cfu/100ml for the coliform group. (c) The dealer shall inspect and/or clean the system if a weekly sample tests positive for the coliform group, but is less than or equal to 2 cfu/100ml.

	~~(c)~~ (d)When make-up water of more than ten (10) percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three (3) samples of disinfected water and one (1) sample of the source water prior to disinfection shall be collected over a twenty-four (24) hour period to reaffirm the ability of the system to produce process water with less than or equal to 2 cfu/100ml for the coliform group ~~free from the coliform group or viable bacteria~~. ~~(d)~~ (e)When ultra-violet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be collected and analyzed. Section IV Guidance Documents – Chapter III. Harvesting, Handling, Processing, and Distribution .05 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body If the water sample is ~~positive~~ above 2 cfu/100ml for coliforms in the recirculating system, institute daily sampling.
Public Health Significance	The NSSP regulations for wet storage allow for flow through systems in approved waters without disinfection. However, recirculating wet storage systems in the US currently need to meet a zero coliform threshold for weekly process water tests to meet NSSP regulations. When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows any positive result for the coliform group, daily sampling must be immediately instituted until the problem is identified and eliminated. This is a significant burden on the industry and the shellfish laboratories. This proposal would change the trigger for daily testing to samples that exceed 2 cfu/100ml. This does not reduce public health protections and requires the dealer to inspect and/or clean the system if a sample comes back positive but less than or equal to 2 cfu/100ml. This proposal does not eliminate~~eleiminte~~ the need for the system to be initially verified by testing negative for the coliform group under normal operating conditions. Justification for this proposal is partly based on the Canadian recirculating~~recirulating~~ wet storage process water quality threshold of ≤ 2cfu/100ml which is found in the Canadian Shellfish Sanitation Program manual.
Cost Information	This proposal will result in significant cost savings for the dealers in collecting and shipping daily samples as well as the laboratory in processing unnecessary samples when 2 or less cfu/100ml is observed in process waters.

Proposal No. **23-206**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Wet Storage Sampling Requirements
Specific NSSP Guide Reference	Section II Model Ordinance~~Odrinance~~. Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas. .04 (C)(3) Recirculating Water System
Text of Proposal/ Requested Action	(3) Recirculating Water System. (a) A study shall be required to demonstrate that disinfection for the recirculating system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in Section C. (2) (b) above. (b) Once sanctioned for use, the recirculating process water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group. (c) If the recirculating process water system passes (20) consecutive weekly samples, monthly sampling can be initiated. If a monthly sample fails, weekly sampling will resume until twenty (20) consecutive weekly samples demonstrate that the disinfected water is negative for the coliform group. (d) If the recirculating process water system passes twelve (12) consecutive monthly samples. Quarterly sampling can be initiated. If a quarterly sample fails, weekly sampling will resume until twenty (20) consecutive weekly samples demonstrate that the disinfected water is negative for the coliform group. (e) When make-up water of more than ten (10) percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three (3) samples of disinfected water and one (1) sample of the source water prior to disinfection shall be collected over a twenty-four (24) hour period to reaffirm the ability of the system to produce process water free from the coliform group or viable bacteria. ~~(c)~~(f) When ultraviolet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be collected and analyzed.
Public Health Significance	Many wet storage facilities only operate a few days a week and may only have shellfish products in the wet storage system for a few hours, with potentially different products in the system on a daily basis. Weekly sampling for these recirculating systems is excessive and does not provide an accurate accounting as to whether a facility is going to have a sample failure. We propose a tiered sampling system for facilities that have a history of passing water samples and accounts for what to do when a sample does fail for Total Coliform.

Cost Information	There is significant cost to the shellfish wet storage facilities to overnight samples to a certified lab, in addition to the cost for the sampling and shipping supplies. Additionally, extra costs are incurred by the certified laboratories that have to run more samples.

Proposal No. **23-207**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Repacking Shellstock without a Dealer Facility
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping
Text of Proposal/ Requested Action	F. Shellfish Storage and Handling. (1)… (2)… (3) A dealer whose activity consists of trucks or docking facilities only shall: (a) Have a permanent business address at which records are maintained and inspections can be performed.~~; and~~ [K] ~~(b) Not repack shellstock. [K]~~ (4) A dealer who stores ~~or repacks~~ shellstock shall have: (a) His own facility for proper storage ~~or repacking~~ of shellstock; or [K] (b) Arrangements with a facility approved by the Authority of the storage ~~or repacking~~ of shellstock. [K] (5) Repacking of shellstock shall be conducted under overhead cover on a clean surface meeting the requirements of Chapter XIII. .03 E. (~~5~~6)…
Public Health Significance	There is no public health significance of a Shellstock Shipper repacking shellstock without a facility, as long as proper sanitation controls are put into place. Currently, the exception at the beginning of Chapter XIII states that "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 a building." However, .03 F. requires that a dealer who repacks shellstock have a facility. This makes it appear that the exception does not apply to dealers who repack shellstock. Many states certify dealers without facilities, who may transport shellstock in refrigerated trucks or in coolers with ice. Many dealers without facilities have need to repack minimal amounts of shellstock (for example, if shellstock are harvested in bushel containers but a customer wants only a half bushel). Therefore, it is probable that many states could be out of compliance with this requirement as it is currently written. There is no public health reason why dealers without a facility should not be able to quickly transfer shellstock into different containers, if it is done under overhead cover and on an appropriate surface. Other requirements in Chapter XIII ensure that shellstock will be protected from contamination and temperature abuse during this action.
Cost Information	None.

Proposal No. **23-208**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting

☐ Growing Area
☒ Harvesting/Handling/Distribution
☐ Administrative

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Proposal Subject	Shellstock Time to Temperature Controls
Specific NSSP Guide Reference	Section II Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls.

Text of Proposal/ Requested Action

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:

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

Action Level	Water Temperature	Maximum Hours from Exposure to Temperature Control
Level 1	< 65 °F (10 °C)	36 hours
Level 2	65 °F - 74 °F (18 °C - 23 °C)	18 hours
Level 3	> 74 °F - 84 °F (> 23 °C - 28 °C)	16 hours
Level 4	> 84 °F (≥ 28 °C)	14 hours

Public Health Significance	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)
Cost Information	None

Proposal No. **23-209**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Waivers from Vp & Vp control plans for Authority approved pathogen reduction processes
Specific NSSP Guide Reference	Chapter VIII Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls I. (page 80)
Text of Proposal/ Requested Action	I. Shellstock intended for a validated pathogen reduction process or other pathogen reduction process approved by the Authority where refrigeration or wet storage temperatures exceeding those required in the V.p. or V.v. Contol Plan would reduce efficacy of the process (and appropriately labeled with name of the receiving dealer) ~~is exempt~~ can be granted waivers from the requirements in Chapter VIII. @.02 A. (1) and (2) Chapter IX .04 and Chapter XIII. 01.B. (2) and (3).
Public Health Significance	Temperature controlled wet storage is emerging as a promising means of reducing vibrio in oysters and achieving a significant illness risk reduction. Unfortunately it appears it may not be practical to achieve a 3.0 or 3.52 log reduction to validate the process as prescribed by the Model Ordinance in a reasonable period of time. Taylor Shellfish and their Canadian subsidiary, Fanny Bay Oyster Company have successfully been achieving a 90-95% reduction in vibrio holding oysters in recirculating, refrigerated wet storage at 52°F for 3 – 5 days depending on initial levels. This is above the temperature allowed for holding oysters per Vp control plans. This temperature has been demonstrated through research to be the most effective at reducing vibrio in the shortest period of time. A waiver provision would allow Taylor and other companies interested in deploying this technology the ability to most effectively reduce vibrio in oysters and the associated illness risk.
Cost Information	There would be an unknown cost for Authorities to evaluate pathogen reduction processes for approval. Pursuing waivers for approved pathogen reduction processes is voluntary therefore there is no cost to companies unless they chose to pursue a process. Companies using refrigerated wet storage would have a reduced electrical cost if they are able to operate the system at warmer temperatures to achieve maximum vibrio reduction. Beyond producing oysters with substantially lower vibrio levels, Taylor has experienced significant benefits with refrigerated wet storage, including product quality, inventory control and handling efficiencies.

Proposal No. **23-210**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☒ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative
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Proposal Subject	Addition of NOAA SIP contract language to allow for the harvest of molluscan shellfish from Federal Waters
Specific NSSP Guide Reference	Section II, Model Ordinance Chapter VIII. Control of Shellfish Harvesting, Requirements for Harvesters, .03 Shellstock Harvesting in Federal Waters, A. (1) and (2) and Section II., Model Ordinance Chapter X. General Requirements for Dealers, .09 Restricted Shellfish from Federal Waters A. (1) and (2)
Text of Proposal/ Requested Action	**.03 Shellstock Harvesting in Federal Waters** A. The harvester shall obtain a NOAA contract to land commercial shellfish harvested from Federal waters at a state certified dealer. In addition, if applicable, obtain the required NOAA NMFS managed fisheries harvester license(s) and/or permit(s). ~~A~~B. Prior to harvesting shellfish in Federal waters from an area in the controlled access status~~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~~ ~~(2)~~ (1) Enter into~~Be a party to~~ agreements or memoranda of understanding between the landing stateAuthority, ~~the landing state,~~ NOAA, and the shellfish dealers receiving the shellfish as necessary to comply with the requirements outlined in the NSSP MO, Chapter IV.@.04 B. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. **Chapter X. General Requirements for Dealers** .09 ~~Restricted~~ Shellfish Harvested from Federal Waters A. The dealer shall: (1) ~~Obtain permission from the Authority to receive restricted shellstock prior to receipt.Only receive product from harvesters in Federal waters that have a NOAA contract.~~ (2) ~~Develop~~ If receiving shellstock harvested from Federal waters in the controlled access status, be a party to agreement~~toagreements~~ or memoranda of understanding between the Authority, ~~National Oceanic Atmospheric Administration (~~NOAA~~)~~, and the individual harvesters as necessary to comply with the biotoxin controls outlined in the

	NSSP MO, Chapter IV.@.04 B. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.
Public Health Significance	This proposal allows for contracts to be set up between the Authority, NOAA, and individual harvesters to allow for the safe harvest of molluscan shellfish from Federal Waters. These agreements will assure safe harvest from controlled access status areas.
Cost Information	None known

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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Proposal Subject	Digital Recalls
Specific NSSP Guide Reference	Model Ordinance Chapter X. ,05 Shellstock Identification B. Tags, .06 Shucked Shellfish Labeling A. Shellfish Labeling
Text of Proposal/ Requested Action	.05 B. Tags. (1) The dealers' tags shall: (a) Be durable… (b) Be at least… (2) The dealer's tag shall contain the following indelible, legible information in the order specified below: (a) The dealer's … (b) The dealer's … (c) The original … (d) The harvest … (e) If wet … (f) The most … (g) The type … (h) The following … (i) A link to a digital record where the consumer can check whether the product has been recalled. Link can be a web address, QR code, UPC, or other digital link approved by the Authority. The link destination must be maintained by the harvester, dealer, Authority, or their designee. .06 A. Shellfish Labeling. (1) The dealer … (2) If the … (3) If the dealer … (4) At a minimum … (5) The dealer … (6) The dealer … (7) The dealer … (8) If the dealer … (9) If the dealer … (10) If the dealer … (11) The dealer … (12) A link to a digital record where the consumer can check whether the product has been recalled. Link can be a web address, QR code or other digital link approved by the Authority. The link destination must be maintained by the harvester, dealer, Authority, or their designee.

Public Health Significance	This will save lives by getting contaminated product off the shelves more quickly. Currently recalls rely on all participants in the supply chain communicating effectively and efficiently. Often communications are dropped as product moves and consumers/restaurants/retailers do not know a product has been recalled. Since every product has a tag/label there is a built in mechanism for communicating recalls (or most often the lack of) easily.
Cost Information	Most companies already have a website. Adding a page for recalls and linking to it from a shellfish tag is a minimal cost.

Proposal No. **23-212**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative
Submitter	U.S. Food & Drug Administration (FDA)
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Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Shipping documents and records
Specific NSSP Guide Reference	Chapter X. .08 A. (1-2)
Text of Proposal/ Requested Action	Chapter X. .08 A. Shipping Documents (1) Each shellfish shipment shall be accompanied by a shipping document that contains accurate and legible information to permit a container of shellfish to be traced back to the specific incoming lot of shellfish from which it was taken. (2) The shipping document shall contain: (a) The name, address, and certification number of the shipping dealer.; (b) The name and address of the ~~major~~ consignee.; and (c) The kind and quantity of the shellfish product(s).; and (d) The lot code(s) (if applicable). (e) The growing area(s), date(s) of harvest, and (if possible) the harvester(s) or group of harvester(s) for (i) a lot (or commingled lots as per Section I B. (72) and Chapter I. @.01 G.) of shucked shellfish, (ii) a lot of shellstock (as per Section I B. (70) and Chapter I. @.01 G.), and (iii) a lot of in-shell product (as per Section I B. (69)); and (f) The wet storage history of the shellstock including, original harvest site(s), original harvest date(s), wet storage site(s), and date(s) (if applicable), and wet storage lot number(s); and (g) The depuration history of the shellstock including the date(s) of depuration processing and the depuration cycle or lot number(s); and (h) The federal sequential tag number(s) for federally allocated shellfish (surf clams and ocean quahogs) caught in federal waters using the National Marine Fisheries Service tagging protocol.
Public Health Significance	The NSSP requires certified dealers keep shipping documents and records to trace a shellfish shipment, through all the various dealers who have handled it, back to its point of origin. In the event of a shellfish related illness, tags are a tool, which, used in concert with records must provide for traceability of shellfish from the final consumer back through every middleman, (retailer, wholesaler, carrier, and dealer) who handled the product, to a specific growing area, harvest date, and if possible, the individual person who harvested the shellstock. Shipping documents are often used by certified dealers as part of the traceability record keeping but there must be details on the shipping document that specify the growing area(s), harvest date(s), wet storage details, depuration details, lot code(s), and for federally allocated shellfish (surf clams

	and ocean quahogs) caught in federally regulated waters, the federal sequential tag number(s). Certified dealers often have "records" in the most general sense, but these records are not in the form that meets the intent of the NSSP requirement to provide traceability on a lot-by-lot basis. As a result, follow-up investigations of illnesses and illness outbreaks have been stymied, identification of the cause of the outbreak has been delayed, and outbreaks have continued. In case of an illness or illness outbreak attributable to shellfish, it is necessary that health departments and other appropriate state and federal agencies be able to determine the source of contamination, and thereby to prevent any further outbreaks from this source. This can be done most effectively by following the course of a shipment, through all the various dealers who have handled it, back to the point of origin by means of shipping documents and transaction records kept by the shellfish dealers and retailers.
Cost Information	Not applicable.

Proposal No. **23-213**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Proposal For Clarifying Product Loading Rules During Validation Study of Artificial Wet Storage Systems
Specific NSSP Guide Reference	Chapter 7 .04 C Wet Storage Source Water
Text of Proposal/ Requested Action	The purpose of the Validation study for a Wet Storage system is to demonstrate the ability of the System to properly disinfect the water from all coliforms. The Model ordinance states that this Study should be done under "Normal operating conditions" per Chapter 7 .04 C 3a. For our Artificial Wet Storage System, normal operating conditions means product being taken out, and new product going into the system on a daily basis. To fully test the ability of the system to disinfect from coliforms during a validation study new product would have to be cycled in and out. However, there is no guidance in the model ordinance on the loading of product in the tanks, only the sampling procedure. It seems that Normal Operating Conditions have been interpreted differently by state authorities. Some authorities have the thought that tanks should be fully loaded, and no product should be removed for the duration of the study. The reason for not removing product being the system should always be at max load and removing product for any period would reduce the potential load the system would have to disinfect. It is our belief that removing products and adding new products increases the potential coliform group load by introducing animals that are harboring more potential coliforms. Allowing for removal and adding of new products during the Validation Study is more representative of the maximum number of animals a Wet Storage system would experience. This is what 'Normal Operating Conditions' would mean for us; we are asking for clarification and guidance on Normal Operating Conditions for Land-Based Recirculating Wet Storage Systems.
Public Health Significance	Ensuring artificial wet storage systems are validated under their maximum load as they would during 'Normal Operating Conditions'.
Cost Information	Potential cost increases for Authorities and Shippers. More product used in the validation study would lead to increases in traceability documents on the authorities side. More product needed for the validation study on the Shipper's side.

Proposal No. **23-214**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Shellfish Dealer Receiving Critical Limits for Shellstock Received from a Dealer
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .01 A. (2)&(3) Chapter XIII. Shellstock Shipping .01 A (2)&(3) Chapter XIV. Reshipping .01 A. (1)&(2) Chapter XV. Depuration .01 A (2)&(3)
Text of Proposal/ Requested Action	Chapter XI. Shucking and Packing .01 Critical Control Points A. 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 at or below 45 °F (7.2 °C) ambient air temperature; and [C]~~ ~~(c)~~(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. [C] (3) 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~~XI. .01 A. (2) (c)~~, (d)~~ or (~~e~~d). 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 device or comply with Chapter ~~XIII~~XI. .01 A. (2) (c)~~, (d)~~ or (~~e~~d). Shipments of four (4) hours or less must have documentation as required in Chapter IX..05 A. [C] Chapter XIII. Shellstock Shipping .01 Critical Control Points A. 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 at or below 45 °F (7.2 °C) ambient air temperature; and [C]~~

~~(e)~~(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. [C]

(3) 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) or (~~e~~d). 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 device or comply with Chapter XIII. .01 A. (2) (c)~~,~~ or (d) ~~or (e)~~. Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A. [C]

Chapter XIV. Reshipping

.01 Critical Control Points

A. 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 at or below 45 °F (7.2 °C) ambient air temperature; and [C]~~

~~(e)~~(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less; [C] or

~~(f)~~(e) 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]

(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.~~XIV. .01 A. (2) (c)~~,~~ or (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 device or comply with Chapter XIII. 01 A. (2) (c)~~,~~ or (d) ~~or (e)~~. Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A. [C]

	Chapter XV. Depuration (1) The dealer shall… (2) The dealer shall receive and depurate 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); [C] and (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 at or below 45 °F (7.2 °C) ambient air temperature; and [C]~~ ~~(e)~~(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. [C] (3) Should a dealer receive shellstock from a dealer who is shipping shellstock harvested in accordance with Chapter VIII. @.02 A. (3) or restricted use shellstock that has not been cooled to an internal temperature of 50 °F (10 °C), the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. This product can be received without meeting the receiving requirements of Chapter XIII. .01 A. (2) (c)~~,~~ or (d) ~~or (e)~~. Shipments of four (4) hours or less will not be required to have a time/temperature device. [C]
Public Health Significance	None. This proposal merely corrects a significant problem resulting from Proposal 19-237, which was adopted at the 2019 ISSC. Before this proposal's adoption, the receiving critical limits for shellstock received from a dealer were that, unless adequately iced, the shellstock were shipped in a conveyance at or below 45ºF ambient air temperature OR the shellstock were cooled to an internal temperature of 50ºF or less. Proposal 19-237 changed the "or" to an "and", so that the receiving critical limits for un-iced shellstock are now that they are shipped in a conveyance at or below 45ºF ambient air temperature AND cooled to an internal temperature of 50ºF or less. This has caused significant problems for receiving dealers, with no public health significance. Though un-iced shellstock are required to be shipped in a conveyance with 45ºF ambient air temperature (which remains a requirement in Section II. Chapter IX. Transportation), it is unnecessary as a Receiving critical limit, and also unpracticable due to limitations on accurately measuring the conveyance ambient air temperature upon receipt. The ambient air temperature of a conveyance increases as soon as the door is opened, making it difficult if not impossible to measure accurately by the receiving dealer, especially because this measurement (as a HACCP critical limit) must be conducted with a calibrated thermometer. The shellstock temperature is the receiving critical limit with public health significance, which is why other seafood products under HACCP regulation require only the product temperature at receipt. The current Model Ordinance requires the receiving dealer to perform and document a corrective action if the conveyance ambient air temperature exceeds 45ºF, which is unnecessary if the product temperature is within the critical limit. This requirement puts dealers in such a difficult position that it may lead to falsified records across NSSP-participating jurisdictions when the product was received at a temperature that meets the critical limit but conveyance air temperature may have exceeded the limit due to inability to measure accurately. Pre-chilling and maintaining conveyances remains a requirement for the shipping dealer under Chapter IX. The intent of this proposal is only to remove the ambient air

	temperature of the conveyance as a requirement for the receiving dealer, because it is unnecessary, redundant, and unpractible. There are also what appear to be some minor typos (such as Chapter XI. .01 A. (3) referring to receiving requirements in Chapter XIII.) in the Model Ordinance text that this proposal corrects.
Cost Information	None

Proposal No. **23-215**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Addition of Criticalities to Shellstock Shipping Shellfish Storage and Handling
Specific NSSP Guide Reference	Chapter XIII Shellstock Shipping .03 Other Model Ordinance Requirements F. Shellstock Storage and Handling
Text of Proposal/ Requested Action	(6) All shellstock obtained from a licensed harvester shall be: (a) Adequately iced within two (2) hours of receipt; [C]or (b) Placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt; [C] (c) Product intended for relay, wet storage or depuration, or either geoduck clams (Panopea generosa), or Mercenaria spp. which are being cooled utilizing an Authority approved tempering plan are exempt from the requirements listed above in .03 F. (6).
Public Health Significance	Addition of criticalities to maintain consistency with the rest of Chapter XIII.
Cost Information	N/A

Proposal No. **23-216**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative
Submitter	US Food & Drug Administration (FDA)
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Proposal Subject	Removal of language in "Shellfish Storage and Handling" section of Chapter XIV. (Reshipping) that does not belong in that section
Specific NSSP Guide Reference	NSSP MO Chapter XIV .03.F. Shellfish Storage and Handling
Text of Proposal/ Requested Action	NSSP MO Chapter XIV .03.F. ~~(1) The dealer shall buy shellfish only from sources certified by the Authority or listed in the ICSSL. **[K]**~~ (~~2~~1)- The dealer shall not: (a) Commingle, sort, or repack shellfish; or **[K]** (b) Remove or alter any existing tag or label. **[K]** (~~3~~2) A dealer whose activity consists of trucks only shall… (~~4~~3) During storage frozen shellfish shall be maintained frozen. **[$S^{K/O}$]**
Public Health Significance	Failure to obtain shellfish from a certified dealer is a Critical **[C]** deficiency; however, Chapter XIV erroneously lists this as a Key **[K]** deficiency in the current text of the NSSP Model Ordinance. Furthermore, the statement in question is incorrectly located under ".03 F. Shellfish Storage and Handling". This proposal seeks to correct both errors. Receiving shellfish from a certified dealer is a HACCP CCP in Chapter XIV .01 A.(1)(a), which states that shellfish shall only be obtained and transported by 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]**". All these sections require the tag or label to have a dealer certification number, and a "dealer" is required to be certified by definition (NSSP MO Chapter I (32)). This deficiency has a Critical **[C]** criticality code if not met. While it is true that Reshippers can ship to each other without adding their certification number to the tag or label, the certification number of the shipping dealer must be included in shipping documents under NSSP MO Chapter X. .08.A.(2)(a). Therefore, a shipping dealer would need to be certified in order to meet that requirement. Removing the language in Chapter XIV .03.F. will reduce confusion, since the requirement is covered elsewhere in the NSSP MO as described above.
Cost Information	No Cost

Proposal No. **23-217**

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Removal of Contradictory Information in Reshipping Shellfish Storage and Handling.
Specific NSSP Guide Reference	Chapter XIV Reshipping .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling
Text of Proposal/ Requested Action	F. Shellfish Storage and Handling. ~~(1) The dealer shall buy shellfish only from sources certified by the Authority or listed in the ICSSL. [K]~~ (~~2~~1) The dealer shall not: (a) Commingle, sort, or repack shellfish; or [K] (b) Remove or alter any existing tag or label. [K] (~~3~~2) A dealer whose activity consists of trucks only shall: (a) Have his own facility for the storage of shellfish; or [K] (b) Have arrangements with a facility approved by the Authority for the storage of shellfish; and [K] (c) Have a permanent business address at which records are maintained and inspections can be performed. [K] (43) During storage frozen shellfish shall be maintained frozen. [SK/O]
Public Health Significance	The strikethrough line above is in direct conflict with XIV .01 A, which already describes the requirements of the dealer to receive shellstock from an approved and licensed dealer and lists the criticality as a Critical deficiency.
Cost Information	N/A

Proposal No. 23-218

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
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10. Proposal Subject	Depuration tanks and trays are food contact surfaces
11. Specific NSSP Guide Reference	Chapter XV .02 B. (2) (a)
12. Text of Proposal/ Requested Action	Chapter XV .02 B. (2) Cleaning and sanitizing of food contact surfaces. (a) Food contact surfaces of the depuration units, equipment, and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. ~~Depuration tanks and trays are not considered to be food contact surfaces.~~ The dealer shall: (i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses; [K] (ii) Sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and [K] (iii) Wash and rinse equipment at the end of each day. [K]
13. Public Health Significance	The need to effectively clean and sanitize processing tanks, containers, and pipes carrying process water is well established. The inadequate cleaning and sanitizing of process equipment can result in microorganisms being resuspended in the process water and increasing the bacterial loading to such a level that adequate depuration will not occur. Processing tanks and containers used to hold shellfish that have cracked, rough or inaccessible surfaces, or made of improper material, are apt to harbor accumulations of organic material in which bacteria, including pathogens, may reside and grow. Such organisms can be regularly introduced into the system and these potentially may contaminate the shellfish. Surfaces, therefore, must be smooth and easily cleanable if bacteria are to be flushed out in the cleaning and sanitizing process. Surfaces that cannot be cleaned can result in inconsistent depuration effectiveness, and, possibly, the reintroduction of pathogens into the shellfish. Additionally, there are several references in Chapter XV that clearly state depuration tanks and trays are food contact surfaces, specifically: Chapter XV .01 B. (2) (b) states that containers which may have become contaminated during storage shall be properly washed, rinsed, and sanitized prior to use or are discarded. (c) states, shellstock depuration tanks shall be cleaned and

	sanitized on a regular schedule as part of a plant sanitation standard operating procedure. Chapter XV .02 A. (6) states that the depuration unit, including depuration tanks, reservoir tanks, and related piping…(c) Meets the requirements for food contact surfaces. Chapter XV .03 E. (3) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces.
14. Cost Information	No additional cost to depuration processors.

Proposal No. 23-219

Proposal for Task Force Consideration at the ISSC 2023 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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9. Email	Melissa.Abbott@fda.hhs.gov
10. Proposal Subject	Depuration unit and equipment are food contact surfaces
11. Specific NSSP Guide Reference	Chapter XV .03 E. (3)
12. Text of Proposal/ Requested Action	Chapter XV .03 E. Equipment Condition, Cleaning, Maintenance and Construction of Non-food Contact Surfaces. ~~(3) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. [K]~~ ~~(4)~~(3) All conveyances and equipment which come into contact with the stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
13. Public Health Significance	The need to effectively clean and sanitize the interior of processing tanks, containers, and the interior of pipes carrying process water is well established. The inadequate cleaning and sanitizing of process equipment can result in microorganisms being resuspended in the process water and increasing the bacterial loading to such a level that adequate depuration will not occur. Processing tanks and containers used to hold shellfish that have cracked, rough or inaccessible surfaces, or made of improper material, are apt to harbor accumulations of organic material in which bacteria, including pathogens, may reside and grow. Such organisms can be regularly introduced into the system and these potentially may contaminate the shellfish. Surfaces, therefore, must be smooth and easily cleanable if bacteria are to be flushed out in the cleaning and sanitizing process. Surfaces that cannot be cleaned can result in inconsistent depuration effectiveness, and, possibly, the reintroduction of pathogens into the shellfish. Additionally, there are several references in Chapter XV that clearly state the interior surfaces of depuration tanks and trays are food contact surfaces, specifically: Chapter XV .02 B. Condition and Cleanliness of Food Contact Surfaces. (2) (b) states that containers which may have become contaminated during storage shall be properly washed, rinsed, and sanitized prior to use or are discarded. (c) states, shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure.

	Chapter XV .02 A. Plumbing and Related Facilities. (5) (b) (2) Cleaning and sanitizing of food contact surfaces. (a) Food contact surfaces of the depuration units, equipment, and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. Chapter XV .02 A. (6) Depuration Unit. states that the depuration unit, including depuration tanks, reservoir tanks, and related piping…(c) Meets the requirements for food contact surfaces.
14. Cost Information	No additional cost to depuration processors.