ISSC

Interstate Shellfish Sanitation Conference

Task Force II Proposals for Consideration At the 2027 Biennial Meeting

Newport, Rhode Island
January March 24-29, 2027

ISSC Task Force II
2027 Proposal Inventory

Proposal Number	Proposal Subject	Page
15-226	Vibrio parahaemolyticus (V.p.) Illness Response Guidance Document	6
17-206	Illnesses Associated with V.p.	11
17-225	Clarification of Surf Clams and Ocean Quahogs Exemption from Time/Temperature Requirements whcn "intended for thermal processing".	16
19-240	Alternative for allowing harvest for raw consumption from a growing area closed due to V.p.	18
23-200	Definition of Harvest	22
23-204	Proposal for Clarifying Wet Storage Holding Temperatures for Shipped Shellstock	23
23-205	Recirculation Wet Storage Water Quality Threshold	27
23-2 06	Wet Storage Sampling Requirements	29
23-213	Clarifying Product Loading Rules During Validation Study of Artificial Wet Storage Systems	31
23-215	Addition of Criticalities to Shellstock Shipping Shellfish Storage and Handling	32
27-200	Federal Waters Guidance	33
27-201	Change the definition of a Broker and add the Broker as a new Certified Dealer Type	34
27-202	Federal No Discharge Zone	35
27-203	Restricted shucked shellfish definition	36
27-204	Definition Housekeeping	38
27-205	Dealer Definition Clarification	41
27-206	Shelltock Shipper Processing Requirements	43
27-207	Tempering and tempering plan definitions	44
27-208	Addition of new personnel training requirement for SSI's and SSO's	45
27-209	Notification of Certification Revocation	47

27-210	Clarifying Broker and Importer roles relative to ICSSL certification	49
27-211	Direct reference to recalls in Chapter I.	50
27-212	Written procedures for investigating incidents of shellfish-borne disease	51
27-213	Intent for Consumer Cooking Clarification	52
27-214	Aquaculture Permit Designation	54
27-215	Outbreak Determination & Response Clarification	56
27-216	Vibrio Management Program	62
27-217	Include reference for human pathogens	70
27-218	Clarify that when post-harvest issues are ruled out, the growing area should be deemed to be the source of the issue	71
27-219	Growing Area Closure Period due to V.p. Cases	73
27-220	Notification of growing area closures and recalls due to outbreaks of shellfish related Illness	74
27-221	Notification of precautionary closure	76
27-222	Molluscan shellfish illness reporting	77
27-223	Restricted Shucked Shellfish from the Controlled Access Status	78
27-224	Task Force on End-Product Testing and Clearence	84
27-225	Model Ordinance Effectiveness	85
27-226	Management of Relaying Shellstock of the Harvesting for Delivery to a Low Acid Canned Food Processing Facility Activities-Authority Supervision	90
27-227	Seed Sizes	92
27-228	Returning Shellstock to the Aquaculture Site	94
27-229	Lost and Found Shellfish	97
27-230	Growing Area Transfers	99
27-231	Aquaculture Operational Plan Implementation	101
27-232	Land Based Processing Facility for Land Based Aquaculture on processing and Handling	104
27-233	Aquaculture Sinking for Bird & Mammal Control	105
27-234	Shipping Document Housekeeping	110

27-235	Processing by Harvesters Clarification	121
27-236	A3 exemption for raw product	122
27-237	Harvester Training	124
27-238	Harvester Name on Harvester Tags	126
27-239	Hand Sanitizer on Harvest Vessels	128
27-240	Emergency Notification	129
27-241	Controlled access status harvester tag requirements-restricted shellstock	132
27-242	Bulk tagging transaction record	134
27-243	A(3) Matrix Clarification	135
27-244	Shucked Meat Dislodging	137
27-245	Require geoduck shipments have a Chapter IX. transportation document so that receiving secondary dealers can meet current HACCP Receiving Critical Limits for shipments of four (4) hours or less	139
27-246	Chapters IX & X Criticalities	141
27-247	Remove the "Note" saying that the NMFS sequential tags supersede the tagging requirements in Section .05	156
27-248	Employee Training Requirement Relocation	158
27-249	Corrective Actions	161
27-250	Receiving critical limit for federal waters	163
27-251	Temperature Measuring Device Requirement Relocation	165
27-252	Commingling Prevention Requirement Criticality Code	167
27-253	Exclusion of Pests	169
27-254	Directly Plumbed Handwash Sinks	171
27-255	Complete Dealer Chapters	174
27-256	Guidance for processing, packaging, handling, & shipping fresh shucked oysters on the half shell, (Dead oysters)	192
27-257	Air Gaps	194
27*258	Minimum Frequency of Private Potable Water Supply Sampling	197
27-259	Lack of Time Temperature Consideration and Ambient Air Temperature Monitoring During Conveyance Consideration for Controlling *Vibrio* Pathogen	198

	Growth and Toxin Formation for Shippers	
27-260	Ch XIV. Critical Limit Correction	201
27-261	Lack of Time Temperature Consideration and Ambient Air Temperature Monitoring During Conveyance Consideration for Controlling *Vibrio* Pathogen Growth and Toxin Formation for Shellstock Reshippers.	203
27-262	Remove SSA's exemptions for building requirements for shellstock shipper and reshipper certifications as listed at the beginning of Chapters XIII and XIV.	206
27-263	Cooling prior to Shipment	208
27-264	Molluscan shellfish pathogen reduction	209
27-265	Recall Guidance	211
27-266	Suggested Forms Update	268

Proposal No. **15-226**

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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.
Action by *V.p.* Illness Response Committee, 2023	Recommends 15-226 be referred to the appropriate committee along with 17-206 as determined by the conference chair for continued development of guidance. The committee further recommends the Conference encourage the collection and characterization of environmental and clinical *V.p.* isolates.
Action by Task Force II, 2023	Recommends adopting recommendation of *V.p.* Illness Response Committee's and send 15-226 and 17-206 back to the appropriate committee.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 15-226.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 15-226.

Proposal No. **17-206**

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

receiving States information identifying the dealers shipping the implicated shellfish.

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

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

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

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

(~~d~~d) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.

(~~d~~e) Issue a consumer advisory for all shellfish (or species implicated in the illness).

(4) When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for ~~the following periods of time to determine if additional illnesses have occurred:~~

~~The area will remain closed for~~ a minimum of fourteen (14) days. ~~when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area.~~

~~(a) The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area~~

(5) Prior to reopening an area closed as a result of the number of cases exceeding ~~ten (10)~~ four (4) illnesses within thirty (30) days or ~~four (4)~~ two (2) within seven (7) days or two (2) cases from a single harvest date from the implicated area, the Authority shall:

(a) Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies.; or

(b) Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.

(6) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one or more of the following

	controls: (a) Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams; (b) Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing; (c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority. (7) Molluscan shellfish recalled as a result of *V.p.* illnesses may be reconditioned as described in Chapter II. @.01 J.
Public Health Significance	The national trend with regard to Vp illnesses has not improved over the past several years. This proposal intends to improve the effectiveness of response to Vp illnesses. This proposal retains the tiered approach for response to Vp illnesses, but requires closure of implicated areas and recall for situations where multiple illnesses occur over a short period of time, suggesting a higher risk situation. The requirement to close for a minimum of fourteen (14) days and to collect and analyze water samples prior to re-opening is expected to decrease the numbers of *V.p.* illnesses occurring from particularly high risk growing areas. A reference to @ .01 J has been added for clarification.
Cost Information	
Action by 2017 Task Force II	Recommended referral of Proposal 17-206 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-206.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-206.
Action by 2019 *V.p.* Illness Response Committee	Recommended: 1) the language of proposal 17-206 be replaced with substitute language presented by FDA (included below) for the purpose of referral to an appropriate committee **Section II. Model Ordinance** **Chapter II. Risk Assessment and Risk Management** **@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*** **A. Public Health Significance**

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

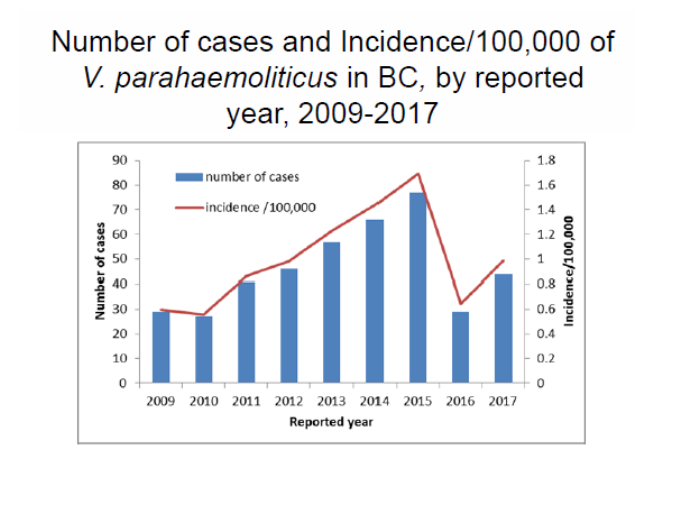
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 17-206
Action by FDA July 7,2023	Concurred with Conference action on Proposal 17-206.

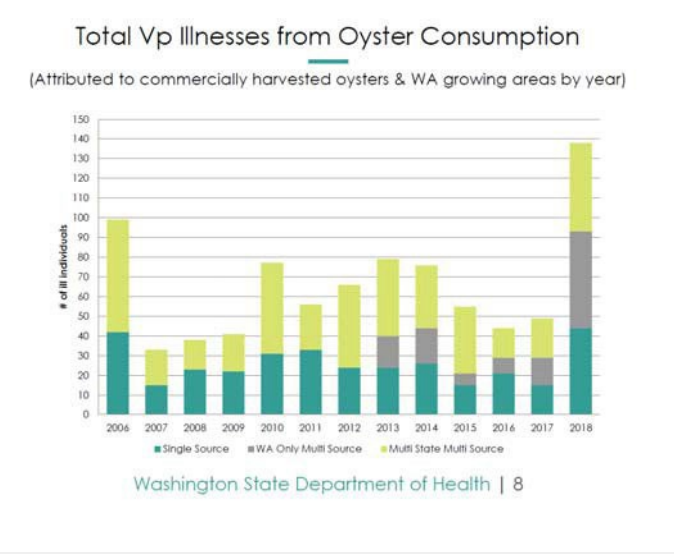
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Proposal Subject	Clarification of Surf Clams and Ocean Quahogs Exemption from Time/Temperature Requirements when "intended for thermal processing".
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.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.
Action by Time Temperature Committee, 2023	Recommendations: The Committee recommends Proposal 17-225 be referred to an appropriate committee as determined by the conference chair.
Action by Task Force II, 2023	Recommends adopting Time Temperature Committee's recommendation that Proposal 17-225 be referred to an appropriate committee as determined by the conference chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 17-225.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-225

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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.
Action by *V.p.* Illness Response Committee, 2023	Recommendation: Refer proposal 19-240 to the appropriate committee as determined by the conference chair. The committee further recommends the Conference consider the development of additional language related to the design of appropriate scientific studies and control measures allow the harvest of shellstock from areas closed as a result of *V.p.* illness.
Action by Task Force II, 2023	Recommends accepting *V.p.* Illness Response Committee's recommendations on Proposal 19-240.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-240.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-240

Proposal No. **23-200**

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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 ~~harvest means the act of removing shellstock from growing areas and its placement on or in a man made conveyance or other means of transport~~ (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.
Action by Task Force II, 2023	Recommends sending proposal 23-200 to appropriate committee as determined by the conference chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-200.
Action by FDA Juy 7, 2023	Concurred with Conference action on Proposal 23-200.

Proposal No. **23-204**

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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.
Action by Task Force II, 2023	Recommends adopting proposal 23-204 with amended language: Chapter XI. Shucking and Packing B. Shellstock Storage Critical Control Point – Critical Limits. The dealer shall ensure

	that: (1) If wet storage or depuration ~~in artificial bodies of water~~ is practiced, water quality meets the requirements outlined in Chapter VII for wet storage for chapter XV for depuration..~~04; and~~ [C] (2) Once placed under temperature control and until shucked the shellstock shall; : (a) Be placed in wet storage or depuration; or [C] (~~a~~b) Be iced; or [C] (~~b~~c) Be placed and stored in a storage area or conveyance maintained at 45 F (7.2 C) or less; and [C] (~~c~~d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than two (2) hours at points of processing or transfer, such as loading docks. [C] ~~Not be permitted to remain without ice, mechanical refrigeration or other approved methods of storage, as required in Section .01 B. (1) B. (2) (a) or (b) for more than two (2) hours of points of processing or transfer such as loading docks. [C].~~ Chapter XIII. Shellstock Shipping B. Shellstock Storage Critical Control Point – Critical Limits. The dealer shall ensure that: (1) If wet storage or depuration ~~in artificial bodies of water~~ is practiced, water quality meets the requirements outlined in Chapter VII for wet storage for chapter XV for depuration..~~04; and~~ [C] (2) Once placed under temperature control and until shucked the shellstock shall; : (a) Be placed in wet storage or depuration; or [C] (~~a~~b) Be iced; or [C] (~~b~~c) Be placed and stored in a storage area or conveyance maintained at 45 F (7.2 C) or less; and [C] (~~c~~d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than two (2) hours at points of processing or transfer, such as loading docks. [C] ~~Not be permitted to remain without ice, mechanical refrigeration or other approved methods of storage, as required in Section .01 B. (1) B. (2) (a) or (b) for more than two (2) hours of points of processing or transfer such as loading docks. [C].~~
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-204
Action by FDA July 7, 2023	The FDA does not concur with Conference action to adopt proposal 23-204 as amended by Task Force II. The initial proposal requested guidance on maintaining wet storage water temperatures at ≤50°F instead of ≤45°F since the NSSP allows internal temp of shellstock to be ≤50°F. The rationale provided was that wet storage water temps are more representative of internal temps than in dry storage. Task Force II discussed the request for guidance, drafted edits to language in Chapters

XI and XIII, and recommended adoption by the General Assembly. The language that was recommended and subsequently adopted by the General Assembly is as follows where it occurs in Chapter XI .01 B. (2) and Chapter XIII .01

B. (2):

"B. (2) Once placed under temperature control and until shucked the shellstock shall:

a) Be placed in wet storage or depuration; or [C]
b) Be iced; or [C]
c) Be placed or stored in a storage area or conveyance maintained at 45°F (7.2°C) or less; and [C]
d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than 2 hours at points of processing or transfer, such as loading docks. [C]"

It is FDA's position that the adopted language is in direct conflict with the principles of 21 CFR 123, *Seafood HACCP Regulation* and the policy outlined in the Fish and Fishery Products Hazards and Controls Guidance, 4th edition (2022 version) (Hazards Guide). CFR 123 and NSSP Guide Chapter X. .01 A. stipulate dealers conduct a hazard analysis which identifies critical control points (CCP) in their process where they can control identified species and process related hazards. Original dealers are responsible for demonstrating the control of pathogen growth from the growing area via critical limits (CL) that demonstrate the hazard has been controlled. At the Receiving CCP, dealers show controls from the harvest area via approved source labeling (tags, harvest controls) and the documentation of time of harvest to time in temperature control during Vibrio control months. The harvest/process related hazard of pathogen growth is controlled at the Storage CCP via the CL of temperature (≤50°F prior to shipping, with a <10-hour clock attached during Vibrio control months).

Since the original dealer is responsible for demonstrating control of the hazard, secondary dealers need only demonstrate how they are maintaining control of the hazard through temperature control until it reaches the final destination (point of sale - where food code takes over). Those controls are demonstrated via documentation of adequate ice/internal temperature of shellstock/temperature of cooler and that shellstock shall not remain out of that temperature control for more than 2 hours at points of processing or transfer.

In other words, once the hazard has been controlled by the original dealer, everyone down the chain documents how it stays in control through their Receiving CCP (receiving temperature), and Storage CCP (temperature of cooler/ presence of ice) showing it can keep that hazard controlled. The reason for having "not to remain out of temp control for more than 2 hrs" is to maintain the control established by the original dealer. All tags/labels are required to say "KEEP REFRIGERATED" for the same reason.

Temperature is our only barrier to control pathogen growth in shellstock (outside of post-harvest processing). Once the original dealer has demonstrated product has been cooled to ≤50°F and controlled the hazard, secondary dealers taking it out of temp control for wet storage or depuration goes against the established principles of CFR

	123 and basically re-introduces the hazard. Please see Chapter 12 of the Hazards Guide for Control Strategy 2- Refrigerated Storage and Refrigerated Processing Control as well as Control Strategy 4- Unrefrigerated Processing Control, and Table 12-5 which shows no more than 2 hours >50°F to ensure control of pathogen growth for ready to eat product. The original dealer controls the potential hazards from the growing area (Chapter 2) and then they and everyone else who touches the product maintains the control via temperature ≤50°F (Chapter 12). In summary, the adopted language allows for potential re-introduction of a hazard that original dealers have controlled if temperature control is not maintained down the chain of custody. FDA recommends that Proposal 23-204 be sent to Committee for further discussion.
Action by ISSC executive Board October 19, 2023	FDA was in nonconcurrence with the action taken by the conference because it is FDA's position that the adopted language is in direct conflict with the principles of 21 CFR 123, Seafood HACCP Regulation and the policy outlined in the Fish and Fishery Products Hazards and Controls Guidance, 4th edition (2022 version) (Hazards Guide). This action will not be published due to being in conflict with federal regulation and Proposal 23-204 will be reconsidered at the next conference.

Proposal No. **23-205**

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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.
Action by Task Force II, 2023	Recommends sending Proposal 23-205 to appropriate committee as determined by the conference chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-205
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-205

Proposal No. **23-206**

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Proposal Subject	Wet Storage Sampling Requirements
Specific NSSP Guide Reference	Section II Model Ordinance. 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.
Action by Task Force II, 2023	Recommends sending Proposal 23-206 to the appropriate committee as determined by the conference chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-206.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-206.

Proposal No. **23-213**

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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.
Action by Task Force II, 2023	Recommends no action on Proposal 23-213 to the appropriate committee as determined by the conference chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-213
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-213

Proposal No. **23-215**

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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
Action by Task Force II, 2023	Recommends sending proposal 23-215 to the appropriate committee as determined by the conference chair, with instructions to consider the appropriate criticality code.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-215.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-215

Proposal No. **27-200**

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

Submitter	ISSC FederalWaters Committee
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Email	issc@issc.org
Proposal Subject	Federal Waters Guidance
Specific NSSP Guide Reference	Section II. Chapter X. .09 A.
Text of Proposal/ Requested Action	**Section II, Chapter X. General Requirements for Dealers** .09 Shellfish Harvested from Federal Waters A. The dealer shall: (1) Only receive product from harvesters in federal waters that have a NOAA contract. (2) If receiving shellstock harvested from Federal waters in the controlled access status, be party to agreement or memoranda of understanding between the Authority, NOAA and the individual harvesters as necessary to comply with the biotoxin controls outlined in the NSSP Chapter IV. @.04 B. and in accordance with Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.
Public Health Significance	Adoption of this dealer requirement would complete the loop from harvester to dealer for the control of harvest and traceability of shellfish harvested from federal waters.
Cost Information	N/A
Action by 2024 Executive Board	Adopted the recommendation of 2024 Federal Waters Committee. Interim Approval on October 30, 2024

Proposal No. 2 7 - 2 0 1
Received: _____

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Alfred R. Sunseri
3. Affiliation	P&J Oyster Company, Inc.
4. Address Line 1	1039 Toulouse Street
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6. City, State, Zip	New Orleans, LA 70112
7. Phone	504-722-9854
8. Email	asunseri@bellsouth.net
9. Proposal Subject	Change the definition of a Broker and add the Broker as a new Certified Dealer Type
10. Specific NSSP Guide Reference	Definitions
11. Text of Proposal/ Requested Action	Broker- means any person who is a dealer that buys oysters directly from a harvester and sells, ships and distributes those molluscan shellfish without taking ownership, physical custody, nor processes the shellfish. They are not authorized to process shellstock. They must have a means to refrigerate the harvesters shellstock upon landing to assure the shellfish are not temperature abused when the transporting vehicle is not located at the harbor when the shellstock is ready to be unloaded..
12. Public Health Significance	The old definition of a broker does not accurately describe what a molluscan shellfish broker does. Brokers need to have more "skin in the game" because of the numerous regulatory changes that have been made to the NSSP since the definition of a broker was developed. Such important developments such as time and temperature guidelines, vibrio guidelines, etc. did not exist in the NSSP when the term broker was defined. Brokers need to be more responsible for the shellstock they are selling and shipping that will be consumed raw in most cases.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	Probably and a change in the ICSSL

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Federal No Discharge Zone
10. Specific NSSP Guide Reference	NSSP MO Section I Purposes & Definitions
11. Text of Proposal/ Requested Action	**(115) Shellfish** means all species of: a) Bivalve mollusks ~~including all species of~~ (~~e.g.,~~ e.g., oysters, clams, mussels, cockles, and scallops~~)~~ whether: i. Shucked or in the shell; ii. Raw, including post-harvest processed; iii. Frozen or unfrozen; iv. Whole or in part~~;~~ ~~and~~ except when the final product form is the adductor muscle only, attached or unattached to the shell. ~~Scallops in any form, except when the final product form is the adductor muscle only, attached or unattached to the shell.~~
12. Public Health Significance	Scallops, when their final form is the adductor muscle, are not currently covered by the NSSP because adductor muscles do not contain the same high risk as whole bivalve mollusks. Adductor muscles from other species represent a similar low risk and should be covered under 21 CFR 123 *Seafood HACCP*. There has been an increase in imported adductor muscles from other bivalve shellfish species and the FDA Division of Import Operations routinely requests evaluation of the imported product to determine if it is covered by the NSSP or the Code of Federal Regulations.
13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
3. Affiliation	U.S. Food & Drug Administration (FDA)
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5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Restricted shucked shellfish definition
10. Specific NSSP Guide Reference	National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish: 2023 Revision, Section I. Purpose & Definitions
11. Text of Proposal/ Requested Action	NSSP Section I. Purpose and Definitions **Definitions** B. Definition of Terms. **(106) Restricted** means a classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration. **(107) 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 shellstock is identified with a tag indicating that the shellstock has restrictions requiring further processing or testing prior to distribution. (108) **Restricted Shucked Shellfish** means shucked shellfish that were processed from restricted shellstock. Restricted shucked shellfish is identified with a label indicating that the shucked shellfish has restrictions requiring further processing or testing prior to distribution. **(1098) Safe Materials** means articles manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of or otherwise adversely affect the characteristics of any food.
12. Public Health Significance	Currently there is no definition of restricted shucked shellfish. There are known instances of shucked shellfish being shipped that have not met all conditions of harvest restrictions prior to being placed in distribution per Chapter IV. @.04 B. (2)(h)
13. Cost Information	Minimal cost

14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Definition Housekeeping
10. Specific NSSP Guide Reference	Section II Model Ordinance, Section I. Purposes & Definitions, Definitions
11. Text of Proposal/ Requested Action	**Authority** means the State or local shellfish control authority or authorities or its designated agents, which are responsible for the enforcement of this ~~Code~~Ordinance. **Certification or Certify** means the issuance of a numbered certificate to a person for a particular activity or group of activities that indicates: (a) Permission from the Authority to conduct the activity; and (b) Compliance with the requirements of this ~~Code~~Ordinance. **Equipment** means shucking tables, shucking benches, blowers, skimmers, sinks, refrigerators, and similar items, used in the operation of a shellfish processing facility. **Floating ~~Aquaculture~~ Gear** means ~~open water~~ aquaculture containers where the shellfish product is suspended at the water surface using floats. **Food Contact Surface** means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish or ice. ~~**Monoculture** means the culture of a single bivalve species.~~ **Lot of Shucked Shellfish** means a collection of containers of no more than one day's shucked shellfish product produced from a single lot of shellstock, produced under conditions as nearly uniform as possible, and designated by a common container code or marking. **Non-Food Contact Surfaces** means all exposed surfaces of equipment and utensils other than food contact surfaces. **Original Dealer** means the dealer who initially received the shellstock from the harvester. The original dealer may be the harvester, if the harvester is certified by the Authority as a dealer. ~~**Repacking**~~ **In-Shell Product Repacking** means the practice of removing in-shell product from containers and placing it into other containers. ~~**Repacking**~~ **Shellstock Repacking** means the practice of removing shellstock from containers and placing it into other containers. **Shucked Shellfish Repacking** means the practice of removing shucked shellfish from containers packed by other dealers and placing it into other containers.

	Shucked Shellfish Packing means the process of placing shucked shellfish in containers for introduction into commerce. **Returnable Container** means a multiple use container for holding or shipping of shucked shellfish. **Shucked Shellfish** means shellfish, or parts thereof, which have been removed from their shells. **Shucking Bucket** means containers for temporarily holding shucked shellfish during the shucking process. **Swing Deficiency** means a deficiency noted on the NSSP Standardized Shellfish Processing Plant Inspection Form which, depending upon the severity and circumstances, can be either a "Critical" or a "Key" deficiency or can be either a "Key" or "Other" deficiency. **Tag** means a durable, waterproof paper which complies with the specifications of Chapter VIII. .02 F. for harvester tags and Chapter X. .05 for dealer tags and which is affixed by a harvester or by a dealer, except a reshipper, to an individual container of shellstock, or to an individual lot of shellstock when a bulk tag is used. **Temperature Control** means the use of adequate icing, mechanical refrigeration, or other means approved by the Authority that is capable of achieving and maintaining the temperature requirements of this Ordinance.
12. Public Health Significance	Housekeeping of the Definitions. One term is defined but used nowhere in the Guide so should be removed. The term "float aquaculture" is not used, but the term "floating gear" is used, so this proposal changes the definition to the latter term. Two terms refer to the Ordinance as a "Code" while the other definitions properly call it the Ordinance. The definition of "lot of shucked shellfish" does not include that a lot of shucked shellfish is produced from shellstock from a single harvest date and a single harvest area (unless commingled under the Authority's commingling plan, which this definition clarification does not affect). There are definitions for "shellstock" and "in-shell product" but no definition for shucked shellfish. Similarly, there are definitions for "repacking shellstock" and "repacking in-shell product" but no definition for repacking shucked shellfish – and there is a definition for "shellstock packing" and "in-shell product packing" but no definition for shucked shellfish packing. The definition for "food contact surface" does not currently specify that it includes surfaces which touch ice, though that is already specified in the dealer chapters. The Model Ordinance contains Swing deficiencies that are either a Key or Other deficiency, but the definition for Swing Deficiency does not state this. Some other definitions added by this proposal are taken from the Shellfish Industry Equipment Construction Guide found in the Guidance Documents, sometimes with slight rewording, while others are new additions that are advisable based on their repeated use within the Model Ordinance.
13. Cost Information	None
14. Changes Needed to Guidance (if	None

proposed change is adopted)	

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell; Sarah Good
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5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904; Richmond, VA 23219
7. Phone	302-608-5511; 804-659-3823
8. Email	andrew.bell@delaware.gov; sarah.good@vdh.virginia.gov
9. Proposal Subject	Dealer Definition Clarification
10. Specific NSSP Guide Reference	Section I. Purposes & Definitions, Definitions; Section II. Model Ordinance, Chapter X. General Requirements for Dealers, .04 Certification Requirements; Section II. Model Ordinance, Chapter XIV. Reshipping, .03 Other Model Ordinance Requirements
11. Text of Proposal/ Requested Action	Section I. Purposes & Definitions, Definitions **(35) Depuration Processor (DP)** means a person who harvests or receives shellstock from growing areas in the approved, ~~or~~ conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process. A depuration processor may act as a shellstock shipper or reshipper, but may not shuck shellfish or repack shucked shellfish. **(123) Shucker-Packer (SP)** means a person who shucks and packs shellfish. A shucker-packer may act as a repacker, shellstock shipper, or reshipper ~~or may repack shellfish originating from other certified dealers~~. **(101) Repacker (RP)** means any person, other than the original certified shucker-packer, who repackages shucked shellfish into other containers. A repacker may act as a shellstock shipper or reshipper, but may not shuck shellfish. **(121) Shellstock Shipper (SS)** means a dealer who receives shellstock from harvesters, stores shellfish, repacks shellstock or in-shell product, or distributes shellfish to other dealers, wholesalers, or retailers. ~~grows, harvests, buys, or repacks and sells shellstock. They are not authorized to shuck shellfish nor to repack shucked shellfish.~~ A shellstock shipper may ~~also buy, repack, and sell in-shell product as well as ship shucked shellfish~~act as a reshipper, but may not shuck shellfish or repack shucked shellfish. **(105) Reshipper (RS)** means a person who ~~purchases~~ receives shellfish from dealers, stores shellfish, and ~~sells~~ distributes the product without repacking, retagging, or relabeling to other dealers, wholesalers, or retailers. A reshipper may not shuck shellfish, repack shucked shellfish, produce in-shell product, repack in-shell product, repack shellstock, or receive shellstock from harvesters. Section II. Model Ordinance, Chapter X. General Requirements for Dealers, .04 Certification Requirements

	B. Types of Certification. (1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer. (2) Repacker.- ~~(a)~~ Any person who repacks shucked shellfish shall be certified as a ~~shucker-packer or~~ repacker or shucker-packer; ~~(b) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker-packer, or repacker;~~ ~~(c) A repacker shall not shuck shellfish.~~ (3) Shellstock Shipper. Any person who receives shellstock from a harvester, stores shellfish, repacks shellstock or in-shell product, or distributes shellfish to other dealers, wholesalers, or retailers after retagging ~~ships and receives shellstock in interstate commerce~~ shall be certified as a shellstock shipper, repacker, ~~or~~ shucker-packer, or depuration processor. (4) Reshipper. Any person who ~~purchases~~ receives shellstock, in-shell product, or shucked shellfish from dealers, stores shellfish, and ~~sells~~ distributes the product without repacking, retagging, or relabeling to other dealers, wholesalers, or retailers shall be certified as a reshipper, shellstock shipper, repacker, shucker-packer, or depuration processor. (5) Depuration Processor. Any person who ~~harvests or~~ receives shellstock from growing areas in the approved, ~~or~~ conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process shall be certified as a depuration processor. Section II. Model Ordinance, Chapter XIV. Reshipping, .03 Other Model Ordinance Requirements Chapter XIV. Reshipping F. Shellfish Storage and Handling. (1) The dealer shall not: (a) Receive shellstock from harvesters; or [C] (~~a~~b) Commingle, sort, or repack shellfish; or [K] (~~b~~c) Remove or alter any existing tag or label.; or [K] (d) Wash shellfish. [K]
12. Public Health Significance	This proposal does not add or alter any existing requirements, but merely is housekeeping to better clarify the definitions of each type of dealer. The current definitions are not as clear as they should be, making them difficult to understand and apply by Authorities and industry. This proposal rewords existing requirements into clearer language for better understanding. It also takes the opportunity to add to the Reshipping chapter explicit language that reshippers are not permitted to receive shellstock from harvesters or to wash shellfish which is an existing requirement that should be emphasized to ensure clear understanding.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Alfred R. Sunseri
3. Affiliation	P&J Oyster Company, Inc.
4. Address Line 1	1039 Toulouse Street
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6. City, State, Zip	New Orleans, LA 70112
7. Phone	504-722-9854
8. Email	asunseri@bellsouth.net
9. Proposal Subject	Shelltock Shipper Processing Requirements
10. Specific NSSP Guide Reference	Definitions-Shellstock Shipper
11. Text of Proposal/ Requested Action	(121) Shellstock Shipper (SS) means a dealer who grows, harvests, buys, or repacks and sells shellstock. A harvester may also be a shellstock shipper as long as all processing, packaging and tagging, occurs in a single use container, over the approved growing area for introduction into commerce.They are not authorized to shuck shellfish nor to repack shellstock or shucked shellfish. A shellstock shipper may also buy~~, repack~~, and sell in-shell product as well as ship shucked shellfish and may repack shellstock, in a certified, HACCP approved land-based processing facility for introduction into commerce..
12. Public Health Significance	Processing, packaging, and labeling shellstock in a single use container that is introduced directly into commerce directly to a restaurant or consumer from a harvester/shellstock shipper must occur over the approved aquaculture growing area and not on the land. If a harvester/shellstock shipper wants to process, wash, sort, cull, package, label, and/or ship the shellstock they processed onshore, on the land, then that type of shellstock shipper must have a certified processing facility by the SSA and FDA.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	Yes

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
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8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Tempering and tempering plan definitions
10. Specific NSSP Guide Reference	NSSP Model Ordinance, Section I Purposes & Definitions
11. Text of Proposal/ Requested Action	**(125) Swing Deficiency** means a deficiency noted on the NSSP Standardized Shellfish Processing Plant Inspection Form which, depending upon the severity and circumstances, can be either a "Critical" or a "Key" deficiency. **(126) Tempering** is the gradual reduction of shellstock temperature under controlled conditions after harvest to reduce thermal shock and mortality of cold-sensitive bivalve molluscan shellfish prior to cold storage. Tempering processes that extend the allowed time from placement under temperature control until cooled to an internal temperature of 50°F require an Authority-approved tempering plan. **(127) Tempering plan** is a written document, describing how tempering is conducted which shall be approved by the Authority prior to the tempering of shellstock. ~~**(126)**~~ **(128) Transaction Record** means the form or forms used to document each purchase or sale of shellfish at the wholesale level and includes shellfish harvest and sales records, ledgers, purchase records, invoices and bills of lading. Re-number rest of section.
12. Public Health Significance	Tempering is mentioned in several sections of the Model Ordinance as is an authority approved tempering plan but there is no definition of either one.
13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
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7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Addition of new personnel training requirement for SSI's and SSO's
10. Specific NSSP Guide Reference	NSSP Model Ordinance, Section II., Chapter I. @.01 H. (1)
11. Text of Proposal/ Requested Action	**A. Personnel training requirements for implementing the NSSP** **(1) Shellfish Dealer Inspections** **(a) Shellfish Standardization Officer (SSO) shall successfully complete:** **(i) the FDA basic shellfish plant sanitation course** **(ii) ~~(i)~~ the FDA standardization training course** **(iii) ~~(ii)~~ Seafood HACCP; and** **(iv) ~~(iii)~~ the field evaluation by a FDA standardization officer** **(b) Shellfish Standardization Inspectors (SSI) shall successfully complete:** **(i) the FDA basic shellfish plant sanitation course** **(ii) ~~(i)~~ the FDA standardization training course** **(iii) ~~(ii)~~ Seafood HACCP; and** **(iv) ~~(iii)~~ The field evaluation by a FDA standardization officer or the SSO.**
12. Public Health Significance	The FDA identified a gap in training for new personnel who would be conducting shellfish plant inspections. Some students who were newly hired were attending the more advanced FD245 Shellfish Plant Standardization course without proper knowledge of shellfish plant sanitation, equipment, inspection techniques, and even at times, knowledge of bivalve molluscan shellfish as a food. Student surveys often commented on the course being too advanced for their knowledge, while others commented that less knowledgeable students slowed the course down. The FDA previously taught a basic shellfish course and determined it was extremely important to bring this basic course back to the shellfish curriculum. The new course, FD145 Basic Shellfish Plant Sanitation, will be a virtual course that FDA plans to offer at least once annually. FD145 is intended to be offered prior to FD245 each fiscal year to ensure students can take them in succession. The course will also be offered as a Partnership for Regulatory Education and Training (PRET) course, which means that once personnel from an authority successfully take an FDA offered course, and complete all requirements, they can then receive the materials to train their own staff. All current SSO and SSI will be grandfathered in and not be required to take FD145.
13. Cost Information	No cost for travel when taking the FDA OTED course due to this being a virtual course. Costs within each state using the PRET may differ depending on if they

	offer the training virtually or in person.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
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5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Notification of Certification Revocation
10. Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures, Procedures of the Interstate Shellfish Sanitation Conference, Procedure III. Responsibilities of the State; Section II Model Ordinance, Chapter I. Shellfish Sanitation Program Requirements for the Authority, @.02 Dealer Certification
11. Text of Proposal/ Requested Action	ISSC Constitution, Bylaws, and Procedures PROCEDURES OF THE INTERSTATE SHELLFISH SANITATION CONFERENCE PROCEDURE III. RESPONSIBILITIES OF THE STATE 3. The Authority of the shipping state shall certify the results of inspections of each interstate certified shellfish ~~shipper~~ dealer meeting NSSP requirements to ~~the~~ FDA ~~headquarters office~~ for inclusion in the Interstate Certified Shellfish Shippers List (ICSSL)~~, with copies to the appropriate FDA Regional Office. The certification inspection report, together with other pertinent information, shall be forwarded with the appropriate FDA~~ through form number FDA 3038b. The most recent certification status of a ~~shipper~~ dealer shall be reported. When the sanitation compliance status of a listed ~~shipper~~ dealer changes, as a result of a new inspection made with the twelve (12) month eligibility period, the most recent status shall apply and shall be submitted to FDA. When an ~~certified~~ interstate ~~shellfish shipper~~certified shellfish dealer changes status because of certificate suspension or revocation, the shipping state shall immediately notify ~~the~~ FDA ~~headquarters office~~through form number FDA 3038b~~, all known receiving states,~~ and the ISSC, which shall distribute the notification to all states with contact information for the shipping state~~, and the appropriate FDA Regional Office~~. Receiving states shall immediately notify shipping states in writing with a copy of irregularities in shellfish received, which may raise questions concerning the source or quality of the product. Chapter I. Shellfish Sanitation Program Requirements for the Authority @.02 Dealer Certification D. Revocation or Suspension of Certification. (1) The Authority shall not allow any dealer whose certification has been suspended or revoked under Section H. to deal in shellfish. (2) The Authority shall not issue certification to a dealer whose certification has been suspended or revoked to deal in shellfish until the dealer meets the requirements for initial certification. (3) The Authority shall notify the ISSC of the suspension or revocation of a certified shellfish dealer. The notification shall include, if known, the type of shellfish product and the dealers or retailers to whom the suspended or revoked dealer was shipping shellfish. The ISSC will distribute the notification to states. (a) After such a notification is made, receiving states should investigate potential receiving dealers or retailers to ascertain that shellfish is not still being shipped from the suspended or revoked dealer. Receiving states shall immediately notify the shipping state of any irregularities in shellfish received which may indicate that the dealer whose certification was revoked is continuing to ship shellfish

	product. The shipping state shall then take any further action required to not allow the dealer whose certification has been suspended or revoked to deal in shellfish.
12. Public Health Significance	While reading the ISSC Constitution, Bylaws, and Procedures, I noticed the existing requirement for shipping states to notify FDA, ISSC, and receiving states when a dealer certification is revoked. This existing requirement is not contained in the Model Ordinance where it belongs; as a result, although it is currently required, states aren't aware of it. It makes sense that after suspending or revoking a dealer certification for significant or chronic non-compliance with sanitation controls, receiving states should be notified so they have the opportunity to investigate (an investigation is not required) to ascertain that shellfish from the suspended or revoked dealer is not still being shipped. If the receiving state becomes aware that shellfish is still being shipped from the suspended or revoked dealer, they would notify the shipping state so that further action can be taken. This procedure, already required by the current ISSC Constitution, is necessary because, even after the suspended or revoked dealer has been removed from the ICSSL, receiving dealers might not be aware that the certification of a dealer from whom they routinely receive shellfish has been suspended or revoked, making communication between the states necessary. This proposal copies this existing requirement from the Constitution into the Model Ordinance, where it belongs so that states can be aware of it. It updates some of the language to be consistent with the current method for states to submit changes in dealer certification to the ICSSL, and it also adds some supporting details. Other than that, this proposal makes one change to this existing requirement: currently, the shipping state is required to notify the ISSC and receiving states whenever a dealer certification is revoked, and this proposal simplifies that process by modifying it so that the receiving state would notify the ISSC, which would then notify receiving states. This change is consistent with existing requirements in Chapter II that require states issuing a product recall to notify the ISSC, which then notifies other states.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Clarifying Broker and Importer roles relative to ICSSL certification
10. Specific NSSP Guide Reference	Chapter I. @.02 E.
11. Text of Proposal/ Requested Action	E. Interstate Certified Shellfish Shippers List (ICSSL). (1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. This includes dealers who are importers that own the product even if they do not take physical custody of the shellfish. This does not include brokers who do not own or take physical custody of the shellfish. The Authority shall include the certification type and any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038.
12. Public Health Significance	A word search for the terms 'broker' and 'importer' in the NSSP-MO reveals that the only usage of those terms currently in the MO is in the Definitions section, likely included to reference terms used in relevant CFRs. This proposal attempts to clarify why those terms are important relative to the NSSP and dealer certification. As the ICSSL is used as a reference document when determining admissibility of imported shellfish into U.S. commerce, it is important that State Authorities understand which entities should be permitted as dealers for inclusion in the ICSSL. In short, brokers neither own nor take possession of shellfish, and are not required to be permitted or listed in the ICSSL. Importers, who by definition own the product (regardless of whether they take physical possession), have a legal obligation to ensure those shipments meet U.S. acceptability criteria, and are therefore required to be inspected and permitted by state authorities for inclusion in the ICSSL.
13. Cost Information	None. This proposal only attempts to clarify existing NSSP requirements.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Direct reference to recalls in Chapter I.
10. Specific NSSP Guide Reference	Chapter I. @.01E. (1)(c)
11. Text of Proposal/ Requested Action	E. Administrative Procedures. (1) The Authority shall have administrative procedures sufficient to: (a) Regulate shellfish harvesting, sale, and shipment; (b) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the State from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its State to purchase the shellstock; (c) Recall, ~~D~~detain, condemn, seize, and embargo shellfish; and (d) Assure compliance with Shellfish Plant Inspection Standardization.
12. Public Health Significance	Chapter II of the Model Ordinance directs the Authority to initiate recall procedures when appropriate in response to incidents that may impact consumers of molluscan shellfish. The addition of "recall" to Chapter I. @.01E. (1)(c) ensures that the Authority has administrative procedures sufficient to execute a recall. Effective recall procedures are critical to ensuring that potentially contaminated products are removed from commerce when an incident occurs.
13. Cost Information	No cost
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Written procedures for investigating incidents of shellfish-borne disease
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. @.01 F. (2)
11. Text of Proposal/ Requested Action	(2) Have written procedures for investigating incidents of shellfish-borne disease.
12. Public Health Significance	Since investigating incidents of shellfish-borne disease is a critical aspect of protecting the safety of shellfish under the NSSP, having written procedures for these investigations is necessary to ensure effective response,
13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Intent for Consumer Cooking Clarification
10. Specific NSSP Guide Reference	Section I. Purposes & Definitions, Purpose
11. Text of Proposal/ Requested Action	Section I. Purposes & Definitions, Purpose The Model Ordinance ~~is intended to cover~~applies to molluscan shellfish that are raw (live, fresh or fresh frozen) and molluscan shellfish subjected to post-harvest processing (PHP) as defined in ~~this Guide~~the Model Ordinance. Cooked shellfish, shellfish subject to 21 CFR part 113 or 114, ~~or~~and raw shellfish ~~packaged with the explicit intent~~ that have undergone further processing such that they ~~will be cooked~~effectively require cooking by the end consumer to render them palatable (such as breaded or marinated) are generally recognized as products that are ~~beyond~~ outside the scope of the NSSP and are subject to the Seafood HACCP regulations (21 CFR 123). The placement of "Must be Cooked," "Cook Before Eating," or similar cooking instructions on the label of a shellfish product does not exempt the product from the requirements of the Model Ordinance. ~~However, such~~All shellfish products intended for interstate commerce are ~~still~~ subject to the appropriate harvest and/or approved source controls outlined in ~~this Guide~~the Model Ordinance when they are necessary to control a food safety hazard.
12. Public Health Significance	Clarification of the Purposes section. It currently says that "raw shellfish packaged with the explicit intent that they will be cooked by the end consumer (such as breaded or marinated) are generally recognized as products that are beyond the scope of the NSSP." This clarifies that the inclusion of cooking instructions on product labels does not exempt raw shellfish products from NSSP requirements. It clarifies that it is products that have undergone further processing that effectively necessitates cooking, such as breading or marinating, that are outside the scope of the NSSP.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	Section III. Public Health Reasons and Explanations – Chapter I. Shellfish Sanitation Program The Model Ordinance ~~is intended to cover~~applies to molluscan shellfish that are raw (live, fresh or fresh frozen) and molluscan shellfish subjected to post-harvest processing (PHP) as defined in ~~this Guide~~the Model Ordinance. Cooked shellfish, shellfish subject to 21 CFR part 113 or 114, ~~or~~and raw shellfish ~~packaged with the explicit intent~~that have undergone further processing such that they ~~will be cooked~~effectively require cooking by the end consumer to render them palatable (such as breaded or marinated) are generally recognized as products that are ~~beyond~~ outside the scope of the NSSP and are subject to the Seafood HACCP regulations (21 CFR 123). The placement of "Must be Cooked," "Cook Before

	Eating," or similar cooking instructions on the label of a shellfish product does not exempt the product from the requirements of the Model Ordinance. ~~However, such~~All shellfish products intended for interstate commerce are ~~still~~ subject to the appropriate harvest and/or approved source controls outlined in ~~this Guide~~the Model Ordinance when they are necessary to control a food safety hazard.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell; Shannon Jenkins
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control; State of North Carolina, Department of Environmental Quality
4. Address Line 1	285 Beiser Boulevard; PO Box 769
5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904; Morehead City, NC 28557
7. Phone	302-608-5511; 252-515-5611
8. Email	andrew.bell@delaware.gov; shannon.jenkins@deq.nc.gov
9. Proposal Subject	Aquaculture Permit Designation
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter I. Shellfish Sanitation Program Requirements for the Authority, E. Interstate Certified Shellfish Shippers List (ICSSL)
11. Text of Proposal/ Requested Action	E. Interstate Certified Shellfish Shippers List (ICSSL). (1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The Authority shall include the certification type and any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038. **Designations:**

Certification	**Designation**
SP – Shucker Packer	PHP – Post-Harvest Processing
RP – Repacker	~~AQ – Aquaculture~~
SS – Shellstock Shipper	WS – Wet Storage
RS – Reshipper	
DP – Depuration	

12. Public Health Significance	Unlike post-harvest processing and wet storage, aquaculture is not an activity performed by a dealer, but rather performed by a harvester/grower. Often, a grower has an aquaculture lease in his or her own name, which is different than the dealer name, making it difficult to know how to apply this requirement and whether the AQ designation must be included with the certification number on dealer tags (which is requirement as per the definition of Certification Number). The dealer certification and the aquaculture operation are often separate entities, and, in any case, aquaculture is not a dealer activity. There is no public health significance to including the AQ designation on dealer tags, and therefore the requirement should be deleted.
13. Cost Information	Dealer certifications with the permit designation "AQ" in the certification number will remain valid until renewal of the certification. The dealer's existing supply of tags will be allowed to be used up before the purchase of new tags without the "AQ" permit designation. If the certification number is "DE-00-SS" and the tag currently says "DE-00-SS,AQ", the tag is still in compliance with this proposal because it contains the certification number "DE-00-SS".

14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative

2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Outbreak Determination & Response Clarification
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter II. Risk Assessment & Risk Management
11. Text of Proposal/ Requested Action	@.01 Outbreaks of Shellfish-Related Illness A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the determination of whether an epidemiological association exists between the illness and the shellfish consumption will be made by the state or local epidemiologist in the state in which the ~~outbreak occurs~~shellfish were consumed. The determination will be made by reviewing: (1) Food history; (2) Whether the disease has the potential or is known to be transmitted by shellfish; and (3) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent. B. When the state or local epidemiologist in the state in which the ~~outbreak occurs~~shellfish were consumed has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption~~, the appropriate Authorities shall~~: (1) The Authority of the state in which shellfish were consumed shall ~~N~~notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred. (2) The appropriate Authorities shall, ~~W~~within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple ~~a~~Authorities in multiple states. The determination of the illness being growing area related will be conducted by the ~~source state~~Authority of the state in which shellfish were harvested. C. When the Authorities determine that the outbreak is not the result of a post-harvest contamination problem or illegal harvesting from a closed area, the Authority of the state in which shellfish were consumed shall determine if the outbreak is from a single source or multiple sources. (1) When the Authority of the state in which shellfish were consumed determines that a single source outbreak has occurred, the Authority of the state where shellfish were harvested shall: (a) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; (b) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area; (c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products. (d) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish. (e) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with

information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(2) When the Authority of the state in which shellfish were consumed determines that a multiple source outbreak has occurred, the Authority~~ies~~ of the state in which shellfish were harvested shall immediately place the implicated portion(s) of the harvest area(s) in a precautionary closure. A specific growing area placed in a precautionary closed status under this section can be immediately re- opened when one (1) or more of the following conditions are met:

(a) When the investigation by the Authority of the state in which shellfish were consumed, conducted in consultation with epidemiologist(s) in the state(s) in which the ~~outbreak occurs~~shellfish were consumed, determines that the shellfish which caused the outbreak did not come from one (1) or more of the implicated growing areas in question based on consumption data provided by victims or other relevant data provided by state investigators. This would include an additional illness(es) that matches one (1) or more of the implicated areas and allows for a more precise identification of the growing area(s) which caused the outbreak.

(b) When an investigation by the Authority of the state in which shellfish were harvested, in accordance with Chapter II @ .01 H, of an implicated growing area identifies an actual or potential pollution source(s) in a specific growing area and no source(s) are identified in other implicated growing areas, the precautionary closures in other implicated growing areas can be reopened. The reopening can only occur in a growing area after the investigation referenced above does not indicate an actual or potential pollution source that could be the cause of the outbreak.

(c) When the investigation, conducted in consultation with the epidemiologists in the state(s) in which the ~~illnesses occur~~shellfish were consumed and the Authorities ~~in~~of the state ~~from~~ in which the shellfish were harvested, provides information that may include but shall not be limited to:

(i) Volume or distribution information which would implicate a specific growing area;

(ii) Illness reporting from immediately adjacent growing areas;

(iii) Pollution source investigation in conjunction with growing area evaluation does not identify a pollution source.

(iv) Epidemiological tools that would link cases based on genetic similarity.

(3) When precautionary closures are established to address an illness outbreak involving multiple sources, Authorities will not be required to initiate voluntary recalls until the investigations indicate a single source.

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

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

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

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

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

E. When the Authority of the state in which shellfish were consumed cannot complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority ~~in the source state~~of the state in which shellfish were harvested shall:

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

area, the suspected growing area can be reopened.
(2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the ~~a~~Authority deems appropriate.
(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the ~~a~~Authority can document a rationale that a recall would be effective.

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

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

I. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with V.v., V.p. or Norovirus may be reconditioned.
(1) Validated reconditioning processes for V.v. and V.p. include subjecting product to validated post-harvest processing (PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority.
(2) Product associated with a Norovirus outbreak may be reconditioned by returning the product, within ten (10) days of harvest, to the area from which it was harvested

for an appropriate period of time. Environmental conditions in the harvest area must be conducive for pumping and feeding. The period of time shall not be less than sixty (60) days. The Authority shall ensure appropriate controls and provide documentation of the activity.

@.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 of the state in which shellfish were harvested shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area. States will not be expected to close growing areas based on V.p. cases that are reported more than thirty (30) days after harvest or when environmental parameters have changed or monitoring indicates the V.p. risk is reduced. Actions taken by the Authority will be based on the number of cases and the span of time as follows.

(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.

(2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area, the Authority shall:

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

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

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

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

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

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

(c) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.

(d) Issue a consumer advisory for all shellfish (or species implicated in the illness).

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

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

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

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

(a) Notify the ISSC and the FDA Shellfish Specialist of the problem; and
(b) Determine the appropriateness of initiating a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.
(c) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish; Should closures and recalls be necessary the ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(6) When the investigation outlined in Model Ordinance Chapter II. @.02 A.(4) does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority of the state in which shellfish were harvested shall:
(a) Follow the procedures outlined in Chapter II @.02 A. (1), (2) and (3).
(b) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
(c) If a recall is required by Chapter II @.02 A. (3)
i. Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.
ii. The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(7) When the ~~State~~ Authority ~~investigating the laboratory confirmed V.p. cases~~in which the shellfish was consumed does not provide information to identify a single growing area and multiple growing areas are implicated, the ~~State~~ Authorities in the states with implicated growing areas shall evaluate to determine if the illness should be attributed to the implicated area(s). Evaluations may include but are not limited to:
(a) Vibrio levels in the growing area around the time and date of harvest
(b) Comparison of other single source illnesses attributed to a growing area(s) involved in a multiple source outbreak. The purpose of this comparison would be to determine if a common growing area can be identified.
(c) Environmental conditions which could increase the risk of V.p. at the time of harvest. This could include conditions such as water temperature, air temperature and tidal stage.
(d) Genetic typing of clinical isolates implicates a common growing area or rules out implicated growing areas

(8) If the evaluation in (7) provides sufficient information to implicate a single area, then the ~~Shellfish~~ Authority shall take actions outlined in A. (6), above.

(9) When a growing area has been closed as a result of V.p. cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:
(a) The area will remain closed for a minimum of fourteen (14) days when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area.
(b) The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area

(10) Prior to reopening an area closed as a result of @.02 A. (9)(a) or (b), 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 area and

	shellfish types.; and (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 area.; or (b) Ensure that environmental conditions have returned to levels not associated with V.p. cases. (11) Shellfish harvesting may occur in an area closed as a result of V.p. illnesses when the Authority implements one (1) or more of the following controls: (a) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total V.p. for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams; (b) Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing; (c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of V.p. illness is no longer reasonably likely to occur, as approved by the Authority.
12. Public Health Significance	This proposal is meant to clarify who does what during illness investigations, not to add or alter any existing requirements. When reading this chapter, it has been unclear to me which states (the state where the shellfish implicated in an illness were consumed, versus the states where the shellfish were harvested) were responsible for the actions required by this chapter. This proposal is intended to ensure that the responsibilities for illness response outlined in this chapter are clearly delineated. It is not meant to add or change any existing requirements, just to provide clarity so that illness response are handled as intended to ensure that outbreak investigation and response can be successful in preventing further illnesses.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Vibrio Management Program
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.01, @.02, @.03, @.06
11. Text of Proposal/ Requested Action	The below text is proposed to replace existing Ch II. @.01 where indicated, all of @.02, @.03, and @.06 as well as strike @.07 in its entirety. **@.01 Outbreaks of Shellfish-Related Illness** A. When shellfish are implicated in an illness outbreak involving two (2) or more persons (or one (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the determination of whether an epidemiological association exists between the illness and the shellfish consumption will be made by the state or local epidemiologist in the state in which the outbreak occurs. The determination will be made by reviewing: (1) Food history; (2) Whether the disease has the potential or is known to be transmitted by shellfish; and (3) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent. NOTE: For additional guidance refer to the International Association for Food Protection Procedures to Investigate Food Borne Illness. B. When the state or local epidemiologist in the state in which the outbreak occurs has determined an epidemiological association… C. When the Authorities determine that the outbreak is not the result of a post-harvest contamination… D. When the appropriate Authorities determine that the illnesses are related to post-harvesting contamination… E. When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours… F. Upon closing an implicated portion(s) of the harvest area(s) for 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 pathogens

	and/or biotoxins are not a public health concern. (4) Shall follow the procedure outlined in Chapter II @ .02 (10)(a) or (b) for closures resulting from *Vibrio* illnesses. (5) 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 determined the problem… H. Whenever an Authority or dealer initiates a recall of shellfish products… I. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *Vibrio* or Norovirus may be reconditioned. (1) Validated reconditioning processes for *Vibrio* include subjecting product to validated post-harvest processing (PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority. (2) Product associated with a Norovirus outbreak… **@.02 Shellfish Related Illnesses Associated with *Vibrio* Species** A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with *Vibrio* spp., the Authority shall determine the number of culture-confirmed cases and the number of laboratory-confirmed cases and the number of *Vibrio* spp. cases diagnosed by culture-independent testing (CIDT) epidemiologically associated with the implicated area. States will not be expected to close growing areas based on vibriosis cases that are reported more than thirty (30) days after harvest or when environmental parameters have changed or monitoring indicates the *Vibrio* risk is reduced. Actions taken by the Authority will be based on the number of cases and the span of time as follows. (1) When at least two (2) cases occur within a thirty (30) day period and are from a single harvest day, the determination of whether the definition of an outbreak has been met should be made as described in @.01 A. If determined to be an outbreak, the requirements of @.01 B.-I. shall be met. (2) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan. (3) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area, the Authority shall: (a) Determine the extent of the implicated area; and (b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and (c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish. (4) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall: (a) Determine the extent of the implicated area; and

	(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and (c) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products. (d) Issue a consumer advisory for all shellfish (or species implicated in the illness). (5) If at least one (1) culture-confirmed *Vibrio* case has been epidemiologically associated with an implicated area, every two (2) *Vibrio* spp. cases diagnosed via CIDT and epidemiologically associated with the implicated area within a 30-day period will be individually enumerated as one (1) case under sections @.02 A.(1)-(4). (6)When the number of cases and the span of time reach the thresholds outlined above, prior to implementing the controls above, the Authority shall conduct an investigation of the illnesses within seventy-two (72) hours of reaching any one (1) of the thresholds of Chapter II @.02 A. (1), (2) or (3) to determine whether the illness is growing area related or is the result of post-harvest abuse or mishandling such as time temperature abuse. (a) If the conditions in Chapter II @.02 A. (2) or (3) are met and the investigation cannot be completed within 72 hours, immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status. (b) Should the Authority later determine that the illnesses are related to post harvest abuse or mishandling the implicated harvest area(s) can be immediately reopened. (7) When the investigation outlined in Model Ordinance Chapter II. @.02 A. (4) demonstrates that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall: (a) Notify the ISSC and the FDA Shellfish Specialist of the problem; and (b) Determine the appropriateness of initiating a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products. (c) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish; Should closures and recalls be necessary the ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information. (8) When the investigation outlined in Model Ordinance Chapter II. @.02 A.(4) does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall: (a) Follow the procedures outlined in Chapter II @.02 A. (1), (2) and (3). (b) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area; (c) If a recall is required by Chapter II @.02 A. (3) i. Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish. ii. The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying

	dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information. (9) When the State Authority investigating the laboratory confirmed *Vibrio* cases does not provide information to identify a single growing area and multiple growing areas are implicated, the State Authorities in the states with implicated growing areas shall evaluate to determine if the illness should be attributed to the implicated area(s). Evaluations may include but are not limited to: (a) *Vibrio* levels in the growing area around the time and date of harvest. (b) Comparison of other single source illnesses attributed to a growing area(s) involved in a multiple source outbreak. The purpose of this comparison would be to determine if a common growing area can be identified. (c) Environmental conditions which could increase the risk of *Vibrio* at the time of harvest. This could include conditions such as water temperature, air temperature and tidal stage. (d) Genetic typing of clinical isolates implicates a common growing area or rules out implicated growing areas. (9) If the evaluation in (8) provides sufficient information to implicate a single area, then the Shellfish Authority shall take actions outlined in A. (7), above. (10) When a growing area has been closed as a result of vibriosis cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred: (a) The area will remain closed for a minimum of fourteen (14) days when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area. (b) The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or at least two (2) cases occur from a single harvest date from the implicated area. (11) Prior to reopening an area closed as a result of @.02 A. (9)(a) or (b), the Authority shall: (a) Collect and analyze samples to ensure that *Vibrio* levels are less than those associated with illness (for *V. parahaemolyticus*, tdh does not exceed 10/g and trh does not exceed 10/g) as determined appropriate by the Authority based on studies. (i) Samples shall be collected to be representative of the area and shellfish types; and (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 area; or (b) Ensure that environmental conditions have returned to levels not associated with vibriosis cases for a minimum of 14 days. (12) Shellfish harvesting may occur in an area closed as a result of *Vibrio* 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; (c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *Vibrio* illness is no longer reasonably likely to occur, as approved by the Authority.

@. 03 Annual Assessment of *Vibrio* spp. Illnesses and Shellfish Production
A. The Authority shall assess annually vibriosis cases associated with the consumption of molluscan shellfish. The assessment will include a record of all vibriosis shellfish-associated cases, culture-confirmed and CIDT-positive, reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.
B. The Authority shall collect by month and report annually to the ISSC the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species. Where available the volume breakdown of the production data will be reported by utilization type (raw, shucked, PHP, etc.).

@.04 Presence of Human Pathogens in Shellfish Meats…

@.05 Presence of Toxic Substances in Shellfish Meats…

@.06 *Vibrio* spp. Control Plan
The goal of the *Vibrio* Control Plan is to reduce the probability of occurrence of *Vibrio* illness during periods that have been historically associated with illnesses. The Plan is to be implemented as part of a comprehensive program which includes all applicable time and temperature requirements contained in the Model Ordinance.

A. Determination of Need for *Vibrio* Control Plan
(1) Risk Evaluation
Every State from which shellfish are harvested shall conduct a *Vibrio* risk evaluation annually for each species of commercially harvested shellfish. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of vibriosis from the consumption of shellfish harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur (for the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence):
(a) The number of vibriosis cases, culture-confirmed and CIDT-positive, linked to the consumption of commercially harvested shellfish from the State;
(b) Levels of *Vibrio* spp. in the growing waters and in shellfish, to the extent that such data exists;
(c) The water temperatures in the area;
(d) The air temperatures in the area;
(e) Salinity in the area;
(f) Harvest techniques in the area; and
(g) The quantity of harvest from the area and its uses, i.e., raw market, half shell, PHP.
(2) States which have previously met the threshold requiring a *Vibrio* Control Plan will continue to maintain and implement a *Vibrio* Control Plan.
(3) All States not currently implementing a *Vibrio* Control Plan shall develop and implement a *Vibrio* Control Plan if the risk evaluation indicates:
(a) Two (2) or more etiologically confirmed, and epidemiologically linked *V. vulnificus* illnesses from consumption of commercially harvested oysters that originated from the growing waters of that State within the previous ten (10) years; or
(b) Shellfish from the growing waters within the State were epidemiologically linked

to an outbreak of *Vibiro* within the prior five (5) years;
(c) Shellfish from the growing waters within the State were closed due to triggers in @.02 more than 3 times within the prior five (5) years; or
(c) The risk of vibriosis from the consumption of shellfish harvested from a growing area is reasonably likely to occur; or
(d) A shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, unless the risk evaluation determines that vibriosis is not reasonably likely to occur from the consumption of shellfish harvested from those areas and rationale is documented:
(i) Waters bordering the Pacific Ocean: 60 °F.
(ii) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81 °F.
(iii) Waters bordering the Atlantic Ocean (NY and north): 60 °F.

B. *Vibrio* Control Plan
(1) For States required to implement a *Vibrio* Control Plan (VCP), the VCP shall include the administrative procedures and resources necessary to accomplish the following:
(a) Establish one (1) or more triggers for when control measures are needed. These triggers shall be the average monthly daytime water temperatures in @.06 A(3)(d) where they apply, or other triggers as determined by the risk evaluation, which may include:
(i) The air temperatures in the area; when the Average Monthly Maximum Water Temperature (AMMWT) exceeds:
a) 60°F for waters bordering the Pacific Ocean or Atlantic Ocean (NY and north)
b) 81°F for waters bordering the Gulf of Mexico or Atlantic Ocean (NJ and south)
(ii) Salinity in the area; or
(iii) Other factors that affect risk which can be used as a basis for reducing risk.
(b) Implement one (1) or more control measures to reduce the risk of vibriosis at times when it is reasonably likely to occur. The control measures may include:
(i) Closing the area to shellfish harvest;
(ii) 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 shellfish and a three (3) log reduction for the Pacific Coast oysters;
(iii) Subjecting all oysters intended for the raw, half-shell market to approved PHP when the AMMWT exceeds temperatures in B.(1)(a)(i).
(iv) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA. . For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, the State VCP will include controls when water temperature promotes *Vibrio* levels and risk of vibriosis increases.
(v) Limiting time from harvest to refrigeration such that the *Vibrio* levels after the completion of initial cooling to 50F (internal temperature of shellfish) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority.
(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of Vp illness is no longer reasonably likely to occur, as approved by the Authority.
(c) Require the original dealer to cool shellfish to an internal temperature of 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority after

placement into refrigeration during periods when the risk of *Vibrio* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters and/or hard clams has reached 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering. Shellfish without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled for approved post-harvest processing to control the *Vibrio* hazard.

(d) When pre-harvest culture practices have the potential to elevate *Vibrio* levels in market size product intended for immediate harvest, the Authority shall establish Vibrio control measures and include the measures in the State VCP. Such control measures may be implemented on a State-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority shall include record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.

(e) Evaluate the effectiveness of the Plan.

(f) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available, or new technology makes this prudent as determined by the Authority.

(2) When pre-harvest culture practices have the potential to elevate *Vibrio* levels in market size product intended for immediate harvest, the Authority shall establish *Vibrio* control measures and include the measures in the VCP. Such control measures may be implemented on a State-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water, and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.

C. Control Plan Evaluation

(1) The State Authority will conduct annual evaluations of the VCP. At a minimum the Authority will consider:

(a) The annual number of vibriosis cases associated with the State's growing waters and the amount of shellstock sold to determine risk per servings for each temperature period.

(b) Environmental changes which could affect total *Vibrio* levels in shellfish pre- and post-harvest.

(c) Industry compliance with existing controls.

(d) The Authority's enforcement of industries' implementation of the controls.

(2) For the purposes of determining Authority compliance with VCP requirement, the FDA will conduct an annual RARM evaluation of the Authority to determine the following:

(a) Authority compliance with *Vibio* Risk Evaluation as required in Chapter II. @.06 A.

(b) For States requiring the development of VCPs, compliance with Control Plan requirements of Chapter II. @.06 E. (1). The evaluation should determine:

	(i) Appropriate identification of triggers to determine when control measures are needed. (ii) Appropriate implementation of one (1) or more of the control measures required in Chapter II. @.06 B. (1) (b).
12. Public Health Significance	Note that this proposal is being submitted to start the discussion. Due to increases in vibriosis cases and the use of CIDT, which does not align with current Vibrio management strategies, a total vibrio program is being proposed. In recent years, the total number of vibriosis cases continues to increase. According to the CDC BEAM Dashboard, culture confirmed vibrio cases increased from 1,284 (648 foodborne) in 2022 to 1,449 (736 foodborne) in 2024, the most recent year for which data are available. During these year, Vibrio parahaemolyticus and V. vulnificus cases (606 combined in 2022 and 682 combined in 2024) do not account for this increase alone. While not all vibriosis-causing species are reported through the BEAM dashboard, the other species reposnsible for foodborne infections, V. cholerae and V. fluvialis, also increased from 246 combined in 2022 to 300 in 2024, with 63-77% of cases reporting seafood consumption. In addition, the use of CIDT continues to increase. 1,276 CIDT vibrio cases were reported in 2022, with 2,231 reported cases in 2024. When looking only a foodborne associated CIDT cases, there were 1,175 in 2022 and 2,110 in 2024. CIDTs can detect multiple species of vibrio, there is an increasing use of CIDT, and species other than V. parahaemolyticus and V. vulnificus are increasingly identified as causes of vibriosis. Taken together, this indicated the need to update the strategy for evaluating and managing the public health risk associated with vibrios.
13. Cost Information	Unknown.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Include reference for human pathogens
10. Specific NSSP Guide Reference	Section II Model Ordinance - Chapter II. Risk Assessment Risk Management @.01 Outbreaks of Shellfish-Related Illness
11. Text of Proposal/ Requested Action	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. (a) When sample analysis determines that human pathogens are present in shellfish meats, follow procedures outlinesd in Chapter II @.04 D. (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…
12. Public Health Significance	In the course of outbreak investigations, shellfish samples are sometimes collected under Ch. II @.01 F. When resultant sample analyses determine that a pathogen is present in shellfish, the Authority should follow the procedures in Ch II @.04 D. to determine the growing area status, and classification, if appropriate. This proposal clarifies the link between the two sections of the MO to facilitate response to a pathogen outbreak.
13. Cost Information	None.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Clarify that when post-harvest issues are ruled out, the growing area should be deemed to be the source of the issue
10. Specific NSSP Guide Reference	Section II Model Ordinance - Chapter II. Risk Assessment Risk Management @.01 Outbreaks of Shellfish-Related Illness
11. Text of Proposal/ Requested Action	C. When the Authorities determine that the outbreak is not the result of a post-harvest contamination problem or illegal harvesting from a closed area, the Authority shall deem the growing area(s) to be the source of the contamination and determine if the outbreak is from a single source or multiple sources. (1) When the Authority determines that a single source outbreak has occurred, the Authority shall: (a) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; (b) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;…. D. When the appropriate Authorities determine that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination, mishandling or illegal harvesting from a closed area occurred shall:… E. When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority in the source state shall:… F. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:… G. When the growing area is ~~determined~~ deemed to be the source of the contamination ~~problem~~, either through the result of growing area investigation or when no illegal harvesting from a closed area or post-harvest contamination problems issues are identified as described in @.01 C., the Authority shall: (1) Place the growing area in the closed status until: (a) The Authority verifies that the area is properly classified by conducting a review of the growing area to include:…
12. Public Health Significance	Current language in Chapter II. @.01 is unclear that once post-harvest contamination problems or illegal harvesting from a closed area are ruled out as potential sources of contamination leading to an illness outbreak that the growing area should be considered the source of contamination. While growing area

	investigations often do not uncover issues, the potential for small contamination events (e.g., overboard discharge) generally cannot be ruled out due to the time elapsed from illness notification and growing area investigation. Routine growing area sampling may not identify these issues due to their limited nature (potentially small area impacted for a short time frame). The proposed language is to clarify the existing requirements for the Authority to respond to outbreaks for which no post-harvest issues or illegal harvest are identified.
13. Cost Information	None.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Growing Area Closure Period due to V.p. Cases
10. Specific NSSP Guide Reference	Section II Model Ordinance Chapter II. @.02 A. (9) (a) and (b)
11. Text of Proposal/ Requested Action	When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred: (a) The area will remain closed for a minimum of fourteen (14) days from the date of closure when ~~the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or~~ cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area. (b) The area will remain closed for a minimum of twenty-one (21) days from the date of closure 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.
12. Public Health Significance	Maintaining an implicated harvest area in the closed status is a critical step in shellfish-borne illness response. The closure period allows time to determine if additional illnesses have occurred and to ensure that the hazard that caused the illnesses has passed. The current wording of the Model Ordinance specifies minimum closure periods of 14 and 21 days for areas implicated in *V.p.* illnesses, however, the wording is unclear as to when to start counting the 14 or 21 days. Adding that the closure period will extend 14 or 21 days from the date of closure provides clarity and will increase uniformity in meeting the requirement.
13. Cost Information	There would be no cost related to this proposal.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Notification of growing area closures and recalls due to outbreaks of shellfish-related illness
10. Specific NSSP Guide Reference	Section II Model Ordinance Chapter II. @.01 B. (1), C. (1) and @.01 D.
11. Text of Proposal/ Requested Action	Chapter II. @.01 Outbreaks of Shellfish-Related Illness B. When the state or local epidemiologist in the state in which the outbreak occurs has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption, the appropriate Authorities shall: (1) Notify the FDA ~~Shellfish Specialist~~ that a shellfish related outbreak has occurred. (2) … C. …. (1) When the Authority determines that a single source outbreak has occurred, the Authority shall: (a) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; (b) Notify the ISSC and the FDA in writing ~~Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated~~ of the growing area closure; (c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products. (d) Transmit to the ~~ISSC and~~ FDA information identifying the dealers shipping the implicated shellfish. (e) In the case of recalls, the FDA will provide States with information identifying dealers receiving the implicated shellfish and dealers further distributing the implicated product; (f) ~~The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish.~~ Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall ~~information~~ notices. D. When the appropriate Authorities determine that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination,

	mishandling or illegal harvesting from a closed are occurred shall: ~~(1) Notify the ISSC and the FDA Shellfish Specialist of the problem; and~~ (1) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 when a recall is deemed appropriate by the Authority. The recall shall include all implicated products. (2) ~~Inform~~Notify the ISSC and the FDA in writing of the recall. (3) Transmit to the ~~ISSC and~~ FDA information identifying the dealers shipping the implicated shellfish. (i) In the case of recalls, the FDA will provide States with information identifying dealers receiving the implicated shellfish and dealers further distributing the implicated product. (4) ~~The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify states with information identifying dealers shipping the implicated shellfish. Closure and~~ Recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of ~~closure and~~ recall ~~information~~ notices.
12. Public Health Significance	This section directs the Authority to make certain notifications when growing area closures and recalls are necessary to respond to incidents of shellfish-borne illness. It also places requirements on the ISSC and the FDA. Currently, the ISSC is not providing notification about dealers shipping the implicated product to states, so this proposal removes that requirement and clarifies that the FDA will make those notifications and provide further distribution information. In the case of shellfish-borne illness, it is imperative to notify states potentially receiving implicated product as quickly as possible so that product can be removed from commerce. It is more efficient for the FDA to collect distribution information and provide it to states than for the ISSC to do that activity. The role of the ISSC should be to post the closure and recall notices and make the membership aware of the issue. The FDA, through the Shellfish Specialists and other DSS staff are better equipped to assist the states in providing distribution information to impacted states. Additionally, some states are not able to provide specific dealer information and quantity of shellfish shipped due to state information sharing laws to a non-regulatory entity such as the ISSC. States routinely share this information with the FDA, and by taking the ISSC out of the notification chain, efficiency is increased allowing for more rapid notifications.
13. Cost Information	There would be no cost to the industry or Authority related to this proposal.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Notification of precautionary closure
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. @.01 E.
11. Text of Proposal/ Requested Action	Chapter II. @.01 Outbreaks of Shellfish -Related Illness E. When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority in the source state shall: (1) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status. Should the Authorities later determine that the illnesses are related to post-harvest contamination, or mishandling, or harvested from a closed area, the suspected growing area can be reopened. (2) Notify the ISSC and the FDA Shellfish Specialist in writing of the precautionary closure. ~~(2)~~ (3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate. ~~(3)~~ (4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority can document a rationale that a recall would be effective.
12. Public Health Significance	There is no definition in the Model Ordinance for precautionary closed status. The only real difference between closed status for a growing area and precautionary closed status in the event of shellfish-related illness is the reopening criteria. Precautionary closed status should be treated the same as closed status, including making the appropriate notifications.
13. Cost Information	There would be no cost to the industry or Authority related to this proposal.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
3. Affiliation	U.S. Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Molluscan shellfish illness reporting
10. Specific NSSP Guide Reference	Chapter II. @.03 A.
11. Text of Proposal/ Requested Action	@.03 Annual Assessment of ~~Vibrio vulnificus and Vibrio parahaemolyticus~~ Illnesses and Shellfish Production The Authority shall assess annually ~~Vibrio vulnificus (V.v.) and Vibrio parahaemolyticus (V.p.)~~ illnesses associated with the consumption of molluscan shellfish. The written assessment will include a record of all ~~V.v. and V.p.~~ shellfish-associated illnesses reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.
12. Public Health Significance	The reporting of all shellfish associated illnesses (not just V.v. and V.p.) allows for the collection of statistics that show how often a disease occurs and the information can be used to identify outbreaks, disease trends, and track outbreaks. These data can be used by the conference to identify if controls are effective and if different or additional controls should be in place to prevent shellfish illnesses and outbreaks. Chapter I. @.01 F. requires all states to have written protocols and procedures to investigate shellfish associated illnesses. A written annual assessment of illnesses is complementary to the Chapter I. @.01 F. requirement.
13. Cost Information	Minimal cost for additional documentation time.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
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6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Restricted Shucked Shellfish from the Controlled Access Status
10. Specific NSSP Guide Reference	Section I. Purposes & Definitions, Definitions Section II. Model Ordinance; Chapter IV. Shellstock Growing Areas, @.04 Marine Biotoxin Control, B. Marine Biotoxin Management Plan; Chapter VIII. Control of Shellfish Harvesting, .02 Shellstock Harvesting and Handling, F. Shellstock Identification; Chapter X. General Requirements for Dealers, .05 Shellstock Identification, .06 Shucked Shellfish Labeling, .09 Shellfish Harvested from Federal Waters; Chapter XI. Shucking and Packing, Chapter XII. Repacking, Chapter XIII. Shellstock Shipping, Chapter XIV. Reshipping, Chapter XV. Depuration; .01 Critical Control Points
11. Text of Proposal/ Requested Action	Section I. Purposes & Definitions, Definitions **(107) 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, including shellstock from waters in the controlled access status. Restricted shellstock is identified with a tag indicating that the shellstock has restrictions requiring further processing or testing prior to distribution. **(108) Restricted Shucked Shellfish** means shucked shellfish that was processed from restricted shellstock, except for shucked shellfish for which shucking was the intended use. Restricted shucked shellfish is identified with a label indicating that the shellstock has restrictions requiring further processing or testing prior to distribution. Chapter IV. Shellstock Growing Areas, @.04 Marine Biotoxin Control B. Marine Biotoxin Management Plan (2) The plan shall define the administrative procedures and resources necessary to accomplish the following: (h) Ensure that all shellfish harvested from growing areas or portion(s) of growing areas placed in the controlled access status meets all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing or product holds. (5) The marine biotoxin management plan shall include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in a growing area that is placed in the controlled access status. When shellfish is shipped before all conditions of harvest restrictions have been met to allow the shellfish to be placed into distribution, the Authority of the landing state, the Authorities of receiving states and all receiving dealers shall also be included in the agreements or memoranda of understanding Such harvesting shall be conducted with strict assurances of safety and in accordance with the marine biotoxin management strategies listed in (4). The agreements or memoranda of understanding shall identify responsibilities for each agency and dealer. When product is shipped by the dealer before confirmatory biotoxin testing results are received, or otherwise not in compliance with the harvest permit conditions, procedures for the disposition of product and

notification by the shipping dealer to receiving dealers shall be included in the Marine Biotoxin Management Plan.

C. Closed or Controlled Access Status of Growing Areas.

(7) A growing area, or portion(s) thereof, shall be placed in the controlled access status for the taking of shellstock when the Authority determines that additional requirements are necessary to ensure the safe harvest of product. Controlled access status is a designation of an approved area or a conditionally approved area in open status. Additional requirements shall be included in harvest permit conditions. All shellstock harvested from growing areas in the controlled access status shall be tagged with ~~R~~restricted ~~S~~shellstock tags. All shucked shellfish processed from restricted shellstock shall be labeled with restricted shellfish labels until all conditions of harvest restrictions have been met to allow the shellfish to be placed into distribution.

Chapter VIII. Control of Shellfish Harvesting

.02 Shellstock Harvesting and Handling

F. Shellstock Identification

(7) Restricted Shellstock. For restricted shellstock, the tag shall include specific language detailing the intended use of the shellfish.

Chapter X. General Requirements for Dealers

.01 General HACCP Requirements

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(c) Critical control points shall be designed to ensure that shellstock received with restricted shellstock tags and restricted shucked shellfish labels is processed consistent with the stated purpose or, in the case of shellfish from controlled access waters, cleared for distribution after testing or sampling results are received. For Shellstock tagged for restricted use and for shucked shellfish labeled for restricted use, critical control points shall be included in the Certified Dealer's HACCP plan to ensure that the shellstock or shucked shellfish is shipped to another Certified Dealer with the restricted shellstock tag or restricted shucked shellfish label, ~~or~~ processed consistent with the stated purpose, or, in the case of shellfish from controlled access waters, cleared for distribution after testing or sampling results are received.

(5) Include any corrective action plans that have been developed in accordance with Section .01 F. (2), to be followed in response to deviations from critical limits at critical control points. Corrective action plans shall be developed for restricted shellstock and restricted shucked shellfish from controlled access waters to ensure that product not in compliance with harvest permit conditions, and any other impacted products are disposed of in a manner that protects public health and in accordance with applicable Federal, State and local regulations.

.05 Shellstock Identification

B. Tags

(7) Restricted Shellstock. For restricted shellstock, the tag shall include specific language detailing the intended use of the shellfish.

(~~8~~a) If a shellfish producing State selects to implement Chapter II. @.06 E. (1) (b) (i), a statement indicating that the shellstock are for shucking by a certified dealer and/or for approved post harvest processing to control the Vibrio vulnificus hazard shall be included on the tag. When this statement is included, the shellstock shall ultimately be sold to or processed by a certified shucker-packer or post-harvest processor for the purpose of shucking or post-harvest processing.

.06 Shucked Shellfish Labeling

A. Shellfish Labeling

(12) For restricted shucked shellfish, the label shall include specific language detailing the intended use of the shellfish.

.09 Shellfish Harvested from Federal Waters

A. The dealer shall:

(1) If receiving shellstock or shucked shellfish harvested from Federal waters in the controlled access status, be party to agreement or memoranda of understanding

between NOAA, the Authority of the landing state, the Authorities of receiving states and receiving dealers which receive shellfish before all conditions of harvest restrictions have been met to allow the shellfish to be placed into distribution, ~~NOAA~~ and the individual harvesters as necessary to comply with the biotoxin controls outlined in the NSSP Chapter IV. @.04 B. and in accordance with Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.

Chapter XI. Shucking and Packing, .01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; or[C]

(b) Harvested restricted shellstock ~~and~~ which are properly tagged with information describing the restriction; [C]

(c) Harvested shellstock from federal waters which are in accordance with the required NOAA contract and agreements outlined in Chapter VIII. .03.

(~~c~~d) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C]

(~~d~~e) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].

(2) The dealer shall shuck and pack only shellstock obtained and transported from a dealer who has:

(a) Shipped restricted shellstock which are properly tagged or restricted shucked shellfish which are properly labeled with information describing the restriction; and [C]

(~~a~~b) 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~~c) Provided documentation as required in Chapter IX. .05; and [C]

(~~c~~d) Adequately iced the shellstock; or [C]

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

D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(6) Shellfish that is received bearing a restricted shellstock tag or restricted shucked shellfish label is processed consistent with the stated purpose or, in the case of shellfish from controlled access waters, cleared for distribution after testing or sampling results are received. [C]

F. Shellfish Shipping Critical Control Point – Critical Limits. The dealer shall ensure that:

(1) Shellfish that is received bearing a restricted shellstock tag or restricted shucked shellfish label shall only be shipped to a certified dealer and shall include on the tag or label specific language detailing the intended use of the shellfish. The transaction record shall indicate the quantity of restricted shellfish containers. [C]

Chapter XII. Repacking, .01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which originated from a dealer who has:

(1) Shipped the shellfish iced, or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature; [C] and

(2) Shipped restricted shellstock which are properly tagged or restricted shucked shellfish which are properly labeled with information describing the restriction; and [C]

(~~2~~3) Identified the shellfish with a label as outlined in Chapter X. .06. [C]

B. Processing Critical Control Point - Critical Limits.

The dealer shall ensure that:

(1) ~~t~~Repacked shucked shellfish do not exceed an internal temperature of 45 °F (7.2 °C) for more than two (2) hours~~.~~; and [C]

(2) Shellfish that is received bearing a restricted shellstock tag or restricted

shucked shellfish label is processed consistent with the stated purpose or, in the case of shellfish from controlled access waters, cleared for distribution after testing or sampling results are received. [C]

D. Shellfish Shipping Critical Control Point – Critical Limits. The dealer shall ensure that:

(1) Shellfish that is received bearing a restricted shellstock tag or restricted shucked shellfish label shall only be shipped to a certified dealer and shall include on the tag or label specific language detailing the intended use of the shellfish. The transaction record shall indicate the quantity of restricted shellfish containers. [C]

Chapter XIII. Shellstock Shipping, .01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall ship or repack only shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and [C]

(b) Harvested restricted shellstock which are properly tagged or restricted shucked shellfish which are properly labeled with information describing the restriction; [C]

(c) Harvested shellstock from federal waters which are in accordance with the required NOAA contract and agreements outlined in Chapter VIII. .03.

(~~b~~d) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C]

(~~c~~e) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].

(2) The dealer shall ship or repack only shellstock obtained and transported from a dealer who has:

(a) Shipped restricted shellstock which are properly tagged or restricted shucked shellfish which are properly labeled with information describing the restriction; and [C]

(~~a~~b) Identified the shellstock with a tag on each container as outlined in Chapter X. .05; and [C]

(~~b~~c) Provided documentation as required in Chapter IX. .05; and [C]

(~~c~~d) Adequately iced the shellstock; or [C]

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

C. Processing Critical Control Point – Critical Limits. The dealer shall ensure that shellfish that is received bearing a restricted shellstock tag or restricted shellfish label is processed consistent with the stated purpose or, in the case of shellfish from controlled access waters, cleared for distribution after testing or sampling results are received. [C]

~~D~~E. Shell~~stock~~fish Shipping Critical Control Point – Critical Limits. The dealer shall ensure that

(1) Shell~~stock~~fish that is received bearing a restricted shellstock tag or restricted shucked shellfish label shall only be shipped to a certified dealer and shall include on the tag or label specific language detailing the intended use of the ~~shellstock~~shellfish. The transaction record shall indicate the quantity of restricted ~~use shellstock~~ shellfish containers. [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) Shipped restricted shellfish which are properly tagged or restricted shucked shellfish which are properly labeled with information describing the restriction; and [C]

(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) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less: or [C]
(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]

E. Shell~~stock~~fish Shipping Critical Control Point – Critical Limits. The dealer shall ensure that:

(1) Shell~~stock~~fish that is received bearing a restricted shellstock tag or restricted shucked shellfish label shall only be shipped to a certified dealer and shall include on the tag or label specific language detailing the intended use of the shell~~stock~~fish. The transaction record shall indicate the quantity of restricted ~~use~~ shell~~stock~~fish containers. [C]

Chapter XV. Depuration, .01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall receive and depurate only shellstock which is obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; [C] and
(b) Harvested restricted shellstock which are properly tagged with information describing the restriction; [C]
(c) Harvested shellstock from federal waters in accordance with the required NOAA contract and agreements outlined in Chapter VIII. .03.
(~~b~~d) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; [C] and
(~~c~~e) Harvested the shellstock in compliance with the time/temperature requirements of Chapter VIII. @.02 A. (1), (2) or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2). [C]

(2) The dealer shall receive and depurate only shellstock obtained and transported from a dealer who has:

(a) Shipped restricted shellstock which are properly tagged or restricted shucked shellfish which are properly labeled with information describing the restriction; and [C]
(~~a~~b) 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~~c) Provided documentation as required in Chapter IX. .05; and [C]
(~~c~~d) Adequately iced the shellstock, or [C]
(~~d~~e) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. [C]

B. Processing Critical Control Points - Critical Limits. The dealer shall ~~assure~~ ensure that:

(1) All depuration lots are treated for a minimum of forty-four (44) hours; [C]
(2) The water treatment system is operating to design specifications; and [C]
(3) All critical limits established during verification of the specific depuration process are being met. [C]
(4) Shellfish that is received bearing a restricted shellstock tag or restricted shucked shellfish label is processed consistent with the stated purpose or, in the case of shellfish from controlled access waters, cleared for distribution after testing or sampling results are received. [C]

E. Shellfish Shipping Critical Control Point – Critical Limits. The dealer shall ensure that:

(1) Shellfish that is received bearing a restricted shellstock tag or restricted shucked shellfish label shall only be shipped to a certified dealer and shall include specific language on the tag or label detailing the intended use of the shellfish. The transaction record shall indicate the quantity of restricted shellfish containers. [C]

[Additionally, change the term “restricted use shellstock” to “restricted shellstock” throughout the Guide so as to be consistent with the updated term, as per the current Definitions]

12. Public Health Significance	The Model Ordinance currently contains specifications relating to the controlled access status and relating to restricted shellstock. However, these requirements are not worded correctly to apply to a current practice wherein ocean quahogs and surf clams are harvested from federal waters in the controlled access status, then these clams are shipped, shucked, and canned before required biotoxin testing results are received, then cleared for distribution after the testing results are received. This is a unique process for these clam species from federal waters, and only several states deal with this issue. This practice has been ongoing, as per an agreement between FDA, states, and industry, for the past decade, and most of this proposal ensures that MO language is adequate to apply to this existing practice – for example, the MO currently contains a requirement that restricted shellstock be tagged as such, and, to ensure the MO is worded properly to apply to this existing process, it needs to contain an equivalent requirement that shucked shellfish processed from this restricted shellstock be labeled as such, until the restriction is removed once the biotoxin testing results are received. This proposal makes adjustments such as that to ensure that existing requirements pertaining to the controlled access status and restricted shellstock are worded sufficiently to apply to the existing process for clams from federal waters. This proposal has been developed in consultation with FDA and with the states and dealers who participate in this practice. Beyond adjusting language to ensure the MO accommodates this existing practice, the only change which this proposal makes is that it adds states and dealers who receive shellfish from the controlled access status (before the restriction is removed after biotoxin testing results are received) to the required MOU, to ensure that everyone is fully aware of how this special product is controlled. The proposal also takes the opportunity to clarify the existing requirements for HACCP plan specifications pertaining to restricted shellfish by putting those existing requirements into the critical limits sections of the dealer chapters where they belong along with all the other critical limits.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal No. 27-224

~~Date~~

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Joseph J. Myers
3. Affiliation	Sea Watch International, Ltd.
4. Address Line 1	8978 Glebe Park Drive
5. Address Line 2	
6. City, State, Zip	Easton, MD 21601
7. Phone	410-819-8502
8. Email	joe.myers@seawatch.com
9. Proposal Subject	Task Force on End-Product Testing and Clearence
10. Specific NSSP Guide Reference	The Marine Biotoxin Management Plan Section II. MO Ch IV. Shellstock Growing Areas @.04 Marine Biotoxin Control (B)
11. Text of Proposal/ Requested Action	The Heat Processing section compels the Authority to "develop and implement procedures to control the harvesting and transportation of the affected shellfish to the processing plant, as well as end product testing of processed shellfish." The submitter requests the ISSC Executive Office to charge the appropriate committee with developing and recommending a research protocol to understand the parameters under which the many facets of heat processing, which may also include thermal processing, can result in end products that are safe for consumption. If the appropriate committee doesn't already exist, the submitter requests the ISSC Executive Office establish one, possibly comprising of members of the Research Guidance and Management Committee, Study Design Guidance Committee and/or Biotoxin Committee, and others, and task it with the charge above.
12. Public Health Significance	The combined effect of heating and dilution across multiple steps could render product safe to enter commerce from shellstock with previously detected biotoxin levels.
13. Cost Information	None at this time
14. Changes Needed to Guidance (if proposed change is adopted)	Although no specific language change is proposed with this specific proposal, the Heat Processing paragraph in the Marine Biotoxin Management Plan of the MO may require further elaboration on the multiple steps of heat processing and dilution that may reduce biotoxin levels from mechanical shucking through blanching that precedes thermal processing of canned product.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Model Ordinance Effectiveness Review Committee
3. Affiliation	ISSC
4. Address Line 1	4801 Hermitage Rd
5. Address Line 2	
6. City, State, Zip	Richmond,VA
7. Phone	804-330-6380
8. Email	issc@issc.org
9. Proposal Subject	Model Ordinance Effectiveness
10. Specific NSSP Guide Reference	Chapter V. Shellstock Relaying
11. Text of Proposal/ Requested Action	**@.01 General** **The Authority shall assure that:** A. **The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;** B. **The level of contamination in the shellstock can be reduced to levels safe for human consumption;** C. **The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by total coliform or fecal coliform, or poisonous or deleterious substances that may be present in shellstock. For shellstock harvested from areas impacted by WWSD, MSC may be used as a measure for viral reduction that may be present in shellstock; and** D. **If shellstock are relayed in containers:** (1) **The containers are:** (a) **Designed and constructed so that they allow free flow of water to the shellstock; and** (b) **Located so as to assure the contaminant reduction required in Section C.; and** (2) **The shellstock are washed and culled prior to placement in the containers.** **@.02 Contaminant Reduction** A. **The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural cleansing ~~treatment~~ process in the growing area to which shellstock will be**

relayed. The growing area to be used for the ~~treatment~~ cleansing process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.

B. **The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity:**
   (1) **The microbiological quality of each shellfish species is the same microbiological quality as that of the same species already present in ~~the~~ an approved or conditionally approved area; or**
   (2) **Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluations; or**
   (3) **When the source growing area is impacted by WWSD, the viral quality of each shellfish species meets the MSC levels established in Chapter IV@.02 E. or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions identified above.**

C. **The Authority may waive the requirements for a contaminant reduction study if:**
   (1) **Only microbial contaminants need to be reduced; and**
   (2) **The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and**
   (3)**The treatment period exceeds sixty (60) days.**

D. **The time period shall be at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.**

E. **When container relaying is used and the Authority allows a treatment time of less than fourteen**
   (14) **days, the Authority shall require more intensive sampling including:**
   (1) **Product sampling before and after relay;**
   (2) **Monitoring of critical environmental parameters such as temperature and salinity; and**
   (3) **For Authorities using MSC, monitoring before and after relay for shellstock relayed from areas impacted by WWSD .**

F. **The Authority shall establish the time period during the year when relaying may be conducted.**

@.03 Licenses to Relay Shellstock or to Harvest Shellstock for Delivery to a Low Acid Canned Food Processing Facility

	A. **The Authority shall require that each harvester that relays or harvests shellstock for delivery to a low acid canned food processing facility from growing areas in the conditionally approved (in the closed status), restricted or conditionally restricted classification possesses a valid special harvester or relay license.** B. **The special license ~~conditions~~ shall not be transferable.** C. **A license shall be valid only when issued for:** (1) **A specific relay or harvest activity; and** (2) **Not more than 365 days.** D. **The license conditions shall include:** (1) **The source, destination, and species to be relayed or harvested for low acid canned food processing;** (2) **The relayed or harvested for low acid canned food processing shellstock deposition method;** (3) **The method used to maintain adequate separation between different lots of shellfish;** (4) **A requirement for the licensee to keep records which:** (a) **Specify the dates on which the shellstock is harvested, deposited for treatment and harvested again, or delivered to a low acid canned food processing facility;** (b) **Identify the buyer and quantity of shellstock harvested for relaying or delivery to a low acid canned food processing facility; and** (c) **Are submitted to the Authority at a specified frequency, if required by the Authority, or made available to the Authority upon request; and** (5) **A provision for additional information at the discretion of the Authority.** E. **If the relay harvester or harvester for low acid canned food processing fails to comply with the conditions of the license, the Authority shall revoke the license.** **@.04 Management of Relaying Shellstock or the Harvesting for Delivery to a Low Acid Canned Food Processing Facility Activities** A. **The Authority shall be authorized and equipped to enforce the State's procedures for relay and low acid canned food processing. The Authority shall develop and maintain an effective program to control the harvest, transport, replanting, and security of the shellstock until the end of the complete relay activity to prevent**

shellstock from being illegally diverted to direct marketing.

B. **In the event that the control of relaying or harvesting for low acid canning activities is shared among two (2) or more agencies, the Authority shall develop written operating procedures for joint use among the agencies. These procedures shall provide for the achievement of all requirements specified in this Chapter and shall be reviewed annually and updated as necessary.**

C. **If shellstock from growing areas classified as conditionally approved or restricted are to be relayed or harvested for low acid canned food processing across State boundaries, a memorandum of understanding outlining the procedures to be used shall be developed between the appropriate Authorities in each State.**

D. **If a growing area in the conditionally approved classification meets the criteria for the restricted classification when the growing area is in the closed status, the Authority may permit shellstock to be harvested for relaying or low acid canned food processing during the period the area is in its closed status, provided that these activities are addressed in the management plan for the growing area classified as conditionally approved, and all other conditions of this Chapter are met.**

E. **Locations designated to receive relayed shellstock within growing areas which are classified as approved or conditionally approved shall:**

(1) **Be placed in the closed status until the period of treatment is complete and the Authority returns the area to the open status; and**

(2) **Be marked so that these areas are easily identified by harvesters transporting the relayed shellstock and by the Authority. These areas shall:**

(a) **Be marked prior to the placing of any shellstock;**

(b) **Remain marked until the Authority reopens the area and gives written permission to harvest shellstock; and**

(c) **Be adequately separated from the shellstock in adjacent waters to prevent cross- contamination and commingling.**

Requirement for Harvesters

.01 Harvester License Required

A. **Any person who wants to relay shellstock or to harvest shellstock from a growing area classified as conditionally approved, restricted, or conditionally restricted shall make application to the Authority for a valid license to relay or to harvest shellstock.**

B. **No person shall relay shellstock or ~~shall~~ harvest shellstock for low acid canned food processing without a valid harvester license from the Authority.**

12. Public Health Significance	N/A
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
3. Affiliation	U.S. Food & Drug Administration (FDA)
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6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Management of Relaying Shellstock of the Harvesting for Delivery to a Low Acid Canned Food Processing Facility Activities-Authority Supervision
10. Specific NSSP Guide Reference	National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish: 2023 Revision, Section II. Model Ordinance (MO), Chapter V. @.04 A.
11. Text of Proposal/ Requested Action	NSSP MO Chapter V. @.04 A. **@.04 Management of Relaying Shellstock or the Harvesting for Delivery to a Low Acid Canned Food Processing Facility Activities** A. The Authority shall be authorized and equipped to enforce the State's procedures for relay and low acid canned food processing. The Authority shall develop and maintain an effective program that directly supervises the control of harvest ~~to control the harvest~~, transport, replanting, and security of the shellstock until the end of the complete relay activity to prevent shellstock from being illegally diverted to direct marketing.
12. Public Health Significance	Currently Chapter V. Shellstock Relaying does not have the requirement that the Authority supervise shesllstock relay activities. The direct supervision of relay activities is cited in the following three places: 1. Supervision of relay activities is cited in the NSSP MO Chapter IV. : Shellstock Growing Areas, @.03 Growing Area Classifciation, D. Restricted Classification, (1) General, (b)(ii): *"Under the supervision of the Authority."* 2. ISSC Constitution, Bylaws and Procedures: The ISSC Constitution, Bylaws and Procedures, Updated July 22, 2024, Procedure III Responsibilities of the State, Section 6.: *"All phases associated with the relaying of shellfish from closed areas to approved areas shall be under the immediate supervision of the appropriate responsible Authority."*

	3. NSSP Guidnace Documents, Chapter V Shellstock Relaying, .01 Shellstock Relay: *The Authority or the shellfish industry may conduct relay operations. The relay operation must be effectively supervised by the Authority to assure that all the shellstock are actually relayed to harvest areas in the approved classification or in the open status of the conditionally approved classification and sufficiently cleansed. Relay control procedures should preclude any opportunity for shellstock to be inadvertently diverted to sale for human consumption before the natural cleansing process is completed. Controls must be applied to all phases of the operation including initial harvesting, transportation, replanting, the cleansing period, and final harvesting for marketing.* This proposal updates Chapter V. Shellstock Relaying to reflect what is required during the activity of relaying contaminated shellstock. The Chapter IV. requirements cover the classification of the area and what activities can take place. The Chapter V. requirements are specific to the activity.
13. Cost Information	none
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
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8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Seed Sizes
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter VI. Shellfish Aquaculture, @.02 Seed Shellstock
11. Text of Proposal/ Requested Action	Chapter VI. Shellfish Aquaculture @ .02 Seed Shellstock A. The Authority shall establish the maximum seed size for each species of shellfish that can be: (1) ~~p~~Produced in or sourced from prohibited or unclassified waters, conditionally approved waters in the closed status, or conditionally restricted waters in the closed status, as classified on the day the seed is moved. In determining the maximum seed size for seed produced in or sourced from prohibited waters, conditionally approved waters in the closed status, or conditionally restricted waters in the closed status, Authorities shall establish sizes that require a minimum of 120 days of growing to reach market size. (a) As an alternative to establishing maximum seed sizes, the Authority may establish other methods, including record keeping by growers, to ensure that such seed is grown on the aquaculture site for a minimum of 120 days. (2) Produced in or sourced from restricted waters or conditionally restricted waters in the open status, as classified on the day the seed is moved, unless the seed is being subjected to an approved relay process. In determining the maximum seed size for seed produced in or sourced from restricted waters, Authorities shall establish sizes that require a minimum of 60 days of growing to reach market size. (a) As an alternative to establishing maximum seed sizes, the Authority may establish other methods, including record keeping by growers, to ensure that such seed is grown on the aquaculture site for a minimum of 60 days. (3) Produced in or sourced from approved waters or conditionally approved waters in the open status, as classified on the day the seed is moved, if the growing area which the seed is produced in or sourced from is different than the growing area in which the shellfish are to be aquacultured. In determining the maximum seed size for seed produced in or sourced from approved waters or conditionally approved waters in the open status, Authorities shall establish seed sizes that require a minimum of 14 days, or alternative time period established by the Authority based on purging rate studies, of growing to reach market size. (a) As an alternative to establishing maximum seed sizes, the Authority may establish other methods, including record keeping by growers, to ensure that such seed is grown on the aquaculture site for a minimum of 14 days or alternative time period. (2) The Authority may exempt shellstock from the requirements in .02 A. (3) when the harvester tag or an approved recordkeeping method identifies all growing areas in which the shellstock was held within the 14-day or alternative time period. B. The Authority shall establish appropriate corrective actions for when seed exceeds the maximum seed sizes ~~when it has been produced in waters classified as prohibited~~ established in Section @.02 (A).

12. Public Health Significance	In addition to establishing maximum sizes for seed from prohibited waters, it is also necessary to consider conditionally approved waters in the closed status and conditionally restricted waters in the closed status, since those classifications are effectively the same as prohibited. It is also necessary to establish a seed size (or other means methods such as recordkeeping) for seed from restricted waters and conditionally restricted waters in the open status, in order to avoid requirements for relay from becoming relevant (unless relay is being conducted). And, if seed is from a different growing area than the growing area in which it will be aquacultured, it is necessary to establish a seed size (or other means methods such as recordkeeping) for seed from approved waters and conditionally approved waters in the open status, so that the seed spends at least 14 days (or alternative time period, established by the Authority based on purging rate studies) in the new growing area for the purpose of ensuring that it is possible to accurately attribute any illnesses to the correct growing area. For example, in Delaware, we have established max seed sizes of: • 25mm for oysters and 15mm for clams from prohibited waters and conditionally approved waters in the closed status to ensure growing for 120 days • 35mm for oysters and 25mm for clams from restricted waters to ensure growing for 60 days in order to avoid relay requirements • 50mm for oysters and 40mm for clams from approved waters or conditionally approved waters in the open status to facilitate accurate attribution of any illnesses to the correct growing area.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
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9. Proposal Subject	Returning Shellstock to the Aquaculture Site
10. Specific NSSP Guide Reference	Section I. Purposes & Definitions, Definitions Section II. Model Ordinance, Chapter VI. Shellfish Aquaculture
11. Text of Proposal/ Requested Action	Section I. Purposes & Definitions, Definitions **(108) Resubmergence** means the placement by an aquaculture grower of shellstock, arranged so that water flows freely to all shellstock, below the water surface. **(131) Wet Storage** means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater at any permitted land-based activity or facility. Wet storage does not include the transfer of shellstock back to the aquaculture site, for the purposes of reconditioning following illness outbreaks or recalls or for other purposes, before subsequent harvest. Chapter VI. Shellfish Aquaculture @ .01 General A. Aquaculture activities which may pose a significant public health concern and are regulated in this Chapter include, but are not limited to: (1) Seed production in waters classified as Prohibited or Unclassified; (2) Aquaculture structures that attract birds or mammals; and (3) Land based aquaculture. B. The Authority shall: (1) Approve the written operational plan for operations as outlined in @.01A above; (2) Inspect operations outlined in @.01A above at least annually; and (3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A (1). are being implemented~~.~~; (4) ~~Consistent with Chapter IV @ .01 D(1)(e) w~~When aquaculture as defined in the Model Ordinance attracts birds or mammals, consider their presence ~~should be considered~~ for possible adverse effects on growing area water quality, consistent with Chapter IV @ .01 D(1)(e); (5) Determine whether any controls are necessary to ensure compliance with Chapter VIII. @.02 A. and other Model Ordinance requirements for shellstock brought by the aquaculture grower on land for husbandry activities then returned to the aquaculture site before harvest; and (6) Determine whether harvested shellstock may be placed back on the aquaculture site, and determine any necessary controls, including controls

for unsold shellstock, recalled shellstock, and situations when shellstock does not comply with HACCP critical limits, Vibrio control plan requirements, or other requirements of this Ordinance. This determination shall consider whether the following factors are necessary controls:

(a) Restriction of placement back on the aquaculture site to shellstock that have not left the possession of the harvester, original dealer, or dealers;

(b) Development by the grower of a resubmergence strategy that ensures identified controls will be met, and submission of the resubmergence strategy to the Authority;

(c) Notification to or approval from the Authority before transfer back to the aquaculture site;

(d) A minimum time period of resubmergence on the aquaculture site required before re-harvest to allow shellstock to purge;

(e) Methods to ensure shellstock are held below the water surface and arranged to allow the free flow of water to all shellstock;

(f) Segregation of shellstock from other shellstock on the aquaculture site, and methods for ensuring segregation;

(g) Documentation methods to facilitate accurate state reporting of shellfish harvest volume to the ISSC;

(h) Notification to or approval from the Authority before shellstock are re-harvested; and

(i) The actions to be taken when shellstock do not comply with identified controls.

.02 General

A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:

(1) A permit from the Authority for the activity and functioning of his facility;

(2) A harvester's license; and

(3) Certification as a dealer, where necessary.

B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan.

C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.

D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:

(1) The closed status of the conditionally approved classification;

(2) The restricted classification; or

(3) The open status of the conditionally restricted classification.

E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.

G. When placing harvested shellstock back on the aquaculture site, the grower shall follow any controls established by the Authority in accordance with @.01 B. (6).

	~~G~~H. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the: (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification; and (2) Water source, its treatment method, if necessary, and its quality in land based systems.
12. Public Health Significance	Aquacultured shellstock is different than traditional shellstock in numerous ways, including that aquacultured shellstock may be (unless not allowed by the Authority in their state regulations) brought on land then returned to the aquaculture site. This may be done prior to harvest for husbandry purposes, such as tumbling or sorting on land. Or it may be done after harvest, wherein shellstock are "un-harvested" and transferred back to the aquaculture site for various reasons, including product that is unsold but still remains safe for consumption, or as a corrective action for recalled product or product that may be unsafe for consumption. This is different than wet storage because wet storage is the storage of market ready product by a dealer, while in these activities, shellstock are transferred back to the grower then re-harvested later. It has been a challenge to figure out how to regulate these activities and determine requirements for everything from how to recondition unsafe product to ensuring that accurate harvest quantities can be reported to ISSC, but in Delaware we have gradually worked it out. In this proposal, we are offering the ideas we have developed as a framework for Authorities to optionally follow. This proposal does not require Authorities to take any actions, as it is not required for Authorities to establish any controls for the placement of shellstock back on the aquaculture site – it is merely intended to offer an optional framework for Authorities to follow if they think it's necessary. This proposal is in the spirit of providing suggestions for Authorities if they determine that controls are necessary for shellstock that are placed back on the aquaculture site following harvest, and does not require that the Authority institute any of the requirements listed in the framework of suggestions. The intent is to help the NSSP take a small step toward ensuring appropriate, but not excessive, controls for aquacultured shellfish, which is different than the wild-caught shellfish that the NSSP has traditionally considered.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Lost and Found Shellfish
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter VI. Shellfish Aquaculture, .02 General
11. Text of Proposal/ Requested Action	Chapter VI. Shellfish Aquaculture, .02 General A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain: (1) A permit from the Authority for the activity and functioning of his facility; (2) A harvester's license; and (3) Certification as a dealer, where necessary. B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan. C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility. D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in: (1) The closed status of the conditionally approved classification; (2) The restricted classification; or (3) The open status of the conditionally restricted classification. E. Any shellfish lost from the aquaculture site and later recovered from Prohibited or unclassified waters shall be discarded. Other shellfish lost from the aquaculture site and later recovered from a different growing area shall be held on the aquaculture site for time periods established by the Authority based on the classification of the water where shellfish were recovered. (1) If required by the Authority, the grower shall maintain a record log to document compliance with this requirement. ~~E~~F. Only drugs sanctioned by the FDA shall be used for shellfish treatment. ~~F~~G. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV. ~~G~~H. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the: (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification; and

	(2) Water source, its treatment method, if necessary, and its quality in land based systems.
12. Public Health Significance	Shellfish aquaculture containers, especially floating gear, are sometimes lost from the aquaculture lease, such as during storms, and later recovered. If shellfish are recovered in Prohibited or unclassified waters, it is already required that they be discarded, as the Model Ordinance does not allow non-seed shellstock to be transferred from Prohibited or unclassified waters – this proposal simply specifies that existing requirement to ensure ready understanding. For shellfish found in waters of other classification, the Authority should establish time periods for holding on the aquaculture site before harvest. These time periods would depend on the classification of the waters where shellfish were recovered; for example, if shellfish were recovered from restricted waters, it would be necessary for shellfish to spend the same time on the lease as relayed shellfish. The Authority may want to consider the need for recordkeeping, but this proposal does not require Authorities to mandate recordkeeping.
13. Cost Information	None (simply specifies that shellfish lost from the aquaculture lease then recovered in a different growing area is subject to the same requirements as any shellfish from that growing area classification)
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Growing Area Transfers
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter VI. Shellfish Aquaculture, .02 General
11. Text of Proposal/ Requested Action	Chapter VI. Shellfish Aquaculture, .02 General A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain: (1) A permit from the Authority for the activity and functioning of his facility; (2) A harvester's license; and (3) Certification as a dealer, where necessary. B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan. C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility. D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in: (1) The closed status of the conditionally approved classification; (2) The restricted classification; or (3) The open status of the conditionally restricted classification. E. When shellstock, excluding seed and shellstock in a permitted wet storage area, are transferred from one growing area to another, the shellstock shall be held in the new growing area for a minimum of 14 days, or alternative time period established by the Authority based on purging rate studies, except for relayed shellstock for which the Authority has established a shorter time period. (1) If required by the Authority, the grower shall maintain records to document compliance with this requirement. (2) The Authority may exempt shellstock from the requirements in .02 E. when the harvester tag or an approved recordkeeping method identifies all growing areas in which the shellstock was held within the 14-day or alternative time period. ~~E~~F. Only drugs sanctioned by the FDA shall be used for shellfish treatment. ~~F~~G. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.

	~~G~~H. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the: (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification; and (2) Water source, its treatment method, if necessary, and its quality in land based systems.
12. Public Health Significance	Shellfish (except for seed) transferred from one growing area to another should spend at least 14 days (or alternative time period established by the Authority based on purging rate studies) in the new growing area prior to harvest, since if shellfish are transferred to a new growing area and then immediately harvested, it would not be possible to attribute illnesses to the correct growing area. Either that, or both the old growing area and the new growing area should appear on the tag or other recordkeeping system, in order to facilitate accurate traceback to all growing areas that could be responsible for the illness. The idea is to either narrow the growing areas attributable to an illness to one area, or to ensure that all growing areas which may be linked to the illness can be tracked. The length of 14 days is used in this proposal because it is the same time period that is currently used for shellfish relay, after which time the shellstock are considered to have completed purging, although the Authority could establish a different time period based on purging rate studies. This proposal does not pertain to seed or wet stored shellstock. The Authority may want to consider the need for recordkeeping by growers to ensure that the 14-day time period is met, but this proposal does not require recordkeeping.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food and Drug Administration (FDA)
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9. Proposal Subject	Aquaculture Operational Plan Implementation
10. Specific NSSP Guide Reference	Section II Model Ordinance - Chapter VI. Shellfish Aquaculture .03 B., .04 A., .05 A. and .07 B.
11. Text of Proposal/ Requested Action	Requested action: Add the phrase 'and implement' to Chapter VI. Shellfish Aquaculture sections .03 B., .04 A., .05 A. and .07 B. Chapter VI. Shellfish Aquaculture .03 Seed Production in Water Classified as Prohibited or Unclassified Seed may come from any growing area, or from any growing area in any classification, providing that: A. … B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have and implement a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) … (2) … (3) … (4) … (5) … (6) … .04 Aquaculture that Attracts Birds or Mammals A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have and implement a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) … (2) … (3) … (4) … (5) … (6) … (7) … .05 Land Based Aquaculture A. Operational Plan. Each facility shall have and implement a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:

	(1) … (2) … (3) … (4) … (5) … (6) … (7) … (8) … (9) … (10)… B. … C. … D. … .07 Requirements for the Harvester in Aquaculture in Federal Waters A. … B. Operational Plan. Each aquaculture facility shall have and implement a written operational plan as described for Land Based Aquaculture in Section II Chapter VI. .05 (A).
12. Public Health Significance	The Model Ordinance requires operational plans for each aquaculture site that cultures seed in prohibited or unclassified waters, if the Authority determines the aquaculture site may attract birds and/or mammals in sufficient numbers to present a human health risk, for land base aquaculture facilities and for aquaculture in federal waters. The Model Ordinance further requires that the Authority approve the operational plans prior to implementation. However, there is no requirement in the Model Ordinance for the aquaculture operator to actually implement the operational plan. Aquaculture operational plans should be specific to the firm and the activities they are conducting. In some cases, the aquaculture facility has a generic operational plan that is not specific to the firm's operations. Since the plan is not specific to the firm's operation, the plan cannot be effectively implemented. The plan may contain requirements that the firm is not meeting. For example, an operational plan may require bird deterrent measures, but the firm is not employing them. In this example, the firm has a plan, but has not implemented the controls or requirements specified in the plan. By adding the phrase 'and implement' to the current MO language, the firms would be required to not only have a plan, but to put the requirements and controls in the plan into practice. Adding the phrase also gives the Authority regulatory language to point to if firms fail to have controls specified in their plan in place. For comparison, a similar requirement is specified in the Model Ordinance with respect to having and implementing a written HACCP plan (Chapter X. .01 B). Adding the phrase 'and implement' to the requirement to have a written operational plan will add consistency to the requirements of the Model Ordinance.
13. Cost Information	There would be no cost to the industry or Authority related to this proposal.

14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Alfred R. Sunseri
3. Affiliation	P&J Oyster Company, Inc.
4. Address Line 1	1039 Toulouse Street
5. Address Line 2	
6. City, State, Zip	New Orleans, LA 70112
7. Phone	504-722-9854
8. Email	asunseri@bellsouth.net
9. Proposal Subject	Land Based Processing Facility for Land Based Aquaculture on processing and Handling
10. Specific NSSP Guide Reference	Chapter VI. Shellfish Aquaculture-New Section .08
11. Text of Proposal/ Requested Action	Chapter VI. .08 Aquaculture Processing
12. Public Health Significance	Any Shellstock Shipper who processes, handles, sorts, packages, labels, and/or ships shellstock on the land shall meet all the requirements in Sections IX and X. This will assure the sanitary requirements meet common sense, good manufacturing practices and meets the NSSP Model Ordinance. For those certified shellstock shippers that only have a certified refrigerated truck that is used to ship shellstock that has been packaged and labeled on the vessel by the harvester/dealer to a processor or to the market is not required to follow Sections IX and X. Consequently, the SSA shall determine, based on the evaluation of the individual characteristics of the operation, so that the sanitary control measures meet these standards to assure consumers will only receive wholesome raw shellfish suitable for raw consumption.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	Yes

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative

2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
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5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Aquaculture Sinking for Bird & Mammal Control
10. Specific NSSP Guide Reference	Section II. Model Ordinance, Chapter VI. Shellfish Aquaculture, Chapter VIII. Control of Shellfish Harvesting, Chapter IX. Shucking and Packing, Chapter XIII. Shellstock Shipping
11. Text of Proposal/ Requested Action	Section II. Model Ordinance, Chapter VI. Shellfish Aquaculture @ .01 General A. Aquaculture activities which may pose a significant public health concern and are regulated in this Chapter include, but are not limited to: (1) Seed production in waters classified as Prohibited or Unclassified; (2) Aquaculture structures that attract birds or mammals; and (3) Land based aquaculture. B. The Authority shall: (1) Approve the written operational plan for operations as outlined in @.01A above; (2) Inspect operations outlined in @.01A above at least annually; and (3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A (1). are being implemented~~.~~; and (4) ~~Consistent with Chapter IV @ .01 D(1)(e) w~~When aquaculture as defined in the Model Ordinance attracts birds or mammals, consider their presence ~~should be considered~~ for possible adverse effects on growing area water quality, consistent with Chapter IV @ .01 D(1)(e). (a) The Authority shall make a determination of which market size shellstock, if any, require sinking to allow the shellstock to purge potential contamination due to birds or mammals, based on aquaculture gear types and methods, including whether gear types or the use of effective bird or mammal deterrents preclude the need for sinking. For shellstock, if any, that are identified as requiring sinking, the Authority shall establish, as determined necessary and based on the best available science: (i) The minimum time period that shellstock must be sunk prior to harvest; (ii) The minimum depth at which sinking must occur, if determined necessary by the Authority based on the potential of bird or mammal contamination near the water surface; (iii) Methods to ensure that water flows freely to all shellstock; (iv) Methods to ensure adequate separation between shellstock requiring sinking and other shellstock; and (v) The method that the grower shall use to inform the Authority or original dealer of the sinking date. .04 Aquaculture That Attracts Birds or Mammals

A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:

(1) A description of the design and activities of the culture facility;

(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;

(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;

(4) The species of shellfish to be cultured and harvested;

(5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;

(6) A description of the mitigation or deterrent measures to minimize the potential pollution impact of birds and/or mammals; ~~and~~

(7) A description of the method for sinking shellstock identified by the Authority as requiring sinking to purge potential contamination due to birds or mammals; and

(~~7~~8) Maintenance of the required records, including, if required by the Authority, approved methods for informing the Authority or original dealer of the sinking date for any shellstock requiring sinking.

Section VIII. Control of Shellfish Harvesting

F. Shellstock Identification.

(1) Each harvester shall affix a tag to each container of shellstock which shall be in place while the shellstock is being transported to a dealer.

(2) If the shellstock was harvested at more than one (1) location, each container shall be tagged at its growing area.

(3) When the harvester is also the dealer, the harvester has the option to tag the shellfish with a harvester's tag or a dealer's tag meeting the requirements outlined in Chapter X. Section .05.

(4) The harvester's tags shall:

(a) Be durable, waterproof and sanctioned by the Authority prior to use; and

(b) Be at least 13.8 square inches (89.03 cm2) in size.

(5) The harvester's tag shall contain the following indelible, legible information in the order specified below:

(a) The harvesters' identification number as assigned by the Authority;

(b) The date of harvest;

(c) The most precise identification of the harvest location or aquaculture site as is practicable, including the initials of the State of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).

(d) The type and quantity of shellstock; and

(e) The following statement in bold capitalized type on each tag: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS."

(6) For shellstock, if any, required by the Authority to be sunk prior to harvest in accordance with Chapter VI. @.01 B. 4(a):

(a) The harvester's tag shall include the date of sinking , if required by the Authority; or

(b) The harvester shall provide the Authority or the original dealer with

other means, approved by the Authority, of identifying the date of sinking to the original dealer.

(~~6~~7) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in Section .02 F.

(~~7~~8) Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities.

(a) When shellstock are harvested from one (1) harvest area on a single day by a single harvester or aquaculture leaseholder, multiple containers may be utilized on a wrapped pallet, in a tote, in a net bailer, in a single boat, vehicle, conveyance or other container and the unit tagged with a single tag in accordance with the requirements of Section .02 F.

(b) In addition to the information required in Section .02 F. the unit tag shall also include:

(i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest"; and

(ii) Number of individual containers in the unit or an estimate of the total weight, volume or count.

(~~8~~9) Bulk Sale of Shellstock. If shellstock are sold in bulk, the harvester or dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in Section .02 F. with the addition of the name of the consignee.

Section II. Model Ordinance, Chapter XI. Shucking and Packing

.01 Critical Control Points, A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; or[C]

(b) Harvested restricted shellstock and properly tagged with information describing the restriction; [C]

(c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C]

(d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2); and [C]~~.~~

(e) Sunk any shellstock identified by the Authority as requiring sinking prior to harvest for the minimum time period established by the Authority, as determined by the sinking date recorded by the harvester on the harvester tag or by other approved means. [C]

Section II. Model Ordinance, Chapter XIII. Shellstock Shipping

.01 Critical Control Points, A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall ship or repack only shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and [C]

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C]

(c) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2); and [C]~~.~~

	(d) Sunk any shellstock identified by the Authority as requiring sinking prior to harvest for the minimum time period established by the Authority, as determined by the sinking date recorded by the harvester on the harvester tag or by other approved means. [C]
12. Public Health Significance	Throughout its history, the NSSP has had to develop ways of handling newly emerging sanitation concerns to ensure that shellfish harvesting and handling is standardized according to best practices that protect shellfish consumers across jurisdictions. Currently, the emerging concern we are all trying to understand is how to handle bird contamination of oysters grown in floating gear. States and industry are trying various approaches, with little standardization across the NSSP as of yet. This proposal is an idea that offers a framework for states to limit illness risk from bird contamination. As per the language in the proposal, it does not require states to take any action, but simply provides an optional structure for handling the bird issue. Deterrence measures to prevent birds from landing on aquaculture gear is the best way to control the risk of bird contamination, and deterrence or mitigation measures are currently required for aquaculture sites which the Authority has determined to be at risk for attracting birds or mammals. Effective deterrence is necessary but difficult, and sinking oysters that may be contaminated by birds under the water surface for a prescribed length of time prior to harvest is an effective mitigation of this risk that allows oysters to purge any contamination that resulted from deterrents that weren't fully effective. Sinking has been shown to be an effective strategy to control illness risk and prevent emergency closures, product recalls, and other regulatory action. Recent outbreaks of Campylobacter linked to bird contamination of aquaculture sites is a significant hazard for oysters grown in floating gear. The NSSP already contains an effective means of controlling significant hazards through the HACCP plan. It logically follows that, if the state determines that sinking shellstock is a necessary control to mitigate the risk posed by bird contamination, consideration should be given to the establishment of HACCP plan critical limits that ensure the significant hazard of bird contamination is controlled. This proposal establishes an optional framework for the following approach. The Authority determines which aquacultured shellstock (if any – this is only an option, for use when determined necessary and appropriate by states) are at risk of bird contamination and so require sinking, based on time of year, location, effectiveness of bird deterrents, or other factors as determined by the Authority. The grower then sinks that shellstock for a time period established by the Authority. Upon harvest, the grower records the date of sinking on the harvester tag (no new tags must be purchased – the sinking date can be handwritten on the tag), or else records the sinking date in another way approved by the Authority. Then the receiving dealer checks the sinking date on the tag to ensure that the shellstock was sunk for the required time period before harvest, and documents this check along with the other Receiving critical limits. To emphasize, this proposal does not require the Authority to identify any shellstock that require sinking – or, if the Authority does identify shellstock that require sinking, require that it be incorporated into the HACCP system – but simply offers a framework that can be optionally followed.

	We have already instituted this system in Delaware, and it has proven to be relatively easy for growers and dealers (especially as compared to the record logs we formerly required growers to maintain to document sinking for the required time period). The grower simply writes the sinking date on the harvester tag, then the receiving dealer simply checks to ensure that the sinking date was at least 14 days before harvest, which is our required time period for aquaculture sites which we have determined to be at risk of bird contamination. The resubmergence date stays on the harvester tag, and does not need to be transferred onto the dealer tag, as the hazard is controlled by the original dealer. This approach of incorporating control of bird contamination into the HACCP plan has been an easy and effective means of ensuring sinking and controlling risk for us in Delaware, and we are offering it as a suggestion for possible inclusion as an optional framework in the Model Ordinance. We believe that it may be an advisable step toward getting a handle on the bird issue.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
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6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Shipping Document Housekeeping
10. Specific NSSP Guide Reference	Section I. Purposes & Definitions, Definitions Section II. Model Ordinance, Chapter VIII. Control of Shellfish Harvesting, Chapter IX. Transportation, Chapter X. General Requirements for Dealers, Chapter XI. Shucking and Packing, Chapter XIII. Shellstock Shipping, Chapter XIV. Reshipping, Chapter XV. Depuration
11. Text of Proposal/ Requested Action	Section I. Purposes & Definitions, Definition (126) Transaction Record means the form or forms used to document each purchase or sale of shellfish at the wholesale level and includes shellfish harvest and sales records, ledgers, purchase records, invoices, ~~and~~ bills of lading, and shipping documents. Chapter VIII. Control of Shellfish Harvesting .02 Shellstock Harvesting and Handling, F. Shellstock Identification (7) Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities (a) When shellstock are harvested from one (1) harvest area on a single day by a single harvester or aquaculture leaseholder, multiple containers may be utilized on a wrapped pallet, in a tote, in a net bailer, in a single boat, vehicle, conveyance or other container and the unit tagged with a single bulk tag in accordance with the requirements of Section .02 F. (b) In addition to the information required in Section .02 F. the ~~unit~~ bulk tag shall also include: (i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest"; and (ii) Number of individual containers in the unit or an estimate of the total weight, volume or count. (~~8~~c) Bulk Sale of Shellstock. If shellstock are sold in bulk, the harvester ~~or dealer~~ shall provide a ~~transaction record~~shipping document ~~prior to shipment. This transaction record shall~~ containing all the information required in Section .02 F. ~~with the addition of~~including the name of the consignee. Chapter IX. Transportation ~~.05 Transportation Records~~ ~~A. All shipments of shellstock shall be accompanied with documentation indicating the following:~~ ~~(1) Date and time of shipment; and~~ ~~(2) The temperature of the shellstock recorded by the shipping dealer at~~

~~the time of shipment.~~

~~B. For shipments of shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) prior to shipping and where the shipping time is greater than four (4) hours, the documentation shall also indicate the presence of a time/temperature recording device.~~

~~C. Geoduck clams (Panopea generosa) are exempt from these requirements~~

Chapter X. General Requirements for Dealers

.05 Shellstock Identification

C. Bulk Tagging Lots of Shellstock for Sales between Dealers.

(1) When a single lot of shellstock is sold, multiple containers may be used on a wrapped pallet, in a tote, in a net bailer, or other container and the unit tagged with a single bulk tag in accordance with Section .05 B. (1) through (4).

(a) This bulk tagging provision shall not apply to sales to reshippers;

~~(b) The shipment must be accompanied by a transaction record stating the name of the consignee who must be a certified dealer;~~

(~~c~~b) In addition to the information required in Section .05 B. (1) through (4) the ~~unit~~ bulk tag shall also include:

(i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest"; and

(ii) Number of individual containers in the unit.

~~F. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in Section .05 C. with the addition of the name of the consignee.~~

. 08 Shipping Documents and Transaction Records

A. Shipping Documents.

(1) Each shellfish shipment shall be accompanied by a shipping document, including shipments to retailers. The dealer supplying the shellfish shall supply the shipping document to the dealer receiving the shellfish, including when the receiving dealer picks up and transports the shellfish from the supplying dealer.

(2) The shipping document shall contain:

(a) The name, address, and certification number of the ~~shipping~~ supplying dealer;

(b) The name and address of the major consignee; ~~and~~

(c) The kind and quantity of the shellfish product~~.~~;

(d) For all shipments of shellstock:

(i) The date and time of shipment;

(ii) The temperature of the shellstock recorded by the supplying dealer at the time of shipment;

(iii) If shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) has not been cooled to an internal temperature of 50°F (10°C) prior to shipping and where the shipping time is greater than four (4) hours, the shipping document shall indicate the presence of a time/temperature recording device;

(e) For bulk shellstock shipments:

(i) All the information required in Chapter VIII. Section .02 F.

(ii) The number of individual containers in the unit;

(iii) The statement that "All shellstock containers in this lot have the same harvest date and area of harvest";

(iv) The name of the consignee who shall be a certified dealer;
(f) For returnable containers of shucked shellfish:
(i) The original shucker-packer's name and certification number;
(ii) The shucking date;
(iii) The quantity of shucked shellfish per container and the total number of containers.
(g) Geoduck clams (Panopea generosa) are exempt from the requirements of (e) and (f).
(3) The receiving dealer shall:
(a) Maintain in his files a copy of the completed shipping document; and
(b) Make the shipping document available to the Authority upon request.
(4) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace his portion back to the original shipment.

B. Transaction ~~and Shipping~~ Records.
(1) Each dealer shall have a business address at which transaction records are maintained.
(2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:
(a) Document that the shellfish are from a source authorized under this Ordinance;
(b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
(c) Permit a lot (or commingled lots as per Chapter I. @.01 G.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters.
(d) Trace the wet storage history of the shellstock including, original harvest site, original harvest date, wet storage site(s) and dates.
(3) Purchase and sales shall be recorded:
(a) In a permanently bound ledger book; or
(b) Using other recording methods acceptable to and authorized by the Authority. Entries of purchases or sales of shellfish shall be made into a permanently bound ledger book, computer record, or other method acceptable to and authorized by the Authority within seventy-two (72) hours of any purchase or sales.
(4) The transaction records shall be retained:
(a) In the case of fresh shellfish, for a minimum of one (1) year; and
(b) In the case of frozen shellfish, for at least two (2) years or the shelf life of the product, whichever is longer.
(5) If computer records are maintained, the Authority shall approve the format and its use.

.06 Shucked Shellfish Labeling
A. Shellfish Labeling.
(1) The dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers.
(2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. ~~When returnable containers are used, the shipment shall be accompanied by a transaction record containing:~~
~~(a) The original shucker-packer's name and certification number;~~

~~(b) The shucking date; and~~
~~(c) The quantity of shellfish per container and the total number of containers.~~

Chapter XI. Shucking and Packing
.01 Critical Control Points
A. Receiving Critical Control Point - Critical Limits.
(1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has:
(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; or [C]
(b) Harvested restricted shellstock and properly tagged with information describing the restriction; [C]
(c) Identified the shellstock with a tag on each container or bulk tag for each lot, and, for each bulk shipment, a ~~transaction record~~shipping document ~~on each bulk shipment~~, as outlined in Chapter VIII. .02 F; and [C]
(d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].
(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 or a bulk tag for each lot as outlined in Chapter X. .05 ~~or~~and, for each bulk shipment, a ~~transaction record~~shipping document ~~with each bulk shipment~~ as outlined in Chapter ~~VIII. .02 F. (8)~~X. .08 A. (2) (e); and [C]
(b) Provided documentation as required in Chapter ~~IX. .05~~X. .08 A. (2) (f); and [C]
(c) Adequately iced the shellstock; or [C]
(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. [C]
(3) ~~A~~The 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 XI. .01 A. (2) (c) or (d). The product must be accompanied with ~~documentation~~ a shipping document as outlined in Chapter ~~IX. .05 A. and B~~ X. .08 A. (2) (d)~~.~~ and, if the shipment is over four (4) hours, 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 XI. .01 A. (2) (c) or (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 ship or repack only shellstock obtained from a licensed harvester who has:
(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and [C]
(b) Identified the shellstock with a tag on each container or bulk

tag for each lot, and, for each bulk shipment, a ~~transaction record~~shipping document ~~on each bulk shipment~~, as outlined in Chapter VIII. .02 F; and [C]

(c) Harvested the shellstock in compliance with the time temperature requirements of
Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the
harvester described in Chapter VIII. .02 G. (2) [C].

(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 or a bulk tag for each lot as outlined in Chapter X. .05, and, for each bulk shipment, a shipping document as outlined in Chapter X. .08 A. (2) (e).; and [C]

(b) Provided documentation as required in Chapter ~~IX. .05~~ X. .08 A. (2) (d); and [C]

(c) Adequately iced the shellstock; or [C]

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

(3) ~~A~~The 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 requirement of Chapter XIII. .01 A. (2) (c) or (d). The product must be accompanied with ~~documentation~~ a shipping document as outlined in Chapter ~~IX. .05 A. and B.~~ X. .08 A. (2) (d) and, if the shipment is over four (4) hours, 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). Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A.~~ [C]

D. Shellstock Shipping Critical Control Point- The dealer shall ensure that

(1) Shellstock that is received bearing a restricted shellstock tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. The ~~transaction record~~shipping document shall indicate the quantity of restricted use shellstock containers. [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) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less: or [C]

(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~~The 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 XIV. .01 A. (2) (c) or (d). The product must be accompanied with ~~documentation~~ a shipping document as outlined in ~~Chapter IX. .05 A. and B.~~ X. .08 A. (2) (d) and, if the shipment is over four (4) hours, 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). Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A.~~ [C]

E. Shellstock Shipping Critical Control Point. The dealer shall ensure that:

(1) Shellstock that is received bearing a restricted shellstock tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. The ~~transaction record~~shipping document shall indicate the quantity of restricted use shellstock containers. [C]

Chapter XV. Depuration

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall receive and depurate only shellstock which is obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the
open status as indicated by the tag; [C] and

(b) Identified the shellstock with a tag on each container or bulk tag for each lot, and, for each bulk shipment, a ~~transaction record~~shipping document ~~on each bulk shipment~~, as outlined in Chapter VIII. .02 F; [C] and

(c) Harvested the shellstock in compliance with the time/temperature requirements of Chapter VIII. @.02 A. (1), (2) or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2). [C]

(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 or a bulk tag for each lot as outlined in Chapter X. .05 ~~or~~and, for each bulk shipment, a ~~transaction record~~shipping document ~~with each bulk shipment~~ as outlined in Chapter ~~VIII. .02 F. (8)~~ X. .08 A. (2) (e); [C] and

(b) Provided documentation as required in Chapter ~~IX. .05~~ X. .08 A. (2) (d); and [C]

(c) Adequately iced the shellstock, or [C]

(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). Shipments of four (4)~~

	~~hours or less will not be required to have a time/temperature device.~~ The 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 requirement of Chapter XIII. .01 A. (2) (c) or (d). The product must be accompanied with a shipping document as outlined in Chapter X. .08 A. (2) (d) and, if the shipment is over four (4) hours, must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. [C] (4) The dealer shall receive and depurate only shellstock obtained from a special licensed harvester who has: (a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; [C] and (b) Identified the shellstock by ~~transaction records~~a shipping document which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. [C]
12. Public Health Significance	This proposal does not add or modify any requirements. It is intended to provide better organization of existing requirements relating to shipping documents. Currently, the requirements for shipping documents are scattered throughout the Model Ordinance; this proposal puts them all in one place for easy understanding and application. Also, currently there are times when the Model Ordinance refers to a shipping document as a "transaction record," contradicting the current definition of a transaction record to mean a sales log and associated records; this proposal standardizes the term shipping documents for clarification, reserving the term "transaction record" for its actual current definition. The proposal also fixes an inconsistency wherein the Model Ordinance currently requires both a bulk tag and a transaction record for bulk shipments, yet the receiving critical limits require a bulk tag or transaction record. It clarifies that in cases where the receiving dealer is picking up and transporting shellfish from the supplying dealer, the supplying dealer is still required to provide a shipping document. The proposal also changes the term "shipping dealer" (which occurs surprisingly infrequently within the Guide - only twice in the Model Ordinance and a handful of times in the Guidance Documents) to "supplying dealer" to make it clear that applicable requirements do not depend on whether the supplying dealer or the receiving dealer is the one transporting shellfish. Finally, some language is simplified for easier understanding, and some of the outdated guidance is tweaked to match existing requirements. The proposal does not add or modify requirements, but merely provides better organization and wording of the existing requirements for shipping documents
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	Section IV. Guidance Documents, Chapter IV. Growing Areas .03 Classification of Shellfish Growing Waters Adjacent to Waste Water Treatment Plants VIII. Conditionally Approved, F. Model Ordinance Requirements for Depuration There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for depuration. (1) Model Ordinance Chapter XV. Depuration

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall receive and depurate only shellstock which is obtained from a licensed harvester who has:

(b) ~~Identified the shellstock with a tag on each container or transaction record on each bulk shipment~~ Identified the shellstock with a tag on each container or bulk tag for each lot, and, for each bulk shipment, a ~~transaction record~~shipping document ~~on each bulk shipment~~, as outlined in Chapter VIII. .02 F;; [C]

Section IV. Guidance Documents, Chapter X. General Requirements for Dealers

.04 Shellstock Tagging

When a lot of shellstock is sold in bulk (e.g. by the truckload without being placed in containers), the harvester or dealer must provide a bulk tag and a ~~transaction record~~shipping document prior to shipment. ~~If the transaction record is generated by the harvester, t~~The ~~record~~shipping document must contain information identical to that required on the harvester's tags and must also include the name of the consignee. ~~If the transaction record is generated by the dealer, the record must contain information identical to that required on dealer's tags and must include the name of the consignee.~~

The NSSP recognizes two (2) types of shellstock tags: harvester tags and dealer tags. Many of the requirements are the same for both tag types. There are some additional requirements for dealer tags when the product has been wet stored or depurated. ~~Transaction records which provide the same information as the harvester's or dealer's tag may be used in lieu of tags for lot of shellstock sale and lot of shellstock shipment.~~

Depuration Tag Requirements

Shellstock that has been subjected to depuration requires an increased level of control because of the increased potential for contamination. These controls must include packaging and tagging that will serve to help identify the depuration cycle of each harvest lot and to deter illegal commingling of shellstock which has not been depurated with depurated shellstock. The Authority may require the harvester to use special tags or to provide additional information on the tags. At a minimum, the harvester's tags (~~or~~and ~~transaction records~~shipping documents used for bulk shipments) must identify the growing area, provide the harvester's special license number, and specify the harvest date and the quantity of shellstock.

Section IV. Guidance Documents, Chapter XI., XII., XIII. And XIV. Shellfish Processing

.03 Time and Temperature Controls

Conveyances Used to Transport Shellstock from Dealer to Dealer (Common Carriers, ~~or Shipping~~ Supplying Dealer's Conveyance, or Receiving Dealer's Conveyance).

Shellstock being transported from dealer to dealer must be shipped in containers which can be easily cleaned and maintained to prevent contamination. Shellstock must be shipped on pallets when shipped in bulk. Pallets are not necessary if the conveyance has channeled flooring.

If shellstock is shipped with other cargo, the shellstock must be protected from contamination by the other cargo. Shellstock must be refrigerated or cooled at all times when shipping from dealer to dealer. Conveyances must be pre-chilled to 45 °F (7.2 °C) or below prior to loading. It is acceptable to use ice as a means of cooling. ~~The dealer shall keep a record of compliance with the pre-chilling requirement; this record is not intended to be a HACCP record for the shipping dealer.~~

All shipments of shellstock shall be accompanied with a ~~documentation record~~shipping document indicating the date and time of shipment and ~~that all shipping containers were pre-chilled~~the temperature of shellstock at the time of loading. ~~The documentation required in Chapter IX. .05 must include the time of shipment, the means of cooling, and indicate the temperature to which the conveyance was pre-chilled if mechanical refrigeration was the means of cooling.~~ (This documentation is ~~not intended to be~~ a HACCP record for the receiving dealer but not the ~~shipping~~ supplying dealer). In situations when the dealer chooses to ship product not harvested under a State Vibrio Plan that has not achieved the internal temperature of 50 °F (10 °C), the shipping document~~ation~~ must provide notice to the receiving dealer that the product was shipped prior to achieving an internal temperature of 50 °F (10 °C). Additionally, 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. The ~~documentation~~ shipping document stating the time of shipment will accompany the ~~bill of lading~~shipment and will be used by the receiving dealer to determine the length of shipment.

This control will allow product to be shipped while cooling is occurring. Should the receiving dealer choose not to further ship the shellstock with a time/temperature recording device, the dealer must cool the shellstock and document that the ~~product~~ shellstock has reached an internal temperature of 50 °F (10 °C) prior to reshipping.

~~Conveyances Used to Transport Shellstock that are Owned by the Receiving Dealer.~~

~~Shellstock being picked up by the receiving dealer's truck and delivered directly to the receiving dealer's facility must be shipped in containers which can be easily cleaned and maintained to prevent contamination. Shellstock must be shipped on pallets when shipped in bulk. Pallets are not necessary if the conveyance has channeled flooring.~~

~~If shellstock is shipped with other cargo, the shellstock must be protected from contamination by the other cargo. Shellstock must be refrigerated or cooled at all times when shipping from dealer to dealer. Conveyances must be pre-chilled to 45~~

~~°F (7.2 °C) or below prior to loading. It is acceptable to use ice as a means of cooling.~~

~~The dealer shall keep a record of compliance with the pre-chilling requirement (see dealer to dealer shipping section above) or document the time the shipment was received from the selling dealers facility and the ambient air temperature of the shipping container; this record is not intended to be a HACCP record for the shipping dealer. The ambient air temperature of the conveyance must be to 45 °F (7.2 °C) or below prior to loading and time of receipt is a receiving HACCP record for the receiving dealer.~~

~~Additionally, 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. The documentation stating the time of shipment will accompany the bill of lading and will be used by the receiving dealer to determine the length of shipment.~~

~~This control will allow product to be shipped while cooling is occurring. Should the receiving dealer choose not to further ship the shellstock with a time/temperature recording device, the dealer must cool and document that the product has reached an internal temperature of 50 °F (10 °C) prior to reshipping.~~

Chapter XIV Reshipping

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for reshipping must document and maintain a record that the shellstock was received iced~~; in a conveyance at or below 45 °F (7.2°C);~~ or at an internal temperature of 50 °F (10 °C) or less. Dealers receiving shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by a shipping document~~ation~~ indicating (1) date and time of shipment; (2) ~~that conveyance was pre-chilled~~the shellstock temperature at the time of loading; and (3) notice of shellstock harvested under the time temperature requirements of Chapter VIII. @.02 A. (3) or restricted shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

Should the shipping dealer have chosen to ship ~~product~~ shellstock harvested under the time temperature requirements of Chapter VIII. @.02 A. (3) or restricted ~~use~~ shellstock prior to achieving required internal temperatures, for shipments that are more than four (4) hours, the shellstock must be accompanied by a time/temperature recording device which indicates that continuing cooling has occurred. ~~The shipment must also be accompanied by a shipping document indicating the time of shipment and that all shipping containers were prechilled.~~ Shellstock acceptability (receiving Critical Control Points) can be determined as follows:

Section IV. Guidance Documents, Chapter II. Risk Assessment and Risk Management

~~Shipping~~ Supplying Dealer #1
Name & ~~ICSSL~~ Certification #:

Harvest Area	Harvest Date	Receiving Dealer, Retailer, or Food Service *(Include ~~ICSSL~~ Certification #, if known or applicable)*	City, State	Sale Date	Lot No. or Date Shucked	Qty Sold	Product Description	Status *(Consumed, destroyed, returned)*

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

~~Shipping~~ Supplying Dealer #2
Name & ~~ICSSL~~ Certification #:

Harvest Area	Harvest Date	Receiving Dealer, Retailer, or Food Service *(Include ~~ICSSL~~ Certification #, if known or applicable)*	City, State	Sale Date	Lot No. or Date Shucked	Qty Sold	Product Description	Status *(Consumed, destroyed, returned)*

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative

2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Processing by Harvesters Clarification
10. Specific NSSP Guide Reference	Section II Model Ordinance; Chapter VIII. Control of Shellfish Harvesting, .02 Shellstock Harvesting and Handling
11. Text of Proposal/ Requested Action	.02 Shellstock Harvesting and Handling A. Harvesters. Any harvester who engages in shellfish packing, washing, or processing, as defined in this Ordinance, after harvest and landing shall: (1) Be a dealer; or (2) Pack, wash, or process shellstock for a dealer and in accordance with the time to temperature requirements of Chapter VIII. @.02 A and the applicable sanitation requirements for shellfish processing in Chapter XIII .02 and .03.
12. Public Health Significance	There is an existing requirement that harvesters should not pack shellstock, unless they are packing shellstock for a dealer. This proposal clarifies that the intent is that similar activities like washing and processing after harvest and landing should be performed by a dealer, or by the harvester for a dealer. It clarifies that the temperature requirements that apply to this activity are those in Chapter VIII. @.02 A., and that the sanitation requirements that apply are those, as applicable, Chapter VIII. .02 and .03. The intent is to provide clarification to the current requirement that shellstock be packed by a dealer or for a dealer by clarifying which requirements pertain to processing activities after harvest and landing. Currently, these activities are something of a gray area, so the intention is to provide some needed clarification.
13. Cost Information	None (clarification of an existing requirement)
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	A3 exemption for raw product
10. Specific NSSP Guide Reference	Section II Model Ordinance – Chapter VIII. Control of Shellfish Harvesting @.02
11. Text of Proposal/ Requested Action	@.02 Shellstock Time to Temperature Controls A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one (1) of the following: (1) The State V.v. Control Plan as outlined in Chapter II. @.06; or (2) The State V.p. Plan as outlined in Chapter II. @.07; or (3) All other shellstock shall comply with the matrix below…. **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 - 60 °F (10 - 15 °C) / 24 hours **Level 3** / >60 - 80 °F (15 - 27 °C) / 18 hours **Level 4** / >80 °F (27 °C) / 12 hours B. If the Authority's Vibrio Control Plan… C. For the purposes of this section, temperature control is defined as… D. The Authority shall establish… E. For the purpose of time to temperature control… F. The Authority shall ensure… G. Shellstock intended for… H. Ocean quahogs (*Arctica islandica*) and surf clams (*Spisula solidissima*) are not subject to ~~exempt from~~this temperature control plan ~~when these~~ except when products are intended for raw consumption ~~thermal processing~~. I. Authorities shall…
12. Public Health Significance	Current language allows an exemption of ocean quahogs and surf clams from time-to-temperature requirements when intended for thermal processing. The intent of the time-to-temperature controls is to minimize growth of human pathogenic bacteria (e.g., *Vibrio* spp.), which is primarily a risk from raw or undercooked product. The proposed language is allowing an exemption of time-to-temperature controls for these particular species unless they are specifically intended for raw consumption.
13. Cost Information	Potential for additional cost associated with implementing appropriate time-to-temperature controls for ocean quahogs and surf clams intended for raw consumption.

14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
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6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Harvester Training
10. Specific NSSP Guide Reference	Section II Model Ordinance; Chapter VIII. Control of Shellfish Harvesting
11. Text of Proposal/ Requested Action	.01 General A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities. B. Each harvester shall obtain Authority approved training before initial licensing and thereafter at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. ~~A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education.~~ (1) A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing. (2) When training is not available before certification, recertification, or licensing, the harvester shall be allowed ninety (90) days following initial licensing to obtain the required training. (3) The Authority may accept equivalent training obtained by the harvester in another state within the interval determined by the Authority not to exceed five (5) years. (~~2~~4) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. C. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license. D. In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the riparian owner or lessee shall be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease. E. Each harvester shall report harvest quantities by species to the Authority. The reporting shall be at a frequency not to exceed monthly. Should the State choose to collect production data from certified dealers, harvesters may be exempt from this requirement to avoid double counting.
12. Public Health Significance	This proposal is a minor change to provide specification to existing requirements. It presents a risk of illegal harvesting or mishandling if a harvester is actively harvesting for up to 90 days before receiving training on fundamental concepts such as harvest, handling, and transportation practices necessary to prevent illnesses, so this proposal states that harvester training should be obtained prior to licensure. This proposal retains the grace period of 90 days to obtain harvester training only for situations where it is not available before licensure. It also specifies that states may, at their discretion, choose to accept training obtained by the harvester in another state.

13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
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6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Harvester Name on Harvester Tags
10. Specific NSSP Guide Reference	Section II. Model Ordinance, Chapter VIII. Control of Shellstock Harvesting, .02 Shellstock Harvesting and Handling, F.(5)(a)
11. Text of Proposal/ Requested Action	(5) The harvester's tag shall contain the following indelible, legible information in the order specified below: (a) The harvester's identification number as assigned by the Authority, or, if allowed by the Authority, the harvester's name; (b) The date of harvest; (c) The most precise identification of the harvest location or aquaculture site as is practicable, including the initials of the State of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number). (d) The type and quantity of shellstock; and (e) The following statement in bold capitalized type on each tag: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS."
12. Public Health Significance	This proposal provides more flexibility to states and harvesters by adding an option for states to allow harvesters to list either their name or identification number on harvester tags. This proposal does not mandate that states allow the harvester name to be listed on the harvester tag instead of the harvester identification number, but simply gives the states the option to allow it. The impetus for this proposal is that some states track harvesters primarily by their name instead of their identification number, so states should have the option to allow harvester names on tags.
13. Cost Information	None (does not require harvester tags to be changed, but simply adds the option for the state to allow the harvester to list either their name instead or identification number on the tag, so that this proposal will not require the purchase of new tags)
14. Changes Needed to Guidance (if proposed change is adopted)	Section IV Guidance Documents – Chapter X. General Requirements for Dealers Harvester Tag Requirements .04 Shellstock tagging Information on the harvester's tags must be legible, indelible and arranged in the following specific order: • A place may be provided where the dealer's name, address and certification number as assigned by the Authority may be added; • The harvester's identification number as assigned by the Authority, or, if allowed by the Authority, the harvester's name;

	• The date of harvesting; • The most precise identification of the harvest location or aquaculture site as is practicable; this identification must include at least the State (initials) in which the shellfish were harvested and the designated growing area with that State as assigned by the Authority of the producing State. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed or lot number); • Type and quantity of shellfish; • The following statement, in bold capitalized type on each bag: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS." and • All shellstock intended for raw consumption shall include a consumer advisory and follow the Time-Temperature Matrix Control. The following statement, from section 3-603.11 of the 2001 Food Code, or an equivalent statement shall be included on all shellstock: “RETAILERS, INFORM YOUR CUSTOMERS” “Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of food borne illness, especially if you have certain medical conditions”

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
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8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Hand Sanitizer on Harvest Vessels
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter VIII. Control of Shellfish Harvesting, D. Disposal of Human Sewage and Vomitus
11. Text of Proposal/ Requested Action	Chapter VIII. Control of Shellfish Harvesting, D. Disposal of Human Sewage and Vomitus. (1) Human sewage and vomitus shall not be discharged overboard from any vehicle or vessel used in the harvesting of shellstock. (2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel or available for the vehicle operator's use for the purpose of containing human sewage and vomitus. If the vessel or vehicle is provided with a marine sanitation device, portable toilet or other sewage disposal receptacle, a container of commercially available hand sanitizer or other means of hand cleaning shall be provided on the vessel or available for the vehicle operator's use. (3) Portable toilets shall: (a) Be used only for the purpose intended; (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage; (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the vehicle or vessel; and (e) Not be cleaned in equipment used for washing or processing food. (4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are: (a) Constructed of impervious, cleanable materials and have tight fitting lids; (b) Indelibly labeled "Human Waste" in contrasting letters at least three (3) inches in height; and (c) Meet the requirements in Section D. (3).
12. Public Health Significance	For harvest vessels that are equipped with an MSD, portable toilet, or bucket, it follows that they should also be equipped with a simple bottle of hand sanitizer. Harvesters are handling food in an isolated location and so should be equipped with a means to sanitize their hands, especially after they may come into contact with bodily fluids if the required MSD, portable toilet, or bucket is used. This proposal does not require that they sanitize their hands at any particular time; it just seems commonsense that they should have a means to do so available, for use at their discretion. It's a very easy requirement to comply with.
13. Cost Information	Less than $5 for a container of hand sanitizer on each harvest boat
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
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7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Emergency Notification
10. Specific NSSP Guide Reference	Section II Model Ordinance; Chapter X. General Requirements for Dealers, Chapter VIII. Control of Shellfish Harvesting
11. Text of Proposal/ Requested Action	Chapter X. General Requirements for Dealers .03 Other Model Ordinance Requirements A. Each dealer shall comply with the requirements specified in Chapter XI. .03, Chapter XII. .03, Chapter XIII. .03, Chapter XIV. .03, and Chapter XV. .03 that are appropriate to the plant and the food being processed. However, monitoring and record keeping for these conditions and practices is not required, unless specifically stated. B. Recalls. (1) Dealers shall adopt written procedures for conducting recalls of adulterated or misbranded shellfish products, including shellfish affected by the situations outlined in Chapter X. .03 D., as appropriate. These written procedures for conducting recalls shall be based on, and complementary to, the FDA Enforcement Policy on Recalls, CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement Policy, (NSSP Guide for the Control of Molluscan Shellfish, Federal Regulations). (2) Dealers shall follow their written recall procedures to include timely notification of the Authority of a situation requiring recall, timely notification of consignee who received the affected product, and effective removal or correction of the affected product. C. Each dealer shall report harvest quantities by species to the Authority. The reporting shall be at a frequency not to exceed monthly. Should the State choose to collect production data from harvesters, certified dealers are exempt from this requirement to avoid double counting. D. Dealers shall notify the Authority within 24 hours and immediately implement measures as necessary to protect shellfish from contamination and loss of temperature control when shellfish that are or were in their possession are affected by events indicating a significant risk of illness or significant non-compliance with the requirements in this Ordinance, including: (1) Deviations from critical limits and other critical deficiencies for which appropriate corrective action is not or cannot be taken; (2) Non-compliance with requirements for temperature control and mechanical refrigeration failures for which appropriate corrective action is not or cannot be taken;

	(3) Failures of equipment critical to food safety for which appropriate corrective action is not or cannot be taken; (4) Flooding, fires, or electrical power outages at shellfish processing facilities; (5) Spills of sewage, poisonous or deleterious substances, or other contaminants into growing areas; and (6) Situations that may warrant product recall. Chapter VIII. Control of Shellfish Harvesting .01 General A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities. B. Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education. (1) A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing. (2) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. C. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license. D. In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the riparian owner or lessee shall be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease. E. Each harvester shall report harvest quantities by species to the Authority. The reporting shall be at a frequency not to exceed monthly. Should the State choose to collect production data from certified dealers, harvesters may be exempt from this requirement to avoid double counting. F. Harvesters shall notify the Authority within 24 hours and immediately implement measures as necessary to protect shellfish from contamination and loss of temperature control when shellfish that are or were in their possession are affected by events indicating a significant risk of illness or significant non-compliance with the requirements in this Ordinance, including: (1) Non-compliance with requirements for temperature control for which appropriate corrective action is not or cannot be taken; and (2) Spills of sewage, poisonous or deleterious substances, or other contaminants from the harvester's vessel into growing areas.
12. Public Health Significance	It is important that harvesters, dealers, and Authorities collaborate as necessary to ensure that shellfish affected by temperature control problems, cross-contamination, and similar situations that may have caused shellfish to become unsafe for consumption. This includes notification by harvesters and dealers to the

	state of these situations (unless the problem has already been corrected by the dealer, in which case notification is not necessary), so that the state can provide guidance to ensure that regulatory requirements are met and that shellfish are safe for consumers.
13. Cost Information	None (shellfish affected by these emergency events are already subject to existing requirements which ensure that unsafe product is controlled; this proposal merely adds that the Authority should be made aware of the situation)
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
3. Affiliation	U.S. Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Controlled access status harvester tag requirements-restricted shellstock
10. Specific NSSP Guide Reference	National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish: 2023 Revision, Section II. Model Ordinance (MO), Chapter VIII. .02
11. Text of Proposal/ Requested Action	NSSP MO Chapter VIII. .02 …(8) Bulk Sale of Shellstock. If shellstock are sold in bulk, the harvester or dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in Section .02 F. with the addition of the name of the consignee. (9) Controlled Access Status. All shellstock harvested from growing areas in the controlled access status shall be tagged with restricted shellstock tags. G. Shellstock Temperature Control (1) All harvesters shall comply with the applicable time to temperature requirements of (a) State *V.v.* and *V.p.* Control Plans outlined in Chapter II. @.06 and @.07; or (b) Chapter VIII. @.02 Shellstock Time to Temperature Controls A. (3). (2) All harvesters shall provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements. ~~H. Controlled Access Status. All shellstock harvested from growing areas in the controlled access status shall be tagged with restricted shellstock tags.~~ H. ~~I.~~ Ice production: (1) Any ice used in the storage or cooling of shellfish during harvest shall: (a) Be made from a potable water source or from a growing area in the approved classification or in the open status of the conditionally approved classification; or (b) Come from a facility approved by the…
12. Public Health Significance	Currently there is no requirement for harvesters in Chapter VIII. (Control of Harvest) for tagging shellstock harvested in areas designated in the controlled

	access status with restricted tags. There is a requirement in Chapter IV. @.04 C.(7) (Closed or Controlled Access Status of Growing Areas) that all shellstock harvested from growing areas in the closed or controlled access status shall be tagged with restricted shellstock tags. Chapter IV. @.04 is a requirement for the authority, not the harvester. This proposal adds language to Chapter VIII. .02, making it a requirement of the harvester to use restricted shellstock tags.
13. Cost Information	Minimal cost
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
3. Affiliation	U.S. Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Bulk tagging transaction record
10. Specific NSSP Guide Reference	Chapter VIII. .02 F. (8) Chapter X. .05 F.
11. Text of Proposal/ Requested Action	Chapter VIII. .02 F. (8) Bulk Sale of Shellstock. If shellstock are sold in bulk, the harvester or dealer shall provide a transaction record ~~prior to shipment. This transaction record shall~~ containing all the information required in Section .02 F. ~~with the addition of~~including the name of the consignee. Chapter X. .05 F. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record ~~prior to shipment. This transaction record shall~~ containing all the information required in Section .05 C. ~~with the addition of~~including the name of the consignee.
12. Public Health Significance	As long as a transaction record is provided with the bulk shipment, it doesn't matter that it's sent prior to shipment. There is no added public health significance with sending a transaction record prior to shipment and it often does not happen creating compliance issues.
13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
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5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	A(3) Matrix Clarification
10. Specific NSSP Guide Reference	Section II. Model Ordinance, Chapter VIII. Control of Shellfish Harvesting, @.02 Shellstock Time to Temperature Controls, A(3) Matrix
11. Text of Proposal/ Requested Action	Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one (1) of the following: (1) The State V.v. Control Plan as outlined in Chapter II. @.06; or (2) The State V.p. Plan as outlined in Chapter II. @.07; or (3) All other shellstock shall comply with the matrix below:
12. Public Health Significance	This is intended as housekeeping to ensure clarity, not as a change to any existing requirements. The wording of "Maximum Hours from Exposure to Receipt at a Dealer's Facility" is imprecise because some shellstock shippers don't have facilities. Also, in some states, some harvesters are certified as dealers so that they can load their product from the landing dock onto the truck of an out-of-state dealer. The rewording in this proposal clarifies how the A(3) matrix is to be applied in these situations. This rewording is consistent with the existing purpose of the matrix.
13. Cost Information	None
14. Changes Needed to	Section IV. Guidance Documents Chapter XI., XII., XIII., and XIV. Shellfish Processing .03 Time and Temperature Controls

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

Guidance (if proposed change is adopted)

Chapter VIII Harvesters Time to Temperature Control
B. Harvesters.

Harvesters must be aware of the applicable time to temperature requirements. Harvesters can obtain this information by contacting the Authority responsible for regulating shellfish harvesting. Harvesters must adhere to the time to temperature requirements of the individual State Vibrio Plans or follow the matrix below.

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

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative

2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
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5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Shucked Meat Dislodging
10. Specific NSSP Guide Reference	Section II. Model Ordinance, Chapter IX. Shucking and Packing & Chapter XII. Repacking
11. Text of Proposal/ Requested Action	Section II. Model Ordinance, Chapter IX. Shucking and Packing F. Shellfish Storage and Handling. The dealer shall: (1) Assure that shellstock is: (a) Reasonably free of sediment [O]; and (b) Culled; [K] (2) Assure shucking buckets are completely empty at the packing room so that no overage is returned to the shucker. [K] (3) Inspect incoming shipments and shall reject dead or inadequately protected shellstock. [K] (4) Not allow the use of dip buckets for hand or knife rinsing. [K] (5) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source. [K] (6) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161 Section 130. [K] (7) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room. [K] (8) Conduct packing activities so as to conform to applicable food additive regulations; [K] (9) Assure that shellfish are maintained frozen during storage frozen. [SK/O] (10) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan. [K] (11) For mechanical shucking operations, not allow shucked meats to become entangled or lodged on equipment for more than 30 minutes during processing operations. [K] (a) Actions shall be taken to dislodge meats from equipment at intervals not to exceed 30 minutes. [K] These meats may be reintroduced into processing operations. (b) Meats which have become entangled or lodged for more than 30 minutes shall be removed and discarded. [K] (1~~1~~2) Ensure that all shellstock obtained from a licensed harvester are (a) Adequately iced within two (2) hours of receipt; (b) Placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt; or (c) Shucked within two (2) hours of receipt. [SC/K] (d) 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. (11). Section II. Model Ordinance, Chapter XII. Repacking F. Shellfish Storage and Handling. ~~(1)~~ The dealer shall: (~~a~~1) Not commingle shellfish from different lots; [K] (~~b~~2) Repack shucked shellfish meats only into containers labeled with the authorized certification number; [K] (~~c~~3) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source; [K] (~~d~~4) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161 Section 130; [K] (~~e~~5) Thoroughly drain, clean as necessary, and repack shucked shellfish meats promptly; [K] (~~f~~6) Conduct repacking activities so as to conform to applicable food additive regulations; and [K] (~~g~~7) During storage frozen shellfish shall be maintained frozen. [SK/0] (8) For mechanical repacking operations, not allow shucked meats to become entangled or lodged on equipment for more than 30 minutes during processing operations. [K] (a) Actions shall be taken to dislodge meats from equipment at intervals not to exceed 30 minutes. [K] These meats may be reintroduced into processing operations. (b) Meats which have become entangled or lodged for more than 30 minutes shall be removed and discarded. [K]
12. Public Health Significance	The Model Ordinance already requires rapid product handling. This proposal adds specifications to ensure that rapid product handling is achieved during mechanical shucking or repacking operations. In mechanical operations, shucked meats frequently become hung up at locations along the processing line, and it is necessary to take actions to dislodge these meats at regular intervals. Regular dislodging of meat ensures that all shellfish meet the existing required critical limits that shucked meats are cooled to 45°F within 3 hours of shucking or within 4 hours of removal from refrigeration – it is necessary to dislodge hung up meats from the shucking line at 30 minutes intervals to ensure that these critical limits will be met for all meats. Additionally, dislodging meats at 30 minute intervals is necessary to ensure compliance with the existing MO requirement "The dealer shall wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161 Section 130," which requires that shellfish do not spend 30 minutes or more in contact with water.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Require geoduck shipments have a Chapter IX. transportation document so that receiving secondary dealers can meet current HACCP Receiving Critical Limits for shipments of four (4) hours or less
10. Specific NSSP Guide Reference	Chapter IX. .05 C.
11. Text of Proposal/ Requested Action	Chapter IX. .05 C. Geoduck clams (*Panopea generosa*) are exempt from ~~these requirements~~ the requirements in .05 B. above.
12. Public Health Significance	The current exemptions for geoduck in Chapters XIII .01 B. and IX .04 and .05 could prevent secondary dealers from meeting current HACCP receiving critical limits. Chapter XIII .01 B. (5), exempts geoduck, which are being cooled using an Authority-approved tempering plan, from the requirement to be cooled to an internal temperature of 50°F prior to shipment. Chapter IX .04 exempts geoduck from the requirements of being shipped iced, or in a pre-chilled conveyance at or below 45°F, and Chapter IX .05 exempts geoduck shipments from needing a transportation record that has the time and temperature at shipment. However, there still exists the HACCP Receiving Critical Limits in Chapters XIII and XIV .01 that secondary dealers receive only shellstock which has been "cooled to an internal temperature of 50°F (10°C) or less", or if Chp. VIII. @.02 A.(3) shellstock is shipped prior to being cooled to 50°F (geoduck), that it either be accompanied by a time/temperature recording device indicating continued cooling

	has occurred, or if the shipment time is four (4) hours or less, that the shipment have documentation as required in Chapter IX. 05 A. (which we established earlier that geoduck are currently exempt from having). For a secondary dealer to meet the current receiving critical limits for geoduck that was shipped (four hours or less) by the original dealer above 50°F, the geoduck would need to cool in-transit to 50°F or below, a scenario that could be unlikely for local shipments. This proposal attempts to fix this discrepancy by requiring shipments of geoduck to be accompanied by transportation document indicating the ship date, time and temperature at shipment.
13. Cost Information	No cost to industry aside from requiring original dealers that ship geoduck to record date/time/temperature at shipment on a transportation record. Potential cost-savings to industry by preventing local geoduck shipments from being rejected.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell; Sarah Good
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control; State of Virginia, Department of Health
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6. City, State, Zip	Dover, DE 19904; Richmond, VA 23219
7. Phone	302-608-5511; 804-659-3823
8. Email	andrew.bell@delaware.gov; sarah.good@vdh.virginia.gov
9. Proposal Subject	Chapters IX & X Criticalities
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter IX. Transportation & Chapter X. General Requirements for Dealers
11. Text of Proposal/ Requested Action	**Chapter IX. Transportation** .01 Conveyances Used to Transport Shellstock to the Original Dealer A. Any conveyance used to transport shellstock to the original dealer shall be properly constructed, operated and maintained to prevent contamination, deterioration, and decomposition. [O] B. Storage bins on conveyances used in the transport of shellstock shall be: (1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; [$S^{C/K}$] and (2) Provided with effective drainage. [$S^{K/O}$] C. When transporting shellstock to the original dealer within the applicable time to temperature controls in Chapter VIII. @.02 A. (1), (2), and (3) the temperature inside the conveyance or truck shall not exceed the ambient air temperature when the ambient air temperature is above 50 °F (10 °C). [$S^{C/K}$] D. When mechanical refrigeration units are used, the units shall be: (1) Equipped with automatic controls; [O] and (2) Maintained at an ambient air temperature necessary to comply with .01 C. above. [$S^{C/K}$] E. Any ice used to cool shellstock during transport shall: meet the requirements of Chapter XI. .02 A. (2). [C] F. Cats, dogs, and other animals shall not be allowed in any part of the conveyance where shellstock is stored. [K] G. Disposal of Human Sewage and Vomitus (1) Human sewage and vomitus shall not be discharged overboard from any vehicle or vessel which buys shellstock while the vehicles or vessels are in growing areas. [C] (2) As required by the Authority, in consultation with FDA, an approved MSD, portable toilet or other sewage disposal receptacle shall be provided on the vessel or available for the vehicle operator's use for the purpose of containing human sewage and vomitus. Portable toilets shall meet the requirements of VIII. .02. D. (3). [K] .02 Conveyances Used to Transport Shellstock from Dealer to Dealer A. All containers used to transport shellstock shall be:

(1) Constructed to allow for easy cleaning; [O] and
(2) Operated and maintained to prevent product contamination. [S$^{C/K}$]

B. All containers shall be cleaned with:
(1) Potable water; [S$^{C/K}$] and
(2) Detergents, sanitizers, and other supplies acceptable for food contact surfaces. [K]

C. Disposal of Human Sewage and Vomitus
(1) Human sewage and vomitus shall not be discharged overboard from any vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas. [C]
(2) As required by the Authority, in consultation with FDA, an approved MSD, portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage and vomitus. Portable toilets shall meet the requirements of VIII. .02. D. (3). [K]

.03 Cargo Protection From Cross Contamination

A. General. All containers used for storing shellfish shall be clean and fabricated from safe materials. [K]

B. Shellfish Cargo Only.
(1) The entire cargo shall consist of shellfish products only.
(2) Except for bulk shipments, shellstock shipments shall be shipped on pallets. [K]
(3) In-shell product shipments shall be shipped on pallets. [K]
(4) If the conveyance does not have a channeled floor, pallets shall be used for all shellfish. [K]

C. Mixed Cargoes. Shellfish shall be shipped as part of a mixed cargo of seafood or other food product only when:
(1) Shellfish products are protected from contamination by the other cargo; [S$^{C/K}$]
(2) All cargo is placed on pallets; [K] and
(3) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers. [K]

D. Ice. Any ice used to cool shellfish shall: meet the requirements of Chapter XI. .02 A. (2). [C]

.04 Shipping Temperatures

Shellfish dealers shall ship shellfish adequately iced; or in a conveyance pre-chilled at or below 45 °F (7.2 °C) ambient air temperature. [C] Geoduck clams (Panopea generosa) are exempt from these requirements

.05 Transportation Records

A. All shipments of shellstock shall be accompanied with documentation indicating the following:
(1) Date and time of shipment; [K] and
(2) The temperature of the shellstock recorded by the shipping dealer at the time of shipment. [K]

B. For shipments of shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) prior to shipping and where the shipping time is greater than four (4) hours, the documentation shall also indicate the presence of a time/temperature recording device. [K]

C. Geoduck clams (Panopea generosa) are exempt from these requirements

Chapter X. General Requirements for Dealers

.01 General HACCP Requirements

A. Hazard Analysis. Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventive measures that the dealer can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent dealer would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of shellfish product being processed in the absence of those controls. In the hazard analysis, the dealer shall consider the critical control points listed in Chapters XI., XII., XIII., XIV., and XV. [K]

B. HACCP Plan. Every dealer shall have and implement a written HACCP plan. [S$^{C/K}$] A HACCP plan shall be specific to:

(1) Each location where shellfish products are processed by that dealer; and

(2) Each kind of shellfish product processed by the dealer. The plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in Section .01 C. are identical for all shellfish products so grouped or for all production methods so grouped.

C. Contents of the HACCP Plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with Section .01 A. and that thus must be controlled for each shellfish product. [O] Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(a) Natural toxins;
(b) Microbiological contamination;
(c) Chemical contamination;
(d) Pesticides;
(e) Drug residues;
(f) Unapproved use of direct or indirect food or color additives; and
(g) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(a) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during and after harvest. At a minimum, the critical control points shall include those identified in Chapter XI. .01, Chapter XII. .01, Chapter XIII. .01, Chapter XIV. .01 and Chapter XV. .01, as applicable. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required with the exception of receiving which shall always be considered as a critical control point. [K]

(b) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through

a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required. At a minimum, the critical control points shall include those identified in Chapter XI. .01 A., Chapter XII. .01 A., Chapter XIII. .01 A., Chapter XIV. .01 A. and Chapter XV. .01 A., as applicable. [K]

(c) Critical control points shall be designed to ensure that shellstock received with restricted shellstock tags is processed consistent with the stated purpose. For Shellstock tagged for restricted use, critical control points shall be included in the Certified Dealer's HACCP plan to ensure that the shellstock is shipped to another Certified Dealer with the restricted shellstock tag or processed consistent with the stated purpose. [K]

(3) List the critical limits that must be met at each of the critical control points. At a minimum, the critical limits shall include those listed in Chapter XI. .01, Chapter XII. .01, Chapter XIII. .01, Chapter XIV. .01 and Chapter XV. .01, as applicable. As an alternative the dealer may establish other critical limits which the dealer has demonstrated provide equivalent public health protection with the exception of receiving which shall always be considered as a critical control point. In any case, the critical limits identified in Chapter XI. .01, Chapter XII. .01, Chapter XIII. .01, Chapter XIV. .01 and Chapter XV. .01 shall be met as components of good manufacturing practices. [K]

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits. [K]

(5) Include any corrective action plans that have been developed in accordance with Section .01 F. (2), to be followed in response to deviations from critical limits at critical control points. [K]

(6) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring. [O]

(7) List the verification procedures, and frequency thereof, that the dealer will use in accordance with Section .01 G. (1). [O]

D. Signing and Dating the HACCP Plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual on site at the processing facility or by a higher-level official of the dealer. This signature shall signify that the HACCP plan has been accepted for implementation by the dealer. [O]

(2) The HACCP plan shall be signed and dated:

(a) Upon initial acceptance; [O]

(b) Upon any modification; [O] and

(c) Upon verification of the plan in accordance with Section .01 G. (1) (a). [O]

E. Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Section .02 they need not be included in the HACCP plan, and vice versa.

F. Corrective Actions.

(1) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:

(a) Following a corrective action plan that is appropriate for the particular deviation, [$S^{C/K}$] or

(b) Following the procedures in Section .01 F. (3). [$S^{C/K}$]

(2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with Section .01 C. (5), by which they predetermine the corrective actions that they will take whenever there is a

deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; [K] and

(b) The cause of the deviation is corrected. [K]

(3) When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall:

(a) Segregate and hold the affected product until:

(i) There is a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. [K] Adequate training may or may not include training in accordance with Section .01 I.; and

(ii) Corrective action is taken when necessary, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation. [$S^{C/K}$]

(b) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Section .01 I., to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary. [K]

(4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Section .01 G. and the record keeping requirements of Section .01 H. [$S^{K/O}$]

G. Verification.

(1) Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. [K] Verification shall include, at a minimum:

(a) A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. [K] These changes may include: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Section .01.I. [K] The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Section .01.C. [C]

(b) Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the dealer to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points; [K]

(ii) The calibration of process-monitoring instruments; [K] and

(iii) At the option of the dealer, the performing of periodic end product or in-process testing.

(c) A review, including signing and dating, by an individual who has been trained in accordance with Section .01 I., of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are

complete and to verify that they document values that are within the critical limits. This review shall occur within one (1) week of the day that the records are made; [K]

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Section .01 F. This review shall occur within one (1) week of the day that the records are made; [K] and

(iii) The calibrating of any process monitoring instruments used at critical control points and the performing of any periodic end product or in process testing that is part of the dealer's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made. [K]

(2) Dealers shall immediately follow the procedures in Section .01 F. whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action. [$S^{C/K}$]

(3) The calibration of process-monitoring instruments, and the performing of any periodic end- product and in-process testing, in accordance with Section .01 G. (1) (b) (ii) and (iii) shall be documented in records that are subject to the record keeping requirements of Section .01 H. [$S^{K/O}$]

H. Records.

(1) All records required by Section .01 and Section .02 shall include:

(a) The name and location of the dealer; [O]

(b) The date and time of the activity that the record reflects; [O]

(c) The signature or initials of the person performing the operation; [O] and

(d) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. [O]

(2) All records required by Section .01 and Section .02 shall be retained at the processing facility for at least one (1) year after the date they were prepared in the case of refrigerated products and for at least two (2) years after the date they were prepared in the case of frozen products. [K]

(3) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least two (2) years after their applicability to the product being produced at the facility. [O]

(4) If the processing facility is closed for a prolonged period between seasonal operations, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal operations but shall be immediately returned for official review upon request.

(5) All records required by Section .01 and Section .02 and HACCP plans required by Section .01 B. and Section .01 C. shall be available for official review and copying at reasonable times.

(6) Tags on containers of shellstock are not subject to the requirements of this section unless they are used to fulfill the requirements of Chapter X. .05.

(7) The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.

I. Training.

(1) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to shellfish processing at least equivalent to that received under standardized curriculum recognized as adequate by the Authority or who is otherwise qualified through job experience to perform these functions:

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan that is appropriate for a specific processor, in order to meet the requirements of Section .01 C.; [K]

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Section .01 F. (3) (b), and the HACCP plan in accordance with the verification activities specified in Section .01 G. (1) (a); [K] and

(c) Performing the record review required by Section .01 G. (1) (c). [K]

(2) Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum as determined by the Authority.

(3) The trained individual need not be an employee of the dealer.

.02 General Sanitation Requirements

A. Sanitation Monitoring. Each dealer shall monitor conditions and practices that are both appropriate to the plant and the food being processed with sufficient frequency to ensure, at a minimum, conformance with the requirements specified in Chapter XI. .02, Chapter XII. .02, Chapter XIII. .02, Chapter XIV. .02 and Chapter XV. .02. [K] The requirements specified in these Sections relate to the following sanitation items:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice, hereinafter referred to as: Safety of Water for Processing and Ice Production;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Condition and Cleanliness of Food Contact Surfaces;

(3) Prevention of cross contamination from unsanitary objects to food, food packaging materials, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Prevention of Cross Contamination;

(4) Maintenance of hand washing and toilet facilities, hereinafter referred to as: Maintenance of Hand Washing and Toilet Facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants, hereinafter referred to as: Protection from Adulterants;

(6) Proper labeling, storage, and use of toxic compounds, hereinafter referred to as: Proper Labeling, Storage, and Use of Toxic Compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces, hereinafter referred to as: Control of Employees with Adverse Health Conditions; and

(8) Exclusion of pests from the food plant hereinafter referred to as "Exclusion of Pests".

While monitoring of those specified conditions and practices (listed in 1-8) that are not appropriate to the plant and the food being processed is not required, compliance with such conditions and practices remains mandatory.

B. Sanitation Monitoring Records. Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by Section .02 A. [K] These records are subject to the requirements of Section .01 H.

C. Relationship to HACCP Plan. Sanitation controls may be included in the HACCP Plan, required by Section .01 B. However, to the extent that they are monitored in accordance with Section .02 A. they need not be included in the HACCP Plan, and vice versa.

.03 Other Model Ordinance Requirements

A. Each dealer shall comply with the requirements specified in Chapter XI. .03, Chapter XII. .03, Chapter XIII. .03, Chapter XIV. .03, and Chapter XV. .03 that are appropriate to the plant and the food being processed. However, monitoring and record keeping for these conditions and practices is not required, unless specifically stated.

B. Recalls.

(1) Dealers shall adopt written procedures for conducting recalls of adulterated misbranded shellfish products. These written procedures for conducting recalls shall be based on, and complementary to, the FDA Enforcement Policy on Recalls, CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement Policy, (NSSP Guide for the Control of Molluscan Shellfish, Federal Regulations). [K]

(2) Dealers shall follow their written recall procedures to include timely notification of the Authority of a situation requiring recall, timely notification of consignee who received the affected product, and effective removal or correction of the affected product. [$S^{C/K}$]

C. Each dealer shall report harvest quantities by species to the Authority. The reporting shall be at a frequency not to exceed monthly. Should the State choose to collect production data from harvesters, certified dealers are exempt from this requirement to avoid double counting.

.04 Certification Requirements

A. General.

(1) No person shall act as a dealer prior to obtaining certification. [C]

(2) Any person who wants to be a dealer shall:

(a) Make application to the Authority for certification;

(b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the Federal Register of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.

(c) Ensure that all individuals who manufacture, process, pack, or hold food obtain training in accordance with 21 CFR 117.4. [K] A dealer shall be allowed thirty (30) days following initial hiring of a new employee to provide the required education.

(i) Proof of training for all employees shall be presented to the Authority prior to certification, recertification, or licensing. [K]

(ii) The dealer shall maintain the record of the completed training. [K]

(3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.

B. Types of Certification.

(1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer.

(2) Repacker.

(a) Any person who repacks shucked shellfish shall be certified as a

shucker-packer or repacker;
(b) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker-packer, or repacker;
(c) A repacker shall not shuck shellfish.
(3) Shellstock Shipper. Any person who ships and receives shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer.
(4) Reshipper. Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers shall be certified as a reshipper.
(5) Depuration Processor. Any person who harvests or receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process.

.05 Shellstock Identification
[Note: All Federally allocated shellfish (surf and quahog) caught in Federally regulated waters must follow the National Marine Fisheries Service tagging protocol. These Federal sequential tags ~~will~~ shall supersede the tagging requirements in Section 05.]
A. General.
(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; [K] or
(b) Emptied to wash, grade, or pack the shellstock. [K]
(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.
B. Tags.
(1) The dealers' tags shall:
(a) Be durable, waterproof and sanctioned by the Authority prior to use; [K] and
(b) Be at least 13.8 square inches (89.03 cm2) in size. [O]
(2) The dealer's tag shall contain the following indelible, legible information in the order specified below: [K]
(a) The dealer's name and address.
(b) The dealer's certification number as assigned by the Authority.
(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required.
(d) The harvest date; or if depurated, the date of depuration processing, or if wet stored, the original harvest date, and the final harvest date which is the date removed from wet storage.
(e) If wet stored or depurated, the wet storage or depuration cycle or lot number. The wet storage lot number shall begin with the letter "w".
(f) The most precise identification of the harvest location as is practicable including the initials of the State of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriated geographical or administrative designation must be used (e.g., Long Bay, Decadent County, lease number, bed, or lot number).
(g) The type and quantity of shellstock.
(h) The following statement in bold capitalized type on each tag:
"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL

CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS." "RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____."

Note: Shellstock tagged for restricted should not include the retailer guidance language "RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____."

(i) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all shellstock: "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(j) The statement "Keep Refrigerated" or an equivalent statement.

(3) If a dual-purpose tag is used (harvester and dealer), duplicate information is not required on both sides of the tag, or

(4) If a two-tag system is used, the dealer tag shall meet the requirements in .05 B. [K]

(5) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in Section .05 B. If the shellstock is received bearing a restricted shellstock tag all specific use language shall be transferred to the new shipping tag until processed consistent with the stated purpose. [K]

(6) Country of origin information (USDA 2004) may be included on the dealer tag.

(7) When shellstock intended for retail sale are packed in containers of five (5) pounds or less and shipped in a master container which includes a tag in compliance with Chapter X. .05 B. (1) the individual containers of five (5) pounds or less shall not require tags as specified in Chapter X. .05 B. (1) but may be labeled in some other manner with indelible, legible, information which at a minimum is adequate to trace the shellfish back to the lot of shellstock it is part of.

(8) If a shellfish producing State selects to implement Chapter II. @.06 E. (1) (b) (i), a statement indicating that the shellstock are for shucking by a certified dealer and/or for approved postharvest processing to control the Vibrio vulnificus hazard shall be included on the tag. When this statement is included, the shellstock shall ultimately be sold to or processed by a certified shucker-packer or post-harvest processor for the purpose of shucking or post-harvest processing. [K]

C. Bulk Tagging Lots of Shellstock for Sales between Dealers.

(1) When a single lot of shellstock is sold, multiple containers may be used on a wrapped pallet, in a tote, in a net bailer, or other container and the unit tagged with a single tag in accordance with Section .05 B. (1) through (4).

(a) This bulk tagging provision shall not apply to sales to reshippers;

(b) The shipment must be accompanied by a transaction record stating the name of the consignee who must be a certified dealer; [K]

(c) In addition to the information required in Section .05 B. (1) through (4) the unit tag shall also include:

(i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest"; [O] and

(ii) Number of individual containers in the unit. [O]

D. Tagging of a Lot of Shellstock during Intermediate Processing.

(1) When the shellstock is removed from the original container, the dealer

shall:
(a) Keep the harvester tag for ninety (90) days; [K]
(b) Keep track of the growing area and date of harvest for shellstock; [K] and
(c) Maintain the lot identity of all shellstock during any intermediate stage of processing. [K]
(2) A dealer receiving bulk tagged lots of shellstock ~~must~~ shall have an intermediate processing plan approved by the Authority to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification. [K]
(3) In order for a dealer to tag a lot container (e.g., a pallet) of shellstock in lieu of meeting the requirement in Section .05 B. for a harvester or dealer tag on each individual container, the dealer shall have an intermediate processing plan approved by the Authority, which establishes the procedures, the dealer shall use to tag the lot during the washing, packing or staging of shellfish. [K]
(4) Unless the dealer is included in the Authority's commingling plan under Chapter I. @.01 F., the dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. [K] The identification shall be provided by:
(a) A harvester's or dealer's tag which meets the requirements of Section .05 B.; or
(b) A tag for each lot of shellstock that contains the following information:
(i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest";
(ii) Harvest date;
(iii) Growing area;
(iv) Original dealer certification number; and
(v) Number of individual containers in each lot of shellstock container (e.g., a pallet) after washing, packing or staging has been completed.
(5) When a dealer has an approved intermediate processing plan, the dealer shall tag each lot of shellstock in accordance with the intermediate processing plan while the lot of shellstock is being processed in the plant. [K]
E. All restricted 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. [C]
F. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in Section .05 C. with the addition of the name of the consignee. [K]

.06 Shucked Shellfish Labeling
A. Shellfish Labeling.
(1) The dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers. [K]
(2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment

shall be accompanied by a transaction record containing:
(a) The original shucker-packer's name and certification number; [K]
(b) The shucking date; [K] and
(c) The quantity of shellfish per container and the total number of containers. [K]
(3) If the dealer uses master shipping cartons, the master cartons are exempt from these labeling requirements when the individual containers within the carton are properly labeled.
(4) At a minimum the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.130, and 161.136) and the Federal Fair Packaging and Labeling Act. [K]
(5) The dealer shall assure that the shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish. [K]
(6) The dealer shall label each individual package containing less than sixty-four (64) fluid ounces of fresh or fresh frozen shellfish with the following:
(a) The words "SELL BY" or "BEST IF USED BY" followed by a reasonable date when the product would be expected to reach the end of its shelf life; [K]
(b) The date shall consist of the abbreviation for the month and number of the day of the month; [K] and
(c) For fresh frozen shellfish, the year shall be added to the date. [K]
(7) The dealer shall label each individual package containing sixty-four (64) fluid ounces or more of fresh or fresh frozen shellfish with the following:
(a) The words "DATE SHUCKED" followed by the date shucked located on both the lid and sidewall or bottom of the container; [K]
(b) The date shall consist of either the abbreviation for the month and number of the day of the month or in Julian format (YDDD), the last digit of the four digit year and the three digit number corresponding the day of the year; [K] and
(c) For fresh frozen shellfish, the year shall be added to the date (for non-Julian format). [K]
(8) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen. [O]
(9) If the dealer freezes fresh shucked shellfish, the dealer shall label all frozen shellfish as frozen in type of equal prominence immediately adjacent to the type of the shellfish and the year shall be added to the date (for non-Julian format). [O]
(10) If the dealer uses lot codes to track shellfish containers, the lot codes shall be distinct and set apart from any date listed on the container. [O]
(11) The dealer shall assure that each package of fresh or frozen shucked shellfish shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all packages: “Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.” [K]

B. Shucked Shellfish. If the dealer elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with Section .06 except that the original date of shucking shall be added to the new repacked container as specified in Section A. (7) or the original date of shucking shall be used in establishing the SELL BY DATE as specified in Section A. (6). [K]

.07 In-Shell Product or Post-Harvest Processed In-Shell Labeling

A. The dealer shall tag or label all in-shell product with tags meeting the

requirements of Chapter X. 05 B. (1). [S^K/O]

B. In-Shell Product Tags or Labels.

(1) The dealer tag or label on in-shell product shall contain the following indelible, legible information in the order specified below: [K]

(a) The dealer's name and address;

(b) The dealer's certification number as assigned by the Authority;

(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;

(d) A “SELL BY DATE” which is a reasonable subsequent shelf-life or the words “BEST IF USED BY” followed by a date when the product would be expected to reach the end of its shelf-life. The date shall include, month, day and year;

(e) If depurated, the depuration cycle number or lot number;

(f) The most precise identification of the harvest location as is practicable including the initials of the State of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g., Long Bay, Decadent County, lease number, bed, or lot number).

(g) The type and quantity of in-shell product; and

(h) The following statement in bold capitalized type on each tag or label: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS." “RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____.” OR “THIS LABEL IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RELABELED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS.” “RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____.”

(i) All in-shell product intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all shellstock: "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(j) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag or label.

(~~k~~2) At a minimum the dealer shall tag or label each individual container in a legible and indelible form in accordance with CFR 21, Part 101; Part 161. Subpart B (161.130 and 161.136) and the Federal Fair Packaging and Labeling Act. [K]

(~~ii~~3) Country of origin information (USDA 2004) may be included on the shucker-packer or reshipper tag or label.

(~~i~~C) If the in-shell product is removed from the original container, the tag or label on the new container shall meet the requirements in Section .07.B.

(~~iii~~D) When in-shell product intended for retail sale are packed in containers of five (5) pounds or less and shipped in a master container which includes a tag in compliance with Chapter X. .05 B. (1), the individual containers of five (5) pounds or less shall not require tags as specified in Chapter X. .05. .B. (1) but may be labeled in some other manner with indelible, legible, information which at a minimum is adequate to trace the in-shell shellfish back to the lot of in-shell product it is part of. Consumer advisory information identified in Chapter X. .07

B. (1) (i) shall be included on each retail package.
~~NOTE: The Consumer Advisory shall be required for both A. and B.~~

.08 Shipping Documents and Records
A. Shipping Documents.
(1) Each shellfish shipment shall be accompanied by a shipping document. [K]
(2) The shipping document shall contain:
(a) The name, address, and certification number of the shipping dealer; [K]
(b) The name and address of the major consignee; [K] and
(c) The kind and quantity of the shellfish product. [K]
(3) The receiving dealer shall:
(a) Maintain in his files a copy of the completed shipping document; [K] and
(b) Make the shipping document available to the Authority upon request. [K]
(4) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace his portion back to the original shipment. [K]
B. Transaction and Shipping Records.
(1) Each dealer shall have a business address at which transaction records are maintained. [K]
(2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:
(a) Document that the shellfish are from a source authorized under this Ordinance; [K]
(b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken; [K]
(c) Permit a lot (or commingled lots as per Chapter I. @.01 G.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters. [K]
(d) Trace the wet storage history of the shellstock including, original harvest site, original harvest date, wet storage site(s) and dates. [K]
(3) Purchase and sales shall be ~~recorded~~:
(a) Recorded ~~I~~in a permanently bound ledger book~~;~~ or
~~(b) U~~using other recording methods acceptable to and authorized by the Authority. [K]
~~(b) Entries of purchases or sales of shellfish shall be made~~Recorded into a permanently bound ledger book, computer record, or other method acceptable to and authorized by the Authority within seventy-two (72) hours of any purchase or sales. [K]
(4) The transaction records shall be retained:
(a) In the case of fresh shellfish, for a minimum of one (1) year; [K] and
(b) In the case of frozen shellfish, for at least two (2) years or the shelf life of the product, whichever is longer. [K]
(5) If computer records are maintained, the Authority shall approve the format and its use. [K]
.09 Shellfish Harvested from Federal Waters
A. The dealer shall:
(1) If receiving shellstock harvested from Federal waters in the controlled access status, be party to agreement or memoranda of understanding between the Authority, NOAA and the individual harvesters as necessary to comply with the biotoxin controls outlined in the NSSP Chapter IV. @.04

	B. and in accordance with Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans. [C]
12. Public Health Significance	Unlike the other requirements for dealers in Chapters XI through XV, Chapter IX (Transportation) and Chapter X (General Requirements for Dealers) contain no criticality codes. The requirements in this section need to be assigned criticality codes so that states apply these requirements consistently. Currently there are criticality codes pre-filled in on the inspection form, but they aren't accurate – for example, the Transportation chapter has a pre-filled in criticality code of K, but contains requirements that should be $S^{C/K}$, K, and O. In assigning criticality codes to these chapters, where possible we duplicated the criticality codes for the equivalent requirements in other parts of the Model Ordinance or from the inspection form (for items #2 and #4). Where there were no equivalents in other chapters or criticality codes already provided on the inspection form we assigned criticality codes based on the definitions of criticality codes in the Model Ordinance.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	The NSSP Standardized Shellfish Processing Plant Inspection Form would have to be updated to remove the pre-filled criticality codes from numbers 16, 25, 26, and 27. These pre-filled criticality codes were never accurate given the range of requirements (from a simple recordkeeping error all the way up to shellfish contamination), as based on the criticalities for corresponding requirements in the Model Ordinance.

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Remove the "Note" saying that the NMFS sequential tags supersede the tagging requirements in Section .05
10. Specific NSSP Guide Reference	Section II. Model Ordinance (MO), Chapter X. .05
11. Text of Proposal/ Requested Action	NSSP MO Chapter X. .05 Shellstock Identification **.05 Shellstock Identification** ~~*[Note: All Federally allocated shellfish (surf and quahog) caught in Federally regulated waters must follow the National Marine Fisheries Service tagging protocol. These Federal sequential tags will supersede the tagging requirements in Section 05.]*~~ A. General. (1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is:…
12. Public Health Significance	Currently, there is a "Note" in Section II, Chapter X. .05, that states, "[*Note: All Federally allocated shellfish (surf and quahog) caught in Federally regulated waters must follow the National Marine Fisheries Service tagging protocol. These Federal sequential tags will supersede the tagging requirements in* Section 05.]." This "Note" is not relevant anymore and should be removed. All shellfish harvesters in federal waters are now required to obtain a NOAA SIP contract and use the unique NOAA SIP contract number on harvester tags while landing shellstock harvested from federal waters at a state certified shellfish dealer. As a result, the "Note" language should be removed. Per the NMFS fisheries permit, for federally managed shellfish species, the federal waters shellfish harvester will still be required to follow the NMFS tagging protocol. Per the NSSP, the federal waters shellfish harvester will also be required to follow the tagging requirements in Chapter VIII. .02 F. and if harvesting from a controlled access status area, follow the requirements for the use of restricted shellstock tags per Section II, Chapter IV.@.04 C.(7).
13. Cost Information	No change in cost.

14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Employee Training Requirement Relocation
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter X. General Requirements for Dealers, .04 Certification Requirements, A.(2)(c) 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; .03 Other Model Ordinance Requirements, H. Supervision
11. Text of Proposal/ Requested Action	Chapter X. General Requirements for Dealers .04 Certification Requirements A. General. (1) No person shall act as a dealer prior to obtaining certification. (2) Any person who wants to be a dealer shall: (a) Make application to the Authority for certification; (b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the Federal Register of December 18, 1995, except for the requirement for harvester identification on a dealer's tag. ~~(c) Ensure that all individuals who manufacture, process, pack, or hold food obtain training in accordance with 21 CFR 117.4. A dealer shall be allowed thirty (30) days following initial hiring of a new employee to provide the required education.~~ ~~(i) Proof of training for all employees shall be presented to the Authority prior to certification, recertification, or licensing.~~ ~~(ii) The dealer shall maintain the record of the completed training.~~ Chapter XI. Shucking and Packing H. Supervision (4) The dealer shall require: (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. [K] (b) Supervisors to assure that proper sanitary practices are implemented, including: (i) Plant and equipment clean-up; [K] (ii) Rapid product handling; and [K] (iii) Shellfish protection from contamination. [K] (c) Supervisors to not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K] (d) All employees who manufacture, process, pack, or hold food to ~~be~~obtain train~~ed~~ing in proper food handling and personal hygiene practices, in accordance with 21 CFR 117.4. [K] (i) A dealer shall be allowed thirty (30) days following initial hiring of a new employee to provide the required education. (ii) The dealer shall maintain the record of the completed training.

Chapter XII. Repacking of Shucked Shellfish

Chapter XIII. Shellstock Shipping
H. Supervision
(4) The dealer shall require:
(a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. [K]
(b) Supervisors to assure that proper sanitary practices are implemented, including:
(i) Plant and equipment clean-up; [K]
(ii) Rapid product handling; and [K]
(iii) Shellfish protection from contamination. [K]
(c) Supervisors to not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
(d) All employees who manufacture, process, pack, or hold food to ~~be~~obtain train~~ed~~ing in proper food handling and personal hygiene practices, in accordance with 21 CFR 117.4. [K]
(i) A dealer shall be allowed thirty (30) days following initial hiring of a new employee to provide the required education.
(ii) The dealer shall maintain the record of the completed training.

Chapter XIV. Reshipping
H. Supervision
(4) The dealer shall require:
(a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. [K]
(b) Supervisors to assure that proper sanitary practices are implemented, including:
(i) Plant and equipment clean-up; [K]
(ii) Rapid product handling; and [K]
(iii) Shellfish protection from contamination. [K]
(c) Supervisors to not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
(d) All employees who manufacture, process, pack, or hold food to ~~be~~obtain train~~ed~~ing in proper food handling and personal hygiene practices, in accordance with 21 CFR 117.4. [K]
(i) A dealer shall be allowed thirty (30) days following initial hiring of a new employee to provide the required education.
(ii) The dealer shall maintain the record of the completed training.

Chapter XV. Depuration
H. Supervision
(4) The dealer shall require:
(a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. [K]
(b) Supervisors to assure that proper sanitary practices are implemented, including:
(i) Plant and equipment clean-up; [K]
(ii) Rapid product handling; and [K]
(iii) Shellfish protection from contamination. [K]
(c) Supervisors to not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
(d) All employees who manufacture, process, pack, or hold food to ~~be~~obtain train~~ed~~ing in proper food handling and personal hygiene practices, in accordance with 21 CFR 117.4. [K]
(i) A dealer shall be allowed thirty (30) days following initial hiring of a new employee to provide the required education.
(ii) The dealer shall maintain the record of the completed training.

12. Public Health Significance	This proposal moves the existing requirement for employee training. When requirements for employee training were added to the Model Ordinance in 2017, they were added to the incorrect location, probably mistakenly. As a result of the misplacement, the record of the employee training can be checked only during certification inspections, resulting in the possible scenario an employee hired shortly after a recertification inspection then the training record for that employee not being able to be inspected for up to 11 months before the next certification inspection. By moving the existing requirement for employee training to the correct location, the record of employee training can be checked during all inspections, as was presumably intended when the requirement was originally added to the Model Ordinance.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
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5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Corrective Actions
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter X. General Requirements for Dealers, .04 Certification Requirements, A.(2)(c); 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, .03 Other Model Ordinance Requirements, H. Supervision
11. Text of Proposal/ Requested Action	Chapter X. General Requirements for Dealers .01 General HACCP Requirements C. Contents of the HACCP Plan. The HACCP plan shall, at a minimum: (5) Include ~~any~~ corrective action plans that have been developed in accordance with Section .01 F. (2), to be followed in response to deviations from critical limits at critical control points. F. Corrective Actions. (1) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by: (a) Following a corrective action plan that is appropriate for the particular deviation, or (b) Following the procedures in Section .01 F. (3). (2) Dealers ~~may~~ shall develop written corrective action plans, which become part of their HACCP plans in accordance with Section .01 C. (5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that: (a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and (b) The cause of the deviation is corrected. ~~(3) When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall:~~ ~~(a) Segregate and hold the affected product until:~~ ~~(i) There is a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Section .01 I.; and~~ ~~(ii) Corrective action is taken when necessary, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.~~ ~~(b) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Section .01 I., to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.~~ (43) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Section .01 G. and the record keeping requirements of Section .01 H.

12. Public Health Significance	A deviation from a HACCP plan critical limit represents a critical situation wherein shellfish product presents a threat to the health of the consumer. Currently, it is optional for dealers to include corrective action plans that identify the proper response taken in response to these critical situations. It is necessary for dealers to have pre-existing corrective action plans (which are typically as brief and simple as one or two sentences included in the corrective actions column of the HACCP plan) so that they are prepared to appropriately handle these critical situations in order to ensure that no injurious product reaches the consumer. It is better for dealers to have determined how to respond to critical limit deviations before they occur, than for dealers to have to segregate and hold product until the proper action is determined. It is reasonable and necessary for dealers to determine the proper corrective action (usually one-two sentences describing the disposition of the effected product) to take in response to the exceedance of each critical limit before it occurs, so that they have a basic plan to follow, rather than having to figure it out in the moment.
13. Cost Information	Minimal – the majority of dealers already include corrective action plans in their HACCP plans, and for the minority of dealers who do not, development of corrective action plans should not require much cost.
14. Changes Needed to Guidance (if proposed change is adopted)	The NSSP Standardized Shellfish Processing Plant Inspection Form would have to be updated to remove the words “if identified” from #2(h).

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
3. Affiliation	U.S. Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Receiving critical limit for federal waters
10. Specific NSSP Guide Reference	NSSP Model Ordinance, Section II, Chapter X. General Requirements for Dealer, Chapter XI. Shucking and Packing, .01 Critical Control Points, A. (1) and Chapter XIII. Shellstock Shipping, .01 Critical Control Points, A. (1)
11. Text of Proposal/ Requested Action	Chapter X. .06 Shucked Shellfish Labeling A. Shellfish Labeling. (1) The dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers. (2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing: (a) The original shucker-packer's name and certification number; (b) The shucking date; and (c) The quantity of shellfish per container and the total number of containers. (d) All restricted shucked shellfish shall include a label containing all information required in Section .06 of Model Ordinance Chapter X. In addition, the label will include specific language detailing the restrictions requiring further processing or testing prior to distribution. Chapter XI. .01 Critical Control Points A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; or[C] (b) Harvested restricted shellstock and properly tagged with information describing the restriction; [C] (c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C] (d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].

	(e) Harvested the shellstock from federal waters in compliance with a NOAA SIP contract, and if applicable, a state issued license, and are listed on the NOAA SIP Contract Harvester List. [**C**] B. – E. F. Receiving restricted shellfish shucked from shellstock harvested from federal waters is labeled in compliance with X. .06 and not released for sale or shipment prior to testing results required under the NOAA SIP contract. [C] Chapter XIII A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall ship or repack only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]** (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and **[C]** (c) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) **[C]**. (d) Harvested the shellstock from federal waters in compliance with a NOAA SIP contract, and if applicable, a state issued license, and are listed on the NOAA SIP Contract Harvester List. [**C**]
12. Public Health Significance	Dealers receiving shellstock from harvesters that harvest in federal waters must have a critical limit in their HACCP plan at the receiving critical control point. Dealers must obtain shellstock from federal waters from harvesters with a NOAA contract and if applicable, a state issued license. Currently, there is no requirement for restricted shucked shellfish labeling in Chapter X. .06. For example, shellfish that has been shucked and shipped for further processing that was harvested in areas designated in the controlled access status in federal waters. There is only a requirement in Chapter X. .05 for shellstock with restricted tags. There are known instances of federal waters restricted shucked shellfish being shipped that have not met all conditions of harvest restrictions prior to being placed in distribution per Chapter IV. @.04 B. (2)(h) Dealers receiving shucked shellfish from shellstock harvested in federal waters must have a critical limit in their HACCP plan. If receiving federal waters shucked shellfish prior to testing and release for distribution must hold product until testing and release under the NOAA SIP contract as having met all conditions of release.
13. Cost Information	Minimal cost for implementing an additional critical limit.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell; Sarah Good
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4. Address Line 1	285 Beiser Boulevard; 109 Governor Street
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6. City, State, Zip	Dover, DE 19904; Richmond, VA 23219
7. Phone	302-608-5511; 804-659-3823
8. Email	andrew.bell@delaware.gov; sarah.good@vdh.virginia.gov
9. Proposal Subject	Temperature Measuring Device Requirement Relocation
10. 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
11. Text of Proposal/ Requested Action	Chapter XI. Shucking and Packing .02 Sanitation B. Condition and Cleanliness of Food Contact Surfaces. ~~(e) The dealer shall provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures. [K]~~ Chapter XII. Repacking .02 Sanitation B. Condition and Cleanliness of Food Contact Surfaces. ~~(e) The dealer shall provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures. [K]~~ Chapter XI. Shucking and Packing .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling. (12) Provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures. [K] Chapter XII. Repacking .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling. (h) Provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures. [K] Chapter XIII. Shellstock Shipping .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling. (7) The dealer shall provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures. [K] Chapter XIV. Reshipping .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling.

	(4) The dealer shall provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures. [K] Chapter XV. Depuration .03 Other Model Ordinance Requirements F. Shellstock Storage and Handling. (13) The dealer shall provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures. [K]
12. Public Health Significance	It is a current requirement for shucker packers and repackers to have a temperature measuring device (such as a basic thermometer) for use in monitoring product temperatures. Oddly, this requirement is currently placed in the Condition and Cleanliness of Food Contact Surfaces section and should be moved to the Shellfish Storage and Handling section, where it belongs. It should also appear in the other three dealer chapters, as all types of dealers should have a thermometer.
13. Cost Information	Less than $20 for a thermometer, although almost all dealers will already have a thermometer.
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
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5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Commingling Prevention Requirement Criticality Code
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. .03 F.(10); Chapter XII. .03 F.(1)(a) Chapter XIII. .03 F.(7); Chapter XIV. .03 F.(1)(a); and Chapter XV. .03 F.(9)
11. Text of Proposal/ Requested Action	Chapter XI. .03 F. Shellfish Storage and Handling. … (10) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan. ~~[K]~~ [S^C/K] Chapter XII. .03 F. Shellfish Storage and Handling. (1) The dealer shall: (a) Not commingle shellfish from different lots; ~~[K]~~ [S^C/K] Chapter XIII .03 F. Shellfish Storage and Handling. (1) The dealer shall assure that shellstock is: (a) Alive; **[K** (b) Reasonably free of sediment **[O]**; and (c) Culled. **[K]** … … (7) The dealer shall not commingle shellstock unless the dealer is included in the authority's commingling plan [S^C/K] Chapter XIV. .03 F. (1) The dealer shall not: (a) Commingle, sort, or repack shellfish; or ~~[K]~~ [S^C/K] Chapter XV. .03 F. … (9) Assure that different harvest lots of shellfish are not commingled during washing, culling, processing, or packing. If more than one (1) harvest lot of shellfish is being processed at the same time, the identity of each harvest lot is maintained throughout the stages of depuration. ~~[K]~~ [S^C/K]
12. Public Health Significance	Currently, Chapter XIII. (Shellstock Shipping) is the only dealer chapter that

	does not include a requirement for the dealer not to commingle shellstock under section .03 F. Shellfish Storage and Handling. Since commingling could occur during shellstock shipping, it is important that the requirements for commingling be included in Chapter XIII. for consistency with the other chapters of the model ordinance This proposal is to change the criticality code from a key, **[K]**, to a swing, **[S$^{C/K}$],** for commingling violations in all the dealer chapters to allow the authority the option to cite the violation as a critical, **[C]**, in cases where the authority determines illegal commingling could present a threat to the consumer There have been cases where shellstock and shellfish from multiple harvest areas were commingled during processing without an authority approved commingling plan. This could lead to problems with traceback and identifying the original harvest area(s) and date(s) in the event of an illness outbreak or other public health reason. Commingling outside of an authority approved commingling plan has occurred with shellfish received from other states. If shellfish from multiple harvest areas, including areas located in different states, are illegally commingled it would impede the outbreak investigation and the closure of harvest areas and recalls, if needed. This could lead to additional illnesses and is a significant concern in the protection of public health. In cases where the authority determines that illegal commingling does not present a potential threat to the consumer, such as cases of commingled shellfish from the same harvest area but different harvest dates for which a recall time period could be expanded or cases in which the authority would consider allowing the harvest areas in question to be added to a commingling plan (e.g., due to their proximity), this could still be cited as a key, **[K]**, deficiency.
13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
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8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Exclusion of Pests
10. 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, .02 Sanitation, H. Exclusion of Pests
11. Text of Proposal/ Requested Action	Chapter XI. Shucking and Packing H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [~~K~~S$^{C/K}$] Chapter XII, Repacking of Shucked Shellfish H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [~~K~~S$^{C/K}$] Chapter XIII. Shellstock Shipping H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [~~K~~S$^{C/K}$] Chapter XIV. Reshipping H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [~~K~~S$^{C/K}$] Chapter XV. Depuration H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [~~K~~S$^{C/K}$]
12. Public Health Significance	Pest presence in a dealer facility is currently a Key deficiency but is more appropriately a Swing (Critical or Key) deficiency. Depending on severity and circumstances, pest presence ranges from meeting the definition of a Critical deficiency (defined as a condition which results in the production of a product that is unwholesome or presents a threat to the health or safety of the consumer) to meeting the definition of a Key deficiency (defined as a condition which may result in unwholesome product), therefore this item is more appropriately a Swing deficiency. The public health risk inherent in a pest problem matches the definition for a Swing deficiency of "depending upon the severity and circumstances".

	Whether the inspector assigns it as Critical or Key would be accomplished through the same means for all Swing deficiencies, by determining whether the pest problem meets the definition of a Critical deficiency or meets the definition of a Key deficiency, depending on the severity and circumstances. For example, the inspector would likely determine that ants or a moderate number of flies would be a Key, whereas an infestation of cockroaches or mice would likely be a Critical since it represents an imminent health hazard.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
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8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Directly Plumbed Handwash Sinks
10. Specific NSSP Guide Reference	Section I. Purposes & Definitions, Definitions 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; .02 Sanitation, D. Maintenance of Hand Washing and Toilet Facilities
11. Text of Proposal/ Requested Action	Section I. Purposes and Definitions, Definitions **(3) Air Gap** means the unobstructed vertical distance (at least twice the diameter of the largest supplying pipe) through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a sink, tank, plumbing fixture, drain or other device and the flood level rim of that receptacle. Chapter XI. Shucking and Packing D. Maintenance of Hand Washing and Toilet Facilities. (1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [SK/0] (~~2~~a) Hand washing facilities shall be provided which are: (~~a~~i) Convenient to work areas; [O] (~~b~~ii) Separate from the three (3) compartment sinks used for cleaning equipment and utensils; [K] (~~c~~iii) Directly plumbed to an approved sewage disposal system or drained after an air gap directly into the floor drain of an approved sewage disposal system; and[SO/K] (~~d~~iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K] (~~3~~b) The dealer shall provide at least one (1) hand sink in the packing room. [O] (~~4~~c) The dealer shall provide at each hand washing facility: (~~a~~i) Supply of hand cleansing soap or detergent; [K] (~~b~~ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O] (~~c~~iii) Easily cleanable waste receptacle; and [O] (~~d~~iv) Hand washing signs in a language understood by the employees; [O] (~~5~~2) Sewage [C] and liquid disposable wastes shall be properly removed from the facility [K] (~~6~~3) The dealer shall provide: (a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; [K] (b) An adequate number of conveniently located, toilets; and [K]

(c) Each toilet facility with an adequate supply of toilet paper. [K]

Chapter XII. Repacking
D. Maintenance of Hand Washing and Toilet Facilities.
(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [SK/O]
(a) Hand washing facilities shall be provided which are:
(i) Convenient to work areas; [O]
(ii) Separate from the three (3) compartment sinks used for cleaning equipment and utensils; [K]
(iii) Directly plumbed to an approved sewage disposal system or drained after an air gap directly into the floor drain of an approved sewage disposal system; and[SK/O]
(iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]

Chapter XIII. Shellstock Shipping
D. Maintenance of Hand Washing and Toilet Facilities.
(1) Handwashing facilities with warm water at a minimum temperature of 100 °F (37.8 °C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [SK/O]
(a) Handwashing facilities shall be provided which are:
(i) Convenient to work areas; [O]
(ii) Separate from the three (3) compartment sinks used for cleaning equipment and utensils; [K]
(iii) Directly plumbed to an approved sewage disposal system or drained after an air gap directly into the floor drain of an approved sewage disposal system; and [SO/K]
(iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use. [K]

Chapter XIV. Reshipping
D. Maintenance of Hand Washing and Toilet Facilities.
(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [SK/O]
(a) Hand washing facilities shall be provided which are:
(i) Convenient to work areas; [O]
(ii) Separate from the three (3) compartment sinks used for cleaning equipment and utensils; [K]
(iii) Directly plumbed to an approved sewage disposal system or drained after an air gap directly into the floor drain of an approved sewage disposal system; and [SK/O]
(iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use. [K]

Chapter XV. Depuration
D. Maintenance of Hand Washing and Toilet Facilities
(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8°C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [SK/O]
(~~2~~a) Hand washing facilities shall be provided which are:
(~~a~~i) Convenient to work areas; [O]

	(~~b~~ii) Separate from the three (3) compartment sinks used for cleaning equipment and utensils; [K] (~~c~~iii) Directly plumbed to an approved sewage disposal system or drained after an air gap directly into the floor drain of an approved sewage disposal system; and [SK/O] (~~d~~iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use. [K] (~~3~~b) The dealer shall provide at each hand washing facility: (~~a~~i) Supply of hand cleansing soap or detergent; [K] (~~b~~ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O] (~~c~~iii) Easily cleanable waste receptacle; and [O] (~~d~~iv) Hand washing signs in a language understood by the employees. [O] (~~4~~2) Sewage [C] and liquid disposable wastes [K] shall be properly removed from the facility. (~~5~~3) The dealer shall provide: (a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; [K] (b) An adequate number of conveniently located toilets; and [K] (c) Each toilet facility with an adequate supply of toilet paper. [K]
12. Public Health Significance	The current requirement that handwashing sinks be directly plumbed into a sewage disposal system is not necessary and currently is not enforced by many states because it is not consistent with standard plumbing practices, which often use an air gap between the sink drain and a floor drain to prevent backflow into the sink. As long as the handwashing sink is drained directly into the floor drain, an air gap between the sink drain and the floor drain is an accepted sanitary practice. This proposal will make this part of the Model Ordinance consistent with plumbing methods already being practiced at dealer facilities in many states. This proposal also takes the opportunity to standardize the formatting of these requirements across the dealer chapters, because currently there are two different ways these requirements are formatted across those five chapters.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
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6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Complete Dealer Chapters
10. 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
11. 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 ~~shuck and pack~~receive only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; or[C] (b) Harvested restricted shellstock ~~and~~ which is properly tagged with information describing the restriction; and [C] (c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C] (d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C]. (2) The dealer shall ~~shuck and pack~~ receive only shell~~stock~~fish obtained ~~and transported~~ from a dealer who has: (a) Identified the shellstock with a tag on each container, or a bulk tag on each lot, as outlined in Chapter X. .05 ~~or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8)~~, identified the in shell product with a tag or label 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 a shipping document~~ation~~ as required in Chapter IX. .05; and [C] (c) Adequately iced the shellstock~~;~~ or ~~[C]~~ ~~(d) C~~cooled the shellstock to an internal temperature of 50 °F (10 °C) or less~~.~~; and [C] (d) Supplied the shucked shellfish adequately iced or in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature; and [C] (e) Supplied the in-shell product adequately iced or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature or cooled the in-shell product to an internal

temperature of 45 °F (7.2 °C) or less. [C]

(3) A dealer may receive shellstock from a dealer who has ~~elected to ship~~supplied ~~shellstock in accordance with Chapter XIII. .01 D. (2)~~ restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and supplyed prior to achieving the internal temperature of 50 °F (10 °C without the shellstock meeting the receiving requirements of Chapter XI. .01 A. (2) (c) ~~or (d)~~. Where the transportation time is greater than four (4) hours, ~~T~~the ~~product~~ shellstock ~~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 XI. .01 A. (2) (c) or (d). Shipments of four (4) hours or less must have documentation as required in Chapter IX..05 A.~~ [C]

~~(4) The dealer shall shuck and pack only in-shell product obtained from a dealer who has:~~

~~(a) Shipped the in-shell product adequately iced; or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature; or 45 °F (7.2 °C) internal temperature or less; and [C]~~

~~(b) Identified the in-shell product with a tag on each container. [C]~~

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter VII. .04; and [C]

(2) Once placed under temperature control and until shucked or until sale to the processor or final consumer, the shellstock shall;

(a) Be iced; or [C]

(b) Be placed and stored in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less; and [C]

(c) Not be permitted to remain without ice~~,~~ or mechanical refrigeration ~~or other approved methods of storage, as required in Section .01 B. (1) or Section .01 B. (2) (a) or (b)~~ for more than two (2) hours at points of processing or transfer such as loading docks. [C]

(3) All oysters harvested under State Vibrio Control Plans other than those labeled for a restricted use shall meet the following temperature requirements:

(a) Cooled to an internal temperature of 55 °F (12.7 °C) within the time periods outlined in the State V.v. Control Plans. [C]

(b) Cooled to an internal temperature of 50 °F (10 °C) within the time periods outlined in the State V.p. Control Plans. Shellstock cooled to an internal temperature of 55 °F (12.7 °C) to comply with a V.v. Control Plan is considered in compliance with this requirement. [C]

(4) All other shellstock obtained from a licensed harvester or received prior to reaching an internal temperature of 50 °F (10 °C) shall be placed in a conveyance pre chilled or a storage area maintained to 45 °F (7.2 °C) or less and cooled to an internal temperature of 50 °F (10 °C)

prior to shipment, unless shipped in accordance with Chapter XI. .01 F. (2). [C]

(5) 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 requirement listed above in .01 B. (4) above. [C]

C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall ~~be~~:

(1) Be ~~I~~iced; or [C]

(2) Be ~~P~~placed ~~and stored~~ in a storage area or conveyance maintained at an ambient air temperature of 45 °F (7.2 °C) or less. [C]

D. Shucked Meat Storage Critical Control Point - Critical Limits. The dealer shall ensure that shucked shellfish shall:

(1) Be iced; or [C]

(2) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less. [C]

~~D~~E. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) For shellstock which has not been refrigerated prior to processing:

(a) Shucked meats are chilled to an internal temperature of 45 °F (7.2 °C) or less within three (3) hours of shucking. [C]

(b) In-shell product is chilled to an internal temperature of 45 °F (7.2 °C) or less within three (3) hours of processing. [C]

(2) For shellstock refrigerated prior to processing:

(a) Shucked meats are chilled to an internal temperature of 45 °F (7.2 °C) or less within four (4) hours of removal from refrigeration. [C]

(b) In-shell product is chilled to an internal temperature of 45 °F (7.2 °C) or less within four (4) hours of removal from refrigeration. [C]

(3) If heat shock is used~~.~~:

(a) ~~o~~Once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45 °F (7.2 °C) or less within two (2) hours after the heat shock process~~.~~; and [C]

(~~4~~b) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45 °F (7.2 °C) within two (2) hours from time of heat shock. [C]

(5) For in-shell product the internal temperature of meats does not exceed 45 °F (7.2 °C) for more than two (2) hours during processing. [C]

(6) Repacked shucked shellfish do not exceed an internal temperature of 45 °F (7.2 °C) for more than two (2) hours. [C]

(7) For shellstock received bearing a restricted use tag, the dealer shall ensure that:

(a) The shellstock is processed consistent with the stated purpose on the tag; or [C]

(b) The shellstock is supplied to a certified dealer bearing a tag containing specific language detailing the intended use of the shellstock and that the shipment is accompanied by a transaction record indicating the quantity of restricted use shellstock containers. [C]

~~E. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall~~

~~store shucked and packed shellfish in covered containers at an ambient temperature of 45 °F (7.2 °C) or less or covered with ice. [C]~~

F. Shipping Critical Control Point – Critical Limits. The dealer shall ensure that:

(1) Shellstock that is received bearing a restricted shellstock tag shall only be supplied 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) For restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and shipped prior to achieving the internal temperature of 50 °F (10 °C), if the transportation time is greater than four (4) hours, the shipment shall be accompanied with a time/temperature recording device. [C]

G. Other Critical Limits. The dealer shall ensure that shellfish comply with all other critical limits identified in the dealer's HACCP plan.

.02 Sanitation

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) The dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guide~~lines~~*. [K]

(2) Cleaning and sanitizing of food contact surfaces.

(e) If used, the finger cots or gloves shall be:

(i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; [O]

(ii) Sanitized at least twice daily; [K]

(iii) Cleaned more often, if necessary; [K]

(~~iii~~iv) Properly stored until used; and [K]

(~~iv~~v) Maintained in a clean, intact, and sanitary condition. [K]

C. Prevention of Cross Contamination.

(3) Employee practices.

(d) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

~~a.~~(i) Store clothing or other personal belongings; [O]

~~b.~~(ii) Eat or drink; [K]

~~c.~~(iii) Spit; and [K]

~~d.~~(iv) Use tobacco in any form. [K]

F. Proper Labeling, Storage and Use of Toxic Compounds.

(2) Use and labeling of toxic compounds.

(d) The dealer shall ~~P~~provide a test kit, strips or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. [K]

.03 Other Model Ordinance Requirements

E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces.

(4) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and non-food contact surfaces. [K]

F. Shellfish Storage and Handling

The dealer shall:

(10) Not commingle lots of shellstock, lots of in-shell product, or lots of

shucked shellfish ~~during shucking~~ unless the dealer is included in the Authority's commingling plan. [K]

(11) Ensure that during storage frozen shellfish shall be maintained frozen. [SK/0]

Chapter XII. Repacking of Shucked Shellfish

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall receive only shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; or[C]

(b) Harvested restricted shellstock which is properly tagged with information describing the restriction; and [C]

(c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C]

(d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].

(2) The dealer shall ~~repack~~receive only shellfish ~~which originated~~obtained ~~-~~from a dealer who has:

(a) Identified the shellstock with a tag on each container, or a bulk tag on each lot, as outlined in Chapter X. .05, identified the in shell product with a tag or label 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 a shipping document as required in Chapter IX. .05; and [C]

(c) Adequately iced the shellstock or cooled the shellstock to an internal temperature of 50 °F (10 °C) or less; and [C]

(e) Supplied the shucked shellfish adequately iced or in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature; and [C]

(e) Supplied the in-shell product adequately iced or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature or cooled the in-shell product to an internal temperature of 45 °F (7.2 °C) or less. [C]

~~(1) Shipped the shellfish iced, or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature; [C] and~~

~~(2) Identified the shellfish with a label as outlined in Chapter X. .06. [C]~~

(3) A dealer may receive shellstock from a dealer who has elected to supply restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and supplied prior to achieving the internal temperature of 50 °F (10 °C) without the shellstock meeting the receiving requirements of Chapter XII. .01 A. (2) (c). Where the transportation time is greater than four (4) hours, the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. [C]

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter VII. .04; and [C]
(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall:
(a) Be iced; or [C]
(b) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less; and [C]
(c) Not be permitted to remain without ice or mechanical refrigeration for more than two (2) hours at points of processing or transfer such as loading docks. [C]
(3) All oysters harvested under State Vibrio Control Plans other than those labeled for a restricted use shall meet the following temperature requirements:
(a) Cooled to an internal temperature of 55 °F (12.7 °C) within the time periods outlined in the State V.v. Control Plans. [C]
(b) Cooled to an internal temperature of 50 °F (10 °C) within the time periods outlined in the State V.p. Control Plans. Shellstock cooled to an internal temperature of 55 °F (12.7 °C) to comply with a V.v. Control Plan is considered in compliance with this requirement. [C]
(4) All other shellstock obtained from a licensed harvester or received prior to reaching an internal temperature of 50 °F (10 °C) shall be placed in a conveyance pre chilled or a storage area maintained to 45 °F (7.2 °C) or less and cooled to an internal temperature of 50 °F (10 °C) prior to shipment, unless shipped in accordance with Chapter XII. .01 F. (2). [C]
(5) 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 requirement listed above in .01 B. (4) above. [C]

C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall:
(1) Be iced; or [C]
(2) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less. [C]

D. Shucked Meat Storage Critical Control Point - Critical Limits. The dealer shall ensure that shucked shellfish shall:
(1) Be iced; or [C]
(2) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less. [C]

~~B~~E. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shucked shellfish do not exceed an internal temperature of 45 °F (7.2 °C) for more than two (2) hours. [C]

~~C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45 °F (7.2 °C) or less or covered with ice. [C]~~

F. Shipping Critical Control Point – Critical Limits. The dealer shall ensure that:
(1) For shellstock received bearing a restricted use tag, the dealer shall ensure that the shellstock is supplied to a certified dealer bearing a tag containing specific language detailing the intended use of the shellstock and that the shipment is accompanied by a transaction record indicating the quantity of restricted use shellstock containers. [C]

(2) For restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and shipped prior to achieving the internal temperature of 50 °F (10 °C), if the transportation time is greater than four (4) hours, the shipment shall be accompanied with a time/temperature recording device. [C]

G. Other Critical Limits. The dealer shall ensure that shellfish comply with all other critical limits identified in the dealer's HACCP plan.

.02 Sanitation

A. Safety of Water for Processing and Ice Production.

(3) Shellstock Washing.

(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. [C]

(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:

(i) Obtain approval for the construction or remodeling of the system from the Authority. [K]

(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and [C]

(iii) Test bacteriological water quality daily; [SC/K]

(c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed twenty (20) nephelometric turbidity units (NTUs) measured using the method in the APHA Standard Methods for the Examination of Water and Wastewater. [K]

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XII. .02 B. (1) (a), (b), and (c). [K]

(h) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:

(i) Is easily accessible for cleaning and inspection; [K]

(ii) Is self-draining; and [K]

(iii) Meets the requirements for food contact surfaces. [K]

(2) Cleaning and sanitizing of food contact surfaces.

(b) Shellfish shall be protected from contamination by washing and rinsing repacking containers and sanitizing before each filling. [K]

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [SC/K]

(~~a~~b) ~~Shucked s~~Shellfish shall be protected from

contamination. [SC/K]

(c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. [K]

(~~b~~d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. [SK/O]

(2) Separation of operations.

(a) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers. [K]

(~~2~~3) Employee practices

~~(a) The dealer shall assure that all employees working in direct contact with shellfish processing activities or food contact surfaces maintain a high level of personal hygiene and cleanliness. [K]~~

F. Proper Labeling, Storage and Use of Toxic Compounds.

(2) Use and labeling of toxic compounds.

(d) The dealer shall ~~P~~provide a test kit, strips or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. [K]

.03 Other Model Ordinance Requirements

F. Shellfish Storage and Handling.

(1) The dealer shall:

(a) Assure that shellstock is reasonably free of sediment [O] and culled; [K]

(b) Inspect incoming shipments and shall reject dead or inadequately protected shellstock; [K]

(c) Not allow the use of dip buckets for hand or utensil rinsing; [K]

(a) Not commingle lots of shellstock, lots of in-shell product, or lots of shucked shellfish ~~from different lots~~unless the dealer is included in the Authority's commingling plan; [K]

(b) Repack shucked shellfish meats only into containers labeled with the authorized certification number; [K]

(c) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source; [K]

(d) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161 Section 130; [K]

(e) Thoroughly drain, clean as necessary, and repack shucked shellfish meats promptly; [K]

(f) Conduct repacking activities so as to conform to applicable food additive regulations; and [K]

(g) During storage frozen shellfish shall be maintained frozen. [SK/0] (h) Ensure that all shellstock obtained from a licensed harvester are

(i) Adequately iced within two (2) hours of receipt;

(ii) Placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt; or

(iii) Shucked within two (2) hours of receipt. [SC/K]

(iv) 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. (11).

Chapter XIII. Shellstock Shipping

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall ~~ship or repack~~receive only shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and [C]

(b) Harvested restricted shellstock which is properly tagged with information describing the restriction; and [C]

(~~b~~c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C]

(~~c~~d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].

(2) The dealer shall ~~ship or repack~~ receive only shell~~stock~~fish obtained ~~and transported~~ from a dealer who has:

(a) Identified the shellstock with a tag on each container, or a bulk tag on each lot, as outlined in Chapter X. .05, identified the in shell product with a tag or label 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 a shipping document~~ation~~ as required in Chapter IX. .05; and [C]

(c) Adequately iced the shellstock~~;~~ or ~~[C]~~

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

(d) Supplied the shucked shellfish adequately iced or in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature; and [C]

(e) Supplied the in-shell product adequately iced or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature or cooled the in-shell product to an internal temperature of 45 °F (7.2 °C) or less. [C]

(3) A dealer may receive shellstock from a dealer who has ~~elected to ship~~supplied ~~shellstock in accordance with Chapter XIII. .01 D. (2)~~ restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and supplied prior to achieving the internal temperature of 50 °F (10 °C without the shellstock meeting the receiving requirement of Chapter XIII. .01 A. (2) (c) ~~or (d)~~. Where the transportation time is greater than four (4) hours, ~~T~~the ~~product must be accompanied with documentation as outlined in Chapter IX. .05 A. and B. and~~shellstock 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). Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A.~~ [C]

~~(4) The dealer shall ship or repack only in-shell product obtained from a dealer who has:~~

~~(a) Shipped the in-shell product (i) Adequately iced; or (ii) In a conveyance at or below 45 °F (7.2 °C) ambient air temperature; or (iii) At an internal temperature of 45 °F (7.2 °C) or less; and [C]~~

~~(b) Identified the in-shell product with a tag on each container. [C]~~

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter VII. .04; and [C]

(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall:

(a) Be iced; or [C]

(b) Be placed in a storage area or conveyance maintained at an ambient temperature 45 °F (7.2 °C) or less; and [C]

(c) Not be permitted to remain without ice~~,~~ or mechanical refrigeration ~~or other approved methods of storage, as required in Section .01 B. (1) or Section .01 B. (2) (a) or (b)~~ for more than two (2) hours at points of processing or transfer such as loading docks. [C]

(3) All oysters harvested under State Vibrio Control Plans other than those labeled for a restricted use shall meet the following temperature requirements:

(a) Cooled to an internal temperature of 55 °F (12.7 °C) within the time periods outlined in the State V.v. Control Plans. [C]

(b) Cooled to an internal temperature of 50 °F (10 °C) within the time periods outlined in the State V.p. Control Plans. Shellstock cooled to an internal temperature of 55 °F (12.7 °C) to comply with a V.v. Control Plan is considered in compliance with this requirement. [C]

(4) All other shellstock obtained from a licensed harvester or received prior to reaching an internal temperature of 50 °F (10 °C) shall be placed in a conveyance pre chilled or a storage area maintained to 45 °F (7.2 °C) or less and cooled to an internal temperature of 50 °F (10 °C) prior to shipment, unless shipped in accordance with Chapter XIII. .01 E. (2). [C]

(5) 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 requirement listed above in .01 B. (4) above. [C]

C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall ~~be~~:

(1) Be ~~I~~iced; or [C]

(2) Be ~~P~~placed ~~and stored~~ in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less. [C]

D. Shucked Meat Storage Critical Control Point - Critical Limits. The dealer shall ensure that shucked shellfish shall:

(1) Be iced; or [C]

(2) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less. [C]

~~D~~E. Shellstock Shipping Critical Control Point ~~-~~ Critical Limits. The dealer shall ensure that:~~-~~

(1) ~~Shellstock that is received bearing a restricted shellstock 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]~~ For shellstock received bearing a restricted use tag, the shellstock is supplied to a certified dealer bearing a tag containing specific language detailing the intended use of the shellstock and that the shipment is accompanied by a transaction record indicating 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~~For restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and shipped prior to achieving the internal temperature of 50 °F (10 °C)~~.~~. ~~Should the original dealer choose this option~~ if the transportation time is greater than four (4) hours, 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]

F. Other Critical Limits. The dealer shall ensure that shellfish comply with all other critical limits identified in the dealer's HACCP plan.

.02 Sanitation

A. Safety of Water for Processing and Ice Production.

(3) Shellstock Washing.

(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. [C]

(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:

(i) Obtain approval for the construction or remodeling of the system from the Authority. [K]

(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and [C]

(iii) Test bacteriological water quality daily; [SC/K]

(c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed twenty (20) nephelometric turbidity units (NTUs) measured using the method in the APHA Standard Methods for the Examination of Water and Wastewater. [K]

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XIII. .02 B. (1) (a), (b), and (c). [K]

(3) If used, the finger cots or gloves shall be:

(a) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; [O]

(b) Cleaned ~~more often, if~~as necessary; [K]

(c) Properly stored until used; and [K]

(d) Maintained in a clean, intact, and sanitary condition. [K]

C. Prevention of Cross Contamination

(2) Separation of operations.

(a) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers. [K]

F. Proper Labeling, Storage and Use of Toxic Compounds.

(2) Use and labeling of toxic compounds.

(d) The dealer shall ~~P~~provide a test kit, strips or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. [K]

.03 Other Model Ordinance Requirements

E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces.

(4) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and non-food contact surfaces. [K]

F. Shellfish Storage and Handling.

(1) The dealer shall assure that shellstock is:

~~(a) Alive; [K]~~

(~~b~~a) Reasonably free of sediment [O]; and

(~~c~~b) Culled. [K]

(3) The dealer shall not allow the use of dip buckets for hand or knife rinsing. [K]

(6) The dealer shall not commingle lots of shellstock or lots of in-shell product unless the dealer is included in the Authority's commingling plan

Chapter XIV. Reshipping

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall ~~reship~~ receive only shellfish obtained ~~and transported~~ from a dealer who has:

(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05, identified the in shell product with a tag or label 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 a shipping document~~ation~~ as required in Chapter IX. .05; and [C]

(c) Adequately iced the shellstock~~,~~ or ~~[C]~~

~~(d) C~~cooled the shellstock to an internal temperature of 50 °F

(10 °C) or less~~:~~; ~~or~~ and [C]

(~~e~~d) ~~Shipped~~ Supplied 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~~.~~; and [C]

(e) Supplied the in-shell product adequately iced or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature or cooled the in-shell product to an internal temperature of 45 °F (7.2 °C) or less. [C]

(2) A dealer may receive shellstock from a dealer who has ~~elected to ship~~ supplied ~~shellstock in accordance with Chapter XIII. .01 D. (2)~~ restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and supplied prior to achieving the internal temperature of 50 °F (10 °C) without the shellstock meeting the receiving requirements of Chapter XIV. .01 A. (2) (c) ~~or (d)~~. Where the transportation time is greater than four (4) hours, ~~T~~the ~~product must be accompanied with documentation as outlined in Chapter IX. .05 A. and B. and~~shellstock 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). Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A.~~ [C]

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall:

(1) Be iced; or [C]

(2) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less; ~~and~~ [C]

(3) Not be permitted to remain without ice~~,~~ or mechanical refrigeration~~, or other approved means of storage~~ for more than two (2) hours at points of processing or transfer such as loading docks~~.~~; and [C]

(4) If received prior to reaching an internal temperature of 50 °F (10 °C), be placed in a conveyance pre chilled or a storage area maintained to 45 °F (7.2 °C) or less and cooled to an internal temperature of 50 °F (10 °C) prior to shipment, unless shipped in accordance with Chapter XIV. .01 E. (2). [C]

C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall ~~be~~:

(1) Be ~~I~~iced; or [C]

(2) Be ~~P~~placed ~~and stored~~ in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less. [C]

D. Shucked Meat Storage Critical Control Point - Critical Limits. The dealer shall ~~store~~ ensure that shucked shellfish shall:

(1) Be iced; or [C]

(2) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less ~~or covered with ice~~. [C]

E. Shellstock Shipping Critical Control Point – Critical Limits. The dealer shall ensure that:

(1) ~~Shellstock that is received bearing a restricted shellstock 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]~~ For shellstock received bearing a restricted use tag, the shellstock is

supplied to a certified dealer bearing a tag containing specific language detailing the intended use of the shellstock and that the shipment is accompanied by a transaction record indicating 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~~For restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and shipped prior to achieving the internal temperature of 50 °F (10 °C)~~.~~, ~~Should the dealer choose this option~~ if the transportation time is greater than four (4) hours, 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]

F. Other Critical Limits. The dealer shall ensure that shellfish comply with all other critical limits identified in the dealer's HACCP plan.

.02 Sanitation

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces. All equipment used to handle ice shall:

(a) Be constructed in a manner and with materials that can be cleaned and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]

(b) Be free from any exposed screws, bolts, or rivet heads on food contact surfaces; [K]

(c) Be fabricated from food grade materials; [K]

(d) Have joints with smooth easily cleanable surfaces that are welded; [K]

(d) ~~b~~Be kept clean and stored in a sanitary manner~~, and shall meet the construction requirements in Chapter XI. .02 B. (1), (a), (b), and (c)~~. [K]

C. Prevention of Cross Contamination

(2) Separation of operations.

(a) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers. [K]

.03 Other Model Ordinance Requirements

A. Plants and Grounds.

(2) Flooding.

(a) Facilities in which shellfish are stored~~, shucked, packed, repacked~~ or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. [C]

(b) If facilities are flooded: (i) Shellfish processing~~, shucking or repacking~~ or reshipping activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. [C]

(ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. [C]

Chapter XV. Depuration

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall receive and depurate only shellstock ~~which is~~ obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; [C] and

(b) Harvested restricted shellstock which is properly tagged with information describing the restriction; and [C]

(~~b~~c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; [C] and

(~~c~~d) Harvested the shellstock in compliance with the time/temperature requirements of Chapter VIII. @.02 A. (1), (2) or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2). [C]

(2) The dealer shall receive and depurate only shell~~stock~~fish obtained ~~and transported~~ from a dealer who has:

(a) Identified the shellstock with a tag on each container, or a bulk tag on each lot, as outlined in Chapter X. .05 ~~or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8)~~ identified the in shell product with a tag or label as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; [C] and

(b) Provided a shipping documentation as required in Chapter IX. .05; and [C]

(c) Adequately iced the shellstock~~,~~ or ~~[C] (d) C~~cooled the shellstock to an internal temperature of 50 °F (10 °C) or less~~.~~; [C]

(d) Supplied the shucked shellfish adequately iced or in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature; and [C]

(e) Supplied the in-shell product adequately iced or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature or cooled the in-shell product to an internal temperature of 45 °F (7.2 °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). Shipments of four (4) hours or less will not be required to have a time/temperature device. [C]~~ A dealer may receive shellstock from a dealer who has elected to supply restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and supplied prior to achieving the internal temperature of 50 °F (10 °C without the shellstock meeting the receiving requirement of Chapter XV. .01 A. (2) (c). Where the transportation time is greater than four (4) hours, the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred.

(4) The dealer shall receive and depurate only shellstock obtained from a special licensed harvester who has:

(a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; [C] and

(b) Identified the shellstock by transaction records which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. [C]

B. Processing Critical Control Points - Critical Limits. The dealer shall ~~assure~~ ensure that:

(1) All depuration lots are treated for a minimum of forty-four (44) hours; and [C]

(2) The water treatment system is operating to design specifications; and [C]

(3) All critical limits established during verification of the specific depuration process are being met. [C]

C. ~~Finished~~ Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ~~assure~~ ensure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter VII. .04; [C] and

(2) Once placed under temperature control while in the possession of the dealer, shellstock shall be:

(a) Iced; [C] or (b) Placed in a storage area or conveyance maintained at an ambient air temperature of 45 °F (7.2 °C) or less; [C] and

(c) Not permitted to remain ~~outside temperature control~~without ice or mechanical refrigeration for more than two (2) hours at points of processing or transfer such as loading docks. [C]

(3) All oysters harvested under State Vibrio Control Plans other than those labeled for a restricted use shall meet the following temperature requirements:

(a) Cooled to an internal temperature of 55 °F (12.7 °C) within the time periods outlined in the State V.v. Control Plans. [C]

(b) Cooled to an internal temperature of 50 °F (10 °C) within the time periods outlined in the State V.p. Control Plans. Shellstock cooled to an internal temperature of 55 °F (12.7 °C) to comply with a V.v. Control Plan is considered in compliance with this requirement. [C]

(4) All other shellstock obtained from a licensed harvester or received prior to reaching an internal temperature of 50 °F (10 °C) shall be placed in a conveyance pre chilled or a storage area maintained to 45 °F (7.2 °C) or less and cooled to an internal temperature of 50 °F (10 °C) prior to shipment, unless shipped in accordance with Chapter XIII. .01 E. (2). [C]

(5) 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 requirement listed above in .01 B. (4) above. [C]

C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall:

	(1) Be iced; or [C] (2) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less. [C] D. Shucked Meat Storage Critical Control Point - Critical Limits. The dealer shall ensure that shucked shellfish shall: (1) Be iced; or [C] (2) Be placed in a storage area or conveyance maintained at an ambient temperature of 45 °F (7.2 °C) or less. [C] E. Shellstock Shipping Critical Control Point – Critical Limits. The dealer shall ensure that: (1) For shellstock received bearing a restricted use tag, the shellstock is supplied to a certified dealer bearing a tag containing specific language detailing the intended use of the shellstock and that the shipment is accompanied by a transaction record indicating the quantity of restricted use shellstock containers. [C] (2) For restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) and shipped prior to achieving the internal temperature of 50 °F (10 °C), if the transportation time is greater than four (4) hours, the shipment shall be accompanied with a time/temperature recording device. [C] F. Other Critical Limits. The dealer shall ensure that shellfish comply with all other critical limits identified in the dealer's HACCP plan. .02 Sanitation C. Prevention of Cross Contamination. (1) Protection of shellfish. (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [SC/K] (b) Shellfish shall be protected from contamination. [SC/K] (~~b~~c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. [K] E. Protection from Adulterants. (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable Federal and State laws and regulations. [K] .03 Other Model Ordinance Requirements E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces. (4) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and non-food contact surfaces. [K] F. Shellstock Storage and Handling. (9) Assure that different ~~harvest~~ lots of ~~shellfish~~ shellstock and lots of in-shell product are not commingled during washing, culling, processing, or packing. If more than one (1) ~~harvest~~ lot of ~~shellfish~~ shellstock is being processed at the same time, the identity of each harvest lot is maintained throughout the stages of depuration. [K]
12. Public Health Significance	This proposal does not add or alter any existing requirements; it is housekeeping to improve the organization of existing Model Ordinance requirements. Currently, Chapter XI through Chapter XV are organized by the type of activity the

	dealer is currently performing (although that method of organization is inconsistent). This method of organization makes these chapters very difficult to understand and apply by both regulators and industry: it requires an arcane knowledge to be able to know where in these chapters to look for the requirements that are applicable to the type of activity the dealer is currently conducting, especially when it comes to figuring out which critical limits apply. One is required to think along the lines of "This dealer is a shucker-packer, but is currently acting as a shellstock shipper, so I need to look in the shellstock shipper chapter to see what requirements apply" and "This dealer is a repacker, but is currently reshipping this product, so I need to look in the reshipper chapter to see what requirements apply." This method of organization (which, again, is currently not even consistent) makes application of the Model Ordinance very confusing and difficult. These chapters should instead be organized so that all the requirements for each type of dealer are fully contained in the chapter for that dealer. That way, shucker-packers need only consult their own chapter, shellstock shippers need only consult their chapter, and so on. This proposal achieves that, by putting all existing requirements applicable to each type of dealer in the chapter of that dealer to ensure ease of use for the Model Ordinance and ready understanding of all applicable requirements for dealers and regulators. Additionally, for the critical limits, certain critical limits are currently required for restricted shellstock in Chapter X but are not listed with the other critical limits in the chapters for each type of dealer, and this proposal fixes that omission. This proposal also makes verbiage consistent across the dealer chapters and fixes a number of typos (if this proposal is passed, there would still be a number of verbiage inconsistencies and typos across these chapters, but this proposal is a step in the right direction by correcting many of them). This proposal does not add or alter any current requirements for dealers, simply ensures that these chapters are self-sufficient so that existing requirements can be readily understood.
13. Cost Information	None – reorganization of existing requirements
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative

2. Submitter	Alfred R. Sunseri
3. Affiliation	P&J Oyster Company, Inc.
4. Address Line 1	1039 Toulouse Street
5. Address Line 2	
6. City, State, Zip	New Orleans, LA 70112
7. Phone	504-722-9854
8. Email	asunseri@bellsouth.net
9. Proposal Subject	Guidance for processing, packaging, handling, & shipping fresh shucked oysters on the half shell, (Dead oysters)
10. Specific NSSP Guide Reference	Chapter XI. Shucking and Packing- Guidance Document
11. Text of Proposal/ Requested Action	Guidance must be developed for fresh raw oysters that are shucked and left on half of its shell for sale in commerce. This new product that has entered the marketplace must be packaged, handled, and shipped in a safe and sanitary manner. Guidance for Fresh Shucked Oysters processed, packaged and shipped in the ½ Shell form 1. All shellfish intended for the fresh shucked raw half shell market a. shall be shucked in a manner such that they will not be subjected to contamination. b. shall be reasonably free of mud when shucked. c. shall only be wholesome and safe shellfish that will be shucked, and any shellfish with badly broken shells shall be discarded. d. Shellfish are not subject to contamination or held for an excessive time at unsafe temperatures during shucking and packing. e. All fresh shucked raw half-shell containers shall be fabricated from safe materials and so designed for a single use. f. Containers used for packaging shall be clean, constructed of food-grade materials, and designed and fabricated such that the contents will be protected from contamination during shipping and storage. g. Each carton of shellfish containing individual trays of fresh shucked raw half shell oysters shall have the word SHUCKED followed by the actual shucking date shall appear on the lid and on the side wall or bottom of durable containers. The date shall consist of the common abbreviation for the month and number of the day of the month or the number of the day of the year (Julian calendar day. h. Shucked shellfish are held and transported at temperatures of 7.2°C (45°F) or less. If wet ice is used to store and ship the sealed containers of shucked shellfish, the packaging must keep the fresh shucked raw oysters free from contamination from melting ice that may contaminate the packed shellfish. (This language came directly from the NSSP) 2022 U.S. Food Code 3-303 Preventing Contamination from Ice Used As a Coolant

	3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient. After use as a medium for cooling the exterior surfaces of FOOD such as melons or FISH, PACKAGED FOODS such as canned BEVERAGES, or cooling coils and tubes of EQUIPMENT, ice may not be used as FOOD. P 3-303.12 Storage or Display of Food in Contact with Water or Ice. (A) PACKAGED FOOD may not be stored in direct contact with ice or water if the FOOD is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water (B) Except as specified in ¶¶ (C) and (D) of this section, unPACKAGED FOOD may not be stored in direct contact with undrained ice. (C) Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water. (D) Raw poultry and raw FISH that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale. ANNEX 3- Public Health Reasons/Administrative Guidelines 3-302.11 Packaged and Unpackaged Food – Protection Separation, Packaging, and Segregation. Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.
12. Public Health Significance	The potential for contamination of fresh raw half-shell oysters being packaged and shipped in unsealed containers have a high risk of contamination from melting ice as well as other possible contaminants following packaging, during shipping and storage.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	Yes

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
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6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Air Gaps
10. Specific NSSP Guide Reference	Section I. Purposes and Definitions, Definitions 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, .02 Sanitation, A. Safety of Water for Processing and Ice Production
11. Text of Proposal/ Requested Action	Section I. Purposes and Definitions, Definitions **(3) Air Gap** means the unobstructed vertical distance (at least twice the diameter of the largest supplying pipe) through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a sink, tank, plumbing fixture, drain or other device and the flood level rim of that receptacle. Chapter XI. Shucking and Packing .02 Sanitation, A. Safety of Water for Processing and Ice Production (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. [$S^{C/K}$] Air gaps shall be provided between the lowest opening from any pipe or faucet supplying water and the flood level rim of a sink, tank, or other plumbing fixture. [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. Repacking .02 Sanitation, A. Safety of Water for Processing and 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; [$S^{C/K}$] (ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. [$S^{C/K}$] Air gaps shall be provided between the lowest opening from any pipe or faucet supplying water and the flood level rim of a sink, tank, or other plumbing fixture. [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. Shellstock Shipping
.02 Sanitation, A. Safety of Water for Processing and Ice Production
(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. [$S^{C/K}$] Air gaps shall be provided between the lowest opening from any pipe or faucet supplying water and the flood level rim of a sink, tank, or other plumbing fixture. [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. Reshipping
.02 Sanitation, A. Safety of Water for Processing and 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; [$S^{C/K}$]
(ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. [$S^{C/K}$] Air gaps shall be provided between the lowest opening from any pipe or faucet supplying water and the flood level rim of a sink, tank, or other plumbing fixture. [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. Depuration
.02 Sanitation, A. Safety of Water for Processing and Ice Production
(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; [$S^{C/K}$]
(ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. [$S^{C/K}$] Air gaps shall be provided between the lowest opening from any pipe or faucet supplying water and the flood level rim of a sink, tank, or other plumbing fixture. [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]

12. Public Health Significance	The Model Ordinance contains a definition for "Air Gap" but does not use the term (except for using it in a slightly different context when requiring air gaps for floor drainage in the Plumbing and Related Facilities sections of Chapter XI through Chapter XV). This proposal clarifies the use of air gaps, specifying that there should be an air gap between a water supplying pipe or faucet and the flood level rim of the receiving sink or tank in order to prevent backflow of contaminated water into the pipe or faucet. Air gaps are already standard means to prevent backflow on sinks and related plumbing; this proposal simply clarifies their necessity after it was realized that the term was defined but then not properly used in the Model Ordinance.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None

osal for Task Force Consideration **e ISSC 2027 Biennial Meeting** *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Kim Coulbourne
3. Affiliation	Maryland Department of Health
4. Address Line 1	6 St. Paul Street
5. Address Line 2	Ste. 1301
6. City, State, Zip	Baltimore, Maryland 21202
7. Phone	(443)690-3106
8. Email	kim.coulbourne@maryland.gov
9. Proposal Subject	Minimum Frequency of Private Potable Water Supply Sampling
10. Specific NSSP Guide Reference	Section II Model Ordinance – Chapter XI. Shucking and Packing Section II Model Ordinance – Chapter XII. Repacking of Shucked Shellfish Section II Model Ordinance – Chapter XIII. Shellstock Shipping Section II Model Ordinance – Chapter XIV. Reshipping Section II Model Ordinance – Chapter XV. Depuration
11. Text of Proposal/ Requested Action	**.02 Sanitation** A. Safety of Water for Processing and Ice Production. (1) Water Supply. (a) The dealer shall provide a potable water supply in accordance with applicable Federal, State and local regulations. [C] (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K] (i) Prior to use of the water supply; [C] (ii) ~~Every six (6) months~~ **Annually** while the water supply is in use; and [K] (iii) After the water supply has been repaired and disinfected. [SC/K]
12. Public Health Significance	Reduces the minimum sampling frequency for private potable water supplies from twice a year to annually to align with the minimum requirement for all other food manufacturing firms regulated under the FDA manufactured foods program.
13. Cost Information	No additional costs. May reduce industry costs in some instances by reducing the number of samples required for compliance with the NSSP MO.
14. Changes Needed to Guidance (if proposed change is adopted)	none

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	1) Joe Kalmin (Director, Policy & Government Affairs); 2) Keith Jackson (Vice President, Corporate Quality Assurance)
3. Affiliation	1) International Foodservice Distributors Association, as representative of Performance Food Group, Sysco, and others; 2) Performance Food Group
4. Address Line 1	1660 International Drive
5. Address Line 2	Suite 550
6. City, State, Zip	McLean, VA 22102
7. Phone	703-962-9941
8. Email	jkalmin@ifdaonline.org
9. Proposal Subject	Lack of Time Temperature Consideration and Ambient Air Temperature Monitoring During Conveyance Consideration for Controlling *Vibrio* Pathogen Growth and Toxin Formation for Shippers.
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping .01 Critical Control Points
11. Text of Proposal/ Requested Action	IFDA formally requests that the NSSP Model Ordinance expressly include the option for Shellstock Shippers (Chapter XIII) to monitor for proper mechanical refrigeration through transit at the Receiving Critical Control Point, as this would be aligned with the guidance published throughout the rest of the Model Ordinance, as well as aligned with the FDA guidance outlined in the *Fish and Fishery Products Hazards and Control Guidance-June 2022 Edition* for controlling pathogen growth. ***Chapter XIII. Shellstock Shipping*** *.01 Critical Control Points* *A. Receiving Critical Control – Critical Limits.* *... (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) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less; or* ***[C]*** *(e) Shipped the shucked, in-shell, and/or live molluscan shellstock in a conveyance at or below 45 °F (7.2 °C) ambient air temperature and has not permitted the shucked, in-shell, and/or live molluscan shellstock to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C).* ***[C]*** *... (4) The dealer shall ship or repack only in-shell product obtained from a dealer who has:* *(a) Shipped the in-shell product* *(i) Adequately iced; or* *(ii) In a conveyance at or below 45 °F (7.2 °C) ambient air temperature and has not permitted the in-shell product to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air*

	temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C); or ***[C]*** *(iii) At an internal temperature of 45 °F (7.2 °C) or less; and* ***[C]*** *(b) Identified the in-shell product with a tag on each container.* ***[C]*** *... C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be: (1) Iced; or* ***[C]*** *(2) Placed and stored in a storage area or conveyance maintained at 45 °F (7.2 °C) or less and not stored in a storage area or conveyance without ice, mechanical refrigeration, or other approved methods of storage, as required in Section .01 B. (1) or Section .01 B. (2) (a) or (b) for more than two (2) hours at points of processing or transfer.* ***[C]***
12. Public Health Significance	The proposed revisions would not have a negative impact on public health. Industry has historically measured the ambient air temperature of the conveyance to monitor receiving CCPs, and there is no indication that this practice poses risks to public health or consumer safety. In fact, data from Sensitech provided with this submission show, with proper placement of the time/temperature recording device on the outside of the case, the representative internal temperature of the product is comparable to the ambient air temperature. In contrast, requiring internal product temperature readings for each lot may create potential food safety risks by eliminating visibility into shipping temperatures and would result in significant operational challenges and additional costs for industry resulting from regulatory action without achieving a measurable benefit in public health. Indeed, monitoring conveyance temperature is better protective of public health as it demonstrates continual temperature control throughout transportation and provides a holistic view of the cold chain of the product, rather than a one-time product temperature check. Finally, shellstock dealers (specifically shellstock shippers and reshippers) have previously been permitted to use documentation and records that reflect that shellstock was transported from the previous certified dealer in a conveyance at or below 45 °F (7.2°C) without harming public health. We note that this approach is consistent with FDA's approach to sanitary transportation for other food systems.[1] Further, FDA's guidance, *Fish and Fishery Products Hazards and Control Guidance* (2022) provides a relevant example of a critical limit for fish products delivered refrigerated. This example requires that "lots received are accompanied by transportation records that show that the product was held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit."[2] This example suggests ambient air temperature reading at receipt is an appropriate way to monitor the CCP. Additionally, the *Fish and Fisheries Hazard Control Guidance* (Appendix 4; pg. 421, Table A-2), outlines the established maximum cumulative time and temperature safe exposure combinations for fish and fishery products with respect to pathogens of greatest concerns.[3] This data can be extrapolated for

[1] See, Sanitary Transportation of Human and Animal Food, 81 Fed. Reg. 20092 (Apr. 6, 2016).
[2] Fish and Fishery Products Hazards and Controls Guidance: June 2022 Edition, page 220, FDA (June 2022) available at: https://www.fda.gov/media/80637/download.
[3] Fish and Fishery Products Hazards and Controls Guidance: June 2022 Edition, page 418, 421, FDA (June 2022) available at: https://www.fda.gov/media/80390/download.

	shellfish/shellstock and, as shown in the table below, the proposed limits of (1) a maximum of two hours without mechanical refrigeration and (2) ambient temperatures not to exceed 70°F (21.1 °C) are in line with the data on the growth of *Vibrio parahaemolyticus* and *Vibrio vulnificus*. GROWTH OF ***VIBRIO PARAHAEMOLYTICUS*** — 41-50°F (5-10°C) — 21 days 51-70°F (11-21°C) — 6 hours 71-80°F (22-27°C) — 2 hours Above 80°F (27°C) — 1 hour[2] GROWTH OF ***VIBRIO VULNIFICUS*** — 46.4-50°F (8-10°C) — 21 days 51-70°F (11-21°C) — 6 hours 71-80°F (22-27°C) — 2 hours Above 80°F (27°C) — 1 hour[2]
13. Cost Information	No cost to industry or regulatory bodies would be incurred with the proposed changes. Failure to consider the proposed changes will lead to product rejections of shellstock, shucked, and in-shell products considered time-temperature abused based on current 2023 Model Ordinance language.
14. Changes Needed to Guidance (if proposed change is adopted)	**Section IV, Chapter XIII, Page 430:** "Dealers receiving shellfish and/or shellstock from another certified dealer for shipping and repacking must document and maintain a record that the shellfish and/or shellstock was received iced; in a conveyance at or below 45 °F (7.2 °C) ambient air temperature and was not without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C); or at an internal temperature of 50 °F (10 °C) or less. Dealers receiving shellfish and/or shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellfish and/or shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred." **Section IV, Chapter XIII, Page 431:** "Shellfish and ~~S~~shellstock acceptability (receiving Critical Control Points) can be determined as follows: 1. The presence of enough ice on the shellfish to provide cooling to achieve required internal temperatures; or 2. An ambient temperature of 45 °F (7.2 °C) or less in the conveyance as measured by a thermometer or a time/temperature recording device; or…"

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Ch XIV. Critical Limit Correction
10. Specific NSSP Guide Reference	Section II Model Ordinance Chapter XIV.
11. Text of Proposal/ Requested Action	**.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 <u>in-shell</u> 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) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less: or [C] (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 XIV. .01 A. (2) (c) or (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). Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A. [C]~~ ~~E. Shellstock Shipping Critical Control Point. The dealer shall ensure that: (1) Shellstock that is received bearing a restricted shellstock 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]~~
12. Public Health Significance	The reshipping activity and the reshipper certification type (RS) are not receiving from harvesters and are not responsible for demonstrating shellstock has been cooled to 50 °F (10 °C). Further, reshipping and the reshipper certification type are not shipping restricted use product or product that has not been cooled to 50 °F (10 °C). Only original dealers are allowed to conduct these activities and bear this responsibility of demonstrating the hazard has been controlled. Reshippers maintain the control through the supply chain to the final consumer. This proposal fixes the inadvertent addition of two erroneous critical limits to the Chapter XIV. Receiving and Shipping Critical Control Points by deleting critical limits that shall not apply to the reshipping activity nor the Reshipper certification type.
13. Cost Information	No cost information for this change.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	1) Joe Kalmin (Director, Policy & Government Affairs); 2) Keith Jackson (Vice President, Corporate Quality Assurance)
3. Affiliation	1) International Foodservice Distributors Association, as representative of Performance Food Group, Sysco, and others; 2) Performance Food Group
4. Address Line 1	1660 International Drive
5. Address Line 2	Suite 550
6. City, State, Zip	McLean, VA 22102
7. Phone	703-962-9941
8. Email	jkalmin@ifdaonline.org
9. Proposal Subject	Lack of Time Temperature Consideration and Ambient Air Temperature Monitoring During Conveyance Consideration for Controlling *Vibrio* Pathogen Growth and Toxin Formation for Shellstock Reshippers.
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIV. Reshipping .01 Critical Control Points.
11. Text of Proposal/ Requested Action	IFDA formally requests that the NSSP Model Ordinance expressly include the option for Shellstock Reshippers (Chapter XIV) to monitor for proper mechanical refrigeration through transit at the Receiving Critical Control Point, as this would be aligned with the guidance published throughout the rest of the Model Ordinance, as well as aligned with the FDA guidance outlined in the *Fish and Fishery Products Hazards and Control Guidance-June 2022 Edition* for controlling pathogen growth. ***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 inshell 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) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less; or* ***[C]*** *(e) Shipped the shucked, in-shell, ~~shellfish~~ and/or live molluscan shellstock ~~in-shell product adequately iced or~~ in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature, which has not been permitted to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C).* ***[C]*** *... C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:* *(1) Iced; or* ***[C]*** *(2) Placed and stored in a storage area or conveyance maintained at 45 °F (7.2 °C) or less; and~~-~~* ***[C]*** *(3) Permitted to remain without ice, mechanical refrigeration, or other*

	approved means of storage for no more than two (2) hours at points of processing or transfer such as loading docks. ***[C]*** D. *Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45 °F (7.2 °C) or less or covered with ice; and not be permitted to remain without ice, mechanical refrigeration, or other approved means of storage for more than two (2) hours at points of processing or transfer such as loading docks.* ***[C]***
12. Public Health Significance	The proposed revisions would not have a negative impact on public health. Industry has historically measured the ambient air temperature of the conveyance to monitor receiving CCPs, and there is no indication that this practice poses risks to public health or consumer safety. In fact, data from Sensitech provided with this submission show, with proper placement of the time/temperature recording device on the outside of the case, the representative internal temperature of the product is comparable to the ambient air temperature. In contrast, requiring internal product temperature readings for each lot may create potential food safety risks by eliminating visibility into shipping temperatures and would result in significant operational challenges and additional costs for industry resulting from regulatory action without achieving a measurable benefit in public health. Indeed, monitoring conveyance temperature is better protective of public health as it demonstrates continual temperature control throughout transportation and provides a holistic view of the cold chain of the product, rather than a one-time product temperature check. Finally, shellstock dealers (specifically shellstock shippers and reshippers) have previously been permitted to use documentation and records that reflect that shellstock was transported from the previous certified dealer in a conveyance at or below 45 °F (7.2°C) without harming public health. We note that this approach is consistent with FDA's approach to sanitary transportation for other food systems.[1] Further, FDA's guidance, *Fish and Fishery Products Hazards and Control Guidance* (2022) provides a relevant example of a critical limit for fish products delivered refrigerated. This example requires that "lots received are accompanied by transportation records that show that the product was held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit."[2] This example suggests ambient air temperature reading at receipt is an appropriate way to monitor the CCP. Additionally, the *Fish and Fisheries Hazard Control Guidance* (Appendix 4; pg. 421, Table A-2), outlines the established maximum cumulative time and temperature safe exposure combinations for fish and fishery products with respect to pathogens of greatest concerns.[3] This data can be extrapolated for shellfish/shellstock and, as shown in the table below, the proposed limits of (1) a maximum of two hours without mechanical refrigeration and (2) ambient temperatures not to exceed 70°F (21.1 °C) are in line with the data on the growth of *Vibrio parahaemolyticus* and *Vibrio vulnificus*.

[1] See, Sanitary Transportation of Human and Animal Food, 81 Fed. Reg. 20092 (Apr. 6, 2016).
[2] Fish and Fishery Products Hazards and Controls Guidance: June 2022 Edition, page 220, FDA (June 2022) available at: https://www.fda.gov/media/80637/download.
[3] Fish and Fishery Products Hazards and Controls Guidance: June 2022 Edition, page 418, 421, FDA (June 2022) available at: https://www.fda.gov/media/80390/download.

	<table><tr><td>GROWTH OF ***VIBRIO PARAHAEMOLYTICUS***</td><td>41-50°F (5-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80°F (27°C)</td><td>21 days 6 hours 2 hours 1 hour[2]</td></tr><tr><td>GROWTH OF ***VIBRIO VULNIFICUS***</td><td>46.4-50°F (8-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80°F (27°C)</td><td>21 days 6 hours 2 hours 1 hour[2]</td></tr></table>
13. Cost Information	No cost to industry would be incurred with the proposed changes. Failure to consider the proposed changes will lead to product rejections of shellstock, shucked, and in-shell products considered time-temperature abused based on current 2023 Model Ordinance language.
14. Changes Needed to Guidance (if proposed change is adopted)	**Section IV, Chapter XIV, Page 432:** "Should the shipping dealer have chosen to ship product harvested under the time temperature requirements of Chapter VIII. @.02 A. (3) or restricted use shellstock prior to achieving required internal temperatures, the shellstock must be accompanied by a time/temperature recording device which indicates that continuing cooling has occurred. The shipment must also be accompanied by a shipping document indicating the time of shipment and that all shipping containers were prechilled. Shellfish and ~~S~~shellstock acceptability (receiving Critical Control Points) can be determined as follows: 1. The presence of enough ice to contact the shellfish and provide cooling to achieve required internal temperatures; or 2. An ambient temperature of 45 °F (7.2 °C) or less in the conveyance as measured by a thermometer or a time/temperature recording device demonstrating the shellfish and shellstock was not permitted to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C); or…" **Section IV, Chapter XIV, Page 433:** "Prying open the shells of shellfish is a time consuming and inherently destructive process (those animals measured must be discarded). The internal temperature of shellstock is, under most circumstances, reflected by the external temperature of the space surrounding the shellfish, or the external temperature of the shell of the animal, at the center of a packaged mass of shellstock (box, sack, bag, etc.). This temperature may be measured by (1) inserting a standard analog or digital thermometer probe into the package to an appropriate depth; ~~or~~ (2) ~~by~~ exposing the shellfish at the center of the package for rapid measurement of the external shell temperature such as is made possible with laser guided infrared temperature measurement devices~~.~~ ; or (3) recording the ambient air temperature in conveyance through the use of a time/temperature recording device demonstrating the shellfish and/or shellstock was not be permitted to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C)." Page 3 of 3

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative

2. Submitter	Alfred R. Sunseri
3. Affiliation	P&J Oyster Company, Inc.
4. Address Line 1	1039 Toulouse Street
5. Address Line 2	
6. City, State, Zip	New Orleans, LA 70112
7. Phone	504-722-9854
8. Email	asunseri@bellsouth.net
9. Proposal Subject	Remove SSA's exemptions for building requirements for shellstock shipper and reshipper certifications as listed at the beginning of Chapters XIII and XIV.
10. Specific NSSP Guide Reference	Chapters XIII and XIV.
11. Text of Proposal/ Requested Action	Remove the language at the beginning of Chapter XIII, "Exceptions. Shellstock Shippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a shellstock shipper's practices and conditions do not warrant requiring a building." and remove the language at the beginning of Chapter XIV., "Exceptions. Reshippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a reshipper's practices and conditions do not warrant requiring a building.".
12. Public Health Significance	All "on-shore" processing of shellstock that includes handling, sorting, sizing, washing, packing, labeling, or storing of shellfish in preparation for distribution, a certified building must be required to practice these activities in a safe and sanitary manner. Contamination can be caused by not using potable water, if rodent and vermin are not prevented from entering the processing area, if processing surfaces are not sanitized before processing of shellstock nor after processing ends, if light-colored walls can not be easily cleaned and if doors do not separate the outdoors to the processing area to maintain a sanitary work area. Time-temperature controls must be maintained following harvest of shellstock and before shellstock is being culled, sized, sorted, washed, packaged, and labeled following landing onshore. Also, it takes a significant amount of time and many times more than 2 hours from harvesting until all shellstock has been completely processed to enter commerce. If the processed culled and sorted shellstock is being returned to the growing area, no shellfish is allowed to be harvested from that growing area for 2 weeks because that shellfish has been temperature abused so that contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluations.

13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	yes

Proposal for Task Force Consideration at the ISSC 2027 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)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Cooling prior to Shipment
10. Specific NSSP Guide Reference	Section II Model Ordinance Chapter XV. .01
11. Text of Proposal/ Requested Action	C. Finished Shellstock Storage Critical Control Point - Critical Limits. The dealer shall assure that: (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter VII. .04; [C] and (2) Once placed under temperature control while in the possession of the dealer, shellstock shall be: (a) Iced; [C] or (b) Placed in a storage area or conveyance maintained at 45 °F (7.2 °C) or less; [C] and (c) Not permitted to remain outside temperature control for more than two (2) hours at points of processing or transfer such as loading docks. [C] (3) All shellstock obtained from a licensed harvester and depurated according to XV. .01 B. shall be placed in a conveyance pre-chilled or a storage area maintained to 45°F (7.2°C) or less and cooled to an internal temperature of 50°F (10°C) prior to shipment. [C]
12. Public Health Significance	This proposal fixes an inadvertent omission to Ch XV. and adds cooling finished, depurated product to an internal temperature of 50 prior to shipment.
13. Cost Information	No cost information, dealers are implementing cooling requirements prior to shipment.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
3. Affiliation	U.S. Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Molluscan shellfish pathogen reduction
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter XVI. .01 A. (2) (a), (3), and (4)
11. Text of Proposal/ Requested Action	(2) Validate the process by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s). The process shall be validated by a study as outlined in Section IV Guidance Documents – Chapter XVI. Processes and Procedures for Pathogen Reduction, .01 - .03 ~~Guidance Documents Chapter IV., Naturally Occurring Pathogens, Section .02~~ and be approved by the Authority, with concurrence of FDA. (a) The dealer must demonstrate that the process reduces the level of *V.v.* ~~and/~~or *V.p.* in the process to non-detectable (<30 MPN/g) and the process achieves a minimum 3.52 log reduction. Determination of *V.v.* and~~/or~~ *V.p.* levels must be done using the MPN protocols described in Section IV Guidance Documents – Chapter XVI. Processes and Procedures for Pathogen Reduction, .01 - .03 ~~Guidance Documents Chapter IV., Naturally Occurring Pathogens, Section.02~~ followed by confirmation using methods approved for use in the NSSP. (b) For processes that target other pathogens the dealer must demonstrate that the level of those pathogens in processed product has been reduced to levels below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC. 3) Conduct verification sampling to verify that the validated process is working properly. Verification sampling shall be at least equivalent to the verification protocol found in Section IV Guidance Documents – Chapter XVI. Processes and Procedures for Pathogen Reduction, .01 - .03~~Guidance Documents, Chapter IV., Naturally Occurring Pathogens, Section .02~~ as determined by the Authority and shall be reviewed annually by the Authority. 4) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subject to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X. .05, X. .06, and X. .07~~6~~. (5) Keep records in accordance with Chapter X. .08.
12. Public Health Significance	The references to Post- Harvest Processing (PHP) Validation/Verification Guidance for *Vibrio vulnificus* (*V.v.*) and *Vibrio parahaemolyticus* (*V.p.*), .02 Method for Validation and Verification of a Two (2) or Three (3) Log Reduction of *Vibrio parahaemolyticus* (*V.p.*) in Oysters, and .03 Template for Submission of Post-Harvest Process Validation Studies were not updated in the Chapter XVI. text after the guidance was updated. Also, the requirements for labeling in-shell product or post-harvest processed in-shell labeling was not included in the text.

13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Recall Committee - Kohl Kanwit, Chair
3. Affiliation	ISSC/SE DMR
4. Address Line 1	4801 Hermitage Rd
5. Address Line 2	
6. City, State, Zip	Richmond,VA
7. Phone	(803) 3306380
8. Email	issc@issc.org
9. Proposal Subject	Recall Gudance
10. Specific NSSP Guide Reference	Section IV Guidance Documents, Chapter II, @01
11. Text of Proposal/ Requested Action	

Chapter II. Risk Assessment and Risk Management

@.01 Outbreaks of Shellfish-Related Illness

.01 Guidance for Investigating an Illness Outbreak ~~and Conducting Recall~~

A. Requirements for the Authority.
Shellfish are filter feeders and therefore have the ability to concentrate microorganisms, including human pathogens and toxigenic micro-algae, from the water column if these organisms are present in the growing area. Concentrations in the shellfish may be as much as 100 times that found in the water column. If the microorganisms concentrated are harmful to humans, and if, in the case of human pathogens, the shellfish are consumed raw or partially cooked, human disease can result. Shellfish can also be contaminated during transport and post- harvest processing; i.e. wet storage, etc. Shellfish can be mishandled during processing which can contribute to the growth of existing microorganisms to the point where consumption can cause illness.

Documentation of the information supporting growing area classification, proper tagging and record keeping, expeditious follow-up on reported illnesses, effective recall of implicated product and public warning announcements are all requisite to protecting public health. Shellfish growing areas implicated through epidemiological association between illness and shellfish consumption must be closed immediately to prevent additional implicated product from reaching the consumer. In addition, shellfish product from the implicated growing areas may be detained and an effective recall of product initiated if the investigation determines that it is necessary to protect public health.

When an illness outbreak investigation indicates that there is an

epidemiological association between shellfish consumption and the illnesses, the investigating Authority shall immediately inform the producing Authority of the illnesses, the stage of the investigation, and epidemiological link to consumption of molluscan shellfish. Prompt reporting, even in the initial stages of an investigation, will allow the producing Authority to conduct its investigation (in accordance with Chapter II. @.01 B.) and determine whether harvest area closure, notification, and recall are required.

When an illness outbreak has occurred, immediate closure of the implicated growing area(s) will significantly reduce the chance of additional illnesses during the investigatory process. Immediate closure for the purposes of this Guidance Document means within twenty-four (24) hours of notification of the illness (NSSP Model Ordinance Chapter IV. @.03 A. (1)). If a preliminary investigation reveals that the growing area is not implicated, an immediate closure is not necessary. Additional information concerning investigation of an outbreak of shellfish related illness believed to be associated with a naturally occurring pathogen can be found in the NSSP Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* . Additional information concerning the disease causing potential of shellfish can be found in the NSSP Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* .

The Authority should assign an Illness Investigation~~/Recall~~ Coordination Lead (the Lead) for the agency to be listed on the ISSC website as the agency contact person. The Lead will be the agency contact for the duration of the event.

During and after the immediate closure, the Authority must be in the process of investigating, evaluating and conducting increased surveillance. ~~Immediate closures will not always result in an immediate recall of product~~. It is imperative that the Authority communicate with State Epidemiologists, local health officials, pertinent State agencies, industry and others as necessary to complete a thorough investigation.

Additionally, immediate closures may not be necessary if the investigation reveals that the illness outbreak was caused by a specific activity by a single entity which can be controlled through a product recall and an immediate corrective action in the processing or transport of product.

An illness outbreak investigation must include an evaluation of the health hazard presented and consideration of the following factors, including but not limited to:

1. Immediately send staff members out to perform growing area reconnaissance.
2. Review documentation of the information supporting growing area classification, review environmental sample trends, secure additional shellstock and/or water samples if necessary.
3. Review toxin sample trends, sampling protocol and supporting

information for biotoxin closures, secure additional shellstock and/or water samples if necessary.

4. Interview local sources regarding any anecdotal or factual information on the origin of contaminants (large passenger vessels, point and non-point sources).
5. Immediately send staff members out to interview certified dealer(s), restaurant staff members or retail establishment staff members to secure additional details regarding tagging, record keeping, refrigeration temperatures, handling practices, shipping and receiving information and where and from whom the shellfish products were purchased, name and telephone number of contact person.
6. When possible, interview harvesters in the area of concern to determine handling practices and specific harvest area(s).
7. Determine the identity of the product involved, the extent of distribution of implicated product, total amount of the suspected product, total amount in distribution chain, distribution information and ~~proposed recall strategy~~ determine if a recall is necessary.

~~A product recall may not be appropriate when an illness outbreak investigation reveals the following, including but not limited to:~~

1. ~~When the etiological and epidemiological evidence confirms that shellfish from a specific growing area or lease area are the cause of the illnesses.~~
2. ~~When it has been determined that a specific process conducted by a dealer is the cause of the illnesses.~~

~~A product recall may not be appropriate when an illness outbreak investigation reveals, but is not limited to, the implicated product is no longer available in the market.~~

When the source of the illness is found to be the distribution and processing system, shellfish product should be also detained and an effective recall of product initiated, and the problem immediately corrected. Under these circumstances no closure of the growing waters is warranted in accordance with NSSP Model Ordinance, Chapter II. @.01 D.

An area which was closed due to an illness outbreak can be reopened using the criteria outlined in the NSSP Model Ordinance, Chapter IV. @.03 A. (5) (~~e~~d): Reopened Status. A growing area temporarily placed in the closed status (as provided in (b) above), shall be returned to the open status only when:

1. The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock

to pre- closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or

2. The requirements for biotoxins or conditional area management plans as established in Section .01 and Section .03, respectively, are met; and
3. Supporting information is documented by a written record in the central file.

~~Whenever an Authority initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, Authorities in other States/countries, ISSC, and industry involved in the recall. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market and issue public warnings if necessary to protect public health.~~

~~Pursuant to the NSSP Model Ordinance Chapter II. @.01 C. (4) and D. (2) an Authority initiated recall shall include procedures consistent with The Recall Strategy as provided in 21 CFR Part 7.41, 7.42 and 7.50 as listed below: [for purposes of this guidance "the Authority" will be substituted for "the agency for a Food and Drug Administration"]~~

~~FDA will decide whether to audit or issue public warnings after consultation with the Authority(ies), and after taking into account the scope of the product distribution and other related factors. After consultation with the Authority(ies) and after taking into account the scope of the product distribution and other related factors, FDA may audit and/or issue public warnings. If the FDA determines that any Authority involved in the recall fails to implement effective actions to protect public health, the FDA may audit, classify the severity of, and publish the recall, including the issuance of public warnings when appropriate.~~

~~21 CFR Part 7.41:~~

~~Health hazard evaluation and recall classification.~~

~~(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:~~

~~(1) Whether any disease or injuries have already occurred from the use of the product.~~

~~(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health~~

~~hazard determination.~~

~~(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.~~

~~Assessment of the degree of seriousness of the health hazard to which the~~

~~(4) populations at risk would be exposed.~~

~~(5) Assessment of the likelihood of occurrence of the hazard.~~

~~(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.~~

~~(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.~~

~~Section 7.42 Recall strategy.~~

~~(a) General.~~

~~(1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:~~

~~(i) Results of health hazard evaluation.~~

~~(ii) Ease in identifying the product.~~

~~(iii) Degree to which the product's deficiency is obvious to the consumer or user.~~

~~(iv) Degree to which the product remains unused in the market place.~~

~~(v) Continued availability of essential products.~~

~~(b) Elements of a recall strategy. A recall strategy will address the following elements regarding the conduct of the recall:~~

~~(1) Depth of recall. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:~~

~~(i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or~~

~~(ii) Retail level, including any intermediate wholesale level; or~~

~~(iii) Wholesale level.~~

~~*Means of notification, methods of collecting related information, and summary of findings. Recall notification*~~

~~*procedures should be standardized to assure compliance with Title 21 CFR, Section7.42:*~~

~~(2) Public warning. The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:~~

~~(i) General public warning through the general news media, either national or local as appropriate, or~~

~~(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.~~

~~Section 7.50 Public Notification of Recall.~~

~~The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration requested or firm initiated, and the specific action being taken by the recalling firm.~~

~~Organization of the recall procedures must take into consideration the need for work week, weekend, and holiday notifications. Various recall notification strategies may be used depending on the nature of the illness outbreak and recall. (See attached Appendices and supporting forms for example of a Recall Standard Operating Procedure). Complete removal of shellfish from interstate and intrastate commerce is vital for effective recall reaction. Timely notification and reaction by public health officials utilizing the Title 21 CFR, Part 7 requirements and associated State procedures must provide a safeguard against contaminated shellfish reaching the market. In some cases, duplication of the Federal requirements by States may be the method selected to assure standardization of necessary steps to ensure effective recalls.~~

~~Educational programs should be developed for both industry and the public describing the public health necessity for effective recall notifications and eliminating potentially unsafe shellfish products from the market place. Programs developed specifically for participation of key industry people may~~

~~be especially helpful in eliciting cooperative efforts of the entire industry. Such programs should focus on incentives to standardize the procedures for effective and timely recall activities.~~

~~The adequacy of State procedures as a basis for assuring rapid and thorough reaction to illness outbreaks and product recall efforts is an important component of this activity. Shellfish recall will be ineffective and/or compromised if State procedures are so written or interpreted that effective reaction cannot be successfully initiated. It is important that consistent recall expectations and notification procedures be standardized by participating public health Authorities in order to effectively safeguard the general public from potentially hazardous food.~~

~~When a recall of shellfish products is initiated, the Authority shall:~~

1. ~~Immediately notify the appropriate FDA Shellfish Specialist of the recall and provide a recall status report every five (5) working days after the initiation of the recall. Subsequent recall monitoring reports should be provided as information is acquired. The recall monitoring report, which may be verbal or written notification, will include the following information:~~
    a. ~~The name and address of the recalling dealer(s), plus certification numbers;~~
    b. ~~The identity of the affected product;~~
    c. ~~The reason for the recall;~~
    d. ~~Any other actions deemed appropriate to address the recall such as closing the growing area, conducting surveys, conducting monitoring and contacting other agencies, tribes and stakeholders, in regard to possible growing area closures and investigation of the situation requiring the recall including but not limited to sanitary or shoreline survey activities, water quality factors, and other environmental factors under consideration;~~
    e. ~~All relevant product identification (harvest date, harvest location, date shucked, lot code, quantity etc.); and~~
    f. ~~Distribution and redistribution of all shipments of the suspected lots.~~
2. ~~Establish procedures that ensure support staff members who are conducting investigation efforts will report provide results of the investigation activities to the Lead to be added to the progress updates~~

    ~~and final recall summary report. Activities include:~~
    a. ~~Review illness investigation reports.~~
    b. ~~Review facility inspection reports.~~
    c. ~~Review harvest site applications/information.~~
    d. ~~Review Survey of pollution sources.~~
    e. ~~Review marine water quality test results.~~
    f. ~~Review biotoxin test results.~~
    g. ~~Draft a summary of growing area findings for pollution,~~

~~biotoxins, etc. as needed.~~

~~3. Prepare a complete recall summary that determines the effectiveness of the recall. The Authority will forward the recall summary documents to the appropriate FDA Shellfish Specialist within five (5) working days of the completion of the recall. The recall summary will include:~~

~~a. The quantity, type, and status of recalled products returned to or recovered by the recalling dealer(s);~~

~~b. The quantity, type and status (if known) of recalled products not returned to or not recovered by the recalling dealer;~~

~~c. The reason for initiating the recall;~~

~~d. The date the recall was initiated;~~

~~e. The date the recall was completed;~~

~~f. Dealer inspection results or other evidence where appropriate; and~~

~~g. A listing, in chronological order, of any complaints or injuries associated with the product.~~

~~h. Final disposition of all recalled product.~~

~~i. All other actions taken to address the recall such as closing the growing area, conducting surveys, conducting monitoring, contacting other agencies, tribes and stakeholders, etc. relating to possible growing area closures and investigation of the situation requiring the recall, such as sanitary or shoreline survey activities, water quality factors, and other environmental factors for consideration.~~

~~4. Provide a summary of the details involving the recall to the appropriate Authorities upon conclusion of the recall. Each respective element of the recall activities will be described in sufficient detail to provide adequate trace back information and/or account for providing public health protection as a result of the recall. Upon approval of the report, copies will be provided via email and or hard copy to the FDA Shellfish Specialist and other agencies needing the information.~~

B. Requirements for Dealers

When an illness has occurred or has been reported to a certified dealer or harvester, they shall immediately notify the Authority. Immediate notification to the appropriate agency will significantly reduce the chance of additional illnesses and will limit the duration and extent of any precautionary growing area closures and product recalls.

The Authority will provide the contact information for the Illness Investigation~~/Recall~~ Coordination Lead (the Lead) for the agency. The Lead will be the contact for the duration of the event.

The affected industry must cooperate with the Authority during the investigation and evaluation. It is imperative that the industry and the Lead

communicate as necessary to complete a thorough investigation.

If the investigation reveals that the source of the illness is found to be the distribution and processing system, shellfish product should be detained and an effective recall of product initiated. The investigation may reveal a problem with the processing of product, if that is the case, the Authority should work with the processor to immediately correct the problem.

~~Whenever a certified dealer conducts a recall of shellfish products, the dealer shall:~~

1. ~~Follow the written recall procedures adopted in accordance with NSSP Model Ordinance Chapter X. 03 B. (1) and (2);~~
2. ~~Immediately notify the Authority which is responsible for the enforcement of shellfish sanitation, unless directed initially by the Authority, that a product recall has been initiated; and~~
3. ~~Immediately notify the receiving shipper(s) or other receiver/user that a product recall has been initiated;~~
4. ~~Provide the Authority and the receiver of the product with:~~
    a. ~~The type and quantity of shellfish being recalled;~~
    b. ~~The name and license or permit number of each harvester or shipper certification number, as necessary;~~
    c. ~~The harvest area; and~~
    d. ~~The date(s) of harvest and shipment as they appear on the shipping tag or invoice.~~
5. ~~Direct each receiver of the recalled product to examine their receiving records and invoices and report:~~
    a. ~~The quantity of product received;~~
    b. ~~The quantity remaining;~~
    c. ~~The quantity shipped and to whom, including name, address, phone number and date of reshipment; and~~
    d. ~~All product being held and considered embargoed.~~
6. ~~Advise the receiver that:~~
    a. ~~The product is not to be sold or shipped;~~
    b. ~~Unless advised otherwise by the Authority, the product is to remain on the premises until the Authority representative or other designee arrives;~~
    c. ~~When appropriate, they should notify their customers who received the product about the recall; and~~
    d. ~~All receiving and shipping records and invoices for implicated products are to be available for inspection by the Authority's officials.~~
7. ~~Provide a recall status report to the Lead every five (5) working days after the initiation of the recall. Subsequent recall monitoring report, which may be verbal or written notification. Unless otherwise specified or inappropriate in a given recall case, the recall progress update should contain the following information:~~
    a. ~~Number of consignees notified of the recall and the date and method of notification;~~

b. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received;
c. Number of consignees that did not respond (if needed, the identity of non-responding consignees may be requested by the Authority and the Food and Drug Administration);
d. Number of products returned or corrected by each consignee contacted and the quantity of products accounted for;
e. Number and results of effectiveness checks that were made; and
f. Estimated time frames for completion of the recall.

The dealer must fulfill any additional reporting requirements in accordance with the Food Drug and Cosmetic Act (21 CFR Parts 7.40-7.59 and 207 FDA Section 1005). The recalling dealer has the initial responsibility

for determining if the recall is progressing satisfactorily. It is also the obligation of all recalling dealers to determine the effectiveness of their recall. Effectiveness checks aid in verifying that all known, affected consignees received notification about the recall and have taken appropriate action.

C. Requirements for FDA

Whenever a certified dealer conducts a recall of shellfish products, the FDA Shellfish Specialist shall:

1. Monitor the Authority and FDA actions ensure that the product recall is consistent with the requirements of the NSSP Model Ordinance;
2. Inform other FDA offices as appropriate as new or pertinent recall information from the Authority becomes available; and
3. Coordinate all FDA and other Federal assistance provided, as necessary, to affected States.

D. Dispute Resolution.

The ISSC recognizes that States should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish. In instances where prudent action is not taken by a State during recall or illness outbreak situations, an Authority or FDA must notify the Executive Board regarding the State's decision and rationale for taking an action or failure to take an action. The Authority should provide the rationale for the proposed action by describing, at a minimum:

1. The potential effect on the public health within that State;
2. The potential effect on the public health in other States;

~~3. The potential economic impact on States;~~
~~4. The necessity for the action within the proposed timeframe~~

~~The ISSC will consider the rationale of the Authority and the Executive Board may decide to contact the appropriate agency head or Governor in order to secure prudent public health protection. In the event that action is not taken after deliberation between the Conference and the State, the ISSC may recommend the State as an unresolved issue under the ISSC Constitution, By-Laws and Procedures, Procedure IX. Section 3.~~

.02 Guidance for Harvest Area Closure ~~and Recall Notification~~

Chapter II @.01 requires states to provide notification of harvest area closures ~~and recalls~~ to the ISSC. The following forms which include the required information are provided to assist states in complying with notification requirements.

Example Notification

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

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

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

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

~~**Example Notification**~~

~~**DISTRIBUTION**~~

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

~~On **(DATE)**, **(NAME OF AUTHORITY)** determined an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption, determined that this outbreak is~~

~~growing area related, and initiated recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 to recall all implicated **(SPECIES)** harvested **from (IMPLICATED HARVEST/GROWING AREA)** from **(DATES OF HARVEST)**. This email serves to provide distribution information to ISSC and FDA.~~

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

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

~~Distribution information is as follows:~~

Shipping Dealer #1
Name & ICSSL #:

Harvest Area	Harvest Date	Receiving Dealer, Retailer, or Food Service *(Include ICSSL #, if known or applicable)*	City, State	Sale Date	Lot No. or Date Shucked	Qty Sold	Product Description	Status *(Consumed, destroyed, returned)*

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

Shipping Dealer #2
Name & ICSSL #:

Harvest Area	Harvest Date	Receiving Dealer, Retailer, or Food Service *(Include ICSSL #, if known/applicable)*	City, State	Sale Date	Lot No. or Date Shucked	Qty Sold	Product Description	Status *(Consumed, destroyed, returned)*

~~**Attachments:**~~

~~**References**~~

- ~~Watkins, W. and S. McCarthy. 1994. *Proceedings of the 1994 Vibrio vulnificus Workshop*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-400), Shellfish~~

~~Sanitation Branch, 200 C Street, SW, Washington, D.C. 175 pages.~~

Appendices

- Appendix A
- ~~Appendix B~~
- ~~Appendix C~~
- ~~Appendix D~~
- ~~Appendix E~~
- ~~Appendix F~~
- ~~Appendix G~~

NOTE: To view, print, or download Appendix A, ~~B, C, D, E, F, or G~~ click on the link below.

Checklists for Recalls, Closures and Special Events

.03. Guidance for Conducting a Recall

The following guidance relies on the Recall Process Flow Chart found in Appendix X. The Recall Process Flow Chart is the parent document to the various job aids presented in Appendices X-X. The Recall Process Flow Chart along with the various job aids and the descriptive text in this section should be used to inform the initiating dealer and Authority of the steps to take to manage a shellfish recall.

Shellfish recalls are an important tool used by shellfish dealers and Authorities to stop the distribution of unsafe shellfish to potentially prevent illnesses. Recalls are guided by the NSSP Model Ordinance and 21 CFR Part 7and are a voluntary action that recognizes the responsibility of dealers to protect public health. An effective recall depends on both the dealer and the Authority understanding the recall process and having an existing plan ready to execute in the event a recall is initiated. Dealers and Authorities must understand the role they play in any recall and be prepared to take appropriate steps quickly to trace and recover as much shellfish product as possible and thereby have the greatest protective effect. Dealers and Authorities are encouraged to conduct mock recall exercises to test their readiness. This guidance includes several job aids that may be used in the event of an actual recall or in a mock shellfish recall.

Both dealers and Authorities should designate an individual as the recall coordinator. This individual should be trained in recall procedures in general and specific recall procedures for their company and industry. For example, the dealer's recall coordinator should know how to access company records to conduct an efficient trace forward. Similarly, the Authority recall coordinator should know what shellfish species their industry deals with and how they generally distribute their products. The Authority recall coordinator should be identified on the ISSC website and the information kept current by each Authority through notification to the ISSC Executive Office. This ensures there is easy access to current contact information for trained

individuals in each member state.

A. Determining if a Recall is Necessary.

The first step in any recall process is determining that a recall of shellfish is necessary (NSSP Chapter II). This determination can be made by a dealer and/or an Authority.

To determine if a recall is necessary the dealer and/or Authority should conduct a health hazard assessment consistent with 21 CFR Part 7.41 and consider:

1. Have any illnesses or injuries occurred from the use of the shellfish?
2. Do conditions exist that will expose humans to a health hazard?
3. What populations are at risk of exposure?
    a. Consider individuals who may be at greatest risk
4. What is the degree of seriousness of the illness or injury?
5. What likelihood exists for the occurrence of the illness or injury?
6. What are the consequences of the illness or injury (immediate or long-range)?

Based on the health hazard assessment, the dealer and/or Authority will determine if a recall is necessary and proceed with the shellfish recall as deemed appropriate. The result of the health hazard assessment answers as to why a recall is or is not initiated.

A shellfish recall may not be appropriate when an illness outbreak investigation reveals any of the following conditions, or others which may not be listed:

1. Source Contamination: when evidence confirms shellfish from a specific location (e.g. a single aquaculture lease site) are the cause of the illnesses/injuries and can be controlled easily and effectively.
2. HACCP Failure: when it is determined a dealer, processor, shipper, or retailer has failed to comply with any component of its Hazard Analysis and Critical Control Plan (HACCP) and shellfish are still within their control
3. Process Correction: when after harvest or processing the cause of potential illness/injury can be corrected and controlled easily and effectively by a firm.
4. Market Access: when it is determined the recalled shellfish are no longer available in the marketplace given reasonable assumptions regarding shelf life and how the shellfish product is intended to be used and stored.

B. Determining the Scope of a Recall.

When the health hazard assessment indicates a recall is necessary, the dealer and/or Authority shall determine what shellfish need to be

recalled. This assessment should be consistent with 21 CFR 7.42 and consider the following:

1. Can the shellfish be identified?
2. How are the shellfish identified?
3. Is the product hazard obvious and easy to explain to users?
4. Does the shellfish remain in the marketplace?
5. Is there continued availability of the shellfish?

Based on this assessment the dealer and/or Authority can identify the shellfish to be recalled using data such as the type of shellfish, form of the shellfish (shellstock, shucked, etc.), the Traceability Lot Code(s) (TLC), harvest date(s), wet storage date(s), harvest location, shipping date(s), ship to locations, and quantities of affected product shipped.

Determining the product dates or TLCs to be recalled should include consideration for:

1. What is the first date affected shellfish reached the marketplace?
2. What is the type of shellfish?
3. What is the intended use of the shellfish?
4. What is the expected shelf life of the product?
5. How likely will an end user not use the shellfish as intended?
6. What is the extent to which end users may not follow the intended use?
7. When will all affected shellfish be out of the marketplace (used, expired, or destroyed)?

A recall justification written by the dealer and/or Authority should include information on all factors considered to determine the date range of the shellfish recall.

C. Conducting a Shellfish Recall.

The Recall Process Flow Chart, identifying the various steps involved in conducting a shellfish recall can be found in Appendix X. This flow chart is the primary reference document for the associated job aids (Appendices X-X) created to assist dealers and Authorities in the event a recall is deemed necessary. These materials are recommended but not required to be used to assure completeness and consistency during a recall.

When a recall is initiated by a dealer, the dealer must immediately inform the Authority. When a recall is initiated by an Authority, the authority will immediately inform the affected dealer or dealers. When using the job aides in Appendices X-X as a reference, dealer(s) who initiate a recall, by their own determination or as directed by the Authority, are considered to be the "initiating dealer(s)." Dealers who initiate a recall have a specific role throughout the recall process to the Authority. The Authority in the jurisdiction of the initiating dealer is considered the principal coordinating Authority(ies) and has a specific role throughout the recall process. If a recall involves multiple shellfish origins, then the FDA should operate as the

principal coordinating authority compiling all data. However, when multi-origin recalls occur, Authorities should continue to share recall information with all other Authorities to maintain efficiency and effectiveness of the recall.

Once a recall is initiated, the initiating dealer(s) begins the recall following their recall procedures. All shellfish dealers are required to have a written recall plan (NSSP Chapter X .03 B.) which have been approved by the Authority.

Job Aid No. 1: Understanding the Recall Process.

- This job aid outlines the steps necessary for a dealer to initiate and complete a recall including the following steps: identifying the need for a recall, identifying affected shellfish, stop product distribution, notifying management and regulatory authorities, notifying customers, conducting effectiveness checks, controlling disposition of recalled shellfish, conducting a root cause analysis and corrective actions, records maintenance, and terminating the recall.

Job Aid No. 2: Developing a Recall Notice.

- This job aid outlines for a dealer that initiates a recall, the information necessary for the recall notice. The initiating dealer must provide key data elements (KDEs) including: the Initiating dealer name, address and phone number, the Initiating dealer contact person, the shellfish involved (product description, type, and form), the shellfish quantities, the Traceability Lot Code (TLC) and Traceability Lot Code Source (TLCS), the shipping date or date range, the reason for the recall, if the recall has been reported to the Authority, if the shellfish have been shipped to other states and what actions receiving dealers must take. It is recommended for all KDEs to be managed using a sortable spreadsheet (See FDA Food Traceability Rule Templates)

Once the recall notice is developed by the initiating dealer and provided to the Authority, the Authority must distribute the information to receiving states, the FDA and the ISSC (NSSP Chapter II).

Job Aid 2A: Authority Recall Alert Notice Template to Other Authorities.

- This job aid is an example of a recall alert notice as developed by the producing state Authority and distributed to receiving states. Included in the recall alert notice are all necessary key data elements (KDEs) for receiving states with specific details on receiving dealers in the receiving states; information should be presented in a sortable spreadsheet for clarity, completeness and consistency. The Authority may decide to post the recall alert notice on their website or use other means of expanding distribution.

The following considerations may be used by the Authority to determine when a recall alert notice is posted to its website or further distributed by more expansive communication protocols:

(i) Is there suitable assurance the shellfish have been effectively removed from commerce?
(ii) Did the dealer send their Recall Notice/Press Release to the Associated Press or other appropriate media outlets?
(iii) Is recall expansion necessary, based on investigation findings and recall effectiveness checks?
(iv) Is there evidence that affected product was commingled with, or transformed into, other lot codes/product by other processors (e.g. wet or dry storage, shellstock to shucked)?

The Authority may choose to assess or reassess posting or further distributing recall alert notices at any point in the recall process.

The Authority must also provide notice to the FDA (NSSP MO) who will then further distribute the recall alert notice internally to State Liaisons, and externally to all NSSP Authorities, and states not yet identified as receiving product, for awareness. The FDA will determine if a public safety alert is warranted to amplify the recall information. FDA will decide whether to audit or issue public safety alert after consultation with the Authority, and after taking into account the scope of the shellfish distribution and other related factors. After consultation with the Authority and after taking into account the scope of the shellfish distribution and other related factors, FDA may audit and/or issue public safety alert. If the FDA determines that any Authority involved in the recall fails to implement effective actions to protect public health, the FDA may audit, classify the severity of, and publish the recall alert notice, including the issuance of public safety warnings when appropriate. The purpose of a public safety alert is to alert the public that shellfish being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled shellfish appear inadequate. The recall strategy will specify whether a public safety alert is needed and whether it will issue as:

(i) General public safety alert through the news media, either national or local as appropriate, or
(ii) Public safety alert through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

Job Aid 2B: Template for a Recall Alert Notice from the Authority for ISSC.

- The Authority must provide notice to the ISSC (NSSP MO) who will further distribute the recall alert notice to the membership and post on their website. This job aid is an example recall alert notice developed by the recalling Authority and distributed to ISSC and is similar to 2A, but does not include specific details on receiving dealers, since some state laws and regulations prevent sharing of sensitive information with a third party; individuals coordinating the recall on behalf of the Authority should understand and follow these restrictions. This template is not required to be used by the Authority, but is highly recommended for clarity, completeness and consistency.

Simultaneously with the notifications being distributed by the Authority to receiving states, the FDA and the ISSC, the initiating dealer must issue a

recall alert notice to all affected customers identified from the dealer's shipping critical tracking events (CTE). Receiving customers may include wholesale shellfish dealers, retailers, or direct retail customers. The receiving entities are considered "affected customers" of the initiating dealer and are referred to as "Tier 2" entities in the job aids (Appendices X-X) Tier 2 entities may have a further and specific roles in the recall process.

Job Aid No. 3: Recall Alert Notice developed by the initiating dealer to their affected customers (Tier 2).

- This job aid is an example of a recall alert notice developed by the initiating dealer and distributed to their affected customers (Tier 2). The Recall Alert Notice includes the Initiating dealer name, address and phone number, the Initiating dealer contact person, the shellfish involved (product description, type, and form), the shellfish quantities, the Traceability Lot Code (TLC) and Traceability Lot Code Source (TLCS), the shipping date or date range, the reason for the recall, if the recall has been reported to the Authority, if the shellfish have been shipped to other states and what actions receiving dealers must take. It is recommended for all KDEs to be managed using a sortable spreadsheet (See FDA Food Traceability Rule Templates) key data elements (KDEs).

Job Aid No. 4: Initiating Dealer Contacts Customer to verify receipt of recall alert notice and disposition of the affected shellfish. This job aid frames the entire recall process for the initiating dealer and their affected customers.

- This job aid outlines the steps necessary for an initiating dealer to conduct a recall with their affected customers including: gathering details and developing recall alert notices, identifying affected shellfish received and on-hand quantities, identifying affected shellfish that has shipped, identifying affected customers and getting contact information, notifying customers who received shellfish, notifying the Authority, controlling and disposition of on-hand shellfish, conducting a supplier root cause analysis and corrective actions, conducting an effectiveness check, maintaining recall records, and terminating the recall.

At this point, the initiating dealer has notified all affected customers. The affected customers may have further distributed shellfish and must themselves forward the recall information to their affected customers ("Tier 3"). This trace forward process continues through the distribution chain until it reaches the shellfish end point. All information is sent up the distribution chain through the various dealers/customers.

For example, if the shellfish end point was a retail seafood shop two steps removed from the initiating dealer, that shop would collect their data and provide it to the secondary dealer. The secondary dealer would then provide that information to the initiating dealer. This "roll-up" of recall data allows all the information to be compiled by the initiating dealer. The initiating dealer should provide the data to the Authority as it is received or daily until the recall is terminated.

The Authority where the initiating dealer is located is responsible for managing the recall key data elements. This is a difficult task given the amount of information that may be received by the initiating dealer and is why the FDA expects all key data elements to be transmitted by all affected firms using a sortable spreadsheet (FDA FTR reference).

Job Aid No. 5 and 5A: Recall Key Data Element sortable spreadsheet template and example.

- This job aid is a sortable spreadsheet template to collect recall key data elements and is an example sortable spreadsheet filled out with the recall key data elements provided in Job Aid No. 3. The recall sortable spreadsheet can be used by the initiating dealer to conduct the trace forward and record the recall key data elements or by the Authority to compile all of the key data elements sent by the initiating dealer from the trace forward. This template is not required to be used by the Authority, but is highly recommended for clarity, completeness and consistency. The sooner the sortable spreadsheet is used in the recall process, the easier the collection of key data elements will be complete and communication among the entities involved in the recall will be final. The top of the sortable spreadsheet includes the initiating dealer (Tier 1) key data elements, the reason for the recall and the shellfish information. The table below the initiating dealer data is set up to collect key data elements from their customers (Tier 2) and their subsequent customers (Tier 3 etc.). The instructions for filling out the fields are included on the second tab of the sortable spreadsheet.

In cases of recalls conducted in multiple states, the Authority(ies) in the receiving state(s) may compile the key data elements for their affected firms. Key data elements should be provided to the Authority where the initiating dealer is located and added to the master sortable spreadsheet. Authorities in other states may choose to pass recall KDEs through the FDA but should be aware that federal data sharing limitations may prevent effective exchange of information to other states. Therefore, it is recommended that Authorities share recall KDEs with each other directly and include the FDA as a courtesy. Contact information for individuals responsible for recalls in each member state may be found on the ISSC website. If a non-member state or foreign country is involved in a recall, the Authority can request contact information from the FDA.

Job Aid No. 6: Role of the principal coordinating Authority.

- The Authority where the initiating dealer is located should monitor the progress and effectiveness of the recall. This is best accomplished through regular communication and free sharing of data. Job Aid No. 6 outlines the procedure for an Authority to monitor a shellfish recall including providing dealers with the recall KDE spreadsheet or establishing how KDEs should be collected and provided, establishing communication and a communication schedule,

compiling data into a sortable spreadsheet, communicating with other Authorities, communicating with the FDA, and writing a final report.

Job Aid No. 7: Completing a Final Recall Report.

- This is an example of a final recall report, compiled by the principal coordinating Authority once a recall is terminated. This template is not required to be used by the Authority, but is highly recommended for clarity, completeness and consistency. The final report should include all relevant information related to the recall including an overall summary, the notification and communication process and final disposition of the shellfish.

.04. Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak

.05. Determining the Size of Closed Area as a Result of Illnesses

.06. Dispute Resolution.

The ISSC recognizes that shellfish Authorities should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish. In instances where prudent action is not taken by an Authority during recalls or illness outbreak situations, an Authority or FDA must notify the Executive Board regarding the Authority's decision and rationale for taking an action or failure to take an action. The Authority should provide the rationale for the proposed action by describing, at a minimum:

1. The potential effect on public health within that jurisdiction;
2. The potential effect on public health in other jurisdictions;
3. The potential economic impact on jurisdictions; and
4. The necessity for the action within the proposed timeframe.

The ISSC will consider the rationale of the Authority, and the Executive Board may decide to contact the appropriate agency head, Governor or other jurisdictional authority to secure prudent public health protection. If action is not taken after deliberation between the ISSC and the Authority, the ISSC may recommend an unresolved issue under the ISSC Constitution, By-Laws and Procedures, Procedure IX. Section 3.

~~**.05. Determining the Harvesting Periods Associated with Implicated Product for Identifying Shellfish to be Included in the Recall**~~

~~A. Identify the harvest date of all reported illness(es).~~
~~B. Determining the likelihood of product remaining in the marketplace with consideration of shellstock vs. in-shell vs. fresh shucked vs. frozen shucked.~~
~~C. Identify the date of [last] most recently reported illness(es) and the date of growing area closure.~~

	~~**.01 Determining the Scope of Implicated Product for Conducting a Recall**~~ ~~A. Are illnesses related to:~~ ~~(1) single harvester~~ ~~(2) single dealer or~~ ~~(3) single route of transportation~~ ~~(4) single retailer~~ ~~(5) single consumption event (e.g. party)~~ ~~(6) single product type or species~~ ~~(7) single growing area or harvest area~~ ~~B. Have any post harvest handling issues been identified that may have contributed to the occurrence of illness(es) including but not limited to harvesters, dealers, restaurants, retail, common carriers, or consumers.~~ ~~C. Production Consideration~~ ~~(1) Harvest event(s) and amount of production from growing area or areas (if commingling has occurred).~~ ~~(2) Number of harvesters associated with implicated shellfish~~ ~~(3) Number of dealers associated with implicated shellfish~~ ~~(4) Determine likelihood of product remaining in the marketplace (shellstock vs. in-shell vs. fresh shucked vs. frozen shucked).~~ ~~(5) Harvest or culture practices including wet storage, relay, resubmergence, transplant, etc.~~ ~~D. Strength of evidence, i.e. the evaluation should consider strength of evidence collected in relation to items .05 A., B., and C. above.~~ **.07 Guidance on Studies Used in the Reopening of an Area Temporarily Placed in the Closed Status Due to an Emergency Condition, a Discharge of Raw Sewage, or when Conditional Area Management Plan (CAMP) Performance Standards are not Met**
12. Public Health Significance	Recalls are an important tool used by dealers and Authorities to control the distribution of contaminated shellfish and minimize or eliminate the possibility of consumers becoming ill. The revised guidance submitted by the ISSC Recall Committee explains how to conduct a successful recall and provides job aids dealers and Authorities can use to train for or execute a recall.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A – Included in proposal text.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Andrew Bell
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7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	Suggested Forms Update
10. Specific NSSP Guide Reference	Section V. Suggested Forms
11. Text of Proposal/ Requested Action	Section V. of the Guide contains Suggested Forms, such as receiving logs and sales logs, for use by dealers in meeting Model Ordinance requirements. These suggested forms haven't been updated in some time, and so are no longer compatible with current MO requirements and are no longer useful. This proposal replacements the following outdated suggested forms: Shellfish Harvest Record (page 456), Shellfish Harvest/Purchase Record (page 457), Shellfish Harvest Purchase/Record (page 458), Shellfish Sales Record (459), Shellfish Disposition Record (page 460). The outdated suggested forms are replaced with the following suggested forms (attached): Receiving Record for Shellstock from Harvesters, Receiving Record for Shellstock from Dealers, Receiving Record for Shucked Shellfish, Receiving Record for In-Shell Product, Transaction Record, Corrective Action Record, Daily Sanitation Record (daily form), Daily Sanitation Record (weekly form), Monthly Thermometer Calibration Record
12. Public Health Significance	Currently the Guide contains suggested forms that are not in compliance with existing Model Ordinance requirements. If these outdated suggested forms are used, shellfish would not meet the necessary requirements for temperature control and shellfish sanitation. These forms should be updated with versions that are compliant with existing Model Ordinance requirements.
13. Cost Information	None. It is not a requirement to use these suggested forms – they are included in the Guide for optional use to aid dealers in meeting Model Ordinance requirements, but dealers may develop their own equivalent forms and continue using existing forms that have been approved by Authorities.
14. Changes Needed to Guidance (if proposed change is adopted)	Section V. Suggested Forms