Proposal No. 2 7 - 2 2 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
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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