Proposal Subject: Transportation and Critical Control Points

Specific NSSP Guide Reference:
Section II Model Ordinance, Chapter IX. Transportation
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

Text of Proposal/ Requested Action:

Recommended Changes to Chapter IX. Transportation

Requirements for the Harvester/Dealer.

.01 Trucks or Other Vehicles Used to Transport Shellstock to the Original Dealer.

A. The harvester, or dealer who transports shellstock from the harvester to the original dealer, shall assure that all trucks used to transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.
B. Storage bins on trucks or other vehicles used in the transport of shellstock for direct marketing shall be:
   (1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; and
   (2) Provided with effective drainage.
C. Shellstock shall be transported in adequately refrigerated trucks or iced when the shellstock have been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.
D. Prechilling trucks or other vehicles to 45º or below shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.
E. When mechanical refrigeration units are used, the units shall be:
   (1) Equipped with automatic controls; and
   (2) Maintained at an ~~Capable of maintaining the~~ ambient air temperature in the storage area at temperatures of 45º Fahrenheit (7.2º Centigrade) or less in the storage area
F. Any ice used to cool shellstock during transport shall meet the requirements of Chapter XI.02A~~(~~. (2).
G. Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where shellstock is stored.

.02 Receiving Shellfish

A. The dealer shall reject or discard any shellfish shipments which:
   (1) Do not originate from a licensed harvester or dealer; and/or
   (2) Are unwholesome, inadequately protected, or whose source cannot be identified.
B. Transportation agents or common carriers used by a dealer are not required to be certified.
C. The dealer shall:
   (1) Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in this Chapter;
   (2) Place shellstock under temperature control within 2 hours after receipt from the harvester, or when the dealer is also the harvester, when shellstock reaches the dealer's facility;
   (3) Ensure that shellstock are not permitted to remain without ice,

mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50° Fahrenheit (10° Centigrade) or less for more than 2 hours at points of transfer such as loading docks;

(4) Ensure that shucked shellfish and in-shell product are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and

(5) Ensure that frozen shellfish remain frozen.

D. For the purpose of this section, temperature control is defined as the management of the environmental temperature of the shellstock by means of ice, mechanical refrigeration or other means approved by the Authority.

.05 Shipping Times.

A. Shipping Time is No More Than Four Hours.

(1) When the shipping time is four hours or less, the dealer shall ship all shellfish:

(a) Well iced; or

(b) Using other acceptable means of refrigeration.

(2) When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be ~~capable of~~ maintained~~ing the ambient air in the storage area~~ at temperatures of 45° Fahrenheit (7.2°Centigrade) or less in the storage area.

(3) The dealer shall not be required to provide thermal recorders during shipment.

(4) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.

B. Shipping Time is Greater Than Four Hours.

(1) When the shipping time is greater than four hours, the dealer shall ship all shellfish in:

(a) Mechanically refrigerated conveyances ~~which are equipped with automatic controls and capable of maintaining the ambient air in the storage area~~ at temperatures of 45° Fahrenheit (7.2° Centigrade) or less in the storage area; or

(b) Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2° Centigrade) or less.

(2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.

(3) The initial dealer shall note the date and time on the temperature-indicating device, if appropriate.

(4) Each receiving dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.

(5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.

(6) An inoperative temperature-indicating device shall be considered as no recording device.

Recommended Changes to Chapters XI. Shucking and Packing

Requirements for Dealers.
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only:
   (1) Shellstock obtained from a licensed harvester who has:
      (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and [C]
      (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or [C]
   (2) Shellstock obtained from a dealer other than the original harvester who has:
      (a) ~~Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature;~~ and~~or~~ 50°F (10°C) internal temperature or less; ~~or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less;~~ [C]; and
      (b) Identified the shellstock with a tag on each container or transaction record with each bulk shipment. [C]
   (3) 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 X.08; and **[C]**
   (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;
      (a) Iced; or **[C]**
      (b) Placed and stored in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**
      (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in **§**B (1) or **§**B (2) for more than 2 hours at points of transfer such as loading docks. **[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. **[C]**

D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:
   (1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three hours of shucking. **[C]**
   (2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within four hours of removal from refrigeration. **[C]**

(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° F (7.2° C) or less within two hours after the heat shock process. **[C]**

(4) 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 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 2 hours during processing. **[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. Shellstock Shipping Critical Control Point.~~

(1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

Recommended Changes to Chapter XII. Repacking of Shucked Shellfish
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:

(1) Originated from a dealer who has:

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

(b) 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 repacked shucked shellfish do not exceed an internal temperature of 45° F (7.2° C) for more than 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 in ice. **[C]**

D. Shellstock Shipping Critical Control Point Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

Recommended Changes to Chapter XIII. Shellstock Shipping
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only:

(1) 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; or **[C]**

(2) Shellstock obtained from a dealer other than the original harvester who has:

(a) ~~Shipped the shellstock adequately iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature~~ and~~or~~ 50°F (10°) internal temperature ~~or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°) or less **[C];**~~ and

(b) Identified the shellstock with a tag on each container. **[C]**

(3) In-shell product obtained from a dealer who has;

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

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

B. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only:

(1) 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; or **[C]**

(2) Shellstock obtained from a dealer other than the original harvester who has:

(a)Shipped the shellstock adequately iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature or 50°F (10°) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°) or less **[C]**; and

(b)Identified the shellstock with a tag on each container. **[C]**

(3) In-shell product obtained from a dealer who has:

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

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

C. 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 X.08; and **[C]**

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

(a) Iced; or **[C]**

(b) Placed in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**

(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §~~B(~~B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

D. 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. **[C]**

E. Shellstock Shipping Critical Control Point

(1) Shellstock that is received bearing a restricted use tag shall only be

shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

(2) Should a State be implementing a *Vibrio parahaemolyticus* or *Vibrio vulnificus* Control Plan the dealer shall only ship shellstock that has been cooled to the temperature outlined in the State Plan.

Recommended Changes to Chapter XIV. Reshipping
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:

(1) Originated from a dealer other than the original harvester who has:

(a) ~~Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; and~~or 50°F (10°C) internal temperature or less; ~~or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less; [C];~~ and/or

(b) Shipped the shucked shellfish and/or in-shell product iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]** and

(c) 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. **[C]**

Shellstock Shipping Critical Control Point Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

Public Health Significance:

The present *Vv* and *Vp* Control Plans of the Model Ordinance include time to temperature controls which require that shellstock be cooled and maintained at specific temperatures to limit post-harvest growth of *Vv* and *Vp*. For these controls to be effective it is imperative that the shellstock be maintained at the temperatures outlined in the Control Plans. The proposed changes to Chapter IX., XI., XIII., and XIV. are intended to modify present requirements to ensure that these temperatures are maintained. Recent FDA audits of *Vv* and *Vp* Control Plan compliance and reports from States and the industry suggest that these modifications are necessary.

Action by 2011 Task Force II

Recommended referral of Proposal 11-201-B to an appropriate committee with representation from all regions to develop Model Ordinance language changes to support the time temperature requirements of the State's *Vibrio* Management Plans. This committee will be appointed and approved by the Executive Board at its closing Board meeting. The committee will be expected to meet within two (2) weeks of the close of the Conference. After its initial meeting, the committee shall meet by teleconference biweekly prior to an Executive Board meeting until the proposal is completed and at least once subsequent to the dissemination of the proposal and prior to an Executive Board meeting. The draft proposal that is to be considered by the Executive Board shall be disseminated to the ISSC membership a minimum of three (3) weeks prior to the next Executive Board meeting and posted on the ISSC web site.

The Committee is directed to make recommendations to the Executive Board for interim approval with an effective date prior to the 2012 *Vibrio* season. The State's Authorities are requested to begin advising and educating their industries of these changes. Additionally, the committee will develop guidance for implementation of

these controls.

Action by 2011 General Assembly

Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part B

Action by USFDA 02/26/2012

FDA concurred with Conference action on Proposal 11-201Part B but did not concur with Conference action on Proposal 11-201 Part A.

Action by 2012 Shipping and Receiving Committee

Recommended adoption of Proposal 11-201B as amended.

Recommended Changes to Definitions

(1) Adequate Icing means that the amount and application of the ice is sufficient to ensure that immediate cooling begins and continues for all shellfish. If ice slurry is used and the shellfish are submerged the presence of ice in the slurry indicates adequate icing.

(23) Conveyance means any type of container used to transport shellfish. The controls of the National Shellfish Sanitation Program (NSSP) are intended to address the container in which the shellfish are being held during transport from landing to final consumer. For the purposes of meeting the NSSP time temperature requirements for conveyances, the containers in which the shellfish are being held must meet the required temperatures. Should shellfish be shipped in a small container within a cargo space the temperature requirement would apply only to the temperature within the container.

(62) Landing means the point at which shellstock is put on land or a dock.

(65) Lot of Shellstock means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area gathered by one or more harvesters. A lot may also be used to segregate the harvest times and intended uses of shellstock for the purposes of complying with time to temperature requirements.

(87) Processing means any activity associated with the handling, shucking, freezing, packing, labeling or storing of shellfish in preparation for distribution. This would include the activities of a shellstock shipper, shucker packer, repacker, reshipper, or depuration processor.

(92) Receipt of Shellfish means the Critical Control Point where a shellfish dealer takes possession of shellfish at a location where it will be processed and/or will be shipped to another dealer or retail establishment. At this (location) point the dealer will monitor at receiving Critical Control Points to ensure compliance with Critical Limits. This is also the (location) point at which the dealer will monitor storage and shipping Critical Control Points.

(120) Trip Records means a form of written documentation that includes the date and time of each lot of shellfish harvested.

Recommended Changes to 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 of the following:

(1) The State *Vibrio vulnificus* Control Plan as outlined in Chapter II. @.04; or

(2) The State *Vibrio parahaemolyticus* Plan as outlined in Chapter II. @.05; or

A. 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°F - 60 °F (10°C - 15 °C)	24 hours
Level 3	>60 °F - 80 °F (15 °C - 27 °C)	18 hours
Level 4	>80 °F (>27 °C)	12 hours

B. For the purposes of this section, temperature control is defined as the management of the temperature of shellstock by means of ice, mechanical refrigeration or other approved means necessary to lower and maintain the temperature of the shellstock to comply with Chapter XI, XIII., or XIV.

C. The Authority shall establish the water or air temperature to be applied to the requirements above for each growing area by averaging the previous five (5) years maximum monthly water or air temperatures.

D. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.

E. The Authority shall ensure that harvesters document and provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements

F. Shellstock intended for Wet Storage, Depuration, Post Harvest Processing (PHP) or "For Shucking Only by a Certified Dealer" must either be shucked, introduced into PHP, Wet Storage, or Depurated within the times outlined in the matrix in Chapter VIII. @ .02 A (3) or meet the applicable time to temperature controls of Chapter VIII. @ .02 A. (3). Shellstock harvested under a State *Vibrio* Plan intended for Wet Storage or Depuration, must be placed in Wet Storage, Depuration or refrigeration to comply with time to temperature controls outlined in the State Authority *Vv* or *Vp* Control Plan.

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.

H. ~~H.~~ Authorities shall consider the need for shading in developing *Vv* and *Vp* Control Plans. Shading shall be required when deemed appropriate by the Authority when implementing @.02 A. (1) (2) and (3).

.02 Shellstock Harvesting and Handling.

G. Shellstock Temperature Control

(1) All harvesters shall comply with the applicable time to temperature requirements of

(a) State *Vv* and *Vp* Control Plans outlined in Chapter II. @.04 and @.05; 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.

NOTE: State *Vv* and *Vp* Control Plans can be accessed on the ISSC web site using the following link: www.issc.org.

~~**.03 Shellstock Temperature Control.**~~

~~Note: The Authority shall select one of the following options for implementation in its State. The time-temperature matrix for each of the options applies only to the original harvester or harvester/dealer of shellstock for the purposes of handling and transporting shellstock to the first point of processing or packing.~~

~~OPTION 1~~

~~**(Mandatory for confirmed *Vibrio vulnificus* problem) *If the waters of a State have been confirmed as an original source of product associated with two (2) or more Vibrio vulnificus illnesses, the Authority shall adopt the following exposure time to temperature controls in the time-temperature matrix below only for shellfish intended to be consumed raw.***~~

~~**For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering the temperature of the shellstock and will maintain it at 50 degrees Fahrenheit (10 degrees Centigrade) or less.**~~

~~**Time-Temperature Matrix for *Vibrio vulnificus*:**~~

~~**Action Level**~~	~~**Water Temperature**~~	~~**Maximum Hours from Exposure to Temperature Control**~~
~~**Level 1**~~	~~**<65 °F**~~	~~**36 hours**~~
~~**Level 2**~~	~~**65 °F - 74 °F (18 °C - 23 °C)**~~	~~**14 hours**~~
~~**Level 3**~~	~~**>74 °F - 84 °F (>23 °C - 28 °C)**~~	~~**12 hours**~~
~~**Level 4**~~	~~**> 84 °F (>28 °C)**~~	~~**10 hours**~~

~~**The Authority shall establish the water temperature to be applied in the matrix above for each growing area by averaging the previous 5 years maximum monthly water temperatures.**~~

~~**The time to refrigeration in the above matrix shall be based upon the first**~~

~~**shellstock harvested.**~~

~~**During Action Levels 2, 3, and 4, the product shall be shaded.**~~

~~**The Authority may approve other measures proposed by the industry to provide controls equivalent to the time-temperature requirements in the above matrix.**~~

~~**The Authority may set up a plan that allows for exemption of this option for shellstock that is to be post-harvest processed with an approved post-harvest process in accordance with NSSP Model Ordinance Chapter XVI. The Authority must develop a plan to ensure the security of shellstock harvesting.**~~

~~**The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.**~~

~~OPTION 2~~

~~***If a growing area in the State has been confirmed as an original source of product associated with two (2) or more* Vibrio parahaemolyticus illnesses within the past three years, the Authority shall adopt the following exposure time to temperature controls in the time-temperature matrix below or use Option 1. This *Vibrio parahaemolyticus* control measure applies only to shellfish from the affected growing area(s) which are intended to be consumed raw.**~~

~~***For the purposes of this control measure, identify and define growing areas in the State affected by* Vibrio parahaemolyticus based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.**~~

~~**For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at 50 °Fahrenheit (10 °Centigrade) or less.**~~

~~**Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.**~~

~~**The Authority may set up a plan that allows for exemption of this option for shellstock that is to be post-harvest treated with an approved post-harvest process in accordance with NSSP Model Ordinance Chapter XVI. The Authority must develop a plan to ensure the security of shellstock harvesting.**~~

~~**The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.**~~

~~**Time-Temperature Matrix for *Vibrio parahaemolyticus*:**~~		
~~**Action Level**~~	~~**Average Monthly Maximum Air**~~	~~**Maximum Hours from**~~

	~~Temperature~~	~~Exposure to Temperature Control~~
~~Level 1~~	~~≤66 °F (18 °C)~~	~~36 hours~~
~~Level 2~~	~~66 °F - 80 °F (19 °C - 27 °C)~~	~~12 hours~~
~~Level 3~~	~~≥81 °F (≥27 °C)~~	~~10 hours~~

~~OPTION 3~~

~~For those states that do not have to follow Option 1 or Option 2, the following time/temperature matrix will apply.~~

~~For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at, 50 °Fahrenheit (10 °Centigrade) or less.~~

~~Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempted from this temperature control plan when these products are intended for thermal processing.~~

~~Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service, and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.~~

~~The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.~~

~~Action Level~~	~~Average Monthly Maximum Air Temperature~~	~~Maximum Hours from Exposure to Temperature Control~~
~~Level 1~~	~~≤66 °F (18 °C)~~	~~36 hours~~
~~Level 2~~	~~66 °F - 80 °F (19 °C - 27 °C)~~	~~24 hours~~
~~Level 3~~	~~≥81 °F (≥27 °C)~~	~~20 hours~~

Recommended Changes to Chapter IX. Transportation

Requirements for the Harvester/Dealer.

~~**Requirements for the Authority**~~

~~**@.01 General.**~~

~~A. The Authority shall apply these requirements to all shellfish shipped in interstate commerce.~~

~~B. The Authority shall assure that:~~

(1) Shellfish are transported and maintained in accordance with the requirements of this Chapter; and
(2) Shellfish shipments originate from a dealer.

C. The Authority shall use the temperatures included in the sections below entitled @.02 Shipment Acceptability, @.03 Shipment Rejection, and @.04 Bacteriological Examination of Shellfish Shipments as the initial basis for taking regulatory action against any shellfish shipment in interstate commerce.

D. If an interstate shipment of shellfish is monitored, the monitoring shall take place within 24 hours of the shellfish entering the State.

@.02 Shipment Acceptability.

Shellfish shipments shall be considered acceptable when:

E. Shipments are properly identified with tags and/or labels and shipping documents;

F. Shellstock is alive and cooled to an internal shellstock body temperature of 50° Fahrenheit (10 ° Centigrade) or less;

G. Shucked shellfish and in-shell product are cooled to a temperature of 45° Fahrenheit (7.2 ° Centigrade) or less; and

H. The time-temperature indicating device shows that the ambient air temperature has exceeded 45° Fahrenheit (7.2 ° Centigrade) but the shellstock internal body temperature is 50 ° Fahrenheit (l0 ° Centigrade) or less; and

I. All other conditions of shipment in this Chapter are met.

Additional Guidance - Section IV Guidance Documents
Chapter II.12 Bacteriological Examination of Shellfish Shipments Decision Tree

@.03 Shipment Rejection.

J. Shellfish shall be rejected when:

(1) Shellfish are not properly identified with tags or shipping documents;
(2) The internal shellstock body temperature exceeds 60° Fahrenheit (15.6 Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII §@.03;
(3) Shucked shellfish temperature or the internal body temperature of in-shell product exceeds 50° Fahrenheit (10° Centigrade); or
(4) The Authority determines that the product is unwholesome or unsafe for human consumption.The Authority shall notify the shipping dealer, the receiving dealer, and the Authority in the State where the shipment originated of the shipment's rejection.

@.04 Bacteriological Examination of Shellfish Shipments.

If the State chooses to sample, the following protocol shall be used.

K. Bacteriological samples of any shellfish taken for the purpose of rejection of shipments from out-of-state dealers shall be collected within twenty-four hours of the shellfish entering a State.

L. Bacteriological examination shall be made of the shellfish shipment if:

(1) The internal body temperature of the shellstock exceeds 50° Fahrenheit (10° Centigrade) and is less than or equal to 60° Fahrenheit

~~(15.6° Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII @.03;~~
~~(2) The shucked shellfish temperature or the internal body temperature of in-shell product exceeds 45° Fahrenheit (7.2° Centigrade) and is less than or equal to 50° Fahrenheit (10° Centigrade);~~
~~(3) The shipping time exceeds four hours and there is no temperature recording device or the recording device is inoperative; or~~
~~(4) The Authority determines it is necessary.~~

.01 Trucks or Other ~~Vehicles~~ **Conveyances** Used to Transport Shellstock to the Original Dealer.

~~b.~~A. The harvester, or dealer wh~~o transports shellstock from the harvester to the original dealer, shall assure that all trucks~~Any conveyance used to transport shellstock ~~are~~ to the original dealer shall be properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.

~~c.~~B. Storage bins on conveyances ~~trucks or other vehicles~~ used in the transport of shellstock ~~for direct marketing~~ shall be:

~~a.~~(1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; and

~~b.~~(2) Provided with effective drainage.

~~d.~~C. Shellstock shall be transported in adequately refrigerated trucks~~ or iced when the shellstock have been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.~~ 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).

~~e. Prechilling trucks or other vehicles to 45º or below shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.~~

~~f.~~D. When mechanical refrigeration units are used, the units shall be:

~~a.~~(1) Equipped with automatic controls; and

~~b.~~(2) Maintained at an ambient air temperature necessary to comply with .01C above. ~~in the storage area at temperatures of 45º Fahrenheit (7.2º Centigrade) or less in the storage area~~

~~g.~~E. Any ice used to cool shellstock during transport shall meet the requirements of Chapter XI. .02 A. (2).

~~h.~~F. Cats, dogs, and other animals shall not be allowed in any part of the ~~truck or other vehicle~~ conveyance where shellstock is stored.

~~**.02 Receiving Shellfish**~~

~~A. The dealer shall reject or discard any shellfish shipments which:~~
~~(1) Do not originate from a licensed harvester or dealer; and/or~~
~~(2) Are unwholesome, inadequately protected, or whose source cannot be identified.~~

~~B. Transportation agents or common carriers used by a dealer are not required to be certified.~~

~~C. The dealer shall:~~
~~(1) Inspect incoming shellfish shipments to assure that the shipments are~~

~~received under the conditions required in this Chapter;~~
~~(2) Place shellstock under temperature control within 2 hours after receipt from the harvester, or when the dealer is also the harvester, when shellstock reaches the dealer's facility;~~
~~(3) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50° Fahrenheit (10° Centigrade) or less for more than 2 hours at points of transfer such as loading docks;~~
~~(4) Ensure that shucked shellfish and in-shell product are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and~~
~~(5) Ensure that frozen shellfish remain frozen.~~

~~D. For the purpose of this section, temperature control is defined as the management of the environmental temperature of the shellstock by means of ice, mechanical refrigeration or other means approved by the Authority.~~

.0~~3~~2 ~~Transportation Containers~~.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; and
(2) Operated and maintained to prevent product contamination.

B. All containers shall be cleaned with:
(1) Potable water; and
(2) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

.0~~4~~3 Cargo Protection From Cross Contamination.

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

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.
(3) In-shell product shipments shall be shipped on pallets.
(4) If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.

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;
(2) All cargo is placed on pallets; and
(3) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.

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

.0~~5~~4 Shipping **Temperatures**~~Times~~.

Shellfish dealers shall ship shellstock adequately iced; or in a conveyance pre-chilled at or below 45°F (7.2°C) ambient air temperature.

~~E. Shipping Time is No More Than Four Hours.~~
~~(1) When the shipping time is four hours or less, the dealer shall ship all~~

~~shellfish:~~

~~(a) Well-iced; or~~

~~(b) Using other acceptable means of refrigeration.~~

~~(2) When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be maintained at temperatures of 45° Fahrenheit (7.2°Centigrade) or less in the storage area.~~

~~(3) The dealer shall not be required to provide thermal recorders during shipment.~~

~~(4) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.~~

~~F. Shipping Time is Greater Than Four Hours.~~

~~(1) When the shipping time is greater than four hours, the dealer shall ship all shellfish in:~~

~~(a) Mechanically refrigerated conveyances at temperatures of 45° Fahrenheit (7.2° Centigrade) or less in the storage area; or~~

~~(b) Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2° Centigrade) or less.~~

~~(2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.~~

~~(3) The initial dealer shall note the date and time on the temperature-indicating device, if appropriate.~~

~~(4) Each receiving dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.~~

~~(5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.~~

~~(6)~~(1) An inoperative temperature-indicating device shall be considered as no recording device.

.05 Transportation Records

All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of Chapter IX. .04. This documentation must include a notice of all shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) and indicate the presence of a time/temperature recording device.

Recommended Changes to Chapters XI. Shucking and Packing

Requirements for Dealers.
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. ~~The dealer shall shuck and pack only:~~

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

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

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

~~ii.~~(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 shuck and pack only ~~S~~shellstock obtained and transported from a dealer ~~other than the original harvester~~ who has:
~~(a) and 50°F (10°C) internal temperature or less; [C]; and~~
(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); and~~.~~
(b) Provided documentation as required in Chapter IX. .04 and .05; and
~~(a)~~(c) ~~Shipped the shellstock a~~Adequately iced the shellstock; ~~or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C)~~ or ~~less~~
~~(b)~~(d) Placed Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or
~~(c)~~(e) Cooled the shellstock to an ~~50°F (10°C)~~ internal temperature of 50°F (10°C) or less.~~; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less;~~ [C]

(3) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (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) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

(4) The dealer shall shuck and pack only ~~I~~in-shell product obtained from a dealer who has:
(a) Shipped the in-shell product:
(i) Aadequately 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:
~~(7)~~(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
~~(1)~~(2) Once placed under temperature control and until shucked the ~~sale to the processor or final consumer,~~ shellstock shall ~~be;~~:
(a) Be ~~I~~iced; or **[C]**
(b) Be ~~P~~placed and stored in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**
(c) Not be permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in ~~§~~ **.01** B (1) or ~~§~~ **.01** B (2) (a) or (b) for more than two (2) hours at points of processing or transfer such as loading docks. **[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. **[C]**

D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three (3) hours of shucking. **[C]**
(2) For shellstock refrigerated prior to shucking, 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]**
(3) If heat shock is used, 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. **[C]**
(4) 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]**

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. Shellstock Shipping Critical Control Point.
(1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

.03 Other Model Ordinance Requirements

G. Shellfish Storage and Handling
(11) All shellstock obtained from a licensed harvester shall be:
(a) Adequately iced;
(b) Placed in a storage area maintained at 45°F (7.2°C); or
(c) Shucked within two (2) hours of receipt. **[S C/K]**

Recommended Changes to Chapter XII. Repacking of Shucked Shellfish
.01 Critical Control Points.

H. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:
(1) Originated from a dealer who has:
(a) Shipped the shellfish iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]** and
(b) Identified the shellfish with a label as outlined in Chapter X.06. **[C]**

I. 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 2 hours. **[C]**

J. 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 in ice. **[C]**

~~K. Shellstock Shipping Critical Control Point Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.~~

Recommended Changes to Chapter XIII. Shellstock Shipping
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. ~~The dealer shall ship or repack only:~~

(1) The dealer shall ship or repack only ~~S~~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; ~~or~~ and **[C]**

~~(b)~~(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 ~~S~~shellstock obtained and transported from a dealer who has ~~other than the original harvester 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. .04 and .05; and **[C]**

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

(d) Shipped the shellstock in a convenyance maintained at or below 45° F (7.2°C) ambient air temperature; or **[C]**

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

(3) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (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) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

~~11.~~(4) The dealer shall ship or repack only ~~i~~in-shell product obtained from a dealer who has;

~~•~~(a) Shipped the in-shell product:

(i) ~~a~~Adequately iced; or

(ii) ~~i~~In a conveyance or at or below 45°F (7.2°C) ambient air temperature; or

(iii) At an internal temperature of 45°F (7.2°C) ~~internal temperate~~ or less; and **[C]**

~~(a)~~(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 X.08; and **[C]**

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

(a) Be ~~I~~iced; or **[C]**

(b) Be ~~P~~placed in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**

(c) Not be permitted to remain without ice, mechanical refrigeration or other approved methods of ~~refrigeration~~storage, as required in ~~$D(~~.01 B. (1) or ~~$~~.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 Vv Control Plans. [C]

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

(4) All other shellstock obtained from a licensed harvester 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]

(5) Product intended for relay, wet storage, depuration, or Mercenaria sp which is 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) Iced; or **[C]**

(2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. **[C]**

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

(1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

(2) Should a State be implementing a ~~*Vibrio parahaemolyticus* or *Vibrio vulnificus* Control Plan the dealer shall only ship shellstock that has been cooled to the temperature outlined in the State Plan.~~ All shellstock is cooled to meet the requirements outlined in .01 B. 3. and 4. above prior to shipment. The original dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. 3. prior to achieving the internal temperature of 50°F (10°C). Should the original dealer choose this option the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. **[C]**

.03 Other Model Ordinance Requirements

F. Shellfish Storage and Handling.

(6) All Shellstock obtained from a licensed harvester shall be:

(a) Adequately iced;

(b) Placed in a storage area maintained at 45°F (7.2°C); or

(c) Processed within two (2) hours of receipt. **[S$^{c/k}$]**

Recommended Changes to Chapter XIV. Reshipping

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. ~~The dealer shall reship only shellfish which:~~

(1) The dealer shall reship only shellfish obtained and transported ~~Originated~~ from a dealer ~~other than the original harvester~~ who has:

~~(a) and 50°F (10°C) internal temperature or less; and/or~~

~~(b) Shipped the shucked shellfish and/or in-shell product iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]** and~~

(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. **[C]**

(b) Provided documentation as required in Chapter IX. .04 and .05; and **[C]**

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

(d) Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or **[C]**

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

(2) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (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) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[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 ~~be~~:

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

~~b.~~(2) Be ~~P~~placed in a storage area or conveyance maintained at 45 °F (7.2 ° C) or less; and **[C]**

~~c.~~(3) 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]**

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. **[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.**[C]**

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

~~(1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.~~ **[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]**

Recommended Changes to Chapter XV. Depuration.
Requirements for the Dealer
.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 transaction record on each bulk shipment; **[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) iIdentified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); **[C]** and

(b) Provided documentation as required in Chapter IX .04 and .05; and **[C]**

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

(d) Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or **[C]**

(e) 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), (d) or (e).Shipments of four (4) hours or less will not be required to have a time/temperature device. **[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 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 that:

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

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

(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 that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; **[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 °Fahrenheit (7.2 °Centigrade) or less; **[C]** and

(c) Not permitted to remain outside temperature control for more than 2 hours at points of processing or transfer such as loading docks. **[C]**

.03 Other Model Ordinance Requirements

F. Shellstock Storage and Handling.

(11) Depurated packaged shellstock shall be protected from contamination at all times and be held at an ambient temperature not to exceed 45 °Fahrenheit (7.2 °Centigrade). **[K]**

(12) All shellstock received from a licensed harvester intended for depuration must be introduced into depuration, adequately iced, or placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt.

Recommended Changes to Chapter XVI. Post Harvest Processing.

C. For the purpose~~s~~ of ~~refrigeration~~ product temperature the receiving and storage critical control points of Chapter XI~~,~~ shall apply to shellstock prior to PHP processing. Following PHP processing, if the product is dead, the product shall be treated as in-shell or shucked product. If the product is live, the product shall be treated as shellstock.

Recommended Changes to Section IV Guidance Documents, Chapter III. .07 Time and Temperature Controls.

Introduction.

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish Guidance Documents provide the public health principles supporting major components of the NSSP, its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most States apply the requirements intrastate. All requirements of the Program can be found in the current edition of the NSSP Model Ordinance.

A goal of the NSSP is to control the safety of molluscan shellfish for human consumption by preventing unnecessary growth of bacterial pathogens resulting from improper or ineffective cooling or from time to temperature abuse.

Chapter II. Risk Assessment and Risk Management.

Authorities must conduct Risk Assessments to determine the appropriateness of developing *Vibrio vulnificus (V.v.)* or *Vibrio parahaemolyticus (V.p.)* Control Plans.

The Authority in conjunction with the FDA will determine whether the State will implement a *V.v.* plan, a *V.p.* plan, or the control option for all other harvested shellstock (see Table 1). In developing *V.v.* and *V.p.* Control Plans the Authority must conduct *V.v.* and *V.p.* risk evaluations. The specific requirements of these evaluations are detailed in Chapter II. @ .04 and Chapter II. @ .05.

Chapter VIII. Harvesters Time to Temperature Control.

There are several pathogens that can cause illness from consumption of molluscan shellfish. Not all known pathogens associated with shellfish reproduce in the shellfish. However there are several pathogens that multiply in shellfish and present a health concern. Most Vibrios grow in shellfish and the rate of growth is dependent upon temperature. To minimize illness, the NSSP includes controls to limit exposure to warm temperatures. The controls begin at harvest and are applied at every level of processing and handling. This guidance document provides an explanation of those controls.

A. Authority Responsibilities.

Authorities must establish time to temperature controls for harvesters. The Authority in conjunction with the FDA will determine whether the State will implement a *V.v.* Plan (Chapter II. @.04), a *V.p.* Plan (Chapter II. @.05), or the control option of Chapter VIII. @.02 A. (3). In developing *V.v.* and *V.p.* Control Plans the Authority must conduct *V.v.* and *V.p.* risk evaluations. The specific requirements of these evaluations are detailed in Chapter II. @.04 and Chapter II. @.05. The Authority will advise the industry of the applicable harvest controls. The water and air temperatures used to establish these controls shall be representative of the temperatures of growing areas of the state from which harvesting is occurring.

B. Harvesters.

Harvesters must be aware of the applicable time to temperature requirements. Harvesters can obtain this information by contacting the

Shellfish Control 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 the Dealers Facility**
Level 1	≤50°F (10°C)	36 hours
Level 2	50°F - 60 °F (10°C - 15 °C)	24 hours
Level 3	>60 °F - 80 °F (15 °C - 27 °C)	18 hours
Level 4	>80 °F (>27 °C)	12 hours

The harvest controls and *V.v.* and *V.p.* State Control Plans and the matrix above apply only to the harvester or harvester/dealer of shellstock for the purposes of handling and delivery of shellstock to the original dealer.

The harvester must provide harvest records to the original shellfish dealer demonstrating compliance with the applicable time and temperature requirements. This record may be in the form of a harvester tag, trip record, or other record deemed appropriate by the Authority. The record must include the date and time harvest begins for each lot of shellfish harvested. For States that establish and limit harvest times the recording of the time harvest begins may not be necessary. The time harvest begins is the time when the first shellstock in a lot is taken from the water or, in the case of intertidal harvest, the time of first exposure. Should the harvesting technique used involve re-submerging, the Authority must approve the harvesting technique to assure that the harvest method does not promote post harvest growth of pathogens associated with shellfish. The Authority shall not allow re-submerging techniques that promote Vibrio growth. It is expected that some harvest vessels will be equipped with refrigeration capabilities to accommodate large volume harvesting. Where cooling occurs on a harvest vessel, or prior to delivery to the original dealer, the harvester must provide documentation to the original dealer that the time and temperature requirements established by the Authority have been met.

To comply with the time to temperature requirements for harvested shellstock (Chapter VIII. @.02 A (1), (2), and (3)), the type of cooling must be capable of achieving the required internal temperature within the time frames required in the State Vibrio Control Plans or 50°F (10°C) prior to shipment (see shellstock storage critical control point Chapter XIII. .01 B. (3) and (4)). The use of temporary or inadequate cooling is not acceptable. Cooling that occurs prior to receipt by the original dealer does not alleviate the dealer requirement to document the time to internal temperature requirements.

To comply with the time to temperature requirements for shellstock intended for Wet Storage, Depuration, Post Harvest Processing (PHP), or "For Shucking Only by a Certified Dealer", the dealer must comply with one of the options below:

Option 1

The dealer must shuck or introduce into Wet Storage or Depuration, within the applicable time to temperature controls of Chapter VIII. @.02 A (3) and Chapter XIII .03; or

Option 2
The dealer must place the shellstock in temperature control within the applicable time to temperature controls of Chapter VIII. @.02 A (3) and Chapter XIII .03.

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. Authorities may exclude other species when intended for thermal processing.

In harvesting situations which expose shellstock to direct sunlight that increases product temperature, the Authority must consider the appropriateness of shading in the development of *V.v.* and *V.p.* Control Plans and may require shading when implementing controls for all other shellstock harvesting.

Chapter IX.

Conveyances Used to Transport Shellstock to the Original Dealer.

Conveyances used to transport shellstock from the harvest area to the original dealer shall be constructed to prevent contamination, deterioration, or decomposition of the shellstock during transport.

For shellstock being delivered within the time to temperature controls of Chapter VIII. @.02 A. (1) (2) and (3), refrigeration of the conveyance is not required. However, shellstock transport must comply with Chapter IX .01 C. and may not be shipped in a manner which would cause the temperature of the shellstock to increase. Persons responsible for transporting shellstock must take reasonable steps to assure that the shellstock temperature is not increased unnecessarily as a result of the method of transport. An example would be a closed-in truck with a high internal temperature caused by very warm ambient temperature or exposed to direct sunlight for a long period of time while closed. The Authority shall monitor this activity to assure compliance. When temperature control is necessary during transport to the original dealer to comply with the Authority established time to temperature controls, the shellstock must be cooled with ice or mechanical refrigeration. This cooling must be capable of achieving the required internal temperature of 55°F (12.7°C) for shellstock harvested under State *V.v.* Plans or 50°F (10°C) for all other shellstock.

Should compliance with internal temperatures involve refrigeration on board the vehicle or in the transportation conveyance prior to reaching the original dealer, shellstock must be cooled as necessary to comply with the internal temperature of 55°F (12.7°C) for shellstock harvested under State *V.v.* Plans or 50°F (10°C) for all other shellstock. Refrigeration units must be pre-chilled to 45°F (7.2°C) and the refrigeration unit must be maintained at a temperature to ensure that the shellstock temperature is not allowed to increase. Ice can also be used to cool shellstock. Any ice on-site at a certified dealer shall be from

potable water in a commercial ice machine or come from a source certified by the Authority or the appropriate regulatory Authority. Once cooling of the shellstock begins, that cooling must be continued using an acceptable cooling method.

Conveyances Used to Transport Shellstock from Dealer to Dealer.

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 indicating the time of shipment and that all shipping containers were pre-chilled. 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 shipping 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 documentation 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 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 XI. Shucking and Packing Dealer Requirements.

Shellstock Received from Harvesters

Dealers receiving shellstock from a harvester must only accept shellstock that is accompanied by documentation from the harvester indicating the time of harvest. The original dealer must document and maintain a record that cooling of the shellstock began at a time that was compliant with the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3). Shellstock intended for shucking must include the same harvester documentation as shellstock intended for raw consumption. The documentation may be in the form of a harvester tag which includes date and time of harvest or a trip record, or other form that meets the requirements of the Authority.

Although a record is not required of the shipment temperature from the harvester, dealers should make sure that the means of transport to the dealer does not allow unreasonable temperature increases.

The dealer must document and maintain a HACCP record that the shellstock received from harvesters are either shucked or placed in a refrigeration unit at or below 45°F (7.2°C) within the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3) and Chapter XIII .03.

Storage Requirements

All shellstock obtained from a licensed harvester shall be placed in a storage area maintained at 45°F (7.2°C) or less within two (2) hours of receipt. This two (2) hour requirement does not allow the dealer to exceed the time to temperature requirements of Chapter VIII. @.02 A. (1) or (2) as outlined in State Vibrio Control Plans.

In cases when shellstock that is harvested in compliance with State *V.v.* or *V.p.* Plans does not reach the dealer within the time periods outlined in the State Vibrio Plans, the dealer may elect as a corrective action to convert the shellstock to a restricted use such as PHP or "For Shucking Only by a Certified Dealer". Should the dealer choose this option the dealer must adhere to the time to temperature requirements of Chapter VIII. @ .02 A. (3).

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for shucking and packing 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 documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

When a dealer receives shellstock that was harvested in compliance with Chapter VIII @ .02 A (3) not cooled to an internal temperature of 50°F (10°C) prior to shipment the receiving dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05 (Indicate in a record the presence of a time/temperature recording device). For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation. Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary. If the shipment is less than four (4) hours, a time temperature recording device is not required.

Storage Requirements

Shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required

in Model Ordinance Chapter XI. .01 B. (1) or B. (2) for more than two (2) hours at points of processing or transfer such as loading docks.

Once shellstock has been shucked by the dealer, the dealer shall comply with the processing and storage Critical Control Points of Chapter XI. .01 D. and E.

All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Chapter XIII. Shellstock Shipping Dealer Requirements.

Shellstock Received from Harvesters

Dealers receiving shellstock from a harvester must only accept shellstock that is accompanied by documentation from the harvester indicating the time of harvest. The original dealer must document and maintain a record that cooling of the shellstock began at a time compliant with the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3). Shellstock intended for further processing must include the same harvester documentation as shellstock intended for raw consumption. The documentation may be in the form of a harvester tag which includes date and time of harvest or a trip record or other form that meets the requirements of the Authority.

Although a record is not required of the shipment temperature from the harvester, dealers should make sure that the means of transport to the dealer does not allow unreasonable temperature increases.

The dealer must document and maintain a HACCP record that the shellstock was shucked, iced, or placed in a refrigeration unit at or below 45°F (7.2°C) within the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3).

Storage Requirements

All shellstock obtained from a licensed harvester shall be placed in a storage area maintained at 45°F (7.2°C) or less within two (2) hours of receipt. This two (2) hour requirement does not allow the dealer to exceed the time to temperature requirements of Chapter VIII. @.02 A. (1)or (2) as outlined in State Vibrio Control Plans.

Shellstock received from harvesters that harvested shellstock in compliance with the State *Vibrio vulnificus* Control Plan as outlined in Chapter VIII. @.02 A. (1) must be placed in refrigeration within the times outlined in the State *V.v.* Control Plan and cooled by the original shipper to 55°F (12.7°C) within the time period outlined in the State *V.v.* Control Plan (see Chapter XIII. .01 B. (3)), unless the shellstock is labeled for a restricted use. The original dealer must document that the internal temperatures listed above were achieved within the time frame outlined in the State *V.v.* Control Plan.

Shellstock received from harvesters that harvested shellstock in compliance with the State *V.p.* Control Plan as outlined in Chapter VIII. @.02 A. (2) must be cooled by the original shipper to 50°F (10°C) (see Chapter XIII. .01 B. (3)), unless the shellstock is labeled for a restricted use. The original dealer must document that the internal temperatures listed above were achieved within the time frame outlined in the State *V.v.* Control Plan. 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. It is assumed that refrigeration capable of achieving an internal temperature of 55°F (12.7°C) within six (6) hours would also achieve an internal temperature of 50°F (10°C) within ten (10) hours.

Shellstock received from harvesters that harvested shellstock in compliance with the time to temperature control matrix outlined in Chapter VIII. @.02 A. (3) and restricted use shellstock must be cooled to an internal temperature of 50°F (10°C) prior to shipment (see Chapter XIII. .01 B. (4)). (Product intended for relay, wet storage, depuration, or *Mercenaria sp* which is being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed in Chapter XIII. .01 B. (4).) The original dealer must document that the internal temperatures listed above have been achieved prior to shipment.

In cases when shellstock that is harvested in compliance with State *V.v.* or *V.p.* Plans does not reach the dealer within the time periods outlined in the State Vibrio Plans, the dealer may elect as a corrective action to convert the shellstock to a restricted use such as PHP or "For Shucking Only by a Certified Dealer". Should the dealer choose this option the dealer must adhere to internal temperature requirements of Chapter XIII .01 B. (4).

Where cooling occurs on a harvest vessel, or prior to delivery to the original dealer, the harvester must provide documentation to the original dealer that the time and temperature requirements the Authority and outlined in the State Vibrio Control Plan have been met. The information must be included in the dealer's HACCP records.

Shipping Requirements

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature recording device indicating that continuing cooling has occurred.

Prior to shipping shellstock received from harvesters the dealer must comply with the internal temperature requirements of Chapter XIII. .01 B. (3) and (4).

Should the original dealer choose to ship shellstock which was harvested in compliance with the time to temperature control matrix outlined in Chapter VIII. @.02 A. (3) but has not been cooled to an internal temperature of 50°F (10°C), the dealer shall include 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) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary.

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for shipping and repacking 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 documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

When a dealer receives shellstock that was not cooled to an internal temperature of 50°F (10°C) prior to shipment the receiving dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. Additionally the dealer must indicate in a record the presence of a time/temperature recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation. Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary. If the shipment is less than four (4) hours, a time temperature recording device is not required.

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
3. An internal temperature of 50°F (10°C) which can be measured by opening the shellstock and measuring the meat or using a temperature indicating gun which measures product temperature; or
4. The shipment of shellfish is accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting internal temperature required and notice of the presence of a time/temperature device indicating that continuous cooling has occurred.
5. For shellstock which was shipped prior to achieving an internal temperature of 50°F (10°C) the dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. The dealer must indicate in a record the presence of a time/temperature recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation.

Storage Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration, or other approved methods of refrigeration, as required in Model Ordinance Chapter XI. .01 B. (1) or B. (2) for more than two (2) hours at points of processing or transfer such as loading docks. All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Shipping Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of 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 original dealer choose to ship shellstock which was received with documentation indicating that the product was not cooled to an internal temperature of 50°F (10°C) prior to shipment, the dealer must adhere to one of the following:

1. Include documentation indicating that the shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuing cooling has occurred. The shipment must 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 device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**
2. Should a dealer receive shellstock from a dealer who has elected to ship the shellstock prior to achieving required internal temperatures the dealer may choose to cool the product to an internal temperature of 50°F (10°C) or less prior to shipment. In this case a time temperature device will not be required. The dealer must document in a HACCP record that the internal temperature of 50°F (10°C) was met prior to shipment.

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 documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of 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 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.

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
3. An internal temperature of 50°F (10°C) which can be measured by opening the shellstock and measuring the meat or using a temperature indicating gun which measures product temperature; or
4. The shipment of shellfish is accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting internal temperature required and notice of the presence of a time/temperature device indicating that continuous cooling has occurred.
5. For shellstock which was shipped prior to achieving an internal temperature of 50°F (10°C) the dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. The dealer must indicate in a record the presence of a time/temperature recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation.

Storage Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in Model Ordinance Chapter XI. .01 B (1) or B (2) for more than two (2) hours at points of processing or transfer such as loading docks. All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Shipping Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of 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 original dealer choose to ship shellstock which was received with documentation indicating that the product was not cooled to an internal temperature of 50°F (10°C) prior to shipment, the dealer must adhere to one of the following:

1. Include documentation indicating that the shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuing cooling has occurred. The shipment must 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 device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**
2. Should a dealer receive shellstock from a dealer who has elected to ship the shellstock prior to achieving required internal temperatures the dealer may

choose to cool the product to an internal temperature of 50°F (10°C) or less prior to shipment. In this case a time temperature device will not be required. The dealer must document in a HACCP record that the internal temperature of 50°F (10°C) was met prior to shipment.

Internal Temperature Measurements.

When monitoring the internal temperature of shellstock, it is acceptable to open the shellstock and measure the temperature of the shellfish directly using a thermometer or use a temperature detector device which provides the external temperature of the product. Where possible, but especially in cases in which product appears to be packaged for final sale, methods for determining the internal temperature of the shellstock should not compromise the integrity of the container. Should circumstances dictate that the measurement of the internal temperature of individual shellfish is necessary then particular care should be taken so as to avoid transferring heat from the equipment used by, and from the hands of the inspector to the shellfish. Individual oysters are typically no more than 0.2 kg in mass and can be warmed relatively quickly through handling by bare hands and when exposed to equipment or environments which are at a higher temperature than the original internal temperature of the animal.

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 inserting a standard analog or digital thermometer probe into the package to an appropriate depth or 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.

Time/Temperature Recording Devices – The time/temperature recording device must allow the receiving dealer to document that continuing cooling has occurred during transport.

Cooler Process Study Guidance

An alternative to monitoring product temperatures would be properly designed cooling process studies that demonstrate that cooling critical limits will be met. The cooling process studies must evaluate cooling times under worst case conditions found in the facility.

Factors including ambient air temperatures, product temperatures at arrival, amount of product to be cooled, arrangement of product in the cooler, and opening of the cooler door must be considered in the study. In conducting the studies, confirmatory product temperatures should be taken at the area of the cooler that is likely to have the least cooling ability. For instance, product temperature should be taken in the middle of a pallet in the most difficult cooling portion of the cooler.

Once a study is completed, the study should detail requirements needed to achieve compliance with the critical limits. Requirements could include such items as cooler capacity or arrangement of product in the cooler. Once

identified, the monitoring of the critical limits would include records to document that the requirements identified in the study to meet the critical limit are in place. The written study remains with the HACCP records.

This guidance can be utilized as a guide by the Authority when a certified dealer chooses not to physically monitor the initial temperature storage Critical Control Point (CCP) for each incoming lot of shellstock under the NSSP Model Ordinance as required by State *Vibrio vulnificus (V.v.)* or *Vibrio parahaemolyticus (V.p.)* Control Plans. The dealer can demonstrate the ability of the cooler to achieve required internal shellstock temperatures through a study that demonstrates that their mechanical refrigeration unit is able to cool shellstock to 50°F for *V.p.* or 55°F for *V.v.* within the required maximum time frame. This would enable the firm to monitor the ambient temperature of the refrigeration unit without requiring the firm to take the internal shellstock temperatures at the exact time of ten (10) hours (*V.p.*) or six (6) hours (*V.v.*) for each lot of shellfish on each day of the *V.v.* or *V.p.* Control Plan season. This guidance assumes that the refrigeration unit has a continuous temperature recording device (TRD) or the dealer manually monitors the cooler ambient temperature each day.

1. Determine the parameters of the cooler process study based on expected maximum load during implementation of a *V.v.* or *V.p.* Control Plan. This study can be used to satisfy internal temperature requirements for A. (3) shellstock.

2. Over three (3) days of refrigerated storage, starting with the first day of the *V.v.* or *V.p.* season, record the "internal" shellstock temperature at the time of loading into the cooler.

3. Record the days' maximum air and water temperature in the vicinity of the harvest area.

4. Record the internal shellstock temperatures after six (6) hours of refrigerated storage for *V.v.* and at ten (10) hours of refrigerated storage for *V.p.* and record the results.

5. If the internal shellstock temperatures meet the Model Ordinance requirements for cooling, continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

6. When the air or water temperatures in the vicinity of the harvest area have increased by 10°F since the initial process study date repeat process study as described in No. 1 through No. 4 above.

7. If results meet the Model Ordinance requirements for cooling continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

8. When the air or water temperatures in the vicinity of the harvest area have increased by another 10°F since the initial process study date repeat process study as described in No.1 through No. 4 above.

9. If results meet the Model Ordinance requirements for cooling continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

10. If following the process studies the cooler has been shown to achieve the required internal shellstock temperature, including at least one (1) three (3)-day period of maximum loading under elevated air and water temperatures, then the study is considered successful and the certified dealer needs only to continue to monitor the routine cooler ambient temps as per their HACCP Plan.

Note: Changes to maximum shellfish loading or cooler capacity or changes to cooler compressor would require additional Re-Validation Process Studies.

Time/Temperature Decision Trees

Click here for Proposal 11-201-B Decision Trees

Action by ISSC Executive Board 01/22/2013

The ISSC Executive Board adopted 2012 Shipping and Receiving Committee recommendations on Proposal 11-201Part B.

NOTE: These changes were adopted as interim requirements and are included in the 2011 Revision of the NSSP Guide for the Control of Molluscan Shellfish.

Action by USFDA 02/28/2013

FDA concurred with ISSC Executive Board action on Proposal 11-201Part B.

Action by 2013 Task Force II

Recommends adoption of Proposal11-201-B as amended.

Chapter VIII. @.02

I. Shellstock intended for a validated pathogen reduction process where refrigeration would reduce efficacy of the process (and appropriately labeled with name of the receiving dealer) is exempt from the requirements in Chapter VIII. @.02 A. (1) and (2).

Chapter VIII. @.02

E. The Authority shall ensure that harvesters document and provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements. For states that establish and limit harvest times that assure compliance with the times outlined in the matrix of Chapter VIII. @.02 A. (3) recording the time harvest begins is not required.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 11-201-B.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 11-201-B.