

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

Key Words: *Vibrio vulnificus* Risk Management

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 45° 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 45° Fahrenheit (7.2° 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 maintaining 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~~ 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 temperature 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 temperature 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 V_v and V_p 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 V_v and V_p . 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 V_v and V_p Control Plan compliance and reports from States and the industry suggest that these modifications are necessary.

**Cost Information:
(if available)**

**Action by 2011
Task Force II** Refer to Proposal 11-201 Pages 335 and 336.

**Action by 2011
General Assembly** Refer to Proposal 11-201 Pages 335 and 336.

**Action by FDA
February 26, 2012** Refer to Proposal 11-201 Pages 336 – 338.