Proposal No. 2 7 - 2 4 6

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

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

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

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

.03 Cargo Protection From Cross Contamination

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

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

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

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

.04 Shipping Temperatures

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

.05 Transportation Records

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

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

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

Chapter X. General Requirements for Dealers

.01 General HACCP Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

D. Signing and Dating the HACCP Plan.

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

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

(a) Upon initial acceptance; [O]

(b) Upon any modification; [O] and

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

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

F. Corrective Actions.

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

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

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

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

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

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

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

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

(a) Segregate and hold the affected product until:

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

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

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

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

G. Verification.

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

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

(b) Ongoing verification activities including:

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

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

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

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

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

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

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

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

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

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

H. Records.

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

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

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

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

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

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

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

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

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

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

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

I. Training.

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

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

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

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

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

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

.02 General Sanitation Requirements

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

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

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

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

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

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

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

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

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

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

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

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

.03 Other Model Ordinance Requirements

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

B. Recalls.

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

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

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

.04 Certification Requirements

A. General.

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

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

(a) Make application to the Authority for certification;

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

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

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

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

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

B. Types of Certification.

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

(2) Repacker.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

shall:

(a) Keep the harvester tag for ninety (90) days; [K]

(b) Keep track of the growing area and date of harvest for shellstock; [K] and

(c) Maintain the lot identity of all shellstock during any intermediate stage of processing. [K]

(2) A dealer receiving bulk tagged lots of shellstock ~~must~~ shall have an intermediate processing plan approved by the Authority to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification. [K]

(3) In order for a dealer to tag a lot container (e.g., a pallet) of shellstock in lieu of meeting the requirement in Section .05 B. for a harvester or dealer tag on each individual container, the dealer shall have an intermediate processing plan approved by the Authority, which establishes the procedures, the dealer shall use to tag the lot during the washing, packing or staging of shellfish. [K]

(4) Unless the dealer is included in the Authority's commingling plan under Chapter I. @.01 F., the dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. [K] The identification shall be provided by:

(a) A harvester's or dealer's tag which meets the requirements of Section .05 B.; or

(b) A tag for each lot of shellstock that contains the following information:

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

(ii) Harvest date;

(iii) Growing area;

(iv) Original dealer certification number; and

(v) Number of individual containers in each lot of shellstock container (e.g., a pallet) after washing, packing or staging has been completed.

(5) When a dealer has an approved intermediate processing plan, the dealer shall tag each lot of shellstock in accordance with the intermediate processing plan while the lot of shellstock is being processed in the plant. [K]

E. All restricted shellstock shall include a tag containing all information required in Section .05 of Model Ordinance Chapter X. In addition, the tag will include specific language detailing the restrictions requiring further processing or testing prior to distribution. [C]

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

.06 Shucked Shellfish Labeling

A. Shellfish Labeling.

(1) The dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers. [K]

(2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment

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

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

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

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

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

B. In-Shell Product Tags or Labels.

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

(a) The dealer's name and address;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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