



**Proposal for Task Force Consideration
at the ISSC 2017 Biennial Meeting**

- ☐ Growing Area
☒ Harvesting/Handling/Distribution
☐ Administrative

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Proposal Subject	Reduced Oxygen Packaging (ROP) of Shucked Shellfish Meats
Specific NSSP Guide Reference	<p>Section I. Purposes and Definitions</p> <p>Section II. Model Ordinance Chapter IX. Transportation Section .04 Shipping Temperatures;</p> <p>Section II. Model Ordinance Chapter X. General Requirements for Dealers Section .04 Certification Requirements;</p> <p>Section II. Model Ordinance Chapter X. General Requirements for Dealers Section .06 Shellfish Labeling;</p> <p>Section II. Model Ordinance Chapter XI. Shucking and Packing Section .01 Critical Control Points D. Processing Critical Control Point – Critical Limits and E. Shucked Meat Storage Critical Control Point – Critical Limit;</p> <p>Section II. Model Ordinance Chapter XIV. Reshipping Section .01 Critical Control Points A. Receiving Critical Control Point - Critical Limits and D. Shucked Meat Storage Critical Control Point – Critical Limit</p>
Text of Proposal/ Requested Action	<p>Definitions Add a new definition for Reduced Oxygen Packaging and number appropriately:</p> <p><u>Reduced Oxygen Packaging means the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level) and involves a food for which the hazard of <i>Clostridium botulinum</i> requires control in the final packaged form.</u></p> <p>Chapter IX.</p> <p>.04 Shipping Temperatures.</p> <p><u>A. Shellfish dealers shall ship shellstock adequately iced; or in a conveyance pre-chilled at or below 45°F (7.2°C) ambient air temperature.</u></p> <p><u>B. Shellfish dealers shall ship shucked meats that are packed in Reduced Oxygen Packaging (ROP) containers adequately iced; or in a conveyance pre-chilled below 38°F (3.3°C) ambient air temperature.</u></p>

Chapter X.

.04 Certification Requirements

B. Types of Certification.

- (1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer.
- (2) Repacker.
 - (1) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker;
 - (2) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker- packer, or repacker;
 - (3) A repacker shall not shuck shellfish.
 - (d) A repacker shall not repack shucked shellfish received in ROP containers.
- (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.

.06 Shucked Shellfish Labeling

A. Shellfish Labeling

- (1) The dealer shall maintain lot integrity when shucked shellfish are stored using in- plant reusable containers.
- (2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:
 - (a) The original shucker-packer's name and certification number;
 - (b) The shucking date; and
 - (c) The quantity of shellfish per container and the total number of containers.
- (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 (161.30, and 161.136) and the Federal Fair Packaging and Labeling Act.
- (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.
- (6) The dealer shall label each individual package containing less than 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;

	<p>(b) The date shall consist of the abbreviation for the month and number of the day of the month; and</p> <p>(c) For fresh frozen shellfish, the year shall be added to the date.</p> <p>(7) The dealer shall label each individual package containing 64 fluid ounces or more of fresh or fresh frozen shellfish with the following:</p> <p>(a) The words "DATE SHUCKED" followed by the date shucked located on both the lid and sidewall or bottom of the container;</p> <p>(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; and</p> <p>(c) For fresh frozen shellfish, the year shall be added to the date (for non-Julian format).</p> <p>(8) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.</p> <p>(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).</p> <p>(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.</p> <p>(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."</p> <p><u>(12) The dealer shall assure that each package of fresh shucked shellfish packed in ROP containers is labeled "Keep below 38°F (3.3°C) ambient air temperature."</u></p> <p>(13) The dealer shall assure that each package of frozen shucked shellfish packed in ROP containers is labeled "Important, Keep frozen. Thaw under refrigeration below 38°F <u>(3.3°C) immediately before use."</u></p> <p>Chapter XI. Shucking and Packing</p> <p>.01 Critical Control Points</p> <p>A. Receiving Critical Control Point <u>for Shellfish</u> - Critical Limits.</p> <p><u>B. Receiving Critical Control Point for Time Temperature Indicator Devices (TTI) – Critical Limits. The dealer shall use only TTIs that:</u></p> <p><u>(1) Are suitable for use; [C]</u></p> <p><u>(2) Have an alert indicator at a combination of time and temperature exposures that will prevent the formation of non-proteolytic C. botulinum toxin formation; and</u></p> <p><u>(3) Are functional. [C]</u></p> <p><u>BC.</u> Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:</p> <p><u>CD.</u> In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in- shell product shall be:</p>
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DE. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

- (1) For shellstock which has not been refrigerated prior to shucking:
 - (a) Shucked meats are chilled to an internal temperature of 45°F (7.2°C) or less within three (3) hours of shucking. [C]
 - (b) Shucked meats packed into ROP containers are chilled to an internal temperature below 38°F (3.3°C) within three (3) hours of shucking. [C]
- (2) For shellstock refrigerated prior to shucking:
 - (a) Shucked meats are chilled to an internal temperature of 45°F (7.2°C) or less within four (4) hours of removal from refrigeration. [C]
 - (b) Shucked meats packed into ROP containers are chilled to an internal temperature below 38°F (3.3°C) within four (4) hours of shucking. [C]
- (3) If heat shock is used, once heat shocked shellstock is shucked:
 - (a) 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]
 - (b) Shucked meats packed into ROP containers are chilled to an internal temperature below 38°F (3.3°C) within two (2) hours of shucking. [C]
- (4) When heat shocked shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45°F (7.2°C) within two (2) hours from time of heat shock. [C]
- (5) For in-shell product the internal temperature of meats does not exceed 45°F (7.2°C) for more than two (2) hours during processing. [C]
- (6) For shucked shellfish that are ROP packaged, each individual container must have a TTI properly attached and activated per manufacturer specifications. [C]

EF. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall:

- (1) 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]
- (2) Store shucked meats packed into ROP containers at an ambient air temperature below 38°F (3.3°C) or covered in ice. [C]

EG. Shellstock Shipping Critical Control Point – Critical Limits.

H. TTI Storage Critical Control Point – Critical Limits.

The dealer shall store TTIs under conditions that prevents loss of functionality.

Chapter XIV. Reshipping

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

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

	<p>(a) Identified the shellstock with a tag as outlined in Chapter X. .05, identified the in- shell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and [C]</p> <p>(b) Provided documentation as required in Chapter IX. .04 and .05; and [C]</p> <p>(c) Adequately iced the shellstock; or [C]</p> <p>(d) Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or [C]</p> <p>(e) Cooled the shellstock to an internal temperature of 50°F (10°C) or less. [C]</p> <p><u>(f) Shipped shucked meats packed in ROP containers below an ambient air temperature of 38°F (3.3°C) or covered in ice. [C]</u></p> <p><u>(g) Shipped shucked meats packed in ROP containers with an appropriately attached and activated TTI that indicates the temperature was maintained below 38°F (3.3°C) throughout transit. [C]</u></p> <p><u>D.</u> Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall:</p> <p><u>(1)</u> SStore shucked shellfish at an ambient temperature of 45°F (7.2°C) or less. [C]</p> <p>(2) Store shucked shellfish packed into ROP containers below an ambient air temperature of <u>38°F (3.3°C) or covered in ice. [C]</u></p>
Public Health Significance	Available upon request.
Cost Information	
Action by 2015 Task Force II	Recommended no action on Proposal 15-208. Rationale: Not recognized as a public health issue that warrants attention for shucked shellfish at this time
Action by 2015 General Assembly	Recommends referral of Proposal 15-208 to an appropriate committee as determined by the Conference Chair.
Action by FDA January 11, 2016	<p>Concurred with Conference action on Proposal 15-208 with the following comments and recommendations.</p> <p>FDA applauds and concurs with action by the ISSC voting delegates to refer Proposal 15-208 to an appropriate committee.</p> <p>The recommendation from Task Force II to the voting delegates was to take "No Action" on Proposal 15-208, stating that Clostridium botulinum (C. botulinum) is not recognized as a public health issue associated with Reduced Oxygen Packaging (ROP) of molluscan shellfish. A "No Action" vote by the ISSC would have created a difficult situation for FDA and ultimately the ISSC. Present FDA policy, set forth in the Fish and Fishery Products Hazards and Controls Guidance and which supports Federal Regulation CFR 21 Part 123, identifies C. botulinum as a hazard for raw oysters, clams and mussels when reduced oxygen packaged (e.g. mechanical vacuum, steam flush, hot-filled, modified atmosphere packaging, CAP, hermetically sealed or packed in oil). FDA could not have concurred with a Conference vote of "No Action" and the Agency would have been obligated to consider other regulatory options. However, ISSC action to refer Proposal 15-208 to committee provides an opportunity for further consideration and joint resolution by ISSC and FDA. A number of issues surrounding ROP will need to be examined as part of the committee's deliberative process, including identification of the</p>

	<p>packing types that would be affected, the cost of changing packaging practices and meeting new critical limits, whether existing NSSP requirements provide control or inhibit C. botulinum growth, and identification of other alternatives for C. botulinum control.</p> <p>FDA is prepared to offer assistance to the ISSC to address the ROP concern, including subject matters experts regarding the science and control of C. botulinum and associated packaging issues and technologies. With a coordinated effort among state and federal health authorities, industry representatives and subject matter experts, FDA is confident that a reasonable approach can be developed to ensure that C. botulinum is effectively addressed by the NSSP.</p>
Action by ISSC ROP Committee November 2016	<p>To facilitate a broader discussion and provide the Committee with additional technical information, the ISSC sponsored an ROP Workshop in Atlanta, Georgia on November 1-2, 2016. The ISSC membership was requested to present questions and concerns for discussion by an expert panel. The ROP Committee was given opportunity to ask questions and discuss technical, scientific, and policy issues associated with C. Botulinum. Following the Workshop, the ROP Committee discussed Proposal 15-208 and made the following recommendations to the ISSC Executive Board.</p> <ol style="list-style-type: none"> 1. The ISSC Executive Board identify funding for studies to determine the following: <ol style="list-style-type: none"> a. Are the present shucking and packing practices providing controls that can explain why there are no reported cases of illness associated with C. Botulinum? b. Determine the effect that normal product deterioration has on PH. Determine if PH reaches a level that prohibits C. Botulinum growth. c. Determine if a reduced shelf life offers a potential C. Botulinum control. d. Conduct a study of competitive bacteria and its effect on C. Botulinum growth. 2. The ISSC Executive Board requested that FDA conduct a cost analysis of the impact of Proposal 15-208. 3. The ISSC Executive Board requested that FDA determine how packaging changes would affect exports. 4. The ISSC Executive Board requested that FDA consult with other countries to determine what other countries are doing to address C. Botulinum in shucked shellfish. 5. The ISSC Executive Board requested that FDA provide the rationale for the Agency's determination that C. Botulinum is reasonably likely to cause illness associated with consumption of shucked shellfish.
Action by ISSC Executive Board November 2016	<p>The Executive Board approved all of the recommendations and agreed to prioritize Item1. a. through d.; present recommendations to FDA and seek advice on costs to conduct studies; and report results to Executive Board.</p>
Action by FDA December 8, 2016	<p>Following the ROP Workshop on November 1-2, 2016, the USFDA submitted correspondence to the ISSC requesting the ISSC take no action on the proposal changes to the NSSP Model Ordinance as recommended in Proposal 15-208 (see excerpts below). The FDA advised the ISSC Executive Board of FDA plans to conduct package studies and present findings and additional recommendations at a later time.</p> <p>At the 2015 Interstate Shellfish Sanitation Conference (ISSC) in Salt Lake City, Utah the US Food and Drug Administration (FDA) submitted Proposal 15-208 to address the potential risk of Clostridium botulinum in Reduced Oxygen Packaging (ROP) containing shucked molluscan shellfish. The state voting delegates voted to refer Proposal 15-208 to</p>

an appropriate ISSC Committee for further discussion. In November, 2016 the ISSC held a ROP workshop to begin discussion of the Proposal. The workshop included members of the ISSC ROP Committee and a panel of subject matter experts with expertise and knowledge of the science and issues associated with C. botulinum and Reduced Oxygen Packaging.

The FDA appreciates the efforts of the ISSC in planning the ROP workshop held in Atlanta, Georgia on November 1-2, 2016. The workshop provided the participants with helpful insight from microbiologists, wholesalers, retailers, shellfish processors, the packaging industry, and state food safety inspection agencies. After careful consideration, the FDA would like to request that the ISSC take No Action on the proposed changes to the National Shellfish Sanitation Program (NSSP) Model Ordinance as recommended in Proposal 15-208. While the science is clear regarding ROP foods and the potential for C. botulinum toxin production, it is the view of the FDA that additional studies and discussion specific to molluscan shellfish are needed prior to adoption of ROP control strategies into the NSSP Model Ordinance. The ISSC ROP Committee recommended, with ISSC Executive Board concurrence, that additional information be gathered and that studies to be considered to assess the potential risk of C. botulinum in shucked molluscan shellfish packaged in ROP containers. FDA concurs with those recommendations and will provide assistance as appropriate.