Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

Submitter	Floyd Raymond Burditt and Mary Losikoff
Affiliation	US Food & Drug Administration (FDA)
Address Line 1	Center for Food Safety & Applied Nutrition (CFSAN)
Address Line 2	5800 Paint Branch Parkway
City, State, Zip	College Park, Maryland 20740
Phone	240-402-1562
Fax	301-436-2601
Email	floyd.burditt@fda.hhs.gov
Proposal Subject	Reduced Oxygen Packaging (ROP) of Shucked Shellfish Meats
Specific NSSP Guide Reference	Section I. Purposes and Definitions Section II. Model Ordinance Chapter IX. Transportation Section .04 Shipping Temperatures; Section II. Model Ordinance Chapter X. General Requirements for Dealers Section .04 Certification Requirements; Section II. Model Ordinance Chapter X. General Requirements for Dealers Section .06 Shellfish Labeling; 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; 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
Text of Proposal/ Requested Action	**Definitions** Add a new definition for Reduced Oxygen Packaging and number appropriately: **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 *Clostridium botulinum* requires control in the final packaged form. **Chapter IX.** **.04 Shipping Temperatures.** 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. 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 38ºF (3.3ºC) ambient air temperature.

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.

(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.

(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;

(b) The date shall consist of the abbreviation for the month and number of the day of the month; and

(c) For fresh frozen shellfish, the year shall be added to the date.

(7) The dealer shall label each individual package containing 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;

(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

(c) For fresh frozen shellfish, the year shall be added to the date (for non-Julian format).

(8) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.

(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).

(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.

(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."

(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."

(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 38ºF (3.3°C) immediately before use."

Chapter XI. Shucking and Packing
.01 Critical Control Points

A. Receiving Critical Control Point for Shellfish - Critical Limits.

B. Receiving Critical Control Point for Time Temperature Indicator Devices (TTI) – Critical Limits. The dealer shall use only TTIs that:

(1) Are suitable for use; **[C]**

(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

(3) Are functional. **[C]**

~~B~~C. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

~~C~~D. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in- shell product shall be:

~~D~~E. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) For shellstock which has not been refrigerated prior to shucking~~,~~:

(a) ~~s~~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 38ºF (3.3ºC) within three (3) hours of shucking. **[C]**

(2) For shellstock refrigerated prior to shucking~~,~~:

(a) ~~s~~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 38ºF (3.3ºC) within four (4) hours of shucking. **[C]**

(3) If heat shock is used, once heat shocked shellstock is shucked~~,~~:

(a) ~~t~~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 38ºF (3.3ºC) 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]**

~~E~~F. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall:

(1) ~~s~~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 38ºF (3.3ºC) or covered in ice. **[C]**

~~F~~G. 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: (a) Identified the shellstock with a tag as outlined in Chapter X. .05, identified the in- shell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and **[C]** (b) Provided documentation as required in Chapter IX. .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]** (f) Shipped shucked meats packed in ROP containers below an ambient air temperature of 38ºF (3.3ºC) or covered in ice. **[C]** (g) Shipped shucked meats packed in ROP containers with an appropriately attached and activated TTI that indicates the temperature was maintained below 38ºF (3.3ºC) throughout transit. **[C]** D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall: (1) ~~s~~Store shucked shellfish at an ambient temperature of 45°F (7.2°C) or less. **[C]** (2) Store shucked shellfish packed into ROP containers below an ambient air temperature of 38ºF (3.3ºC) or covered in ice. **[C]**
Public Health Significance	In a 1981, as a result of research published on the risks of vacuum (VAC) and modified atmosphere packaging (MAP) of raw fish products, NMFS issued a moratorium on the use of VAC / MAP for refrigerated fresh fish. In 1985, the National Research Council of the National Academy of Sciences recommended that studies were needed on the potential hazard of non-proteolytic C. botulinum toxin production in vacuum and modified atmosphere fresh fish. They were concerned that the non- proteolytic strains of C. botulinum commonly associated with seafood products could grow and produce toxin at refrigeration temperatures with no visible signs of growth to alert the consumer. They stated that "This practice is not recommended until safety is validated" The National Advisory Committee for Microbiological Criteria for Foods (NACMCF) reviewed the topic in 1991 and determined that refrigeration below 3.3C (38F) was the only control for the growth of non-proteolytic C. botulinum in raw fish that is vacuum or modified atmosphere packaged. The NACMCF recommended that the unrestricted use of VAC / MAP should not be permitted. They stated that VAC / MAP would be permitted for raw fishery products when: Products were packaged under an established HACCP plan. Detectable spoilage and rejection by the consumer precedes the possibility of toxin production. High quality

raw fish is used. Packaged product is stored below 38°F (3.3°C). Product is adequately labeled for storage temperature, shelf life, and cooking requirements.

To address the need to demonstrate that detectable spoilage and rejection by the consumer precedes the possibility of toxin production, several studies were initiated by FDA. In salmon packaged under modified atmosphere, toxin production coincided with spoilage under moderate temperature abuse at 8C (46.5F). Temperatures below 4C (39.2F) were needed to prevent toxin formation. Similar studies were done in cod, tilapia, and catfish.

A number of conditions can result in the creation of a reduced oxygen environment. Packaging in hermetically sealed containers (e.g., double-seamed cans, glass jars with sealed lids, and heat-sealed plastic containers), or packing in deep containers from which the air is expressed, or packing in oil. These and similar processing and packaging techniques prevent the entry of oxygen into the container. Any oxygen present at the time of packaging (including oxygen that may be added during modified atmosphere packaging) may be rapidly depleted by the activity of spoilage bacteria, resulting in the formation of a reduced oxygen environment.

For processed products, a number of controls exist that inhibit or prevent C. botulinum toxin formation such as, water activity, salt, heat, etc. For raw products, the options are fewer and include refrigeration below 38F, freezing, or the use of oxygen permeable packaging. If a processor selects refrigeration as the control, then the temperature is the critical control point with a critical limit of below 38°F (3.3°C). Time Temperature Indicators are used to monitor the temperature. Skinner, G and J Larkin described a safe time and temperature exposure curve ("Skinner-Larkin curve") that may be useful in evaluating the suitability of a TTI for control of C. botulinum toxin formation in reduced oxygen packaged fish and fishery products. TTIs are to be attached to each individual consumer package, and not just the master carton. TTIs should be designed to monitor the time and temperature exposures of the packages and create a visible and permanent change to indicate when an unsafe time and temperature exposure has occurred that may result in *C. botulinum* toxin formation. Products affected include: refrigerated, reduced oxygen packaged raw, unpreserved fish (e.g., refrigerated, vacuum-packaged fish fillets) and refrigerated, reduced oxygen packaged, unpasteurized, cooked fishery products (e.g., refrigerated, vacuum-packaged, unpasteurized crabmeat, lobster meat, or crayfish meat.

If freezing is the control, then the processor needs to ensure that products are immediately frozen after processing, maintained frozen throughout storage in the facility, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use"). Labeling would be the critical control point.

FDA considers packaging material with an oxygen transmission rate (OTR) greater than 10,000 cc/m2/24h at 24ºC to be oxygen permeable packaging for seafood. The OTR is listed in the packaging specifications from the packaging manufacturer. This OTR should provide sufficient oxygen exchange to allow aerobic spoilage organisms to grow and spoil the product prior to toxin formation. Industry has the option of providing data to establish a different OTR.

Use of an oxygen permeable package may not always be appropriate. For example, when the spoilage organisms are eliminated or significantly reduced as in high pressure processing or product heated in the package. Anaerobic conditions can

occur in products packed in oil, deep containers from which the air is expressed, products with oxygen scavengers in the packaging, products with high respiration rate like vegetables, raw products where respiration can use up oxygen, and cooked products where the heat drives off oxygen.

Processors also have the option of performing a study that shows detectable spoilage and rejection by the consumer precedes the possibility of toxin production under moderate abuse conditions.

In 1997, the Seafood HACCP Regulation was issued and provided a preventive rather than reactive approach to food safety for seafood. There are seven principles of HACCP. First, the processor must conduct a Hazard Analysis. A hazard is defined as "A Biological, Chemical, or Physical Agent That is Reasonably Likely to Cause Illness or Injury in the Absence of its Control." Once a hazard is identified, the processor needs to identify the preventative measures that will control the hazard, identify Critical Control Points (CCP), establish Critical Limits, monitoring procedures, Corrective Actions to be taken when a Critical Limit deviation occurs, keep records and verify that the HACCP plan is working.

Oyster processors are subject to the Seafood HACCP regulation because oysters are mollusks and included in the definition of fish 21 CFR 123.3 (d). The Model Ordinance includes the need to comply with 21 CFR 123 in Chapter X. General Requirements for Dealers lists ".01 General HACCP Requirements B. HACCP Plan. Every dealer shall have and implement a written HACCP plan. 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."

The Fish and Fishery Products Hazards and Controls Guidance was issued by FDA to assist processors in identifying hazards associated with their products. This document addresses both species-specific hazards and process-related hazard. Under process- related hazards, page 73 indicates that raw oysters, clams and mussels have a C. botulinum hazard when packed in reduced oxygen packages (e.g. mechanical vacuum, steam flush, hot-fill, modified atmosphere packaging, CAP, hermetically sealed or packed in oil. Examples of hermetically sealed containers include double seam cans and glass jar with lid.

A number of factors affect oxygen availability in foods. The packaging itself, for example high barrier materials like foil, metal, glass and some polymers prevent or slow the diffusion of oxygen into the food. In addition, bacterial growth can modify the atmosphere within the package; aerobic bacteria can grow on a food and consume the available oxygen. Also when a food is heated, the heat drives air (and thus oxygen) out of the foods.

FSMA also addresses the need to prevent hazards:

FSMA Preventive controls: risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing,

processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified in the hazard analysis…and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

The HAZARD

Clostridium botulinum produces the most potent neurotoxin known, particularly when taken orally (7 – 70 μg for a typical person). The toxin produces the disease Botulism. Onset of symptoms generally occurs within 12 to 36 hours with a range of 2 hrs – 14 days. At first, a person may experience early weakness and vertigo but that progresses to bilateral, descending weakening and paralysis of the skeletal muscles. Classic symptoms are double vision, difficulty in speaking, swallowing, and breathing.

Ultimately respiration is inhibited and the person suffocates to death. There is a low incidence of disease but a high mortality if a person is not treated quickly with botulinal antitoxin and mechanical ventilation.

The organism C. botulinum is classified by toxin type: A, B, C, D, E, F, G. Types C and D do not affect man. Most human illness is caused by types A, B and E and occasionally F. It is a spore-forming bacteria that is anaerobic which means it grows well in the absence of oxygen. The vegetative cells are susceptible to heat. The spores are heat resistant and can survive adverse conditions like drying. The toxin is not resistant to heat and can be eliminated by boiling but is resistant to acid and freezing The organism is widely distributed in nature and found throughout the world in soil, marine and freshwater environments. It is detected in sediments of streams, lakes, and coastal waters. Spores are common in root vegetables, many spices, the intestinal tracts of fish and mammals, and the gills and viscera of crabs and other shellfish.

The scientific literature indicate that C. botulinum has been isolated from oysters; 5 of 16 Pacific oysters tested were positive for type E and two of 74 oysters harvested from Mobile Bay were also positive for C. botulinum type E. C. botulinum types B and E were detected in 12.3% of the total sediment samples examined from the Upper Chesapeake Bay.

There are two types of Clostridium botulinum. One type is proteolytic (strains A, B, F) which means that it breaks down protein, providing visual signs of growth and offensive odors. The lower limit for growth is 10C (50F).

The other type is non-proteolytic (strains B, E, F) which does not degrade protein so a product may be toxic without signs of growth. The lower limit for growth is 3.3C (38F). Type E is primarily associated with seafood products. It can grow at refrigeration temperatures. It is non-proteolytic so there is no visual sign that a product may be toxic.

As the shelf life of refrigerated foods is increased in ROP, more time is available for C. botulinum growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. A food processor should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, safe refrigeration temperatures will not be maintained (especially for the non-proteolytic group). Surveys of retail display cases indicate that temperatures of 45 to 50°F (7 to 10°C) are not uncommon.

Surveys of home refrigerators indicate that temperatures can exceed 50°F (10°C).

Most cases of botulism are due to home-prepared foods. Outbreaks due to commercially processed low acid canned foods are rare. Recent botulism outbreaks due to commercial foods are the result of extreme temperature abuse that occurred in refrigerated foods stored at room temperature. It occurs primarily in products that appear shelf stable. From 1990 to 2000 in the United States, there were 160 foodborne botulism events with 263 people affected which is an annual incidence of 0.1 per million. The highest incidence was in Alaska, Idaho, and Washington with 131 cases (50%) type A, 27 (10%) type B and 97 (37%) type E. During this time botulism due to commercially packed products resulted from the consumption of salted, eviscerated fish (mohola), grilled raw Palani (surgeon fish), Burrito, Clam chowder, and Bean dip.

Botulism from restaurant made products included Cheese sauce and a potato dip. More Recently, Botulism outbreaks as a result of proteolytic strains included refrigerated pasta sauce in a plastic pouch in a cardboard carton, refrigerated garlic in oil, refrigerated carrot juice in a plastic bottle, sautéed onions left in a warm skillet overnight, baked potato wrapped in foil. Botulism outbreaks due to nonproteolytic strains of C. botulinum occurred in Kapchunka – uneviscerated fish, beached whale meat, fermented salmon roe, frozen vacuum packed scallops, and frozen vacuum packed prawns.

Few clinicians have ever seen a case of botulism. In an outbreak involving cheese sauce, of 8 patients – 5 were hospitalized and one died. Initial diagnoses were inner ear infection, stroke, allergic reaction to a tranquillizer, and astigmatism. Three people did not seek medical care. Botulism can also be confused with Guillain-Barre syndrome or myasthenia gravis.

Summary

A. Botulinum is identified as a hazard in ROP oysters in the Fish and Fishery Products Hazards and Controls Guide. Oyster processors are subject to the Seafood HACCP regulation because oysters are mollusks and included in the definition of fish 21 CFR 123.3 (d). The Model Ordinance includes the need to comply with 21 CFR 123 in Chapter X. General Requirements for Dealers lists .01 General HACCP Requirements
B. HACCP Plan. Every dealer shall have and implement a written HACCP plan.
C. Botulinum type E is primarily associated with seafood products and has been isolated from oysters. It can grow at refrigeration temperatures as low as 38F. It is non- proteolytic so there may be no visual sign that a product may be toxic. The temperature listed in the Model Ordinance for storage of oyster is 45F. The shelf life of refrigerated foods is increased in ROP, which allows more time for C. botulinum growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. A food processor should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, safe refrigeration temperatures will not be maintained (especially for the non-proteolytic group). Surveys of retail display cases indicate that temperatures of 45 to 50°F (7 to 10°C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50°F (10°C). Botulism is a difficult disease to diagnose. Few clinicians have ever seen a case of botulism. Botulism can also be confused with Guillain-Barre syndrome or myasthenia gravis.

The options for control of raw ROP seafood products are:

Reduce the temperature of storage listed in the Model Ordinance to below 38F for oysters packed in ROP and use TTIs to monitor the temperature of the oysters, or Freeze the ROP product with labeling as a CCP. Suggested statement: "Important, Keep frozen, thaw under refrigeration immediately before use, or Use oxygen permeable packaging so that the packaging is not considered ROP, or Conduct a study that detectable spoilage and rejection by the consumer precedes the possibility of toxin production at moderate abuse temperatures.

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Cost Information	