# Interstate Shellfish Sanitation Conference

# Task Force II Report

## 2017 Biennial Meeting
## October 14 – 19, 2017
## Sheraton Hotel & Convention Center
## *Myrtle Beach*

South Carolina

THE PALMETTO STATE

Kohl Kanwit, Chair
Robert Hein, Non-Procuding
Eric Hickey, Region 1 Regulatory
Sue Ritchie, Region 2 Regulatory
Jimmy Bloom, Region 2 Industry
Tim Parsons, Region 3 Industry, Vice Chair
Barry Hurt, Region 4 Industry
Joe Jewell, Region 5 Regulatory
Miranda Ries, Region 6 Industry
David Fyfe, Executive Board Consultant
David Wiggins, FDA
Angela Ruple, NOAA / NMFS

**Proposal No.** **13-200**

| | |
|---|---|
| Submitter | Executive Office |
| Affiliation | Interstate Shellfish Sanitation Conference (ISSC) |
| Email | issc@issc.org |
| Proposal Subject | Reducing the Risk of Vibrio Illnesses |
| Specific NSSP Guide Reference | NSSP Guide for the Control of Molluscan Shellfish |
| Text of Proposal/ Requested Action | A Vibrio workshop was held in Dauphin Island, Alabama in November 2012 to discuss possible solutions for addressing illness risks. State Shellfish Control Authority representatives, Vibrio researchers, and the USFDA participated in the two-day workshop. The participants identified several topics (listed below) that are related to Vibrio controls. These topics should be addressed by the collective participants of the ISSC. The purpose of this proposal is to request the ISSC Executive Board work collaboratively with the USFDA to address the information gaps that are obstacles to identifying effective control strategies for reducing the risk of illness associated with Vibrioses.<br><br>Requested Action Items:<br><br>1. Rewrite Chapter II. Risk Assessment *V.p.* (section 05).<br>2. Incorporate salinity (and other environment factors?) into *V.v.* and *V.p.* risk calculators.<br>3. Develop protocol for validating the effectiveness of non-labeling PHPs.<br>4. Develop protocol for ensuring that growing/harvest/handling (production) practices do not increase risk of Vibrio illness.<br>5. Request FDA to develop sampling protocol for closing versus reopening growing areas after outbreaks including the development of resources to sustain the present capabilities.<br>6. Develop new labeling/tagging system for oysters produced under conditions achieve equivalent levels as validated PHP (for labeling), including validation protocol.<br>7. ISSC request FDA to reexamine risk assessments and risk calculators (*V.p.* and *V.v.*).<br>8. ISSC request FDA to reexamine illness and landings data to determine observed risk per serving.<br>9. Develop the process for using local data to refine calculators to more accurately reflect risk in the region or state.<br>10. Determine how best to estimate national consumption patterns for molluscan bivalves. Mega study.<br>12. ISSC request FDA technical assistance for enhancing state vibrio programs (data management, laboratory support, think tank, BMPs, evaluation of effectiveness of new controls, statistical support) .<br>13. States request FDA assistance with developing approved method(s) to temper clams.<br>14. Draft proposal for acceptance of laboratory methods validated by other accrediting bodies. |
| Public Health Significance | The ISSC continues to struggle with identifying practical cost effective strategies for reducing the risk of Vibrio illnesses associated with the consumption of molluscan shellfish. This proposal identifies information needs that are obstacles to the development of control strategies. |

| | |
|---|---|
| Cost Information | |
| Research Needs Information Proposed (specific research need/problem to be addressed) | 1. Is total *V.v.* a valid indicator of risk?<br>2. Are there differential effects of validated PHP on virulent subpopulations?<br>3. How do environmental factors affect levels of virulent subpopulations?<br>4. Compile collection of *V.v.* for future virulence research.<br>5. Do other species react to controls the same as *V.v.* and *V.p.*?<br>6. Determine relative virulence of *V.p.* subpopulations.<br>7. What are Vibrio (total and virulent) levels at harvest (in oysters and clams)?<br>8. How much Vibrio (total and virulent) growth results from the current time/temperature controls (in oysters and clams)?<br><br>Priorities:<br>1. What information is needed to supply more tools to the "toolbox"?<br>2. What regional information is needed to refine risk assessments and risk calculator tools for implementation of effective control plans?<br>3. What is the significance of salinity to Vibrio levels in shellfish?<br>4. Is there a salinity/temperature matrix that determines Vibrio levels?<br>5. What are the key virulence factors (or combination thereof) for *V.v.* and *V.p.*?<br>6. Need to know dose response of different Vibrio strains and populations<br>7. What are the regional differences in pathogenic strains of *V.v.* and *V.p.*?<br>8. What is the percentage of pathogenic strains of Vibrio in growing waters?<br>9. Should the "viable but not culturable" state in pathogenic Vibrios be a concern? |
| Action by 2013 Task Force II | Recommended referral of Proposal 13-200 to an appropriate committee as determined by the Conference Chairman with instructions to the committee as follows:<br><br>1. Request that FDA reexamine its risk assessments and risk calculators (*V.p.*) and (*V.v.*) and present the results to ISSC, including the factors and methodology used to calculate risk per serving.<br>2. Develop a process for using local data including regional or state illness and landings information, to more accurately reflect risk in a region or state.<br>3. Determine how best to estimate consumption patterns, including collection data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods.<br>4. Evaluate existing NSSP regulations to reduce risk of Vibrio illness caused by improper handling, storing, or transportation of shellstock and the effectiveness of existing enforcement mechanisms.<br>5. Provide recommendations to ISSC based on the results of the above study and evaluation. |
| Action by 2013 General Assembly | Adopted recommendation of 2013 Task Force II on Proposal 13-200. |
| Action by FDA May 5, 2014 | FDA concurred with Conference action on Proposal 13-200 with the following comments and recommendations.<br><br>FDA concurs with ISSC referral of Proposal 13-200 to Committee. As appropriate, FDA will provide support to the Committee via participation of Agency Vibrio research and risk assessment experts to assist in addressing Committee charges as set forth in Proposal 13-200. The Agency will look to the Conference to advance recommendations made by the Committee for purposes of implementing appropriate controls to reduce the Vibrio |

| | |
|---|---|
| | risk. Results of ISSC actions in response to Proposal 13-204 will be integral to answering key questions associated with the Committee's charges. |
| Action by 2015 Vibrio Management Committee | Recommended the following action on Proposal 13-200:<br><br>That the ISSC recognize the new *V.v.* and *V.p.* calculators as a tool available to calculate the actual risk and assess the effectiveness of state controls.<br><br>Continue to monitor the activities addressed in items 2 & 3 and report annually to the VMC regarding progress.<br><br>That a workgroup be formed to evaluate the effectiveness of existing NSSP regulations to reduce risk of Vibrio illnesses caused by improper handling, storing, or transportation of shellstock; to identify areas within the NSSP needing improvement; and make recommendations to the ISSC. The workgroup will consist of FDA, state and industry representatives. |
| Action by 2015 Task Force II | Recommended adoption of VMC recommendations 2. And 3. with referral of Proposal 13-200 to an appropriate committee with a recommendation that States be allowed to pilot the new *V.v.* and *V.p.* calculators and to provide input to the FDA and report back to VMC prior to the next ISSC meeting. |
| Action by 2015 General Assembly | Adopted recommendation of Task Force II on Proposal 13-200. |
| Action by FDA January 11, 2016 | Concurred with Conference action on Proposal 13-200. |
| Action by 2017 Vibrio Management Committee | a. Monitor the development of processes for using local data including regional or state illnesses and landings information, to more accurately reflect risk in a region or state.<br><br>Recommendation:<br>The VMC recommended the Conference support and promote the collection of production data and recommends in every case possible the data be provided in product form.<br><br>b. Monitor activities to estimate consumption patterns, including collection of data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods.<br><br>Recommendations:<br>1. The VMC recommended that the ISSC continue to identify funding to collect data regarding shellfish consumption patterns to include serving size and product form and also distribution patterns.<br><br>2. VMC recommended the Conference identify funding to conduct pilots in each region of the country to gather information on consumption patterns, including collection of data regarding the number of shellfish consumed per serving.<br><br>c. Evaluate the effectiveness of existing NSSP guidelines in reducing the risk of Vibrio illness caused by improper handling, storing or transportation of shellstock and effectiveness of existing enforcement mechanisms. |

| | |
|---|---|
| | Recommendation:<br>VMC recommended no action. Rationale: This charge is part of VMC ongoing mission. |
| Action by 2017 Task Force II | Recommends adoption of Vibrio Management Committee recommendations as submitted. |

**Proposal No.** **13-204**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | paul.distefano@fda.hhs.gov |
| Proposal Subject | Vibrio Control Plans |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter II. @ .05 *Vibrio vulnificus* Control Plan<br>Chapter II. @ .06 *Vibrio parahaemolyticus* Control Plan |
| Text of Proposal/ Requested Action | @.05 *Vibrio* ~~*vulnificus*~~ Control Plan ~~(Effective January 1, 2012)~~<br><br>A. Risk Evaluation<br>Each shellfish producing State that is not currently implementing a *Vibrio* ~~*vulnificus (V.v.)*~~ control plan for purposes of controlling the risk of *Vibrio vulnificus (V.v.)* and/or *Vibrio parahaemolyticus (V.p.)* shall conduct a *Vibrio* ~~*vulnificus*~~ risk evaluation annually. The evaluation ~~shall~~should consider factors deemed appropriate by the State Authority for effectively assessing whether or not~~each of the following factors, including seasonal variations in the factors, in determining~~ the risk of *Vibrio vulnificus* or *Vibrio parahaemolyticus* infection from the consumption of shellfish harvested from the State's growing waters is reasonably likely.<br>(1) In conducting the risk evaluation the State Authority may ~~will at a minimum~~ consider any number of factors, for example~~the following~~:<br>(a) The number of *Vibrio vulnificus* *and Vibrio parahaemolyticus* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and<br>(b) Levels of *Vibrio vulnificus* and *Vibrio parahaemolyticus* in the growing waters and in shellfish, to the extent that such data exists; and<br>(c) Levels of tdh+ and trh+ *Vibrio parahaemolyticus* in the growing area to the extent that such data exists; and<br>(d) The water temperatures in the growing area; and<br>(e) The air temperatures in the growing area; and<br>(f) Salinity in the growing area; and<br>(g) Harvesting techniques in the growing area; and<br>(h) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.<br><br>B. The State shall develop a *Vibrio* Contingency Plan should the risk evaluation indicate:<br>(1) Any etiologically confirmed shellfish-borne *Vibrio vulnificus* or *Vibrio parahaemolyticus* illness from the growing waters of that State but the number of cases does not reach the illness threshold established in Chapter II @.05 D or E; and<br>(2) Information on Levels of *Vibrio vulnificus* or *Vibrio parahaemolyticus*, if available, in the growing waters or in shellfish that is reasonably likely to cause an illness;<br><br>BC. States which have previously met the illness threshold for *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* requiring a *Vibrio* ~~*vulnificus*~~ Control Plan will continue to maintain and implement a *Vibrio* ~~*vulnificus*~~ Control Plan~~.~~<br><br>CD. All States not currently implementing a *Vibrio* ~~*vulnificus*~~ Control Plan shall develop and implement a *Vibrio* ~~*vulnificus*~~ Control Plan should the risk evaluation indicate two (2) or more etiologically confirmed, and epidemiologically linked *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters that originated from the growing waters of that state within the previous ten (10) years. |

E. All states not currently implementing a *Vibrio* Control Plan shall develop and implement a *Vibrio* Control Plan should the risk evaluation indicate that the State has a shellfish growing area that was the source of oysters or hard clams (*Mercenaria mercenaria*) that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years.

~~D. The State shall develop a *Vibrio vulnificus* Contingency Plan should the risk evaluation indicate:~~

~~(1) Any etiologically confirmed shellfish borne *Vibrio vulnificus* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.04 C.; and~~

(2) Information on Levels of ~~*Vibrio vulnificus*, if available in the growing waters or in shellfish that is reasonably likely to cause an illness;~~

E. *Vibrio* Control Plan

(1) The *Vibrio* ~~*vulnificus*~~ Control Plan shall include the following:

~~(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One or more of the following triggers will be used:~~

~~(i) The water temperatures in the area; and~~

~~(ii) The air temperatures in the area; and~~

~~(iii) Salinity in the area; and~~

~~(iv) Harvesting techniques in the area; and~~

(v) Other factors which affect risk which can be used as a basis for reducing risk.

(~~b~~a) Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* illness:

(i) Labeling oysters and/or hard clams, "For shucking by a certified dealer", when the ~~Average Monthly Maximum W~~water ~~T~~temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold ~~70°F~~.

(ii) Subjecting all oysters and/or hard clams intended for the raw, half-shell market to Authority approved post-harvest processing when the ~~Average Monthly Maximum W~~water ~~T~~temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold ~~70°F~~.

(iii) Cooling oysters and/or hard clams to 50°F within one hour of harvest when the water temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering.

~~Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *V.v.* plans will include controls when water temperature promotes *V.v.* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when Average Monthly Maximum Wwater~~

~~Ttemperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when Average Monthly Maximum Water temperature exceeds 70°F but is less than or equal to 80 °F. BMPs will ensure that when the water temperature exceeds 70°F but is less than or equal to 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperature exceeds 75°F but is less than or equal 80 °F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *Vibrio vulnificus* calculator.~~

~~(iv)~~ Prohibiting the harvest of oysters and/or hard clams when water temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold.~~The State Authority may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.05 E. (1) (b) (iii) when water temperatures exceed 70°F.~~

(2) Control Plan Evaluation

(a) ~~In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.~~The State Authority will conduct an evaluation of the plan. At a minimum the Authority will consider:

(i) Changes in the annual number of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* cases associated with the State's growing waters.

(ii) Environmental changes which could affect total *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in shellfish pre and post-harvest.

(iii) Industry compliance with existing controls.

(iv) The Authorities enforcement of industries' implementation of the controls.

(b) ~~The Control Plan shall be modified when the evaluation shows the Plan is ineffective, or when new information or more effective technology is available as determined by the Authority.~~ For the purposes of determining Authority compliance the FDA will conduct an annual Vibrio evaluation to determine the following:

(i) Authority compliance with the *Vibrio* Risk Evaluation as required in Chapter II @ .05 A.

(ii) For States required to develop and implement a *Vibrio* Control Plan, compliance with Control Plan requirements of Chapter II @ .05 F. (1). The evaluation shall determine:

a. Did the Authority implement one or more of the control measures required in Chapter II @ .05 F. (1)?

(iii) For Authorities required to develop *Vibrio* Contingency Plans the evaluation shall determine:

a. Did the risk evaluation indicate the need for a Contingency Plan?

b. Does the plan include the regulatory steps to be implemented should the number of illnesses reach the illness threshold requiring implementation of a Vibrio Control Plan?

(c) The results of the State and USFDA evaluations will be shared with the ISSC Vibrio Management Committee for use in conducting trend evaluations as stated in the ISSC Constitution, Bylaws, and Procedures.

FG. Contingency Plan

(1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a *Vibrio* ~~v.~~. Control Plan.

(2) Contingency Plan Evaluation

In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

~~**@.06 *Vibrio parahaemolyticus* Control Plan**~~

~~A. Risk Evaluation.~~

~~Every State from which oysters and/are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters and/ harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)~~

~~(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and~~

~~(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and~~

~~(3) The water temperatures in the area; and~~

~~(4) The air temperatures in the area; and~~

~~(5) Salinity in the area; and~~

~~(6) Harvesting techniques in the area; and~~

~~(7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.~~

~~B. Control Plan~~

~~(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters and/ harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or~~

~~(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:~~

~~(a) Waters bordering the Pacific Ocean : 60°F.~~

~~(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.~~

~~(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.~~

~~(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;~~

~~(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or~~

~~(3) If a State has a shellfish growing area that was the source of oysters and/that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.~~

~~(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:~~

~~(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.~~

~~(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:~~

~~(i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for the Pacific Coast oysters;~~

~~(ii) Closing the area to oyster harvest;~~

~~(iii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;~~

~~(iv) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;~~

~~(v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;~~

~~(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.~~

~~(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.~~

~~(d) Evaluate the effectiveness of the Plan.~~

~~(e) Modify the Control Plan when the evaluation shows the Plan is~~

| | |
|---|---|
| | ~~ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.~~<br>~~(f) Optional cost-benefit analysis of the *Vibrio parahaemolyticus* Control Plan.~~<br>~~C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.~~ |
| Public Health Significance | While *Vibrio parahaemolyticus* and *Vibrio vulnificus* Control plans (VPCP and VVCP) rely primarily on time and temperature controls to reduce post-harvest vibrio growth, the controls implemented vary widely from state to state. States requiring *V.v.* controls generally must implement more restrictive harvest controls than states which only require *V.p.* control plans. Additionally, risk per serving standards associated with VVCP require corrective actions that are absent in VPCP. This disparity creates an economic advantage for industry in states with less stringent requirements and favors higher production of more risky product. This may partially explain the increases in reported *V.v.* illnesses in recent years while *V.v.* cases have remained relatively static over this same period. Post-harvest growth increases the risk of *V.p.*, *V.v.* and likely other Vibrio spp. and shall be prevented by any reasonable means. Enforcement of current time and temperature controls is problematic as it is difficult to determine when the product was harvested. Immediate cooling would prevent any vibrio growth and maintain the vibrio levels at harvest providing enhanced public health protection relative to the current control plans. Immediate cooling would also facilitate enforcement and improve compliance. This approach is consistent with Codex Guidance for bivalve mollusks and industry cooling practices with other seafood products that are inherently less risky. Environmental monitoring with the current capabilities and capacity is not an effective means for mitigating vibrio risk. While immediate cooling is not as effective as Post-Harvest Processing (PHP) or closures, it is far less disruptive to industry than these approaches. Acceptance of this proposal would unify and simplify the control approach used for *V.p.* and *V.v.* and provide a level playing field for industry.<br><br>FDA intends to provide additional information in support of this Proposal in advance of the ISSC 2013 Biennial Meeting. |
| Cost Information | |
| Action by 2013 Task Force II | Recommended adoption of Proposal 13-204 as substituted.<br><br>The ISSC Executive Board is tasked to work with states to seek and obtain funding for the purpose of assessing the efficacy of time and temperature controls on post-harvest Vibrio growth. Efforts shall be directed at developing robust science to define the combination(s) of prevention and post-harvest time and temperature controls that, when fully implemented, will minimize post-harvest Vibrio growth. The ISSC Executive Director, ISSC Chair, in consultation with an appropriate work group including some members of the Vibrio Management Committee shall provide guidance and administrative oversight to promote a coordinated effort among states, industry and the FDA to:<br><br>1. Assess regional and environmental differences that may better define the combination(s) of post-harvest time and temperature controls that will be most effective for a given region or state and;<br>2. Ensure that the results of research efforts will be fully considered by the membership of the ISSC. |

| | |
|---|---|
| | In addition to new research activities directed at scientifically defining effective time and temperature controls, the Executive Office shall request that states and industry submit to the VMC data and information relative to efforts in their respective state associated with time and temperature assessment and control activities. This work shall be conducted over the next one to two years and the science that is generated and compiled shall be used to compose an ISSC Proposal for consideration at the 2015 biennial meeting of the ISSC for controlling the post-harvest growth of Vibrios. The Executive Board shall be briefed at each of its semiannual meetings regarding all ongoing work associated with this effort.<br><br>Additionally FDA requested that the remaining Vibrio Proposals be debated as submitted. |
| Action by 2013 General Assembly | Adopted recommendation of 2013 Task Force II on Proposal 13-204. |
| Action by FDA May 5, 2014 | Concurred with Conference action on Proposal 13-204. |
| Action by 2015 Vibrio Management Committee | Recommended no action on Proposal 13-204. Rationale: The final reports from the ISSC funded studies have not been finalized and submitted to the ISSC. The final reports, when available, will be shared with VMC. The VMC will make recommendations to Task Force II to address Proposal 13-204 at that time. |
| Action by 2015 Task Force II | Recommended deferring action on Proposal 13-204. Rationale: The final reports from the ISSC funded studies have not been finalized and submitted to the ISSC. The final reports, when available, will be shared with VMC. The VMC will make recommendations to Task Force II to address Proposal 13-204 at that time. |
| Action by 2015 General Assembly | Adopted recommendation of Task Force II on Proposal 13-204. |
| Action by FDA January 11, 2016 | Concurred with Conference action on Proposal 13-204. |
| Action by 2017 Vibrio Management Committee | Recommended that the VMC routinely compile and evaluate the information included in a., b., and c. below.<br><br>a. Assess regional and environmental differences that may better define the combination(s) of post-harvest time and temperature controls that will be most effective for a given region or state.<br>b. Ensure that the results of research efforts will be fully considered by the membership of the ISSC.<br>c. Submit state and industry data and information relating to efforts associated with time and temperature assessments and control activities.<br><br>Additionally, recommended:<br><br>d. The development of a database of current *V.p.* research to make it more accessible to the ISSC.<br>e. Based on the information discussed at the *V.p.* Workshop, recommended that no additional controls be included into the Model Ordinance at this time. |
| Action by 2017 Task Force II | Recommends adoption of the VMC recommendations on Proposal 13-204. |

**Proposal No.** **13-209**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | Re-submerging of Shellstock |
| Specific NSSP Guide Reference | Section I. Purpose and Definitions<br>Section II. Model Ordinance Chapter V. Shellstock Relaying |
| Text of Proposal/ Requested Action | Chapter I. Purpose and Definitions<br>Definitions.<br>Add new definition:<br>(92) Re-submerging means the process of short term submersion of shellstock in an approved growing area following initial harvest for purposes of reducing naturally occurring bacterial pathogens to background levels.<br><br>Renumber existing definitions 92 through 121.<br><br>Chapter V. Shellstock Relaying and Re-submerging<br>Requirements for the Authority<br><br>@.01 General<br><br>The Authority shall assure that:<br>A. The shellstock:<br>(1) ~~u~~Used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;<br>(2) Used in re-submerging activities is harvested from growing areas classified as approved or conditionally approved;<br>B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;<br>C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by the coliform group of indicator organisms~~ in the water~~, or naturally occurring pathogens such as *Vibrio* spp., or poisonous, or deleterious substances that may be present in shellstock to occur; and<br>D. If shellstock are relayed in containers:<br>(1) The containers are:<br>(a) Designed and constructed so that they allow free flow of water to the shellstock; and<br>(b) Located so as to assure the contaminant reduction required in Section C.; and<br>(2) The shellstock are washed and culled prior to placement in the containers.<br><br>@.02 Contaminant Reduction<br><br>A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.<br>B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the relay or resubmerging activity:<br>(1) The bacteriological quality of each shellfish species is the same bacteriological quality as that of the same species already present in the approved or |

| | |
|---|---|
| | conditionally approved area; or<br>(2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels; or<br>(3) The level of naturally occurring pathogens (*Vibrio* spp.) in each shellfish species is the same level of naturally occurring pathogens as that of the same species already present in the approved or conditionally approved area. |
| Public Health Significance | States that have a significant Vibrio risk as determined by risk assessment have adopted requirements to limit the time between harvest and initial refrigeration. Compliance with these time restrictions have created operational difficulties for various industry sectors and resubmerging oysters after initial harvest is being pursued as a means to mitigate Vibrio growth during temperature abuses. However, the effectiveness of this approach for reducing Vibrios has not been demonstrated for the various approaches and practices that have been employed or proposed. This practice has the potential to greatly increase Vibrio levels, especially if the oysters are unable to purge due to handling issues, transfer to different environmental conditions, gear type or over stacking. If the oysters are unable to pump, Vibrios will continue to grow at a rate determined largely by water temperature. While resubmerging has great potential to reduce Vibrio levels, the best practices need to be determined and implemented. |
| Cost Information | |
| Action by 2013 Task Force II | Recommended referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chair. |
| Action by 2013 General Assembly | Adopted recommendation of 2013 Task Force II on Proposal 13-209. |
| Action by FDA May 5, 2014 | Concurred with Conference action on Proposal 13-209 with the following comments and recommendations.<br><br>FDA concurs with Conference action to refer Proposal 13-209 to committee. Proposal 13-209 requires that a study be conducted to ensure that shellstock transplanted or re-submerged, for purposes of mitigating levels of naturally occurring pathogens, are allowed sufficient time to reduce levels to background. While the intended purpose of re-submerging is to reduce naturally occurring pathogens such as Vibrio spp. to pre-harvest levels, re-submerging also has the potential to greatly increase Vibrio levels, especially if shellstock purging is limited as a result of environmental conditions, handling practices, over-stacking, etc. If shellstock cannot effectively pump, Vibrio levels will remain the same or possibly increase, depending on water temperature. While re-submerging can effectively reduce Vibrio levels, as demonstrated by FDA-ISSC studies conducted in 2013, effective application needs to be scientifically demonstrated. |
| Action by 2015 Shellstock Resubmerging Committee | Recommended adoption of the following substitute language.<br><br>Re-submerging means the process of short term submersion of shellstock following exceedance of the time temperature requirements of a vibrio control plan. The purpose of resubmerging is to allow shellstock harvested under conditions that are not compliant with Vibrio time temperature controls to return to background levels.<br><br>Wet Storage means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater at any permitted land-based activity or facility. Wet Storage can only be used for shellstock that is harvested under conditions that are compliant with the time temperature controls included in Chapter VIII. @.02. |

| | |
|---|---|
| | Chapter V. Shellstock Relaying and Resubmerging<br><br>Add a new section Resubmerging. Renumber existing sections as appropriate.<br><br>@.02 Resubmerging<br>A. General. The Authority shall assure that:<br>(1) The shellstock used in re-submerging activities is harvested from growing areas classified as approved, conditionally approved, restricted or conditionally restricted;<br>(2) The level of contamination in the shellstock can be reduced to levels safe for human consumption;<br>(3) The shellstock are held in growing areas classified as approved or conditionally approved, restricted, or conditionally restricted for a sufficient time under adequate environmental conditions so as to allow reduction of naturally occurring pathogens such as Vibrio spp. that may be present in shellstock to occur; and<br>B. Natural Pathogen Reduction<br>(1) The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.<br>(2) The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the submerging activity. The level of naturally occurring pathogens (Vibrio spp.) in each shellfish species is the same level of naturally occurring pathogens as that of the same species already present in the approved, conditionally approved, restricted or conditionally restricted area.<br>(3) A study will not be required if shellstock remains in the growing area for a time period of at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate. |
| Action by 2015 Task Force II | Recommended referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chairperson. |
| Action by 2015 General Assembly | Adopted recommendation of Task Force II on Proposal 13-209. |
| Action by FDA January 11, 2016 | Concurred with Conference action on Proposal 13-209. |
| Action by 2017 Shellstock Resubmerging Committee | Recommended adoption of the substitute language below. Additionally, the Committee requested the Conference work with FDA and others to obtain additional funding to allow further studies to be performed for various practices treatments, and techniques taking into account regional and state differences. |

Model Ordinance Chapter II. Risk Assessment and Risk Management
@.06 *Vibrio vulnificus* Control Plan

E. Control Plan

1. The *Vibrio vulnificus* Control Plan shall include the following:

(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One or more of the following triggers will be used:

(i) The water temperatures in the area; and
(ii) The air temperatures in the area; and
(iii) Salinity in the area; and
(iv) Harvesting techniques in the area; and
(v) Other factors which affect risk which can be used as a basis for reducing risk.

(b) Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* illness:

(i) Labeling oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 70°F.

(ii) Subjecting all oysters intended for the raw, half-shell market to Authority approved post-harvest processing when the Average Monthly Maximum Water Temperature exceeds 70°F.

(iii) Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *V.v.* plans will include controls when water temperature promotes *V.v.* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when Average Monthly Maximum Water Temperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when Average Monthly Maximum Water temperature exceeds 70°F but is less than or equal to 80 °F. BMPs will ensure that when the water temperature exceeds 70°F but is less than or equal to 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperature exceeds 75°F but is less than or equal 80 °F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *Vibrio vulnificus* calculator. A State is in compliance with the NSSP when it effectively implements the controls established in its plan using the FDA calculator to determine the risk per serving for the established water temperatures.

(iv) The State Authority may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.05 E. (1) (b) (iii) when water temperatures exceed 70°F.

(c) When pre-harvest culture practices have the potential to elevate *Vibrio* levels in market size product intended for immediate harvest, the Authority shall establish Vibrio control measures and include the measures in the State *Vibrio* Control Plan. Such control measures may be implemented on a state-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.

Model Ordinance Chapter II. Risk Assessment and Risk Management
@.07 *Vibrio parahaemolyticus* Control Plan

B. Independent Species Specific Control Plan

(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or

(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

(a) Waters bordering the acific Ocean: 60°F.

(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.

(c) Waters bordering the Atlantic Ocean (NY and north): 60°F.

(d) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters or hard clams harvested from those areas.

(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;

(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters or hard clams that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:

(i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and hard clams and a three (3) log reduction for the Pacific Coast oysters;

(ii) Closing the area to oyster and/or hard clam harvest;

(iii) Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iv) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;

(v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters or hard clams) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

(c) Require the original dealer to cool oysters and/or hard clams to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters and/or hard clams has reached 50°F (10°C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering. Oysters and/or hard clams without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.

(d) Evaluate the effectiveness of the Plan.

(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.

(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.

(5) When pre-harvest culture practices have the potential to elevate Vibrio levels in market size product intended for immediate harvest, the Authority shall establish Vibrio control measures and include the measures in the State Vibrio Control Plan. Such control measures may be implemented on a state-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should

| | |
|---|---|
| | consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority. |
| Action by 2017 Task Force II | Recommends adoption of Shellstock Re-submerging Committee recommendations to modify NSSP Guide Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan E. 1. c. and @.07 *Vibrio parahaemolyticus* Control Plan B. 5.<br><br>Task Force II additionally requests the Conference seek additional funding to allow further studies to be performed for various practices, treatments, and techniques taking into account regional and state differences. |

**Proposal No.** **15-203**

| | |
|---|---|
| Submitter | Executive Office |
| Affiliation | Interstate Shellfish Sanitation Conference |
| Email | issc@issc.org |
| Proposal Subject | Annual Assessment of Shellfish Production and Utilization |
| Specific NSSP Guide Reference | NSSP Guide for the Control of Molluscan Shellfish Section II><br>Chapter II. Risk Assessment and Risk Management<br>@.03 Annual Assessment of Vibrio vulnificus and Vibrio parahaemolyticus Illnesses and Shellfish Production |
| Text of Proposal/ Requested Action | A. The Authority shall assess annually *Vibrio vulnificus* and *Vibrio parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *Vibrio vulnificus* and *Vibrio parahaemolyticus* shellfish-associated illnesses reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.<br>B. The Authority shall ~~determine annually, and~~ report monthly to the ISSC, the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species. ~~associated with Vibrio illnesses, including, if available,~~ The production data will include a volume breakdown by utilization type (raw, shucked, PHP, etc.). |
| Public Health Significance | The present reporting requirement in Chapter II. @.03 does not provide the specific information needed to evaluate the effectiveness of Vibrio controls or to conduct risk assessments. The production data must be submitted in a manner that will give the Authority the ability to determine risks in the months in which their Vibrio Plans are in effect. |
| Cost Information | |
| Action by 2015 Task Force II | Recommended adoption of Proposal 15-203 as amended with instructions that a workgroup be formed to investigate production reporting standardization and methodology.<br><br>B. The Authority shall collect by month and report annually to the ISSC. ~~determine annually, and report monthly to the ISSC,~~ the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species. ~~The production data will include a volume breakdown by utilization type~~ Where available the volume breakdown of the production data will be reported by utilization type. (raw, shucked, PHP, etc.). |
| Action by 2015 General Assembly | Adopted recommendation of Task Force II on Proposal 15-203. |
| Action by FDA January 11, 2016 | Concurred with Conference action on Proposal 15-203. |
| Action by 2017 Production Reporting Committee | Recommended adoption of the following language in the Model Ordinance.<br><br>Chapter VIII. Control of Shellfish Harvesting<br>.01 General<br><br>E. Each harvester 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 certified dealers, harvesters may be exempt from this requirement. |

Chapter X. General Requirements for Dealers
.03 Other Model Ordinance Requirements

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 may be exempt from this requirement.

Additionally, recommends adoption of the following guidance in Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens of the NSSP Guide for the Control of Molluscan Shellfish.

**.07 Production Reporting Guidance**

**Introduction**

The NSSP Model Ordinance Chapter II @.03 B. includes a requirement for the Authority to report production data to the ISSC.

The primary purpose of the requirement is to ensure that the data necessary to conduct *V.v* and *V.p.* risk evaluations is collected by the Authority. Additionally, production trend data would be used by the ISSC in evaluating illness trends. To utilize the data for both of these intended purposes, it is important that the production data be collected and reported timely at appropriate intervals and in metrics that allow the development of national production trends.

**Timely Reporting**

The Authority should annually report monthly production data no later than March 1 of the subsequent year. The ISSC will compile state information which will be shared with the ISSC Executive Board at the Spring ISSC Executive Board Meeting. The information will also be provided to the ISSC Vibrio Management Committee and posted on the ISSC website.

**Reporting Intervals**

The annually reported data will include production totals for each month of the preceding year. The monthly reporting will allow shellfish authorities to conduct risk analysis for the time periods that coincide with the higher risk periods.

**Reporting Metrics**

The State may use the reporting metric that is most appropriate for conducting the risk analysis that are required in Chapter II @.06 and @.07 and are optional in Chapter II@.02. It is expected that all states will not choose the same metric. Should the Authority choose a metric other than pounds of shellfish meat, the Authority should provide a conversion factor that allows the ISSC to convert the metric into pounds of Shellfish meat. Chapter II @.03 B includes the reporting of utilization type (raw, shucked, PHP, etc.) when available. Authorities are encouraged to provide utilization type. The current risk models assume that at all times of the year, 50% of harvested shellfish are consumed raw. The reporting of utilization type could provide valuable insight into that assumption and could result in more precise vibrio calculators.

**Proposal No.** **15-203**

| | |
|---|---|
| Action by 2017 Task Force II | Recommends adoption of the Production Reporting Committee recommendations on Proposal 15-203. |

**Proposal No.** **15-208**

| | |
|---|---|
| Submitter | Floyd Raymond Burditt and Mary Losikoff |
| Affiliation | US Food & Drug Administration (FDA) |
| 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<br><br>Section II. Model Ordinance Chapter IX. Transportation<br>Section .04 Shipping Temperatures;<br><br>Section II. Model Ordinance Chapter X. General Requirements for Dealers<br>Section .04 Certification Requirements;<br><br>Section II. Model Ordinance Chapter X. General Requirements for Dealers Section .06 Shellfish Labeling;<br><br>Section II. Model Ordinance Chapter XI. Shucking and Packing<br>Section .01 Critical Control Points<br>D. Processing Critical Control Point – Critical Limits and<br>E. Shucked Meat Storage Critical Control Point – Critical Limit;<br><br>Section II. Model Ordinance Chapter XIV. Reshipping Section<br>.01 Critical Control Points<br>A. Receiving Critical Control Point - Critical Limits and<br>D. Shucked Meat Storage Critical Control Point – Critical Limit |
| Text of Proposal/ Requested Action | Definitions<br>Add a new definition for Reduced Oxygen Packaging and number appropriately:<br><br>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.<br><br>Chapter IX.<br><br>.04 Shipping Temperatures.<br><br>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.<br><br>~~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.<br><br>Chapter X.<br><br>.04 Certification Requirements<br><br>B. Types of Certification.<br>(1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer.<br>(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;
(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:

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

DE. 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]**<br>(f) Shipped shucked meats packed in ROP containers below an ambient air temperature of 38ºF (3.3ºC) or covered in ice. **[C]**<br>(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]**<br><br>D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall:<br>(1) ~~s~~Store shucked shellfish at an ambient temperature of 45°F (7.2°C) or less. **[C]**<br>(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 | 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 | Concurred with Conference action on Proposal 15-208 with the following comments and recommendations.<br><br>FDA applauds and concurs with action by the ISSC voting delegates to refer Proposal 15-208 to an appropriate committee.<br><br>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 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.<br><br>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. |
| Action by ISSC ROP Committee November 2016 | 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.<br><br>1. The ISSC Executive Board identify funding for studies to determine the following:<br>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?<br>b. Determine the effect that normal product deterioration has on PH. Determine if PH reaches a level that prohibits C. Botulinum growth.<br>c. Determine if a reduced shelf life offers a potential C. Botulinum control.<br>d. Conduct a study of competitive bacteria and its effect on C. Botulinum growth.<br>2. The ISSC Executive Board requested that FDA conduct a cost analysis of the impact of Proposal 15-208.<br>3. The ISSC Executive Board requested that FDA determine how packaging changes would affect exports.<br>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.<br>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 | 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. |
| Action by FDA December 8, 2016 | 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 exerpts 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.<br><br>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 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.<br><br>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. |
| Action by 2017 Task Force II | Recommends no action on Proposal 15-208.<br>Rationale: FDA is conducting research to evaluate packaging and will share findings with the Conference. |

**Proposal No.** **15-211**

| | |
|---|---|
| Submitter | Gulf Oyster Industry Council (GOIC) |
| Affiliation | Gulf Oyster Industry Council (GOIC) |
| Email | cnelson@bonsegourfisheries.com |
| Proposal Subject | Shucked Shellfish Labeling |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter X. General Requirements for Dealers |
| Text of Proposal/ Requested Action | .06 Shucked Shellfish Labeling.<br><br>A. Shellfish Labeling.<br>(1) The dealer shall maintain…<br><br>(7) The dealer shall label each individual package containing 64 fluid ounces or more of fresh or fresh frozen shellfish with the following:<br>(a) The words "DATE SHUCKED" or "USE BY" or "SELL BY" followed by the same information located ~~date shucked located~~ on both the lid and sidewall or bottom of the container;<br>(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<br>(c) For fresh frozen shellfish, the year shall be added to the date(for non-Julian format) |
| Public Health Significance | Control of naturally occurring Vibrios. |
| Cost Information | |
| Action by 2015 Task Force II | Recommended referral of Proposal 15-211 to an appropriate committee as determined by the Conference Chairperson. |
| Action by 2015 General Assembly | Adopted recommendation of Task Force II on Proposal 15-211. |
| Action by FDA January 11, 2016 | Concurred with Conference action on Proposal 15-211. |
| Action by 2017 Labeling Committee | Recommended adoption of Proposal 15-211 as submitted. |
| Action by 2017 Task Force II | Recommends no action on Proposal 15-211.<br>Rationale: The ISSC Model Ordinance already requires the date shucked. The dealer or processor already has the option to add additional date information. There is no public health significance. |

**Proposal No.** **15-213**

| | |
|---|---|
| Submitter | John Veazey |
| Affiliation | US Food and Drug Administration Southeast Regional Office |
| Email | john.veazey@fda.hhs.gov |
| Proposal Subject | Temperature Control Following Receipt from Harvesters |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter XI. Shucking and Packing .03 Other Model Ordinance Requirements<br>F. Shellfish Storage and Handling (11) and<br>Chapter XIII. Shellstock Shipping .03 Other Model Ordinance Requirements<br>F. Shellfish Storage and Handling (6) |
| Text of Proposal/ Requested Action | Chapter XI. Shucking and Packing .03 Other Model Ordinance Requirements<br><br>F. Shellfish Storage and Handling<br>(11) All shellstock obtained from a licensed harvester shall be<br>(a) Adequately iced within two (2) hours of receipt;<br>(b) Placed in a storage area maintained at 45°F (7.2°C) within two (2) hours of receipt; or<br>(c) Shucked within two (2) hours of receipt. **[SC/K]**<br><br>Chapter XIII. Shellstock Shipping .03 Other Model Ordinance Requirements<br><br>F. Shellfish Storage and Handling<br>(6) All shellstock obtained from a licensed harvester shall be<br>(a) Adequately iced within two (2) hours of receipt; or<br>(b) Placed in a storage area maintained at 45° F (7.2° C) within two (2) hours of receipt.~~; or~~<br>~~(c) Processed within two (2) hours of receipt. [SC/K]~~ |
| Public Health Significance | 2009 Model Ordinance Chapter IX. .02 C. (2) required that the dealer "Place shellstock under temperature control within two (2) hours after receipt from the harvester, or when the dealer is also the harvester, when shellstock reaches the dealer's facility; "The ISSC removed that requirement in 2011 and there was no requirement pertaining to how long a dealer had to place shellstock under refrigeration after receipt from harvesters in the 2011 Model Ordinance.<br><br>In 2013 the ISSC added Chapter XI. .03 F. (11) and Chapter XIII. .03 F. (6) to the Model Ordinance. However, if taken literally, the language of those two sections does not require that shellstock be placed under temperature control within two (2) hours of receipt from harvesters. There are, literally, two (2) hour time limits involving shucking in Chapter XI. .03 F. (11) and involving being "processed" in Chapter XI. 03 F. (6) but no time limits for icing and refrigeration.<br><br>Additionally, Chapter XIII. .03 F. (6) (c) is literally an exclusion to temperature control requirements. For example: Because of the use of "or" Chapter XIII. .03 F. (6) literally means that if a dealer repacks shellstock into boxes that dealer does not have to place the shellstock under temperature control. The dealer will have processed the oysters within two (2) hours and thereby satisfied the requirements.<br><br>Clear and unambiguous Model Ordinance requirements for placing shellstock under temperature control with two (2) hours of harvest are particularly important because there is no unambiguous Model Ordinance requirement that "All other shellstock..." referenced in Chapter VIII. @.02 A. (3) be placed under temperature control within any particular period after harvest. Chapter VIII. @.02 A. (3) references a matrix and the |

| | |
|---|---|
| | matrix specifies "Maximum Hours from Exposure to Receipt at a Dealer's Facility."<br><br>NSSP Guide for the Control of Molluscan Shellfish Section IV, Chapter III, Guidance Documents .07 indicates, "All shellstock obtained from a licensed harvester shall be placed in a storage area maintained at 45°F (7.2°C) or less within two (2) hours of receipt."<br><br>However, language in a Section IV. Guidance Documents is not satisfactory compliance language unless it is referenced as such in Model Ordinance language and the subject language is not so referenced. Also, the purpose of the Model Ordinance format is to provide language a State or other jurisdiction can adopt in order to provide a legal basis for controlling molluscan shellfish. If a State adopts the language of the 2013 Model Ordinance without adding a clear requirement pertaining to how long a dealer has to place shellstock under temperature control after receiving from harvesters the State may not have the legal authority to require any particular time to temperature control. In fact, if the 2013 Model Ordinance language is taken literally it certainly will not. |
| Cost Information | Cost will be the same as it was before the referenced 2009 Model Ordinance requirement was removed. |
| Action by 2015 Task Force II | Recommended referral of Proposal 15-213 to an appropriate committee as determined by the Conference Chairperson. |
| Action by 2015 General Assembly | Adopted recommendation of Task Force II on Proposal 15-213. |
| Action by FDA January 11, 2016 | Concurred with Conference action on Proposal 15-213. |
| Action by 2017 Time Temperature Committee | Recommended adoption of Proposal 15-213 as amended.<br><br>Chapter XI. Shucking and Packing .03 Other Model Ordinance Requirements<br><br>F. Shellfish Storage and Handling<br>(11) All shellstock obtained from a licensed harvester shall be<br>(a) Adequately iced within two (2) hours of receipt;<br>(b) Placed in a storage area maintained at 45°F (7.2°C) within two (2) hours of receipt; or<br>(c) Shucked within two (2) hours of receipt. **[SC/K]**<br>(d) Product intended for relay, wet storage or depuration, or either geoduck clams (Panopea generose), or Mercenaria sp which are being cooled utilizing an Authority approved tempering plan are exempt from the requirements listed above in .03 F. (11).<br><br>Chapter XIII. Shellstock Shipping .03 Other Model Ordinance Requirements<br><br>F. Shellfish Storage and Handling<br>(6) All shellstock obtained from a licensed harvester shall be<br>(a) Adequately iced within two (2) hours of receipt; or<br>(b) Placed in a storage area maintained at 45° F (7.2° C) within two (2) hours of receipt.~~; or~~<br>~~(c) Processed within two (2) hours of receipt. **[SC/K]**~~<br>(c) Product intended for relay, wet storage or depuration, or either geoduck clams (Panopea generose), or Mercenaria sp which are |

| | |
|---|---|
| | being cooled utilizing an Authority approved tempering plan are exempt from the requirements listed above in .03 F. (6). |
| Action by 2017 Task Force II | Recommends adoption of Time Temperature Committee recommendations on Proposal 15-213. |

**Proposal No.** **15-226**

| | |
|---|---|
| Submitter | ISSC Executive Office |
| Affiliation | Interstate Shellfish Sanitation Conference (ISSC) |
| Email | issc@issc.org |
| Proposal Subject | *V.p.* Illness Response Guidance Document |
| Specific NSSP Guide Reference | Section IV. Guidance Documents<br>Chapter V. Illness Outbreaks and Recall Guidance |
| Text of Proposal/ Requested Action | Add new section:<br>.03 *V.p.* Illness Response Guidance Document<br><br>I. Introduction<br><br>Chapter II @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*) is intended to address three (3) distinct *V.p.* illness situations as follows:<br><br>A. Traditional sporadic cases from a State in which single cases occur that most often do not involve a single growing area and occur weeks or months apart. The occurrences of these types of illnesses have historically been considered as an acceptable risk in the National Shellfish Sanitation Program (NSSP) and have not involved closures or recalls.<br><br>B. Frequent sporadic cases which often begin when water temperatures reach a level which supports reproduction of *V.p.* to levels which can cause illness. The illness risk usually persists until the environmental conditions no longer support *V.p.* levels of illness causing potential. This illness situation involves clusters of sporadic cases in multiple individual growing areas or may be limited to a single growing area when the environmental conditions are favorable for the persistence of illness causing levels of *V.p.*<br><br>C. A true outbreak with multiple cases with multiple harvest areas and varying routes of transportation indicates a more widespread contamination of a growing area. The outbreak may be characterized by a high attack rate. In this situation, a single growing area is usually involved with multiple cases of illness occurring from a single harvest day or from a relatively short harvest time frame.<br><br>The strains of *V.p.* associated with these different illness situations are not the same. The attack rates are very different and the reported illnesses reflect the differences in attack rates. Although strain identification is time consuming, knowing the strain aids the Shellfish Control Authority in addressing the problem.<br><br>II. Illness Investigation<br><br>When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time. |

The Shellfish Control Authority is encouraged to coordinate the investigation and response with other appropriate State entities and the US Food and Drug Administration (FDA) to facilitate and streamline the reporting process to promote prompt and appropriate regulatory responses to illness.

III. Risk per Serving Determinations

In determining a risk per serving, the Shellfish Control Authority should use a recognized serving size and credible landing data. The period of time for evaluating the risk per serving should be consistent with the time of harvest of the shellfish that was associated with the illness (es) and should not exceed thirty (30) days

IV. Regulatory Response

When a case(s) is reported, the State Shellfish Control Authority will determine the number of cases and the time period between the harvest dates of reported cases and the extent of the implicated area.

When determining the number of illnesses in the thirty (30) day period, the harvest date will be used. When an illness occurs, the Shellfish Control Authority will determine the number of cases that have occurred during the previous thirty (30) days. Every subsequent harvest associated with a new reported case will require a review of the previous thirty (30) days.

A. Should the number of cases and the period of time result in a risk that is less than one (1) per 100,000 servings or involves at least two (2) but not more than four (4) cases in which no two of these were from a single harvest day from an implicated area, the State Shellfish Control Authority will evaluate and attempt to ensure compliance, where appropriate, with the existing Vibrio Management Plan. Regulatory response to multiple illnesses occurring from a single harvest day from an implicated area are addressed in IV. B and IV. C.

B. Should the number of cases and the period of time result in a risk that exceeds one (1) illness per 100,000 servings or if the number of cases within a thirty (30) day period from the implicated area is more than four (4) but less than ten (10) or if two (2) or more but less than four (4) cases occur from a single harvest day from the implicated area, the Shellfish Control Authority is required to:

(1) Determine the extent of the implicated area; and
(2) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and
(3) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish

The notification is intended to facilitate the reporting of other illnesses that may have occurred associated with the implicated harvest area. Although the State is not required to report this information to the Interstate Shellfish Sanitation Conference (ISSC), if requested, the ISSC will assist the States with notification.

C. Should the number of cases exceed ten (10) within a thirty (30) day period or four (4) or more cases occurred from a single harvest day from the implicated area, the Shellfish Control Authority is required to:

(1) Determine the extent of the implicated area; and
(2) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and
(3) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products; and
(4) Issue a consumer advisory for all shellfish (or species implicated in the illness). The consumer advisory shall be in the form of a news release and will be shared with the State Shellfish Control Authorities in all states receiving the implicated shellfish.

V. Closure Periods

A. When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area the Shellfish Control Authority will close the implicated growing area. The area will remain closed for a minimum of fourteen (14) days.

B. When the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area the Shellfish Control Authority will close the implicated growing area. The area will remain closed for a minimum of twenty-one (21) days.

VI. Reopening of Closed Areas

Prior to reopening an area closed as a result of the number of cases exceeding ten (10) illnesses within thirty (30) days or four (4) cases from a single harvest date from the implicated area, the Authority shall:

A. Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g or other such values as determined appropriate by the Authority based on studies.

B. Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.

C. Implicated areas that have been closed when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area do not require sampling or review of environmental conditions prior to reopening.

| | |
|---|---|
| | VII. Harvesting From Closed Areas<br><br>Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one or more of the following controls:<br><br>A. Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams;<br><br>B. Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;<br><br>C. Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.<br><br>VIII. Laboratory<br><br>All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Office or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP.<br><br>IX. Approved Laboratory Methods<br><br>Methods for the analyses of shellfish and shellfish growing or harvest waters shall be:<br><br>The Approved NSSP Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI. of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the NSSP Guide for the Control of Molluscan Shellfish Section IV Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. |
| Public Health Significance | The purpose of this document is to provide guidance to States in implementing the requirements of Chapter II. @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*). |
| Cost Information | |
| Action by 2015 Task Force II | Recommended referral of Proposal 15-226 to an appropriate committee as determined by the Conference Chair with instruction to remove this section from the NSSP Guide as interim guidance. |
| Action by 2015 General Assembly | Adopted recommendation of Task Force II on Proposal 15-226. |
| Action by FDA January 11, 2016 | Concurred with Conference action on Proposal 15-226. |
| Action by 2017 Vibrio Management Committee | The Vibrio Management Committee recommended that the Conference Chairperson appoint an appropriate workgroup to amend the *Vibrio parahaemolyticus* Illness Response guidance document to submit to the Executive Board as interim approval following the Biennial Meeting. |
| Action by 2017 Task Force II | Recommends adoption of Vibrio Management Committee recommendation on Proposal 15-226. |

**Proposal No.** **17-200**

| | |
|---|---|
| Submitter | Thomas Dameron, BK Rastogi, and Chris Shriver |
| Affiliation | Surfside Foods, Atlantic Capes Fisheries, and LaMonica Fine Foods |
| Email | tdameron@surfsidefoods.com brastogi@surfsidefoods.com cshriver@atlanticcapes.com |
| Proposal Subject | Individual Shellfish Dealer with harvest vessels landing ocean quahogs (Arctica islandia) and surf clams (Spisula solidissima) from federal waters in another state. |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter I. Shellfish Sanitation Program Requirements for the Authority<br>@.01 Administration., E. Administrative Procedures (2) |
| Text of Proposal/ Requested Action | E. Administrative Procedures.<br><br>The Authority shall have administrative procedures sufficient to:<br>(1) Regulate shellfish harvesting, sale, or shipment; and<br>(2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the state from which the shellstock are harvested or landed, unless:<br>(a) The Authority has a memorandum of understanding with the Authority in another State to allow dealers from its state to purchase the shellstock, or<br>(b) The shellfish are ocean quahogs (Arctica islandia) or surf clams (Spisula solidissima) intended for thermal processing, originating from the harvester and are being shipped directly to an out of state individual shellfish dealer listed on the FDA Interstate Certified Shellfish Shippers List.<br>(3) Detain, condemn, seize, and embargo shellfish.<br>(4) Assure compliance with Shellfish Plant Inspection Standardization. |
| Public Health Significance | Ocean quahogs (Arctica islandia) or surf clams (Spisula solidissima) from Federal waters, intended for thermal processing, are landed in 32 bushel cages, weighing up to 3,500 pounds per cage, shipped in 50' trailers, in truckloads of up to 40,000 pounds each. This shellfish is normally intended for processing immediately upon arrival at the shucking plant. In many cases when the harvest vessel lands the shellfish, the individual shellfish processor is waiting for the shipment to process it. Ocean quahogs and surf clams intended for thermal processing are offloaded directly to pre-chilled trailers for transportation. This transportation should be as direct as possible. To have truckloads of ocean quahogs or surf clams diverted from the harvester to a shellfish dealer located within the state of landing is an unnecessary burden on industry, it degrades the bacterial quality of the shellfish, and has in many cases become an unnecessary exercise and expense. All necessary NSSP records, traceability and monitoring will still occur and will be provided to the receiving dealer in the state where it will be shucked and processed. |
| Cost Information | Dealers within a state charge up to $.25 per bushel for the paperwork to show the shellfish originating from their dealership so that ocean quahogs or surf clams can be shown to originate from a dealer in the state of landing. These dealers may have no other relationship to the harvester or processor but because the regulation requires origination from a dealer within the state this allows them to act as the middleman in a transaction that they should not be a party to. Regulators are forced to ensure truckloads are making a scheduled stop at a shellfish dealer located within the state so that the shellfish can 'originate' from a dealer within the state or spend the time issuing variances to counter this injustice. This proposed update to the Model Ordinance will streamline an unnecessarily burdensome requirement at a cost savings to both industry and regulators. |
| Action by 2017 Task Force II | Recommends no action on Proposal 17-200.<br>Rationale: This issue is adequately addressed in the Model Ordinance. |

**Proposal No.** **17-201**

| | |
|---|---|
| Submitter | ISSC Executive Office |
| Affiliation | Interstate Shellfish Sanitation Conference |
| Email | issc@issc.org |
| Proposal Subject | Notices of Illness Outbreaks, Recalls and Closures |
| Specific NSSP Guide Reference | NSSP Guide for the Control of Molluscan Shellfish Section II.<br>Chapter II. Risk Assessment and Risk Management<br>@.01 Outbreaks of Shellfish-Related Illnesses |
| Text of Proposal/ Requested Action | @.01 Outbreaks of Shellfish-Related Illness<br><br>B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:<br>(1) Notify the FDA Regional Shellfish Specialist that a shellfish related outbreak has occurred.<br>(~~1~~2) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.<br>(~~2~~3) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.<br><br>C. When the investigation outlined in Model Ordinance Chapter II. @.04 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:<br>(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;<br>(2) Notify ~~receiving states~~, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;<br>~~(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and~~<br>(3~~4~~) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21CFR Part 7. The recall shall include all implicated products.<br>(4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.<br>(5) The ISSC will notify States and FDA Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.<br><br>D. When the investigation outlined in Model Ordinance Chapter II. @.04 B. demonstrates that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:<br><br>(1) Notify ~~receiving states,~~ the ISSC and the FDA Regional Shellfish Specialist of the problem; and<br>(2) Initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall |

| | |
|---|---|
| | include all implicated products.<br>(3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.<br>(4) The ISSC will notify States and FDA Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information. |
| Public Health Significance | The proposed language in Section B. would ensure that FDA is immediately aware of shellfish related outbreaks. The proposed language changes in Section C. would more clearly outline the responsibility associated with notification to FDA and States. Currently notification requirements are not included for recalls associated with post-harvest contamination. Additionally, there are no requirements for notification to States that are not identified as a State receiving recalled product. It is important that all States be notified of recalls. In many cases the complete list of States cannot be determined by identifying the initial dealers. The proposed change would also establish an inventory of closures and recalls. Without an inventory it is difficult to assess program trends. |
| Cost Information | |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-201 with recommendations to the ISSC Executive Board to appoint a committee to develop guidance which details recall and closure information sharing. |

**Proposal No.** **17-202**

| | |
|---|---|
| Submitter | Al Sunseri |
| Affiliation | P & J Oyster Company |
| Email | asunseri@bellsouth.net |
| Proposal Subject | Delete Performance Based Inspection Program |
| Specific NSSP Guide Reference | Section II, Chapter I@.02.G. |
| Text of Proposal/ Requested Action | ~~G. Performance Based Inspection Program (PIP).~~<br><br>~~(1) A performance based inspection program may be instituted by the Authority for any dealer who meets the requirements of this section.~~<br><br>~~(2) The minimum frequency of inspection under a PIP shall be no less than one inspection per certification period. The recertification inspection may qualify as the required minimum inspection frequency.~~<br><br>~~(3) To be eligible for a PIP, the dealer shall have demonstrated a history of satisfactory compliance for the previous three-year period. The three-year demonstration shall include:~~<br>~~(a) Full compliance with the minimum inspection frequency shown under Section F.;~~<br>~~(b) Recertification of the dealer by the Authority;~~<br>~~(c) Verification that no critical deficiencies, no more than one key deficiency and no more than two other deficiencies have occurred in any one inspection;~~<br>~~(d) Correction of all identified deficiencies in accordance with the compliance schedule approved by the Authority; and~~<br>~~(e) No repetition of the identified deficiencies.~~ |
| Public Health Significance | Performance based inspections are obsolete and inadequate to meet the *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* Control Plan requirements of the NSSP-Model Ordinance. Refrigeration equipment, specifically a refrigerated truck or refrigerated truck body which is being used by the certified dealer as the sole source of refrigeration, it's impossible for that equipment to meet the refrigeration requirements under the current NSSP-Model Ordinance. |
| Cost Information | None |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-202 as submitted. |

**Proposal No.** **17-203**

| | |
|---|---|
| Submitter | Al Sunseri |
| Affiliation | P & J Oyster Company |
| Email | asunseri@bellsouth.net |
| Proposal Subject | Delete unannounced inspections and require appointments for inspections of facilities, records, and equipment used to hold and transport shellfish. |
| Specific NSSP Guide Reference | Section II, Chapter I. Shellfish Sanitation Program @.02 Dealer Certification |
| Text of Proposal/ Requested Action | F. Inspections.<br><br>(1) After any person is certified, the Authority shall make an appointment for inspections of the dealer's facilities, records, and equipment used to hold and transport shellfish: ~~unannounced inspections of the dealer's facilities:~~<br>(a) During periods of activity; and<br>(b) At the following minimum frequencies:<br>(i) Within thirty (30) days of beginning activities if the dealer was certified on the basis of a pre-operational inspection;<br>(ii) At least monthly for dealer facilities certified as depuration processors;<br>(iii) At least quarterly for dealer's activities certified as shucker-packer or repacker; and<br>(iv) At least semiannually for other dealer activities.<br><br>(2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation at the time of inspection. The inspection form shall contain a listing of deficiencies by area in the operation and inspection item with corresponding citations to this Model Ordinance. |
| Public Health Significance | Every State Control Authority must give the same, uniform courtesy when inspecting certified dealers of shellfish. Currently SCA's make appointments with shellfish dealers who work out of a truck to conduct "announced" inspections and should do the same for those certified dealers that have a "brick and mortar" place of business. |
| Cost Information | None |
| Action by 2017 Task Force II | Recommends no action on Proposal 17-203.<br>Rationale: Proposal is adequately addressed in the Model Ordinance. |

**Proposal No.** **17-204**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | Add in-field Compliance Criteria for Control of Harvest Element |
| Specific NSSP Guide Reference | Section II. Model Ordinance - Chapter I@03B.3 |
| Text of Proposal/ Requested Action | 3. ~~Patrol~~ Control of Harvest (Change "Patrol Element" to "Control of Harvest Element" in Chapter I@03B.3 Section.)<br>a. Requirements for evaluation ….<br><br>(new) i. In-field (Harvester) Compliance Criteria<br><br>i. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities.<br><br>**95% of harvesters have valid license Critical**<br><br>ii. Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education.<br><br>A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing. At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. The harvester shall maintain record of the completed training.<br><br>**100% of licensed harvesters have required training within specified time.Critical**<br><br>iii. Harvesters. Any harvester who engages in shellfish packing as defined in this Ordinance shall: Be a dealer; or Pack shellstock for a dealer.<br><br>**95% of harvesters engaging in shellfish packing meet this requirementCritical**<br><br>iv. Non-Vessel Harvesting. Harvesters shall assure shellstock are harvested, handled, and transported to prevent contamination, deterioration, and decomposition.<br><br>**95% of the non-vessel harvesters meet this requirement Key**<br><br>v. Vessels. The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock.<br><br>**95% of the harvest vessels meet this requirement Key** |

Cats, dogs, and other animals shall not be allowed on vessels.

**95% of the harvest vessels meet this requirement Key**

Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

**100% of harvest vessels meet this requirement Critical**

As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

**95% of the harvest vessels meet this requirement Critical**

~~i.~~vi. Shellstock Washing. The harvester shall be primarily responsible for washing shellstock.

If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility. Water used for shellstock washing shall be obtained from: A potable water source; or a growing area in the: Approved classification; or in the open status of the conditionally approved classification.

If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter XI. 02 A. (3) and Chapter XIII. 02 A. (3).

**95% of the harvesters meet this requirement Critical**

vii. Shellstock Identification. Each harvester shall affix a tag that meets Chapter VIII.02.F to each container of shellstock which shall be in place while the shellstock is being transported to a dealer.

**95% of the harvesters meet this requirement Critical**

viii. Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities meets the requirements of Chapter VIII02.F(7).

**95% of the harvesters utilizing bulk tagging meet this requirementCritical**

ix. Shellstock Temperature Control. All harvesters shall comply with the applicable time to temperature requirements of a State *V.v.* and *V.p.* Control Plans outlined in Chapter II. @.06 and @.07; or Chapter VIII. @.02 Shellstock Time to Temperature Controls A. (3). All harvesters shall provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements.

**95% of the harvesters meet these requirements Critical**

| | |
|---|---|
| | j~~i~~. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above ~~patrol~~ Control of Harvest evaluation criteria.<br>i. The overall ~~Patrol Program~~ Control of Harvest element will be assigned one of the following designations:<br>(a) **Conformance:** The program is in compliance with all of the criteria listed above.<br>(b) **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item.<br>(c) **Non-Conformance:** The program has:<br>i. at least one (1) critical deficiency;<br>ii. ~~two (2)~~ four (4) or more key deficiencies; or<br>iii. a repeat **[Key]** deficiency from the previous evaluation.<br>(d) **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.<br>ii. …. |
| Public Health Significance | Adds in-field compliance criteria to address Control of Harvest Element evaluation activities related to NSSP MO Chapter VIII Requirements for Harvesters. Proposal will bring in the in-field compliance criteria which is similar to plant compliance criteria which have administrative and in-field components. |
| Cost Information | N/A |
| Action by 2017 Task Force II | Recommends referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chair with instructions that this proposal be assigned to the appropriate multiple committees. |

**Proposal No.** **17-205**

| | |
|---|---|
| Submitter | ISSC Executive Office |
| Affiliation | Interstate Shellfish Sanitation Conference |
| Email | issc@issc.org |
| Proposal Subject | State MOU for Reporting of Shellfish Related Illnesses |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter I. Shellfish Sanitation Program @.01. Administration |
| Text of Proposal/ Requested Action | Chapter I. Shellfish Sanitation Program<br>@.01. Administration<br><br>F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness.<br><br>The Authority shall:<br>(1) Develop an MOU with the appropriate State agencies responsible for collecting epidemiological information related to reported foodborne illnesses. The MOU shall outline the procedure to ensure that all shellfish related illnesses are reported to the shellfish Authority(s).<br>(2) Have procedures for investigating incidents of shellfish borne disease. |
| Public Health Significance | Illness reporting is a fundamental and necessary component of an effective food safety system. The NSSP presently does not address mechanisms for ensuring that shellfish Authorities receive shellfish related illness information in a manner which allows for effective regulatory action to minimize outbreaks. The NSSP does require that shellfish Authorities have procedures for investigating illness; however, the Model Ordinance does address State illness reporting mechanisms. |
| Cost Information | |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-205 as amended.<br><br>Chapter I. Shellfish Sanitation Program<br>@.01. Administration<br><br>F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness.<br><br>The Authority shall:<br>(1) Have ~~Develop~~ a written protocol ~~an MOU~~ with the appropriate State agencies responsible for collecting epidemiological information related to reported foodborne illnesses. The protocol ~~MOU~~ shall outline the procedure to ensure that all shellfish related illnesses are reported to the shellfish Authority(s).<br>(2) Have procedures for investigating incidents of shellfish borne disease. |

**Proposal No.** **17-206**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | Shellfish Illness Response Associated with *Vibrio parahaemolyticus* (*V.p.*) |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *V.p.* |
| Text of Proposal/ Requested Action | A. When ~~the investigation outlined~~ shellfish are implicated in ~~Section @.01 A. indicates the~~ illness(es) ~~are~~ associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine ~~the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows~~ whether an epidemiological association exists between the illness(es) and shellfish consumption by reviewing:~~:~~<br>(1) Each consumer's food history;<br>(2) Shellfish handling practices by the consumer and/or retailer.<br><br>B. When the Authority has determined an epidemiological association between *V.p.* illness(es) and shellfish, including illnesses described as sporadic, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and span of time as follows:<br><br>(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) ~~but not more than four (4)~~ cases occurring within a ~~thirty (30)~~seven (7) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. ~~The Authority will make reasonable attempts to ensure~~ and evaluate compliance with the ~~existing~~ State Vibrio Control ~~Management~~ Plan. If at least two (2) cases occur from a single harvest day, the Authority shall refer to @.02 B. (3).<br><br>(2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed ~~four (4)~~two (2) but not more than ~~ten (10)~~four (4) over a ~~thirty (30) day~~ time period greater than seven (7) but less than thirty (30) days, from the implicated area ~~or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area,~~ the Authority shall:<br>(a) Determine the extent of the implicated area; and<br>(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and<br>(c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish.<br><br>(3) When the number of cases exceeds ~~ten (10)~~ (four (4) illnesses within a thirty (30) day period or two (2) illnesses within a seven (7) day period from the implicated area ~~or four (4) or more cases occurred from a single harvest date from the implicated area~~, ~~T~~the Authority shall:<br>(a) Determine the extent of the implicated area; and<br>(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and<br>(c) As soon as determined by the Authority, transmit to the ISSC, FDA, and receiving States information identifying the dealers |

shipping the implicated shellfish.

(~~c~~d) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.

(~~d~~e) Issue a consumer advisory for all shellfish (or species implicated in the illness).

(4) When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for ~~the following periods of time to determine if additional illnesses have occurred:~~

~~(a) The area will remain closed for~~ a minimum of fourteen (14) days. ~~when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area.~~

(a) ~~The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area~~

(5) Prior to reopening an area closed as a result of the number of cases exceeding ~~ten (10)~~ four (4) illnesses within thirty (30) days or ~~four (4)~~ two (2) within seven (7) days or two (2) cases from a single harvest date from the implicated area, the Authority shall:

(a) Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies~~.~~; or

(b) Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.

(6) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one or more of the following controls:

(a) Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams;

(b) Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

(7) Molluscan shellfish recalled as a result of *V.p.* illnesses may be reconditioned as described in Chapter II. @.01 J.

| | |
|---|---|
| Public Health Significance | The national trend with regard to Vp illnesses has not improved over the past several years. This proposal intends to improve the effectiveness of response to Vp illnesses. This proposal retains the tiered approach for response to Vp illnesses, but requires closure of implicated areas and recall for situations where multiple illnesses occur over a short period of time, suggesting a higher risk situation.<br><br>The requirement to close for a minimum of fourteen (14) days and to collect and analyze water samples prior to re-opening is expected to decrease the numbers of *V.p.* illnesses occurring from particularly high risk growing areas.<br><br>A reference to @.01 J has been added for clarification. |
| Cost Information | |
| Action by 2017 Task Force II | Recommends referral of Proposal 17-206 to an appropriate committee as determined by the Conference Chair. |

**Proposal No.** **17-207**

<table>
<tr><td>Submitter</td><td>John A. Tesvich</td></tr>
<tr><td>Affiliation</td><td>Louisiana Oyster Task Force</td></tr>
<tr><td>Email</td><td>jatesvich@yahoo.com</td></tr>
<tr><td>Proposal Subject</td><td>V. vulnificus Control Plan</td></tr>
<tr><td>Specific NSSP Guide Reference</td><td>Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management Requirements for the Authority @.06 Vibrio vulnificus Control Plan</td></tr>
<tr><td>Text of Proposal/ Requested Action</td><td>Add Section @.06 E. (1) (c)<br><br>(c) A state has the option to implement a Vibrio vulnificus Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70°F. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below:<br><br>
<table>
<tr><th>Action Level</th><th>Water Temperature</th><th>Maximum hours from Exposure to Temperature Control</th></tr>
<tr><td>Level 1</td><td><65°F</td><td>36 hours</td></tr>
<tr><td>Level 2</td><td>65°F - 70°F (18°C – 23°C</td><td>14 hours</td></tr>
</table>
</td></tr>
<tr><td>Public Health Significance</td><td>In the Gulf there has been no significant risk of V.v. illness during the coldest months, Dec-Feb. This will allow a state with a Vibrio vulnificus Control Plan to more effectively tailor a comprehensive harvesting time-temp control plan without a 70 degree F average maximum water temperature limit.</td></tr>
<tr><td>Cost Information</td><td>No expected increase in cost.</td></tr>
<tr><td>Action by 2017 Task Force II</td><td>Recommends referral of Proposal 17-207 to an appropriate committee as determined by the Conference Chair.</td></tr>
</table>

**Proposal No.** **17-208**

| | |
|---|---|
| Submitter | ISSC Model Ordinance Effectiveness Review Committee |
| Affiliation | Interstate Shellfish Sanitation Conference (ISSC) |
| Email | issc@issc.org |
| Proposal Subject | Ineffective Model Ordinance Requirement |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter VIII. Control of Shellfish Harvesting |
| Text of Proposal/ Requested Action | Requirements for Harvesters.<br><br>.01 General.<br>A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities.<br>B. Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education.<br>(1) A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing.<br>(2) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.<br>~~(3) The harvester shall maintain record of the completed training.~~<br>C. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license.<br>D. In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the riparian owner or lessee shall be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease. |
| Public Health Significance | A harvester is required to obtain proof of completion as required under Chapter VIII. .01 B. (1), and present that to the Authority prior to licensing. There is no real need for the harvester to maintain the record as long as the authority is. |
| Cost Information | |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-208 as submitted. |

**Proposal No.** **17-209**

<table>
<tr><td>Submitter</td><td>John A. Tesvich</td></tr>
<tr><td>Affiliation</td><td>Louisiana Oyster Task Force</td></tr>
<tr><td>Email</td><td>jatesvich@yahoo.com</td></tr>
<tr><td>Proposal Subject</td><td>Shellstock Time to Temperature Controls</td></tr>
<tr><td>Specific NSSP Guide Reference</td><td>Section II Model Ordinance Chapter VIII. Control of Shellfish Harvesting<br>@.02 Shellstock Time to Temperature Controls.</td></tr>
<tr><td>Text of Proposal/ Requested Action</td><td>A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one of the following:<br><br>(1) The State Vibrio vulnificus Control Plan as outlined in Chapter II. @.06; or<br>(2) The State Vibrio parahaemolyticus Plan as outlined in Chapter II. @.07; or<br>(3) All other shellstock shall comply with one of the ~~matrix~~ matrices below:<br><br>
<table>
<tr><th>Action Level</th><th>Average Monthly Maximum Air Temperature</th><th>Maximum Hours from Exposure to Receipt at a Dealer’s Facility</th></tr>
<tr><td>Level 1</td><td><50 °F (10 °C)</td><td>36 hours</td></tr>
<tr><td>Level 2</td><td>50 °F - 60 °F (10 °C - 15 °C)</td><td>24 hours</td></tr>
<tr><td>Level 3</td><td>>60 °F - 80 °F (15 °C - 27 °C)</td><td>18 hours</td></tr>
<tr><td>Level 4</td><td>>80 °F (≥27 °C)</td><td>12 hours</td></tr>
</table>
<br>
<table>
<tr><th>Action Level</th><th>Water Temperature</th><th>Maximum Hours from Exposure to Temperature Control</th></tr>
<tr><td>Level 1</td><td><65 °F</td><td>36 hours</td></tr>
<tr><td>Level 2</td><td>65 °F - 74 °F (18 °C - 23 °C)</td><td>14 hours</td></tr>
<tr><td>Level 3</td><td>>74 °F - 84 °F (>23 °C - 28 °C)</td><td>12 hours</td></tr>
<tr><td>Level 4</td><td>> 84 °F (>28 °C)</td><td>10 hours</td></tr>
</table>
</td></tr>
<tr><td>Public Health Significance</td><td>No adverse public health significance. Gulf states have had no significant historical bacterial based risk during cold water months Dec-Feb. This will allow states the option to have the harvest time to temperature controls based on Average Monthly Maximum water temperature instead of only Average Monthly Maximum Air Temperature, (as it was prior to 2012)</td></tr>
<tr><td>Cost Information</td><td>None</td></tr>
<tr><td>Action by 2017 Task Force II</td><td>Recommends referral of Proposal 17-209 to an appropriate committee as determined by the Conference Chair.</td></tr>
</table>

**Proposal No.** **17-210**

| | |
|---|---|
| Submitter | Miranda Ries, Pacific Coast Shellfish Growers Association (PCSGA) |
| Affiliation | Pacific Coast Shellfish Growers Association (PCSGA) |
| Email | margaretbarrette@pcsga.org and anoysterpearlgirl@gmail.com |
| Proposal Subject | *Panopea generosa*, Use of a State Approved Temperature Control Plan |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter IX Transportation .04 Shipping Temperatures and .05 Transportation Records |
| Text of Proposal/ Requested Action | .04 Shipping Temperatures.<br><br>Shellfish dealers shall ship shellstock adequately iced; or in a conveyance pre-chilled at or below 45 °F (7.2 °C) ambient air temperature, or in compliance with an Authority approved tempering plan for geoduck clams (Panopea generosa).<br><br>.05 Transportation Records.<br><br>All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of Chapter IX. .04. This documentation must include a notice of all shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50 °F (10 °C) and indicate the presence of a time/temperature recording device for trips greater than four (4) hours, or in compliance with an Authority approved tempering plan for geoduck clams (Panopea generose). |
| Public Health Significance | The current requirements in Chapter IX are inconsistent with the Receiving requirements in Chapter XIII. Shipping geoduck clams with adequate ice or with the lower temperatures contained in the Shipping Temperature requirement in Chapter IX causes significant mortality in Geoduck clams during the summer months. This high mortality creates a public health risk. |
| Cost Information | No expense expected potential for cost savings. |
| Action by 2017 Task Force II | Task Force II recommends approval of Proposal 17-210 as amended<br><br>.04 Shipping Temperatures.<br><br>Shellfish dealers shall ship shellstock adequately iced; or in a conveyance pre-chilled at or below 45 °F (7.2 °C) ambient air temperature., ~~or in compliance with an Authority approved tempering plan for g~~Geoduck clams (Panopea generosa) are exempt from these requirements.<br><br>.05 Transportation Records.<br><br>All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of Chapter IX. .04. This documentation must include a notice of all shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50 °F (10 °C) and indicate the presence of a time/temperature recording device. ~~for trips greater than four (4) hours, or in compliance with an Authority approved tempering plan for g~~Geoduck clams (Panopea generose) are exempt from these requirements. |

**Proposal No.** **17-211**

| | |
|---|---|
| Submitter | ISSC Executive Office |
| Affiliation | Interstate Shellfish Sanitation Conference |
| Email | issc@issc.org |
| Proposal Subject | Transportation Shipping Temperatures |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter IX. Transportation<br>.04 Shipping Temperatures |
| Text of Proposal/ Requested Action | Shellfish dealers shall ship shellfish ~~shellstock~~ adequately iced; or in a conveyance pre-chilled at or below 45°F (7.2°C) ambient air temperature. |
| Public Health Significance | Presently the Model Ordinance does not include a shipping temperature requirement for shucked shellfish. The change would require both shucked shellfish and shellstock to be cooled during shipment |
| Cost Information | |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-211 as submitted. |

**Proposal No.** **17-212**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | Dealer Record Retention |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter X. General Requirements for Dealers .01 H. (2) and .08 B. (4) |
| Text of Proposal/ Requested Action | .01 General HACCP Requirements<br><br>H. Records.<br>(1) All records required…<br>(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~~.<br>(3) Records that relate...<br>(4) If the processing…<br>(5) All records required…<br>(6) Tags on containers…<br>(7) The maintenance of…<br><br>.08 Shipping Documents and Records<br><br>B. Transaction and Shipping Records.<br>(1) Each dealer shall…<br>(2) Each dealer shall…<br>(3) Purchase and sales…<br>(4) The transaction records shall be retained for at least two (2) years after the date they were prepared.~~:~~<br>~~(a) In the case of fresh shellfish, for a minimum of one (1) year; and~~<br>~~(b) In the case of frozen shellfish, for at least two (2) years or the shelf life of the product, whichever is longer.~~<br>(5) If computer records |
| Public Health Significance | CFR 117 Subpart F applies to all food facilities (including shellfish facilities) and requires that firms retain records for a minimum of 2 years. This change will mirror that requirement. |
| Cost Information | Minimal. |
| Action by 2017 Task Force II | Recommends approval of Proposal 17-212 as submitted. |

**Proposal No.** **17-213**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | Employee Training |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter X. General Requirements for Dealers .04 A. (2) (c) |
| Text of Proposal/ Requested Action | .04 Certification Requirements.<br><br>A. General.<br>(1) No person shall act as a dealer prior to obtaining certification. (2) Any person who wants to be a dealer shall:<br>(a) Make application to the Authority for certification;<br>(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.<br>(c) Ensure that all individuals who manufacture, process, pack, or hold food ~~O~~obtain training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties. ~~Authority-approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required processing, handling, and transportation practices as determined by the Authority.~~ A dealer shall be allowed ninety (90) days following initial licensing to obtain the required education.<br>(i) A dealer shall receive proof of completion of the required training. Proof of training obtained by the dealer shall be presented to the Authority prior to certification, recertification, or licensing.<br>~~(ii) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.~~<br>(ii~~i~~) The dealer shall maintain the record of the completed training.<br>(3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted. |
| Public Health Significance | Current Model Ordinance language in Chapter X does not meet the new requirements in 21 CFR 117 Subpart A Section 117.4. This language will bring the Model Ordinance requirement in to compliance with the CFR requirement. |
| Cost Information | Minimal cost. |
| Action by 2017 Task Force II | Recommends tabling Proposal 17-213 so a workgroup can be formed to work with the submitter to amend this proposal and report back to Task Force II tomorrow for consideration. |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-213 as amended.<br><br>.04 Certification Requirements.<br><br>A. General.<br>(1) No person shall act as a dealer prior to obtaining certification. (2) Any person who wants to be a dealer shall:<br>(a) Make application to the Authority for certification;<br>(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 ~~O~~obtain training in accordance with 21 CFR 117.4. ~~the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties. Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required processing, handling, and transportation practices as determined by the Authority.~~ A dealer shall be allowed ~~ninety (90)~~ thirty (30) days following initial ~~licensing~~ hiring of a new employee to ~~obtain~~ provide the required education.

(i) ~~A dealer shall receive proof of completion of the required training.~~ Proof of training ~~obtained by the dealer~~ for all employees shall be presented to the Authority prior to certification, recertification, or licensing.

~~(ii) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.~~

(ii~~i~~) The dealer shall maintain the record of the completed training.

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

**Proposal No.** **17-214**

| | |
|---|---|
| Submitter | Al Sunseri |
| Affiliation | P & J Oyster Company |
| Email | asunseri@bellsouth.net |
| Proposal Subject | Delete Performance Based Inspection Program |
| Specific NSSP Guide Reference | Section II Model Ordinance Chapter X. General Requirements for Dealers<br>.04 Certification Requirements |
| Text of Proposal/ Requested Action | A. General.<br><br>(1) No person shall act as a dealer prior to obtaining certification.<br>(2) Any person who wants to be a dealer shall:<br>(a) Make application to the Authority for certification;<br>(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.<br>(c) Obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required processing, handling, and transportation practices as determined by the Authority. A dealer shall be allowed ninety (90) days following initial licensing to obtain the required education.<br>(i) A dealer shall receive proof of completion of the required training. Proof of training obtained by the dealer shall be presented to the Authority prior to certification, recertification, or licensing.<br>(ii) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.<br>(iii) The dealer shall maintain the record of the completed training.<br>(3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.<br>(4) Each dealer shall have GPS tracking equipment on their refrigerated truck or conveyance when the only refrigeration source is a truck or refrigerated conveyance for the State Control Authority to be able to conduct an unannounced inspection. |
| Public Health Significance | When a dealer only has a refrigerated truck or refrigerated conveyance as the sole source of refrigeration, it's impossible for the State Control Agency to do an unannounced inspections to assure compliance with time-temperature requirements of the State's *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* Control Plans required by the NSSP-Model Ordinance. |
| Cost Information | None |
| Action by 2017 Task Force II | Recommends no action on Proposal 17-214. Rationale: The current inspection process by State regulators complies with the requirements of the Model Ordinance. The situation outlined in the public health significance section is being addressed on a State-by-State basis and including this requirement into the Model Ordinance may conflict with State due process requirements. |

**Proposal No.** **17-215**

| | |
|---|---|
| Submitter | Al Sunseri |
| Affiliation | P & J Oyster Company |
| Email | asunseri@bellsouth.net |
| Proposal Subject | Shellstock Dealer Unannounced Inspection using GPS |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter X. General Requirements for Dealers<br>.04 Certification Requirements |
| Text of Proposal/ Requested Action | A. General.<br><br>(1) No person shall act as a dealer prior to obtaining certification.<br>(2) Any person who wants to be a dealer shall:<br>(a) Make application to the Authority for certification;<br>(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.<br>(c) Obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required processing, handling, and transportation practices as determined by the Authority. A dealer shall be allowed ninety (90) days following initial licensing to obtain the required education.<br>(i) A dealer shall receive proof of completion of the required training. Proof of training obtained by the dealer shall be presented to the Authority prior to certification, recertification, or licensing.<br>(ii) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.<br>(iii) The dealer shall maintain the record of the completed training.<br>(3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.<br>(4) A dealer shall have a GPS tracking device on their refrigerated conveyance, (refrigerated truck), so the State Authority can conduct unannounced inspections to assure compliance with time-temperature requirements of the State's *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* Control Plans. |
| Public Health Significance | Every Certified Dealer, including those who only have a refrigerated truck, must be able to have an unannounced inspection conducted by the State Authority to meet satisfactory compliance with the NSSP-Model Ordinance. |
| Cost Information | None or very little cost-An application can be added to a cell phone to track the certified shellstock dealers truck. |
| Action by 2017 Task Force II | Recommends no action on Proposal 17-215.<br>Rationale: This proposal is adequately in the Model Ordinance. |

**Proposal No.** **17-216**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | Shellstock and In-Shell Product Tagging/Labeling Change |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter X. General Requirements for Dealers |
| Text of Proposal/ Requested Action | Change the language required on shellstock tags and in-shell/PHP labeling, in order to reinforce shellfish tag retention requirements to retailers.<br><br>.05 Shellstock Identification B. Tags<br><br>(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:<br>(a) The dealer's name and address.<br>(b) The dealer's certification number as assigned by the Authority.<br>(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required.<br>(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.<br>(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".<br>(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).<br>(g) The type and quantity of shellstock.<br>(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: RECORD ON THIS TAG THE DATE WHEN THE LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED."**<br><br>.07 In-shell Product or Post Harvest Processed In-Shell Labeling B. In-Shell Product Tags or Labels.<br><br>(1) The dealer tag or label on in-shell product shall contain the following indelible, legible information in the order specified below:<br>(a) The dealer's name and address.<br>(b) The dealer's certification number as assigned by the Authority;<br>(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;<br>(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;<br>(e) If depurated, the depuration cycle number or lot number;<br>(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).<br>(g) The type and quantity of in-shell product; and<br>(h) (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: RECORD ON THIS TAG THE DATE WHEN THE LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED." 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: RECORD ON THIS TAG THE DATE WHEN THE LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED."**<br>(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."<br>(j) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag or label.<br>(k) 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 (161.30 and 161.136) and the Federal Fair Packaging and Labeling Act.<br>(i~~1~~) 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.<br>(ii~~2~~) Country of origin information (USDA 2004) may be included on the shucker- packer or reshipper tag or label.<br>(iii~~3~~) 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) (j) shall be included on each retail package.<br><br>NOTE: Implementation will be delayed until January 1, 2019 to allow shellfish dealers adequate time to use up existing tag inventories. |
| Public Health Significance | During shellfish illness investigations, properly kept tags at the retail level are a critical element in performing product traceback. Unfortunately, tags that are not kept in good order are frequently an impediment to illness investigations. The current FDA Retail Food Code requirement for maintaining shellstock tags is listed below. This proposal |

| | |
|---|---|
| | would require additional language on shellfish dealer tags that would reinforce the shellfish tag retention requirements of the current Retail Food Code.<br><br>**Retail Food Code**<br>**3-203.12 Shellstock, Maintaining Identification.**<br><br>(A) Except as specified under Subparagraph (C) (2) of this section, SHELLSTOCK tags or labels shall remain attached to the container in which the SHELLSTOCK are received until the container is empty. [Pf]<br>(B) The date when the last SHELLSTOCK from the container is sold or served shall be recorded on the tag or label. [Pf]<br>(C) The identity of the source of SHELLSTOCK that are sold or served shall be maintained by retaining SHELLSTOCK tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under ¶ B of this section, by: [Pf]<br>(1) Using an APPROVED record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under ¶ B of this section; [Pf] and<br>(2) If SHELLSTOCK are removed from its tagged or labeled container:<br>(a) Preserving source identification by using a record keeping system as specified under Subparagraph (C)(1) of this section, [Pf] and<br>(b) Ensuring that SHELLSTOCK from one tagged or labeled container are not COMMINGLED with SHELLSTOCK from another container with different CERTIFICATION NUMBERS; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the CONSUMER. |
| Cost Information | Minimal. A delayed implementation date of January 01, 2019 is recommended to allow shellfish dealers adequate time to use up existing tag inventories. |
| Action by 2017 Task Force II | Task Force II recommends approval of Proposal 17-216 as amended.<br><br>Change the language required on shellstock tags and in-shell/PHP labeling, in order to reinforce shellfish tag retention requirements to retailers.<br><br>.05 Shellstock Identification B. Tags<br><br>(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:<br>(a) The dealer's name and address.<br>(b) The dealer's certification number as assigned by the Authority.<br>(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required.<br>(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.<br>(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".<br>(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: ~~RECORD ON THIS TAG THE~~ DATE WHEN ~~THE~~ LAST SHELLFISH FROM THIS CONTAINER ~~WAS~~ SOLD OR SERVED _____."**

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

(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) (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: ~~RECORD ON THIS TAG THE~~ DATE WHEN ~~THE~~ LAST SHELLFISH FROM THIS CONTAINER ~~WAS~~ SOLD OR SERVED _____." 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: ~~RECORD ON THIS TAG THE~~ DATE WHEN ~~THE~~ LAST SHELLFISH FROM THIS CONTAINER ~~WAS~~ SOLD OR SERVED _____."**

(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) 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 (161.30 and 161.136) and the Federal Fair Packaging and Labeling Act.<br>(i~~1~~) 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.<br>(ii~~2~~) Country of origin information (USDA 2004) may be included on the shucker- packer or reshipper tag or label.<br>(iii~~3~~) 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) (j) shall be included on each retail package.<br><br>NOTE: Implementation will be delayed until January 1, 2019 to allow shellfish dealers adequate time to use up existing tag inventories. |

**Proposal No.** **17-217**

| | |
|---|---|
| Submitter | Susan Ritchie |
| Affiliation | New York State Department of Environmental Conservation |
| Email | susan.ritchie@dec.ny.gov |
| Proposal Subject | Removal of Harvester Tags being Shipped by Shellfish Dealers |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter X. General Requirements for Dealers<br>.05 Shellstock Identification |
| Text of Proposal/ Requested Action | B. Tags<br>(1) The dealers' tags…<br>(2) The dealer's tag…<br>(3) ~~When both the dealer and harvester tag appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.~~ The harvester tag must be removed from each container prior to being shipped. The harvester tag shall be replaced with a dealer tag and shall meet the requirements in Section .05 B.<br>(4) If the shellstock…<br>(5) Country of origin…<br>(6) When shellstock intended…<br>(7) If a shellfish… |
| Public Health Significance | There should not be any harvester tags at restaurants because only harvesters who are also certified dealers can sell directly to retail or ship interstate making harvesters an unapproved source. When both tags are affixed to the container, there will also be a blank dealer's tag that may potentially be used by an unauthorized person. Excerpt from Shellfish Plant Sanitation Course. "Shellfish harvesters are authorized to: grow and harvest shellstock. Wash, sort, bag and tag harvested shellstock. Sell the product to certified dealers in the State, depending on the State's regulations. Only a harvester who is also a certified dealer can sell directly to retail or ship interstate."<br><br>https://www.accessdata.fda.gov/ORAU/ShellfishPlantSanitation/SPS_01_000.htm |
| Cost Information | $0.00 |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-217 as submitted. |

**Proposal No.** **17-218**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | In-Shell Processing |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter XI. Shucking and Packing .01 Critical Control Points D. (1-2) |
| Text of Proposal/ Requested Action | D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:<br><br>(1) For shellstock which has not been refrigerated prior to ~~shucking~~ processing:<br>(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]**<br>(b) In-shell product is chilled to an internal temperature of 45°F (7.2°C) or less within three (3) hours of processing. **[C]**<br><br>(2) For shellstock refrigerated prior to ~~shucking~~ processing:<br>(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]**<br>(b) In-shell product is chilled to an internal temperature of 45°F (7.2°C) or less within four (4) hours of removal from refrigeration.[C] |
| Public Health Significance | Current Model Ordinance language is not clear on what is required as critical limits for the Processing CCP on In-shell Product. Adding language in Chapter XI. .01 D. (1-2) clarifies what the requirements are for product starting at shellstock and being processed in to in-shell product. Chapter XI. .01 D. (5) then refers to product that was already processed in to in-shell, and then is further processed in to shucked meats. |
| Cost Information | No Additional Cost |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-218 as submitted. |

**Proposal No.** **17-219**

| | |
|---|---|
| Submitter | ISSC Model Ordinance Effectiveness Review Committee |
| Affiliation | Interstate Shellfish Sanitation Conference (ISSC) |
| Email | issc@issc.org |
| Proposal Subject | Ineffective Model Ordinance Requirement |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter XI. Shucking and Packing |
| Text of Proposal/ Requested Action | Requirements for Dealers.<br><br>**.**01 Critical Control Points.<br>A. Receiving Critical Control Point - Critical Limits.<br>(1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has:<br>(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and **[C]**<br>(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and **[C]**.<br>(c) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) **[C].**<br>(2) The dealer shall shuck and pack only shellstock obtained and transported from a dealer who has:<br>(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); and **[C]**<br>(b) Provided documentation as required in Chapter IX. .04 and .05; and **[C]**<br>(c) Adequately iced the shellstock; or **[C]**<br>(d) Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or **[C]**<br>(e) Cooled the shellstock to an internal temperature of 50°F (10°C) or less. **[C]**<br>(3) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c), (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (b) and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c), (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**<br>(4) The dealer shall shuck and pack only in-shell product obtained from a dealer who has:<br>(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]**<br>(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:<br>(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X. .08; and **[C]**<br>(2) Once placed under temperature control and until shucked the shellstock shall;<br>(a) Be iced; or **[C]**<br>(b) Be placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less; and **[C]**<br>(c) Not be permitted to remain without ice, mechanical refrigeration or other approved methods of storage, as required in Section .01 B. (1) or Section .01 B. (2) (a) or (b) for more than two (2) hours at points of processing or transfer such as loading docks. **[C]**<br>C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in- shell product shall be:<br>(1) Iced; or **[C]**<br>(2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. **[C]**<br>D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:<br>(1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45°F (7.2°C) or less within three (3) hours of shucking. **[C]**<br>(2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45°F (7.2°C) or less within four (4) hours of removal from refrigeration. **[C]**<br>(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45°F (7.2°C) or less within two (2) hours after the heat shock process. **[C]**<br>(4) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45°F (7.2°C) within two (2) hours from time of heat shock. [C]<br>(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]<br>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]<br>F. ~~Shellstock Shipping Critical Control Point.~~<br>~~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. The transaction record shall indicate the quantity of restricted use shellstock containers.~~ |
| Public Health Significance | This requirement already appears in Model Ordinance Chapter XIII. .01 D. (1). |
| Cost Information | |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-219 as submitted. |

**Proposal No.** **17-220**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | Hand Sanitizer |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter XI. .02 D. (4);<br>Section II. Model Ordinance Chapter XII. .02 D. (1) (c);<br>Section II. Model Ordinance Chapter XIII. .02 D. (1) (b);<br>Section II. Model Ordinance Chapter XIV. .02 D. (1) (b); and<br>Section II. Model Ordinance Chapter XV. .02 D. (3) |
| Text of Proposal/ Requested Action | Chapter XI. Shucking and Packing .02 Sanitation<br>D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.<br>(1) Hand washing facilities…<br>(2) Hand washing facilities…<br>(3) The dealer shall…<br>(4) The dealer shall provide at each hand washing facility:<br>(a) Supply of hand cleansing soap or detergent; [K]<br>(b) Supply of hand sanitizer; **[K]**<br>(c~~b~~) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]<br>(d~~c~~) Easily cleanable waste receptacle; and [O]<br>(e~~d~~) Hand washing signs in a language understood by the employees; [O]<br>(5) Sewage [C] and liquid…<br>(6) The dealer shall provide…<br><br>Chapter XII. Repacking of Shucked Shellfish .02 Sanitation.<br>D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.<br>(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]<br>(a) Hand washing facilities…<br>(b) The dealer shall…<br>(c) The dealer shall provide at each hand washing facility:<br>(i) Supply of hand cleansing soap or detergent; [K]<br>(ii) Supply of hand sanitizer; **[K]**<br>(iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]<br>(iv~~ii~~) Easily cleanable waste receptacle; and [O]<br>(~~i~~v) Hand washing signs in a language understood by the employees; [O]<br>(2) Sewage [C] and liquid…<br>(3) The dealer shall…<br><br>Chapter XIII. Shellstock Shipping .02 Sanitation.<br>D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.<br>(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]<br>(a) Handwashing facilities shall…<br>(b) The dealer shall provide at each handwashing facility:<br>(i) Supply of hand cleansing soap or detergent; [K]<br>(ii) Supply of hand sanitizer; **[K]** |

| | |
|---|---|
| | (iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]<br>(iv~~ii~~) Easily cleanable waste receptacle; and [O]<br>(~~i~~v) Handwashing signs in a language understood by the employees; [O]<br>(2) Sewage [K] and liquid…<br>(3) The dealer shall…<br><br>Chapter XIV. Reshipping .02 Sanitation.<br>D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.<br>(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]<br>(a) Handwashing facilities shall…<br>(b) The dealer shall provide at each handwashing facility:<br>(i) Supply of hand cleansing soap or detergent; [K]<br>(ii) Supply of hand sanitizer; **[K]**<br>(iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]<br>(iv~~ii~~) Easily cleanable waste receptacle; and [O]<br>(~~i~~v) Handwashing signs in a language understood by the employees; [O]<br>(2) Liquid disposable wastes…<br>(3) The dealer shall…<br><br>Chapter XV. Depuration .02 Sanitation<br>D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities<br>(1) Hand washing facilities…<br>(2) Hand washing facilities…<br>(3) The dealer shall provide at each hand washing facility;<br>(a) Supply of hand cleansing soap or detergent; [K]<br>(b) Supply of hand sanitizer; **[K]**<br>(c~~b~~) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]<br><br>(d~~c~~) Easily cleanable waste receptacle; and [O]<br>(e~~d~~) Hand washing signs in a language understood by the employees; [O]<br>(4) Sewage [C] and liquid… |
| Public Health Significance | Current Model Ordinance language in Chapters XI-XV .02 C. Prevention of Cross Contamination, requires that employees wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility. Currently D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities addresses an adequate supply of hand cleaning soap or detergent, but does not address an adequate supply of hand sanitizer. Adding the new language in will make current language more consistent and enforceable by State inspectors. |
| Cost Information | Minimal cost. |
| Action by 2017 Task Force II | Recommends referral of Proposal 17-220 to an appropriate committee as determined by the Conference Chair. |

**Proposal No.** **17-221**

| | |
|---|---|
| Submitter | ISSC Executive Office |
| Affiliation | Interstate Shellfish Sanitation Conference |
| Email | issc@issc.org |
| Proposal Subject | Criticality Codes |
| Specific NSSP Guide Reference | Section II. Model Ordinance<br>Chapter XI. .02 Sanitation A. Safety of Water for Processing & Ice Production<br>Chapter XII. .02 Sanitation A. Safety of Water for Processing & Ice Production<br>Chapter XIII. .02 Sanitation A. Safety of Water for Processing & Ice Production<br>Chapter XIV. .02 Sanitation A. Safety of Water for Processing & Ice Production<br>Chapter XV. .02 Sanitation A. Safety of Water for Processing & Ice Production |
| Text of Proposal/ Requested Action | Chapter XI. .02 A. (4) (a) (i-ii) Shucking and Packing<br>(4) Plumbing and Related Facilities.<br><br>(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:<br><br>(i) Prevent contamination of water supplies; ~~[C]~~ [S^C/K^]<br><br>(ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. ~~[C]~~ [S^C/K^] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]<br><br>Chapter XII. .02 A. (3) (a) (i-ii) Repacking of Shucked Shellfish<br><br>(3) Plumbing and Related Facilities.<br><br>(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:<br><br>(i) Prevent contamination of water supplies; ~~[C]~~ [S^C/K^]<br><br>(ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. ~~[C]~~ [S^C/K^] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]<br><br>Chapter XIII. .02 A. (4) (a-b) Shellstock Shipping<br><br>(4) Plumbing and Related Facilities. The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:<br><br>(a) Prevent contamination of water supplies; ~~[C]~~ ~~[S^C/K^]~~<br><br>(b) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. ~~[C]~~ [S^C/K^] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]<br><br>Chapter XIV. .02 A. (3) (a-b) Reshipping<br><br>(3) Plumbing and Related Facilities. The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to: |

| | |
|---|---|
| | (a) Prevent contamination of water supplies; ~~[C]~~ [S^C/K^]<br><br>(b) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. ~~[C]~~ [S^C/K^]The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]<br><br>Chapter XV. .02 A. (5) (a) (i-ii) Depuration<br><br>(5) Plumbing and Related Facilities.<br><br>(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:<br><br>(i) Prevent contamination of water supplies; ~~[C]~~ [S^C/K^]<br><br>(ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. ~~[C]~~ [S^C/K^]The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K] |
| Public Health Significance | These criticality code changes are from [C] to [SC/K]. There are currently two instances under .02 A. Safety of Water for Processing and Ice Production, where the Model Ordinance citation is a Critical. This requirement should be a Swing (Critical/Key), because there are instances where the situation would not warrant a Critical, and an immediate corrective action which could even include a recall. FDA and States have been incorrectly marking these to avoid having to take action on product when there is no immediate public health risk. |
| Cost Information | |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-221 as submitted. |

**Proposal No.** **17-222**

| | |
|---|---|
| Submitter | ISSC Executive Office |
| Affiliation | Interstate Shellfish Sanitation Conference |
| Email | issc@issc.org |
| Proposal Subject | Shipping CCP for Shucked Shellfish |
| Specific NSSP Guide Reference | NSSP Guide for the Control of Molluscan Shellfish Section II<br>Chapter XI. Shucking and Packing<br>Chapter XII. Repacking of Shucked Shellfish |
| Text of Proposal/ Requested Action | Chapter XI. Shucking and Packing .01 Critical Control Points<br><br>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]**<br><br>F. All shucked shellfish is cooled to meet the requirements outlined in .01 E. above, prior to shipment.<br><br>G. Shellstock Shipping Critical Control Point.<br>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. The transaction record shall indicate the quantity of restricted use shellstock containers.<br><br>Chapter XII. Repacking of Shucked Shellfish .01 Critical Control Points<br><br>C. Shucked Meat Storage Critical Control Point - Critical Limit.<br>The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45 °F (7.2 °C) or less or covered with ice. **[C]**<br><br>D. All shucked shellfish is cooled to meet the requirements outlined in .01 C. above, prior to shipment. |
| Public Health Significance | Currently there is not a shipping critical control point for shucked shellfish. This language change will ensure that both shellstock and shucked shellfish are cooled to appropriate internal temperatures prior to shipping. |
| Cost Information | |
| Action by 2017 Task Force II | Recommends no action on Proposal 17-222.<br>Rationale: This is adequately addressed in the Model Ordinance. |

**Proposal No.** **17-223**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | *V.p.* Levels During Wet Storage |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter XIII. Shellstock Shipping<br>.01 Critical Control Points |
| Text of Proposal/ Requested Action | B. Shellstock Storage Critical Control Point – Critical Limits.<br><br>The dealer shall ensure that:<br><br>(3) All oysters and/or hard clams harvested under State Vibrio Control Plans other than those labeled for a restricted use shall meet the following temperature requirements:<br>(a) Cooled to an internal temperature of 55° F (12.7° C) within the time periods outlined in the State V.v. Control Plans. [C]<br>(b) Cooled to an internal temperature of 50° F (10° C) within the time periods outlined in the State V.p. Control Plans. Shellstock cooled to an internal temperature of 55° F (12.7° C) to comply with a V.v. Control Plan is considered in compliance with this requirement. [C]<br>(4) When held in land based wet storage or depuration, the dealer must demonstrate, through a validation study, the process does not increase levels of Vibrio. The validation study must be approved by the State Shellfish Control Authority with concurrence from the FDA. The dealer must have a verification procedure approved by the State Shellfish Control Authority. [C]<br>(54) All other shellstock obtained from a licensed harvester shall be placed in a conveyance pre-chilled or a storage area maintained to 45° F (7.2° C) or less and cooled to an internal temperature of 50° F (10° C) prior to shipment. [C]<br>(65) Product intended for relay~~, wet storage or depuration,~~or either geoduck clams (*Panopea generose*), or Mercenaria sp., which are being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed above in .01 B. (4) above. [C] |
| Public Health Significance | When *Vibrio* spp. are present in the waters used for wet storage and depuration, or present in the oysters and/or hard clams placed there, there is the potential for a significant hazard if the conditions become favorable for vibrio growth.<br><br>An informal investigation into a partial list of illnesses reported through the FDA Regional Shellfish Specialists from 2011 – 2016 reveal approximately 20 *V.p.* illnesses associated with wet stored or depurated product. During the associated traceback investigations, no deficiencies were noted regarding compliance with harvester time to temperature requirements under Vibrio Control Plans.<br><br>In addition, data are not available to confirm that the contact time of UV to water in a re-circulating wet storage/depuration UV system is sufficient to significantly reduce vibrios present in the water. Rapid changes in environment (temperature, salinity, etc.), such as transfer to wet storage or depuration, can cause shellfish to cease, or reduce, pumping which can allow the growth of vibrios inside the shellfish. Data, such as, confirming the effectiveness of UV treatment on vibrios in depuration water, as well as demonstration of active pumping of shellfish, could be provided to ensure the holding of shellstock in a wet storage or depuration system is not increasing the risk from vibrio. |
| Cost Information | |
| Action by 2017 Task Force II | Recommends no action on Proposal 17-223.<br>Rationale: FDA will provide additional data and information at a later time. |

**Proposal No.** **17-224**

| | |
|---|---|
| Submitter | US Food & Drug Administration (FDA) |
| Affiliation | US Food & Drug Administration (FDA) |
| Email | Melissa.Abbott@fda.hhs.gov |
| Proposal Subject | Conveyances Used to Transport Shellstock |
| Specific NSSP Guide Reference | Section IV. Guidance Documents Chapter III. Harvesting, Handling, and Distribution .07 Time and Temperature Controls Section Chapter IX. |
| Text of Proposal/ Requested Action | **Conveyances Used to Transport Shellstock from Dealer to Dealer (Common Carriers or Shipping Dealers Conveyance).**<br><br>Shellstock being transported from dealer to dealer must be shipped in containers which can be easily cleaned and maintained to prevent contamination. Shellstock must be shipped on pallets when shipped in bulk. Pallets are not necessary if the conveyance has channeled flooring.<br><br>If shellstock is shipped with other cargo, the shellstock must be protected from contamination by the other cargo. Shellstock must be refrigerated or cooled at all times when shipping from dealer to dealer. Conveyances must be pre-chilled to 45°F (7.2°C) or below prior to loading. It is acceptable to use ice as a means of cooling. The dealer shall keep a record of compliance with the pre-chilling requirement; this record is not intended to be a HACCP record for the shipping dealer.<br><br>All shipments of shellstock shall be accompanied with a documentation record indicating the time of shipment and that all shipping containers were pre-chilled. The documentation required in Chapter IX. .05 must include the time of shipment, the means of cooling, and indicate the temperature to which the conveyance was pre-chilled if mechanical refrigeration was the means of cooling (This documentation is not intended to be a HACCP record for the shipping dealer). In situations when the dealer chooses to ship product not harvested under a State Vibrio Plan that has not achieved the internal temperature of 50°F (10°C), the shipping documentation must provide notice to the receiving dealer that the product was shipped prior to achieving an internal temperature of 50°F (10°C). Additionally, the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. The documentation stating the time of shipment will accompany the bill of lading and will be used by the receiving dealer to determine the length of shipment.<br><br>This control will allow product to be shipped while cooling is occurring. Should the receiving dealer choose not to further ship the shellstock with a time/temperature recording device, the dealer must cool and document that the product has reached an internal temperature of 50°F (10°C) prior to reshipping<br><br>**Conveyances Used to Transport Shellstock that are Owned by the Receiving Dealer.**<br><br>Shellstock being picked up by the receiving dealers truck and delivered directly to the receiving dealers facility must be shipped in containers which can be easily cleaned and maintained to prevent contamination. Shellstock must be shipped on pallets when shipped in bulk. Pallets are not necessary if the conveyance has channeled flooring.<br><br>If shellstock is shipped with other cargo, the shellstock must be protected from contamination by the other cargo. Shellstock must be refrigerated or cooled at all times when shipping from dealer to dealer. Conveyances must be pre-chilled to 45°F (7.2°C) or below prior to loading. It is acceptable to use ice as a means of cooling. |

| | |
|---|---|
| | The dealer shall keep a record of compliance with the pre-chilling requirement (see dealer to dealer shipping section above) or document the time the shipment was received from the selling dealers facility and the ambient air temperature of the shipping container; this record is not intended to be a HACCP record for the shipping dealer. The ambient air temperature of the conveyance must be to 45°F (7.2°C) or below prior to loading and time of receipt is a receiving HACCP record for the receiving dealer.<br><br>Additionally, the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. The documentation stating the time of shipment will accompany the bill of lading and will be used by the receiving dealer to determine the length of shipment.<br><br>This control will allow product to be shipped while cooling is occurring. Should the receiving dealer choose not to further ship the shellstock with a time/temperature recording device, the dealer must cool and document that the product has reached an internal temperature of 50°F (10°C) prior to reshipping.<br><br>**Conveyances Used to Transport Shellstock Directly to Retail.**<br><br>Dealers shipping shellstock directly to retail should comply with state laws governing retail foods. In many cases these laws require the shellstock to be at an internal temperature of 45°F (7.2°C) or less at receipt. A dealer could be in compliance with the shipping and documentation requirements of Chapter IX. .04 and .05 and the shellstock fail to meet retail food requirements.<br><br>The documentation requirements of Chapter IX. .05 are to provide receiving dealers with information necessary to meet the receiving critical limit requirements included in Chapters XI., XII., XIII., XIV., and XV. Receiving requirements for retailer and food service operators are outlined in the USFDA Food Code and State Retail Food regulations and the information included in the documentation required in Chapter IX. .05 is not necessary for retailers and food services operators to comply with the receiving requirements for retail food. Therefore, the documentation requirement in Chapter IX. .05 does not apply for shipments to retailers and food service operators. |
| Public Health Significance | The purpose of this additional guidance is to address situations in which the receiving dealer is also the shipper. This guidance provides compliance clarification and addresses necessary documentation |
| Cost Information | |
| Action by 2017 Task Force II | Recommends adoption of Proposal 17-224 as submitted. |

**Proposal No.** **17-225**

| | |
|---|---|
| Submitter | Chris Shriver, GM and Daniel Cohen, President |
| Affiliation | Atlantic Capes Fisheries, Inc. |
| Email | cshriver@atlanticcapes.com and dcohen@atlanticcapes.com |
| Proposal Subject | Clarification of Surf Clams and Ocean Quahogs Exemption from Time/Temperature Requirements whcn "intended for thermal processing". |
| Specific NSSP Guide Reference | Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls G.<br>Section IV. Guidance Documents Chapter II. Handling, Processing, and Distributing B. |
| Text of Proposal/ Requested Action | Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting<br>@.02 Shellstock Time to Temperature Controls<br><br>G. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempt from this temperature control plan when these products are intended for thermal processing, which includes when a Processor represents, labels, or intends for the products to be cooked prior to consumption pursuant to the Processor's HACCP Plan as defined in FDA 21 CFR Part 123 Seafood HACCP regulations. For clarity, if Surf Clams or Ocean Quahogs are distributed live with the intention they could eaten raw, those Surf Clams and Ocean Quahogs are not exempt from this temperature control plan.<br><br>Section IV. Guidance Documents Chapter III. Handling, Processing and Distributing<br><br>B. Ocean Quahogs (*Arctica islandia*) and Surf Clams (*Spisula solidissima*) are excluded from the time to temperature controls of State Vibrio Control Plans or the matrix outlined in Chapter VIII. @.02 A. (1) (2) and (3). This exclusion applies only when these products are intended for thermal processing, which includes when a Processor represents, labels, or intends for the product to be cooked prior to consumption pursuant to the Processor's HACCP Plan as defined in FDA 21 CFR Part 123 Seafood HACCP regulations. Authorities may exclude other species when intended for thermal processing. For clarity, if Surf Clams or Ocean Quahogs are distributed live with the intention they could eaten raw, those Surf Clams and Ocean Quahogs are not exempt from this temperature control plan. |
| Public Health Significance | There is no adverse public health significance by this clarification of the meaning of the exemption for surf Clams and Ocean Quahogs *"intended for thermal processing".* There will be no change from current practices, which include HACCP process controls adopted by each Processor. The additional wording merely clarifies a misinterpretation that the definition of *"intended for thermal processing"* is limited to low acid canning of 21 CFR 113.3(o). The Surf Clam and Ocean Quahog processors have been shucking surf clams and selling them in the uncooked state (both as fresh clam meats and frozen clam meats) for decades to customers with the intention that all of their customers will fully cook the Surf Clam meats and Ocean Quahogs prior to consumption. Thermal processing and cooked is not limited to only low aid canning, but also includes other forms of cooking and thermal processing as defined in the NSSP MO in Definitions (B) (94). Intended use guidance and controls are already established, this proposal simply clarifies and documents current practices, and aligns with common use of Surf Clams and Ocean Quahogs. As per FDA 21 CFR Part 123 Seafood HACCP regulations the Surf Clam and Ocean Quahog processors shall identify the intended use of their products. Additionally the Surf Clam and Ocean Quahog processors shall be required, consistent with their HACCP Plans, to issue annual HACCP Compliance Letters to all their customers which also identify the intended use of their products. |

| | |
|---|---|
| Cost Information | None. There will be no additional cost to industry, public, or the regulators by this clarification. |
| Research Needs Information | None. There are no research needs. |
| Action by 2017 Task Force II | Recommends referral of Proposal 17-225 to an appropriate committee as determined by the Conference Chair. Task Force Member Joe Jewell (Mississippi) requested the record reflect he abstained from the vote. |